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ACCF/AHA/SCAI Clinical Competence Statement

ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac Interventional Procedures

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JOURNAL OF THE AMERICAN HEART ASSOCIATION

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Preamble

The granting of clinical staff privileges to physicians is a primary mechanism used by institutions to uphold the quality of care. The Joint Commission on Accreditation of Health Care Organizations requires that the granting of continuing medical staff privileges be based on the criteria specified in the medical staff bylaws. Physicians themselves are thus charged with identifying the criteria that constitute professional competence and with evaluating their peers accordingly. Yet, the process of evaluating physicians' knowledge and competence is often constrained by the evaluator's own knowledge and ability to elicit the appropriate information, problems compounded by the growing number of highly specialized procedures for which privileges are requested.

The American College of Cardiology Foundation/American Heart Association/American College of Physicians (ACCF/AHA/ACP) Task Force on Clinical Compe-

tence 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 utilized to formulate recommendations. Indications and contraindications for 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 health care providers entering practice for the first time and/or those who are in practice and undergo periodic review of their practice expertise or who apply for privileges at a new institution. 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 cardiac 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/or adult cardiology and is not meant to be a clinical competence statement on procedures for congenital heart disease in the child or young adult.

The ACCF/AHA/ACP Task Force makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the ACCF/AHA/ACP Writing Committee. Specifically, all members of the Writing Committee were asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest relevant to the document topic. These statements were reviewed by the Writing Committee and updated as changes occurred. The relationships with industry for authors and peer reviewers are published in the appendices of the document.

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Introduction

Coronary intervention has evolved from an investigational procedure to a widely practiced, mature mainstream clinical therapy (1). Conventional balloon angioplasty, while still a core procedure in interventional cardiology, has been augmented by adjunctive stenting, which greatly improves procedure efficacy and modestly reduces the risk of restenosis (2). Bare-metal stents have been replaced by drug-eluting stents in the majority of cases, which further reduce the risk of restenosis (3). Because stents or other interventional devices are commonly used, the coronary angioplasty procedure is more aptly termed "percutaneous coronary intervention" (PCI).

The AHA estimated that more than 1,000,000 PCIs were performed in the United States in 2003 (4). Physicians performing these procedures represent approximately 25% of board-certified cardiologists in the United States (5).

As a result of the maturation of PCI as a discipline and the ongoing clarification of its role in the management of coronary heart disease, the public can and should appropriately expect consistent access to high-quality PCI capability. However, there is potential for substantial variation in the quality of PCI services. PCI is often a complex, demanding procedure. To perform PCI optimally, an operator must possess a substantial cognitive knowledge base as well as considerable technical skill. In addition, the technical difficulty of a particular procedure can vary greatly from one patient to another. Furthermore, serious complications of coronary interventional procedures may occur unpredictably in procedures that initially appear to be straightforward. Recognition and management of complications are critical components of PCI procedures that require skill, knowledge, experience, and judgment. Since there can be variation among operators in cognitive knowledge and skill and among procedures in technical difficulty, there is a potential for substantial variation in procedure safety and efficacy.

Credentialing physicians to perform procedures is the responsibility of the governance of the local health care facility. The Joint Commission on the Accreditation of Health Care Organizations requires that medical staff privileges be granted to applicants only after assessment based on professional criteria. Physicians are charged with the responsibility to establish the criteria that constitute professional competence and to evaluate their peers on the basis of such criteria. The U.S. health care system relies, in part, on this process of granting and renewing clinical privileges to maintain quality.

The issue of determining quality standards and credentialing criteria has presented a major challenge to the medical profession. Developing standards has been difficult because, until recently, there were few data available on which to base them and because PCI techniques, indications, and capability have evolved rapidly. During the past several years, documents have been published that have offered guidelines and standards for the training and maintenance of competence (6–15). Because of the paucity of clinical data, the earlier standards were developed principally through observation, experience, and intuition. These standards relied heavily on operator activity level as a surrogate for skill and quality.

The most recent document published by the ACC was based on the information available in 1998 (16). The recommendations of this and other similar documents require updating as technology and training evolve (17).

Percutaneous noncoronary cardiac interventions, such as aortic and mitral valvuloplasty, atrial septal defect (ASD) and patent foramen ovale (PFO) closure, and alcohol septal ablation therapy, were not addressed in the previous document (16). These procedures, although constituting a

small minority of interventional activity, are performed by interventional cardiologists and are included in the Accreditation Council on Graduate Medical Education (ACGME) curriculum and the American Board of Internal Medicine (ABIM) certifying exam. There have been no statements addressing clinical competence in noncoronary interventions.

The ACC, the ACP, the SCAI, the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS) have jointly developed a document on acquisition and maintenance of competence in vascular medicine and catheter-based vascular interventions (18); however, PCI and other percutaneous cardiac procedures are not addressed by the current document. This document is divided into 2 sections: PCI and percutaneous noncoronary cardiac interventions.

Purpose

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 interventional procedures when performed by highly 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 standards to assess operator proficiency and institutional program quality. These include standards for data collection to permit monitoring of appropriateness and effectiveness of PCI procedures both at the level of the operator and the institution.
6. To expand the scope of this competency document, previously limited to coronary procedures, to also include noncoronary cardiac interventions.

Writing Group Composition

The Writing Group was selected to represent a broad range of experience and expertise to bear on this issue. The members of the Writing Group were identified on the basis of 1 or more of the following attributes: PCI operators with a broad range of experience (in practice and in academic settings); individuals who have performed clinical research studying the outcome of PCI procedures; individuals who direct catheterization laboratories with a broad cross section of interventional operators; and individuals with broad clinical experience who have had considerable previous involvement with PCI.

Literature Review

A literature search was conducted with 5 goals:

1. To identify published coronary and other cardiac interventional outcomes data that could be used as benchmarks for quality assessment. In addition, the process sought to identify those risk adjustment variables that affect the likelihood of success and complications. This review focused on outcomes of coronary interventions, including the latest interventional devices as of the date of this revision.
2. To identify data that examines the relationships between operator and institutional experience, and activity levels, and their impact on procedural success and complication rates.
3. To assess the issues and problems associated with judging operator and institutional proficiency based on outcome statistics—in particular, the challenge of accurately assessing the performance of low-volume operators and institutions.
4. To expand the recommendations beyond coronary interventions to other cardiac interventional procedures.
5. To identify methods for monitoring appropriateness of performance of PCI.

Percutaneous Coronary Intervention

Evolution of Competence and Training Standards

Initially, because experience was limited, the coronary angioplasty technique was disseminated informally among physicians who were highly experienced at diagnostic cardiac catheterization. During this period, physicians acquired angioplasty skills through “on-the-job” experience, and no standards existed for either training requirements or for demonstration of competence.

As the coronary angioplasty knowledge base grew and techniques evolved, standards were developed for training (19). Formal angioplasty training programs were first organized in the early 1980s. The most recent recommendations were published by the ACC in 1999 (20). The ABIM developed an Examination in Interventional Cardiology that was first administered in 1999. As of 2005, 5,020 physicians had successfully passed the examination and become board certified in interventional cardiology. Currently, eligibility to sit for the ABIM interventional cardiology examination requires completion of a fourth-year fellowship in interventional cardiology in an ACGME-accredited program. During academic year 2004 to 2005, there were 122 accredited interventional cardiology programs in the United States that had 240 filled training positions.

Professional organizations have addressed the issue of standards and criteria for proficiency in PCI procedures since 1986, with an increasing focus on the issue of

maintenance of proficiency and skills (6–15). These documents have universally endorsed an annual caseload goal for maintenance of proficiency. The most commonly endorsed activity level has been 75 procedures per year per operator. This standard was initially based on general consensus of experts. In recent years, considerable research has examined the volume–outcome relationship and, in general, has affirmed it (21,22).

Since the previous guidelines were published, there has been debate over the relationship between volume and quality. While a relationship between volume and outcomes exists, volume alone does not determine quality. Also, the ABIM interventional cardiology board exam has been established to certify a level of knowledge and experience in the field. This competency document addresses these factors as they relate to determinations of overall operator and institutional quality.

Evolution of Coronary Interventional Capabilities

The cognitive and technical knowledge base required for proficiency in PCI has expanded. The fundamental concepts of coronary angioplasty technique, namely the coaxial guide catheter and the dilation catheter with a minimally compliant cylindrical balloon, were formulated by Andreas Gruntzig (23). Because of the initial comparatively primitive equipment design and capability, coronary angioplasty was only applicable to readily accessible discrete proximal coronary stenoses. Subsequent refinement in instrumentation has greatly enhanced procedural success and extended the indications for the performance of PCI. Complex anatomic situations now considered technically suitable for PCI procedures include multivessel disease (24–30), distal and bifurcation stenoses, total occlusions (31), saphenous vein graft stenoses (32), and complex stenoses. Challenging clinical situations now considered appropriate for coronary intervention include patients with unstable angina (33,34) and myocardial infarction (MI) (35,36) and those who are not considered candidates for coronary bypass surgery.

Nonballoon devices, including coronary stents, and directional, rotational, and laser atherectomy devices, have been introduced. These devices augment conventional balloon angioplasty and extend its capability; however, they all require specific training and mentoring by a previously experienced operator. To become competent in the use of any of these newer interventional devices, an operator must acquire the additional knowledge and technical skills specific to each device.

A number of adjunctive antithrombotic and antiplatelet medications have been introduced for the purpose of reducing acute thrombus-related treatment site complications. Understanding the appropriate indications for and complications associated with the use of these medications, which are powerful anticoagulants, requires knowledge of hemostatic mechanisms.

Procedural Success and Complications of Coronary Interventional Procedures

Recent clinical studies have demonstrated that despite a continuing increase in clinical and angiographic complexity, procedural and clinical success rates have remained high and complication rates have remained low (37–45) (Table 1). Angiographic success occurs in over 95% of patients. Among patients without ST-segment elevation myocardial infarction (STEMI), PCI is associated with an average mortality rate of less than 1%, a Q-wave MI rate of less than 1%, and an emergency coronary artery bypass surgery (CABG) rate of less than 1%. Table 1 contains data from 5 large contemporary registries of PCI procedures and the first 2 National Heart, Lung, and Blood Institute (NHLBI) registries for historical comparison. These data constitute a point of departure for developing benchmarking standards.

Adverse events related to PCI procedures are categorized either by the mechanism of the complication or by the adverse event caused by the procedure. A given adverse event, such as death, may be caused by a variety of complications.

Complications can be divided into 3 mechanistic categories:

1. **Coronary vascular injury.** Coronary arterial injury can occur when devices are introduced into coronary vessels or result from embolization of thrombotic or atherosclerotic material from devices or vessel walls. Examples include coronary dissection, thrombosis, perforation, and embolization.
2. **Other vascular events.** Other vascular events are caused either by injury to a peripheral vessel by catheter insertion, manipulation, or removal, or by embolization of thrombotic or atherosclerotic material. Examples include pseudoaneurysm, retroperitoneal hemorrhage, arteriovenous fistula, and stroke.
3. **Systemic nonvascular events.** Systemic nonvascular adverse events are caused by the procedure but are not due to vascular injury. They include all the systemic hazards of cardiovascular radiographic angiography procedures. Examples include contrast agent-induced nephropathy and acute pulmonary vascular congestion.

For the purpose of assessing clinical competence, complications may be divided into 8 basic outcome categories:

1. **Death:** related to the procedure, regardless of mechanism
2. **Stroke**
3. **MI:** related to the procedure, regardless of mechanism
4. **Ischemia requiring emergency CABG:** either as a result of procedure failure or a procedure complication
5. **Vascular access site complications**
6. **Contrast agent nephropathy**
7. **Excessive bleeding, requiring treatment**
8. **Other (such as coronary perforation and tamponade)**

The first 4 of these categories are generally considered major adverse cardiac and cerebral events (MACCE). Be-

Table 1. Changes in Coronary Interventional Practice and Outcome From Registry Data

Variable	NHLBI-1 (40)	NHLBI-2 (38,39)	NHLBI Dynamic Registry (41)	ACC National Cardiovascular Data Registry (42)	Northern New England Consortium (43)	Michigan Blue Cross Consortium (44)	New York State Registry (45)		
	1977-1981	1985-1986	1997-2002	1998-2005	2000-2004	2002	Nonemergent	Emergent	
Years of entry	1977-1981	1985-1986	1997-2002	1998-2005	2000-2004	2002	2001-2003		
No. of patients	1,155	1,802	6,183	1,082,690	36,831	5,901	124,096	14,946	
Stent use (%)	0	0	78	91.6	86	84.0	87.5	92.7	
Mean patient age (yrs)	54	58	63	61	62	63	65	60	
Unstable angina (%)	37	49	44	35	43	32.0	27.8	83.6	
ST-segment elevation MI (%)	0	0	25	13	12	18.9	0	53	
Clinical Characteristics									
Angiographic success (%)	68	91	93	2005: stented lesions: 99; nonstented lesions: 86	94	NA	97.5	97.5	
Emergency CABG (%)	5.80	3.40	1.00	0.4	0.4	0.51	0.20	0.54	
Mortality (%)	1.2	1.0	1.33	1.2 unadjusted rate	1.17	1.27	0.36	3.25	
Success and Complication Indicators									

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ACC = American College of Cardiology; CABG = coronary artery bypass graft surgery; MCD = multicenter database; MI = myocardial infarction; NA = not available; NHLBI = National Heart, Lung, and Blood Institute.

cause adverse events are definite end points, they are easily recognized and captured for statistical summary purposes. The ACC-National Cardiovascular Data Registry (NCDR)[®] has developed a comprehensive data dictionary with rigorous definitions of recognized adverse events (46). It may be impossible to determine conclusively whether death or a complication was caused by a procedure. Nonetheless, for the purposes of monitoring performance, rate of complications or deaths substantially above that expected, after adjustment for patient risk factors, is a cause for concern.

Patient, Lesion, and Institutional Variables Influencing Success and Complication Rates

A number of factors have improved the overall success and complication rates of PCI procedures. These include increased operator experience, modifications in conventional instrumentation (balloon catheters, guide catheters, guide wires), newer interventional devices (stents and embolization protection devices), and advances in adjunctive pharmacologic therapy. Concurrently, these improvements have led to the extension of interventional treatment to higher-risk patients with more complex coronary anatomy and comorbid disease. These factors have influenced overall acute and long-term outcome associated with PCI procedures.

Measures/Definitions of Success

Anatomic success. The definition of anatomic success focuses exclusively on the enlargement of the lumen at the target site and blood flow through the epicardial coronary artery. Although there has been disagreement, the current definition of success of PCI with stenting is the achievement of a minimal diameter stenosis of less than 20% as visually assessed by angiography and maintenance of Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 (15). Anatomic success of PCI without stenting is defined as stenosis diameter reduction greater than 20% with residual stenosis less than 50%. Notably, there is frequently a disparity between the visual estimate of lumen diameter and quantitative measurements (47,48).

Procedural success. Procedural success has been defined as the achievement of anatomic success of all treated lesions without the major complications of death, MI, or emergency CABG (14,40). Although emergency CABG during hospitalization and death are easily identified end points, the definition of periprocedural MI has been more problematic. Some definitions require the development of Q waves in addition to a threshold value for creatine kinase (CK) elevation. However, more recent reports have included non-STEMIs with CK elevations greater than 3 or 5 times the upper limit of normal as clinically significant, since they have been shown to correlate with long-term mortality (49). Although major adverse cardiac events (MACE) have been

used to judge success, some recent studies also include MACCE.

Short-term clinical success. Short-term clinical success requires, in addition to procedural success, the relief of signs and symptoms of myocardial ischemia.

Longer-term clinical success. Longer-term clinical success requires that the initial clinical success remains durable and that the patient has persistent relief of signs and symptoms of myocardial ischemia for 6 to 9 months after the procedure. Restenosis remains the principal cause of a lack of clinical success over the first year following a successful procedure. This directly leads to target lesion revascularization (TLR), target vessel revascularization, and target vessel failure. Thereafter, clinical events are usually caused by progression of disease at other sites. Clinically important restenosis may be judged by the frequency with which subsequent TLR procedures are performed after the index procedure. Incomplete revascularization, new lesion formation, and stent thrombosis may also limit long-term clinical success, especially in subsequent years (50).

Patient and Lesion Characteristics Related to Procedural Success and Complication Rates

Angioplasty procedural success and complication rates are influenced by a variety of patient and target lesion characteristics. These characteristics must be taken into consideration through risk adjustment when assessing adverse event rates. In addition, they must also be weighed in determining procedure appropriateness.

Patient clinical characteristics. The clinical factors associated with an increased risk of an adverse outcome after intervention include advanced age, female gender, acute coronary syndrome (especially STEMI), chronic renal insufficiency, heart failure, and multivessel coronary disease (7,12,14,15). Patients with impaired renal function, particularly patients with diabetes, are at increased risk for contrast-induced nephropathy (51).

Target lesion anatomic factors. Particular lesion morphologic characteristics are predictive of immediate outcome with coronary intervention (7,12,14,52). Lesion length, presence of thrombus, and degenerated saphenous vein grafts are independently associated with abrupt vessel closure and major ischemic complications. Chronic total occlusions (greater than or equal to 3 months) are associated with a lower procedural success rate. On the basis of these observations, a previous ACC/AHA Clinical Task Force on Clinical Privileges in Cardiology (13) proposed a classification scheme based on lesion morphology to estimate the likelihood of procedural success and complications. This scheme was subsequently modified by others (52) and has served as a useful guide for assessing the risk of an adverse outcome associated with a particular lesion. More recent experience indicates that improved devices and techniques

have higher success rates in more complex lesions (53–56). As a result, lesion morphology may be less predictive of complications currently than it has been in the past (57).

Strategies for Risk Stratification and Operator Evaluation

Several large retrospective studies of patients undergoing PCI have identified clinical and angiographic characteristics that correlate with procedural success, in-hospital morbidity, and mortality (21,22,44) (Table 2). These observations have been used to develop multivariate logistic regression models that can stratify patients before the procedure. Model reliability is best assessed by relative predictive accuracy (C-statistic: moderate is greater than 0.80, excellent is greater than 0.90) and scaling accuracy (the Hosmer-Lemeshow statistic). Several models predict periprocedural mortality with C-statistic greater than 0.80 (Table 2). Prediction of other events is typically less accurate (58–60). Model utility also must consider the frequency and clinical importance of the event measured. Very infrequently occurring events, even if severe, may not allow adequate evaluation of operators with low volume. Results of several years of experience should be considered in order to have sufficient numbers of events to be adequately assessed from a statistical standpoint. Operators and catheterization laboratories should be encouraged to submit information to large databases that allow for evaluation of risk-adjusted outcomes.

Impact of the Facility on Procedural Success

Physical facility requirements. The physical facility in which interventional procedures are performed has an important impact on procedural success. The facility must provide radiologic equipment, monitoring, and patient support equipment to enable operators to perform at the best of their ability. The video and “cine” image quality of radiologic imaging equipment must be optimal to facilitate accurate catheter and device placement and enable proper assessment of procedure results. Physiologic monitoring equipment must provide continuous, accurate information about the patient’s condition. Requisite support equipment must be available and in good operating order to respond to emergency situations.

Overall institutional system 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 consecutive patients and consistent feedback of results to providers brings important quality control to the entire interventional program. The ACC/AHA/SCAI 2005 Guideline Update for PCI (15) recommends that each interventional program performing elective PCI

Table 2. Odds Ratios* for Significant Independent Risk Factors† for Short-Term Mortality Related to PCI

Source	New York State	Northern New England	Michigan BMC2	ACC-NCDR	ACC-NCDR Update		COAP
No. of patients	50,046	15,331	10,796	100,253	No acute MI (142,817)	Acute MI (30,926)	19,358
Incidence (%)	0.58	1.1	1.6	1.4	N/A	N/A	1.6
Years	2003	1994–1996	1997–1999	1998–2000	1998–2001	1998–2001	1999–2000
Clinical							
Acute MI less than 12–24 h	8.6	5.5	2.8	1.3			+
Age	+	+	+	+	+	+	+
Cardiac arrest			3.7				
CHF	3.2	8.6					1.6
COPD				1.3	1.7	1.5	1.8
Diabetes				1.4	1.25		
Female	1.5		1.8				1.4
IABP pre		26.2		1.7		1.9	
Peripheral vascular disease	2.6	3.3	1.6				1.6
Prior CABG	1.4						
Priority (salvage, emergent urgent, elective)		+		+	+	+	+
Renal insufficiency	3.1	6.4	5.5	3.0	3.5	2.0	3.5
Shock	22.1	32.2	11.5	8.5	9.8	8.8	9.8
Anatomic							
ACC lesion score, C		2.9					
Ejection fraction	+	+		+	+	+	+
LMT lesion				2.0	1.5	2.1	
Number of diseased vessels	+		+				
Prox LAD lesion				2.0	1.3	1.3	+
SCAI lesion score				+	+	+	
Thrombus			+				
Procedural							
Lytic use				1.4		1.25	
Nonstent use				1.6	1.6	1.4	
C-statistic	0.905	0.88	0.90	0.89	0.85	0.87	0.87

*Values are odds ratios for binary variables unless otherwise noted; †specific definitions of risk factors may vary from series to series; +relationship exists for continuous or ordinal variables (61–66).

ACC-NCDR = American College of Cardiology National Cardiovascular Data Registry; BMC2 = Blue Cross Blue Shield of Michigan Cardiovascular Consortium; CABG = coronary artery bypass graft; CHF = congestive heart failure; COAP = clinical outcome assessment program; COPD = chronic obstructive pulmonary disease; IABP = intra-aortic balloon pump; LAD = left anterior descending; LMT = left main trunk; MI = myocardial infarction; PCI = percutaneous coronary intervention; SCAI = Society for Cardiovascular Angiography and Interventions.

should have in-house surgical support. Institutions that do not have in-house surgical support and are performing primary PCI only for STEMI, should have an established, well-organized system for emergency transfer to surgery at another institution.

Components of Operator Competence

Cognitive Knowledge Base

The knowledge needed to perform PCI, including that expected to be acquired in ACGME-approved interventional training programs, has been addressed by expert panels (7,8,20,67,68). The core knowledge is now tested by the ABIM Interventional Cardiology certifying examination which has been administered since 1999. Through 2003, physicians trained by a nontraditional pathway were eligible to take the examination based on either practice-based procedure activity and experience or by completion of an interventional training program. Since 2003, only individuals who have completed an ABIM-qualified training

program are eligible to take the certifying examination. Individuals who train in interventional cardiology should become ABIM certified in interventional cardiology.

Training programs and the qualifying examination (20,69) require that interventional cardiologists be knowledgeable in anatomy, physiology, and pathophysiology of the cardiovascular system. In particular, one should understand the biology of coronary artery disease, be knowledgeable about the pathophysiology of myocardial ischemia and MI, and understand the dynamics of cardiac dysfunction. Interventionalists should possess a fundamental knowledge of stents and be familiar with the polymers and drugs that are incorporated into stents, coagulation cascade, thrombolysis, and the pharmacology, therapeutic application, and risks of antiplatelet, antithrombin, and fibrinolytic drugs that are used in association with PCI. Competent operators must have knowledge of the indications for PCI and adjunctive and alternative use of medical therapy and surgery for patients with coronary artery disease based on an in-depth

understanding of published clinical trials. Coronary interventionalists must understand the role of primary angioplasty compared with fibrinolytic therapy for STEMI and the alternative therapeutic approaches for treating STEMI that depend upon the time of presentation, anticipated door-to-balloon time, and the presence or absence of ongoing symptoms and/or electrocardiographic abnormalities.

Cognitive knowledge must be bolstered by clinical skills and experience that support the rational selection of optimal treatment strategies for each patient. Such decisions are based on symptoms, anatomy, and associated risk factors. Thus, equally important to knowing the indications for PCI is an understanding of its limitations and contraindications, particularly as these relate to comorbid systemic diseases and special anatomical subsets. Physicians performing these procedures should be conversant with the applicable guidelines (e.g., PCI, CABG, STEMI, unstable angina/NSTEMI [15,70–72]).

Coronary interventionalists must also have a thorough knowledge of specialized equipment, techniques, and devices used to perform PCI competently, including:

1. The theoretical and practical aspects of X-ray imaging, radiation physics and safety, and other equipment to generate digital images; quality control of images; image archiving; consequences of exposure of patients and personnel to ionizing radiation; and methods of reducing patient and staff radiation exposure (73).
2. Specialized catheterization recording and safety equipment (physiological data recorders, pressure transducers, blood gas analyzers, defibrillators) (74).
3. Catheters, guide wires, balloon catheters, stents, atherectomy devices, ultrasound catheters, intra-aortic balloon pumps, puncture site sealing devices, contrast agents, distal protection devices, and thrombus extraction devices.

Operators must be knowledgeable about the prevention, prompt recognition, and treatment of procedural complications. It is extremely important to have the knowledge and skills to diagnose and manage vessel perforation, no reflow, coronary dissection, expanding hematoma, pseudoaneurysm, arterial venous fistulas, and retroperitoneal hemorrhage. Interventionalists must also be cognizant of systemic complications, including cerebrovascular events and contrast-related nephropathy.

Technical Skills

Many of the skills required to perform coronary interventional procedures are closely related to those needed to perform diagnostic cardiac catheterization and coronary angiography. These include manual dexterity and the ability to obtain percutaneous arterial and venous access and maintain sterile surgical technique.

Most of the other required technical skills are unique to coronary interventional procedures and can only be acquired

during training and by performing actual procedures under the direction of an experienced interventionalist. These include the manipulation and operation of guide catheters, coronary angioplasty guide wires, coronary angioplasty balloon catheters, specialized atherectomy devices, stents, and intracoronary ultrasound catheters. Such training appropriately occurs in standardized training programs that are ACGME-approved and lead to eligibility for board certification.

Nonballoon Devices

A special area of competence involves use of lesion assessment tools. Intracoronary devices commonly used by interventional cardiologists for assessment of intraluminal coronary anatomy and/or physiology include intravascular ultrasound (IVUS) or intracoronary ultrasound (ICUS), Doppler flow wires, and pressure wires. Competency in the use of angioscopy, optical coherence tomography, spectroscopy, intravascular thermography, and intravascular magnetic resonance imaging is beyond the scope of this document. Expertise in device manipulation and image interpretation is required to use these intravascular assessment devices safely and effectively. The risks of these devices is the same as those with PCI and include vessel spasm; myocardial ischemia; coronary artery dissection; plaque disruption; thrombosis; air, plaque, or thrombotic embolization; acute occlusion; coronary artery perforation; and contrast nephropathy, stroke, and access site complications. Therefore, only an interventional cardiologist skilled in transluminal coronary techniques such as balloon angioplasty and stenting who is able to diagnose and treat complications of interventional procedures should employ these devices. Recommendations regarding the use of IVUS, Doppler flow wires, and pressure wires are published in Appendix C of the ACC/AHA Guidelines for Coronary Angiography (75).

It is also important to ensure quality image acquisition, measurement, and reporting for each of the intravascular assessment devices. For ICUS, the reader is referred to the ACC Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies (76). No such documents are available for Doppler analysis of coronary flow reserve and pressure wire analysis of fractional flow reserve, but many of the general principles in the IVUS document may be of some benefit in guiding appropriate use of these other modalities.

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

Evidence Reviewed

Computerized literature searches of English language publications, review of recent abstract publications, and solicitation of manuscripts under review for publication from

Table 3. Published Data Relating Hospital Coronary Angioplasty Volume to Complication Rates

Study	Data Source	No. of Patients/ Hospitals Studied	Conclusions	Comments
Hartz et al. (78)	1989–1991 Wisconsin Medicare	2,091/16	No relation between volume and outcome	Very low number of cases and hospitals examined
Ritchie et al. (86)	1989 California State (Adm)	24,883/110	Increased CABG (not death) less than 20 cases per yr; finding is valid for both acute MI and nonacute MI patients	
Jollis et al. (85)	1987–1990 MEDPAR (Adm)	217,836/1,194	Death and CABG increased with low volume (risk increases with Medicare patient volume* (less than 100–200 total per yr for death, 200–300 per yr for CABG)	
Kimmel et al. (84)	1992–1993 SCAI	19,594/48	Fewer major complications for labs with greater than 400 cases per yr	Able to risk adjust more completely than most other analyses
GUSTO (IIb) Angioplasty Substudy Group (36)	GUSTO IIb trial	565/59	No difference, 200–625 vs. greater than 625 cases per yr for acute MI patients	All operators greater than or equal to 50 cases per yr
Kato et al. (79)	1991 HCFA (RAND Corp.)	113,576/862	Except for Medicare volume* less than 50, higher volume hospitals had higher mortality rates	
Stone et al. (80)	PAMI II trial	1,100/34	No difference, less than 500, 501–1,000, greater than 1,000 cases per yr for acute MI patients	
Jollis et al. (77)	1992 Medicare (Adm)	97,498/984	Incremental decrease in death and bypass surgery as hospital Medicare volume* less than 100, 100–200, greater than 200 per yr	
Tiefenbrunn et al. (83)	Second National Registry of MI (U.S.)	4,939/?	Increased acute MI mortality for hospital less than 25 acute MI cases per yr	
Hannan et al. (82)	1991–1994 NY State	62,670/31	Death alone and same-stay CABG increased with annual caseloads less than 600	Risk-adjusted
Zahn et al. (81)	1992–1995 German Hospital Consortium	4,625/?	For patients with acute MI; increased mortality in hospitals with less than or equal to 40 acute MI PTCA per yr	No risk-adjusted
Moscucci et al. (22)	1998–1999 NY State and MI	11,374/8	In-hospital death increased for hospital volume less than 400	Risk-adjusted
Hannan et al. (21)	1998–2000 NY State	107,713/34	Death, same-day CABG, same-stay CABG increased for hospital volume less than 400	Risk-adjusted

*Medicare patients usually constitute 35% to 50% of total interventional caseload.

Adm = administrative data set; CABG = coronary artery bypass graft; GUSTO = Global Use of Strategies to Open Occluded Coronary Arteries in Acute Coronary Syndromes; HCFA = Health Care Financing Administration; MEDPAR = Medicare provider analysis and review; MI = myocardial infarction; PAMI = Primary Angioplasty in Myocardial Infarction; PTCA = percutaneous transluminal coronary angioplasty; SCAI = Society for Cardiovascular Angiography and Interventions.

many physicians and epidemiologists expert in the field were used to compile the relevant available scientific evidence relating institutional and operator activity level to outcomes (Table 3). In general, greater weight was given to recent, fully peer-reviewed publications of high quality. No single work was considered definitive. It was recognized that many analyses were limited to some extent by lack of capacity to fully adjust expected outcomes for differences in patient characteristics, changes and advances in the field of interventional cardiology, and inability to generalize the results to a broader population.

Relationship of Institutional Volume to Procedural Outcome

The preponderance of data suggest that, on average, hospitals in which fewer coronary interventions are performed

have a greater incidence of procedure-related complications, notably death and need for bypass surgery for failed intervention, than hospitals performing more procedures. Multiple data sources support the existence of a curvilinear, perhaps logarithmic, statistical relation between caseload and outcome (Fig. 1). However, for CABG, the continued importance of the relationship between volume and outcomes has been recently confirmed using contemporary clinical data (87). For PCI, the majority of the studies available either predate the widespread introduction in interventional practice of coronary stenting and adjunctive use of glycoprotein receptor blockers, or were obtained through analysis of Medicare claims data or other administrative data. Recognized limitations of Medicare data include the need to extrapolate the total number of proce-

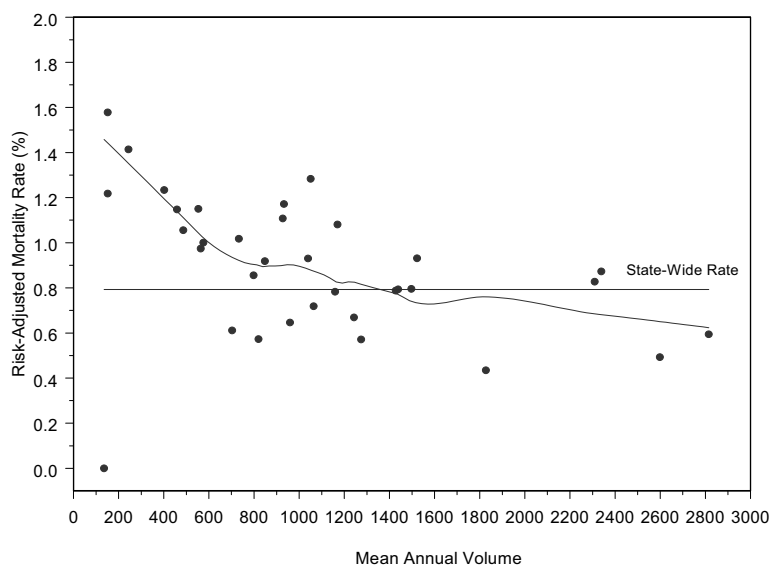


Figure 1. Mean Annual Hospital PCI Volume and Risk-Adjusted In-Hospital Mortality Rate in New York State, 1998–2000

Reprinted with permission from Hannan EL, Wu C, Walford G, et al. Volume-outcome relationships for percutaneous coronary interventions in the stent era. *Circulation* 2005; 112:1171–9 (21). PCI = percutaneous coronary intervention.

dures from the number of Medicare procedures, the incomplete reporting in Medicare claims of comorbidities that might be important predictors of adverse outcomes (16,17), and the possibility of miscoding complications as comorbidities (18).

The direct relationship between institutional volume and outcomes has been recently confirmed by 2 more contemporary analyses of large clinical registries. The first study compared data collected between 1998 and 1999 in a multicenter PCI registry in Michigan with data from the New York State data registry (22). An institutional annual volume less than 400 cases per year was found to be independently associated with an increased risk of in-hospital death compared with hospitals with annual volumes of at least 400 (adjusted odds ratio [OR] 1.77, 95% confidence interval [CI] 1.16 to 2.70). The second study (21), based on the New York State data registry, evaluated 107,713 procedures performed in 34 hospitals in New York State during 1998 to 2000. The same hospital volume threshold of less than 400 procedures per year was found to be associated with an increased risk of in-hospital mortality (adjusted OR 1.98, 95% CI 1.17 to 3.35), “same day” CABG surgery (adjusted OR 2.07, 95% CI 1.36 to 3.15) or “same stay” CABG surgery (adjusted OR 1.51, 95% CI 1.03 to 2.21). Figure 1 from the New York study presents the continuous relationship between hospital volume and risk-adjusted in-hospital mortality.

It is important to underscore that advancements in technology have resulted in a progressive improvement in outcomes of PCI, and that this improvement has at least in part offset the adverse institution volume–outcome relationship. In a recent study evaluating temporal trends in the volume–outcome relationship in the state of California, it

was found that over time, the disparity in outcomes between low- and high-volume hospitals had narrowed, and that outcomes had improved significantly for all hospitals (88). The author of this study concluded that given these improvements, lower minimum volume standards might be justifiable in less populated areas, where the alternative is no access to angioplasty at all. Importantly, procedural volume is only one of many factors contributing to the variability of measured outcomes (58,82,89). Furthermore, there is no clear “cut-off” above or below which hospitals, or groups of hospitals in aggregate, perform well or poorly. There are institutions with low volumes that appear to achieve very acceptable results. For an individual institution, however, such an impression must be tempered by the statistical imprecision of the estimate of risk.

Volume and Outcomes Relationship for Primary PCI in Acute MI

The relationship between operator and institutional volume and outcome of primary PCI for acute MI has been examined nearly exclusively at hospitals with onsite cardiac surgery. In an analysis including 62,299 patients with acute MI and enrolled in the National Registry of Myocardial Infarction, Magid et al. (90) analyzed data from 446 acute-care hospitals providing primary angioplasty services. Hospitals were classified as low volume (less than 16 procedures per year), intermediate volume (17 to 48 procedures per year), and high volume (more than 49 procedures per year). In high-volume hospitals, mortality for acute MI patients was significantly lower with primary angioplasty when compared with fibrinolysis, while in low-volume hospitals, there were no differences in mortality rates between primary angioplasty and fibrinolysis. Two other

analyses from the same registry and 2 studies using the New York State data registry have shown a direct relationship between hospital volume of primary angioplasty and mortality. In the analysis by Canto et al. (91), hospital volume was divided in quartiles. In-hospital mortality was 28% lower in patients treated in the highest volume quartile (greater than 33 primary PCIs per year) when compared with patients treated in the lowest volume quartile (less than 12 primary PCIs per year). Similar results were obtained by Cannon et al. (92). In this analysis, a procedure volume greater than 3 PCIs per month was found to be associated with a lower in-hospital mortality rate when compared with a procedure volume of less than 1 PCI per month, or with a procedure volume between 1 and 3 PCIs per month.

Recently, Hannan et al. (21) reported data from the New York State Coronary Angioplasty Reporting System Registry collected in the years 1998 to 2000, a period when stenting was used in a large majority of the STEMI patients. A trend toward an increased odds ratio of in-hospital mortality was observed for low-volume operators when compared with high-volume operators both for a volume cut of 8 procedures per year (OR 1.40, 95% CI 0.89 to 2.20) and with a volume cut of 10 procedures per 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 primary PCI, regardless of whether the institutional volume cut point was set at 36 procedures per year (OR 2.01, 95% CI 1.27 to 3.17), 40 procedures per year (OR 1.73, 95% CI 1.1 to 2.71), or 60 procedures per year (OR 1.45, 95% CI 1.01 to 2.09).

Volume and outcomes relationship for PCI in hospitals without onsite cardiac surgery. There is only 1 report indicating a relationship between institutional PCI volume and outcome in hospitals without onsite cardiac surgery. Wennberg et al. (93) reported that among Medicare recipients, there was no difference in mortality after primary/rescue PCI (emergency procedure on the same day for STEMI) performed at hospitals with or without cardiac surgery onsite. However, they did report a higher mortality for PCI patients, excluding primary/rescue PCI, at hospitals without cardiac surgery onsite (adjusted OR 1.38, 95% CI 1.14 to 1.67; $p = 0.001$). The relationship between institutional volume and PCI affecting this outcome was confined mainly to hospitals without cardiac surgery onsite performing 50 or fewer nonprimary/rescue PCIs in Medicare recipients per year. Among hospitals performing more than 100 PCIs in Medicare recipients, mortality was not higher in hospitals without surgery onsite (adjusted OR 0.76, 95% CI 0.52 to 1.11; $p = 0.16$). These hospitals likely perform more than 200 PCIs per year based on the assumption that 100 Medicare PCIs represent approximately 200 total PCIs per year.

Taken together, these data suggest that the relationship between institutional volume of PCI patients (excluding primary/rescue PCI) and mortality in hospitals without

surgery onsite may be similar to the relationship in hospitals with surgery onsite. For facilities without onsite surgery, it is mandatory that there be an established, well-organized plan for transfer for surgery if needed.

Relationship of Individual Operator Volume to Procedural Outcome

Several large studies have assessed the potential relation between individual operator caseload and procedural complications (93). Recently, McGrath et al. (94) analyzed relatively contemporary data (calendar year 1997) from the Medicare database. Based on a slightly different assumption than Wennberg et al. (93) that Medicare patients represent 35% to 45% of total PCI procedure volume, they estimated that 30 PCIs per operator per year on Medicare patients could be extrapolated to a total procedure volume of 70 PCIs per operator per year (94). A significant relationship between operator volume and outcomes was also reported in their study, with better outcomes observed in patients treated by high-volume operators when compared with patients treated by low-volume operators. Similar results were obtained in the study by Hannan et al. (21) in the analysis of data collected from the 107,713 procedures performed in the 34 hospitals performing PCI in New York State during 1998 to 2000. Operator volume thresholds were set at 75 procedures per year based on ACC/AHA recommendations, and at slightly higher levels of 100 and 125 procedures per year. There were no differences in risk-adjusted mortality between patients undergoing PCI performed by lower volume operators and patients undergoing PCI performed by higher volume operators for any of the 3 volume thresholds that were examined. However, for all 3 volume thresholds, significant differences for "same day" CABG surgery and for "same stay" CABG surgery were observed. For example, patients undergoing PCI with operators performing less than 75 procedures per year had a 65% increased odds of undergoing same-day CABG surgery, and a 55% increased odds of undergoing "same-stay" CABG surgery.

Further confirmation of the adverse operator volume–outcome relationship with contemporary PCI comes from an analysis by Moscucci et al. (95) of another regional, audited, clinical PCI registry. In that analysis including 18,504 procedures performed in 14 Michigan hospitals in calendar year 2002, operator volume was subdivided in quintiles (1 to 33 PCIs per year, 34 to 89 PCIs per year, 90 to 139 PCIs per year, 140 to 206 PCIs per year, and 207 to 582 PCIs per year). The primary end point was a composite of MACE, including death, CABG, stroke, transient ischemic attack, MI, and repeat PCI at the same lesion site. Stent utilization was greater than 80%, and greater than 70% of patients received a glycoprotein (GP_{IIb/IIIa}) receptor inhibitor. After adjustment for comorbidities, patients treated by operators in the 2 lower volume quintiles (Quintiles 1 and 2) had a 63% increase in the odds of MACE

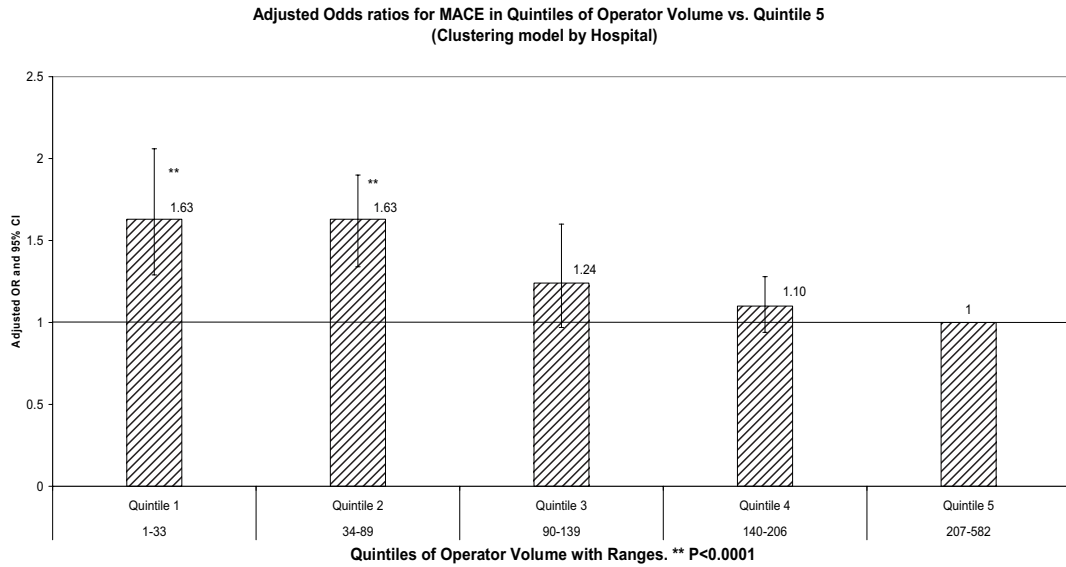


Figure 2. Adjusted Odds Ratios for MACE by Quintile of Operator Volume

Reprinted with permission from Moscucci M, Share D, Smith D, et al. Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice: an analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database. *J Am Coll Cardiol* 2005; 46:625–32 (95). MACE = major adverse cardiac events.

(Fig. 2). No significant relationship was observed between operator volume and risk of in-hospital death. The adverse relationship between operator volume and outcomes appeared to be relatively independent of patient risk. A detailed analysis of individual operator risk-adjusted outcomes revealed the presence of several low-volume operators with better than expected outcomes, and of a few high-volume operators with worse than expected outcomes, thus suggesting that there are exceptions to the rule, and that low-volume operators should be tracked over a longer period of time to ascertain their true performance (Fig. 3).

Combination of Individual Operator Volume and Institutional Volume on Procedural Outcome

The combined impact of hospital volume and operator volume on adverse outcomes was assessed by Hannan et al. (21). Patients undergoing PCI performed by operators with volumes below 75 per year in hospitals with volumes below 400 per year were found to have significantly higher odds of dying in the hospital than patients undergoing PCI performed by operators with volumes of 75 or more in hospitals with volumes of 400 or more (OR 5.92, 95% CI 3.25 to

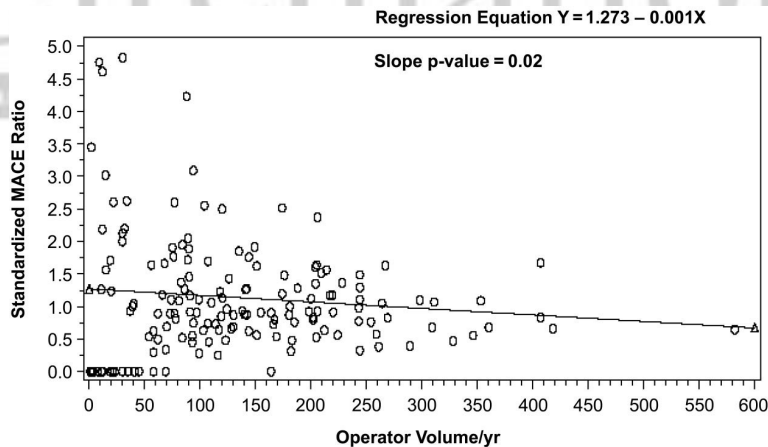


Figure 3. Linear Plot of Standardized MACE Ratios (Observed/Predicted Rates) Versus Annual Operator Volume

Reprinted with permission from Moscucci M, Share D, Smith D, et al. Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice: an analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database. *J Am Coll Cardiol* 2005; 46:625–32 (95). MACE = major adverse cardiac events.

10.97). Also, patients undergoing PCI performed by operators with annual volumes of below 75 in hospitals with annual volumes below 400 experienced significantly higher same-day CABG rates than patients with high-volume operators (greater than 75 annually) in high-volume hospitals (greater than 400 annually), with an OR of 4.02. For same-stay CABG surgery the respective OR was 3.19. It should be noted that the magnitude of these ORs demonstrates that the increase in adverse outcomes compound when patients undergo PCIs performed by low-volume operators (less than 75 annually) in low-volume hospitals (less than 400 annually).

In summary, analysis of more contemporary data supports the hypothesis that technological advancements have not completely offset the influence of “practice” in determining proficiency of contemporary PCIs. However, procedure volume is only a poor substitute for quality and outcomes; therefore, it should not be used as a replacement for appropriately risk-adjusted outcomes. Nevertheless, it is easy to measure, and its potential implications are easily understood by patients undergoing PCI. As such, it seems appropriate to continue to include procedure volume among the several indirect quality indicators of contemporary PCI practice.

However, it is also important to underscore that there are significant limitations to the simplistic interpretation of procedure volume statistics as a measure of competence and quality. First, it is uncertain whether this relationship is a result of the “practice makes perfect” principle, or the fact that patients are more frequently referred to high-quality operators. Second, it remains unclear where the “cut-off” number should be set. Third, studies have shown significant variability in the volume–outcome relationship within the same registry, with some low-volume operators having better than expected outcomes, and a few high-volume operators having worse-than-expected outcomes. Furthermore, at present, few or no data exist linking operator volume to case selection, appropriateness of procedures, periprocedural MI, long-term clinical outcome, or cost-effectiveness, each of which measures a component of quality of care, or linking clinical outcomes to operator experience as measured by the number of years in practice, total procedure volume over a lifetime career, or board certification.

The development of national, regional, and state registries for outcome assessment is also promoting a shift of the paradigm surrounding quality of PCI from a mere collection of procedure volume to objective assessment of clinical outcomes. In addition, the past decade has been characterized by substantial advancement in methodology, scientific rigor, and acceptance of risk adjustment. Factors related to in-hospital mortality following PCI are now well defined, and progress is being made toward the development of statistical models for other outcomes. Clearly, the calculation of risk-adjusted outcomes using data from clinical registries is a more accurate way to assess outcomes than

using volume as a surrogate, and as more registry data become available, procedure volume will likely no longer be used as a replacement or a surrogate for quality assessment.

Yet, limitations related to the effect of random variation and to the evaluation of rare events continue to exist. These limitations make it difficult to assess the true performance of very-low-volume operators. In such situations, close scrutiny of case selection and close monitoring of outcomes on a case-by-case basis might serve as a substitute/complement to risk adjustment.

In summary, while there are inherent limitations in using procedure volume as a surrogate of quality and outcomes, recent data suggest that there is still a relationship between experience and outcomes. In the analysis of the New York State data, the relationship appeared to be at a level of 75 procedures per year, with further improvement in outcomes observed at a volume threshold of greater than 100 procedures per year. In the analysis of the Michigan data, the relationship was at a level of 100 procedures per year. On the basis of these data, it is recommended that the operator volume threshold continue to be 75 procedures per year. Independent of procedure volume, all operators should participate in a regional or national program for outcome assessment and quality improvement. In addition, it is recognized that there are limitations in the application of the risk-adjustment methodology in the evaluation of rare events and of low-volume operators, and that there might be substantial variations in the volume–outcome relationship. For operators that do not meet a threshold of 75 cases per year measured in 2-year intervals, it is recommended that a case-by-case review, case selection, and prior experience including the total number of cases in a lifetime career be included in their evaluation. They could also partner with higher volume operators to perform cases together to gain further experience.

Ongoing Quality Improvement and Maintenance of Competence

Maintenance of competence in interventional procedures should be accomplished for both the individual physician operator and for the institutions in which cardiac interventional procedures are performed. The goals in setting criteria for maintaining competence include:

1. Ensuring quality of patient care and outcomes;
2. Enabling quality interventionalists and institutions to continue to perform PCI;
3. Providing standards that all institutions and operators should strive to achieve.

Institutional Maintenance of Quality

It is recommended that all institutions have a regular (at least monthly) catheterization laboratory conference. The opportunity for ongoing dialogue and collaboration among angiographers, interventional operators, and cardiothoracic surgical colleagues is highly desirable. New developments in

the angioplasty literature should be reviewed, and procedural complications should be discussed.

Maintenance of competence also requires that patient outcomes be determined longitudinally for each procedure by the institution's quality assessment program. Participation in a state, regional, or national database is highly encouraged. This allows institutions to measure risk-adjusted outcomes and compare them to regional and national benchmarks for improving quality of care.

It is recommended that lower volume institutions (less than 400 interventions per year) consider holding conferences with a partnering, more highly experienced institution. It is also recommended that any institution that falls outside the risk-adjusted national benchmarks in mortality or emergency same-stay CABG during 2 of 3 contiguous 6-month periods have an external audit looking for opportunities to improve quality of care.

Individual Maintenance of Quality

To maintain a cognitive knowledge base, it is recommended that individual operators attend at least 30 h of interventional cardiology continuing medical education (CME) every 2 years. This could include catheterization conferences and PCI meetings in addition to expanding the use of simulation cases for procedure use and competence.

To ensure appropriate patient selection and quality of technical skills, it is recommended that all operators have 5 randomly selected cases and all major complications reviewed each year by the catheterization laboratory director or a Quality Assessment Committee at the institution. Any operator performing less than 75 cases per year should have 10 cases reviewed per year. These performance evaluations should include feedback to the operator. If it is determined that the quality of PCI care being provided does not meet national benchmarks, the catheterization laboratory director should have the discretion of making recommendations for improving quality and reassessing over the next 6 months. If disagreements concerning corrective action occur, external review is often helpful.

Quality Assurance

Definition of Quality in PCI

Satisfactory quality in PCI may be defined as selecting patients appropriately for the procedure and achieving risk-adjusted outcomes that are comparable to national benchmark standards in terms of procedure success and adverse event rates. To achieve optimal quality and outcomes in PCI it is necessary that both the physician operator and the supporting institution be appropriately skilled and experienced.

Institutional Quality Assurance Requirement

In the United States, responsibility for quality assurance is vested in the health care institution that is responsible to the

public to ensure that patient care conducted under its jurisdiction is of acceptable quality. Quality assessment review should be conducted both at the level of the entire program and at the level of the individual practitioner.

Each institution that performs PCI must establish an ongoing mechanism for valid peer review of its quality and outcomes. The program should provide an opportunity for interventionalists as well as physicians who do not perform angioplasty, but are knowledgeable about it, to review its overall results on a regular basis. The review process should tabulate the results achieved both by individual physician operators and by the overall program and compare them to national benchmark standards with appropriate risk adjustment. Valid quality assessment requires that the institution maintain meticulous and confidential records that include the patient demographic and clinical characteristics necessary to assess appropriateness and to conduct risk adjustment.

Role of Risk Adjustment in Assessing Quality

A raw adverse event rate that is not appropriately risk adjusted has little meaning. Data compiled from large registries of procedures performed in recent years have generated multivariate risk adjustment models for adverse event rates for PCI in the current era. Six multivariate models of the risk of mortality following PCI have been published (62,64,96–99).

Although these models differ somewhat, they are consistent in identifying acute MI, shock, and age as important risk stratification variables for mortality. The ACC-NCDR® reported an univariate in-hospital mortality of 0.5% for patients undergoing elective PCI, mortality of 5.1% for patients undergoing primary PCI within 6 h of the onset of STEMI and mortality of 28% for patients undergoing PCI for cardiogenic shock (64). Thus, it is clear that, in order to assess PCI mortality rates, patients should be stratified by whether they are undergoing elective PCI, primary PCI for acute STEMI without shock, or primary PCI for STEMI with shock.

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. Accurate assessment of quality becomes more problematic for low-volume operators and institutions because absolute event rates are expected to be small. Thus, particularly in low-volume circumstances, quality may be better assessed by an intensive case-review process conducted by recognized experts who can properly judge all of the facets of the conduct of a case. Case review also has merit in high-volume situations as it can identify subtleties of case selection and procedure conduct that may not be reflected in pooled statistical data.

Table 4. Key Components of a Quality Assurance Program

Clinical proficiency
<ul style="list-style-type: none"> • General indications/contraindications • Institutional and individual operator complication rates, mortality, and emergency coronary artery bypass grafting • Institutional and operator procedure volumes • Training and qualifications of support staff
Equipment maintenance and management
<ul style="list-style-type: none"> • Quality of laboratory facility (see ACC/SCAI Expert Consensus Document on Catheterization Laboratory Standards [100])
Quality improvement process
<ul style="list-style-type: none"> • Establishment of an active concurrent database to track clinical and procedural information and patient outcomes for individual operators and the institution. Participation in multicenter database is highly encouraged.
Radiation safety
<ul style="list-style-type: none"> • Educational program in the diagnostic use of X-ray • Patient and operator exposure

Requirement for Institutional Resources and Support

A high-quality PCI program requires appropriately trained, experienced, and skilled physician operators. However, the operator does not work in a vacuum. An operator 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. Thus, 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.

The Quality Assessment Process

Quality assessment is a complex process that includes more than a mere tabulation of success and complication rates. Components of quality in coronary interventional procedures include appropriateness of case selection; quality of procedure execution; proper response to intraprocedural problems; accurate assessment of procedure outcome both short- and long-term; and appropriateness of postprocedure management. It is important to consider each of these parameters when conducting a quality assessment review. A quality program performs appropriately selected procedures while achieving risk-adjusted outcomes, in terms of procedure success and complication rates, that are comparable to national benchmark standards. It is accepted that quality assurance monitoring is best conducted through the peer-review process despite the political challenges associated with colleagues evaluating each other. There has been considerable controversy surrounding efforts to define standards, criteria, and methodologies for conducting quality assessment. There are many challenges to conducting this process in a fair and valid manner.

The cornerstone of quality assurance monitoring is the assessment of procedure outcomes in terms of success and adverse event rates. Other components of quality assurance monitoring include establishing criteria for assessing procedure appropriateness and applying proper risk adjustment to interpret adverse event rates. As adverse events should be

rare, a valid estimate of a properly risk-adjusted adverse event rate generally requires tabulating the results of a large number of procedures. This adds an additional challenge to the valid assessment of low-volume operators and institutions. The responsible supervising authority should monitor the issues outlined in Table 4.

In addition, mere tabulation of adverse event rates, even with appropriate risk adjustment, is inadequate to judge operator or program quality. Such tabulations do not address numerous other quality issues—in particular, appropriateness. Thus, the quality assessment process should also conduct detailed reviews of both cases that have adverse outcomes, to determine the cause(s) of the adverse event, and of uncomplicated cases, in order to judge case selection appropriateness and procedure execution quality. These reviews should be conducted by recognized experienced interventionalists, drawn either from within the institution or externally, if a requisite number of appropriately qualified unconflicted individuals are not available.

Conclusions and Recommendations for PCIs

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. Institutional and programmatic quality is ultimately determined by its success in achieving that goal.

Success and Complication Rates

Coronary interventional procedures may be complex and technically demanding to perform. Complications of these procedures may be life-threatening and can occur unpredictably. Nonetheless, recent clinical studies have demonstrated that despite increased clinical and angiographic complexity, procedural and clinical success has remained high and complications have remained low. Angiographic success (at least 1 lesion successfully dilated by greater than 20%, with a residual stenosis of less than 50%), excluding

STEMI patients, occurs in over 95% with an average mortality rate of less than 1%, a Q-wave MI rate of less than 1%, and an emergency CABG rate of less than 1%.

Risk Adjustment

Several large retrospective studies have identified both clinical and angiographic characteristics of PCI that correlate with procedural success, hospital morbidity, and mortality. These studies have been used to develop multivariate logistic regression models that can stratify patients into risk groups before the procedure which have moderate predictive value for mortality (C-statistic 0.85 to 0.90), and slightly less predictive value for morbidity (C-statistic 0.67 to 0.78).

Volume–Activity Relationships

Analysis of more contemporary data supports the hypothesis that technological advancements have not offset the influence of “practice” in determining proficiency of contemporary PCIs. There are statistical associations between activity levels and short-term complication rates (emergency CABG and mortality) (17,58,85,89,97,101) for both institutions and for individual operators. In particular, low-volume operators operating at low-volume hospitals had an increased mortality rate. However, procedural volume is only one of many factors contributing to the variability of measured outcomes. Furthermore, there is no clear “cut-off” above or below which hospitals or individual operators perform well or poorly. Procedural volume continues to be correlated with outcomes, but should not serve as a substitute for a well-controlled analysis of results and does not ensure quality. The development of national, regional and state registries for outcome assessment is promoting objective assessment of clinical outcomes.

The expected low complication rate for coronary interventional procedures presents a major statistical power problem when attempting to estimate the true complication rate of the low-volume operator with meaningful precision. In such situations, close scrutiny of case selection and close monitoring of outcomes on a case-by-case basis would serve as a complement to risk adjustment.

Highly complex procedures require much more skill and experience, and should be undertaken by operators possessing these attributes. Complex cases appropriate for interventions should be referred, not denied.

Recommendations for Institutional Maintenance of Quality

It is recommended that all institutions have a regular (at least monthly) catheterization laboratory conference. Patient outcomes should be determined longitudinally for each procedure by the institution’s quality assessment program. Participation in a state, regional, or national registry is highly encouraged to allow institutions to measure risk-adjusted outcomes and compare them to national benchmarks for improving quality of care.

For both institutional and individual volume assessments, ongoing 2-year volumes should be measured, then averaged to arrive at annual statistics. It is recommended that lower volume institutions (less than 400 per year) consider holding conferences with a more experienced partnering institution, with all staff expected to attend on a regular basis.

It is also recommended that any institution that falls more than 2 standard deviations outside the risk-adjusted national benchmarks in mortality or emergency same-stay CABG during 2 of 3 contiguous 6-month periods have an external audit looking for opportunities to improve quality of care.

An institution offering coronary interventional procedures should have a physician-director who is responsible for the program’s overall quality. The director should be certified in interventional cardiology by the ABIM, with a career experience of more than 500 procedures. The director should perform procedures at the facility that he or she directs.

Recommendations for Individual Maintenance of Quality

To maintain an appropriate cognitive knowledge base for PCIs, it is recommended that individual operators attend at least 30 h of PCI CME every 2 years. The overall performance of physicians whose complication rates exceed national benchmark standards for 2 of 3 contiguous 6-month periods should be reviewed by the program director, with careful attention to statistical power and risk-adjustment issues. It is recommended that the operator volume threshold continue to be 75 procedures per year. Monitoring of physicians with an annual procedural volume of less than 75 should be particularly detailed because of the difficulty of estimating their true complication rate. These performance evaluations should include feedback to the operator.

If it is determined that the quality of PCI care being provided does not meet national benchmarks, the catheterization laboratory director should have the discretion of making recommendations for improving quality and reassessing over the next 6 months. These recommendations could include establishing a defined mentoring relationship with an experienced operator. If the operator in question disputes this assessment, then external review may be helpful in determining the most appropriate methods of assuring quality performance.

Percutaneous Noncoronary Interventions

Introduction

Noncoronary interventions are a growing and important contribution to the field of interventional cardiology. The majority of procedures have had their origin in the pediatric population, and several have expanded to the adult patient. The purpose of this section is to discuss the training and experience necessary for the safe and successful performance

of valvuloplasty, alcohol septal ablation, and percutaneous repair of ASD/PFO.

The knowledge, skills, and training necessary for competency in noncoronary interventional procedures are different from that required for coronary interventions. Therefore, special study of the anatomy, physiology, and pathology of these conditions is a prerequisite for safe and effective treatment. Furthermore, an in-depth understanding of the clinical indications for treatment and the unique complications of these treatments are essential.

Although the scope of this document is focused on competency, this section will expand the discussion somewhat to describe some anatomical and procedural details. Such details are well known for PCI, and their performance is widespread, whereas these noncoronary procedures, in the estimation of this Writing Committee, warrant some discussion of background information and procedural alternatives.

Disorders of the Atrial Septum

Criteria for Competency

The knowledge base required for performing PCI is different than that required for percutaneous closure of ASD and PFO. Extensive knowledge of structural cardiac anatomy, especially that of the atrial septum and the adjacent structures, is required, as is the understanding of the impact of abnormal anatomy and function, and the relative value of therapeutic options (85,101–105). Therefore, specific training and experience is necessary to safely and successfully treat this subgroup of patients. The Food and Drug Administration guidelines on the use of device closure of PFOs in these patients state that only patients who have failed anticoagulation or have a compelling medical reason to not be anticoagulated are appropriate for device closure. These guidelines should be fully discussed with patients during the informed consent process. In addition, complications such as cardiac perforation, device embolization, thrombus formation on the device, infective endocarditis, arrhythmias, and early as well as late erosion of the device through the atrial wall or aorta should be disclosed. Currently, 2 studies are underway comparing percutaneous closure of PFO to standard oral anticoagulation, which should clarify the indications for interventional treatment.

Since these procedures are relatively new to interventionalists trained in adult cardiology, no pre-existing guidelines are available on which to base current opinion. In the absence of such guidelines, we arrived at these recommendations from discussions with colleagues actively performing these percutaneous closures.

Cardiologists in Training Programs

Acquisition of the knowledge and skills necessary to perform percutaneous procedures to treat ASD and PFO should be incorporated into the formal training of interventional cardiologists. There are no data regarding the mini-

imum number of cases required for maintenance of competency and proficiency. A survey of Pediatric Cardiology Interventional Catheterization training programs concluded that a minimum of 10 percutaneous ASD closures is necessary for a trainee to gain clinical competence with the procedure (102).

With this in mind, it is recommended that interventional cardiologists who intend to perform these procedures independently, should be involved in these procedures during training with at least 10 of these cases being secundum ASD closures. Furthermore, as part of the procedure, the fellow should be fully conversant in the use of transesophageal echocardiography and/or intracardiac echocardiography. He or she should understand how to obtain the appropriate views to image necessary structures in order to perform the procedure safely and to exclude other anatomical problems such as a primum or sinus venosus ASD, anomalous pulmonary venous drainage, fenestrated or multiple ASD, or lipomatous hypertrophy of the septum. Obviously, not all fellows in training will be able to gain this experience and, therefore, concentrating the experience in training should be limited to a few trainees.

Cardiologists in Practice

Interventional cardiologists in practice who were not specifically trained in ASD/PFO closure but would like to perform these procedures should be fully credentialed in interventional techniques in their institution. The first several cases should be done with a proctor. To ensure safety and success, it seems prudent that the first 10 cases be proctored by someone fully credentialed in these techniques such as a pediatric cardiologist or adult cardiologist trained in congenital heart disease. Proctors should also be present for the first 3 to 5 cases if a different device is to be used after the initial credentialing proctorship.

Maintenance of Competency for Percutaneous ASD/PFO Closure

To maintain physician proficiency and competency in percutaneous ASD/PFO closure, a minimum of 10 cases per year is recommended. Similarly, to maintain catheterization laboratory proficiency, a minimum of 10 cases per year should be performed in each institution each year. To achieve this experience, it may be necessary to concentrate the procedures in the hands of only a few operators. A multidisciplinary program, including neurology consultation for PFO closure, prospective evaluation of case selection, and evaluation of clinical outcomes is critical to ensure appropriateness and maintain safety and efficacy. Laboratories and individual operators that are not active enough to maintain quality outcomes should reconsider treating these patients.

Quality Assurance

The quality improvement process used for oversight of ASD/PFO closure should include concurrent case review, and will also benefit from regular case conferences to discuss indications, procedural techniques, and case outcomes. It is particu-

larly useful in any developing procedural area to share results with other institutions through informal and formal conferences. Because there are, as of yet, no large databases of outcomes for these procedures, participation in local, regional, and national registries is encouraged. Focusing the performance of these procedures in the hands of a few experienced operators is also recommended.

Hypertrophic Cardiomyopathy and Alcohol Septal Ablation

Hypertrophic cardiomyopathy is the most common genetic cardiovascular disease, with a prevalence in the general population estimated to be 0.2% (103). Physicians performing these procedures should have extensive knowledge of the outcomes, limitations and complications of medical therapy (104), dual chamber pacing and surgical myectomy (105–107), and alcohol septal ablation (105–114). No comparative trial against surgical myectomy has been performed.

Criteria for Competency

Acquisition of competence. It is strongly recommended that alcohol septal ablation be offered within a multidisciplinary program that includes the contribution of experienced cardiac surgeons, echocardiographers, general cardiologists, and electrophysiologists. Although there are currently no data regarding the minimum number of procedures required for training and for credentialing, a minimum number of 10 procedures seems to be appropriate.

Maintenance of competence. It is recommended that individual operators perform a minimum of 6 cases per year to maintain competence in performance of septal ablation for hypertrophic cardiomyopathy. Each institution should employ a multidisciplinary program with prospective evaluation of case selection and clinical outcomes. Such an approach is critical for any institution offering alcohol septal ablation as a treatment option for symptomatic patients with hypertrophic obstructive cardiomyopathy.

Quality assurance. Quality assurance in such low-volume procedures requires an approach similar to that outlined for ASD and PFO closures, as previously described.

Valvular Heart Disease

Cognitive Knowledge Base

Physicians performing invasive procedures on stenotic cardiac valves must have extensive knowledge of the pathoanatomy, the hemodynamic alterations, the clinical course, and the outcomes of various therapeutic options. Complications of aortic (115,116) and mitral (117–119) valvuloplasty should be well understood.

Criteria for Competency

Acquisition of competence. Mitral valvuloplasty is one of the most challenging cardiac procedures. The presence of a “learning curve” has been well described (120,121). Thus, training in the performance of mitral valvuloplasty requires the

acquisition of clinical skills for the evaluation of indications for the procedure and the assessment of suitable valve morphology. It requires the development of proficiency in the performance of transseptal cardiac catheterization, device manipulation, and online evaluation of hemodynamic parameters. The interventionalist must be able to recognize and manage complications specific to mitral valvuloplasty, including acute mitral regurgitation, cardiac perforation, pericardial tamponade, and stroke. Although a learning curve has been well described, there are currently no specific data regarding the minimum numbers needed for competency. Nonetheless, 5 to 10 cases should be done with an experienced colleague before attempting to perform balloon valvuloplasty independently. Any program offering mitral valvuloplasty as an alternative to mitral valve replacement or surgical commissurotomy for the treatment of mitral stenosis should include a thorough quality assurance program and close monitoring of case selection and clinical outcomes. As with other infrequently performed procedures, concentration of experience among a small subset of interventional cardiologists within an institution is appropriate.

Maintenance of competence. With the low prevalence of mitral stenosis in the United States, maintaining experience is difficult. Given this limitation, concentration of this experience among institutional and perhaps regional centers may be appropriate.

Quality assurance. Quality assurance in such low-volume procedures requires an approach similar to that outlined for ASD and PFO closures, as previously described.

Percutaneous Ventricular Assist Devices

Percutaneous ventricular assist devices are becoming available. They require training and proctored supervision to attain competence, as well as periodic use or refresher drills to maintain competence. As with other seldom-used techniques, experience should be concentrated among a limited number of operators and laboratory staff who have received appropriate training.

Laboratory and Staff Competence

In order for laboratories to become competent in the performance of noncoronary cardiac procedures, the supervising or performing operator should be fully credentialed in the procedure. Initially, this may require off-site training, simulation training, a visiting proctor, or a combination of these approaches. The operator responsible for the performance of the procedure in the catheterization laboratory should supervise the staff in acquiring the necessary skills and equipment for the procedure. As is the case for the operators of lower volume procedures, there should be a small number of dedicated staff members trained to perform specific noncoronary interventions, concentrating the experience. If and when a specific procedure becomes more common, then the training may be expanded to the remainder of the staff and operators.

Conclusions and Recommendations

Percutaneous Noncoronary Interventions

Noncoronary cardiac interventions require special training that is not possible for all operators to obtain because of the small number of these procedures. Therefore, it is necessary to concentrate the activity both in training and practice so that adequate experience can be obtained to allow for quality performance. Hospitals should develop clear credentialing criteria, despite the small number of cases and empiric data from which to judge appropriateness, as well as success and complication rates of these procedures.

The quality improvement process used for oversight of percutaneous noncoronary interventions should include concurrent case review, and will also benefit from regular case conferences to discuss indications, procedural techniques, and case outcomes. It is particularly useful in any developing procedural area to share results with other institutions through informal and formal conferences. Since there are, as of yet, no large databases of outcomes for these procedures, participation in local, regional, and national registries is encouraged. Focusing the performance of these procedures in the hands of a few experienced operators is also recommended.

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY—ACCF/AHA/SCAI WRITING COMMITTEE TO UPDATE THE CLINICAL COMPETENCE STATEMENT ON CARDIAC INTERVENTIONAL PROCEDURES

Name	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder	Other
Dr. Thomas Aversano	None	None	None	None	None	None	None
Dr. William L. Ballard	None	None	None	None	None	None	None
Dr. Robert H. Beekman, III	• AGA Medical	None	None	None	None	None	None
Dr. Michael J. Cowley	None	None	None	None	None	None	None
Dr. Stephen G. Ellis	• Boston Scientific • Celera • Cordis • Guidant • Viacon	• Celera • Centacor/Lilly • Cordis	• Boston Scientific • Cordis • Viacon	None	None	None	None
Dr. David P. Faxon	• Bristol-Myers Squibb/Sanofi	None	• Boston Scientific	None	None	• Medical Technology Informational	None
Dr. Edward L. Hannon	None	None	None	None	None	None	None
Dr. John W. Hirshfeld, Jr.	None	None	• Bracco Inc. • Bristol-Myers Squibb/Sanofi	None	None	None	None
Dr. Alice K. Jacobs	None	None	None	None	None	None	• Wyeth-Spouse's Employer
Dr. Mirle A. Kellett, Jr.	None	None	None	None	None	None	None
Dr. Stephen E. Kimmel	None	None	None	None	None	None	None
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Dr. Louis S. McKeever	None	None	None	None	None	None	None
Dr. Mauro Moscucci	None	• BlueCross/BlueShield	None	• Aventis • Pfizer	None	None	• Cordis-Fellowship Training Grant
Dr. Richard M. Pomerantz	• Medacorp. • Sanofi/Aventis	None	None	• Sanofi/Aventis	None	• Pfizer	None
Dr. Karen M. Smith	None	None	None	None	None	None	None
Dr. George W. Vetrovec	Merck	• Cordis/Johnson & Johnson • NHLBI	None	• Lilly • Pfizer	None	• Johnson & Johnson	None

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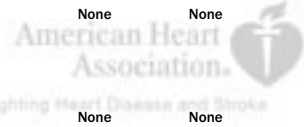
APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY—ACCF/AHA/SCAI 2007 UPDATE OF THE CLINICAL COMPETENCE STATEMENT ON CARDIAC INTERVENTIONAL PROCEDURES

Name	Representation	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder	Other
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Dr. Carl J. Pepine	• Official-ACC Board of Trustees	• Abbott • CV Therapeutics	• Abbott • AstraZeneca • Berlex Laboratories • Pfizer	None	None	None	None	• Educational grant-AstraZeneca, CV Therapeutics, GlaxoSmithKline, King Pharmaceuticals, Monarch Pharmaceuticals, Pfizer, Sanofi-Aventis, Schering-Plough, Wyeth-Ayerst Laboratories
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Dr. Samuel J. Shubrooks	• Official-ACC Board of Governors	None	None	None	None	None	None	None
Dr. Alan Yeung	• Official-AHA	• Medtronic	• Abbott • Boston Scientific	• Abbott • Boston Scientific • Cordis	None	None	• Boston Scientific	None
Dr. Gregory Dehmer	• Organizational-Society for Cardiovascular Angiography and Interventions	None	None	None	None	None	None	None
Dr. John Hodgson	• Organizational-Society for Cardiovascular Angiography and Interventions	• Volcano Corp	• Boston Scientific • GE Medical • Lilly • RADi Medical • Volcano Corp	• Volcano Corp	• GE Medical • Pfizer	None	• Technology Solutions Group • BioInfo Accelerator Fund • Volcano Corp	• Management-Mytogen Technology Solutions Group • BioInfo Accelerator Fund
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Dr. Ronald Krone	• Organizational-Society for Cardiovascular Angiography and Interventions	None	None	None	None	None	None	None
Dr. Douglass A. Morrison	• Organizational-Society for Cardiovascular Angiography and Interventions	None	None	None	None	None	None	None
Dr. Mark Reisman	• Organizational-Society for Cardiovascular Angiography and Interventions	None	None	• Abbott • Boston Scientific • Cordis • Medtronic	• Boston Scientific • Cordis	None	None	None
Dr. Barry Uretsky	• Organizational-Society for Cardiovascular Angiography and Interventions	None	None	None	None	None	None	None
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Dr. Hani Jneid	• Content-AHA Diagnostic & Interventional Cardiac Catheterization Committee	None	Pfizer	None	None	None	None	None
Dr. Fred M. Krainin	• Content-ACCF Cardiac Catheterization and Intervention Committee	None	None	None	None	None	• Boston Scientific • Johnson & Johnson • Medtronic	None
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Dr. E. Murat Tuzcu	• Content-AHA Diagnostic & Interventional Cardiac Catheterization Committee	None	None	None	None	None	None	None
Dr. Matthew Wolff	• Content-ACCF Cardiac Catheterization and Intervention Committee	None	None	None	None	None	None	None
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