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CLINICAL COMPETENCE STATEMENT

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 Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures)

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This document was approved by the American College of Cardiology Foundation (ACCF) Board of Trustees, the American Heart Association (AHA) Science Advisory and Coordinating Committee, and the Society for Cardiovascular Angiography and Interventions (SCAI) Board of Trustees in April 2013. For the purpose of complete transparency, disclosure information for the ACCF Board of Trustees, the board of the convening organization of this document, is available at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Officers-and-Trustees.aspx. ACCF board members with relevant relationships with industry to the document may review and comment on the document but may not vote on approval.

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Preamble

Granting clinical staff privileges to physicians is the primary mechanism institutions use to uphold quality care. The Joint Commission requires that medical staff privileges be based on professional criteria specified in medical staff bylaws. Physicians themselves are charged with

defining the criteria that constitute professional competence and with evaluating their peers accordingly. The process of evaluating physicians' knowledge and competence has become more complex as various subspecialties have evolved over time.

The American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/American College of Physicians (ACP) Task Force on Clinical Competence and Training was formed in 1998 to develop recommendations for attaining and maintaining the cognitive and technical skills necessary for the competent performance of a specific cardiovascular service, procedure, or technology. These documents are evidence based, and where evidence is not available, expert opinion is used to formulate recommendations. Indications for and contraindications to specific services or procedures are not included in the scope of these documents. Recommendations are intended to assist those who must judge the competence of cardiovascular healthcare providers entering practice for the first time and/or those in practice undergoing periodic review of their expertise. The assessment of competence is complex and multidimensional; therefore, isolated recommendations contained herein may not necessarily be sufficient or appropriate for judging overall competence. The current document addresses competence in coronary-based cardiovascular interventional procedures and is authored by representatives of the ACCF, the AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI). This document applies to specialists trained in internal medicine and adult cardiology and is not meant to be a clinical competence statement on procedures for congenital heart disease in the child or young adult.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACCF/AHA/ACP Task Force on Clinical Competence and Training reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry or other entity (RWI), led by a chair with *no relevant* RWI. Authors with *relevant* RWI are not permitted to draft or vote on text or recommendations pertaining to their RWI. RWI is reviewed on all conference calls and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices 1 and 2, respectively. Additionally, to ensure complete transparency, *authors' comprehensive healthcare-related disclosure information*—including RWI not pertinent to this document—is available online (see Comprehensive RWI Table). Disclosure information for the ACCF/AHA/ACP Task Force on Clinical Competence and Training is also available online at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx, as well as the ACCF disclosure policy for document development at http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx.

The work of the writing committee was supported exclusively by the ACCF without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and attended only by committee members.

Jonathan L. Halperin, MD, FACC, FAHA
Chair, ACCF/AHA/ACP Task Force on Clinical Competence and Training

1. Introduction

Physician competence is an essential component in the provision of optimal health care. Physicians must have the appropriate training, fund of knowledge, clinical decision making, and technical skills to deliver their services in a competent and caring manner. Healthcare systems and payers also expect optimal care delivered in an efficient and cost-sensitive manner. In formulating conclusions and recommendations, it is important to emphasize that the ultimate goal of setting standards is to facilitate the attainment of optimal patient outcomes. Optimal outcome is most likely when operators select clinically appropriate patients for interventional procedures and perform these procedures at a requisite level of proficiency and competency. Institutional and programmatic quality is ultimately determined by its success in achieving that goal.

This document is an update of the 2007 ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures (1). The operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (PCI) (2). Although the 2011 PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing committee, tasked specifically with examining volume thresholds, would be the primary source and that the PCI guidelines would be subsequently modified.

1.1. Document Development Process

1.1.1. Writing Committee Organization

The writing committee consisted of a broad range of members representing 3 societies, identified on the basis of 1 or more of the following attributes: PCI operators with experience in various clinical settings (e.g., private practice, hospital-based, and academic settings; high-, medium-,

and low-volume operators; small, medium, and large catheterization labs; hybrid labs; and labs with and without surgical backup); physicians experienced in both radial and femoral access; physicians with broad clinical experience who have had considerable previous involvement with PCI; physicians with expertise in systems of care for patients presenting with acute myocardial infarction; a cardiac surgeon; cardiovascular training program directors; catheterization laboratory directors with experience managing a broad cross section of interventional operators; general cardiologists; quality assurance experts; and clinical researchers who have studied PCI outcomes. This writing committee met the College's disclosure requirements for relationships with industry as described in the Preamble.

1.1.2. Document Development and Approval

The writing committee convened by conference call and email to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately, sign off on the document for external peer review. The ACCF, AHA, and SCAI participated in peer review, resulting in 36 reviewers representing 316 comments. Comments were reviewed and addressed by the writing committee. A member of the ACCF/AHA/ACP Task Force on Clinical Competence and Training served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and task force approved the final document to be sent for Board review. The ACCF Board of Trustees, AHA Science Advisory and Coordinating Committee, and the SCAI Board of Trustees reviewed the document, including all peer review comments and writing committee responses, and approved the document in April 2013. This document is considered current until the Task Force on Clinical Competence and Training revises or withdraws it from publication.

1.2. Purpose of This Document

This document was developed to review the currently available scientific data with the following purposes:

1. To characterize the expected success and complication rates for coronary artery interventional procedures when performed by skilled operators.
2. To identify comorbidities and other risk factors that may be used for risk adjustment when assessing procedure-specific expected success and complication rates.
3. To assess the relationship between operator activity level and success rates in PCI procedures as assessed by risk-adjusted outcome statistics.
4. To assess the relationship between institutional activity level and success rates in PCI procedures as assessed by risk-adjusted outcome statistics.
5. To develop recommendations for assessment of operator proficiency and institutional program quality, including data collection to permit monitoring of appropriateness and effectiveness of PCI procedures both at the level of the operator and the institution.
6. To assess the use of coronary procedures in patients with structural disease.

This document addresses coronary-based interventions in the adult and does not address procedures for non–coronary-based interventions involving structural heart disease in the child or adult.

2. Percutaneous Coronary Interventions

2.1. Evolution of Competence and Training Standards

PCI has become a widely practiced and integral component of cardiovascular therapy. The subspecialty has evolved into treating a wide range of both stable and acutely ill patients presenting with a broad spectrum, not only of increasingly complex coronary artery disease, but also of other cardiovascular conditions. The range and complexity of the equipment, adjunctive techniques, and ancillary components used to perform PCI (along with the clinical settings in which it is utilized, e.g., elective and acute coronary disease; native vessel and venous bypass; and lesion location and characteristics) have also evolved dramatically. Coincident with this has been recognition of the specialized knowledge and technical skills required to perform PCI, and the critical roles of formalized training, continuing education, and outcomes monitoring. Formal interventional cardiology training programs were first organized in the 1980s; and in 1999, the American Board of Internal Medicine (ABIM) offered its first examination for added certification in Interventional Cardiology. Currently, eligibility to qualify for this examination requires board certification in general cardiology, and successful completion of a 1-year dedicated interventional cardiology fellowship, in a program accredited by the Accreditation Council of Graduate Medical Education (ACGME). In 2012 to 2013, there were 141 ACGME-accredited programs in Interventional Cardiology, with 319 enrolled fellows. The current ACGME program and educational requirements for interventional cardiology were published in 2007; new/updated requirements became effective in July 2012 (3). The ACCF has further contributed to the definition of training standards and recommendations via its Adult Cardiovascular Medicine Core Cardiology Training (COCATS) documents (4).

During the past several years, there has also been a move toward a more structured definition of competency-based requirements and training. This includes the use of the 6 competency domains promulgated by the ACGME, and adopted and endorsed by the ABIM (medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication

skills; and professionalism). This format is also increasingly utilized, not only for training programs, but also for demonstration of maintenance of competency for practicing physicians. ACCF has also adopted this format as part of its training and lifelong learning competency documents, and has developed tools and programs to assist physicians in assessing, enhancing, and documenting competency. Section 2.7 of this document depicts core competency components of PCI utilizing this structure. A key characteristic of a competency-based system is the use of outcomes-based evaluations. For training programs, the evaluation tools, for example, include direct observation by instructors, as well as in-training examination, procedure logbooks/portfolios, and simulation. For practicing physicians, the maintenance of the competencies can include, for example, physician-specific data from registries (e.g., ACCF–National Cardiovascular Data Registry [NCDR®]) as well as from hospital databases and quality programs, along with maintenance of certification (MOC) and continuing medical education (CME). The competency framework includes definitions of competency components and potential evaluation tools related to an individual's practice-based learning, as well as skills related to working effectively in healthcare systems, communication with patients and other members of the healthcare team, and professionalism (see Section 2.7).

2.2. Evolution of Coronary Interventional Capabilities

Andreas Gruentzig pioneered the field of coronary intervention with the first coronary balloon angioplasty in 1977 (5,6). During the past 35 years, the field has rapidly expanded. The evolution of the cognitive and technical knowledge base for proficiency in PCI has paralleled the advancements in interventional equipment and the broadening of clinical and angiographic indications for PCI.

Although the basic structure of coronary balloons and atherectomy devices has not changed substantially over the years, the development of the coronary artery stent dramatically altered the practice of coronary intervention. The initial stents available markedly reduced the need for PCI-related emergency coronary bypass surgery (7), and drug-eluting stents have substantially lowered the occurrence of restenosis and the need for repeat revascularization following PCI (8). These technical innovations continue to evolve at a rapid pace, with new devices on the horizon (9,10). These advances come with the responsibility that the interventional cardiologist acquires the technical and cognitive skills necessary to use these emerging devices optimally to provide the best outcomes for their patients.

In tandem with these technical developments, the use of PCI has expanded to more complex lesion subsets such as chronic total occlusions, left main stenosis, and bifurcation lesions (11). These unmet needs spurred industry to produce an expanding selection of specialized devices (e.g., balloons, catheters, wires, and dedicated stents) to facilitate successful procedure completion. Similar to the evolution in the device field, pharmacological advances have continued at a robust pace, contributing to the increased clinical benefit appreciated by patients in recent years (12). These advances most notably involving antithrombotic and antiplatelet agents require the interventional cardiologist to have a solid working knowledge of the pharmacokinetics, indications, contraindications, and optimal timing of long-term monitoring of these drugs (13,14). New oral antithrombin and anti-Xa agents are emerging, which require further understanding of their indications and side effects.

The recognition that coronary angiography provides an imperfect assessment of coronary structure and stenosis severity has led to new imaging modalities such as intravascular ultrasound, optical coherence tomography, and near infrared spectroscopy (15). Assessment of the intermediate-severity stenosis based on the coronary angiogram alone has always been challenging. Following publication of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) trial (16), functional testing of angiographic intermediate coronary stenosis with measurement of the fractional flow reserve is now increasingly recommended when noninvasive evidence of ischemia is absent before considering revascularization of such lesions. Furthermore, the FAME 2 trial demonstrated that a fractional flow reserve–guided PCI strategy in patients with stable angina improves outcome beyond that of optimal medical therapy, particularly with regard to reduction of repeat hospitalization for coronary ischemia (17). The correct application of all these new devices requires continued expansion of both cognitive and procedural skill sets by the practicing interventional cardiologist.

Finally, the increasing complexity of PCI in patients with poor cardiac reserve has encouraged the development of several percutaneous left ventricular support devices (18). Insertion and monitoring of these devices necessitates a solid understanding of cardiovascular hemodynamics. In summary, the evolution of the field of interventional cardiovascular medicine has, and will continue, to require an unwavering commitment from the physician community to maintain excellence through lifelong learning.

2.3. Procedural Success and Complications of Coronary Interventional Procedures

2.3.1. PCI Success

PCI success can be defined using angiographic, procedural, and clinical variables. Factors associated with increased success and decreased complication rates include improvements in equipment (e.g., balloon catheters, guide catheters, guidewires), coronary stents (bare-metal stents and drug-eluting stents), embolization protection, aspiration thrombectomy devices, and advances in adjunctive pharmacotherapy (2,19–23).

Historically, angiographic success for balloon angioplasty has been defined as a reduction of minimum percent diameter stenosis to <50% with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow and without side branch loss, flow-limiting dissection or angiographic thrombus. For coronary stents, a minimum percent diameter stenosis of <20% was the previous angiographic benchmark of an optimal result (24,25). However, with current stents and the recognized importance of adequate stent deployment (26,27), the 2011 ACCF/AHA/SCAI PCI guideline suggests a minimum percent diameter stenosis of <10% (or optimally as close to 0% as possible) as the new angiographic benchmark for stent results (2). In addition, following the conclusion of a successful procedure, there should be TIMI grade 3 flow and no occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus.

Procedural success is defined as angiographic success without in-hospital major complications such as death, myocardial infarction (MI), stroke, and emergency coronary artery bypass graft (CABG) surgery. The definition of PCI-related MI has evolved over time, and the current definition is provided below in Section 2.3.2 (2,24,25,28–30).

Short-term clinical success includes angiographic and procedural success with the subsequent relief of signs and/or symptoms of myocardial ischemia. Long-term clinical success requires that the relief of myocardial ischemia remain durable, persisting for more than 1 year after the procedure (2). The most common reason for a failure of long-term clinical success has been restenosis. Stent thrombosis is an uncommon, but an important, cause of short- and long-term clinical failure.

2.3.2. PCI Complications

PCI complications were reviewed comprehensively in the 2011 ACCF/AHA/SCAI PCI guideline (2). Major PCI-related complications include death, MI, emergency CABG surgery, and stroke, commonly denoted as MACCE (major adverse cardiovascular and cerebrovascular events). Other important complications include vascular complications (e.g., pseudoaneurysm, arteriovenous fistula, retroperitoneal bleeding, clinically overt atheroembolism), any major bleeding, and contrast nephropathy. The incidence of in-hospital mortality for PCI, determined from the NCDR CathPCI database between 2004 and 2007, was 1.27%, ranging from 0.65% in elective procedures to 4.81% for PCI performed in the setting of ST-elevation myocardial infarction (STEMI) (31). However, an important perspective is provided from a large contemporary single-center series reporting an overall mortality of approximately 1%, but with half of all deaths due to primarily noncardiac causes (32). The incidence of PCI-related MI depends on the criteria used to define MI. The clinical significance of "enzymatically defined" MIs in the absence of clinical or angiographic correlates has been controversial. The third iteration of the ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction now requires for the diagnosis of PCI-related MI ("type 4a") both: 1) elevation of troponin (>5 × 99th percentile upper reference limit in patients with normal baseline values or a rise in troponin values >20% if the baseline values are elevated and stable or falling); *and* 2) either symptoms suggestive of myocardial ischemia, or new ischemic echocardiographic (ECG) changes (or new left bundle-branch block), or angiographic evidence of PCI complication, or imaging demonstrating new loss of viable myocardium (30). The need for emergency CABG surgery for a failed PCI has decreased dramatically especially since the introduction of coronary artery stents noting an incidence of 0.4% reported from the NCDR® database from 2004 to 2006 (33). The incidence of PCI-related stroke is also low at 0.22%; however, in-hospital mortality for these patients is quite high, reported to be 25% to 30% (34,35). Finally, it has been recently appreciated that periprocedural bleeding is associated with increased mortality, and accordingly, strategies to avoid bleeding are continuing to be developed (36,37). Factors reported to be associated with an increased risk of bleeding include advanced age, low body mass index, chronic kidney disease, baseline anemia, excessive platelet and/or thrombin inhibition, noncompressible vascular access site, and larger sheath size (2,38,39).

2.4. Patient and Lesion Variables Influencing Success and Complication Rates

Patient characteristics associated with an increased risk of adverse outcome include advanced age, diabetes, chronic kidney disease, heart failure, multivessel disease, clinical presentation with an acute coronary syndrome (non-STEMI or STEMI), and cardiogenic shock (31,40–42). Lesion-related characteristics associated with increased complications and/or lower procedural success include lesion length, thrombus, degenerated saphenous vein grafts, and chronic total occlusions (40,43). With advances in PCI technology, lesion morphology may be currently less predictive of procedural complications compared with the past (44).

The most widely accepted model to predict PCI mortality is the NCDR® CathPCI Risk Score system (Table 1), which utilizes multiple variables to predict inpatient mortality (2,31). This model performs very well (C statistic: approximately 0.90), although the predictive capability decreases in high-risk patients. Consideration of certain general and neurological patient factors in addition to NCDR® variables improves the predictive value of the model (32). Consideration of "compassionate use" features (coma on presentation, active hemodynamic support during PCI, and cardiopulmonary resuscitation at PCI initiation) has

Table 1. The NCDR® CathPCI Risk Score System

Variable	Scoring Response Categories				Total Points	Risk of In-Patient Mortality
Age	<60	≥60, <70	≥70, <80	≥80	0	0.00%
	0	4	8	14	5	0.10%
Cardiogenic shock	No	Yes			10	0.10%
	0	25			15	0.20%
Prior CHF	No	Yes			20	0.30%
	0	5			25	0.60%
Peripheral vascular disease	No	Yes			30	1.10%
	0	5			35	2.00%
Chronic lung disease	No	Yes			40	3.60%
	0	4			45	6.30%
GFR	<30	30–60	60–90	>90	50	10.90%
	18	10	6	0	55	18.30%
NYHA functional class IV	No	Yes			60	29.00%
	0	4			65	42.70%
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.60%
	12	15	20	38	75	71.20%
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.00%
	0	8	20	42	85	89.20%
					90	93.80%
					95	96.50%
					100	98.00%

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CathPCI indicates catheterization percutaneous coronary intervention; CHF, congestive heart failure; GFR, glomerular filtration rate; NCDR®, National Cardiovascular Data Registry; NYHA, New York Heart Association; and STEMI, ST-elevation myocardial infarction.

similarly been shown to increase the predictive ability of the model (45). Models to predict procedural success include the modified ACC/AHA score (40) and the SCAI score (46,47) (Table 2), with good to very good discrimination (C statistic: 0.70 to 0.82). More recently, the SYNTAX (Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) score, which is based on an angiographic calculation, has been shown to have value determining which patients with unprotected left main or multivessel disease undergoing PCI are at greatest risk for long-term major adverse cardiac events (MACE) (48–50). There are similar models available that help predict bleeding in patients with acute coronary syndromes undergoing PCI. Best treatment option proposals are facilitated by the heart team approach endorsed as a Class I recommendation by the ACCF, AHA, Society of Thoracic Surgeons (STS), and American Association for Thoracic Surgery (AATS), particularly when addressing complex patients and/or coronary anatomy. An operator should be familiar with the concepts of anatomical and clinical risk to facilitate optimal clinical decision making when recommending a revascularization strategy for an individual patient.

Table 2. The SCAI Lesion Classification System

Type I lesions (highest success expected, lowest risk)
1. Does not meet criteria for C lesion
2. Patent

Type II lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90 degrees
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
2. Patent

Type III lesions
1. Does not meet criteria for C lesion
2. Occluded

Type IV lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90 degrees
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
   - Occluded for >3 months
2. Occluded

Reprinted with permission from Krone et al. (47).

ACC indicates American College of Cardiology; AHA, American Heart Association; CME, continuing medical education; ECG, electrocardiographic; MOC, maintenance of certification; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.

2.5. Institutional Characteristics Related to Procedural Success and Complication Rates

2.5.1. Impact of the Facility on Procedural Success

Physical facility requirements. Characteristics of the physical facility in which interventional procedures are performed have important influences on achieving procedural success. The facility must provide the

necessary radiologic, monitoring, and adjunctive patient support equipment to enable operators to perform in the safest and most effective environment. The real-time fluoroscopic and acquired image quality must be optimal to facilitate accurate catheter and device placement and facilitate the correct assessment of procedural results. Physiological monitoring equipment must provide continuous, accurate information about the patient's condition. Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve should be available. Hemodynamic support devices such as intra-aortic balloon pumps and percutaneous ventricular assist devices should be available in institutions routinely performing high-risk PCI. These requisite support equipment must be available and in good operating order to respond to emergency situations (51).

Overall institutional system requirements. The interventional laboratory must have a support system of specifically trained laboratory personnel. Access to (or a detailed plan to access) cardiothoracic surgical, respiratory, and anesthesia services should be available to respond to emergency situations in order to minimize detrimental outcomes (51). The ACCF/AHA/SCAI PCI guideline supports the heart team approach to revascularization for high-risk complex patients (2). The institution should have systems for credentialing, governance, data gathering, and quality assessment. Prospective, unbiased collection of key data elements on all patients and consistent timely feedback of results to providers brings important quality control to the entire interventional program and is critical to assessing and meeting Appropriate Use Criteria for coronary revascularization (52). The 2011 ACCF/AHA/SCAI PCI guideline update (2) recommends that:

- Primary PCI (PPCI) is reasonable in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished (Class IIa) (53,54).
- Elective PCI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Class IIb) (54–56).
- Primary or elective PCI should not be performed in hospitals without onsite cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer (Class III).

2.6. Strategies for Risk Stratification and Operator Evaluation

Large prospective and retrospective databases involving patients undergoing PCI have identified clinical and angiographic characteristics that correlate with procedural success, in-hospital morbidity, and mortality (57–59). These observations have been used to develop multivariate logistic regression models that can stratify patients before the procedure and also predict outcomes based on events during the procedure.

Risk stratification is not perfect and is frequently developed from a large population analysis and must then be validated prospectively in robust clinical data sets. Reliability of the model is best assessed by relative predictive accuracy (C statistic: moderate is >0.80, excellent is >0.90) and scaling accuracy (the Hosmer-Lemeshow statistic). Several models predict periprocedural mortality with C statistic >0.80. Efforts are underway to formulate periprocedural bleeding and postprocedural contrast-induced nephropathy models (60–62).

Model utility also must consider the frequency and clinical importance of the event measured. Very infrequent events, even if severe, may not allow adequate evaluation of operators with low volume. Results of several years of experience must be considered to have a sufficient number of events to support statistical validity without excessively large confidence intervals. Operators and catheterization laboratories should be strongly encouraged to submit information to large and transparent clinical databases that allow for adequate benchmarking and the development of contemporary risk-adjusted outcomes. Comparison of operator outcomes should be only 1 component of a comprehensive continuous quality improvement program at a facility.

2.7. Components of Operator Competence

Table 3 identifies the components of operator competence for PCI utilizing the ACGME core competency structure (see Section 2.1). Included in each of the sections are potential tools for evaluation and outcome assessment.

2.7.1. ABIM Certification

Although ABIM-IC certification and MOC are strongly recommended, it is recognized that for some individuals not eligible for ABIM certification because their training was obtained outside the United States, alternative tools may be acceptable. Interventional cardiologists should also attain at least 30 hours of CME every 2 years.

2.8. Relationships of Institutional and Operator Experience and Activity to Outcomes in Coronary Interventional Procedures

Since the original observation by Luft et al. (63) in 1979 showing fewer deaths among patients undergoing procedures at higher-volume hospitals, the interplay of volume and outcome has been the subject of much investigation. In 1988, the ACC and AHA first adopted

Table 3. Core Competency Components for Percutaneous Coronary Interventions

Medical Knowledge
1. Know normal coronary artery anatomy, its variations and congenital abnormalities, and the physiology of coronary/myocardial blood flow.
2. Know the pathology of atherosclerotic and nonatherosclerotic coronary diseases.
3. Know the causes, pathophysiology, and differential diagnosis of myocardial ischemia and infarction.
4. Know the pathophysiology, clinical characteristics, and management of PCI-related spasm, slow reflow, abrupt closure, and restenosis.
5. Know the structural and polymer characteristics of coronary stents and drugs incorporated into them.
6. Know the coagulation cascade, and the indications, risks, and clinical pharmacology of antiplatelet, anticoagulant, and fibrinolytic drugs used in conjunction with, or in place of, PCI.
7. Know the indications for PCI and the adjunctive and alternative uses of medical therapy and surgery for patients with coronary artery disease.
8. Know the methods to assess functional significance of coronary lesions in the catheterization laboratory.
9. STEMI: know the roles of time of presentation, facility capability, anticipated door-to-device time, presence or absence of ongoing symptoms, and ECG abnormalities on the selection of reperfusion strategy.
10. Know the signs and hemodynamics of cardiac dysfunction, and their impact on reperfusion strategy and PCI decisions.
11. Know the limitations and contraindications of PCI, particularly as these relate to comorbid systemic diseases and special anatomical subsets.
12. Know the specialized equipment, techniques, and devices used to perform PCI, including, but not limited to: • X-ray imaging, radiation safety, and measures to minimize radiation exposure of patients, operators, and staff. • Specialized catheterization recording and safety equipment (physiological data recorders, pressure transducers, blood gas analyzers, defibrillators). • Catheters, guidewires, balloon catheters, stents, atherectomy devices, ultrasound catheters, intra-aortic balloon pumps, puncture site sealing devices, contrast agents, distal protection devices, and thrombus extraction devices.
13. Know the risk factors for, and the signs and management of, major PCI procedural complications and bleeding—including coronary vascular (e.g., dissection, thrombosis, perforation, embolization), and other vascular (e.g., pseudoaneurysm, retroperitoneal hemorrhage, arteriovenous fistula, and stroke) complications.
Know the systemic complications of PCI, including acute pulmonary congestion and contrast-related nephropathy, along with mechanisms to reduce their risk of occurrence.
Evaluation Tools: *ABIM-IC certifying examination; ABIM-IC MOC (see Section 2.7.1); accredited CME.*
Patient Care and Procedures
1. Skill to integrate clinical and laboratory data in selecting appropriate candidates for PCI, incorporating evidence-based guideline and clinical trial information.
2. Skills to perform percutaneous arterial (femoral and brachial/radial) and venous access, including postprocedural management and appropriate use of closure devices.
3. Skills to perform and analyze coronary angiograms, assess functional significance of coronary lesions, and determine risk/benefit of PCI (and the type of PCI) versus alternative revascularization or medical treatments.
4. Skills to effectively and safely operate and manipulate intravascular guidewires, coronary angioplasty balloon catheters, atherectomy devices, and coronary stents.
5. Skill to appropriately select and utilize intracoronary ultrasound, Doppler flow wires, and pressure wires.
6. Achievement of volume and quality outcome benchmarks for PCI—in training and in practice.
7. Skills to promptly detect and treat complications of PCI—both in the laboratory and postprocedure.
8. Skills to promptly recognize, identify cause of, and treat hemodynamic instability, including the appropriate emergent use of pharmacological agents and/or percutaneous mechanical circulatory assist devices.
9. Skills to carry out postprocedural evaluation, establish medical regimen and subsequent outpatient follow-up; including appropriate use of follow-up outpatient testing.
Evaluation Tools: *ABIM-IC certification; direct observation; professional society (ACCF) registries; hospital quality programs; conference participation.*

Continued on the next page

a physician volume standard of about 1 percutaneous transluminal coronary angioplasty (PTCA) case/week to maintain proficiency (64). The first Clinical Competence Statement on PTCA was subsequently published in 1990 by the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology and advocated a minimum of 75 PTCA procedures/year to maintain continuing competence (65). Since then, the use of PCI volume as a surrogate for quality and the adoption of arbitrarily-defined annual volume standards, despite the lack of

Table 3. Continued

Practice-Based Learning and Improvement
1. Review personal outcomes data via registry and/or hospital quality monitoring programs to identify and carry out areas of focused education or quality initiative.
2. Attend at least 30 hours of PCI CME every 2 years (this may include participation in the hospital's CME-approved multidisciplinary catheterization conference).
3. Participate in PCI quality programs of the hospital, including review of major complications.
4. Carry out structured education regarding new technologies and procedures.
Evaluation Tools: *Professional society registry data; hospital/catheterization lab quality data; catheterization/morbidity and mortality conferences; simulation; ABIM-IC MOC.*
Systems-Based Practice
1. Participate in regular (at least monthly) catheterization laboratory conferences, including participation by clinical cardiologists, interventional operators, and cardiothoracic surgeons.
2. Participate in a hospital-based state, regional, or national database to measure risk-adjusted PCI outcomes of the laboratory and compare them with regional and national benchmarks for improving quality of care.
3. Incorporate risk/benefit and cost awareness factors in clinical decisions and management of patients undergoing PCI.
4. Effectively lead the catheterization laboratory team in the performance of the procedure and care of the patient.
5. In conjunction with the hospital, ensure that the catheterization laboratory meets the following requirements: • Provides safe and quality radiologic, monitoring, and patient support equipment. • Has appropriate and qualified staffing.
Evaluation Tools: *Multisource (360) evaluations, professional society registry outcomes data; hospital/catheterization lab quality data.*
Professionalism
1. Practice evidence-based, guideline-directed, and patient-centered care within the scope of personal technical skills and expertise.
Evaluation Tools: *Multisource evaluations; outcomes and registry data.*
Interpersonal Skills and Communication
1. Communicate effectively and demonstrate sensitivity with patients across a broad socioeconomic, ethnic, and cultural spectrum.
2. Communicate effectively and professionally (and carry out effective transition) with referring physicians and other members of the cardiovascular team.
Evaluation Tools: *Patient satisfaction data; multisource (360) evaluations.*

ABIM-IC indicates American Board of Internal Medicine–Interventional Cardiology; ACCF American College of Cardiology Foundation; CME, continuing medical education; ECG, electrocardiography; MOC, maintenance of certification; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

definitive evidence, have generated much controversy (66,67).

2.8.1. Evidence Reviewed

SEARCH STRATEGY

To compile the relevant available scientific evidence relating institutional and operator activity level to outcomes (Online Appendices 1 to 3), we performed a computerized systematic literature search of all publications using Medline (PubMed and Ovid) and Cochrane Databases for studies published since January 1990. We also reviewed abstracts from recent ACCF, AHA, European Society of Cardiology, and Transcatheter Cardiovascular Therapeutics (TCT) proceedings, solicited manuscripts under review for publication from experts in the field, and conducted a manual review of the reference lists from the available studies. Greater weight was given to recent, peer-reviewed publications of high quality. No single work was considered definitive, and the shortcomings of the reviewed studies are discussed at length below.

2.8.1.1. RELATIONSHIP OF INSTITUTIONAL VOLUME TO PROCEDURAL OUTCOME

We identified 17 studies examining the impact of institutional volume to outcomes of PCIs (Online Appendix 1). Of the 8 studies conducted in the PTCA era (46,68–74), all except 1 (68) demonstrated a relationship between hospital volume and outcomes, with lower volume predicting predominantly the need for in-hospital CABG surgery (6 studies) (69–74) or in-hospital mortality (4 studies) (70–73). Of the 9 studies (57,58,75–81) in the stent era, 6 studies demonstrated an inverse relationship between mortality and PCI volume (57,58,75,78–80); 1 study showed a decrease in 30-day and 2-year CABG surgery in high-volume hospitals (77); and another showed a reduction in 30-day and 1-year adjusted rates of death,

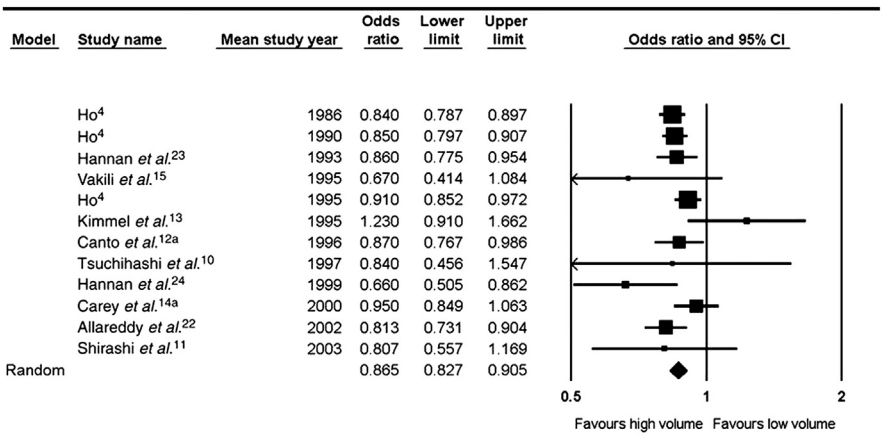
MI, or target-vessel revascularization in high-volume hospitals (81). The relationship between institutional procedural volume and outcome has been confirmed by multiple contemporary large registries, of which 3 included >100,000 patients (58,75,78).

A recent meta-analysis examined the relation between volume and outcome of PCI in 10 reports between 1995 and 2003 from an original pool of 140 papers (82). Of those, 8 studies were conducted in the United States and 7 used high-quality clinical data. The final meta-analysis included 1,322,342 patients from 1,746 hospitals. Patients treated in high-volume hospitals (≥600 PCIs/year) experienced lower in-hospital mortality (odds ratio [OR]: 0.87; 95% confidence interval [CI]: 0.83 to 0.91) compared with patients treated in lower-volume hospitals (400 to 600 PCIs per year) (Figure 1), noting moderate heterogeneity existed. When limiting the analyses to studies using the cutoff point of 400 PCIs/year, heterogeneity was diminished, but the effect estimate remained unchanged (OR: 0.86, 95% CI: 0.82 to 0.90). Interestingly, the more contemporary studies suggested a slightly smaller effect size than earlier studies ($p = 0.06$); however, meta-regression did not show notable changes in the effect size over the years (82).

Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures. This relation is supported by earlier studies in the PTCA era (46,69–74), contemporary studies in the stent era (57,58,75–81), and a recent meta-analysis (82). The writing committee recognizes the wide variability of institutional volume thresholds used in the different studies and the complexity and multitude of factors influencing PCI outcomes. However, it is important to note that a signal exists suggesting that an institutional volume threshold <200 PCIs/year appears to be consistently associated with worse outcomes across the various studies (Online Appendix 1) (58,75,80). Full-service (both primary and elective PCI) laboratories performing <200 total cases annually require additional considerations. Many such low-volume laboratories do not have onsite surgery and were developed to provide PPCI services to underserved or geographically isolated populations; a situation that the 2011 PCI guideline acknowledges may be acceptable. Elective PCI is often performed in these facilities to increase the volume of procedures and thus maintain facility and operator proficiency. There are also some laboratories that provide only PPCI service to similar populations. Such facilities 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. The continued operation of low-volume laboratories that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should close. This becomes increasingly relevant in an era of declining procedural volumes and expanded care delivery models for patients with STEMI (83).

2.8.1.2. RELATIONSHIP OF INDIVIDUAL OPERATOR VOLUME TO PROCEDURAL OUTCOME

We identified 9 studies examining the relationship between individual operator caseload and procedural outcomes in the stent era (Online Appendix 2). Of these, 4 studies demonstrated the existence of a relationship between low operator volume and increased adverse outcomes (58,84–86), predominantly CABG, but only 1 showed a modest correlation with in-hospital mortality (86). Notably, the 3 largest reports, each with a study population >100,000 patients, supported the existence of such a relationship (58,84,86).



[a]Unpublished results.

Figure 1. Results of Meta-Analysis of Studies Investigating the Effect of Center Volume on In-Hospital Mortality After PCI

CI indicates confidence interval; and PCI, percutaneous coronary intervention. Reprinted with permission from Post et al. (82).

The largest and most contemporary study involved 3,649 physicians (excluding those performing <10 PCIs/year) from the NCDR® CathPCI Registry and included 345,526 PCI procedures performed in 543 hospitals over 4 consecutive quarters, ending in July 2009. Using hierarchical logistic regression modeling to adjust for patient demographics, comorbidities, cardiac status, and hospital volume, this study compares outcomes including in-hospital mortality of patients treated by operators who performed <75 PCIs/year with those performing ≥75 PCIs/year. Median operator PCI annual volume was 75 PCIs (IQR: 38 to 127) and overall in-hospital mortality was 1.31%. After multivariable adjustment, in-hospital mortality remained significantly higher among physicians performing <75 PCIs/year (OR: 1.14; 95% CI: 1.05 to 1.24), noting that the correlation between in-hospital mortality and operator volume was modest ($R^2 = -0.0057$), and there was no clear inflection point for a minimal volume threshold (Figure 2). The absolute difference in mortality was 0.3% (86). Lower-volume operators had significantly higher rates of other complications, including bleeding, emergency PCI, and the need for postprocedural CABG surgery. A higher mean length of stay was also found in low-volume operator patients. This large NCDR® CathPCI Registry analysis, representing approximately 70% to 80% of all PCIs performed in the United States, has several important limitations including: data are limited to only voluntarily participating hospitals, and long-term outcome data are not available. These findings were reported at the 2011 AHA Scientific Sessions in Orlando, Florida (86), and the final peer-reviewed publication is not yet available.

An earlier report by McGrath et al. (84) analyzed data from the 1997 Medicare national claims database on 167,208 patients undergoing PCI by 6,534 operators. A significant relationship between operator volume and outcome was found, noting a lower risk of post-PCI CABG surgery in patients treated by high-volume operators (>60 PCIs/year); however, there was no observed difference in 30-day mortality (84). Similar findings were obtained by Hannan et al. (58), who analyzed data from 107,713 PCI procedures reported in the New York State Database from 1998 through 2000. Operator volume thresholds were set at 75 PCIs/year on the basis of the ACCF/AHA recommendations, and were compared with higher levels of 100 and 125 procedures/year. There were no differences in risk-adjusted mortality between patients undergoing PCI performed by low- versus high-volume operators for any of the 3 volume thresholds examined (58). However, significant differences for same-day and same-stay CABG surgery were observed for all 3 volume thresholds. For instance, patients undergoing PCI with operators performing <75 PCIs/year had a 65% increase of undergoing same-day CABG surgery and a 55% increase of undergoing same-stay CABG surgery (58). Another study by Moscucci et al. (59) involving 18,504 PCI procedures performed in 14 Michigan hospitals in 2002, demonstrated that patients treated by low-volume operators (<90 PCIs per year) experienced a 63% increase of MACE (a composite of death, MI, stroke or transient ischemic attack, CABG surgery, and repeat PCI) ($p<0.0001$) after multivariable adjustment, but not in-hospital mortality, compared with patients treated by operators in the higher-volume quintile. When using the 75 PCIs/year cutoff, no significant differences in adjusted MACE or mortality rates were observed (85).

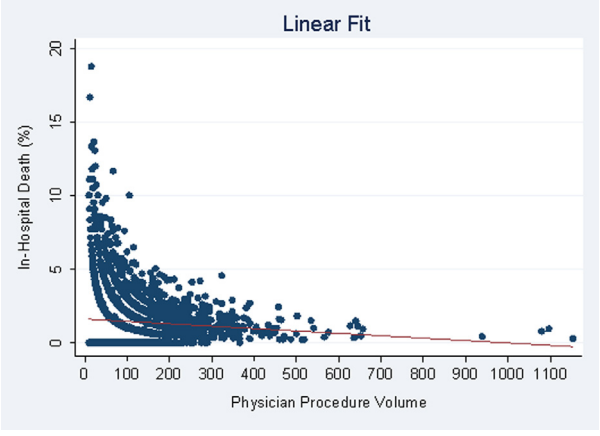


Figure 2. Scatter Plot of PCI Volume Versus In-Hospital Mortality

PCI indicates percutaneous coronary intervention. Reprinted with permission from Minges et al. (86).

The writing committee recognizes that the majority of interventional cardiologists in the United States are not achieving the previously recommended threshold of 75 PCIs annually (87). This may be related to many factors, including but not limited to: (a) the reduction of restenosis related to the widespread use of drug-eluting stents; (b) improved medical therapies and increasing appreciation of the importance of upfront guideline-directed medical management of stable CHD; (c) the presence of more interventional cardiologists and centers in the United States; and (d) the development and implementation and increasing awareness of Appropriate Use Criteria for coronary revascularization (52). We also recognize the increased use of invasive coronary physiological and anatomic assessments (e.g., fractional flow reserve, intravascular ultrasound) by many interventional cardiologists, which are usually not counted as PCI procedures but which, however, may conceivably influence PCI volume. There is also a shift towards the performance of noncoronary-based (structural) cardiac interventions by many experienced high-volume operators.

Overall, it is the opinion of the writing committee that the available evidence does not send a loud signal supporting a consistently strong relationship between operator caseload and mortality (58,84–86). In part, this is a function of the extremely low procedural-related mortality that now exists for PCI. The preponderance of data available is related to

clinical outcomes other than mortality and does suggest a possible relationship between operator volume and emergency CABG surgery and other PCI complications. On the basis of available data and the judgment of the writing committee involving all of these considerations, the writing committee recommends interventional cardiologists perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency. The writing committee acknowledges that this number is established primarily by expert opinion derived from the interpretation of substantial data from multiple sources (each with inherent limitations). Because of the limitations of these data, the writing committee believes operators performing <50 PCIs/year should not be denied privileges or excluded from performing coronary interventions based solely on their procedural volume. The committee acknowledges that there are low-volume operators who provide excellent clinical care and achieve excellent outcomes. In instances where operators are performing <50 PCIs annually, the writing committee strongly encourages both institutions and operators to carefully assess whether their performance is adequate to maintain competence. Other metrics are needed, in addition to volume and risk-adjusted outcomes, which have very wide confidence intervals at low procedure volumes, and thus are difficult to assess accurately. The committee suggests that each facility develop alternative pathways for the evaluation of low-volume operators. These pathways may be established and monitored by an independent institutional committee (consisting of physicians and relevant healthcare personnel) or an external review organization. The writing committee emphasizes that volume is but 1 of several factors that should be considered when assessing an individual operator's competence. Other factors to consider for low-volume operators include (but are not limited to): performance of additional noncoronary cardiovascular interventional procedures, lifetime experience, ABIM certification in interventional cardiology, attendance at educational symposiums, CME credits, and simulation courses.

Although this recommendation focuses on the minimal procedural volume considered acceptable for maintaining competence, the writing committee believes it is important to evaluate the performance of all operators. Separate concerns may exist for very high-volume operators. Compliance with suggested guidelines and appropriateness of procedures are important metrics to consider when evaluating competency of all operators.*

*Although the 2011 ACCF/AHA/SCAI PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing group, tasked specifically with examining volume thresholds, would be the primary source and that the 2011 PCI guidelines might be subsequently modified. Therefore, the operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (2).

2.8.1.3. VOLUME AND OUTCOMES RELATIONSHIP FOR PRIMARY PCI IN ACUTE MI

PPCI requires several clinical, cognitive, and procedural skills not necessarily involved with performing elective PCI. Online Appendix 3 summarizes 16 published studies examining the relationship between operator and institutional volume and outcomes in patients undergoing PPCI. Of those studies, 4 showed no relationship between volume and mortality (88–91), although the latter (the only U.S. study of all 4 reports) demonstrated shorter door-to-balloon (DTB) time and greater adherence to evidence-based therapies observed in higher-volume PPCI centers (91). Of the 12 remaining reports, 10 studies (58,92–100) demonstrated a significant inverse relationship between hospital PPCI volume and in-hospital mortality, whereas 2 studies (101,102) showed similar relationships relating hospital total PCI volume to mortality. Only 2 studies (97,99) demonstrated a significant inverse relationship between the operator PPCI volume and in-hospital mortality, whereas 1 report (58) failed to show such a relationship after multivariable adjustment. It is important to note that these relationships were examined nearly exclusively at hospitals with onsite cardiac surgery.

Hannan et al. (58) examined data from the New York State Coronary Angioplasty Reporting System Registry collected between 1998 and 2000, a period when stenting was used in a large majority of STEMI patients. A non-significant trend towards increased in-hospital mortality was observed for low-volume operators when compared with high-volume operators both for volume cutoffs of 8 PPCIs/year (OR: 1.40; 95% CI: 089 to 2.20) and 10 PPCIs/year (OR: 1.27; 95% CI: 0.87 to 1.87). Importantly, a significant increase in the odds of in-hospital mortality was observed with lower institutional volume of PPCI, regardless of whether the threshold was set at 36 PPCIs/year (OR: 2.01; 95% CI: 1.27 to 3.17), 40 PPCIs/year (OR: 1.73; 95% CI: 1.1 to 2.71), or 60 PPCIs/year (OR: 1.45; 95% CI: 1.01 to 2.09). Recently, Srinivas et al. (99) examined the impact of annual hospital and physician volume and their interaction on risk-adjusted mortality in 7,321 patients undergoing PPCI for acute MI from the New York State PCI Registry (2000 to 2002). High-volume operators performing >10 PPCIs/year and those performing >20 PPCIs/year demonstrated a 34% and 37% reduction in risk-adjusted mortality, respectively, compared with their low-volume counterparts ($p < 0.05$). High-volume hospitals (>50 PPCIs/year) also achieved statistically significant reductions in mortality (adjusted OR: 0.58; 95% CI: 0.38 to 0.88). The thresholds at which the benefit was observed were similar to the ACCF/AHA volume recommendations, and as such, the investigators recommended adherence to current guidelines and the monitoring of PPCI performance by low-volume operators (99). A recent analysis (91) explored the relationship between hospital volume (primary and total PCI volumes) and patient outcomes in the AHA's Get With the

Guidelines–Coronary Artery Disease (GWTG–CAD) National Registry (2001 to 2007). Hospitals were divided into tertiles of PPCI volume as low (<36 PPCIs/year), medium (36 to 70 PPCIs/year), and high (>70 PPCIs/year). Total PCI volume was similarly calculated, and hospitals were again divided into tertiles based on the ACCF/AHA recommended thresholds as low (<200 PCIs/year), medium (200 to 400 PCIs/year), and high (>400 PCIs/year). A total of 29,513 patients with STEMI were treated with PPCI at 166 hospitals across the United States. Hospital annual PPCI volume ranged between 9 and 225 patients, with a median of 49 (IQR: 27 to 78) patients. Compared with low- and medium-volume centers, high-volume centers had better median DTB times (98 versus 90 versus 88 minutes, respectively; p for trend <0.001) and were more likely to follow evidence-based guidelines at discharge. The investigators found no significant differences in crude mortality between the PPCI volume groups, even after sequential multivariable adjustment (91). By contrast, patients presenting to low total PCI volume hospitals had a higher crude mortality compared with medium- and high-volume hospitals (3.5% versus 3.3% versus 3.0%, respectively; p for trend = 0.05), which did not remain statistically significant after multivariable adjustment (91). The importance of the GWTG–CAD study (91) stems from its inclusion of a large patient population and representation of real-world contemporary practices from all U.S. census regions. The lack of mortality benefit, although it stands out in contrast to other reports (58,92–100), does not eliminate volume as an important marker of PPCI quality, especially given the differences in secondary outcomes and quality measures (91).

Although a large body of evidence supports the existence of a relationship between hospital volume of PPCI and outcome (Online Appendix 3), only a paucity of studies related total hospital PCI volume to outcome of acute MI (79,102). Spaulding et al. (102) examined the relationship between hospital PCI volume and outcomes after emergency PCI procedures from the CARDIO-ARHIF (Agence Régionale d'Hospitalisation d'Ile de France) Registry, which included a total of 37,848 total PCIs from 44 centers in the greater Paris area (2001 to 2002). Emergency PCI was defined as PCI performed for acute MI, cardiogenic shock, or successfully resuscitated out-of-hospital cardiac arrest. The investigators used a threshold of 400 PCIs/year to define low- (<400) and high-volume (≥400) centers. In this relatively contemporary study in the stent era, the investigators found no relationship between hospital PCI volume and in-hospital mortality for non-emergency procedures. However, a clear inverse relationship existed between hospital volume and mortality for emergency PCIs (8.5% versus 6.8%, p = 0.028), which persisted after multivariable adjustment (102). Complication rates were higher in low-volume centers in patients undergoing both planned and emergency procedures, even after multivariable adjustment (102). In another contemporary study by Zahn et al. (79), a small but significant inverse volume–outcome relationship existed for in-hospital mortality (using total PCI volume threshold of 325 PCIs/year); however, this relationship was only apparent in high-risk subgroups, such as patients presenting with acute MI. Both of these studies have important implications (79,102), because they reinforce the notion that the volume–outcome relationship, if existent in the contemporary era, is likely to be most apparent among high-risk patients undergoing emergency and PPCI procedures.

Based on the available literature, strong evidence exists for an inverse relationship between hospital PPCI volume, in-hospital mortality (with the exception of the GWTG–CAD study) (91) and other major adverse cardiovascular outcomes. No clear signal relating operator PPCI volume and hospital total PCI volume to acute MI outcomes exists. The writing committee endorses the 2011 ACCF/AHA/SCAI PCI guideline recommendation that PPCI for STEMI be performed by experienced operators who perform more than 11 PPCI procedures per year, and ideally, these procedures should be performed at facilities that perform >36 PPCI procedures annually (2). However, the writing committee acknowledges that geographic challenges to timely access for PPCI may exist in some areas. Low-volume centers that only perform PPCI (typically without onsite surgery) and exist to meet critical access needs must demonstrate acceptable outcomes. This can be accomplished through the reliance on stringent systems and process protocols along with close monitoring of clinical outcomes. Such centers enhance their chance of success by an association with larger facilities and the rotation of interventionalists, clinical catheterization lab staff, and hospital support staff at a high-volume PCI center (53).

2.8.1.4. OUTCOMES RELATIONSHIP FOR PCI IN HOSPITALS WITHOUT ONSITE CARDIAC SURGERY

Controversy over the performance of PCI without onsite cardiac surgery has existed for a considerable time in the United States, although it is more widely accepted in many countries abroad (54,103). After publication of the quantitative review by Keeley et al. in 2003, the superiority of PCI over thrombolytic therapy for the treatment of STEMI became widely accepted (104). This acknowledgement encouraged the development of primary PCI programs at hospitals without cardiac surgery in an effort to provide this treatment rapidly to patients with STEMI in their local communities (105). Difficulties sustaining the proficiency of support personnel and operators within a PCI program limited to patients with STEMI were used to support the performance of PCI cases in patients presenting without ST-elevation MI at facilities without onsite cardiac surgery in an attempt to maintain higher PCI volumes and staff expertise (106,107). Despite guideline recommendations in place at the time, the number of PCI facilities without onsite cardiac surgery in

the United States continued to grow (108). In 2007, the SCAI published an expert consensus document, which reviewed the topic of PCI without onsite surgery and provided recommendations to assure appropriate patient care in this setting (54). This document acknowledged the reality that as of 2007, primary and elective PCI without onsite surgery was already being performed in 28 states despite the guideline recommendations current at the time.

2.8.1.4.1. THE SAFETY OF PCI WITHOUT ONSITE CARDIAC SURGERY

As techniques for performing PCI and drug therapies used during PCI continued to improve, the safety of PCI without onsite cardiac surgery has been reevaluated in several recent studies and meta-analyses (33,109–113) (Online Appendix 4). Separate analyses of registry data from Sweden and the United States showed no differences for in-hospital mortality, 30-day mortality, or the need for emergency CABG surgery among hospitals with and without onsite surgery (33,109). Two recent meta-analyses also showed no difference in mortality for primary or non-primary PCI among hospitals with and without onsite surgery and no difference in the need for emergency CABG surgery (110,111). However, in both analyses, heterogeneity was observed in the outcomes for non-primary PCI among sites without onsite surgery, prompting the authors to make strong recommendations about how such sites should function to ensure optimal results. Finally, the Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial randomized patients undergoing elective PCI to treatment at hospitals with and without onsite surgery (113). Within the context of this well-controlled study, elective PCI at hospitals without onsite surgery was shown to be not inferior to PCI at hospitals with onsite surgery.

Reflecting the continued accumulation of data on the safety of PCI without onsite surgical backup, the most recent ACCF/AHA/SCAI PCI guideline classified primary PCI without onsite surgery as Class IIa (Level of Evidence: B) and elective PCI as Class IIb (Level of Evidence: B) indications, providing appropriate planning for program development has been accomplished (2). Elective PCI without onsite cardiac surgical backup was considered appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Numerous personnel, facility, operator, and structural requirements adapted from the SCAI expert consensus documents were described (2,54).

2.8.1.4.2. EXISTING RECOMMENDATIONS FOR OPERATOR COMPETENCY AT HOSPITALS WITHOUT ONSITE CARDIAC SURGERY

Noting that PCI without onsite surgery is more routinely practiced, it is important to emphasize that almost all safety data come from well-controlled studies or registries at facilities with a strong commitment to quality outcomes. Little has been written concerning operator competency requirements specifically at hospitals without onsite surgery, but it is reasonable to assume that outcomes similar to those reported in the literature would require facilities and operators to adhere to the same requirements outlined in the published studies of PCI without onsite surgery. For example, in CPORT-E, operators were required to meet the requirements for competency set forth in the ACCF/AHA/SCAI guideline existing at the time of the study (minimum 75 PCIs annually), and facilities were required to have an annual PCI volume of 200 cases after the first year of operation. Within these studies, other factors noted as contributing to the favorable outcomes in hospitals without onsite surgery included: a) submitting data to a national repository for benchmarking; b) linkage of such facilities to a tertiary care center for consultation; c) cross-training of personnel; d) similar processes and structures of care for a patient undergoing PCI; e) expeditious transfer for emergency CABG surgery; and f) use of risk-adjustment tools for case selection, outcomes analyses, and comparison of operator performance (33,112,113). It has also been shown that patients admitted to PCI centers without onsite surgery have a higher mortality and are less likely to receive guideline-recommended medications or to receive reperfusion therapy (114). However, when the analysis was restricted to patients who received PPCI, the mortality difference was not significant.

The 2011 ACCF/AHA/SCAI PCI guideline emphasizes that *all* PCI programs need a robust quality improvement program that routinely reviews quality and outcomes for the entire program and for individual operators. Elements of this Class I recommendation include peer review of complicated cases or cases with poor outcome plus random case reviews and participation in a registry so appropriate benchmarks are established and risk adjustment can be performed. Board certification and MOC in interventional cardiology is strongly encouraged (2). Maintenance of certification in interventional cardiology currently requires physicians to document a minimum of 150 interventional cases over the 2 years before expiration of the current certification, completion of self-assessment modules of their medical knowledge, participation in a practice-based quality-improvement activity, and passage of a knowledge-based examination. Operator and hospital volume requirements in the 2011 ACCF/AHA/SCAI PCI guideline were carried forward from the 2005 guideline with the writing committee acknowledging that the volume recommendations were controversial and should have a Level of Evidence C rather than B as in the prior guideline.

The SCAI Expert Consensus Document proposed more rigorous requirements for operators and facilities without onsite surgery to reflect the opinion of the SCAI writing group that a greater experience level is appropriate for PCI

in the absence of onsite surgery (54). They recommended that initial operators at a facility without onsite surgery should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without onsite surgery with <500 cases of lifetime experience should be mentored and monitored by qualified physicians until it is determined their skills and judgment are satisfactory and outcomes equivalent or superior to the national benchmarks. Accordingly, this writing committee recommends operators performing PCI without onsite surgery should perform >50 total PCIs per year, including >11 primary PCIs per year. 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 onsite surgical backup to meet these annual volume requirements.[†]

2.8.1.4.3. VOLUME–OUTCOME RELATIONSHIP AT FACILITIES WITHOUT ONSITE SURGERY

As noted in an earlier section, the relationship between both operator and hospital volume and outcomes at facilities with onsite cardiac surgery is not straightforward and may be inconsistent across low-volume institutions or operators. This is especially problematic because data from the NCDR® shows a predominance of low-volume hospitals are facilities without onsite surgery (33,83). Several strategies have been suggested to ensure optimal quality and outcomes at low-volume facilities without onsite surgery, including: a) having both operators and support personnel rotate at a high-volume facility to enhance experience; and b) rigorous quality monitoring program with oversight from a high-volume facility or formal evaluation by an external accreditation organization. Performing adequate peer review may be especially difficult at low-volume facilities with only a few operators. It should be emphasized, however, that the strongest rationale for the development of PCI facilities without onsite surgery was the desire to provide rapid PPCI to patients in their communities. Since 2000, there has been a substantial decline in the incidence of STEMI, and there is now greater emphasis on developing systems of care for STEMI patients as promoted in the *Mission Lifeline* initiative (115,116). All of these factors will further challenge smaller facilities wishing to sustain PCI programs, potentially reducing the number of PCIs performed per facility and per operator. Accordingly, the writing committee recommends that an institution without onsite surgery with a volume fewer than 200 procedures annually, unless in a region underserved because of geography, should strongly consider whether or not it should continue to offer this service. This becomes increasingly relevant in an era of declining procedural volumes and expanded institutional capabilities (83).[†]

2.8.1.5. THE INTERPLAY BETWEEN OPERATOR AND INSTITUTIONAL PCI VOLUME AND OUTCOME

It has been widely acknowledged that institutional experience may modify the volume–outcome relationship at the individual operator level. In 1990, Ryan et al. (65, p. 1473) recognized that "operator skill and judgment are greatly influenced by personal experience … and by the environment in which the operator practices."

Hannan et al. (58) demonstrated that, compared with patients undergoing PCI by high-volume operators (≥75/year) in high-volume hospitals (≥400/year), patients undergoing PCI by low-volume operators (<75/year) in low-volume hospitals (<400/year) had significantly higher rates of in-hospital mortality (OR: 5.92; 95% CI: 3.25 to 10.97), same-day CABG (OR: 4.02; 95% CI: 1.04 to 15.57), and same-stay CABG (OR: 3.19; 95% CI: 1.51 to 6.77). A comparison of the size of the effect estimates showed that the increase in adverse outcomes became additive when PCIs are performed by low-volume operators in low-volume hospitals (58). A similar institutional–operator volume relationship (117) to outcomes was reported in 452,404 patients undergoing PCI in Florida and New York between 1996 and 2001. Operators performing ≥75 PCIs at hospitals performing >400 PCIs had the lowest occurrence of the overall composite outcome (in-hospital mortality and emergency CABG surgery) in each year (117). Srinivas et al. (99) demonstrated a significant interaction between hospital and physician volume with respect to adjusted mortality (p=0.02) among acute MI patients undergoing PPCI from the New York State PCI Registry (2000 to 2002). PPCI by high-volume physicians (>10 PPCIs/year) in high-volume hospitals (>50 PPCIs/year) was associated with the lowest risk-adjusted mortality, followed by high-volume physicians in low-volume hospitals, low-volume physicians in high-volume hospitals, and finally, low-volume physicians in low-volume hospitals.

2.8.1.6. LIMITATIONS OF THE EXISTING EVIDENCE

The majority of evidence related to volume–outcome relationship is derived from retrospective administrative data, observational studies, or large registry data; all of which have shortcomings (Online Appendices 1–3). Many of these studies used administrative data to analyze volume–outcome relations. Incomplete reporting of comorbidities is an important limitation of administrative data (73,76). A comparison of administrative versus clinical data in patients found that the former failed to identify more than half of patients with a prognostically important condition

[†]Although the 2011 ACCF/AHA/SCAI PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing group, tasked specifically with examining volume thresholds, would be the primary source and that the 2011 PCI guidelines might be subsequently modified. Therefore, the operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (2).

identified by the clinical information system (118). Administrative data may also be confounded by miscoding, including increased coding of comorbidities to raise reimbursement (118). Additional recognized limitations of specific databases exist. When using the Medicare data, for example, one needs to extrapolate the total number of procedures from the number of Medicare procedures (68,70,71,84). By contrast, the GWTG initiative is a quality improvement registry and not meant to examine the volume–outcome relationships (91). Data are submitted voluntarily to the GWTG–CAD database by participating hospitals and collected by medical chart review, and are thus dependent on the accuracy and completeness of abstraction (91). The New York Registry (58,97,99,101,117) is characterized by mandatory participation and a comprehensive auditing process, which ensures accuracy and minimizes self-reporting bias. However, because of New York's certificate of need system, the number of low-volume hospitals in the registry is limited, so it is more difficult to study their performance. Data on timeliness of reperfusion are also lacking, and the generalizability of data from a single state registry remains questionable. The latter is not an issue for the Nationwide Inpatient Sample database, which represents a 20% stratified sample of community hospitals in the United States. However, the Nationwide Inpatient Sample database does not capture long-term mortality and clinical outcomes, and has no information on the severity of the primary diagnosis or comorbid conditions, which precludes robust risk-adjustment analyses (78).

Overall, data from these studies should be viewed in the context of their retrospective observational nature. They identify only associations rather than causality. In addition, despite the use of intricate multivariable analyses in the various studies, no amount of adjustment in regression models can completely separate the greater illness severity from worse outcomes, and some portion of the relationship may still be due to selection bias. Referral bias is also an important confounder, with low-volume hospitals having disproportionately more patients with acute coronary syndrome and a lower percentage of stable coronary artery disease patients. The National Surgical Quality Improvement Program studies underscored the limitations of claims data and administrative databases in the provision of adequate risk-adjustment models that are crucial for volume–outcome studies (67).

2.8.2. Volume as a Surrogate for Quality

2.8.2.1. PLAUSIBLE EXPLANATIONS FOR THE VOLUME–OUTCOME RELATIONSHIP

Various factors can explain the relationship between PCI volume and outcome. It is possible that PCI volume is correlated with enhanced care processes, including the implementation of specific clinical practice guidelines for patients undergoing PCI or familiarity with treating its complications and emergencies. The influence of the learning effect among operators (high-volume operators developing more experience) is also important. High-volume hospitals are likely to have high-volume operators and, consequently, experience better outcomes. High-volume hospitals may also be accepting higher-risk patients with more complex anatomy that may adversely affect outcomes.

2.8.2.2. LIFETIME PCI EXPERIENCE RELATIONSHIP TO QUALITY

Historically, volume has been used as a surrogate for quality because it was most easily measureable. However, we feel it is important to note that volume is only 1 of many factors affecting the outcome and quality of PCI. Many studies have emphasized that the quality of systems of care are more important than volume in determining the overall quality of procedural care at an institution. Volume should not be substituted for prospectively monitored and properly risk-adjusted outcomes (67); however, evaluating competency is only feasible when an operator or an institution performs an adequate number of cases to assess risk-adjusted outcomes. The 2011 ACCF/AHA/SCAI PCI guideline emphasized that risk-adjusted outcomes remain preferable to institutional and individual operator volumes as quality measures (2), outlining the importance to shift the paradigm from examining volume (a surrogate of outcome) to direct outcome assessment. Lifetime operator experience and appropriateness of procedure are also important metrics. One small study from Japan (7 operators performing PCI on 121 STEMI patients) demonstrated that junior cardiologists who performed >50 elective PCIs can perform PPCI with similar outcomes to experienced operators (>5 years of experience and board certified). However, the impact of lifetime operator experience needs to be explored in larger studies, especially in our current environment when many experienced operators are increasingly performing structural interventions at the expense of lower coronary interventional volume, and older experienced operators often are required to take less on-call time than younger members of their group. Periodic case review to ascertain appropriateness and quality of PCI procedures is also important (refer to section 2.10.5.1). Low-risk PCIs performed for the wrong indication are likely to have favorable outcomes but still reflect poor PCI quality because of inappropriateness of selection. Variables affecting PCI outcome are summarized in Table 4 (119).

Table 4. Possible Predictors of Clinical Outcomes Following PCI

Case selection
Patient-specific risk factors
Institutional volume: sharing of techniques, more experience in high-risk cases
Operator volume: annual, lifetime
Appropriateness criteria and indication level
High-risk case selection may be related to higher case volume
Location of hospital: rural/suburban, community, academic teaching
Board certification: cognitive learning, evidence-based practice

Reprinted with permission from Klein et al. (128).
PCI indicates percutaneous coronary intervention.

2.8.2.3. CAUTION AGAINST PREOCCUPATION WITH SPECIFIC VOLUME RECOMMENDATIONS

The 2011 ACCF/AHA/SCAI PCI guideline recommended that PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high-volume centers (>400 procedures) with onsite cardiac surgery (2). These volume recommendations were carried over from the 2005 ACCF/AHA/SCAI PCI guideline (25) but downgraded to a Level of Evidence C, recognizing that they represent expert opinion and lack strong and consistent evidence from the literature. The 2011 PCI guidelines also encouraged the ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures writing committee to review this issue (2).

It is the opinion of our writing committee that the public, policymakers, and payers should not overemphasize specific volume recommendations recognizing that this is just 1 of many factors that may be related to clinical outcomes. Notably, 1 report found that <1/3 of physicians performed >10 PPCIs/year (99), whereas another showed that >1/3 of U.S. hospitals did not achieve the 36 PPCIs/year threshold (91). The Leapfrog Group initially focused on minimum volume standards to measure quality and encouraged their members to contract with hospitals that meet minimum volume thresholds (120). However, in 2003, they expanded their measures to include documented adherence to certain clinical care processes and direct outcomes measurement (i.e., risk-adjusted mortality) (121). Of note, the 2010 European Society of Cardiology Guidelines on Myocardial Revascularization avoided giving specific recommendations on operator or hospital minimum volumes (122).

The relative benefit of more favorable outcomes at facilities with higher volumes must be weighed against the potential decline in access resulting from minimum volume standards or regionalization of care. Although regionalization of care may ensure better outcomes (especially in the early stages of a medical intervention), it may also limit healthcare access and may therefore have negative consequences for patients in less populated areas requiring emergency PCI. After reviewing the preponderance of evidence, the writing committee could not identify definite cutoffs for procedural volume above or below which operators perform well or poorly. We recognize that advancements in technology and periprocedural care may result in progressive improvement in PCI outcomes and may at least partially offset the adverse institution volume–outcome relationship. A study evaluating temporal trends in the volume–outcome relationship in California found that over time, the disparity in outcomes between low- and high-volume hospitals had narrowed (73). These findings were, however, disputed by others who found no evidence of attenuation over time of the volume–outcome relationship (82).

Our writing committee recognizes that there are institutions with low volumes that appear to achieve very acceptable results just as there are low-volume operators with better than expected outcomes and a few high-volume operators with worse outcomes (85). Because of the likelihood of statistical imprecision when examining outcomes of low-volume operators, other metrics are needed in addition to volume and risk-adjusted outcomes. It is also important to account for operators' lifetime experiences: many experienced operators are currently performing low-volume coronary interventional work and shifting to structural work or a larger portion of administrative duties, and these should be distinguished from *"inexperienced"* low-volume operators. Institutions are encouraged to perform periodic peer review of random interventional cases for all operators. Importantly, low-volume operators should undergo more scrutinized case review. Participation in regional and national registries such as the NCDR® CathPCI Registry is strongly recommended. Such registries should provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies and other stakeholders can accurately assess the quality of care delivered. Additional emphasis on educational symposia, CME credits, and simulation courses may provide other venues to enhance quality for all operators. Currently, several simulation companies have products designed to present coronary, peripheral, carotid, and structural cardiac cases that can be used for teaching or evaluation of cognitive and procedural skills. The use of these simulators has mostly been in the area of fellow education or MOC modules, or industry has used them to train practitioners to use new or less frequently used devices. Supported by accumulating evidence, many educators advocate the use of simulator-based training as a means to complement conventional training in interventional cardiology (123–126). There are emerging data suggesting that simulators might serve to identify low-ability operators; however, the writing committee acknowledges current technological and access limitations currently exist, presenting challenges to the widespread use of simulation (127).

2.8.3. Conclusions

In the current era, volume–outcome relationships are not as robust as those that were shown when balloon angioplasty was the only treatment modality. More recent data support a modest volume–outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies. An institutional volume threshold <200 PCIs/annually appears to be consistently associated with worse outcomes, but above this level, there was no relationship between even higher annual volumes and improved outcomes. Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year. There is less evidence to support a threshold for individual operator volume for both elective and primary PCI. It is the writing committee's recommendation that interventional cardiologists perform a minimum of 50 PCI procedures per year (averaged over

a 2-year period) to maintain competency. The writing committee cautions against focusing on specific volume recommendations, and emphasizes that procedural volume is 1 of several variables to consider when determining operator competency. Volume is not a surrogate for quality and should not be substituted for risk-adjusted outcomes and other measures of quality. Periodic case review and ascertainment of the appropriateness of procedures should be performed for all operators and at all institutions. Our writing committee strongly encourages the participation in a local or national registry, such as the NCDR® CathPCI Registry, which can help measure performance, assess appropriateness of procedures, and promote continuous quality improvement.

2.9. Radial Access

Radial coronary angiography was first introduced by Lucian Campeau in 1989 (129), followed by radial PCI first performed by Ferdinand Kiemeneij in 1992 (130). Over the last 2 decades, the use of radial coronary angiography and intervention has steadily increased across Europe, Asia, and Canada (131–133). The penetration of the radial approach into the United States, however, has been slow and was estimated at 2% in 2008 (134) but continues to rise (135). The slow adoption of this technique in the United States has been due to a prior lack of formal training during fellowships as well as the lack of well-defined training pathways for physicians in practice.

Use of the radial artery for diagnostic and interventional coronary procedures has been compared with the femoral approach in both observational studies and randomized trials and has demonstrated significant reductions in bleeding and access site complications (131–134,136,137). The most compelling evidence supporting the advantages of radial access comes from the RIVAL (Radial versus Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes) trial (136), which compared outcomes in 7,021 patients randomized to either radial (n = 3,507) or femoral access (n = 3,514). Although the primary endpoint (e.g., death, MI, bleeding, access site complications) was negative, this trial demonstrated that in certain situations (e.g., patients presenting with STEMI) a radial approach may be associated with significant reduction in access site complications and mortality versus a femoral access approach (Figure 3). Furthermore, this study supports prior observations (137,138) reporting a patient preference for the radial approach noting less discomfort and greater postprocedural mobility.

The use of a transradial approach, however, is associated with a steeper learning curve (139), and potential increased radiation exposure and radial artery occlusion that can be as high as 30% if best practices are not followed (140). Patient selection and preprocedural evaluation are critical components of assuring a successful transradial procedure. The ideal patient characteristics include: 1) hemodynamic stability; 2) age <70 years; 3) no history of prior ipsilateral brachial or transradial procedure; and 4) a palpable radial artery with a strong pulse and presence of a normal Barbeau test (141). Relative contraindications to the radial approach include an absent radial pulse, an abnormal Barbeau test, severe vasospastic conditions, planned or existing arteriovenous shunt for dialysis, and the potential use of the radial artery as a conduit for aortocoronary bypass.

The Barbeau test evaluates the patency of the ulnopalmar arterial arches by recording both pulse oximetry and plethysmography during radial artery compression. An oximetric probe is placed on the first finger or thumb of the hand where access is to be obtained. When the radial and ulnar arteries are occluded, the waveform should be dampened, and no oxygen saturation number can be recorded. The Barbeau test is more sensitive than the Allen's or modified Allen's tests, and classifies patients into 4 groups. If the waveform remains dampened after release of the compressed ulnar artery, the test is considered abnormal (type D), and the radial artery should not be punctured. Type D pattern usually occurs in only 1.5% of patients.

2.9.1. Training

Current interventional cardiology training program guidelines provide no specific recommendations regarding training for the transradial approach. The ACCF Core Cardiology Training Symposium (COCATS) guidelines state that one needs the ability to "perform vascular access from the femoral, radial, or brachial route" (142). Also, the current ACGME Program Requirements for Graduate Medical Education in Interventional Cardiology states that "Fellows must have formal instruction, clinical experience, and must demonstrate competence in the performance of coronary interventions [via] femoral and brachial/radial cannulation of normal and abnormally-located coronary ostia" (3, p. 10).

Ideally, interventional fellows would graduate with competency in radial and femoral procedures, and practicing physicians would have a well-defined pathway to gain these skills. However, this has not come to fruition in the United States due to the small number of radial procedures and the limited number of interventional cardiologists skilled in this technique. Training in radial coronary angiography and interventions should include acquisition of knowledge and competence in the following:

1. Anatomy of the upper extremity vasculature
2. Patient evaluation and selection for transradial approach
3. Selection of right or left transradial approach
4. Patient preparation and room set-up
5. Radial artery access
6. Arterial vasodilators and antithrombotic pharmacology
7. Catheter selection and manipulation for diagnostic and interventional procedures
8. Troubleshooting during transradial approach

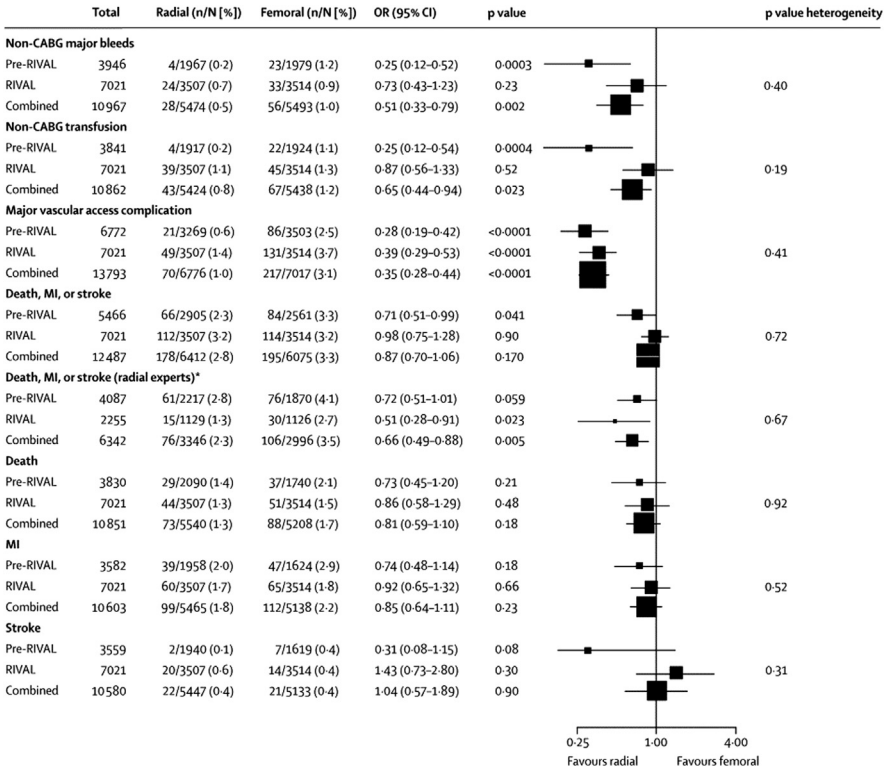


Figure 3. Forest Plot of the Updated Meta-Analysis (RIVAL Trial)

*Defined as centers with radial as the preferred route or known expert centers for pre-RIVAL, and centers with the highest tertile radial intervention center volume for RIVAL. CABG indicates coronary artery bypass graft surgery; CI, confidence interval; MI, myocardial infarction; OR, odds ratio; and RIVAL, Radial vs. Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes trial. Reprinted with permission from Jolly et al. (136).

9. Prevention, recognition, and management of complications
10. Sheath removal and access site management

For physicians in practice, the number of cases required for competency will be based on the expertise of the operator. The learning curve for any new procedure partially depends on the cumulative experience of the operator in catheter-based interventions. Fellows in training will need prospectively defined curricula that cover the spectrum of cognitive and technical skills required to master this approach.

2.9.2. Competency

Currently, there are no standard guidelines that define competency in radial angiography and interventions. The SCAI subcommittee for transradial angiography and intervention proposed the following criteria (141):

- Level 1 competency: able to perform simple diagnostic cases on patients with favorable upper limb anatomy (large men)
- Level 2 competency: Able to perform simple diagnostic and interventional procedures on patients with more challenging upper limb anatomy (elective single vessel PCI; bypass grafts, small women, radial and subclavian loops)
- Level 3 competency: Able to perform complex interventional procedures even with challenging limb anatomy (chronic total occlusions, multivessel, acute MI)

At the present time, as such pathways develop, the outcomes of PCI procedures via the radial approach should be assessed in a similar manner to that of other PCI procedures, with attention to bleeding, access site complications, and overall outcomes. These procedures should be included in the overall volume statistics for the operator, and institutions or operators may wish to separately evaluate operator or laboratory performance based upon route of access. Further expansion of specialized training courses for interventional cardiologists already in practice wanting to acquire competencies in radial coronary angiography and PCI should be provided to meet current needs.

2.10. Quality Assurance

2.10.1. Definition of Quality in PCI

Quality in PCI includes selecting appropriate patients for the procedure, achieving risk-adjusted outcomes that are comparable to national benchmark standards (in terms of procedural success and adverse event rates), using reasonable resources, achieving quality procedure execution

(including the use of evidence-based medical therapies) and providing an acceptable patient experience (143). To achieve optimal quality and outcomes in PCI, including acceptable angiographic, procedural, and clinical success rates, it is necessary that operators and the supporting institution be appropriately skilled and experienced, collect data to allow quality analysis, and have established appropriate systems of care.

2.10.2. Institutional Requirement for a Quality Assurance Program

In the United States, responsibility for quality assurance is vested in the healthcare institution that is responsible to the public to ensure that patient care conducted under its jurisdiction is of acceptable quality. Quality assurance should include continuous quality assessment and improvement (QI) processes, and should be conducted at the levels of the entire program and the individual operator.

The writing committee supports the recommendation of the 2011 ACCF/AHA/SCAI PCI guideline that every PCI program should operate a quality improvement program that routinely: 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews (2). Each institution that provides PCI services must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. The program should provide an opportunity for interventional cardiologists and all involved physicians, including members of an integrated heart team, to review its overall results on a regular basis and receive periodic feedback to enhance deficiencies in PCI care. The review process should tabulate the outcomes achieved both by individual operators and the overall program, and compare them with national benchmark standards with appropriate risk adjustment. The review process should also assess the appropriateness of the interventional procedures, and examine other procedural variables pertinent to quality execution of the procedure, periprocedural management, and resource utilization. Valid quality assessment requires that the institution maintain meticulous and confidential records that include patients' demographics and clinical characteristics necessary to assess these measures and conduct risk adjustment in a transparent manner.

An independent and dedicated committee should be established and ideally include both physicians and relevant healthcare personnel in a cooperative effort minimizing any conflict of interest. Interventional cardiologists are best suited to perform the primary role in evaluating PCI quality and leading the quality assurance program. The process should be instituted with the support of hospital administrators who can help provide resources for registry participation, conduct analyses, and support other aspects of the QI process. The hospital risk management department, responsible for investigating reported events and government-mandated quality indicators, should work in cooperation with the physician-led quality assurance program. Use of the data for non-QI purposes (e.g., marketing strategies, improving referral) should be strongly discouraged. Programmatic deficiencies, in particular, should be identified with the involvement of hospital risk management, when appropriate.

The institution should also ensure that all operators are properly trained and certified (including MOC) and possess the cognitive knowledge and technical skills required to perform PCI (144).

2.10.3. Complexity of Determination of PCI Quality

2.10.3.1. IDENTIFICATION OF PCI QUALITY INDICATORS

Components of an optimal quality assurance program require that several outcome and process measures are routinely and timely collected and analyzed. A dedicated database must be established with hospital support and should include explicitly defined quality indicators that reflect patient outcomes and processes of care. Table 5 provides an example of core PCI outcomes and measures that every quality assurance program is encouraged to

Table 5. PCI Outcomes and Adverse Events

- Major outcomes
  - Mortality (in-hospital, 30 day)
  - Unplanned CABG surgery (same day, same stay: urgent vs. elective)
  - Stroke, TIA, or other neurological events
  - Myocardial infarction* or ischemia
  - Arrhythmias requiring treatment
  - Cardiac arrest in the cardiac catheterization laboratory
  - Hemodynamic instability requiring therapy
  - Major contrast reaction
- Procedural adverse events
  - Coronary
    - Abrupt closure requiring specific therapy
    - Distal embolization/no reflow
    - Coronary perforation
    - Cardiac tamponade
    - Stent thrombosis
    - Other AEs (e.g., stent loss, retained foreign body, guidewire fracture)
  - Systemic/Peripheral
    - Contrast-induced nephropathy/new requirement for dialysis
    - Excess radiation dose (fluoroscopy time/dose)
    - Intracranial hemorrhage
    - Vascular site complications
      - Major drop in hemoglobin (>3.0 g/L) or requirement for blood transfusion
      - Major bleeding
      - Access site vascular injury
      - Retroperitoneal hemorrhage
      - Arterial access vessel occlusion or dissection
      - Access site infection
      - DVT/pulmonary embolism
    - Other AEs (e.g., stent loss—peripheral)
- Additional measures
  - Door-to-balloon time in STEMI
- Wrong patient or procedure

*Universal Definition of Myocardial Infarction should be employed. Adapted with permission from Klein et al. (128).

AEs indicates adverse events; CABG, coronary artery bypass graft surgery; DVT, deep vein thrombosis; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; and TIA, transient ischemic attack.

record and submit to national or regional databases. The QI process can be best implemented by incorporating clinical practice guidelines and appropriateness criteria for coronary revascularization (2,52), as they have been shown to improve clinical outcomes (59,145,146).

2.10.3.2. ROLE OF RISK ADJUSTMENT IN ASSESSING QUALITY

An adverse event rate that is not appropriately risk-adjusted has limited value. Data compiled from large registries of PCI procedures have generated multivariable risk adjustment models for mortality and other adverse events. Most of these models are based on logistic regression analyses of in-hospital events (predominantly mortality) using a large number of prospectively-collected variables. Notably, many of these models were derived from earlier patients' cohorts, and are outdated in the current era of rapidly evolving technology and medical therapy. Contemporary PCI risk scores and predictive models are summarized in Online Appendix 5 (31, 147–153). Sufficient resources must be available to adequately measure baseline patient risk permitting valid risk adjustment of outcomes and determining appropriateness of the intervention.

2.10.3.3. NATIONAL BENCHMARKING

National benchmarking is a means to compare a physician's clinical practice and patient outcomes against his/her peers, and is a valuable means to understand high variances in low incidence adverse events (154). Benchmarking requires standardized collection of clinical and procedural data for PCI using identical elements that are entered into a single electronic repository. This allows regular comparison of risk-adjusted outcomes and complications with national standards. A complete and accurate comprehension of clinical results requires benchmarking of risk-adjusted outcomes to account for differences in patient characteristics and avoid self-reporting bias (155). Appropriate short-term follow-up should also be arranged prior to discharge, because 30-day outcomes have become increasingly required for reimbursement purposes.

The writing committee of the current Clinical Competence Statement echoes the 2011 ACCF/AHA/SCAI PCI guideline in encouraging the participation in a recognized national quality database. Registries such as the ACCF NCDR® CathPCI Registry (156,157), which began in 1998, are designed to standardize reporting of catheterization laboratory outcomes. These types of clinical registries offer the opportunity to have a comprehensive national reporting system that fulfills the goals of assessing and benchmarking quality and outcomes. They can also be utilized to measure performance and utilization rates, promote continuous quality improvement, conduct post-market drug and device surveillance, assess appropriateness of procedures, and track patient safety (154). We look forward to the expansion of currently available databases to better capture important safety, longer-term outcome, quality of life, and resource utilization measurements.

2.10.3.4. OTHER CHALLENGES IN DETERMINING QUALITY

Given the complexity of case selection and procedure conduct, quality is difficult to measure in PCI and is not determined solely by adverse event rates even when properly risk-adjusted. Notably, procedural volume is a weak and inconsistent measure of quality, and it should not be used alone as a quality indicator. In addition, only short-term outcomes (such as in-hospital mortality) are usually used as the benchmark for risk-adjusted outcomes, and long-term outcomes (including repeat revascularization, recurrent MI, death, and re-hospitalization rates) are often underutilized. Accurate assessment of quality is more problematic for low-volume operators and institutions because of small expected absolute event rates and issues of statistical imprecision. Thus, particularly in low-volume circumstances, quality may be better assessed by an intensive case-review process. Case review also has merits in very high-volume situations as it can identify subtleties of case selection and procedure conduct that may not be reflected in pooled statistical data. It is the opinion of the writing committee that all operators should undergo periodic peer review, with more intensive review process for low-volume operators. Although performance of very high-volume operators is more easily monitored using risk-adjusted outcomes models with comparison to national benchmarks, these operators should also be reviewed for the appropriateness of procedures and indications criteria to assure the clinical necessity of these procedures. Finally, the possibility of conflicts of interest among competing physicians exists. It is therefore strongly advised that a formal method of oversight for perceived conflicts of interest among peer reviewers be used and carefully scrutinized.

2.10.4. Requirement for Institutional Resources and Support

A high-quality PCI program requires appropriately trained, experienced, and skilled operators. However, the operator does not work in a vacuum, but rather needs a well-maintained high-quality cardiac catheterization facility to practice effectively. In addition, the operator depends on a multidisciplinary institutional infrastructure for support and response to emergencies, including adequate cardiothoracic surgical support (onsite or with a pre-defined strategy for offsite surgical back-up). System "stress test" drills to assess logistics flow capabilities of both the referring and receiving centers can help refine a well-coordinated emergent transfer. Therefore, to provide quality PCI services, the institution must ensure that its catheterization facility is properly equipped and managed, and that all of its necessary support services, including data collection, are of high quality and are readily available.

Educational activities such as cardiac catheterization and quality improvement conferences should be encouraged by the institution and should be held routinely. Presentation of clinical and technically challenging cases, including those with complications and unexpected developments

during the conduct of a PCI, along with appropriateness reviews, is important. Advances in current communication technologies, such as video conferencing or simulcast case reviews, can facilitate this process. It is important to appreciate that the separation of peer review from more traditional teaching activities is most appropriate for optimal quality assurance.

2.10.5. Quality Assessment and Implementation Processes

Quality assessment is a complex process that includes more than a mere tabulation of success and complication rates. The PCI quality assurance program should be comprehensive and evaluate multiple patient subsets so as to promote both individual physician and system-wide quality improvement.

The core of most PCI quality assurance programs should include: a) the collection of clinically relevant data, which contain variables that allow assessment of clinical processes, performance, and outcomes; b) feedback of this performance and outcomes data to clinicians, ideally with risk-adjustment and benchmarking of the data; and c) implementation of appropriate interventions to promote reduction in inefficient variation in care while simultaneously improving performance (158). PCI quality assurance must include an ongoing, peer review assessment of the clinical proficiency of each operator including random case review, realistic identification of programmatic and individual operator strengths and weaknesses, and comparison of individual and aggregate outcomes against national standards and benchmark databases. Components of quality in coronary interventional procedures include: a) appropriateness of case selection; b) quality of procedural execution; c) proper response to intra-procedural problems; d) accurate assessment of procedural outcome both short- and long-term; and e) appropriateness of periprocedural management. SCAI recently published a report to establish the standard by which interventional program quality should be measured (128). Quality includes the ability of an interventional cardiologist to provide safe and efficient care to appropriately selected patients, and the expertise to treat a wide range of coronary pathology in these patients.

2.10.5.1. THE PEER REVIEW PROCESS

The quality assessment process should also conduct random and detailed reviews of both cases that have adverse outcomes, to determine the causes of the adverse events, and of uncomplicated cases, in order to judge case selection appropriateness and procedural execution quality. These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists, drawn either from within the institution or externally. Noninvasive cardiologists may also participate in the review committees, especially when it comes to assessing procedural appropriateness. A timely and periodically conducted review process is essential as the reviewers should provide continuous feedback to the institutions and operators to enhance the care process. Review of cineangiography films should be undertaken to address technical issues. External review represents a second layer of unbiased review of the interventional program. The Accreditation for Cardiovascular Excellence (ACE), initially created by the SCAI in 2010 and cosponsored by the ACCF, is 1 example of an external peer review body, which offers formal, objective, and independent evaluation and monitoring to PCI facilities to ensure that they meet the highest possible standards for patient care and safety. Other forms of external review options exist and individual institutions will need to determine the appropriate external review option for its particular clinical needs, should that be desired. Confidential and constructive feedback of performance and outcomes data should be given to clinicians to promote changes in practice and improve performance (158).

2.10.5.2. METHODS OF REMEDIATION

When the continuous quality improvement process identifies a systemic problem that requires remediation, the quality assurance committee must investigate the root cause and devise a solution. A formalized plan and implementation strategy (including continued reassessment) should be proposed, and ongoing modification may be required to reach the target result. Recommendations should be based on a comprehensive knowledge of the issue and input from all appropriate stakeholders. When concerns with operator performance arise, remediation should be implemented in a stepwise fashion. Remediation methods may start with an initial discussion with the operator, followed by a nonpunitive action plan with appropriate and constructive feedback, such as proctoring a number of cases by the lab director or an experienced operator, as well as additional CME requirements. If this is unsuccessful or the operator is uncooperative with the plan of remediation, then the next steps may include referral to an external agency or internal hospital committee which may result in penalties or sanctions for the operator, and possibly revocation of the operator's privileges.

2.10.5.3. CONFIDENTIALITY

The Federal Health Care Improvement Act of 1986 recognized the importance of quality assurance programs and the importance of protecting participants and their deliberations. Protecting patient safety is most important in the quality assurance process. The committee must behave equitably and transparently to ensure fairness to the operator, quality for the patient, and credibility for the committee. Outcomes must be presented while maintaining absolute confidentiality of the operators. Use of confidential information to target an individual physician should not be allowed.

2.10.6. Conclusions

The cornerstone of quality assurance monitoring is the transparent reporting and continued assessment of procedural outcome data including adverse events. Equally important components include establishing criteria for assessing procedure appropriateness and applying proper risk adjustment to interpret adverse event rates. A quality interventional program performs appropriately selected procedures while achieving risk-adjusted outcomes that are favorably comparable to national benchmark standards. There has been considerable controversy surrounding the efforts to define standards and methodologies for conducting quality assurance. An objective, physician-led process that includes appropriate evaluation and corrective action plans and is organized to assure a fair and impartial review of performance, provides a reasonable level of assurance that quality is being accurately assessed and promoted. An effective process should also include random case review, develop critical pathways, and accomplish and document positive changes in practice.

2.11. Summary of Key Recommendations for PCI

Physical Facility and Institutional Requirements (*see Section 2.5.1*)

***Physical Facility Requirements*:**

- The facility must provide the necessary radiological, monitoring, and adjunctive patient support equipment to enable operators to perform in the safest and most effective environment.
- The real-time fluoroscopic and acquired image quality must be optimal to facilitate accurate catheter and device placement and facilitate the correct assessment of procedural results.
- Physiological monitoring equipment must provide continuous, accurate information about the patient's condition.
- Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve should be available.
- Hemodynamic support devices such as intra-aortic balloon pumps and percutaneous ventricular assist devices should be available in institutions routinely performing high-risk PCI.
- These requisite support equipment must be available and in good operating order to respond to emergency situations.

***Institutional Requirements*:**

- The interventional laboratory must have an extensive support system of specifically trained laboratory personnel. Cardiothoracic surgical, respiratory, and anesthesia services should be available to respond to emergency situations in order to minimize detrimental outcomes.
- The institution should have systems for credentialing, governance, data gathering, and quality assessment. Prospective, unbiased collection of key data elements on all patients and consistent timely feedback of results to providers brings important quality control to the entire interventional program and is critical to assessing and meeting appropriate use criteria for coronary revascularization.
- The writing committee endorses the ACCF/AHA/SCAI PCI guideline (2) recommendations that:
  - Primary PCI is reasonable in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished (Class IIa).
  - Elective PCI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Class IIb).
  - Primary or elective PCI should not be performed in hospitals without onsite cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer (Class III).
- System "stress test" drills to assess logistics flow capabilities of both the referring and receiving centers can help refine a well-coordinated emergent transfer.

Components of Operator Competence (*see Section 2.7*)

- See Table 3 for the components of operator competence for PCI utilizing the ACGME core competency structure pertaining to medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication skills; and professionalism.

Maintenance of Quality

***Institutional* (*see Section 2.8.1.1*)**

- Full-service laboratories (both primary and elective PCI, with and without onsite 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. 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 close.

***Individual Operator* (*see Section 2.8.1.2*)**

- The individual operator level volume is 1 of several factors that should be considered in assessing operator

competence, including lifetime experience, institutional volume, individual operator's other cardiovascular interventions, and quality assessment of the operator's ongoing performance.
- Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.
- Facilities should develop internal review processes to assess operators <50 PCIs annually.
- Additional emphasis on educational symposiums, CME credits, and simulation courses may provide other venues to enhance quality for all operators.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.
- 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 to take the ABIM certification and recertification exams.

***Primary PCI* (*see Section 2.8.1.3*)**

- Primary PCI for STEMI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI 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.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.

Quality Assurance

***Institutional Requirements* (*see Section 2.10.2*)**

- Each institution that provides PCI services must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes.
- To reach these goals, every PCI program should operate a quality improvement program that routinely: 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews.
- The review process should assess the appropriateness of the interventional procedures. Evaluation should include both the clinical criteria for the procedure and the quality and interpretation of the angiograms.
- Valid quality assessment requires that the institution maintain meticulous and confidential records that include patients' demographics and clinical characteristics necessary to assess these measures and conduct risk adjustment in a transparent manner.
- An independent and dedicated committee should be established and ideally include both physicians and relevant healthcare personnel in a cooperative effort minimizing any conflicts of interest. Interventional cardiologists are best suited to perform the primary role in evaluating PCI quality and leading the quality assurance program.
- The process should be instituted with the support of hospital administrators, who can help provide resources for registry participation, conduct analyses, and support other aspects of the QI process.

***Institutional Resources and Support* (*see Section 2.10.4*)**

- The institution must ensure that its catheterization facility is properly equipped and managed, and that all of its necessary support services, including data collection, are of high quality and are readily available.
- Educational activities such as cardiac catheterization and quality improvement conferences should be encouraged by the institution and should be held routinely. Presentation of clinical and technically-challenging cases, including those with complications and unexpected developments during the conduct of a PCI along with appropriateness reviews, is important.

***National Benchmarking* (*see Sections 2.8.2.3 and 2.10.3.3*)**

- Participation in regional and national registries such as the NCDR® CathPCI Registry is strongly encouraged. Such registries should provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies, and other stakeholders can accurately assess the quality of care delivered.

***Quality Assessment and Implementation Process* (*see Sections 2.10.3.3, 2.10.3.4, 2.10.5, and 2.10.5.1*)**

- PCI quality assurance must include an ongoing, peer review assessment of the clinical proficiency of each operator including random case review, realistic identification of programmatic and individual operator strengths and weaknesses, and comparison of individual and aggregate outcomes against national standards and benchmark databases.
- Performance of all operators should be monitored using risk-adjusted outcome models with comparison to national benchmarks, and operators should be reviewed for the appropriateness of procedures and indications criteria to ensure the clinical necessity of the procedures.
- All operators should undergo periodic peer review, with more intensive review process for low-volume operators.
- In instances where operators are performing less than the suggested range, both institutions and operators are strongly encouraged to carefully assess whether their performance is adequate to maintain their competence and whether they should continue performing coronary interventions.

- A formal method of oversight for perceived conflicts of interest among peer reviewers should be used and carefully scrutinized.
- The quality assessment process should conduct random and detailed reviews of both cases that have adverse outcomes, to determine the causes of the adverse events, and of uncomplicated cases, in order to judge case selection appropriateness and procedural execution quality. These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists drawn either from within the institution or externally. Noninvasive cardiologists may also participate in the review committees, especially when it comes to assessing procedural appropriateness.
- A timely and periodically conducted review process is essential as the reviewers should provide continuous feedback to the institutions and operators to enhance the care process.
- Review of cineangiography films should be undertaken to address technical issues.
- Confidential and constructive feedback of performance and outcomes data should be given to clinicians to promote changes in practice and improve performance.
- Addressing limitations of currently available databases to include other important quality metrics such as longer term efficacy and safety endpoints, quality of life, and resource utilization would be helpful in determining quality performance.

3. Other Coronary Interventions

Coronary interventions are occasionally required to provide an invasive therapeutic approach to hypertrophic cardiomyopathy, ventricular tachycardia (VT), and coronary fistulae. These are rare clinical situations that pose a unique problem for the establishment of operator and staff competency. These procedures should only be performed in major centers where there is a particular interest in the disease processes and adequate clinical volume to provide experience in the appropriate interventional techniques. A dedicated multidisciplinary team should be in place. These procedures require such a multidisciplinary team approach that involves cardiologists, surgeons, technicians, and nurses all working together to achieve optimal results.

3.1. Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy

3.1.1. Background

The first description of the use of alcohol septal ablation for hypertrophic obstructive cardiomyopathy (HOCM) appeared in 1995 (159) and the 10-year follow-up of that first group of 12 patients was recently reported (160). Although most studies have reported single-institutional data, the multicenter North American Registry data (161) reviewed 874 patients who had undergone the procedure. A mortality rate of 0.7% from the procedure was reported. This latter group outlined the major complications associated with the contemporary use of the procedure and the clinical variables that predicted death during follow-up. A recent single-institution nonrandomized report of 177 patients who had alcohol ablation for HOCM revealed a survival rate similar to both the general population and to an age- and gender-matched surgical myomectomy cohort at 5.7 years of follow-up (162).

The principle of alcohol ablation depends on the localized injection of alcohol into a septal perforator artery that supplies the basal interventricular septum to create a controlled MI that will eventually lead to septal scarring and thinning. Localization requires identifying of the myocardium subtended by the coronary perforator. To properly perform the procedure requires a thorough knowledge of the geometric substrate. Usually, left ventricular outflow track (LVOT) obstruction is caused by asymmetrical septal hypertrophy and anterior displacement of the papillary muscle resulting in contact of the septum and anterior mitral leaflet during systole. However, LVOT gradients may also result from an abnormal mitral valve with redundant leaflets or accessory chordae. In addition, changes in aortoventricular alignment may also create obstruction with normal or only mild septal hypertrophy—a feature of LVOT obstruction in the elderly. Finally, gradients at the midventricular level or toward the left ventricular apex may not have the appropriate septal perforator supply and would not be appropriate for the use of alcohol ablation techniques. A thorough knowledge of catheterization anatomy and coronary interventional techniques, as well as echocardiographic and (even magnetic resonance imaging) imaging of the left ventricular and mitral apparatus anatomy, is therefore critical in some cases of HOCM. These skills are a prerequisite for selection of the appropriate patients and for the successful performance of these studies.

The 2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (163) outlines a suggested treatment algorithm for the appropriate use of alcohol septal ablation in the treatment of symptomatic patients with HOCM. It is important that these procedures be performed only at specialized centers dedicated to the comprehensive and multidisciplinary treatment of these patients.

3.1.2. Criteria for Competency

3.1.2.1. OPERATOR COMPETENCY

Using the ACGME core competencies to define the issues, it is the recommendation of this writing committee that the following be considered:

Patient Care: The operator should have a thorough knowledge of the impact HOCM physiology plays in the patient's symptom complex. Many of the symptoms

attributed to HOCM overlap with other disease states, particularly if there is concurrent lung disease, coronary disease, anemia, etc., so optimal patient care requires the operator to differentiate symptoms related to HOCM from these other issues. Medical therapy should be appropriate and considered to have been a failure before the procedure is attempted. At least 1 dedicated surgeon with a working knowledge of myectomy and valve repair should be part of the overall program, and there should be regular case reviews. For complex cases, surgical consultation should be sought, and the multidisciplinary team should agree that the interventional procedure is warranted. Nursing staff should be trained to recognize complications, both early and late, following the procedure.

Medical Knowledge and Procedural Volume: To gain the appropriate skill set for the performance of alcohol ablation requires the knowledge base related to the disease process (as described above) and the technical skills to safely perform the procedure. Medical knowledge regarding the procedure can be gained at courses at major meetings, participation in clinical trials or by working with colleagues at one's own institution or at another facility.

To gain the particular skill of alcohol ablation for HOCM patients, the committee suggests that *initially* each operator perform the first *5 studies in a proctored situation* assisting a skilled operator. These procedures could be done at the operator's own facility or at the skilled operator's facility. The ACCF/AHA HOCM guideline suggests that an *experienced operator* should not be defined until one has performed *>20 procedures* or the procedures have all been performed at a *facility* that has a cumulative volume of *50 procedures*. If the procedures are performed at a facility with a cumulative experience of <50 cases, it is recommended that the catheterization laboratory quality assurance committee (or one appointed by the institution) be responsible for reviewing all of the first 20 cases performed. For maintenance of skills, it is recommended that each *individual principal operator* perform at *least 10 procedures per year*. This latter number has also been suggested in a report from the SCAI training program directors (164) as being the minimal number for certification of cardiovascular trainees within the structural heart disease program who desire alcohol ablation skills as part of their interventional training.

The minimal number of procedures, however, does not correlate with either operator skill or patient outcomes. The committee feels strongly that alcohol ablation for HOCM should be performed only with a multidisciplinary team, and that volume is just 1 of many factors that should be considered in assessing operator competency. After each operator has developed the needed skillset in a proctored environment, then, given the rarity of the procedure, 5 alcohol ablations for HOCM per year should be considered a reasonable volume to maintain that skillset. The bottom line remains that the onus is on the local credentialing process and the quality assurance committee to ensure an operator is qualified and his/her procedural outcomes are of the highest possible quality.

Practice-Based Learning: The facility should provide a regular forum for the presentation of individual cases and provide the operators with feedback on the techniques and results obtained. These reviews should stress the use of evidence-based therapy and discuss best practices. As the field develops, these regular conferences should stress ways to improve the procedure and both institutional and individual outcomes. Literature reviews should be incorporated and verification confirmed that the practices being used conform to the established guidelines.

Interpersonal and Communication Skill: At the recommended periodic review sessions, any communication or conflicts regarding the appropriateness of the procedures or the technical issues should be directly discussed. Patient satisfaction should be addressed and criticisms acted upon. Feedback from staff and nursing should also be provided to ensure optimal patient care is being performed and that staff members are receiving the appropriate training.

Professionalism: Any criticism of the handling of the patient's care at any stage should be addressed. This includes ensuring the patient and his family understand the procedure, are treated respectfully and honestly, the consent process is clear, the referring physician is kept well informed, and all of the team members are acknowledged for their contributions.

Systems-Based Practice: The facility should have a formal commitment to the structural heart disease program and be supportive of establishing and maintaining the highest quality. Because care of the patient requires careful follow-up, it is important that the practitioners in the entire health system be aware of the potential complications from the procedure, and that a system is in place that allows for potential issues to be addressed should an untoward event occur after the procedure. Because many patients will receive the bulk of their care locally and not at the referral center, a systems-wide educational effort should be made to inform the healthcare professionals of the indications and contraindications of the procedure and the expected outcomes. A clear mechanism should be in place that allows ready access to a member of the procedural team should questions arise.

3.1.2.2. STAFF COMPETENCY

Many of the core competencies that apply to the operator are transferrable to staff involved as well. There should be a dedicated staff that has an interest in the procedure. It is particularly important that the cardiac catheterization team and the echocardiographic team work together, and they are considered a vital part of the procedural effort. The staff should be trained to anticipate all aspects of the procedure. Not only should initial training be formalized, but also continuing education should be considered a key element in the program design and maintenance.

3.2. Alcohol Ablation for Ventricular Arrhythmias

3.2.1. Background

When catheter-based ablation techniques to control VT using endocardial and epicardial techniques fail to resolve an intractable VT focus, a controlled infarction of the VT circuit may be feasible with alcohol injection into an epicardial coronary branch that supplies the region of interest on electrophysiological mapping (165). Once a potential branch is identified, the injection of iced saline or transient balloon occlusion of the vessel is performed to observe whether the arrhythmia terminates. Multiple branches may be tested before VT termination is achieved. If such a vessel is identified, alcohol injection then is used to produce a controlled infarction within the VT circuit. In 1 series, the method was reported successful in 56% of the patients attempted (166). The need for this approach has been estimated to be very low at about 1% to 2% of VT ablation cases (167).

3.2.2. Criteria for Competency

Given the highly specialized setting where this procedure is being attempted, only those in a tertiary center with experience in both coronary intervention and electrophysiology studies should consider performing these procedures. There are no established guidelines, and only case reports and very small series have been reported. Operators must meet established criteria for routine competency in this infrequently performed procedure, and should be knowledgeable and capable of describing the risks and benefits of this procedure versus other clinical choices. Alcohol ablation for VT should always be performed in the presence of the electrophysiologist who performed the mapping and the electrophysiology ablation procedure. The alcohol ablation procedure should be performed under continuous direct electrophysiological guidance. Prospective and retrospective catheterization laboratory review of such cases should be routinely undertaken, and at times, institutional review board approval should be sought for unusual situations. Although the committee acknowledges these procedures are being occasionally done in very controlled settings, monitoring these "orphan" procedures necessarily requires a robust quality assurance program to ensure patient safety and to approve operator competence. Institutional board review approval is a requisite.

3.3. Coronary Artery Fistula Closure

3.3.1. Background

The vast majority of coronary fistulae are congenital in nature, though iatrogenic fistulae have been reported after PCI for total occlusions, after septal myectomy for HOCM and following right heart biopsies of the interventricular septum. Congenital fistulae can arise from either coronary and generally (but not always) drain into right heart structures. Large fistulae carry a risk for coronary steal and myocardial ischemia and/or infarction. Rarely dissection, rupture, and endarteritis have been reported. Small fistulae may increase in size over time. Most coronary fistulae are detected as incidental findings during coronary angiography and are of no consequence. Auscultation of large fistulae reveals a continuous murmur. Closure of large fistulae has been achieved most often with coils, though vascular plugs and covered stents may be used when appropriate and feasible. The 2008 ACC/AHA Guidelines for Adults with Congenital Heart Disease (168) recommend that all symptomatic coronary fistulae should be intervened upon, but only large, audible fistula should be occluded if no symptoms. It is recognized that there are no clear definitions of symptoms related to these fistulae, unless there is evidence for a volume overload or demonstrable myocardial ischemia.

3.3.2. Criteria for Competency

3.3.2.1. OPERATOR COMPETENCY

Patient Care: As most patients do not need intervention for incidental coronary fistulae, optimal patient care requires the operator be able to identify those that require closure and understand how to best assess whether the lesion has significance. Surgical consultation should be included in the evaluation to ensure the appropriate approach is being considered. If a vascular interventional radiologist has experience in vascular occlusion, consultation with him/her should be part of good patient care.

Medical Knowledge and Procedural Volume: The operator should have a thorough understanding of the cause and anatomic features of any coronary fistula of concern. Delineation of the course of the fistula is critical to deciding if any percutaneous approach is feasible. The operator must be comfortable with coronary intervention and understand how to use vascular coils, plugs, and covered stents, depending on what is required. The procedures should only be done in centers that have a particular interest in such interventions. Because of the rarity of these procedures, a team approach with interventional radiology and surgery should be considered optimal when the operator is gaining experience. Although the SCAI training director's survey suggested a competency threshold of 10 procedures for cardiovascular fellows (164), this procedure is so uncommon and sporadic that it would be unlikely that such a threshold is achievable even in large programs. The onus once again falls on the credentialing and quality assurance oversight committees to review all of these procedures done at any institution.

Practice-Based Learning: The need for input from physicians outside the interventional cardiac catheterization laboratory mandates that patients proposed for this procedure be presented at a forum where the pros and cons of catheter-based and surgical-based options are presented. Various approaches should be discussed in the context of the group experience and the available literature. Attendance at national or regional meetings to improve the skill set need should be encouraged.

Interpersonal and Communication Skills: Patients and staff should have a thorough understanding of the procedure. Communication with patients' families and referring physicians is vital in case an adverse outcome should result. Operators must be able to work with consultants to arrive at the appropriate decision making.

Professionalism: Operators should be able to accept the advice of colleagues from surgery and radiology regarding the best approach for coronary fistula closure. Team members should be respected for their contributions.

Systems-Based Practice: As with other structural heart disease conditions, there must be a strong commitment from the facility administration to encourage and support a program that provides unique care offered at few other places. Communication of the ability to perform these procedures should be known throughout the respective health system. An effort should be made by the principle faculty and operators in the structural heart disease program to educate physicians in the hospital network as to when the procedure is required. Outcome data should be presented periodically so that physicians and other healthcare providers understand the risks and anticipated results from the procedure.

3.3.2.2. STAFF COMPETENCY

As with all coronary procedures the vital core competencies described must be an integral part of the expectation from staff as well as operators in the cardiac catheterization laboratory. Staff should be informed of procedural requirements and educated about the use of each of the interventional devices that is anticipated to be required. They should be an integral part of the process. They should be educated as to the complications that might occur, so as to best alert the operator at the earliest time when a potential untoward event appears imminent.

3.4. Summary of Key Recommendations Regarding "Other Coronary Interventions"

Multidisciplinary Approach

- Given that coronary interventions in patients with hypertrophic cardiomyopathy, ventricular tachycardia and coronary fistulae are rare, a team approach including coronary interventionalists, cardiothoracic surgeons, and cardiothoracic anesthesiologists is important for optimal results. Dedicated personnel should be identified, and a regular review of program activity and results documented.

Institutional Requirements

- These procedures should only be done in institutions with a strong commitment to provide all of the necessary equipment and staff support required to ensure these rare and complex procedures can be done safely and with a high degree of success.

Operator Competence

- The ACGME Core Competency Structure pertaining to medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication skills; and professionalism are outlined above for each procedure. Although there are no established minimal volume numbers for these procedures, it is suggested for HOCM alcohol ablation that the first 5 procedures be proctored and that maintenance of skills generally requires the performance of at least 5 procedures per year.

The Critical Importance of the Quality Assurance Program

- All of the issues outlined in regard to the quality assurance (QA) program for routine PCI procedures apply to the performance of these procedures. In addition, however, given the rarity of the procedures, it is recommended that all coronary interventions for HOCM, coronary fistula, and VT be reviewed by the multidisciplinary team and the institutional QA process. These processes must be functioning and active to provide appropriate oversight if operators are to perform these uncommon coronary procedures in a safe and monitored environment.

President and Staff

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Key Words: ACCF/AHA/ACP Clinical Competence Statement ■ angioplasty, balloon, coronary ■ clinical competence ■ coronary disease ■ peer review, healthcare ■ percutaneous coronary intervention ■ quality assurance ■ quality improvement.

APPENDIX 1. 2013 ACCF/AHA/SCAI CLINICAL COMPETENCE STATEMENT ON CORONARY ARTERY INTERVENTIONAL PROCEDURES (REVISION OF 2007 STATEMENT)—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
Thomas M. Bashore	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None
Theodore A. Bass	University of Florida Shands Jacksonville Cardiovascular Center—Professor of Medicine; Chief Cardiology Division	• Daiichi Sankyo-Lilly†	None	None	None	None	None
Ralph G. Brindis	University of California, San Francisco—Clinical Professor of Medicine	None	None	None	None	None	None
John E. Brush, Jr.	Eastern Virginia Medical School; Sentara Cardiology Specialists, Sentara Healthcare—Professor of Medicine	• United Healthcare Scientific Advisory Board	None	None	None	None	None
James A. Burke	Lehigh Valley Heart Network—Associate Chief of Cardiology	None	None	None	None	None	None
Gregory J. Dehmer	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	• Direct Flow Medical	None	None
Yuri A. Deychak	Johns Hopkins Community Physicians Heartcare—Cardiologist	None	None	None	None	None	None
John G. Harold	Cedars-Sinai Heart Institute—Attending Physician; Cedars-Sinai Medical Center and David Geffen School of Medicine at UCLA—Clinical Professor of Medicine	None	None	None	None	None	None
Hani Jneid	Baylor College of Medicine and the MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
James G. Jollis	Duke University Medical Center—Associate Professor of Medicine	None	None	None	• Medtronic Foundation† • Sanofi-Aventis†	None	None
Joel S. Landzberg	Hackensack University Medical Center—Clinical Associate Professor of Medicine	None	None	None	• Boehringer Ingelheim, RELY, RELYABLE studies—PI • Roche, dal-OUTCOMES studies—PI	None	None
Glenn N. Levine	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
James B. McClurken	Temple University Hospital Department of Cardiothoracic Surgery—	None	None	None	None	None	None
John C. Messenger	University of Colorado— Director, Cardiac Cath Lab; Associate Professor of Medicine	None	None	None	• Medtronic*	None	None
Issam D. Moussa	Mayo Clinic, Florida—Professor and Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None
J. Brent Muhlestein	Intermountain Medical Center—Professor of Medicine	None	• Bristol-Myers Squibb • Daiichi-Sankyo • Forest • Gilead • Lilly • Merck • Sanofi-Aventis	None	• Glaxo	None	None
Richard M. Pomerantz	St. Agnes Hospital—Chairman, Department of Medicine	None	None	None	None	None	None

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APPENDIX 1. CONTINUED

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Timothy A. Sanborn	Northshore University Healthsystem—Head, Division of Cardiology	None	None	None	None	None	None
Chittur A. Sivaram	University of Oklahoma—Professor of Medicine and Associate Dean	• Medtronic	None	None	None	None	None
Christopher J. White	Ochsner Clinic Foundation—Chairman, Department of Cardiology	• Baxter	None	None	• Boston Scientific* • Neovasc* • St. Jude	None	None
Eric S. Williams	Indiana University School of Medicine Krannert Institute of Cardiology—Professor of Medicine and Associate Dean	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. 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% or more 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.

PI indicates principal investigator.

APPENDIX 2. 2013 ACC/AHA/SCAI CLINICAL COMPETENCE STATEMENT ON CORONARY ARTERY INTERVENTIONAL PROCEDURES (REVISION OF 2007 STATEMENT)—REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Lyndon C. Box	Official Reviewer—Society for Cardiovascular Angiography and Interventions	University of Florida Division of Cardiology—Assistant Professor	None	None	None	None	None	None
George D. Dangas	Official Reviewer—ACCF Board of Trustees	Mount Sinai Medical Center—Program Director, Interventional Cardiology	• Astra-Zeneca • Johnson & Johnson • Merck • Regado • Sanofi-Aventis	None	None	• Abbott* • Bristol Myers Squibb* • Daiichi-Sankyo* • Eli Lilly* • The Medicines Company* • Medtronic* • Sanofi-Aventis*	• Abbott Vascular* • Accumetrics* • Cordis* • EV3* • Gilead* • Infraredx* • Lutonix* • Medtronic* • PLC* • The Medicines Company* • Tryton* • Volcano* • W.L. Gore*	None
David P. Faxon	Official Reviewer—American Heart Association	Brigham and Women's Hospital—Professor of Medicine	• Boston Scientific Corporation	None	• REVA Medical	• Sanofi-Aventis	• Circulation: Cardiovascular Interventions—Editor†	None
Daniel Kolansky	Official Reviewer—American Heart Association	Hospital of the University of Pennsylvania—Director, Cardiac Care Unit	• Up To Date	None	None	None	• Conor MedSystems	• Defendant, cardiology care and cardiac catheterization, 2009 & 2010
John P. Reilly	Official Reviewer—Society for Cardiovascular Angiography and Interventions	Ochsner Clinic Foundation—Director, Cardiovascular CT	None	• Daiichi-Sankyo-Lilly†	• Johnson & Johnson† • Medtronic† • Pfizer	None	None	None

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jean-Francois Tanguay	Official Reviewer—ACCF Board of Governors	Institut de Cardiologie de Montreal—Director, Coronary Unit	None	None	None	None	• Abbott Vascular† • Astra Zeneca† • Eli Lilly† • Merck Canada† • Servier†	None
Andrew Wang	Official Reviewer—ACCF Task Force on Clinical Competence and Training Statements	Duke University Medical Center Division of Cardiovascular Medicine—Associate Professor of Medicine	None	None	None	• Abbott Vascular† • Edwards Lifesciences† • Gilead Sciences†	None	None
H. Vernon Anderson	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Cardiology Division—Professor of Medicine	• Symbios Clinical Research	None	None	None	• Eli Lilly	None
Eric R. Bates	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • Bristol-Myers Squibb • Daiichi-Sankyo • Eli Lilly • Merck • Sanofi-Aventis	None	None	None	None	None
James C. Blankenship	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	Geisinger Medical Center—Director, Cardiac Catheterization Lab	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering-Plough* • The Medicines Company* • Volcano Corporation*	None	None
Emmanouil S. Brilakis	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Southwestern Medical School—Director, Cardiac Catheterization Lab, VA North Texas Healthcare System	• Bridgepoint Medical • HMP Communications • St. Jude† • Terumo	None	None	None	Medtronic†	• Defendant, review of case of left main disease, 2011
John G. Byrne	Content Reviewer—ACCF Surgeon Scientific Council	Vanderbilt University Medical Center—Chair, Department of Cardiac Surgery	None	None	None	None	None	• Defendant, cardiac surgery, 2010
T. Bruce Ferguson, Jr.	Content Reviewer—ACCF Surgeon Scientific Council	East Carolina Heart Institute Brody School of Medicine—Professor of Surgery and Physiology	None	None	None	• Novadaq Technologies, Inc.†	• Edwards Laboratories	None
Kirk N. Garratt	Content Reviewer—ACCF NCDR CathPCI Research and Publications Subcommittee	Lenox Hill Hospital—Associate Professor of Medicine	• Abbott Vascular • Boston Scientific • Daiichi-Sankyo-Lilly† • The Medicines Company	• Abbott Vascular • Boston Scientific • Medtronic • The Medicines Company	None	None	None	• Defendant, blood pressure management and elective angiography, 2008 • Defendant, radial access for angioplasty, 2006 • Defendant, indication for bypass surgery, 2005
Lloyd W. Klein	Content Reviewer—ACCF Interventional Scientific Council	Rush University Medical Center—Professor of Medicine	None	None	None	None	None	None

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Austin H. Kutscher, Jr.	Content Reviewer—ACCF Board of Governors	Hunterdon Cardiovascular Associates	• Medtronic	• Boehringer • Forest Laboratories	None	•Boehringer	• Boehringer, Pradaxa GI study—PI	None
Steven J. Lester	Content—ACCF Task Force on Clinical Competence and Training Statements	Mayo Clinic—Associate Professor of Medicine, Department of Cardiovascular Diseases	None	None	None	None	None	None
Thomas Lewandowski	Content Reviewer—ACCF Board of Governors	Appleton Cardiology Associates—Cardiologist	None	None	None	None	None	None
Sandra Lewis	Official Reviewer—ACCF Board of Governors	NW Cardiovascular Institute—Clinical Associate Professor	None	None	None	Roche	• Medtronic* • Regence BlueCross BlueShield	None
Scott M. Lilly	Official Reviewer—ACCF Board of Governors	University of Pennsylvania—Fellow, Interventional Cardiology	None	None	None	None	None	None
Ehtisham Mahmud	Content Reviewer—ACCF Interventional Scientific Council	University of California, San Diego—Chief of Cardiovascular Medicine; Co-Director, Sulpizio Cardiovascular Center; Director, Interventional Cardiology & Cardiovascular Catheterization Labs	• Eli Lilly† • Gilead • Medtronic	• Eli Lilly† • Medtronic	None	• Abbott Vascular† • Accumetrics† • Boston Scientific† • Gilead† • Merck Schering Plough • Sanofi-Aventis • Eli Lilly† • The Medicines Company†	•St. Jude's	None
Debabrata Mukherjee	Content Reviewer—ACCF Interventional Scientific Council	Texas Tech University Health Sciences Center—Chief, Cardiovascular Medicine	None	None	None	None	None	None
Srinivas Murali	Official Reviewer—ACCF Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Gilead • Bayer	None	None	None	None	None
Srihari Naidu	Content Reviewer—ACCF Interventional Scientific Council	Winthrop University Hospital—Director, Cardiac Catheterization Lab	None	None	None	None	None	None
Rick Nishimura	Content Reviewer—ACCF/AHA Ventricular Heart Disease Guideline	Mayo Clinic, Division of Cardiovascular Services—Judd and Mary Morris Leighton Professor of Medicine	None	None	None	None	None	None
Patrick O'Gara	Content Reviewer—ACCF/AHA ST Elevation Myocardial Infarction Guideline	Harvard Medical School; Brigham and Women's Hospital—Professor of Medicine; Director, Clinical Cardiology	None	None	None	• Lantheus Medical Imaging (DSMB)	None	None
Sunil V. Rao	Content Reviewer—ACCF Interventional Scientific Council	Duke University Medical Center—Associate Professor of Medicine	• AstraZeneca • Daiichi Sankyo-Lilly • Terumo Medical • The Medicines Company	None	None	None	None	• Defendant, catheterization related complications, 2011
Michael E. Ring	Official Reviewer—ACCF Board of Governors	Providence Sacred Heart Medical Center and Children's Hospital	• Boston Scientific • Medtronic	None	None	None		• Defendant, certificate of need for PCI, 2012

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
John F. Robb	Official Reviewer—ACCF Board of Governors	Dartmouth-Hitchcock Medical Center—Director, Interventional Cardiology	None	None	None	• Edwards LifeSciences, Partner 2—PI*		None
Robert A. Shor	Official Reviewer—ACCF Board of Governors	The Cardiovascular Group, PC—Cardiologist	None	None	None	None	None	None
John W. Shuck	Official Reviewer—ACCF Board of Governors	Cardiology Consultants—Cardiologist	None	None	None	None	None	None
George L. Smith	Official Reviewer—ACCF Board of Governors	Northern California Medical Associates—Cardiologist	None	None	None	None	None	None
Carl L. Tommaso	Content Reviewer—ACCF/AHA PCI Performance Measures	Northshore Medical System	None	None	None	None	None	• Defendant, retained wire, 2006
E. Murat Tuzcu	Content Reviewer—ACCF Interventional Scientific Council	Cleveland Clinic Foundation—Professor of Medicine	None	None	None	• Edwards Lifesciences*	None	None
Robert C. Welsh	Official Reviewer—ACCF Board of Governors	University of Alberta and Mazankowski Alberta Heart Institute—Associate Professor; Director, Adult Cardiac Catheterization and Interventional Cardiology	• AstraZeneca • Bayer • Boehringer Ingelheim • Edwards Lifesciences • Eli Lilly • Medtronic • Servier	None	None	• Abiomed	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***. *No financial benefit. †Indicates significant relationship.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; NCDR, National Cardiovascular Data Registry; PCI, Percutaneous Coronary Intervention; SCAI, Society for Cardiovascular Angiography and Interventions.

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APPENDIX 3. ACRONYMS AND ABBREVIATIONS LIST

Acronyms and Abbreviations	
ABIM	American Board of Internal Medicine
ACCF	American College of Cardiology Foundation
ACP	American College of Physicians
AHA	American Heart Association
CABG	coronary artery bypass graft
CME	continuing medical education
COCATS	Core Cardiology Training
DTB	door-to-balloon
ECG	electrocardiogram
HOCM	hypertrophic obstructive cardiomyopathy
LVOT	left ventricular outflow track
MACCE	major adverse cardiovascular and cerebrovascular events
MACE	major adverse cardiac events
MI	myocardial infarction
MOC	maintenance of competence
NCDR	National Cardiovascular Data Registry
PCI	percutaneous coronary intervention
PPCI	primary percutaneous coronary intervention
PTCA	percutaneous transluminal coronary angioplasty
QI	quality improvement
SCAI	Society for Cardiovascular Angiography and Interventions
STEMI	ST-elevation myocardial infarction
VT	ventricular tachycardia