April 15, 2015

Certificate of Need Program
Tertiary Service Review
Attn: Kyle Karinen, Office of Legal Services
Department of Health
Olympia Washington 98504-7873

Dear Mr. Karinen:

This letter, written on behalf of seventeen hospitals in Washington, provides our response to the proposal by CHI Franciscan Health Highline Medical Center, Capital Medical Center, Yakima Valley Memorial Hospital, Legacy Salmon Creek Medical Center, and Walla Walla General Hospital ("the 5-hospital group"). This 5-hospital group recommends that certificate of need ("CON") review be ended for hospitals' provision of elective therapeutic cardiac catheterization, including general percutaneous coronary interventions ("PCIs") and elective percutaneous transluminal coronary angioplasty. The 5-hospital group proposes PCIs be removed from the list of defined tertiary services found in WAC 246-310-020(1)(d)(i).

We represent institutions that provide the majority of PCIs in Washington. We have thoroughly reviewed the 5-hospital proposal, evaluated the COAP data the group provided, undertaken extensive clinical literature review and research, and discussed PCI issues with practicing interventional cardiologists. Accordingly, we have reached numerous conclusions, including the following: the 5-hospital group has significantly oversimplified issues; it has misused COAP statistics, reaching conclusions not supported by the data; and it has ignored virtually all current clinical literature and research regarding PCI services, including, most importantly, the undisputed relationship between the volume of procedures performed and the quality and outcome of care.

Based on unequivocal findings from the clinical literature, percutaneous coronary intervention procedures are a tertiary health service, as defined in RCW 70.38.025(14), and, as such, should continue to be subject to CON review. Certificate of need regulation of elective PCI programs prevents too many facilities from offering PCI procedures in service areas where there is no demonstrated need. This helps prevent programs operating with too few cases and spreading declining PCI volumes across more facilities.

In closing, we recommend the Department of Health retain PCI as a tertiary health service. This is the best approach to insure providers operate programs with sufficient volumes that best assure high quality outcomes. Importantly, this represents an approach wholly consistent with current clinical literature and research.

Please feel free to contact any of us if the Department has questions on any of the materials in this letter and position paper.

Sincerely,

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I. Executive Summary

Introduction and Background

In January 2015, the Department of Health ("the Department") announced it was conducting a review of tertiary health services as listed in WAC 246-310-020(1). Currently, the review process is in Phase 2, a period lasting from March 16, 2015 to April 15, 2015, during which comments may be submitted on proposals submitted during Phase 1.

This position paper responds to the proposal submitted by a group of five hospitals: CHI Franciscan Health Highline Medical Center, Capital Medical Center, Yakima Valley Memorial Hospital, Legacy Salmon Creek Medical Center, and Walla Walla General Hospital (which we will refer to as the "5-hospital group"). The 5-hospital group proposes removing percutaneous coronary intervention ("PCI") procedures from the list of tertiary health services. These hospitals represent a subset of hospitals that do not have certificate of need ("CON") approval to perform elective PCI procedures.[1] Of this 5-hospital group, one of the hospitals, Yakima Valley Memorial, has applied for and been denied CON approval to perform elective PCI, the Department finding there was no need in that planning area.[2]

The hospitals and hospital organizations that are submitting this position paper represent 17 hospitals in Washington, and include:

- Providence Sacred Heart Medical Center
- Providence Holy Family Hospital
- Providence Regional Medical Center Everett
- Providence St. Peter Hospital
- Swedish/Cherry Hill
- Swedish/ First Hill/Ballard
- Swedish/Issaquah
- Swedish/Edmonds
- Kadlec Regional Medical Center
- MultiCare Tacoma General/Allenmore Hospitals
- MultiCare Good Samaritan Hospital
- MultiCare Auburn Medical Center
- MultiCare Mary Bridge Children's Hospital
- Yakima Regional Medical and Cardiac Center
- PeaceHealth St. Joseph Medical Center

[1] It should be noted that Capital Medical Center was approved in 2009 to provide elective PCIs. That approval has since been suspended due to Capital's non-conformance to its stated charity care provisions. We understand this suspension is under appeal. Capital Medical Center has never met its minimum volume standards. Its most recent annual volume was 103 PCIs in 2013.

[2] This is not a surprising result, since Yakima Valley Memorial is just two miles from Yakima Regional Medical and Cardiac Center, which has complete open heart surgery capabilities. The Department found no net need for a second program in the same service area, based on the well-defined quantitative PCI numeric need methodology.

- PeaceHealth Southwest Medical Center
- PeaceHealth St. John's Medical Center

Together, our 17 hospitals accounted for 6,659 of the 11,639 PCIs in Washington hospitals in 2013, a figure that represents over 57% of total PCI cases.[3] Please see Table 1.

Table 1. Total PCI Volumes by Select Washington State Providers, 2013

Provider	Total PCIs (CY2013)	% of Total
Providence Health & Services/Swedish Medical Center /Kadlec Health System	4,054	34.8%
MultiCare Health System	1,018	8.7%
PeaceHealth Washington Hospitals	1,303	11.2%
Yakima Regional Medical and Cardiac Center	284	2.4%
Subtotal - Select Providers Listed Above	*6,659*	*57.2%*
Total - All Washington State Providers	**11,639**	**100.0%**

Source: CHARS 2013 and DOH Outpatient PCI Survey
Includes DRGs 246-251 in CHARS

Summary

PCI is a non-surgical procedure that generally uses a catheter to place a small structure or inflate a small balloon to treat stenotic, or narrowed, coronary arteries of the heart due to the buildup of plaque, a condition known as atherosclerosis. As we point out, however, PCIs are more than a single stent procedure, as incorrectly asserted by the 5-hospital group. This is clearly demonstrated in inpatient PCI case review.

As institutions that provide the majority of PCIs in Washington, we have thoroughly reviewed the 5-hospital proposal, evaluated the COAP ("Clinical Outcomes Assessment Program") data the group provided, undertaken extensive clinical literature review and research, and discussed PCI issues with practicing interventional cardiologists. Accordingly, we have reached numerous conclusions, including the following: the 5-hospital group has significantly oversimplified issues related to PCIs and the tertiary service criteria (WAC 246-310-035(2)); it has misused COAP statistics, reaching conclusions not supported by the data; and it has ignored virtually all current clinical literature and research regarding PCI services, including, most importantly, the positive association between PCI volumes and outcomes.

The foundation of the 5-hospital group's proposal is the assertion there is no volume-quality relationship, and it relies upon COAP data that purportedly demonstrates this. The group is wrong. Furthermore, it ignores unequivocal clinical research and literature that shows there is a positive relationship between PCI volume and outcomes. Interestingly, while the 5-hospital group cites the 2013 ACCF/AHA/SCAI Clinical Competence Statement in its proposal, this

[3] PCI volume figures were obtained from 2013 CHARS and the Department of Health's 2013 survey of outpatient PCIs.

Statement directly contradicts the claim made by the group. After conducting a comprehensive review of the clinical literature available at the time, the ACCF/AHA/SCAI Statement concludes that there *is* a volume quality relationship at institutions performing less than 200 PCIs annually. The report states:

> An institutional volume threshold <200 PCIs annually appears to be consistently associated with worse outcomes, but above this level, there was no relationship between even higher annual volumes and improved outcomes. Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year.[4]

In 2014, SCAI/ACC/AHA released an update to its Expert Consensus Document on Percutaneous Coronary Intervention Without On-Site Surgical Backup. This report reaffirmed the 2013 Clinical Competence Statement recommendations of institutional and operator volume, stating: "The existence of laboratories performing <200 PCIs annually that are not serving isolated or underserved populations should be questioned" and "ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually."[5] The conclusions from both the 2013 Clinical Competence Statement and the 2014 Expert Consensus Document are very clear: there is a positive relationship between operator and institutional volume and the quality of patient outcomes for PCI procedures.

As stated above, the 5-hospital group relies heavily on COAP data, and repeatedly states COAP data "shows" there is no volume-outcome relationship in Washington hospitals. It also includes selected COAP summary bar charts. However, unlike other national clinical trials, where thousands of clinical outcomes have been evaluated, COAP analysis, as presented by the 5-hospital group, is insufficiently well-powered from a statistical perspective to allow inferences from the data. In other words, the COAP data does not distinguish outcomes across different volumes in a statistically meaningful way.

The 5-hospital group asserts that PCIs are not complex procedures and do not carry significant risk. This is incorrect. Even COAP data demonstrate this. PCIs require highly trained and skilled interventional cardiologists and other highly specialized catheterization laboratory ("cath lab") staff. PCIs also require highly specialized equipment found only in cath labs. It is not surprising this significant training and expertise can only be reached and maintained with sufficient experience and procedure volumes. This is precisely what clinical trials have demonstrated. In other words, clinicians become sufficiently skilled with higher PCI volumes. The 5-hospital group contends that PCI volume is irrelevant as a predictor of quality, either at the institutional or operator level. *We demonstrate in this paper, with heavy reliance on clinical literature findings and recommendations, this claim has no basis in fact.*

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[4] Harold et al., ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol, Vol. 62, No. 4, (2013), p. 374.

[5] Dehmer et al., SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup. Circulation, Vol. 129, Issue 24 (2014), p. 2614.

Further, the 5-hospital group attempts to draw parallels between emergent PCIs, which are not subject to CON review, and elective cases, which are. The group ignores the fact emergent PCIs are allowed as life-saving procedures for persons who have suffered an acute myocardial infarction, or heart attack. This situation is fundamentally different from elective PCIs, which treat angina conditions, and can be selectively scheduled. To presume these situations are the same is incorrect. In our opinion, elective PCIs, which can be scheduled, should meet standards of performance, including minimum procedure volumes, that are well-defined and agreed-upon in the clinical literature. To act otherwise is unreasonable and invites avoidable procedure risk and poor outcomes.

From 2008 to 2013, PCI volumes in the State of Washington have steadily declined. In 2008, total PCI volumes at Washington hospitals were just under 14,500 per year. As of 2013, PCI volumes had fallen to 11,639 cases. This is an overall decline of almost 20%, and an annual rate of fall of 4.4%. In this period of time, outpatient PCI volumes peaked in 2010 at approximately 5,000, and have declined over the last three years to about 3,000 PCIs annually, remaining nearly constant over the 2012-2013 period. Inpatient PCI volumes have continually declined, from just over 12,200 in 2008 to about 8,600 in 2013. At the same time, the number of PCI providers has grown, resulting in a situation where falling PCI volumes are spread across a growing number of providers. In fact, these same trends have been seen across the United States: PCI volumes have steadily declined over the past five to ten years and the number of providers has increased. This trend has been identified by numerous studies.[6] The 5-hospital group ignores these volume declines and the obvious adverse implications for maintaining sufficient PCI volumes at institutions and across operators.

In the State of Washington, PCI is regulated by the Department of Health Certificate of Need Program. The CON statutory provisions and regulations regarding the review of tertiary health services and PCI are found in RCW 70.38.025(14), RCW 70.38.105(4)(f), WAC 246-310-010(59), WAC 246-310-020, and WAC 246-310-035. Adult elective PCI programs must meet all standards found in WAC 246-310-700 through 755.

Hospital volume standards for adult elective PCIs are specified in WAC 246-310-720 and include a minimum of 300 PCI procedures per year by the end of the third year of operation and each year thereafter. Further, all existing PCI programs in the planning area must be meeting or exceeding this minimum volume standard prior to approval of a new facility.

Physician volume standards for adult elective PCIs are specified in WAC 246-310-725, requiring physicians performing adult elective PCIs at the applying hospital to perform a minimum of 75 PCI procedures per year. Additionally, applicant hospitals must provide documentation that physicians performed 75 PCI procedures per year for the previous three years prior to the applicant's CON request. It is important to note that the 5-hospital group does not discuss the annual operator volume standards outlined in WAC 246-310-725. These are imperative to any discussion regarding PCI volume effects on patient outcomes, since operators are key to PCI quality and patient outcomes.

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[6] Baron et al., The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes. Circulation, Vol. 130, Issue 16 (2014), pp. 1343-1345.

The 5-hospital group also asserts that removal of CON for elective PCI will somehow improve patients' access to elective PCI, suggesting more providers (including the 5-hospital group) will emerge and increase access. This argument is without validity; contrary to the arguments made by the group, preservation of CON regulation in Washington will prevent non-essential expansion of PCI programs. In fact, hospitals facing CON regulations were 40% less likely to adopt PCI.[7] There are 36 states that maintain CON regulations, and the vast majority, 26 states, include catheterization as a regulated service.[8] Cardiac catheterization is the fifth most frequent service regulated behind nursing home beds, acute hospital beds, long term acute care beds, and ambulatory surgery centers.[9] Clinical studies have shown that in recent years "new PCI programs were systematically duplicative of existing programs and did not help patients gain access to timely PCI."[10]

Further, four of the five hospitals proposing to remove PCI procedures from the list of tertiary services are located in urban areas already served by PCI providers. One of the proposing hospitals, Yakima Valley Memorial Hospital, is less than two miles from an existing CON-approved PCI provider. These facts are consistent with the clinical literature, which has found the addition of PCI services is an economic response, not a response driven by the need for greater access. Patient access will not be improved by this proposal, *and costs per unit of service will necessarily increase as falling volumes are divided across more providers.* This is contrary to proper delivery of high quality, low cost care, a foundation of the Department of Health's certificate of need policy objectives.[11]

We will demonstrate that PCI constitutes a "tertiary health service" as that term is defined by statute and regulation. Most importantly, we will show there is no evidence demonstrating PCI volumes and outcomes are unrelated, as the 5-hospital group would like us to believe. PCI should remain within the list of CON-reviewable tertiary health services.

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[7] Concannon et al., Evidence of Systematic Duplication by New Percutaneous Coronary Intervention Programs. Circulation: Cardiovascular Quality and Outcomes, Vol. 6, Issue 4 (2013), pp. 400 – 408.

[8] Certificate of Need: State Health Laws and Programs. National Conference of State Legislatures. July 2014. Please see:
http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

[9] Ibid.

[10] Concannon et al., Op. cit., Vol. 6, Issue 4 (2013).

[11] Please see Declaration of Public Policy, RCW 70.38.015.

II. Legal Framework

Overview

The governing legal authority for the Department is the statutory definition of "tertiary health service." WAC 246-310-020 enumerates the services included as "tertiary."[12] The criteria used by the Department as guidelines for determining whether a service is tertiary, in accordance with the statutory definition, are set forth in WAC 246-310-035:

(1) The following criteria shall be used as guidelines when examining services to determine whether the service is considered a tertiary service. (2) In determining whether the service is a tertiary service the department shall consider the degree to which the service meets the following criteria:

a. Whether the service is dependent on the skills and coordination of specialties and subspecialties, including, but not limited to, physicians, nurses, therapists, social workers;
b. Whether the service requires immediate access to an acute care hospital;
c. Whether the service is characterized by relatively few providers;
d. Whether the service is broader than a procedure;
e. Whether the service has a low use rate;
f. Whether consensus supports or published research shows that sufficient volume is required to impact structure, process and outcomes of care; and
g. Whether the service carries significant risk or consequence.

The 5-hospital group discusses, and then dismisses, each of the criteria. Accordingly, we shall address each of the criteria, the issues raised by the 5-hospital group, and why, in our opinion, the group's conclusions are wrong.

1. The statutory definition of "tertiary health service" governs the Department's determination of whether to remove elective PCI services from the list of CON-reviewable services.

The Department is reviewing the list of tertiary health services pursuant to the procedure it has established in WAC 246-310-035. However, that review takes place within the framework of the statutory requirements. Thus, the statutory definition of "tertiary health service" constitutes the governing law to be applied by the Department in deciding what services to add to, or remove

[12] WAC 246-310-020(1)(d)(i) identifies the following as "tertiary health services:" (a) Specialty burn services; (b) Intermediate care nursery and/or obstetric services level II; (c) Neonatal intensive care nursery and/or obstetric services level III; (d) Transplantation of specific solid organs; (e) Open heart surgery and/or elective therapeutic cardiac catheterization, including percutaneous coronary interventions generally, and elective percutaneous coronary angioplasty ("PTCA") specifically; (f) inpatient physical rehabilitation services level I; and (g) Specialized inpatient pediatric services

from, the list of services. The Department cannot remove elective PCI services from the list of tertiary health services unless it finds, as a matter of law, those services no longer fall within the statutory definition.

Under the statute, a "tertiary health service" is defined as:

> A specialized service that meets complicated medical needs of people *and* requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

RCW 70.38.025(14) (emphasis added). *See also* WAC 246-310-010(59). It is crucial to recognize the definition contains two parts. Therefore, in order to remove elective PCI services from the list of tertiary health services, the Department must make two separate findings. First, it must find that elective PCI is *not* "a specialized service meeting complicated medical needs of people." Ibid. Second -- and in addition -- it must find that elective PCI is *not* a service that "requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." Ibid.

2. The tertiary health service review criteria set forth in WAC 246-310-035 provide guidance to the Department. However, the Department's determination of whether to remove elective PCI services from the list of tertiary health services is, as a matter of law, governed by the statutory definition. The Department does not "weigh" or "balance" the review criteria in making that determination. Rather, it applies the statutory definition.

On its face, WAC 246-310-035 does not establish a checklist of standards or requirements which, if met or not met, determine whether a particular service should be added to, or removed from, the list of CON-reviewable tertiary health services. This is expressly stated in the opening provision of the regulation: "The criteria in this section *shall be used as guidelines* when examining services to determine whether the service is considered a tertiary service." WAC 246-310-035(1) (emphasis added).

The fact that the criteria serve as "guidelines," not as legal standards or requirements, is further confirmed in the provision which enumerates the seven criteria, as set forth above. The provision states that the Department "shall *consider* the degree to which the service meets" the criteria. It does not direct the Department to make a formal determination as to whether a particular service does or does not satisfy each of the criteria.

The 5-hospital group apparently believes (or would like the Department to believe) that the Department must use the enumerated criteria as a checklist, and, after weighing or balancing the criteria, then make a determination as to whether elective PCI services should be removed from the list of tertiary health services. This is not correct. Significantly, the group fails to even mention the governing statutory definition of "tertiary health service" in its Proposal. This is a telling omission. The statute is unequivocal: if a service falls within the statutory definition of "tertiary health service," it is subject to CON review, and cannot be removed from the list of reviewable services.

As discussed in detail below, the facts clearly demonstrate that elective PCI is a tertiary health service as that term is defined in the CON statute. First, the clinical evidence confirms that elective PCI is "a specialized service that meets complicated medical needs of people." RCW 70.38.025(14). Second, the most recent clinical literature and research, as well as national clinical standards, establish beyond dispute that elective PCI "requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." Ibid. Therefore, as a matter of fact and law, elective PCI services cannot be removed from the list of reviewable tertiary health services.

In Section III below, we will address each of the seven criteria in WAC 246-310-035(2).

III. Analysis of Each Tertiary Service Criterion (WAC 246-310-035(2))

A. Washington Administrative Code 246-310-035(2)(f). Whether consensus supports or published research shows that sufficient volume is required to impact structure, process and outcomes of care.

In its Proposal, the 5-hospital group claims "there is no correlation between volume and outcomes for Elective PCI."[13] This claim is simply wrong, and it is inconsistent with current clinical literature, research and standards. In fact, the clinical literature establishes that higher per-facility and per-operator PCI volumes lead to improved patient outcomes.

1. The Clinical Literature and Research Unequivocally Confirms There is a Volume-Quality Relationship for PCI. Accordingly, the Consensus Clinical Standards Establish an Institutional Minimum Volume Standard Threshold of 200 PCI Procedures per Year.

The 5-hospital group includes the 2013 American College of Cardiology Foundation ("ACCF")/American Heart Association ("AHA")/Society for Cardiovascular Angiography and Interventions ("SCAI") Clinical Competence Statement as Attachment 5 to its proposal. This Statement directly contradicts the claim made by the 5-hospital group. After conducting a comprehensive review of the clinical literature available at the time, ACCF/AHA/SCAI concluded that there *is* a volume-quality relationship at institutions performing less than 200 PCIs annually. The report states:

> An institutional volume threshold <200 PCIs annually appears to be consistently associated with worse outcomes, but above this level, there is no relationship between even higher annual volumes and improved outcomes. Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year.[14]

With respect to primary (i.e., emergent) PCI, ACCF/AHA/SCAI has adopted the following institutional and operator minimum volume standards:

> Primary PCI for STEMI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. *Ideally, these procedures should be performed in institutions that perform more than*

[13] Proposal to Remove Elective PCI from the Listing of Tertiary Services Identified in Certificate of Need Rules. 5-hospital group, February 26, 2015, p. 9.

[14] Harold et al., ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol, Vol. 62, No. 4 (2013), p. 374. See also p. 380.

200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.[15]

Significantly, the ACCF/AHA/SCAI Statement further concludes:

> The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory volumes should close.[16]

The report also states that "interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency."[17]

Prior to setting forth the above-described institutional and operator minimum volume standards, ACCF/AHA/SCAI make a number of significant findings relating to PCI services. With respect to the relationship between PCI procedure volume and quality of care, the report states:

> Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures. This relation is supported by earlier studies in the PTCA era, contemporary studies in the stent era, and a recent meta-analysis. [Literature citations omitted.] The writing committee recognizes the wide variability of institutional volume thresholds used in the different studies and the complexity and multitude of factors influencing PCI outcomes. *However, it is important to note that a signal exists suggesting that an institutional threshold <200 PCIs/year appears to be consistently associated with worse outcomes across the various studies (Online Appendix 1).*[18]

In connection with the finding that "the continued operation of low-volume laboratories that are not serving isolated or underserved populations should be questioned," the report states: "This becomes increasingly relevant *in an era of declining procedural volumes* and expanded care delivery models for patients with STEMI."[19] The issue of declining nationwide and statewide PCI volumes is discussed in detail in subsection 2 below.

In 2014, SCAI/ACC/AHA released an update to its Expert Consensus Document on Percutaneous Coronary Intervention Without On-Site Surgical Backup. This report reaffirmed the 2013 Clinical Competence Statement recommendations of institutional and operator volume, stating: "The existence of laboratories performing <200 PCIs annually that are not serving

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[15] Ibid, p. 381 (emphasis added).
[16] Ibid, p. 380. See also, p. 381.
[17] Ibid, p. 381.
[18] Ibid, page 367 (emphasis added).
[19] Ibid, p. 367 (emphasis added); see also, p. 372.

isolated or underserved populations should be questioned" and "ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually".[20] Accordingly, the conclusions from both the 2013 Clinical Competence Statement and the 2014 Expert Consensus Document are clear: there is a consensus that there is a relationship between institutional and operator volume and the quality of patient outcomes for PCI procedures.

In addition to restating and affirming the 2013 minimum volume standards, the 2014 SCAI/ACC/AHA Expert Consensus Document adopted the following "STEMI Treatment Recommendation" as part of its "Facility Requirements for PCI Programs Without On-Site Surgery:"

> STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.[21]

In addition, recent studies released after the SCAI/ACC/AHA 2014 Expert Consensus Document provide further evidence in support of volume requirements for both institutions and operators. An important study released in 2014 establishes that higher institutional and operator PCI volumes are associated with a statistically significant decline in primary and secondary clinical outcomes. With respect to operator volume, the study found that "predicted probability of mortality dropped with increasing operator volume and flattened approximately 300 procedures per year...A similar relationship was also found between the secondary outcome and annual operator volume"[22] Similar results were demonstrated with institutional volume: an "important finding of this study was an increase in in-hospital mortality in institutions with <200 PCIs/year when compared to that of institutions with 200-to-400 and > 400 PCIs/year."[23]

This study also examined the relationship between institutional and operator volume and length of stay and cost of care. Cost of care and length of stay were found to be negatively correlated with higher institutional and operator volumes. In other words, higher volume facilities have lower total cost and length of stay outcomes than facilities that perform fewer procedures per year.[24]

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[20] Dehmer et al., SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup. Circulation, Vol. 129, Issue 24 (2104), p. 2614; see also, pp. 2616, 2618-2619.

[21] Ibid, p. 2618.

[22] Badheka et al., Impact of Annual Operator and Institutional Volume on Percutaneous Coronary Intervention Outcomes: A 5-Year United States Experience (2005 – 2009). Circulation, Vol. 130, Issue 16 (2014), p. 1399.

[23] Ibid, p. 1403.

[24] Ibid, p. 1402.

Another systematic review and meta-analysis shows mortality and major adverse cardiology events are inversely associated with operator volume.[25] The design of this study precluded evaluation for any particular threshold effect, but it did reaffirm the relationship between clinical outcomes and operator volume, stating: "Higher volume was associated with improved major adverse cardiac events at every threshold, regardless of the threshold evaluated."[26]

2. The Volume of PCIs Has Been Declining On Both a Nationwide and Statewide Basis.

The clinical literature is very clear: higher volumes per-facility and per-operator result in improved patient outcomes. Based on this fact alone, PCI procedures need to be regulated through the CON program to maintain patient quality of care. Elimination of CON regulation will lead to further expansion of PCI programs and reduce the volume of PCI procedures at existing programs and at the operator level, possibly below critical minimum levels. In addition, data from the Nationwide Inpatient Sample cited by both the Agency for Healthcare Research and Quality and the 2014 SCAI/ACC/AHA Expert Consensus Document shows that PCI procedures peaked in 2006 at approximately 900,000. Since 2006, the number of annual PCI procedures has declined to about 600,000 in 2010, approximately a 30% decline.[27] [28] In addition, there is a further projected decline of 3%– 5% per year in the next five years.[29]

The 2014 Expert Consensus Document provides an explanation for the continuing nationwide decrease in PCI volumes:

> Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria. *As a result of these factors, many operators and hospitals now have low-volume practices.*[30]

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[25] Strom et al. , Association Between Operator Procedure Volume and Patient Outcomes in Percutaneous Coronary Intervention A Systematic Review and Meta-Analysis. Circulation: Cardiovascular Quality and Outcomes, Vol. 7, Issue 4 (2014), p. 1.

[26] Ibid.

[27] Dehmer et al., p. 2611.

[28] Laslett et al., The Worldwide Environment of Cardiovascular Disease: Prevalence, Diagnosis, Therapy, and Policy Issues: A Report From the American College of Cardiology, Vol. 60, Suppl S, No. 25 (2012), p. S 18.

[29] Estimator update: Expert Q&A with Brian Contos. The Advisory Board Company. 2012.

[30] Dehmer et al., Op. cit., p. 2611 (emphasis added).

Moreover, while the number of annual PCI procedures has been significantly declining, there has been a simultaneous rapid expansion of PCI programs: 48% in the past decade.[31] This combination has resulted in a decline in PCI volumes at both the facility and operator level, with a substantial number of facilities operating below recommended levels.[32] One study found that median operator levels in the United States are currently below recommended ACC/AHA levels of 50 cases/year.[33] This study also found that "a significant majority of interventional cardiologists (61%) performed 40 or fewer Medicare FFS PCIs in 2008... Given the correlation between higher operator volumes and improved patient outcomes, this data raises questions regarding... the current distribution of PCIs."[34]

The consequences and implications of the continuing decline in PCI volumes are articulated in the 2013 Clinical Competence Statement:

> It should be emphasized, however, that the strongest rationale for the development of PCI facilities without onsite surgery was the desire to provide rapid PCI to patients in their communities. Since 2000, there has been a substantial decline in the incidence of STEMI, and there is now greater emphasis on developing systems of care for STEMI patients as promoted in the Mission Lifeline initiative. All of these factors will further challenge smaller facilities wishing to sustain PCI programs, potentially reducing the number of PCIs performed per facility and per operator. Accordingly, the writing committee recommends that an institution without onsite surgery with a volume fewer than 200 procedures annually, unless in a region underserved because of geography, should strongly consider whether or not it should continue to offer this service. This becomes increasingly relevant in an era of declining procedural volumes and expanded institutional capabilities.[35]

These nationwide trends are confirmed by experience in the State of Washington. In Washington, there has been a consistent, significant decrease in the number of PCIs performed, from a high of 14,473 PCIs in 2008 to 11,639 PCIs in 2013, the most recent year volume statistics are available. This represents a 19.6% decline over a six-year period. Please see Figure 1 below. Declining PCI volume trends in Washington are consistent with national data.[36]

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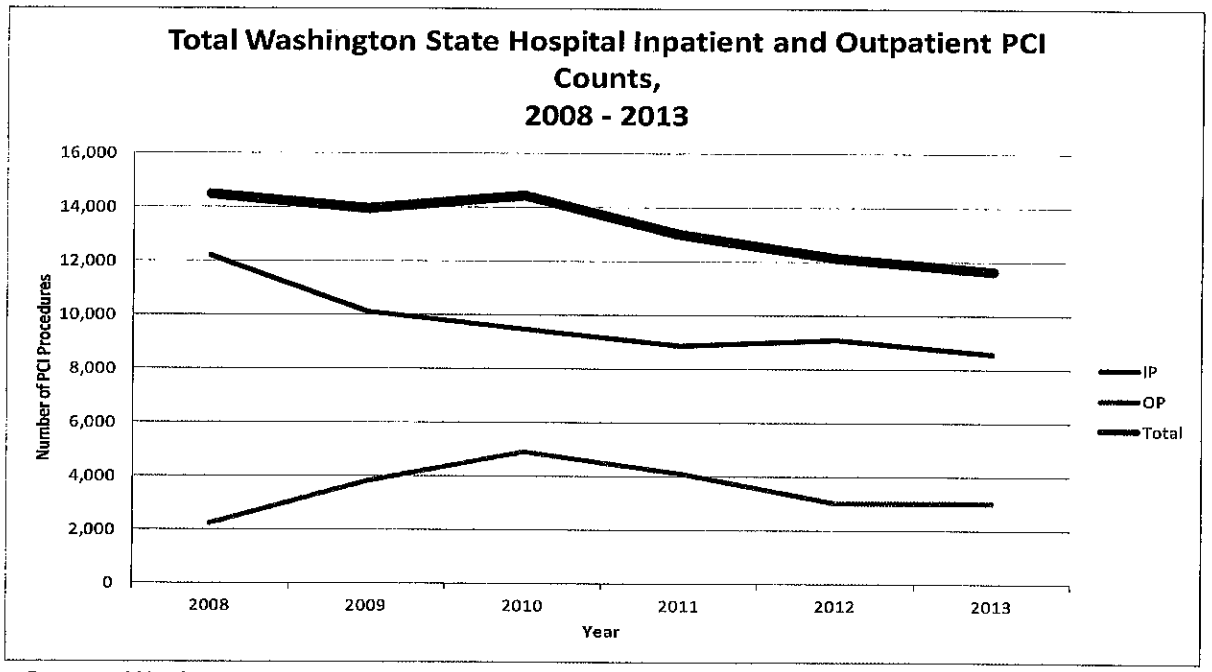
[31] Maroney et al., Current Operator Volumes of Invasive Coronary Procedures in Medicare Patients: Implications for Future Manpower Needs in the Catheterization Laboratory. Catheterization and Cardiovascular Interventions, Vol. 81, Issue 1 (2013), pp. 34-39.
[32] Ibid.
[33] Ibid.
[34] Ibid.
[35] Harold et al., Op. cit., p. 372.
[36] Riley et al., Trends in Coronary Revascularization in the United States From 2001 to 2009 Recent Declines in Percutaneous Coronary Intervention Volumes. Circulation: Cardiovascular Quality and Outcomes, Vol. 4, Issue 2 (2011), pp. 193-197.

Figure 1. Percutaneous Coronary Intervention Case Volumes, Washington State Providers, 2008-2013



Source: Washington Department of Health, Certificate of Need Outpatient Survey Responses, 2008-2013 and CHARS, 2008-2013.

This consistent downturn in PCI volumes means fewer institutional and operator cases overall. This is exacerbated by the increased number of hospitals that provide PCIs in Washington. Please see Table 1, which shows there were 33 providers in 2008 and 36 providers in 2013.

Table 1. Percutaneous Coronary Intervention Case Volumes, Washington State Providers, 2008-2013

Washington State	2008	2013	% Change	2008	2013
				% of Total	
Number of Hospitals Providing PCIs	33	36	9.1%		
IP Cases	12,222	8,598	-29.7%	84.4%	73.9%
OP Cases	2,251	3,041	35.1%	15.6%	26.1%
Total Cases	14,473	11,639	-19.6%	100.0%	100.0%

Source: Washington Department of Health, Certificate of Need Outpatient Survey Responses, 2008-2013 and CHARS, 2008-2013.

Table 1 also shows the shift from inpatient to outpatient care: inpatient cases fell by almost 30%, while outpatient cases, as a percent of total, increased by over 35%. However, this is not to say the number of outpatient PCIs are increasing—they are not, after having reached a peak in 2010, their number has fallen. By itself, this outpatient shift does not mean PCIs are somehow becoming less complex, but with improved technologies, and medical and pharmacologic management, there are fewer PCI cases and fewer of these cases are treated as inpatients.

Another important trend is the increased number of Washington hospitals providing fewer than 300 PCIs per year. In Washington, more than half of PCI programs are operating below the required level of >300 PCIs per year. Table 2 shows the number grew from 17 to 21 over a six-year period, such that, in 2013, almost 60% of Washington hospitals were below the current WAC minimum volume standard. Elimination of PCI procedures from CON regulation will lead to a further decrease in the number of cases per year at existing PCI programs.

Table 2. Washington State Hospitals that Provide PCIs, Grouped by Case Counts, 2008, 2013.

Washington Hospitals That Provide PCIs	Year		Year	
	2008	2013	2008	2013
Total Number of Washington Hospitals that Provide PCIs	32	36		
Count of Hospitals providing > 300 PCIs	15	15	46.9%	41.7%
Count of hospitals providing < 300 PCIs	17	21	53.1%	58.3%
Count of Hospitals providing <100 PCIs	8	8	25.0%	22.2%

(1) Includes all providers, including Children's Hospital and Mary Bridge Children's Hospital. In 2008, these two hospitals provided 70 PCIs, decreasing to 8 PCIs in 2013.

3. Removing Elective PCIs From the List of Tertiary Health Services Will Reduce PCI Volumes at Existing Programs, Further Diluting Annual Institutional and Operator Volumes.

As PCI utilization rates decrease, as national and Washington State trends indicate, further expansion of PCI programs will result in lower quality and higher costs by diluting volume at existing programs.

Contrary to the argument made by the 5-hospital group, the expansion of PCI programs nationally has not led to improvements in access to treatment or improved quality of care.[37] In fact, access to PCI has not appreciably changed despite an increase in the number of PCI programs. Hospitals are more likely to adopt PCI if they operate in competitive markets, and if PCI is already offered in the same market. Thus, based on historical and current evidence, access for patients living in remote areas is not a significant factor driving hospitals to provide PCI services. Further, hospitals in states with CON review for PCI are 40% less likely to adopt PCI.[38]

The fact that the increase in the number of PCI programs has not led to improved patient access is confirmed in the 2014 SCAI/ACC/AHA Expert Consensus Document:

[37] Concannon et al., Op. cit., Vol. 6, (2013).
[38] Ibid.

> Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close proximity to their own families and physicians. *However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.* If the transfer time is <30 minutes, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 minutes, performing PCI on-site is likely to be quicker than a transfer. *The development of PCI facilities within a 30-minute emergency transfer time to an established facility is therefore strongly discouraged.* [39]

These conclusions are directly applicable to the hospitals in the 5-hospital group: all of them are located in service areas that already have one or more PCI providers located within a 30-minute transfer time, and, moreover, only one of them (Walla Walla General Hospital) is located in an area that could potentially be described as "geographically isolated."

In 2006, there were 27 hospitals providing PCI services in Washington, with an average number of 574 cases per hospital. In 2013, there were 36 PCI hospitals, a 33% expansion, with an average case volume of 323 PCI procedures per hospital. It is clear that adding new PCI programs does not address need or improve access. Rather, it simply spreads the declining number of PCI procedures across more hospitals. This reduces overall patient quality because all institutions and physicians perform fewer procedures. As discussed above, the Badheka et. al. study shows that higher volume institutions are associated with lower lengths of stay and lower costs of care.[40] Additionally, results from a study evaluating the comparative effectiveness of STEMI regionalization strategies suggest that new construction and staffing for PCI may not be warranted if an emergency medical services strategy is both available and feasible.[41] Therefore, CON regulations that call for sensible institutional volume requirements not only benefit the community with superior clinical performance, but also avoid unnecessary duplication of services.

4. Conclusion Regarding PCI Volumes and Access.

The purpose of CON regulation for PCI services is to maintain high quality of patient care. Removing PCI from the list of tertiary health services will not improve patient care because it will only increase the number of PCI programs, while community need remains the same, or more likely, declines. Thus, these programs will not be able to maintain sufficiently high patient volumes to ensure provider competency.

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[39] Dehmer et al., Op. cit., page 2619 (emphases added).

[40] Badheka et al.

[41] Concannon et al., Comparative Effectiveness of ST-Segment–Elevation Myocardial Infarction Regionalization Strategies, Circulation: Cardiovascular Quality and Outcomes, Vol. 3, Issue 5 (2010), pp. 506-513.

Studies have also shown that the recent proliferation of new PCI programs has not significantly improved access to PCI services. Thus, there is no discernible benefit to society in continuing to develop new PCI programs. In fact, there are likely substantial societal costs, both monetarily, by duplication of services and increased capital expenditures, and clinically, if patient outcomes are compromised by diluting institutional and operator procedure volumes.[42]

5. The Clinical Outcomes Assessment Program Provides Vital Data Collection and Quality Assessment Services on Behalf of Cardiac Care Providers and Patients in the State of Washington. Unfortunately, however, the 5-hospital group has (1) inaccurately presented and interpreted COAP data and (2) misrepresented COAP's position on elective PCI services.

The Clinical Outcomes Assessment Program ("COAP") is a collaborative, non-governmental program that was created in order to collect cardiac care data and to utilize that data for the purpose of quality assessment. COAP is governed by a Management Committee consisting of physicians and other health care professionals who are involved in the provision of cardiac care. COAP's mission could not be accomplished without the participation of its 35 member hospitals, which voluntarily provide the data upon which COAP relies to carry out its initiatives.

It is crucial to recognize that COAP is *not* a governmental agency or entity. It is a private program that is the product of voluntary collaboration between physicians, health care professionals, and hospitals that provide cardiac care in the State of Washington. Although COAP provides vital data collection, quality assessment, and quality monitoring services, it does not possess any regulatory or enforcement authority with respect to the hospitals that voluntarily participate in its activities.

Given the important services that COAP provides to the cardiac care community, it is understandable that COAP would be perceived as a potential resource by the 5-hospital group in its effort to remove elective PCI from the list of CON-reviewable tertiary health services. Accordingly, the group's Proposal contains numerous references to COAP and its activities. More importantly, the Proposal contains data apparently obtained from COAP that is presented in a manner that purportedly supports the group's position. Further, the group attempts to create the impression that COAP has endorsed the group's proposal, and is supposedly "nominating" elective PCI to be removed from the list of tertiary health services.

However, as discussed in detail below, the facts establish that the 5-hospital group is inappropriately attempting to use COAP's well-earned reputation to serve its own ends. Thus, although the group has apparently utilized COAP data, it has inaccurately presented and interpreted that data. In addition, the group has misrepresented COAP's position on the classification of elective PCI as a tertiary health service. Contrary to the impression that the group attempts to create in its Proposal, COAP has *not* endorsed the group's effort to remove elective PCI from the list of reviewable services, nor has COAP taken the position that elective PCI should be removed from the list.

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[42] Baron et al., The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes. Circulation, Vol. 130, Issue 16 (2014), pp. 1343 – 1345.

It is unfortunate that the 5-hospital group has attempted to appropriate COAP's resources and reputation in this fashion. Because the hospitals who are submitting this position paper are all participating members of COAP, we believe that it is necessary -- and our duty -- to set the record straight.

6. COAP Data, As Provided by the 5-Hospital Group, Does Not Show Statistical Differences of Outcomes Between Low and High Volume PCI Providers.

The 5-hospital group relies heavily on COAP data, and repeatedly states COAP data "shows" there is no volume-outcome relationship in Washington hospitals.[43] It also includes selected COAP summary bar charts. There are a number of flaws in the group's assertions and conclusions. First and foremost, unlike other national clinical trials, where thousands of clinical outcomes have been evaluated, *COAP analysis, as presented by the 5-hospital group, is insufficiently well-powered from a statistical perspective to allow inferences from the data.* In other words, the COAP data does not distinguish outcomes across different volumes in a statistically meaningful way. Second, based on evaluation of the bar charts provided in the group's proposal, its conclusions are incorrect.

The group states:

> The COAP Report provides comparisons of mortality, CABG and Transfer for CABG Composite Adverse events and its conclusions further substantiate that outcomes in Washington do not vary by program size. Specifically: Slide 3: Provides a comparison based of three PCI subgroups. (STEMI, N-STEMI, and Non-Acute). This slide demonstrates that Non-Acute (elective) procedures have statistically significantly lower risk in all 4 measures. Slide 5: Compares outcomes by hospital PCI volume. This slide demonstrates no volume outcome relationship. Slide 6: Demonstrates that 48% of non-acute (elective) PCI are outpatient-not part of a hospital stay (at discharge).[44]

The group actually includes a "slide 4," Association Between Outcomes and On-Site Open Heart Surgery Program, which the group does not discuss. As will be pointed out, this slide is not useful, from a statistical point-of-view. Each of these COAP slides will be discussed in turn.

Slide 3: Association Between Outcomes and PCI Indication. This slide shows percentage on the vertical axis and compares four outcome measures: Mortality, CABG, Transfer for CABG and Adverse Events. It compares these outcome measures across three PCI "populations:" STEMI, N-STEMI and Non-Acute PCIs. The slide includes counts of PCI cases within each outcome measure for each of the three populations.

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[43] Five-hospital group proposal, p. 9.
[44] Ibid, p. 11.

- First, putting aside for a moment statistical issues with this slide, the conclusions reached should not be surprising: STEMI cases, in comparison to Non-Acute cases, are emergent--the presenting patient's medical condition would be more acute and would logically be expected to show higher percentages across these outcome measures. This slide, by itself, does not show anything about the PCI volume-quality relationship.

- Second, the cell size, i.e., the count of cases within each of the four outcome measures for the three populations, is very low from a statistical point-of-view, indicating poor ability to statistically distinguish differences. This simply means the precision, or confidence in the estimates, is low. Stated another way, inferences from these observed values will not be statistically well-powered.

Slide 4: Association Between Outcomes and On-Site Open Heart Surgery Program. This slide also shows percentage on the vertical axis and compares the same four outcome measures: Mortality, CABG, Transfer for CABG and Adverse Events. It compares these outcome measures across two PCI "populations:" Open Heart Surgery Program and No Open Heart Surgery Program. The slide includes counts of PCI cases within each outcome measure for each of the two populations.

- First, the "p-values"[45] shown on this slide for Mortality, CABG, and Adverse Events show there is little precision to any differences in percentages between the two populations. Stated another way, inferences from these percentages are not statistically meaningful. In this regard, this slide has no value.

- Second, as discussed above with respect to slide three, cell size, the count of cases within each of the four outcome measures for the two populations, is very low from a statistical point-of-view, indicating poor ability to statistically distinguish differences. This shows the same lack of precision as discussed above with p-values. Inferences from these observed values will not be statistically well-powered.

Slide 5: Association Between Outcomes and PCI Procedure Volume. This slide is pivotal to the 5-hospital group's assertion that there is no volume-outcome relationship. This slide also shows percentage on the vertical axis and compares the same four outcome measures: Mortality, CABG, Transfer for CABG and Adverse Events. It compares these outcome measures across three PCI "populations:" <200 PCI/Year; 201-300 PCI/Year; and >300 PCI/Year. The slide includes counts of PCI cases within each outcome measure for each of the three populations.

- First, the "p-values" shown on this slide for Mortality, CABG and Adverse Events show there is little precision to any differences in percentages between the three populations.

[45] "P-values" are statistical measures that help determine the significance of hypothesis tests. In the case of the COAP data, the hypothesis test is that a particular outcome measure between populations shows differences. A small p-value, e.g., 0.0001, indicates strong evidence the hypothesis test is valid . A high p-value, e.g., 0.82, as in slide 4 for Mortality, indicates no inferences can be made regarding the hypothesis-it can't be accepted or rejected.

Inferences from these percentages are not statistically meaningful. In this regard, this slide has no value. This slide does not demonstrate what the 5-hospital group purports, specifically: "This slide demonstrates no volume outcome relationship;" in fact, statistically, no conclusive relationships of any sort between PCI volume and outcomes can be obtained from this slide.[46]

- Second, as discussed above with slides three and four, cell size, the count of cases within each of the four outcome measures for the three populations, is very low from a statistical point-of-view, indicating poor ability to statistically distinguish differences. This shows the same lack of precision as discussed above with p-values. Inferences from these observed values will not be statistically well-powered.

Slide 6: Hospital Status According to PCI Indication. This slide also shows percentage on the vertical axis, but it is different than the prior slides. In slide 6, percentage, which varies from 0% to 100%, apparently measures the percentage of cases that are part of a hospital stay. According to the 5-hospital group's explanation, this slide attempts to show the percentage of PCIs that are either inpatient or outpatient. It compares percentages across three PCI "populations:" STEMI, N-STEMI and Non-Acute. The slide includes counts of PCI cases within each of the three populations. For example, slide 6 shows 2,853 Non-Acute PCIs, and of those, 1,269 were performed as part of a hospital stay, where apparently "hospital stay" means "inpatient."

- First, some of the percentage figures in slide 6 that provide the percentage of PCI cases that were part of a hospital stay are wrong. If there were 2,853 Non-Acute cases, and 1,269 were performed as part of a hospital stay, this is 44.8%, not 47.9% as shown in slide 6.

- Second, STEMI and N-STEMI PCIs are emergent cases; the percentages for these cases should be 100%. This is no surprise.

- Third, despite the assertion by the 5-hospital group that "nearly 50% of elective PCI cases, while hospital-based, are performed in an outpatient setting with an average length of stay for elective cases of less than 24 hours,"[47] the clinical literature states that the standard of care is to keep a patient overnight, at a minimum, and depending on "the results of the procedure, [a patient's] stay may be longer."[48] The vast majority of

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[46] It should be noted, however, poor statistical significance notwithstanding, this slide directly contradicts the 5-hospital group's assertion there is no volume-quality relationship. For both Mortality and Adverse Events, there is a difference between low volume (<200 PCIs per year) and higher volume PCI providers (200 or more PCIs per year). Both outcome measures are worse for low volume providers, and in the case of Mortality, 50% worse. This finding is completely consistent with the clinical literature.

[47] Ibid.

[48] "Angioplasty and Stent Placement for the Heart." Johns Hopkins Medicine Health Library. See: <http://www.hopkinsmedicine.org/healthlibrary/test_procedures/cardiovascular/angioplasty_and_stent_placement_for_the_heart_92,P07981/>.

PCI patients (>90%) stay overnight after receiving a PCI, although these patients may be coded as "outpatient." This is the standard protocol because PCI patients should be observed and monitored for any complications or change in condition. Patients are not simply discharged after a PCI procedure due to the significant risk associated with PCI procedures.

- Fourth, the most important point is that, whether the PCI is emergent or elective, and whether the patient is coded as "inpatient" or "outpatient," the highly skilled, specialized cath lab staff and equipment are identical, as detailed below. The 5-hospital group ignores this point when it asserts elective PCIs are somehow not complicated and do not carry significant risk.[49] This is simply wrong.

7. COAP Has Not Endorsed the 5-Hospital Group's Proposal to Remove Elective PCI From the List of Tertiary Health Services. Nor Has COAP "Nominated" Elective PCI to be Removed From the List. The Group's Attempt to Suggest Otherwise is Both Inappropriate and Inaccurate.

From the outset of its campaign to remove elective PCI from the list of tertiary health services, the 5-hospital group has made an effort to leverage COAP's well-deserved reputation, and its resources, to the group's advantage. This effort culminated in the Proposal submitted to the Department on February 26, 2015.

In the Proposal, the group attempts to create the impression that COAP endorses the group's request to remove elective PCI from the list of CON-reviewable services, and that the group and COAP are, in essence, acting as partners in this campaign. Thus, in support of its arguments, the group presents and interprets data obtained from COAP. (The defects in the group's data presentation and interpretation are addressed above.) In addition, the group suggests that COAP has agreed to function as a quality assessment, quality monitoring, and enforcement entity in the event that elective PCI is removed from the list of tertiary health services. Finally, the group presents a letter from COAP's executive team (not from COAP's Management Committee) that purports to constitute a "Nomination to Remove Elective PCI from the Listing of Tertiary Services."

All of this is intended to create the impression that COAP supports, and has endorsed, the 5-hospital group's proposal. However, as discussed below, the group has inappropriately and inaccurately depicted COAP's involvement in, and position on, the group's proposal.

a. COAP has not "nominated" elective PCI to be removed from the list of tertiary health services.

As "Attachment 7" to its Proposal, the 5-hospital group provides a letter on COAP letterhead to the Department dated January 23, 2015. The letter contains the subject line: "Nomination to Remove Elective PCI from the Listing of Tertiary Services." However, the subject line is

[49] Five-hospital group proposal, p. 12.

completely inaccurate: the text of the letter says absolutely *nothing* about the purported "nomination." Instead, the text simply describes (1) COAP's history and mission, (2) its ability to provide PCI quality monitoring services to its voluntary member hospitals, and (3) its willingness to "discuss" its monitoring services with the Department. The text of the letter does not "nominate" elective PCI to be removed from the list of CON-reviewable services, nor does it endorse the 5-hospital group's proposal. Therefore, the subject line of the letter is incongruous and wholly inaccurate.

In addition to not being a "nomination" letter, the letter is also not an official COAP policy statement. The letter is signed by the members of COAP's executive team. However, the executive team cannot issue policy statements, or take any other action, on behalf of COAP without the prior review and approval of the COAP Management Committee. The Management Committee did not, and has not, approved either the contents of the letter or its issuance. In fact, the Committee had no knowledge of the letter until it was disclosed in the 5-hospital group's Proposal.

Accordingly, the letter cannot be interpreted as an endorsement by COAP of the group's proposal. The letter was issued by COAP's executive team (1) with an inaccurate subject line and (2) without the review and approval of the Management Committee. Therefore, it is *not* a "nomination" letter, and, more importantly, it does *not* represent the official position of COAP.

b. COAP has not agreed to--and, further, it does not have authority to -- function as a quality monitoring and enforcement entity in the event that elective PCI is removed from the list of tertiary health services.

Recognizing that the operation of low-volume elective PCI programs raises significant quality concerns, the 5-hospital group again attempts to take advantage of COAP's reputation and resources by suggesting that, if elective PCI is removed from the list of tertiary health services, COAP will be in a position to provide "a continuous monitoring process" that "will immediately identify variations in care and make certain that the quality of care remains high across the state."[50] However, there are two fundamental defects in the group's assertion.

First, the group cites the January 23, 2015, letter from COAP's executive team to the Department (Attachment 7 to the Proposal) as authority for the proposition that COAP possesses an "ability and willingness to work with the Department to establish a working relationship for quality assessment."[51] However, as noted above, the letter was not, and has never been, reviewed and approved by COAP's Management Committee. Thus, the letter does not constitute the official position of COAP. COAP has made no commitment to provide the "continuous monitoring process" described by the group.

[50] Five-hospital group proposal, p. 15.
[51] Ibid.

Second, as noted above, COAP is a private program that depends upon voluntary participation by its member hospitals to carry out its data collection and quality assessment activities. It is not a governmental agency. It does not possess any regulatory or enforcement authority over hospitals that provide PCI services. Because hospital participation in COAP is voluntary, COAP has no ability to impose quality control requirements, and it has no authority to sanction, suspend, or terminate a PCI program that it deems to be unsafe. If COAP attempted to exercise such authority with respect to a hospital, the hospital could simply withdraw from COAP.

Accordingly, the 5-hospital group's effort to transform COAP into a governmental regulatory body has no foundation in fact or in law. Further, expressions of opinion by COAP's executive team do not constitute the official position of COAP in the absence of review and approval by the Management Committee. Moreover, the private and voluntary character of COAP precludes it from functioning as a governmental monitor and regulator of PCI programs.

c. The 5-hospital group's portrayal of its September 30, 2014, "stakeholder" meeting as having resulted in a "consensus" among cardiac care providers regarding the status of elective PCI services is disingenuous and inaccurate.

In an attempt to create the impression that its campaign is not only approved by COAP, but also reflects a purported "consensus" among cardiac care providers, the 5-hospital group convened a so-called "stakeholder" meeting on September 30, 2014. It is important to recognize that the meeting was *not* a COAP meeting, and was not convened or sponsored by COAP. In its Proposal, the group claims that, at the meeting, "there was full consensus that the definition of tertiary is, at best, not clear, and, at worst, confusing."[52] The group also claims that "there was consensus that elective PCI is different than -- an outlier -- from the other services defined as tertiary."[53]

In considering the claims that "consensus" was reached on these two points, it is important to note who attended the meeting: the attendees were certainly not a broadly representative group of cardiac care "stakeholders." The attendees are identified in the minutes of the meeting that were subsequently prepared by a consultant retained by the 5-hospital group. Twenty-two people attended the meeting. Of those 22, 13 are employed by, or work as consultants for, members of the 5-hospital group. There were three attendees from COAP's executive team and two attendees from the Department. The four remaining attendees represented Swedish Health Services, MultiCare Health System, and Evergreen Health.

Thus, the meeting was not in any sense a true "stakeholder" meeting. Rather, it was a meeting that was intended to promote the 5-hospital group's campaign. This is clearly reflected in the three presentations that were made at the meeting. First, Jonathan Seib (a lobbyist retained by the group) provided an introduction. Second, Jody Carona (a CON consultant retained by the

[52] Ibid, p. 4.
[53] Ibid.

group) discussed the tertiary health service regulations. Third, Dennis Hoover (an employee of Yakima Valley Memorial Hospital, which is a member of the group) discussed COAP PCI data.

Given the affiliation of the majority of the attendees, and the content of the presentations made at the meeting, the two points of "consensus" allegedly reached at the meeting are of dubious value. Further, it is interesting to note that the group's own minutes of the meeting contain no mention of the points of purported "consensus." Instead, the minutes merely state: "the group agreed that much additional work and analysis is needed to define tertiary and then determine if elective PCI is still tertiary under any new definition." Whether the "additional work and analysis" was ever done is unknown: the 5-hospital group's Proposal does not mention any further "stakeholder" meetings.

The September 30, 2014, meeting was a failed attempt by the 5-hospital group to generate support for its campaign. It also represented the group's first formal attempt to appropriate the reputation and resources of COAP in support of its campaign. We have taken the time to examine the context and the details of the meeting in order to show that the group's portrayal of the meeting does not square with what actually took place.

8. Conclusions Regarding COAP.

The facts show that the 5-hospital group is attempting to use COAP's well-deserved reputation and its resources to serve its own ends. In doing so, the group has misrepresented COAP's position on whether elective PCI should be removed from the list of tertiary health services, and, in addition, has inaccurately presented and interpreted COAP data. The organizations submitting this position paper are all voluntary participating members of COAP. We are proud of COAP's activities and accomplishments, and we are privileged to be contributors to COAP's quality of care initiatives. Therefore, we believe that it is essential to set the record straight.

B. Washington Administrative Code 246-310-035(2)(a). Whether the service is dependent on the skills and coordination of specialties and subspecialties, including, but not limited to, physicians, nurses, therapists, social workers.

1. Percutaneous Coronary Interventions Very Much Depend on Clinical Expertise of Physicians and Catheterization Laboratory Staff as Well as Highly Specialized Equipment.

The 5-hospital group contends that "[e]lective PCI is not differentiated from other acute care services, most of which are not defined as tertiary, by this criterion."[54] It goes on to claim it is "not certain how this criterion would help establish whether the service is tertiary."[55] This assertion is based upon purported discussion at the so-called "stakeholder" meeting held by the group on September 30, 2014. As noted above, that meeting is of dubious value given that it

[54] Five-hospital proposal, p. 5.
[55] Ibid, p. 5.

was essentially a self-promotional meeting by the group. Moreover, the group's statement simply suggests that it disagrees with this provision of the regulation. But the provision is what it is, and must be applied by the Department.

The group's argument misses the point: the provision of PCIs *does* require highly specialized, well-trained interventional cardiologists, supported by trained cath lab staff, including nurses and cath lab technicians. Accordingly, PCIs meet this criterion. PCIs are only performed in cath labs that are equipped, not only with highly skilled physicians and other trained clinical staff, but also specialized imaging technologies, including intravascular ultrasound devices ("IVUS") and cardiac fractional flow reserve monitoring devices ("FFR").

In addition, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention included a Class I (the highest level) recommendation for a "Heart Team" approach to revascularization for patients with complex coronary artery disease.[56] A "Heart Team" involves a multidisciplinary approach composed of interventional cardiologists and cardiac surgeons to review the patient's medical condition and their coronary anatomy, to determine that PCI and/or CABG is feasible and reasonable and to confer with the patient before a treatment strategy is selected. This type of multidisciplinary coordination for complex PCI illustrates the services and sub-specialties needed to perform PCI.

2. Emergent and Elective PCIs Require the Same Care and the Same Resources.

The 5-hospital group devotes much attention to the fact that emergent PCIs are not CON-reviewable, while elective cases are. Its assertion that elective cases are somehow less complex is not accurate. *EVERY* PCI requires the same staff and specialized equipment, the care process is identical, and procedures are performed in the same cath lab. The difference is that elective cases can be scheduled, Monday through Friday, while emergent PCI care needs to be available 24/7.

Inpatient PCI cases include patients with significant co-morbidities, including patients who have suffered a heart attack ("acute MIs"), where the severity of the heart disease and/or co-morbidities require follow-up monitoring and care. *In other words, while patients may be coded as an outpatient, not inpatient, the resources used to provide the PCIs are identical. Further, there is the same procedure risk.*

3. There is an Important, Related Economic Issue Ignored by the 5-Hospital Group. Specifically, Cath Labs Are High Cost Operations; Spreading a Declining Volume of PCIs Across a Greater Number of Cath Labs Will Increase Costs per Unit of Service. This is Not Efficient and is Counter to CON Policy Principles.

[56] Levine, et al., 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, Journal of the American College of Cardiology, Vol. 28, No. 24 (2011), p. 2555.

It is inefficient to develop and operate very specialized resources, both in terms of staff and equipment, at numerous hospitals when volumes are too low to capture economies of scale. While economics is not the driver for keeping PCI procedures on the list of tertiary health services, it is completely ignored by the 5-hospital group.

A 2013 study, *Evidence of Systematic Duplication by New Percutaneous Intervention Programs*,[57] concluded: "new PCI programs were systematically duplicative of existing programs and did not help patients gain access to timely PCI. The total cost of recent US investments in new PCI programs is large and of questionable value for patients."[58] While this research was conducted using 2004-2008 American Hospital Association statistics, the trends identified in those data have continued, most notably, the continued growth of PCI programs and continued volume declines. In this regard, the conclusions have been confirmed by more recent analysis.

The study found: "New PCI programs were more likely to be introduced in areas that already had a PCI program with more competition for market share, near populations with higher rates of private insurance, in states that had weak or no regulation of new cardiac catheterization laboratories, and in wealthier and larger hospitals."[59] They calculated that, from 2004-2008, new PCI programs added $1.9 billion to $4 billion in new costs to the U.S. healthcare system without improving access.[60]

The study concluded:

> In this era of flat use, furthermore, systematic duplication can only reduce average hospital PCI volumes, a trend that could result in lower procedure quality and worse outcomes for patients with coronary artery disease. Hospital leaders and other leaders may hope that every new program will improve patient health, but quite the opposite may now be happening after introduction of PCI.[61]

Similar findings can be found in *The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention In the Face of Declining Procedural Volumes*, a 2014 article in the journal Circulation.[62] The study concludes:

> Unfortunately, the reality is that most new catheterization laboratories in the United States have opened in areas that already have established PCI programs and therefore do not improve access in any meaningful way. Without improving access to PCI, there really is no discernible

[57] Please see Concannon et.al, op. cit., Vol. 6 (2013).
[58] Ibid, p.400.
[59] Ibid.
[60] Ibid, p. 403.
[61] Ibid, p. 405.
[62] Suzanne Barron, MD, Msc., et.al. , The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention In the Face of Declining Procedural Volumes, Circulation, Vol. 130, Issue 16 (2014), pp. 1343-1345.

> benefit to society to continuing to develop PCI centers. In fact, there is likely substantial societal cost, both monetarily (by duplication of services and increased capital expenditures) and clinically (if patient outcomes are compromised by diluting operator and hospital procedure volumes). ...Improvements in cardiovascular health have created new challenges in the delivery of PCI. A disjointed approach to health services delivery has led to excess PCI capacity and an abundance of low-volume proceduralists without improving access to care, the costs of which will ultimately be borne by patients.[63]

The 2014 SCAI/ACC/AHA Expert Consensus Document is extremely frank in its assessment of the proliferation of unnecessary new PCI programs, quoting with approval the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention:

> Importantly, the ACCF/AHA/SCAI guidelines state, 'desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery.'[64]

These studies both raise the obvious issue of the economic costs of duplicative programs—significant capital investments to develop cath labs and equip them and high operational costs to staff them. Duplicative programs necessarily increase societal resource costs with no offsetting benefit. Furthermore, even ignoring the inefficiency of duplication, as declining volumes are distributed across a growing number of institutions, which is now occurring in Washington, average costs associated with PCI programs will necessarily increase; this, too, is inefficient. As stated above, we do not suggest economics should drive decisions whether to keep PCI as a tertiary health service, but they cannot be ignored, as the 5-hospital group has. The 5-hospital group's proposal would exacerbate duplicative problems and inefficient behaviors.

C. Washington Administrative Code 246-310-035(2)(b) . Whether the service requires immediate access to an acute care hospital.

1. PCI Procedures Are Highly Complex; Whereas the Majority of PCIs Do Not Require Emergent Interventions, Including Open Heart Surgery, Some Cases Do.

The 5-hospital group claims that "[e]lective PCI is not differentiated from other acute care services, most of which are not defined as tertiary, by this criterion."[65] Immediately after making this statement, it then contradicts itself by admitting that "elective PCI does require access to an acute care hospital," claiming that "this is only because the equipment and staff

[63] Ibid, pp. 1344-1345.
[64] Dehmer et al., Op. cit, page 2614.
[65] Five-hospital group proposal, p. 5.

that perform the procedure are hospital-based, not based on risk or transfer needs."[66] In other words, even the 5-hospital group agrees PCIs require access to an acute care hospital, stating on page 5: "Per COAP, the immediate need for transfer for CABG is 0.1%, or less than one person for every 1,000 elective cases." *This is exactly the point of this criterion.* While a comparatively small number of patients require transfer to an acute care hospital with open heart surgery capabilities in an emergency, there are still patients who need such services.

The 5-hospital group's position is simply illogical. This criterion does not specify the reasons a tertiary service requires access to an acute care hospital, only that the service requires such access. Regardless of the specific reason why PCI procedures require access to an acute care hospital, it is a procedure that must be performed in a hospital setting.

In addition, as discussed above, a "Heart Team," which involves a multidisciplinary approach composed of interventional cardiologists and cardiac surgeons, should be available to review the patient's medical condition and coronary anatomy, to determine that PCI and/or CABG is feasible and reasonable, and to confer with the patient before a treatment strategy is selected. This is another example of case complexity associated with PCI procedures.

2. Whether PCI Procedures Are Provided on an Inpatient or Outpatient Basis, the Procedure is Identical.

Additionally, the 5-hospital group states that "nearly 50% of elective PCI cases, while hospital-based, are performed in an outpatient setting with an average length of stay for elective cases of less than 24 hours."[67] In fact, the clinical literature states that the standard of care is to keep a patient overnight, at a minimum, and depending on "the results of the procedure, [a patient's] stay may be longer."[68] The vast majority of PCI patients (>90%) stay overnight after receiving a PCI, although these patients may be coded as "outpatient." This is the standard protocol because PCI patients should be observed and monitored for any complications or change in condition. Patients are not simply discharged after a PCI procedure due to the significant risk associated with PCI procedures. Further, as stated above, whether the PCI is emergent or elective, and whether the patient is coded as "inpatient" or "outpatient," the highly skilled, specialized cath lab staff and equipment are identical.

The key element of this criterion is missed by the 5-hospital group: *PCIs do require immediate access to an acute care facility.* Further, even if PCI is determined to not require immediate access to a hospital, this is not legally determinative. The DOH is required to evaluate all seven criteria in WAC 246-310-035(2) in light of the statutory definition of "tertiary health service."

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[66] Ibid.
[67] Ibid.
[68] "Angioplasty and Stent Placement for the Heart." Johns Hopkins Medicine Health Library. See: <http://www.hopkinsmedicine.org/healthlibrary/test_procedures/cardiovascular/angioplasty_and_stent_placement_for_the_heart_92,P07981/>.

D. Washington Administrative Code 246-310-035(2)(g). Whether the service carries a significant risk or consequence.

1. PCI Procedures Are Highly Complex and Do Carry Significant Risk.

In its proposal, the 5-hospital group states that "[e]lective PCI is not characterized by this criterion; and in fact carries a significantly lower risk than emergency PCI which is not defined as tertiary."[69] The group asserts COAP data "shows" major complications from elective PCI are lower and in line with other elective outpatient procedures, while simultaneously confirming that emergent PCI procedures are higher risk than elective cases.[70] Additionally, the group claims: "The advent of stents, bailout devices, better pharmacotherapy and better equipment/technology has resulted in a dramatic reduction in risks and has allowed elective PCI to largely occur in the outpatient setting."[71]

There are a number of flaws to these statements and assertions. First and foremost, while COAP data indicate the risk of PCI complications is low, emergencies arise: there can be, and are, complications. Second, COAP data cannot demonstrate any comparison with other outpatient procedures since it exclusively focuses on cardiac procedures.[72] Third, emergent PCIs, by their very nature, *must* be provided to save a patient's life, someone who has suffered an acute MI. The fact the Department of Health does not require CON review for emergent PCI services reflects this fundamental difference: emergent PCIs need to be provided to save a life, whereas an elective PCI can be scheduled. Both carry significant risk: the procedures themselves are identical; and both emergent and elective PCIs are provided in the same cath lab, by the same staff, using the same equipment.

The fact that hospitals are permitted to perform emergent PCIs does not, as a matter of law or logic, provide a basis for removing elective PCI from the list of tertiary health services. The standard for emergent PCIs to save lives is not the standard for elective cases, where objective volume and outcome statistics should be used to make an intelligent, informed decision to best meet patient need. This is precisely what the clinical literature findings and recommendations demonstrate. These studies are very clear about their findings, and in fact are found within the attachments provided by the 5-hospital group.

2. Complications, While Infrequent, Do Occur.

The 5-hospital group states: "Per COAP, the immediate need for transfer for CABG is 0.1%, or less than one person for every 1,000 elective cases."[73] While a comparatively small number of patients require immediate transfer to an acute care hospital with open heart surgery capabilities, there are still patients who require such services to save their life.

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[69] Five-hospital group proposal, p. 12.
[70] Ibid.
[71] Ibid, p. 2.
[72] See: http://www.coap.org/overview.
[73] Five-hospital group proposal, p. 5.

Moreover, there are significant risks, and complications, while infrequent, do occur. The 5-hospital group ignores this completely. Side effects of PCI procedures may include:

- Bleeding at the site where the catheter is put into the body (typically the groin, wrist or arm);
- Blood clot or damage to the blood vessel from the catheter;
- Blood clot within the treated blood vessel;
- Infection at the catheter insertion site;
- Arrhythmias (abnormal heart rhythms);
- Heart attack;
- Stroke;
- Chest pain or discomfort;
- Rupture of the coronary artery or complete closing of the coronary artery, requiring open-heart surgery; and
- Allergic reaction to the contrast dye used.[74]

Other risks may also be present depending on a patient's prior medical condition. It is very clear there are risks of PCI procedures; to argue otherwise is incorrect.

Emergent procedures are substantially higher risk for many reasons: patients are unstable, the decision is made quickly to save precious time, and the facility may not be experienced in providing this type of service. However, emergent procedures are allowed in the State of Washington in order to save lives. The fact that PCIs may be performed without a CON does not render PCIs a non-tertiary health service. It simply indicates that the Department of Health allows for riskier practices when a patient's life is in danger.

Furthermore, the decision to perform an elective PCI is entirely different from an emergency decision to perform PCI. Elective PCIs are intended to treat persons with angina, where there is a blockage but not a complete block. Emergent PCIs are conducted to treat persons with acute myocardial infarctions, including STEMIs and N-STEMIs. While these two cases treat slightly different conditions, the procedural risk is the same.

In conclusion, PCIs are clearly a substantially risky procedure with severe potential consequences. *There is simply no valid argument otherwise.* Further, even if technology improves PCI to the point where mortality or other serious consequences are averted entirely, this is not a legally determinative argument for removal of PCI procedures from the list of tertiary services. The Department of Health is required to evaluate all seven criteria in WAC 246-310-035(2) to determine if a service meets the statutory definition of a tertiary health service, which PCI services clearly do.

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[74] "Angioplasty and Stent Placement for the Heart." Johns Hopkins Medicine Health Library. < http://www.hopkinsmedicine.org/healthlibrary/test_procedures/cardiovascular/angioplasty_and_stent_placement_for_the_heart_92,P07981/>

E. Washington Administrative Code 246-310-035(2)(d). Whether the service is broader than a procedure.

1. Elective PCIs are more than a single procedure.

The 5-hospital group argues that "*elective PCI is a single procedure.*"[75] This is incorrect; there are multiple procedures within the definition of PCIs provided in WAC 246-310-705(4)(a)-(g). Review of actual utilization statistics from inpatient cases, as reported in CHARS files, shows the WAC definition of PCIs includes more than a single procedure.

PCI is one treatment modality for coronary artery disease. Other treatment options include coronary artery bypass surgery and medical therapy. Optimal treatment strategies involve using a multidisciplinary team of specialists (cardiologists, interventional cardiologists, and cardiac surgeons) to determine the optimal therapy for each individual patient.

a. Diagnosis Related Group Definition of PCI.

The 5-hospital group uses Medicare Diagnosis Related Groups ("DRGs") 246-251 as one measure of whether PCIs are broader than a procedure.[76] It states: "Each of these DRGs is exactly the same medical procedure—a percutaneous cardiovascular procedure."[77] The group has oversimplified and mischaracterized the issue for at least two reasons. First, based on WAC 246-310-705(4)(a)-(g), there are seven distinct coronary interventions ("PCIs") and they can be very different procedures, including: PTCA, stent implantation, cutting balloon atherectomy, rotational atherectomy, directional atherectomy, excimer laser angioplasty or extractional thrombectomy. Second, based on actual data from CHARS, the 5-hospital group's assertion is wrong. Most importantly, it ignores the fact that, within these DRGs, there are a number of very different interventions.

WAC 246-310-705(4) lists seven distinct procedures, only two of which are stent procedures, which contradicts the 5-hospital group's assertion that DRGs 246-251 involve the exact same medical procedure. Actual data demonstrate this is simply not the case. Evaluation of procedures occurring within DRGs 246-251 shows there are many procedures besides PCIs and stents that occur within these cases.

Table 2 shows that a number of non-stent and non PTCA procedures occur within these DRGs. For example, ICD-9 Procedure Code 37.22, left heart catheterization, occurs very frequently within these DRGs but it is not a PCI. Similarly, ICD-9 Procedure Code 88.53, angiocardiography of left heart structures, also occurs frequently in these DRG cases, but it is not a PCI.

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[75] Five hospital group proposal, p. 6.
[76] Ibid, p.6.
[77] Ibid, p.6.

Table 2. ICD-9 Procedure Code Utilization for DRG 246-251 Discharges, by Procedure Position, 2013

		# times found in each position						
Code	Description	Proc 1	Proc 2	Proc 3	Proc 4	Proc 5	Proc 6	Total Procedures
0066	Percutaneous transluminal coronary angioplasty [PTCA]	7,108	490	114	57	17	3	7,789
3722	Left heart cardiac catheterization	161	257	3,160	508	1,330	565	5,981
3607	Insertion of drug-eluting coronary artery stent(s)	210	5,386	293	34	24	9	5,956
0040	Procedure on single vessel	2	183	872	1,609	1,096	1,641	5,403
0045	Insertion of one vascular stent	4	17	1,085	1,238	1,276	598	4,218
8856	Coronary arteriography using two catheters	34	42	360	939	952	1,738	4,065
8853	Angiocardiography of left heart structures	0	10	120	1,729	662	559	3,080
0046	Insertion of two vascular stents	0	7	433	482	497	213	1,632
3606	Insertion of non-drug-eluting coronary artery stent(s)	57	1,146	113	28	20	4	1,368
0041	Procedure on two vessels	1	11	164	312	212	299	999
3734	Excision or destruction of other lesion or tissue of heart, endovascular approach	696	104	6	3	1	2	812
3726	Catheter based invasive electrophysiologic testing	133	402	101	24	7	3	670
3727	Cardiac mapping	1	146	404	70	15	5	641
0024	Intravascular imaging of coronary vessels	1	8	57	68	278	192	604
	Subtotal; all other codes with <500 total procedures	261	399	1,216	1,064	1,295	1,046	5,281

Source: CHARS 2013

In addition, there are many DRGs other than DRGs 246-251 where PCI procedure codes occur, which simply means these DRGs are not a reliable measure for capturing all PCI cases. Please see Table 3 below.

Table 3. Case Counts Where PCIs Occur, by DRG, 2013.

DRG	Description	Cases Where ICD-9 Proc. Code 00.66, 36.06, 36.07, 36.09, or 17.55 Appears at Least Once in the Record
247	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W/O MCC	4,731
246	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W MCC OR 4+ VESSELS/STENTS	1,222
249	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MCC	930
248	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W MCC OR 4+ VES/STENTS	376
251	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W/O MCC	286
237	MAJOR CARDIOVASC PROCEDURES W MCC	182
250	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W MCC	136
981	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS W MCC	60
232	CORONARY BYPASS W PTCA W/O MCC	53
238	MAJOR CARDIOVASC PROCEDURES W/O MCC	46
216	CARDIAC VALVE & OTH MAJ CARDIOTHORACIC PROC W CARD CATH W MCC	44
231	CORONARY BYPASS W PTCA W MCC	43

*Table excludes DRGs with case counts <40 where one of the following ICD-9 procedure codes appears at least once in the record: 00.66, 36.06, 36.07, 36.09, or 17.55. Please see Table 4 below for PCI procedure code selection rationale.

Source: CHARS 2013

In summary, these PCI DRGs may well include stents, but there are certainly more procedures being performed. Thus, these DRGs are not "exactly the same procedure" as asserted by the 5-hospital group.

b. ICD-9 Procedure Code Definitions of PCIs

While DRGs 246-251 can be associated with percutaneous cardiovascular procedures, the better approach for measuring PCI procedures is to use ICD-9 procedure codes. This is a much more precise measure.

The 5-hospital group correctly states: "Since 2007, the Department has mailed an Annual Outpatient Percutaneous Coronary Intervention Survey to hospitals...In the survey instructions, it states: ICD-9 code 0.66 has been identified as the procedure code for these outpatient PCIs."[78] However, the survey instructions also state immediately after the last sentence of the above quote: "If ICD-9 code 00.66 does not capture all outpatient PCIs performed at your facility, please include the additional PCI counts and identify the ICD-9 code associated with them."[79] In other words, the survey instructions show the Department of Health acknowledges PCIs are broader than a single procedure, and while procedure code 00.66, PTCA, might often be the primary procedure code, there are other procedures associated with PCIs as well. Please see Table 4.

Table 4. ICD-9 Procedure Code and Associated WAC 246-310-705(4) Definition

Procedure Code	Description	WAC 246-310-705(4) Defined PCI Intervention
0066	Percutaneous transluminal coronary angioplasty [PTCA]	(b) Percutaneous transluminal coronary angioplasty (PTCA)
3606	Insertion of non-drug-eluting coronary artery stent(s)	(a) Bare and drug-eluting stent implantation
3607	Insertion of drug-eluting coronary artery stent(s)	(a) Bare and drug-eluting stent implantation
3609	Other removal of coronary artery obstruction	(g) Extractional thrombectomy
1755	Transluminal coronary atherectomy	(d) Rotational atherectomy

The following analysis examined ICD-9 procedure code utilization provided in CHARS for 2013. For simplicity, filters were applied to only show procedure utilization for cases assigned within the DRG 246-251 range. Utilization reported in CHARS, and summarized below in Table 5, demonstrates a number of important findings:

Table 5. PCI ICD-9 Procedure Code Utilization, by Procedure Position, 2013

		# times found in each position						
Code	Description	Proc 1	Proc 2	Proc 3	Proc 4	Proc 5	Proc 6	Total Procedures
0066	Percutaneous transluminal coronary angioplasty [PTCA]	7,108	490	114	57	17	3	7,789
3606	Insertion of non-drug-eluting coronary artery stent(s)	57	1,146	113	28	20	4	1,368
3607	Insertion of drug-eluting coronary artery stent(s)	210	5,386	293	34	24	9	5,956
1755	Transluminal coronary atherectomy	17	52	176	25	8	1	279
3609	Other removal of coronary artery obstruction	6	7	9	1	0	0	23

*ICD-9 procedure codes for discharges with one of the following DRGs: 246-251
**All Ages
Source: CHARS 2013

- While PTCAs generally include stents (i.e. procedure codes 36.06 and 36.07), they do not in all cases. As provided in Table 5 above, total procedures for ICD-9 procedure

[78] Five hospital proposal, p. 7.
[79] Washington State Certificate of Need Program 2014 Annual Outpatient Percutaneous Coronary Intervention Survey for Calendar Year 2013

code 00.66 equals 7,789. This is greater than the total procedures for drug-eluting (5,956) and non-drug-eluting (1,368) coronary stents combined, indicating PTCAs may be utilized independently of stents.

- Table 5 also shows there are a number of other coronary interventions that are properly defined as PCIs. Unlike the 5-hospital group's characterization, they are certainly not stents.

In addition, despite what the 5-hospital group asserts, i.e., that PCIs are a single procedure, actual data shows this is also incorrect. A majority of discharges reported in CHARS for DRGs 246-251 show, in general, there are multiple interventions related to PCIs that occur in a single case.

Table 6 demonstrates this fact. For instance, where "2 or More" is listed in the first column of Table 6, there are a total of 7,279 cases; this shows there were 7,279 cases where more than a single procedure was provided in a given case. Clearly, there are multiple procedures, contrary to the statements by the 5-hospital group. PCI is more than a single procedure.

Table 6. PCI ICD-9 Procedure Code Utilization, 2013

Number of PCI Procedures* For a Single Inpatient Discharge**	Case Count	% of Total
0	988	11.4%
1	402	4.6%
2 or More	7,279	84.0%
Total	**8,669**	**100.0%**

*The following ICD-9 procedure codes were used: 00.66, 36.06, 36.07, 36.09, and 17.55
**DRGs 246-251
***All Ages
Source: CHARS 2013

F. Washington Administrative Code 246-310-035(2)(e). Whether the service has a low use rate.

1. PCI Use Rates Are as Expected; Some Tertiary Services Have Higher Rates, and Others, Lower.

The 5-hospital group claims that "PCI is not characterized by a low use rate...the PCI use rate being significantly higher (2.12 per 1,000) than that of many other tertiary or quaternary services in Washington".[80] To support these claims, the group provides a table showing 2013 tertiary service discharges for Washington State residents.[81] One column in this table shows

[80] Five-hospital group proposal, p. 7.
[81] Ibid, p. 8.

purported "use rates," yet there is no explanation or justification for how these use rates are calculated.

Rather than presenting standard percentage use rates, the use rates in this table are calculated for a population of 1,000. Further, some values in this column are incorrect, as is clearly evident upon closer inspection of this table (e.g., Neonatal Intensive Care and/or OB Level III and Intermediate Care nursery or Level II OB).

We have provided corrected use rates below in Table 7, which are calculated by finding the percentage of discharges from the population, defined as residents 15 years of age and older. All other columns and data of this table are reproduced from the 5-hospital group proposal.

Table 7. 2013 Washington State Tertiary Service Discharges and Corrected Use Rates.

Tertiary Services	# of Hospitals	Metric	2013 Volumes (Discharges), Age 15+	2013 Population, 15+	Use Rate for Total Population (%, corrected)
Transplantation of Solid Organs (pancreas)	1	MSDRGs: 010	1	5,567,598	0.0000%
Transplantation of Solid Organs (kidney/pancreas)	3	MSDRGs: 008	13	5,567,598	0.0002%
Transplantation of solid organs (lung)	1	MSDRGs: 007	35	5,567,598	0.0006%
Transplantation of solid organs (liver/intestines)	3	MSDRGs: 005, 006	70	5,567,598	0.0013%
Transplantation of solid organs (heart)	3	MSDRGs: 001, 002	109	5,567,598	0.0020%
Transplantation of solid organs (bone marrow)	6	MSDRGs: 014, 016, 017	204	5,567,598	0.0037%
Transplantation of Solid organs (kidney)	5	MSDRGs: 652	286	5,567,598	0.0051%
Specialty Burn Services	4	MSDRGs: 927-929, 933-935	469	5,567,598	0.0084%
Open Heart Surgery (Age 15+)	18	MSDRGs: 216-221, 228-236	5,330	5,567,598	0.0957%
Inpatient Rehabilitation Level I	4	50% of Rehab discharges for Level I adult trauma facilities	1,200	5,567,598	0.0216%
PCI (age 15+)	34	COAP Non-Acute[1]	11,828	5,567,598	0.2124%
Neonatal Intensive Care and/or OB Level III	16	MSDRGs: 789, 790 (newborn DRGs)	2,452	*86,819*[2]	2.8243%
Intermediate Care nursery or Level II OB	17	MSDRGs: 791, 792, 793, 794 (Newborn DRGs)	21,072	*86,819*[2]	24.2712%

[1] We used the same "Metric" listing as the 5-hospital group to avoid confusion, but we point out that "Non-Acute" refers to elective PCI procedures. Thus, this label is incorrect and should read "COAP Total PCI."
[2] As indicated in the footnotes of Table 1 on p. 8 of the 5-hospital group proposal, populations listed for Neonatal Intensive Care and/or OB Level III and Intermediate Care nursery or Level II OB include a population of age 0 only.
Source: Five-hospital group proposal, p. 8, Table 1: "Tertiary Service Discharges, 2013 for WA State Residents."

As clearly indicated in Table 7, most of these tertiary services have very low use rates, including PCI, which has a percentage use rate of 0.2%. By comparison, the use rate for Open Heart Surgery, listed in Table 7 as 0.1%, is roughly half of the use rate for PCI procedures. This is reasonable and to be expected, as PCI procedures can be performed in lieu of, or prior to, an open heart surgery procedure. Thus, PCI discharges should be higher than open heart surgery volumes. As open heart surgery discharges are comparatively high in the listed tertiary services, the PCI discharge use rate is very reasonable. If anything, this indicates that heart problems affect more of the population than other serious medical issues, such as kidney or other organ failure. In fact, recent research suggests "that as the obesity epidemic increases, there will be a 30% increase in the number of coronary artery disease diagnoses, many of whom will require invasive and interventional procedures."[82] Thus, it is both reasonable and expected that PCI use rates would be higher than other intensive medical services.

The exception to the low use rates provided in Table 7 above are both tertiary services for infants--Neonatal Intensive Care and/or OB Level III and Intermediate Care Nursery or Level II OB--which have very high use rates. But, as presented in Table 7, these two tertiary services' use rates are calculated using a very much smaller population base, 86,819 persons. The point is that use rate figures, alone, cannot determine whether a service is or is not a tertiary health service. Rather, use rates are just one method of evaluating a healthcare service to determine if it is a tertiary service, but they are by no means the only, or most important, factor in defining tertiary services.

Further, the 5-hospital group includes all PCI procedures in its analysis, not just elective cases. This contradicts its previous discussion, which focuses only on elective cases. In acknowledging this, the 5-hospital group states "even if only looking at elective patients... the use rate of 0.50 procedures per 1,000 residents age 15+ still results in elective PCI being at the high end of many of the services on the tertiary list."[83] However, if one were to calculate the elective PCI use rate, it would equal 0.048%, and, in comparison to Table 7 figures, this figure is less than one-half that for open heart surgery.

2. A High (or Low) Use Rate is Irrelevant If Declining PCI Volumes Reduce Institutional and Operator Volumes Below Minimum Thresholds.

Use rate issues are irrelevant if cases are spread across too many institutions and performed by too many operators. The clinical literature is very clear on this point, and it is increasingly important as PCI volumes fall over time. An important study found:

> "[O]n average, recent large investments in new PCI programs have been low value for patient health because they did not lead to increased access or decreased treatment times. This is true... also for elective PCI...In this era of flat [PCI] use, furthermore, systematic duplication can only reduce average hospital PCI volumes, a trend

[82] Maroney et al., op.cit., pp. 34-39.
[83] Five-hospital group proposal, p. 7.

> that could result in lower procedure quality and worse outcomes for patients with coronary artery disease."[84]

The criterion of a low use rate is intended to assist in the definition of a service being classified as tertiary by limiting the number of providers of a specialized, complicated service in the case where need is present, but low. This is not the case for PCI procedures, which are largely regulated because, as established in the clinical literature, clinical outcomes depend largely on a threshold PCI volume.

The number of annual PCI procedures is not a valid basis for determining whether PCI is a tertiary health service. A service can have high volumes and still constitute a "specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care."[85] The Department must evaluate all seven of the criteria in WAC 246-310-035(2) to determine whether a service meets the statutory definition; use rate alone is not sufficient to remove PCI from the list of tertiary health services. *The bottom line is patient safety: facilities and operators that have more experience performing PCI procedures are consistently associated with better patient outcomes.* PCI meets the definition of a tertiary health service and should be regulated to maintain provider quality of care and patient safety.

G. Washington Administrative Code 246-310-035(2)(c). Whether the service is characterized by relatively few providers.

1. The Number of PCI Providers Is As Expected In Comparison With Other Providers of Tertiary Health Services.

The primary argument made by the 5-hospital group regarding this tertiary service criterion is the following:

> [e]lective PCI is not characterized as having few providers – 1 out of every 3 hospitals performs PCIs, and if critical access hospitals are excluded from the count, virtually 100% of hospitals are performing PCI.[86]

However, this argument proves to be faulty when a fair comparison with other listed tertiary health services is made. Using actual utilization experience provided in CHARS for 2013 and data from the 5-hospital group's proposal to compare the number of hospitals providing tertiary services, the facts show that PCI is not unique among services listed as tertiary. Please see Table 8 for a list of the number of hospitals that provide tertiary services.

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[84] Concannon et al., op. cit., Vol. 6 (2013), p. 406.
[85] RCW 70.38.025(14): definition of "tertiary health service."
[86] Five-hospital proposal, p. 5.

Table 8. Number of Providers by Tertiary Service, 2013

Tertiary Services	Metric	# of Hospitals Performing DRGs
Intermediate Care nursery or Level II OB*	MSDRGs: 791, 792, 793, 794 (Newborn DRGs)	61
Neonatal Intensive Care and/or OB Level III*	MSDRGs: 789, 790 (newborn DRGs)	52
Percutaneous Coronary Intervention**	COAP Non-Acute	34
Open Heart Surgery*	MSDRGs: 216-221, 228-236	20
Transplantation of Solid Organs (bone marrow)	MSDRGs: 014, 016, 017	7
Transplantation of Solid Organs (heart)	MSDRGs: 001, 002	7
Transplantation of Solid Organs (kidney)	MSDRG: 652	5
Specialty Burn Services*	MSDRGs: 927-929, 933-935	4
Inpatient Rehabilitation Level I**	50% of Rehab Discharges for Level I adult trauma facilities	4
Transplantation of Solid Organs (liver/intestine)	MSDRGs: 005, 006	3
Transplantation of Solid Organs (kidney/pancreas)	MSDRG: 008	3
Transplantation of Solid Organs (pancreas)	MSDRG: 010	2
Transplantation of Solid Organs (lung)	MSDRG: 007	1

*Number of Hospitals with greater than or equal to five discharges

**Taken from Table 1 in the 5-Hospital Group's Proposal

***Based on utilization by both Washington State and out-of-state residents of all ages.

Source: CHARS 2013; Five-hospital group proposal, p. 8, Table 1: "Tertiary Service Discharges, 2013 for WA State Residents."

As shown in Table 8 above, PCI is not unique among the set of tertiary services in terms of the number of providers performing the service.

As demonstrated in the table, there are other tertiary services for which there are more providers than is the case with PCIs. This alone is evidence that the number of providers does not necessitate removal of PCI from the list of tertiary health services. Instead, the number of providers for any particular service is just one method of evaluating a healthcare service to determine if it is a tertiary health service, but it is by no means the only, or most important, factor.

2. Emergent PCIs Are Not Regulated Because They Save Lives.

The 5-hospital group also argues against the practice of allowing hospitals to perform emergent PCIs, but restricting said hospitals from performing elective PCIs without CON approval. The group ignores the fact that the fundamental difference between emergent PCIs and elective PCIs is that emergent PCIs are intended to save lives, which logically should have different standards than PCIs performed on an elective basis.

The 5-hospital group further opines that the difference in emergent and elective PCIs is sufficient justification to remove all PCI procedures from CON regulation, going so far as to state the DOH "should be encouraging the providers with emergency programs to add elective capabilities, thereby increasing their ability to sustain these important safety net programs."[87] Aside from being a wholly unrelated and inadequate argument for removing PCIs from the tertiary health service definition, this claim is simply false. As discussed above, research has

[87] Five-hospital proposal, p. 6.

shown that a lack of regulation of PCI programs results in higher numbers of providers and lower quality of patient care.[88]

Numerous clinical studies have found an overall increase in PCI programs across the U.S. in the past decade, yet this has not resulted in improved patient access. Between 2004 and 2008, the Concannon et.al. study, published in 2013 and discussed above, found a 16.5% increase in PCI programs in the U.S., with an increase in patient access of only 1.8%.[89] Further, this study found:

> New PCI programs were more likely to be introduced in areas that already had a PCI program with more competition for market share, near populations with higher rates of private insurance, ***in states that had weak or no regulation of new cardiac catheterization laboratories and in wealthier and larger hospitals.***[90]

PCI is characterized by a comparatively high number of programs across the United States. However, this large, and increasing, number of PCI programs has not improved access: in general, new program development is not driven by patient need, but rather market presence. This is directly contrary to the argument made by the 5-hospital group that its "hospitals are the safety net for both EMS and the community for emergency PCI."[91] In fact, all but one of the five hospitals proposing to remove elective PCI from the list of tertiary health services are located in urban areas, and are relatively large hospitals.

The criterion relating to the number of providers is intended to assist in the definition of a service being classified as tertiary because fewer providers generally implies a more specialized, complicated service; patient need is present in these cases, but low. This is not the case for PCI, which is largely regulated because improved clinical outcomes are positively associated with patient volumes. Furthermore, as discussed above, the 2013 ACCF/AHA/SCAI Clinical Competence Statement concluded that there *is* a volume-quality relationship at institutions performing less than 200 PCIs annually. There is a strong empirical basis for threshold, or minimum necessary, PCI volumes.

In summary, whether a service is deemed to be tertiary should not be wholly based on the number of current providers. This is due to the fact that a service can have any number of providers and still constitute "a specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care."[92] The Department must evaluate all seven of the criteria in WAC 246-310-035(2) to determine whether a service meets the governing statutory definition. The number of providers is not itself sufficient to remove PCI from the list of tertiary health services.

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[88] Concannon et al. op. cit., Vol. 6 (2013).
[89] Ibid.
[90] Ibid. p. 400 *(emphasis added).*
[91] Five-hospital proposal, p. 6.
[92] RCW 70.38.025(14): definition of "tertiary health service."

APPENDIX 1:

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CLINICAL COMPETENCE STATEMENT

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

A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures)

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

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Preamble

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

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

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

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

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

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

1. Introduction

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

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

1.1. Document Development Process

1.1.1. Writing Committee Organization

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

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

1.1.2. Document Development and Approval

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

1.2. Purpose of This Document

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

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

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

2. Percutaneous Coronary Interventions

2.1. Evolution of Competence and Training Standards

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

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

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

2.2. Evolution of Coronary Interventional Capabilities

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

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

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

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

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

2.3. Procedural Success and Complications of Coronary Interventional Procedures

2.3.1. PCI Success

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

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

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

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

2.3.2. PCI Complications

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

2.4. Patient and Lesion Variables Influencing Success and Complication Rates

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

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

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Table 1. The NCDR® CathPCI Risk Score System

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

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

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

Table 2. The SCAI Lesion Classification System

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

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

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

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

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

2.5. Institutional Characteristics Related to Procedural Success and Complication Rates

2.5.1. Impact of the Facility on Procedural Success

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

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

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

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

2.6. Strategies for Risk Stratification and Operator Evaluation

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

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

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

2.7. Components of Operator Competence

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

2.7.1. ABIM Certification

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

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

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

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Table 3. Core Competency Components for Percutaneous Coronary Interventions

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

Continued on the next page

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

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Table 3. Continued

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

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

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

2.8.1. Evidence Reviewed

SEARCH STRATEGY

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

2.8.1.1. RELATIONSHIP OF INSTITUTIONAL VOLUME TO PROCEDURAL OUTCOME

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

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

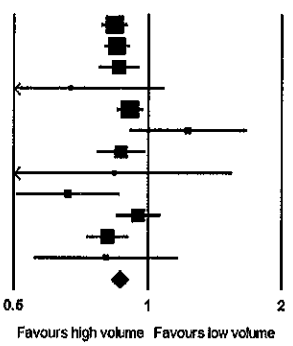
A recent meta-analysis examined the relation between volume and outcome of PCI in 10 reports between 1995 and 2003 from an original pool of 140 papers (82). Of those, 8 studies were conducted in the United States and 7 used high-quality clinical data. The final meta-analysis included 1,322,342 patients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

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

2.8.1.2. RELATIONSHIP OF INDIVIDUAL OPERATOR VOLUME TO PROCEDURAL OUTCOME

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

Model	Study name	Mean study year	Odds ratio	Lower limit	Upper limit
	Ho[4]	1986	0.840	0.787	0.897
	Ho[4]	1990	0.850	0.797	0.907
	Hannan *et al.*[23]	1993	0.860	0.775	0.954
	Vakili *et al.*[15]	1995	0.670	0.414	1.084
	Ho[4]	1995	0.910	0.852	0.972
	Kimmel *et al.*[13]	1995	1.230	0.910	1.662
	Canto *et al.*[12a]	1996	0.870	0.767	0.986
	Tsuchihashi *et al.*[10]	1997	0.840	0.456	1.547
	Hannan *et al.*[24]	1999	0.660	0.505	0.862
	Carey *et al.*[14a]	2000	0.950	0.849	1.063
	Allareddy *et al.*[22]	2002	0.813	0.731	0.904
	Shirashi *et al.*[11]	2003	0.807	0.557	1.169
Random			0.865	0.827	0.905



[a]Unpublished results.

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

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

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

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

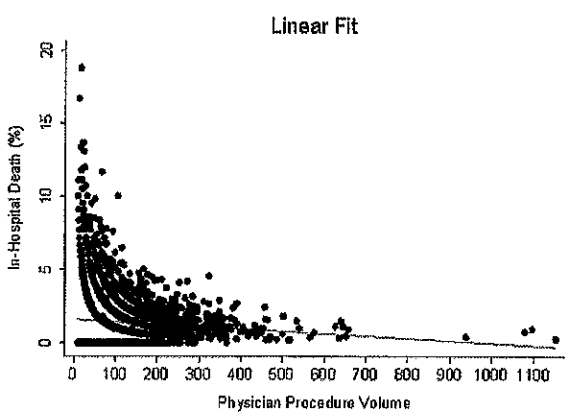

Figure 2. Scatter Plot of PCI Volume Versus In-Hospital Mortality

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.8.1.4.1. THE SAFETY OF PCI WITHOUT ONSITE CARDIAC SURGERY

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

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

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

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

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

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

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

2.8.1.4.3. VOLUME–OUTCOME RELATIONSHIP AT FACILITIES WITHOUT ONSITE SURGERY

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

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

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

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

2.8.1.6. LIMITATIONS OF THE EXISTING EVIDENCE

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

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

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

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

2.8.2. Volume as a Surrogate for Quality

2.8.2.1. PLAUSIBLE EXPLANATIONS FOR THE VOLUME–OUTCOME RELATIONSHIP

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

2.8.2.2. LIFETIME PCI EXPERIENCE RELATIONSHIP TO QUALITY

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

Table 4. Possible Predictors of Clinical Outcomes Following PCI

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

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

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2.8.2.3. CAUTION AGAINST PREOCCUPATION WITH SPECIFIC VOLUME RECOMMENDATIONS

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

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

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

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

2.8.3. Conclusions

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

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

2.9. Radial Access

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

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

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

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

2.9.1. Training

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

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

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

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	Total	Radial (n/N [%])	Femoral (n/N [%])	OR (95% CI)	p value	p value heterogeneity
Non-CABG major bleeds						
Pre-RIVAL	3946	4/1967 (0·2)	23/1979 (1·2)	0·25 (0·12–0·52)	0·0003	
RIVAL	7021	24/3507 (0·7)	33/3514 (0·9)	0·73 (0·43–1·23)	0·23	0·40
Combined	10967	28/5474 (0·5)	56/5493 (1·0)	0·51 (0·33–0·79)	0·002	
Non-CABG transfusion						
Pre-RIVAL	3841	4/1917 (0·2)	22/1924 (1·1)	0·25 (0·12–0·54)	0·0004	
RIVAL	7021	39/3507 (1·1)	45/3514 (1·3)	0·87 (0·56–1·33)	0·52	0·19
Combined	10862	43/5424 (0·8)	67/5438 (1·2)	0·65 (0·44–0·94)	0·023	
Major vascular access complication						
Pre-RIVAL	6772	21/3269 (0·6)	86/3503 (2·5)	0·28 (0·19–0·42)	<0·0001	
RIVAL	7021	49/3507 (1·4)	131/3514 (3·7)	0·39 (0·29–0·53)	<0·0001	0·41
Combined	13793	70/6776 (1·0)	217/7017 (3·1)	0·35 (0·28–0·44)	<0·0001	
Death, MI, or stroke						
Pre-RIVAL	5466	66/2905 (2·3)	84/2561 (3·3)	0·71 (0·51–0·99)	0·041	
RIVAL	7021	112/3507 (3·2)	114/3514 (3·2)	0·98 (0·75–1·28)	0·90	0·72
Combined	12487	178/6412 (2·8)	195/6075 (3·3)	0·87 (0·70–1·06)	0·170	
Death, MI, or stroke (radial experts)*						
Pre-RIVAL	4087	61/2217 (2·8)	76/1870 (4·1)	0·72 (0·51–1·01)	0·059	
RIVAL	2255	15/1129 (1·3)	30/1126 (2·7)	0·51 (0·28–0·91)	0·023	0·67
Combined	6342	76/3346 (2·3)	106/2996 (3·5)	0·66 (0·49–0·88)	0·005	
Death						
Pre-RIVAL	3830	29/2090 (1·4)	37/1740 (2·1)	0·73 (0·45–1·20)	0·21	
RIVAL	7021	44/3507 (1·3)	51/3514 (1·5)	0·86 (0·58–1·29)	0·48	0·92
Combined	10851	73/5540 (1·3)	88/5208 (1·7)	0·81 (0·59–1·10)	0·18	
MI						
Pre-RIVAL	3582	39/1958 (2·0)	47/1624 (2·9)	0·74 (0·48–1·14)	0·18	
RIVAL	7021	60/3507 (1·7)	65/3514 (1·8)	0·92 (0·65–1·32)	0·66	0·52
Combined	10603	99/5465 (1·8)	112/5138 (2·2)	0·85 (0·64–1·11)	0·23	
Stroke						
Pre-RIVAL	3559	2/1940 (0·1)	7/1619 (0·4)	0·31 (0·08–1·15)	0·08	
RIVAL	7021	20/3507 (0·6)	14/3514 (0·4)	1·43 (0·73–2·80)	0·30	0·31
Combined	10580	22/5447 (0·4)	21/5133 (0·4)	1·04 (0·57–1·89)	0·90	

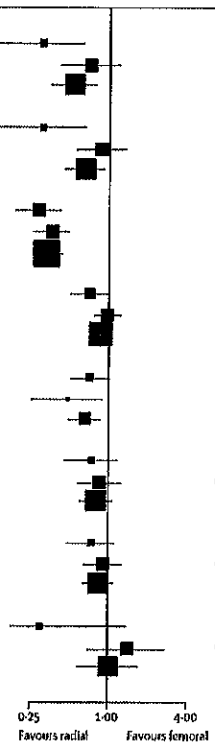

Figure 3. Forest Plot of the Updated Meta-Analysis (RIVAL Trial)

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

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

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

2.9.2. Competency

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

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

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

2.10. Quality Assurance

2.10.1. Definition of Quality in PCI

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

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

2.10.2. Institutional Requirement for a Quality Assurance Program

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

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

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

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

2.10.3. Complexity of Determination of PCI Quality

2.10.3.1. IDENTIFICATION OF PCI QUALITY INDICATORS

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

Table 5. PCI Outcomes and Adverse Events

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

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

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

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

2.10.3.2. ROLE OF RISK ADJUSTMENT IN ASSESSING QUALITY

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

2.10.3.3. NATIONAL BENCHMARKING

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

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

2.10.3.4. OTHER CHALLENGES IN DETERMINING QUALITY

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

2.10.4. Requirement for Institutional Resources and Support

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

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

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

2.10.5. Quality Assessment and Implementation Processes

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

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

2.10.5.1. THE PEER REVIEW PROCESS

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

2.10.5.2. METHODS OF REMEDIATION

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

2.10.5.3. CONFIDENTIALITY

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

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2.10.6. Conclusions

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

2.11. Summary of Key Recommendations for PCI

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

***Physical Facility Requirements*:**

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

***Institutional Requirements*:**

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

Components of Operator Competence (*see Section 2.7*)

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

Maintenance of Quality

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

- Full-service laboratories (both primary and elective PCI, with and without onsite cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should close.

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

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

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competence, including lifetime experience, institutional volume, individual operator's other cardiovascular interventions, and quality assessment of the operator's ongoing performance.

- Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.
- Facilities should develop internal review processes to assess operators <50 PCIs annually.
- Additional emphasis on educational symposiums, CME credits, and simulation courses may provide other venues to enhance quality for all operators.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.
- Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible to take the ABIM certification and recertification exams.

Primary PCI (see Section 2.8.1.3)

- Primary PCI for STEMI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.

Quality Assurance

Institutional Requirements (see Section 2.10.2)

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

Institutional Resources and Support (see Section 2.10.4)

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

National Benchmarking (see Sections 2.8.2.3 and 2.10.3.3)

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

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

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

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

3. Other Coronary Interventions

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

3.1. Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy

3.1.1. Background

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

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

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

3.1.2. Criteria for Competency

3.1.2.1. OPERATOR COMPETENCY

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

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

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

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

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

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

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

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

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

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

3.1.2.2. STAFF COMPETENCY

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

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3.2. Alcohol Ablation for Ventricular Arrhythmias

3.2.1. Background

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

3.2.2. Criteria for Competency

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

3.3. Coronary Artery Fistula Closure

3.3.1. Background

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

3.3.2. Criteria for Competency

3.3.2.1. OPERATOR COMPETENCY

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

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

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

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

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

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

3.3.2.2. STAFF COMPETENCY

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

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

Multidisciplinary Approach

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

Institutional Requirements

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

Operator Competence

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

The Critical Importance of the Quality Assurance Program

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

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

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APPENDIX 1. 2013 ACCF/AHA/SCAI CLINICAL COMPETENCE STATEMENT ON CORONARY ARTERY INTERVENTIONAL PROCEDURES (REVISION OF 2007 STATEMENT)—AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Thomas M. Bashore	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None
Theodore A. Bass	University of Florida Shands Jacksonville Cardiovascular Center—Professor of Medicine; Chief Cardiology Division	• Daiichi Sankyo-Lilly†	None	None	None	None	None
Ralph G. Brindis	University of California, San Francisco—Clinical Professor of Medicine	None	None	None	None	None	None
John E. Brush, Jr.	Eastern Virginia Medical School; Sentara Cardiology Specialists, Sentara Healthcare—Professor of Medicine	• United Healthcare Scientific Advisory Board	None	None	None	None	None
James A. Burke	Lehigh Valley Heart Network—Associate Chief of Cardiology	None	None	None	None	None	None
Gregory J. Dehmer	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	• Direct Flow Medical	None	None
Yuri A. Deychak	Johns Hopkins Community Physicians Heartcare—Cardiologist	None	None	None	None	None	None
John G. Harold	Cedars-Sinai Heart Institute—Attending Physician; Cedars-Sinai Medical Center and David Geffen School of Medicine at UCLA—Clinical Professor of Medicine	None	None	None	None	None	None
Hani Jneid	Baylor College of Medicine and the MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
James G. Jollis	Duke University Medical Center—Associate Professor of Medicine	None	None	None	• Medtronic Foundation† • Sanofi-Aventis†	None	None
Joel S. Landzberg	Hackensack University Medical Center—Clinical Associate Professor of Medicine	None	None	None	• Boehringer Ingelheim, RELY, RELYABLE studies—PI • Roche, dal-OUTCOMES studies—PI	None	None
Glenn N. Levine	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
James B. McClurken	Temple University Hospital Department of Cardiothoracic Surgery—	None	None	None	None	None	None
John C. Messenger	University of Colorado— Director, Cardiac Cath Lab; Associate Professor of Medicine	None	None	None	• Medtronic*	None	None
Issam D. Moussa	Mayo Clinic, Florida—Professor and Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None
J. Brent Muhlestein	Intermountain Medical Center—Professor of Medicine	None	• Bristol-Myers Squibb • Daiichi-Sankyo • Forest • Gilead • Lilly • Merck • Sanofi-Aventis	None	• Glaxo	None	None
Richard M. Pomerantz	St. Agnes Hospital—Chairman, Department of Medicine	None	None	None	None	None	None

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

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PI indicates principal investigator.

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

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

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Jean-Francois Tanguay	Official Reviewer—ACCF Board of Governors	Institut de Cardiologie de Montreal—Director, Coronary Unit	None	None	None	None	• Abbott Vascular† • Astra Zeneca† • Eli Lilly† • Merck Canada† • Servier†	None
Andrew Wang	Official Reviewer—ACCF Task Force on Clinical Competence and Training Statements	Duke University Medical Center Division of Cardiovascular Medicine—Associate Professor of Medicine	None	None	None	• Abbott Vascular† • Edwards Lifesciences† • Gilead Sciences†	None	None
H. Vernon Anderson	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Cardiology Division—Professor of Medicine	• Symbios Clinical Research	None	None	None	• Eli Lilly	None
Eric R. Bates	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • Bristol-Myers Squibb • Daiichi-Sankyo • Eli Lilly • Merck • Sanofi-Aventis	None	None	None	None	None
James C. Blankenship	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	Geisinger Medical Center—Director, Cardiac Catheterization Lab	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering-Plough* • The Medicines Company* • Volcano Corporation*	None	None
Emmanouil S. Brilakis	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Southwestern Medical School—Director, Cardiac Catheterization Lab, VA North Texas Healthcare System	• Bridgepoint Medical • HMP Communications • St. Jude† • Terumo	None	None	None	Medtronic†	• Defendant, review of case of left main disease, 2011
John G. Byrne	Content Reviewer—ACCF Surgeon Scientific Council	Vanderbilt University Medical Center—Chair, Department of Cardiac Surgery	None	None	None	None	None	• Defendant, cardiac surgery, 2010
T. Bruce Ferguson, Jr.	Content Reviewer—ACCF Surgeon Scientific Council	East Carolina Heart Institute Brody School of Medicine—Professor of Surgery and Physiology	None	None	None	• Novadaq Technologies, Inc.†	• Edwards Laboratories	None
Kirk N. Garratt	Content Reviewer—ACCF NCDR CathPCI Research and Publications Subcommittee	Lenox Hill Hospital—Associate Professor of Medicine	• Abbott Vascular • Boston Scientific • Daiichi-Sankyo-Lilly† • The Medicines Company	• Abbott Vascular • Boston Scientific • Medtronic • The Medicines Company	None	None	None	• Defendant, blood pressure management and elective angiography, 2008 • Defendant, radial access for angioplasty, 2006 • Defendant, indication for bypass surgery, 2005
Lloyd W. Klein	Content Reviewer—ACCF Interventional Scientific Council	Rush University Medical Center—Professor of Medicine	None	None	None	None	None	None

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

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John F. Robb	Official Reviewer—ACCF Board of Governors	Dartmouth-Hitchcock Medical Center—Director, Interventional Cardiology	None	None	None	• Edwards LifeSciences, Partner 2—PI*		None
Robert A. Shor	Official Reviewer—ACCF Board of Governors	The Cardiovascular Group, PC—Cardiologist	None	None	None	None	None	None
John W. Shuck	Official Reviewer—ACCF Board of Governors	Cardiology Consultants—Cardiologist	None	None	None	None	None	None
George L. Smith	Official Reviewer—ACCF Board of Governors	Northern California Medical Associates—Cardiologist	None	None	None	None	None	None
Carl L. Tommaso	Content Reviewer—ACCF/AHA PCI Performance Measures	Northshore Medical System	None	None	None	None	None	• Defendant, retained wire, 2006
E. Murat Tuzcu	Content Reviewer—ACCF Interventional Scientific Council	Cleveland Clinic Foundation—Professor of Medicine	None	None	None	• Edwards Lifesciences*	None	None
Robert C. Welsh	Official Reviewer—ACCF Board of Governors	University of Alberta and Mazankowski Alberta Heart Institute—Associate Professor; Director, Adult Cardiac Catheterization and Interventional Cardiology	• AstraZeneca • Bayer • Boehringer Ingelheim • Edwards Lifesciences • Eli Lilly • Medtronic • Servier	None	None	• Abiomed	None	None

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

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APPENDIX 3. ACRONYMS AND ABBREVIATIONS LIST

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

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APPENDIX 1b

2. Dehmer, et al., SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup, Circulation, Vol. 129, Issue 24 (2014).

SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

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Introduction

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

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

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

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

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[5] New York Presbyterian Hospital, New York, NY. SCAI Writing Committee Member
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[7] Detroit Medical Center, Detroit, MI. SCAI Writing Committee Member
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Authors' conflict of interest is available in Appendix 1. Peer reviewers' conflict of interest is available in Appendix 2.

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(*Circulation*. 2014;129:2610-2626.)

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related to PCI without on-site surgery and summarize all relevant information into a single resource document;
4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

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

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states.

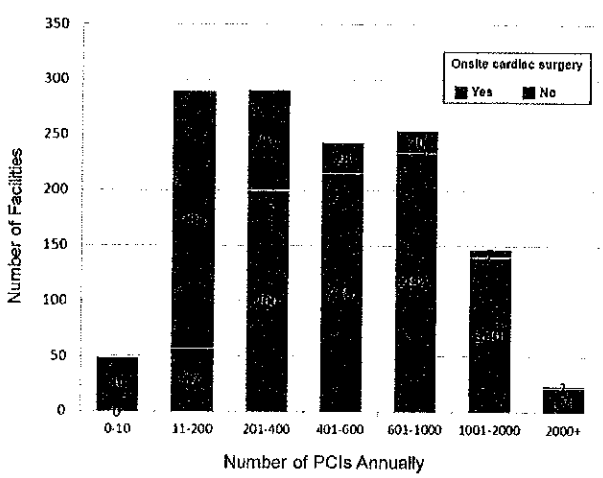

Figure 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref 8 with permission.)

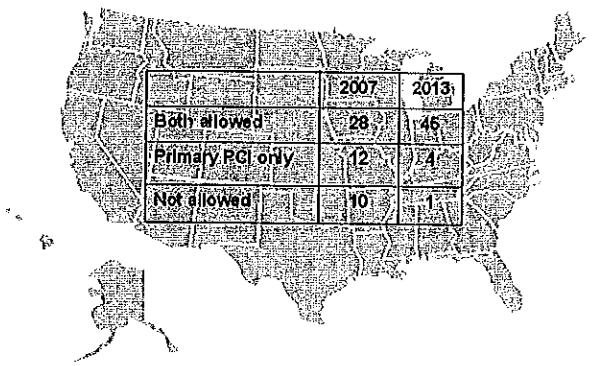

Figure 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial.[9] Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being reevaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration.[10]

Recent Literature on PCI Without On-site Surgery

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

Primary PCI without on-site surgery

Seven studies and 2 meta-analyses of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table 1). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79).[20]

PCI without on-site surgery for conditions other than STEMI

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

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000

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

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

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

patients in a 1:3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively.[9] High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($P = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($P = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals.[11] The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P<0.001$ for noninferiority) and 17.3% and 17.8%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P<0.001$ for noninferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

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

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without

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

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

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

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

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

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

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery.[2] Primary PCI was assigned a class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a class IIb recommendation. Elective PCI, previously assigned a class III recommendation, was given a class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical

backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document.[1] New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document.[4] In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery.[26]

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

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

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

In addition to defining numerous requirements for operator competency, new operator, and facility PCI volume requirements were established.[4] Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually [averaged over 2 years], including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

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

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

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

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

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

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary

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

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand (CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries.[31–39] Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011.[32] CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

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

Mission Lifeline

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

Door-to-Balloon Alliance

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

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population (≥18 years of age) who lived within 60 min of a PCI hospital.[46] An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to

only 79.9%, with the median driving time reduced by <1 min to 10.5 min.[47] Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population.[48] Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access.[49] In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment.[50,51] The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain. This can be an additional financial motivator for developing PCI facilities.[52] How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely.[53,54] However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transferring patients to tertiary hospitals.

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

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined.[55] Despite this, they found no evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality.[56,57] Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service.[52,58] Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy.[59–63] Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective.[64] Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study.[65] In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI.[4] The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be consistently associated with worse outcomes. Primary PCI volume ≤ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR.[66] The cutoff points of <200 total PCIs annually and ≤36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤200 total PCIs annually and 38% performed ≤36 primary PCIs annually.[8,66] Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies.[4] Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

Recommendations

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

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document[4] (Table 3).

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

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in ≤30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery.* Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral.*	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data [via T-1 transmission line] as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required.* Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table 5).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories [both primary and elective PCI, with and without on-site cardiac surgery] performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including: • Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes. • A process for prehospital identification and activation. • Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center. • A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers. • Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	2009 PCI-GL 2011 PCI-GL ML D2B
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML

(*Continued*)

Table 3. Continued

General Recommendations	Source
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis: a. Door-to-first device time, nontransfer patients b. STEMI Referral Hospital ED door-to-balloon [first device used] time c. First medical contact to balloon inflation [first device used] time, nontransfer patients d. First medical contact to balloon inflation [first device used] time, transfer patients e. Proportion of eligible patients receiving reperfusion therapy f. Proportion of eligible patients administered guideline-based class I therapies g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who i. do not undergo acute catheterization because of misdiagnosis ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h h. In-hospital mortality	ML

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

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

Italics font: New or modified recommendation in the document.

Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued

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

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

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

Italics font: New or modified recommendation in the document.

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

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

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

Italics font: New or modified recommendation in the document.

operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.[46–49] If the transfer time is ≤30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been

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

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

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

Italics font: New or modified recommendation in the document.

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

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistical certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized.[67,68] Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence [ACE] are recommended as resources for improving quality.[69,70]

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually (Table 4). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

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

The Delivery of PCI Services in the Future

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

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KEY WORDS: AHA Scientific Statements ■ angioplasty ■ coronary artery bypass surgery ■ consensus

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

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

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

*No financial benefit.

†Significant relationship.

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

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

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

(Continued)

Appendix 2. Continued

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

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

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

*Significant relationship.

†No financial benefit.

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

APPENDIX 1c

3. Baron, et al., The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes, Circulation, Vol. 130, Issue 16 (2014).

Editorial

The Challenges of Success

Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes

Suzanne J. Baron, MD, MSc; Robert W. Yeh, MD, MSc; David J. Cohen MD, MSc

Over the past several decades, major changes in lifestyle, preventive care, and clinical management have contributed to an impressive reduction in coronary artery disease prevalence, incident acute myocardial infarction, and deaths due to coronary heart disease.[1–3] As a result, the use of cardiovascular services in the United States has decreased dramatically in recent years. For patients with coronary artery disease, advances in medical management have allowed more and more patients to avoid elective catheterization procedures, whereas the results of recent studies (eg, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation [COURAGE],[4] Fractional Flow Reserve versus Angiography for Multivessel Evaluation [FAME],[5] and Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery [SYNTAX][6]) have led to the more judicious use of percutaneous coronary intervention (PCI) in patients with chronic coronary artery disease. The combined effect of these trends has been a marked reduction in overall PCI volumes,[7] from a peak of nearly 1 million in the United States in 2006 to ≈600 000 in recent years.[8] At the same time as overall PCI volumes have been decreasing, the number of PCI centers has been increasing as data have emerged indicating that the absence of on-site cardiac surgery does not adversely impact patient outcomes after either emergent or elective PCI.[9,10] Together, declining PCI volumes and the increasing number of PCI centers has led to a decrease in the volume of PCI procedures at both the center and operator level.[11]

Articles see p 1383 and p 1392

Common sense dictates that any skill requires adequate experience to ensure optimal results. This holds true for airline pilots, hairdressers, and physicians alike. What differs among the professions is what qualifies as adequate experience. In his book *Outliers*, Malcolm Gladwell describes the "10 000 hour rule," in which he posits that it takes 10 000 hours of practice to become a master of any skill.[12] The same principle likely holds true in interventional cardiology, because much research demonstrates a positive association between volume of procedures performed and good patient outcomes.[13–16] As a result, minimum volume standards for those physicians performing PCI have been established by multiple professional societies. The 2011 American College of Cardiology Foundation/ American Heart Association/ Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) clinical competence statement on PCI recommended that PCIs be performed only by operators with an annual volume of >75 procedures at hospitals with an annual volume of >400 procedures.[17] In the face of decreasing PCI volumes, however, the 2013 ACCF/AHA/SCAI guidelines were revised and now recommend that PCIs should be performed by operators with an annual volume of >50 procedures averaged over a 2-year period. Despite the wealth of data on the PCI volume-outcome relationship, there are few definitive data on what the threshold for too little volume should be. Consequently, the 2013 ACCF/AHA/SCAI recommendations regarding minimum PCI volumes were based mostly on expert opinion rather than on solid evidence.

In this issue of *Circulation*, Badheka and colleagues add the largest and most contemporary study to the body of literature regarding the PCI volume-outcome relationship.[18] In this study, they analyzed data on PCI outcomes derived from the National Inpatient Sample database between the years of 2005 and 2009. By using *International Classification of Diseases, 9th Revision, Clinical Modification* codes, PCI procedures and procedure-related complications were identified and linked to a unique operator identifying number. After restricting the sample to those patients without missing data, a total of 457 498 patients were identified. Using hierarchical mixed-effects models to take into account the effect of clustering within institutions, and geographic region, as well, they identified a clear and robust relationship between institutional and operator PCI volume and in-hospital outcomes, including mortality and periprocedural complications. Spline analyses suggested that the probability of in-hospital mortality and periprocedural complications was minimized at ≈300 PCIs performed per year by an individual operator. Interestingly, they also observed an inverse relationship between operator volume and hospital length of stay and costs (which were estimated from hospital billing data).

Although the findings described by Badheka and colleagues are consistent with many previous studies, their study is not without limitations. First and foremost, the National Inpatient Sample is based entirely on administrative claims data as opposed to clinical data, which are available in other large data sets such as the New York State PCI Registry or the

The opinions in this article are not necessarily those of the editors or of the American Heart Association.

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NCDR CathPCI Registry. The absence of clinical and procedural data limits the researchers' ability to adjust for a range of technical factors (eg, patient acuity, lesion complexity, etc) that may influence procedural outcomes. Second, the National Inpatient Sample only collects data on inpatient procedures. As such, any outpatient procedures performed by operators are not included in their calculated procedure volumes, making it difficult to know which operators were truly high versus low volume. The distinction between high- and low-volume operators is made even less reliable when one considers the sampling scheme that underlies the National Inpatient Sample database, and the fact, as well, that nearly half the procedures were excluded from the analysis because of a missing unique operator identifying number.

Notwithstanding these limitations, the general finding of the study—that low-volume operators and institutions are associated with poorer PCI outcomes—is consistent with previous literature.[13,14,16,19] One of the more sobering, albeit subtle, findings from this study was that the median operator PCI volume was 75 cases per year, with a substantial fraction of operators falling below 50 PCIs per year, a level that barely meets current ACCF/AHA/SCAI recommendations. Although these numbers may have underestimated true operator volume by excluding outpatient procedures as noted above, they nonetheless fall far below the optimal threshold of ≈300 per year identified in their study. As such, the trend of declining PCI volumes coupled with a clearly defined volume-outcome relationship could spell trouble for PCI patients in the years to come.

In addition to the overall decrease in the number of PCI procedures, one of the key factors leading to the recent decline in operator and institutional PCI volumes has been the proliferation of catheterization laboratories and PCI programs across the country. In some cases, there has been a genuine need for new programs to provide greater availability of primary PCI services in rural and otherwise underserved regions.[20] In many cases, however, the motivation has been financial with hospitals and health systems seeking to take advantage of the favorable reimbursement for PCI or to add to their cachet as a cardiac or chest pain center. In recent years, this proliferation has been aided, in part, by data suggesting that PCI can be performed safely without on-site cardiac surgery.[9,10] Given the aforementioned association between PCI volume and outcomes, the net effect of any such growth is likely to represent a complex balance between improved access and decreasing procedural volumes (both for hospitals and operators).

In this issue of *Circulation*, Maddox and colleagues have performed one of the first studies to systematically examine the effect of increasing access to PCI on clinical outcomes.[21] Using data from the Veterans Affairs (VA) Clinical Assessment, Reporting and Tracking program, a clinical database linked to a variety of administrative databases maintained by the VA system, they examined in-hospital and 1-year clinical outcomes among ≈24 000 patients undergoing PCI at VA facilities with and without on-site cardiac surgery. In a series of carefully constructed analyses, Maddox and colleagues found no significant differences in 1-year clinical outcomes between patients who received PCI at a VA site with on-site cardiac surgery versus a site without on-site cardiac surgery. Moreover, by using geospatial mapping, they found that the availability of PCI centers without on-site cardiac surgery reduced median patient drive time by nearly 90 minutes among patients treated at those facilities. On the basis of these findings, they concluded that, within the VA healthcare system, expanding PCI programs to include facilities without on-site cardiac surgery improved patient access to PCI without compromising clinical outcomes.

The results of this study are both reassuring and concerning at the same time. On the one hand, it is comforting to see that within the VA system, the expansion of PCI facilities has led to enhanced access to services without any detectable compromise in quality. What is disturbing, however, is the fact that the VA experience is unlikely to be generalizable to the United States as a whole. Because the VA is a single payer integrated healthcare delivery system in which patients do not often leave the system for care, the decision to offer PCI programs at facilities without on-site cardiac surgery within the VA system was made in a systematic and organized fashion. Sites for PCI expansion were likely to have been carefully selected so that patient access was maximized. Furthermore, the Clinical Assessment, Reporting and Tracking Program was established concurrently with PCI program expansion to ensure high-quality care. By collecting real-time data on catheterization laboratory procedures, complications, and outcomes, the Clinical Assessment, Reporting and Tracking Program was able to use these data to provide formal site and operator review with the intention of identifying system problems early and addressing them as needed. Unfortunately, this type of quality control program does not commonly exist in health systems outside of the VA, meaning that system and quality issues are harder to diagnose and treat appropriately. Furthermore, there is no centralized body dictating how, where, and when PCI programs are opened at hospitals outside the VA system, with the predictable result that PCI program expansion generally occurs in a haphazard manner.

The question then arises as to the true benefits, risks, and costs of opening new PCI programs. Certainly, if new PCI facilities can improve access to life-saving care (eg, primary PCI) that patients would not be able to otherwise obtain, then the benefits are clear. Unfortunately, the reality is that most new catheterization laboratories in the United States have opened in areas that already have established PCI programs and therefore do not improve access in any meaningful way.[22,23] Without improving access to PCI, there really is no discernible benefit to society in continuing to develop new PCI centers. In fact, there is likely substantial societal cost, both monetarily (by duplication of services and increased capital expenditures) and clinically (if patient outcomes are compromised by diluting operator and hospital procedure volumes).

Society and the cardiology community are then left with the challenging task of balancing the competing priorities of increasing access to PCI while also maintaining a high-quality service. One approach to this dilemma would be to replicate the VA experience by centralizing decision making for developing and maintaining PCI programs. Certificate of Need regulations, designed to govern the introduction of new medical services to communities, are currently active in 26 states for cardiac catheterization laboratories.[24] Although

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these programs may lead to a more appropriate use of PCI,[25] they do not necessarily ensure PCI quality, and they may increase costs. Other, less explicit, approaches could also be considered, such as regionalized systems of PCI care (similar to regional ST-segment elevation myocardial infarction networks that have developed endogenously) or economic disincentives (by reducing payments for PCI services to the point where they no longer are viewed as profitable by some hospitals). Unfortunately, none of these methods are without substantial political and operational challenges, and an array of potential unintended consequence, as well.

Improvements in cardiovascular health have created new challenges in the delivery of PCI. A disjointed approach to health services delivery has led to excess PCI capacity and an abundance of low-volume proceduralists without improving access to care, the costs of which will ultimately be borne by patients. The precise solutions to these issues will and should be hotly debated, but are likely to involve a combination of contraction, redistribution, and central coordination. Whatever these solutions may be, they will require courageous leadership by an engaged cardiology community dedicated to the mission of offering PCI that is safe, effective, and accessible.

Disclosures

None.

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KEY WORDS: Editorials ■ cardiac volume ■ percutaneous coronary intervention ■ quality of health care

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The Challenges of Success: Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes

Suzanne J. Baron, Robert W. Yeh and David J. Cohen

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APPENDIX 1d

4. Concannon, et al., Evidence of Systematic Duplication by New Percutaneous Coronary Intervention Programs, Circulation: Cardiovascular Quality and Outcomes, Vol. 6, Issue 4 (2013).

Original Article

Evidence of Systematic Duplication by New Percutaneous Coronary Intervention Programs

Thomas W. Concannon, PhD; Jason Nelson, MPH; David M. Kent, MD; John L. Griffith, PhD

Background—Evidence suggests that recent and projected future investments in percutaneous coronary intervention (PCI) programs at US hospitals fail to increase access to timely reperfusion for patients with ST-segment elevation myocardial infarction.

Methods and Results—We set out to estimate the annual number and costs of new PCI programs in US hospitals from 2004 to 2008 and identify the characteristics of hospitals, neighborhoods, and states where new PCI programs have been introduced. We estimated a discrete-time hazard model to measure the influence of these characteristics on the decision of a hospital to introduce a new PCI program. In 2008, 1739 US hospitals were capable of performing PCI, a relative increase of 16.5% (251 hospitals) over 2004. The percentage of the US population with projected access to timely PCI grew by 1.8%. New PCI programs were more likely to be introduced in areas that already had a PCI program with more competition for market share, near populations with higher rates of private insurance, in states that had weak or no regulation of new cardiac catheterization laboratories, and in wealthier and larger hospitals.

Conclusions—Our data show that new PCI programs were systematically duplicative of existing programs and did not help patients gain access to timely PCI. The total cost of recent US investments in new PCI programs is large and of questionable value for patients. (***Circ Cardiovasc Qual Outcomes*. 2013;06:400-408.**)

Key Words: angioplasty ■ catheterization ■ mapping ■ percutaneous coronary intervention ■ ST-segment elevation myocardial infarction

For patients with ST-segment elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI) improves survival and reduces serious complications[1] if it can be delivered with minimal reperfusion-related delay.[2,3] Although ≈80% of the US population lives within driving distance of timely PCI,[4] less than half of the patients with STEMI get access to PCI in an emergency.[5]

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There is widespread debate about the potential of voluntary STEMI regional plans to improve use of PCI among patients with STEMI,[6–11] and a variety of such voluntary agreements have been implemented and evaluated.[12–15] As a backdrop to regionalization, individual hospitals have acted unilaterally by introducing new PCI at a robust pace in every state since 2001. In recent work, we have shown that historical[4] and projected future[16] independent investments in new PCI programs do not help patients gain timely access to the procedure. Others have shown that emergent and elective use of PCI has remained flat since 2001,[17] suggesting that new programs are not helping to increase access to the procedure. This is the first analysis using longitudinal data to assess whether new PCI programs duplicate existing ones and identify the factors associated with the decision of a hospital to introduce a new PCI program.

Methods

In previous work, we validated use of American Hospital Association (AHA) Annual Survey data for use in creating annual inventories of the number of US hospitals that can perform PCI emergently.[4] For this analysis, we combined annual AHA survey data from 2004 through 2008 with 2000 Census data and with American Health Planning Association (AHPA) annual directories of State Certificate of Need Programs from 2004 to 2008 to (1) estimate change over time in the number of PCI programs offered by US hospitals, (2) estimate change over time in population access to timely PCI, and (3) assess the hospital-, neighborhood-, and state-level factors that are associated with the introduction of a PCI program where one did not exist before.

Study Data

To meet our inclusion criteria, a hospital had to provide acute care to the US adult (>18 years of age) population. Government facilities, hospital units within an institution, psychiatric and drug dependency hospitals, long-term care facilities, and children's hospitals were excluded from the analysis. We began our analysis in 2004 to coincide with the first year the AHA survey asked hospitals to specify if a laboratory was used for adult interventional care. Before 2004, hospitals were asked about ownership of cardiac catheterization laboratories of any type, not distinguishing interventional from diagnostic laboratories. We judged hospitals as having PCI capability before 2004 only if they reported both owning a catheterization laboratory and offering angioplasty as a service.

Hospital-level characteristics were collected from the AHA survey. Independent variables included measures of hospital size, inpatient

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WHAT IS KNOWN

- Hospital percutaneous coronary intervention programs have grown rapidly since 2001, without clear evidence of improved patient access to the procedure.

WHAT THE STUDY ADDS

- From 2004 to 2008, 251 new PCI programs added $2 to $4 billion in new costs to the US healthcare system without improving access to PCI.
- During this period, hospitals were more likely to adopt PCI if they were larger, they operated in more competitive markets, and PCI was already offered in the same market.
- Hospitals facing stronger Certificate of Need regulation were 40% less likely each year to adopt PCI.
- The methods of this study could be used to evaluate the drivers and outcomes of change in other medical technologies in US hospitals.

and outpatient volume, teaching status, accreditations, and ownership of other advanced medical technologies. Hospital size was measured by number of hospital beds, staffing (physician and dentist full-time equivalents), and expenditures (the sum of payroll and nonpayroll expenses excluding bad debt). Hospital volumes were measured with several variables, including the ratio of outpatient-to-inpatient revenue, total surgical operations, total emergency department visits, and total nonemergency outpatient visits. A hospital was considered a teaching hospital if it reported ≥1 of the following criteria: (1) residency training approval by Accreditation Council for Graduate Medical Education, (2) medical school affiliation reported to American Medical Association, and (3) membership on the Council of Teaching Hospitals of the Association of American Medical Colleges. We defined hospitals as meeting a high accreditation status if they met ≥3 of the following 4 accreditations: (1) Joint Commission on Accreditation of Healthcare Organizations (JCAHO), (2) Hospital-controlled professional nursing school reported by National League for Nursing, (3) Blue Cross contracting or participating, and (4) Medicare certification by the US Department of Health and Human Services. Hospitals were considered high tech if they reported ownership of ≥2 of the following technologies: (1) positron emission tomography, (2) multislice computed tomography, (3) single-photon emission computed tomography, and (4) radiation therapy. To further adjust for the effects of hospital size, several variables were standardized to 100 beds: total hospital expenditures, full-time equivalent physicians and dentists, total surgical operations, emergency room visits, and nonemergency outpatient visits. Several skewed variable distributions were transformed on the natural log scale.

Area and state characteristics were estimated by aggregating selected variables from the Census within uniquely estimated neighborhood boundaries for every hospital in the United States, as described below (Model 2). Census variables included area estimates of sex, age, race, income, and foreign birth. To facilitate comparison, these variables were standardized to a z-distribution; we report effects that are associated with 1 SD change in each of these demographic characteristics. State-by-state Certificate of Need (CON) policy data were collected from American Health Planning Association annual directories.[18] We specified states with no program as the reference category against states with programs that did not require review of catheterization laboratories (class 2) and states with programs that did require review of catheterization laboratories (class 3). The CON variable was allowed to vary over time and was lagged 2 years to account for time to develop a program and report its appearance to the AHA.

The competitive environment was estimated with 2 measures: a design variable to indicate the presence of another PCI laboratory in the neighborhood surrounding the hospital (duplication of PCI); and a modified Herfindahl–Hirschman Index, a measure combining the market shares of all the sellers in a marketplace (concentration of PCI).[19] We modeled Herfindahl–Hirschman Index as the sum of squares of the share of each hospital of the total adjusted average daily hospital census within a neighborhood.[20]

Model 1: The Number and Total Costs of New PCI Programs

We used AHA data to identify hospitals in all 50 states and the District of Columbia that were capable of performing emergent PCI each year from 2004 to 2008 (Table 1). All hospitals were uniquely identified through their AHA identification number and located within a geographic information system using latitude and longitude coordinates. Using longitudinal data, we identified new programs at individual hospitals. We imputed missing observations of PCI capability during the study period by carrying the last observation forward if PCI capability was in place at any time during 1994 to 2007 and by carrying the most recent observation backward if a hospital reported no PCI capability during 2004 to 2008. To track change over time in the number of PCI programs, we estimated both relative and absolute change in the number of new PCI programs for each year after 2004, taking into account hospitals that were lost to follow-up because of closures, mergers, and survey nonresponse.

We updated a previously developed framework for estimating the construction, medical equipment and operations, and costs of introducing a new PCI program[21] to 2008 US dollars, using the National Income and Product Accounts Gross Domestic Product deflator.[22] The introduction of a new PCI program may be made in hospitals with and without existing cardiac surgery programs, but access to onsite or nearby (via transfer) cardiac surgery backup is recommended or required in most places. Hospitals without onsite or nearby backup surgery may, therefore, have to invest in that service along with the opening of a new PCI program. To estimate lower and upper bounds for the cost of new PCI programs to the US healthcare system over our study period, we multiplied the unit cost for a new program developed with and without existing surgical backup.

Model 2: Access to PCI

To assess change in access to PCI, we estimated annual proportions of the population >18 years of age living within a 60-minute drive of every PCI hospital (Table 1). To do this, we followed methods described in previous work on drive times to US hospitals.[23–26] We defined a neighborhood specific to every hospital in the United States, defined as the area covered by a 60-minute drive time to the hospital from neighboring census tracts. Drive times were estimated using road network and speed limit data from Environmental Systems Research Institution, Inc's (ESRI) ArcGIS StreetMap data set with the Network Analyst extension.[27] Extra time was added to account for dispatch of the emergency medical services vehicle (1.4 minutes for urban and suburban tracts and 2.9 minutes for rural tracts), time from emegency medical services depot to scene (total time was multiplied by a constant of 1.6, 1.5, or 1.4 for urban, suburban, or rural tracts, respectively) and time spent on scene (13.5 minutes for urban and suburban tracts and 15.1 minutes for rural tracts). These constants were derived in a meta-analysis of empirically determined prehospital care times for trauma.[28]

The population of a census tract was considered to have access to PCI if its centroid, the geographic location that represents the mean center of a polygon, lay within the neighborhood boundary of the hospital. Populations in tracts covered by multiple hospitals were counted once to avoid duplication. We estimated annual and total change in the potential reach of PCI programs across the United States, the 4 Census Regions, 50 states, and the District of Columbia.

Model 3: Hospital-, Neighborhood-, and State-Level Factors Associated With New PCI Programs

To assess the hospital-, neighborhood-, and state-level factors that are associated with the decision to adopt PCI, we estimated a series

Table 1. Change in Number of and Access to PCI Programs (Models 1 and 2)

Region	Statistic	2004	2005	2006	2007	2008
U.S.	Eligible hospitals (N)	4544	4614	4675	4629	4686
	Hospitals with PCI (N)	1524	1603	1673	1697	1739
	Hospitals with PCI (%)	33.5	34.7	35.8	36.7	37.1
	Hospitals with new PCI (N)	---	84	69	52	46
	Annual growth (%)	---	5.5	4.3	3.1	2.7
	Total growth (%)	---	---	---	---	16.5
	Pop. within 1 hour drive to any hospital (%)	94.4	94.5	94.6	94.4	94.6
	Pop. within 1 hour drive to PCI hospital (%)	79.1	79.7	80.3	80.5	80.9
	Pop. with PCI as closest hospital within 1 hour drive (%)	52.3	54.2	55.5	56.5	57.4
	Median (IQR) estimated elapsed time from 911 call to closest PCI hospital within 1 hour (mins.)	26.1 (21.5, 34.6)	25.9 (21.4, 34.2)	25.7 (21.3, 34.1)	25.7 (21.3, 34)	25.7 (21.2, 33.8)
Midwest	Eligible hospitals (N)	1347	1376	1374	1334	1381
	Hospitals with PCI (N)	389	420	433	437	459
	Hospitals with PCI (%)	28.9	30.5	31.5	32.8	33.2
	Hospitals with new PCI (N)	---	29	17	15	13
	Annual growth (%)	---	7.5	4.0	3.5	3.0
	Total growth (%)	---	---	---	---	19.0
	Pop. within 1 hour drive to any hospital (%)	95.4	95.5	95.5	94.7	95.5
	Pop. within 1 hour drive to PCI hospital (%)	75.2	76.6	76.8	77.0	77.6
	Pop. with PCI as closest hospital within 1 hour drive (%)	54.0	57.2	59.4	60.7	60.8
	Median (IQR) estimated elapsed time from 911 call to closest PCI hospital within 1 hour (mins.)	25.6 (21.1, 34.8)	25.4 (21, 34.1)	25.3 (20.9, 34)	25.3 (20.9, 33.9)	25.2 (20.9, 33.5)
Northeast	Eligible hospitals (N)	626	616	614	613	602
	Hospitals with PCI (N)	230	240	246	255	259
	Hospitals with PCI (%)	36.7	39.0	40.1	41.6	43.0
	Hospitals with new PCI (N)	---	11	8	9	7
	Annual growth (%)	---	4.8	3.3	3.7	2.7
	Total growth (%)	---	---	---	---	15.2
	Pop. within 1 hour drive to any hospital (%)	97.8	97.9	97.9	97.9	97.8
	Pop. within 1 hour drive to PCI hospital (%)	87.4	87.4	87.5	88.0	88.5
	Pop. with PCI as closest hospital within 1 hour drive (%)	44.6	48.0	50.1	52.5	55.2
	Median (IQR) estimated elapsed time from 911 call to closest PCI hospital within 1 hour (mins.)	25.6 (20.8, 34.4)	25.2 (20.6, 34.1)	24.8 (20.3, 34)	24.7 (20.3, 34)	24.7 (20.2, 33.9)
South	Eligible hospitals (N)	1774	1794	1820	1807	1816
	Hospitals with PCI (N)	595	613	655	664	675
	Hospitals with PCI (%)	33.5	34.2	36.0	36.7	37.2
	Hospitals with new PCI (N)	---	29	39	20	19
	Annual growth (%)	---	4.9	6.4	3.1	2.9

(Continued)

Table 1. *(Continued)*

Region	Statistic	2004	2005	2006	2007	2008
	Total growth (%)	---	---	---	---	18.0
	Pop. within 1 hour drive to any hospital (%)	93.3	93.3	93.6	93.4	93.5
	Pop. within 1 hour drive to PCI hospital (%)	74.4	74.9	76.3	76.5	76.8
	Pop. with PCI as closest hospital within 1 hour drive (%)	50.9	51.5	54.0	54.8	56.0
	Median (IQR) estimated elapsed time from 911 call to closest PCI hospital within 1 hour (mins.)	27.5 (22.3, 37.3)	27.5 (22.3, 37.1)	27.3 (22.2, 36.8)	27.4 (22.3, 36.6)	27.3 (22.2, 36.4)
West	Eligible hospitals (N)	797	828	867	875	887
	Hospitals with PCI (N)	310	330	339	341	346
	Hospitals with PCI (%)	38.9	39.9	39.1	39.0	39.0
	Hospitals with new PCI (N)	---	15	5	8	7
	Annual growth (%)	---	4.8	1.5	2.4	2.1
	Total growth (%)	---	---	---	---	11.3
	Pop. within 1 hour drive to any hospital (%)	92.2	92.3	92.6	92.4	92.6
	Pop. within 1 hour drive to PCI hospital (%)	83.3	83.8	83.9	84.0	84.2
	Pop. with PCI as closest hospital within 1 hour drive (%)	59.5	60.9	58.5	58.5	58.2
	Median (IQR) estimated elapsed time from 911 call to closest PCI hospital within 1 hour (mins.)	25.4 (21.6, 31.6)	25.1 (21.5, 31.1)	25 (21.4, 30.9)	25 (21.4, 30.9)	25 (21.4, 30.7)

IQR indicates interquartile range; PCI, percutaneous coronary intervention.

of discrete-time hazard models on hospitals that did and did not adopt PCI after 2004 (Table 2). Hospital-level covariates were time varying and lagged 2 years to account for elapsed time from the decision to adopt PCI and the appearance of a laboratory in the AHA survey. In the event that a new hospital entered the data set, current year values were used in place of nonexistent lagged data. Univariate models were used to identify candidate covariates from AHA-, Census-, and American Health Planning Association-derived variables. Independent variables that were moderately strongly associated ($P<0.10$) with new PCI adoption in univariate models were selected for inclusion in the initial multivariate models.

We estimated 2 models with alternative measures of neighborhood competition. In model 3.1, we measured duplication of PCI with a time-varying and 2-year lagged indicator for the presence of another PCI program within the neighborhood of the hospital (Duplication Model). In model 3.2, we measured concentration of market share with a time-varying and 2-year lagged modified Herfindahl–Hirschman Index (Concentration Model). We assumed proportional hazards and estimated 3 sequential equations for each model, with hospital covariates alone, hospital + neighborhood covariates, and hospital + neighborhood + state covariates. We assessed deviations from the assumption of proportional hazards by graphing the hazard function over time and by testing the significance of independent variable interactions with time. All statistical analyses were completed with SAS version 9.2 (SAS Institute, Cary, NC).

Results

Model 1 (Table 1) revealed a substantial growth in the number of hospitals that introduced a new PCI program between 2004 and 2008. In 2004, 1524 (33.5%) of 4544 acute care hospitals in the 50 states and the District of Columbia were capable of performing adult interventional PCI. Four years later, 1739 (37.1%) of 4686 acute care hospitals were capable of performing the procedure. After accounting for hospital closures and mergers, this increase represented 251 new interventional PCI programs and a 16.5% total growth in the number of PCI-capable hospitals. Both the relative and absolute annual rates of growth in PCI capability declined over time from a high of 5.5% relative growth in 2005 (absolute increase of 84 hospitals or 1.8%) to a low of 2.7% in 2008 (absolute increase of 46 or 1.0%) and averaged 3.9% relative annual growth over the 4 years.

Our estimate of the 2008 per-program cost of introducing a new PCI program was $7 810 892 if backup for surgical revascularization already existed onsite and $16 410 201 if it did not. The total cost for 251 new PCI programs under these 2 scenarios would, therefore, be >$1.9 billion if all 251 hospitals already had cardiac surgery programs in place and $4.1 billion if none of them did. This calculation suggests the total cost of new PCI programs during our study period was $2 to $4 billion.

Model 2 (Table 1) showed that access to PCI grew by a small margin over the period, from 79.1% of the population in 2004 to 80.9% in 2008. Access to PCI-capable hospitals varied by region, and these relationships did not change substantially over time. Access was highest in the Northeast (87.4% in 2004 and 88.5% in 2008) and lowest in the South (74.4% in 2004 and 76.8% in 2008). Access to PCI also varied by state (data not shown). More than 90% of the population in 8 states and the District of Columbia had 60-minute access to primary PCI in 2008, including California (91.1%), Connecticut

Table 2. Factors Associated with New PCI Programs (Model 3)

	Model 3.1 Duplication (Obs=11 293)	Model 3.2 Concentration (Obs =10 919)
	HR (95% CI)	HR (95% CI)
Year	0.83 (0.74–0.94)**	0.85 (0.75–0.95)**
Hospital-level		
Ratio of outpatient-to-inpatient revenue†	0.78 (0.67–0.93)**	0.70 (0.59–0.85)***
Total hospital expenses$ †‡	2.13 (1.70–2.64)***	2.17 (1.73–2.68)***
FTE physicians and dentists, n†‡	0.91 (0.83–0.99)*	0.91 (0.84–0.99)*
Hospital beds, n†	2.48 (2.13–2.89)***	2.37 (2.03–2.77)***
Total surgical operations, n†‡	1.07 (0.96–1.22)	1.07 (0.95–1.22)
ER visits, n†‡	1.06 (0.98–1.17)	1.09 (0.98–1.23)
Other outpatient visits, n†‡	0.89 (0.84–0.95)***	0.90 (0.85–0.97)**
Accreditation (Ref: low)	1.50 (1.05–2.19)*	1.39 (0.97–2.04)
Part of a hospital system (yes vs no)	1.19 (0.87–1.66)	1.16 (0.85–1.61)
Teaching hospital (Ref: no)	0.73 (0.51–1.03)	0.75 (0.52–1.06)
Ownership of advanced technology (Ref: low)	1.40 (1.03–1.92)*	1.41 (1.03–1.94)*
New hospital (Ref: no)	13.06 (8.62–19.43)***	12.81 (8.43–19.13)***
Neighborhood-level		
PCI hospital in neighborhood (Ref: no)	1.48 (1.05–2.10)*	...
HHI§	...	0.80 (0.65–0.98)*
Foreign born, percentage of neighborhood§	0.71 (0.59–0.84)***	0.70 (0.58–0.83)***
>65 y of age, percentage of neighborhood§	0.71 (0.57–0.88)**	0.71 (0.57–0.88)**
<2×FPL, percentage of neighborhood§	1.10 (0.92–1.29)	1.09 (0.91–1.28)
Male, percentage of neighborhood§	0.94 (0.76–1.12)	0.95 (0.76–1.14)
Non-Hispanic White, percentage of neighborhood§	0.96 (0.76–1.23)	0.95 (0.75–1.22)
State-level		
CON (Ref: States with no-CON program)		
CON State without cath laboratory review	1.19 (0.81–1.74)	1.21 (0.83–1.77)
CON State with cath laboratory review	0.60 (0.42–0.85)**	0.57 (0.40–0.82)**

All variables are time varying and lagged 2 y except census data and new hospital indicator. Demographic variables come from the 2000 US Census. CI indicates confidence interval; CON, Certificate of Need; ER, emergency room; FPL, Federal poverty level; FTE, full-time equivalent; HHI, Herfindahl–Hirschman Index; HR, hazard ratio; and PCI, percutaneous coronary intervention.

*P value <0.05, **P value <0.01, ***P value <0.001.

†Log transformed; hazard is expressed as the association of doubling in the predictor in the original scale.

‡ Standardized to 100 beds.

§ Normalized to Z score.

(93.6%), Delaware (91.7%), Florida (91.6%), Maryland (92.5%), Massachusetts (94.6%), New Jersey (96.0%), Rhode Island (96.3%), and Washington, DC (100.0%). Less than 50% of the population in 7 states had 60-minute access to the procedure in 2008, including North Dakota (48.9%), South Dakota (44.6%), Vermont (38.3%), West Virginia (46.4%), Alaska (44.3%), Montana (45.3%), and Wyoming (30.5%). Mississippi had the biggest percentage change in access to PCI during the 5-year period, growing from 42.0% of the population in 2004 to 59.2% in 2008, representing a relative rate increase of 40.9%. This growth was achieved through the expansion of PCI to 14 hospitals that did not offer the procedure in 2004, a relative increase of 140%.

Of populations living within a maximum of 60 minutes from a PCI-capable hospital, the estimated elapsed time from 9-1-1 call to arrival at the closest of those hospitals decreased from a national median of 26.1 minutes in 2004 (interquartile range, 21.5–34.6) to 25.7 minutes in 2008 (interquartile range, 21.2–33.8), a drop of 24 seconds for the typical patient. The median drive time also varied by location in 2004, from a low of 21 to 23 minutes in Illinois, Washington, DC, and Wyoming to a high of 33 to 35 minutes in Missouri and Vermont. This measure did not change by >2 minutes during the 4-year follow-up in any state except Missouri, where it dropped from 33 to 29 minutes.

Model 3 (Table 2) demonstrated that several factors are associated with the decision to introduce a new PCI program. Hospitals were more likely to adopt PCI if they were newly opened, larger (ie, had higher expenditures and more hospital beds), and owned other expensive medical technology, and if PCI was already offered in the neighborhood. By far, the strongest influence on PCI adoption was its inclusion as part of an entirely new hospital, which increased the hazard ≈13-fold in a year. Hospitals with twice the average annual expenditure of other non-PCI hospitals had a >2-fold increased risk of adoption each year. Similarly, having twice the average number of beds than other non-PCI hospitals increased the annual risk of adoption 2-fold. Ownership of other expensive medical technology was associated with a 40% increased yearly risk of adopting PCI, and the previous existence of another PCI laboratory in the neighborhood increased the chances of adoption annually by 50%. The Figure depicts duplicated and newly served census tracts within 60 minutes of new PCI programs after 2004.

Hospitals were less likely to adopt PCI if they had a higher volume of outpatient services (higher outpatient/inpatient revenue and more nonemergency outpatient visits) and if they operated in a more concentrated market, in a neighborhood with a higher percentage of foreign-born and elderly residents, and in a state that maintained laws requiring automatic review of new catheterization laboratories. Having twice the average ratio of outpatient-to-inpatient revenue of other non-PCI hospitals in a year reduced the risk of adopting PCI by 30%, whereas having twice the average number of outpatient visits reduced the risk by ≈10%. One SD above the mean percentage of foreign-born or elderly residents in the neighborhood of a hospital was associated with a decreased risk of adoption each year by 30%. One SD above mean Herfindahl–Hirschman Index reduced the annual risk of adoption by 20%. Teaching hospitals trended toward a lower risk of adopting PCI. Emergency room and surgical volumes were not associated

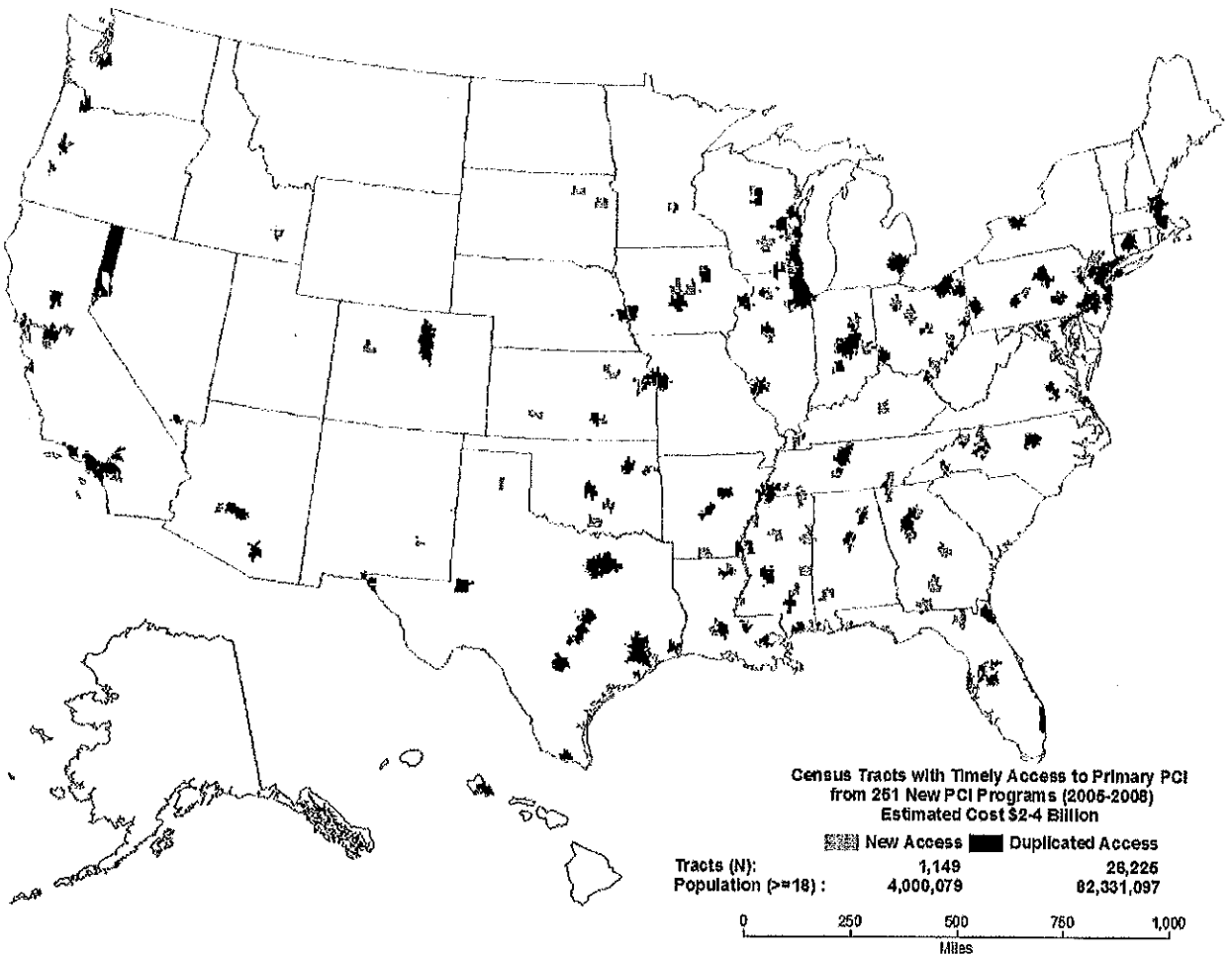

Figure. Timely Access to Primary PCI from 251 New PCI Programs (2005-2008). This map illustrates 60-minute drive times surrounding 251 PCI programs at US hospitals that were newly introduced in 2005-2008. Black-shaded areas depict Census tracts that already had timely access to PCI in 2004 and for which the new program represented duplication. Grey-shaded areas depict Census tracts that did not have timely access to PCI in 2004 and for which the new PCI program represented new access. PCI indicates percutaneous coronary intervention.

with adoption of PCI, nor were area sex, income, or percentage of the population that was of non-Hispanic white race.

Operating in a state that maintained CON with automatic review of catheterization laboratories reduced the risk of PCI adoption by ≈40%. We ran subanalyses to explore this effect in more detail. We interacted CON and our duplication measure to see whether this effect was modified in areas without duplication, but the interaction was nonsignificant. We also assessed whether CON had any effect on times to treatment and access to care. The median estimated elapsed time from 911 to closest hospital declined by 0.3 minutes in no-CON states, by 0.3 minutes in CON states without automatic review, and by 0.8 minutes in CON states with automatic review. These elapsed time reductions amount to 18, 18, and 48 seconds, respectively, not long enough to change outcomes in patients with STEMI. However, we did find a potentially substantial effect of CON with automatic review on access to PCI. In no-CON states, access to PCI was extended to 1.5% of the population, and the population living closest to PCI grew by 1.8%. In states maintaining CON without automatic review, these figures were 2.2% and 3.7%, respectively. In states maintaining CON with automatic review, they were 2.0% and 8.3%, respectively. Automatic review of catheterization laboratories seemed to result in a substantial increase to the population whose closest hospital could perform PCI.

Discussion

New PCI programs from 2004 to 2008 were systematically targeted to neighborhoods that were already served by existing programs, where competition for patients was high, and where they did not improve timely access for patients with STEMI. This finding elaborates on results from previous work on PCI program adoption[4] and is consistent with the findings of a similar study on new cardiac surgery (coronary artery bypass graft) programs in the United States.[29]

Hospital investments in PCI from 2004 to 2008 continued at a fast but slowing pace and have been expensive. During the study period, 251 new programs were introduced in the United States. In the last 2 years of our analysis, 52 and 46 new programs opened up, respectively. Every 50 new PCI programs costs an estimated $400 to $800 million, representing a sizable fixed cost that presumably redounds to increased

insurance premiums, Medicare and Medicaid program costs, and patients' out-of-pocket costs.

Our analysis shows that, on average, recent large investments in new PCI programs have been of low value for patient health because they did not lead to increased access or decreased treatment times. This is true not only for emergent PCI, the focus of our study, but also for elective PCI. If adoption through 2008 was meant to increase access to elective procedures, it has not succeeded: elective procedure rates have also been flat since at least 2001,[17] when ≈563 fewer programs were in place.[24] In this era of flat use, furthermore, systematic duplication can only reduce average hospital PCI volumes, a trend that could result in lower procedure quality and worse outcomes for patients with coronary artery disease. Hospital leaders and other stakeholders may hope that every new program will improve patient health, but quite the opposite may now be happening after introduction of PCI. Future introductions of this service should be assessed in this light.

There are important caveats to our findings. First, in regions with low baseline rates of access to the procedure in 2004, new programs in 2005 and beyond did improve access for patients with STEMI. This was the case in Mississippi, where access to the procedure was low in the baseline year and grew substantially after new PCI programs were introduced in the follow-up years. This may also have been the case in Missouri, where median projected transport times dropped by 4 minutes during the 4-year follow-up. This finding suggests that there may be a role for new PCI programs in underserved areas. Second, the pace of investment in new PCI programs is slowing over time. This suggests that there is an upper limit to the introduction of new PCI programs, and many regions of the United States may be approaching that limit.

At least 3 types of health system strategies are available around the United States to increase or maintain access to PCI for patients with STEMI and to minimize further duplication of existing PCI programs.

Voluntary Interventions

One class of strategies is the development of voluntary STEMI systems of care in local communities or in states.[14,30] Known as STEMI Systems or STEMI Regional Plans, these may be defined as the systematic, iterative assessment and implementation of voluntary agreements between hospitals and emergency medical service systems that are designed to improve access to timely PCI. The largest such program in the United States, the North Carolina Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments (RACE) protocol, has successfully established interhospital agreements and has shown benefit for patients with coronary artery disease.[31] Other plans have been implemented elsewhere and have shown promising results.[15]

Market-Based Interventions

Market interventions such as payment reform may also help to address duplicative investments in PCI. Our results show that PCI investments are declining over time and may soon approach zero; therefore, the prime opportunity for targeted payment reform in this procedure may have passed as many as 10 years ago.[4,17] There is evidence, however, of continued robust investment in PCI. If investments continue while use of the procedure remains flat, payment for these procedures may be reduced potentially to discourage future investments without reducing access to the procedure. Other candidates for this kind of analysis and reform may include interventions in robotics, lasers, nuclear medicine, and radiology.

Regulatory Interventions

Health systems interventions do not have to be voluntary or market based. Twenty-seven states in the United States are equipped with regulatory programs that can be used to compel a formal review of hospitals that wish to open new interventional catheterization laboratories.[18] Our analysis showed that hospitals in states with robust CON programs were 40% less likely to introduce a new PCI program in any given year, suggesting that this policy mechanism can restrain diffusion of interventional catheterization laboratories. Of note, automatic review was the only nonvoluntary regulation that seemed to have an inhibitory effect on the introduction of new PCI programs. Other CON mechanisms, such as review of major medical equipment and capital expenditures above specified thresholds, seemed to have no effect. Further work is needed to establish whether this review mechanism works to restrain low-value diffusion in other medical technologies.

Our findings and those from studies of other technology-intensive medicine also suggest a new priority for health services research: an urgent need to track and assess the value obtained from health system investments in medical technology. Rapid change in medical technology has been a chief suspect in the escalation of US health expenditures for decades, but its value for patient and population health has been unclear. Health technology assessments[32] and economic research[33,34] have sought to address the role of technology in patient and national outcomes, respectively, but the relationship between change in medical technology over time and outcomes in hospitals, accountable care organizations, and other health systems is poorly understood. Better information and methods are needed to assist decision makers in these settings plan for capital investments, regional partnerships, service-line offerings, and other critical health services decisions. Recent advances in spatial statistics, data collection, and computing power have spurred novel methods to describe changes over time in the availability, use, outcomes, and costs of medical technology in cardiac care, imaging, cancer, surgery, trauma, burns, stroke, and other clinical domains.[23–26,28,29,35–42] Health services researchers could make strides in our understanding of the effects of medical technology change in health systems, but a special focus is needed on this theme.

The AHA Annual Survey offers a comprehensive source of information on US hospitals and their capabilities, but it is subject to the usual limitations of self-reported survey data, including problems with nonresponse and misclassification. To address a small amount of missing data in our outcome variable, we used a widely accepted imputation procedure, allowing us to infer the nonexistence of PCI laboratories in hospitals that later reported not owning one and the continued existence of a PCI laboratory in hospitals that previously reported owning one. Some survey data may also suffer from misclassification. In past research, we

have validated AHA self-reports of PCI capability against hospital use data, finding a high rate of congruence between the 2 data sources.[4]

In summary, our data show that new PCI programs in the 4 years after 2004 were systematically duplicative of existing programs and did not help patients gain access to timely PCI. The total cost of recent US investments in new PCI programs is large and of questionable value for patients. We recommend 3 policy options that may help to improve patient access to timely PCI and restrain duplicative investments in PCI programs. We also recommend an emerging priority for health services research to track and assess medical technology change in health systems.

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Disclosures

Dr Concannon had primary responsibility for designing the research, overseeing data collection and analysis, interpreting model results, and writing the article. J. Nelson had responsibility for managing data collection and analysis, interpreting model results, and drafting the article. Drs Kent and Griffith had responsibility for data analysis, interpreting model results, and drafting the article. Dr Concannon was supported by the Agency for Healthcare Research and Quality (K01 HS017726) and by the Tufts Medical Center Research Fund. J. Nelson was supported by the Tufts Medical Center Research Fund. Drs Kent and Griffith were supported by the National Center for Research Resources (UL1 RR025752) and the National Center for Advancing Translational Sciences (UL1 TR000073), National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality or National Institutes of Health.

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APPENDIX 1e

5. Badheka, et al., Impact of Annual Operator and Institutional Volume on Percutaneous Coronary Intervention Outcomes: A 5-Year United States Experience (2005-2009), Circulation, Vol. 130, Issue 16 (2014).

Impact of Annual Operator and Institutional Volume on Percutaneous Coronary Intervention Outcomes

A 5-Year United States Experience (2005–2009)

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Background—The relationship between operator or institutional volume and outcomes among patients undergoing percutaneous coronary interventions (PCI) is unclear.

Methods and Results—Cross-sectional study based on the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample between 2005 to 2009. Subjects were identified by International Classification of Diseases, 9th Revision, Clinical Modification procedure code, 36.06 and 36.07. Annual operator and institutional volumes were calculated using unique identification numbers and then divided into quartiles. Three-level hierarchical multivariate mixed models were created. The primary outcome was in-hospital mortality; secondary outcome was a composite of in-hospital mortality and peri-procedural complications. A total of 457498 PCIs were identified representing a total of 2243209 PCIs performed in the United States during the study period. In-hospital, all-cause mortality was 1.08%, and the overall complication rate was 7.10%. The primary and secondary outcomes of procedures performed by operators in 4th [annual procedural volume; primary and secondary outcomes] [>100; 0.59% and 5.51%], 3rd [45–100; 0.87% and 6.40%], and 2nd quartile [16–44; 1.15% and 7.75%] were significantly less ($P<0.001$) when compared with those by operators in the 1st quartile [≤15; 1.68% and 10.91%]. Spline analysis also showed significant operator and institutional volume outcome relationship. Similarly operators in the higher quartiles witnessed a significant reduction in length of hospital stay and cost of hospitalization ($P<0.001$).

Conclusions—Overall in-hospital mortality after PCI was low. An increase in operator and institutional volume of PCI was found to be associated with a decrease in adverse outcomes, length of hospital stay, and cost of hospitalization. **(*Circulation*. 2014;130:1392-1406.)**

Key Words: complications ■ in-hospital mortality ■ length of stay ■ percutaneous coronary intervention

The 2007 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) clinical competence statement on cardiac interventional procedures[1] and the 2011 percutaneous coronary intervention (PCI) guidelines recommend (Class IC) that PCIs should be performed by operators with an annual volume (>75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery.[2] The last decade has observed a decline in number of PCIs performed, and many interventional cardiologists have experienced a drop in procedural volume.[3,4] As a result, the

Editorial see p 1343
Clinical Perspective on p 1406

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Parts of these data were presented at Society for Cardiovascular Angiography and Intervention 2014 Scientific Sessions. Abstract was selected among the top 3 best of the best abstracts award competition.

*Drs Badheka, Patel, Grover, and Singh contributed equally to this work.

The online-only Data Supplement is available with this article at http://circ.ahajournals.org/lookup/suppl/doi:10.1161/CIRCULATIONAHA.114.009281/-/DC1.

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2013 ACCF/AHA/SCAI clinical competence statement now recommends a minimum requirement of 50 coronary interventional procedures per year (averaged over a 2-year period) to perform PCIs.[5] These recommendations, however, are based on expert opinion derived from the interpretation of data from multiple sources with inherent limitations. Some of these data were derived from state registries and are dated.[5-24]

The purpose of this study was to determine the association of annual PCI operator and institutional volume with in-hospital mortality, peri-procedural complications, length of hospital stay, and cost of hospitalization using the nation's largest available all-payer insurance inpatient database in a recent era (2005–2009) during which procedural techniques and practices have remained relatively stable.

Methods

Data Source

We analyzed 5-year data from the 2005 to 2009 from National Inpatient Sample (NIS) database. The NIS is a subset of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is the largest publicly available all-payer inpatient care database in the United States; including data on approximately 7 to 8 million discharges per year, it is stratified to sample approximately 20% sample of US community (nonfederal, short-term, general, and specialty) hospitals. National estimates are produced using sampling weights provided by the sponsor. The NIS data have been used previously to study trends and predictors of healthcare usage, patterns of major procedures, access and disparity of care, procedural adverse effects, hospitalization trends, cost, quality, and outcomes.[25,26] Each individual hospitalization is deidentified and maintained in the NIS as a unique entry with 1 primary discharge diagnosis and ≤ 24 secondary diagnoses during that hospitalization. Each entry also carries information on demographics.

Annual data quality assessments of the Nationwide Inpatient Sample are performed, to maintain the internal validity of the database. Furthermore, comparisons against the following data sources strengthen the external validity of the Nationwide Inpatient Sample: the American Hospital Association Annual Survey Database, the National Hospital Discharge Survey from the National Center for Health Statistics, and the MedPAR inpatient data from the Centers for Medicare and Medicaid Services.[27-29]

Study Design and Patients

This was a cross sectional study using the NIS database between the years 2005 to 2009. Ascertainment of all diagnoses and procedures was made by using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes. PCI with stent placement was identified by procedure codes 36.06 (non–drug-eluting coronary artery stents) or 36.07 (drug-eluting coronary artery stents) in any of the procedural fields.[27] To restrict our evaluation to the use of PCI in a typical adult population, only participants aged ≥18 years were included (n = 839923). We excluded all observations with a missing unique operator identifying number (n= 382385), missing data for age (n=15), sex (n=14), length of stay (n=1), and mortality during hospitalization (n=10). The final study sample consisted of 457498 procedures (Figure 1). This study involved deidentified data and was therefore exempted from institutional review board.

Outcomes

The primary outcome was in-hospital all-cause mortality, and the secondary outcome was a composite of in-hospital mortality and peri-procedural complications. Preventable procedural complications were identified by Patient Safety Indicators (PSIs), which have been established by the AHRQ to monitor preventable adverse events during hospitalization. These indicators are based on ICD-9-CM codes

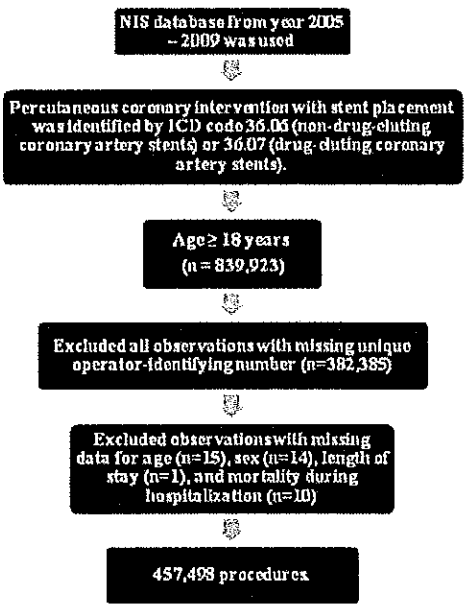

Figure 1. Study design and patients selection. NIS indicates National Inpatient Sample database.

and Medicare severity Diagnosis-Related Groups, and each PSI has specific inclusion and exclusion criteria.[30] PSI individual technical specifications were used to identify and define preventable procedural complications (viz postprocedure respiratory failure, postprocedure physiological and metabolic derangement with acute renal failure requiring dialysis, postprocedure pulmonary embolism or deep vein thrombosis, procedural infectious complications including postprocedure sepsis and central venous catheter related bloodstream infection, and accidental puncture or laceration).

Other procedure related complications including hemorrhage requiring blood transfusion, iatrogenic cardiac complications, pericardial complications, coronary artery bypass graft, procedural stroke or transient ischemic attack, and vascular complications were identified using ICD-9-CM codes (Table I in the online-only Data Supplement) in any secondary diagnosis field. To prevent classification of a preexisting condition (eg, stroke or heart block) as a complication, cases with the ICD-9-CM code for a complication listed as the principal diagnosis (DX1) were excluded. Vascular complications were defined as PSI code for accidental puncture or ICD-9-CM codes for injury to blood vessels, creation of arteriovenous fistula, injury to the retroperitoneum, vascular complications requiring surgery, and other vascular complications not elsewhere classified. "Any complication" was defined as occurrence of one or more procedural complications listed in Table I in the online-only Data Supplement).This methodology has been used in previous studies.[31]

Other outcomes studied were the length of stay and cost of hospitalization. Length of stay includes both observational status and inpatient admissions. Disposition was classified into 3 categories: those who were discharged home or with home care services were classified as home-based discharge, those who were discharged to short- or long-term nursing home or transferred to another facility were classified as discharge to another facility, and those who died in-hospital were classified as in-hospital mortality.

To calculate estimated cost of hospitalization the NIS data were merged with cost-to-charge ratios available from the Healthcare Cost and Utilization Project. We estimated the cost of each inpatient stay by multiplying the total hospital charge with cost-to-charge ratios. Adjusted cost for each year was calculated in terms of the 2010 cost, after adjusting for inflation according to the latest consumer price index (CPI) data released by US government on January 16, 2013.[32] By doing this we standardized costs over the study period.

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Table 1. Baseline Characteristics of the Study Population, According to Quartiles of Annual Operator Volume

	Overall	1st Quartile (≤15)	2nd Quartile (16–44)	3rd Quartile (45–100)	4th Quartile (>100)	P Value
PCI unweighted No.*	457 498	115 813 (25.31%)	115 373 (25.22%)	112 301 (24.55%)	114 011 (24.92%)	
PCI weighted No.†	2 243 209	560 802	560 803	560 802	560 802	
Patient characteristics						
Age, mean±SE	64.56±0.02	64.59±0.04	63.87±0.04	64.53±0.04	65.27±0.04	<0.001
Sex, %						<0.001
Male	66.21	63.93	67.45	67.48	66.03	
Female	33.79	36.07	32.55	32.52	33.97	
Race,‡ %						<0.001
White	69.69	67.39	69.34	70.73	71.38	
Non-white	16.88	20.47	17.12	13.99	15.8	
Comorbidities, %						
Charlson comorbidity index§						<0.001
0	25.17	18.11	23.89	28.53	30.37	
1	39.71	37.47	41.26	40.88	39.29	
≥2	35.12	44.43	34.85	30.59	30.34	<0.001
History of obesity	10.53	11.84	10.84	9.91	9.5	<0.001
History of hypertension	68.78	68.6	67	67.52	71.99	<0.001
History of diabetes mellitus	31.58	33.74	30.32	29.79	32.42	<0.001
History of congestive heart failure	0.68	1.89	0.46	0.2	0.15	<0.001
History of chronic pulmonary disease	14.6	17.91	13.86	12.89	13.65	<0.001
Peripheral vascular disease	10.13	9.86	9.48	10.31	10.89	<0.001
Fluid-electrolyte abnormalities or renal failure	13.19	20.19	12.64	9.83	9.89	<0.001
Neurological disorder or paralysis	2.92	3.99	2.87	2.36	2.44	<0.001
Anemia or coagulopathy	6.83	10.56	6.86	4.91	4.86	<0.001
Hematologic/oncological malignancy	1.34	1.77	1.3	1.14	1.13	<0.001
Weight loss	0.2	1.01	0.39	0.21	0.2	<0.001
Rheumatoid arthritis/other collagen vascular disease	1.53	1.92	1.52	1.44	1.23	<0.001
History of valvular disorder	0.22	0.63	0.14	0.07	0.05	<0.001
Depression, psychosis/substance abuse	6.24	8.36	6.19	5.11	5.21	<0.001
Median household income category for patient's zip code,¶ %						<0.001
0–25th percentile	26.9	26.58	26.67	25.92	28.42	
26–50th percentile	25.89	24.94	26.13	27.07	25.46	
51–75th percentile	23.03	23.84	24.36	23.37	20.54	
76–100th percentile	21.73	22.21	20.33	21.11	23.25	
Primary payer, %						<0.001
Medicare/Medicaid	55.16	55.2	53.12	55.61	60.5	
Private, including HMO	36.07	35.34	37.8	37.06	34.1	
Self pay/no charge/other	7.66	9.1	8.96	7.21	5.33	
Hospital characteristics						
Hospital bed size, %‖						<0.001
Small	6.25	5.35	5.29	6.95	7.46	
Medium	19.64	21.32	19.25	19.38	18.57	
Large	73.66	72.81	74.54	73.39	73.89	
Hospital location, %						<0.001
Rural	5.03	4.41	5.3	6.21	4.22	

(Continued)

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Table 1. Continued

	Overall	1st Quartile (≤15)	2nd Quartile (16–44)	3rd Quartile (45–100)	4th Quartile (>100)	P Value
Urban	94.52	95.07	93.78	93.51	95.7	
Hospital region, %						<0.001
Northeast	24.64	20.41	18.75	24.51	35.04	
Midwest/North Central	15.68	15.77	16.28	15.86	14.82	
South	47.74	48.81	50.22	48.07	43.81	
West	11.94	15	14.75	11.57	6.33	
Hospital teaching status, %						<0.001
Nonteaching	43.9	47.99	45.66	40.5	41.27	
Teaching	55.65	51.49	53.42	59.22	58.65	
Admission types, %						<0.001
Emergent admission	67	82.28	68.69	61.12	55.44	
Elective admission	32.59	17.27	30.8	38.53	44.23	
Admission day, %						<0.001
Weekdays	86.94	80.14	85.29	89.82	92.73	
Weekend	13.06	19.86	14.71	10.18	7.27	
Length of stay, mean±SE	2.81±0.05	4.12±0.01	2.83±0.01	2.28±0.01	2.01±0.01	<0.001
Total adjusted cost in dollars, mean±SE	17894±17$	21111±44$	17997±33$	16669±31$	15783±29$	<0.001
Disposition, %						<0.001
Home	95.24	91.88	95.39	96.68	97.1	
Facility/others	3.4	6.06	3.12	2.22	2.1	
AMA	0.28	0.37	0.34	0.22	0.2	
Vessels involved, %						<0.001
Single vessel single stent	39.73	41.57	40.93	37.93	38.4	
Single vessel more than 1 stent.	16.32	16.1	16.23	16.04	16.93	
Bifurcation stenting	1.3	1.28	1.32	1.32	1.3	
Multivessel PCI	42.64	41.05	41.53	44.71	43.37	
Use of assist devise or IABP, %	2.21	2.76	2.49	1.88	1.71	<0.001
Shock, %	1.9	2.75	2.23	1.52	1.09	
AMI, %	36.45	46.53	41.29	33.13	24.54	
Fractional flow reserve, %	0.12	0.13	0.13	0.1	0.12	
Intravascular ultrasound, %	4.67	4.25	4.46	4.64	5.33	

Frequencies (%) in the columns may not sum to 100% to account for missing data. AMA indicates against medical advice; AMI, acute myocardial infarction; HMO, health maintenance organization; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SE, standard error.

*No. of unweighted PCI.

†No. of weighted PCI.

‡Race was missing in 13.4% of the study population.

§Charlson/Deyo comorbidity index was calculated as per Deyo classification.

¶This represents a quartile classification of the estimated median household income of residents in the patient's ZIP Code. These values are derived from ZIP Code-demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. http://www.hcupus.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp

||The bed size cutoff points divided into small, medium, and large have been done so that approximately one-third of the hospitals in a given region, location, and teaching status combination would fall within each bed size category. State and County QuickFacts. Washington, DC: US Census Bureau; 2012.

Annual Institutional and Operator Procedure Volume

Annual institutional volume was determined using the unique hospital identification number to calculate the total number of procedures performed by a particular institution in a given year. Similarly annual operator volume was computed using operator identification number. The operator identification numbers in NIS do not correlate across years, and hence the same operator performing the procedure in different years may be recorded under a different identifier, but within the same year the operator identifiers do not change. For the above reason, annual operator volume was calculated on a year to year basis by matching the operator identification number related to a particular procedure to the total number of procedures recorded under that operator identification number in the given year.

The relationship between institutional and operator volume and outcomes was represented as a nonlinear polynomial function using restricted cubic spline transformations of the volume measure. The use of splines is an established method to determine whether nonlinearity exists between a continuous variable and a dependent outcome by using all data points to estimate the shape of an association between

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Table 2. Baseline Characteristics of the Study Population, According to Quartiles of Annual Institutional Volume

Demographic Variable	Overall	1st Quartile (<=542)	2nd Quartile (543 – 914)	3rd Quartile (917 – 1641)	4th Quartile (>1641)	*P* Value
PCI unweighted No.*	457 498	114 569 (25.04%)	114 513 (25.03%)	114 172 (24.96%)	114 244 (24.97%)	
PCI weighted No.†	2 243 014	569 426 (25.39%)	551 262 (24.58%)	562 313 (25.07%)	560 012 (24.97%)	
Patient characteristics						
Age, mean±SE	64.56±0.01	63.67±0.04	64.60±0.04	64.84±0.04	65.18±0.04	<0.001
Sex, %						<0.001
Male	66.21	66.37	66.04	66.15	66.26	
Female	33.79	33.63	33.96	33.85	33.74	
Race,‡ %						<0.001
White	69.69	67.41	68.61	76.20	66.54	
Non-white	16.88	18.93	13.97	17.98	16.56	
Comorbidities,§ %						
Charlson comorbidity index¶						<0.001
0	25.17	20.53	25.88	24.87	29.49	
1	39.71	41.15	39.52	39.82	38.31	
≥2	35.12	38.32	34.59	35.31	32.20	
History of hypertension	68.78	65.55	66.82	71.93	70.83	<0.001
History of diabetes mellitus	31.58	30.42	30.47	32.92	32.51	<0.001
History of congestive heart failure	0.68	0.96	0.74	0.64	0.40	<0.001
History of chronic pulmonary disease	14.60	14.96	14.73	14.80	13.91	<0.001
Peripheral vascular disease	10.13	9.19	10.11	11.93	9.29	<0.001
Fluid-electrolyte abnormalities and/or renal failure	13.19	14.50	13.29	13.38	11.56	<0.001
Neurological disorder/paralysis	2.92	3.25	2.91	2.88	2.63	<0.001
Anemia/coagulopathy	6.83	7.58	7.06	6.80	5.86	<0.001
Hematologic/oncological malignancy	1.34	1.46	1.37	1.31	1.22	<0.001
Weight loss	0.46	0.64	0.49	0.41	0.30	<0.001
Rheumatoid arthritis/other collagen vascular disease	1.53	1.71	1.61	1.48	1.33	<0.001
History of Valvular disorder	0.22	0.28	0.24	0.22	0.15	<0.001
Depression, psychosis/substance abuse	6.24	7.05	5.98	6.23	5.66	<0.001
Median household income category for patient's zip code,‖ %						<0.001
0–25th percentile	26.90	29.85	27.60	27.27	22.83	
26–50th percentile	25.89	27.57	26.87	26.50	22.60	
51–75th percentile	23.03	22.48	25.35	22.68	21.68	
76–100th percentile	21.73	17.10	17.72	21.05	31.05	
Primary payer, %						<0.001
Medicare/Medicaid	56.15	52.74	55.18	58.55	58.17	
Private, including HMO	36.07	36.48	36.58	34.69	36.54	
Self pay/no charge/other	7.66	10.62	8.14	6.65	5.20	
Hospital characteristics						
Hospital bed size,# %						<0.001
Small	6.25	7.82	6.97	5.05	5.16	
Medium	19.64	30.59	16.32	12.91	18.53	
Large	73.66	60.51	76.71	81.32	76.31	
Hospital location, %						<0.001
Rural	5.03	12.63	4.15	3.19	0.00	
Urban	94.52	86.30	95.85	96.09	100.00	
Hospital region, %						<0.001

(Continued)

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Table 2. Continued

Demographic Variable	Overall	1st Quartile (<=542)	2nd Quartile (543 – 914)	3rd Quartile (917 – 1641)	4th Quartile (>1641)	*P* Value
Northeast	24.64	12.65	10.55	38.91	36.37	
Midwest or North Central	15.68	20.48	19.13	12.76	10.34	
South	47.74	48.96	47.50	42.49	51.99	
West	11.94	17.90	22.82	5.84	1.30	
Hospital teaching status, %						<0.001
Nonteaching	43.90	61.08	60.60	31.84	22.09	
Teaching	55.65	37.85	39.40	67.44	77.91	
Admission types, %						<0.001
Emergent admission	67.27	71.63	63.56	69.53	64.23	
Elective admission	32.73	28.37	36.44	30.47	35.77	
Admission day, %						<0.001
Weekdays	86.94	82.50	86.15	88.27	90.90	
Weekend	13.06	17.50	13.85	11.73	9.10	
Length of stay, mean±SE	2.82±0.01	3.22±0.01	2.84±0.01	2.75±0.01	2.47±0.01	<0.001
Total adjusted cost, mean±SE	17894±15	19609±35	17774±35	17404±35	12355±35	<0.001
Disposition, %						<0.001
Home	95.24	93.68	95.24	95.75	96.29	
Facility/others	3.40	4.39	3.30	3.04	2.84	
AMA	0.28	0.37	0.31	0.27	0.19	
Vessels involved, %						<0.001
Single vessel single stent	57.2	60.27	58.66	56.98	53.36	
Single vessel more than 1 stent.	20.56	20.01	19.46	20.23	22.33	
Bifurcation Stenting	1.88	1.87	1.71	2.28	1.64	
Multivessel PCI	20.35	17.85	20.16	20.52	22.67	
Shock, %	1.90	2.78	1.97	1.63	1.22	<0.001
AMI, %	36.45	47.57	37.16	33.53	27.40	<0.001
Fractional flow reserve, %	0.12	0.14	0.24	0.07	0.04	<0.001
Intravascular ultrasound, %	4.67	4.69	3.68	4.56	5.72	<0.001

Frequencies (%) in the columns may not sum to 100% to account for missing data. AMA indicates against medical advice; AMI, acute myocardial infarction; HMO, health maintenance organization; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SE, standard error.

*No. of unweighted PCI.

†No. of weighted PCI.

‡Race was missing in 13.4% of the study population.

§Variables are Agency for Healthcare Research and Quality comorbidity measures.

¶Charlson/Deyo comorbidity index was calculated as per Deyo classification.

‖This represents a quartile classification of the estimated median household income of residents in the patient's ZIP Code. These values are derived from ZIP Code-demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. http://www.hcupus.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp

#The bed size cutoff points divided into small, medium, and large have been done so that approximately one-third of the hospitals in a given region, location, and teaching status combination would fall within each bed size category. State and County QuickFacts. Washington, DC: US Census Bureau; 2012.

an exposure (operator volume) and an outcome.[33] To make them clinically relevant and for the ease of interpretation, annual institutional and operator procedure volume were also divided into quartiles.

Baseline characteristics of the study population that were studied for potential confounding assessment included patient and hospital level characteristics. Patient level characteristics such as age, sex, race, comorbid conditions using Deyo modification of Charlson comorbidity index (CCI), median household income according to ZIP Code, primary payer, admission type (urgent/emergent versus elective), day of the admission (weekdays versus weekend), and hospital level characteristics such as hospital location (urban/rural), hospital bed size (small, medium, and large), region (Northeast, Midwest or North Central, South, and West), teaching status, and annual institutional volume quartiles were studied. Length of stay and cost of the hospitalization were also studied.

We defined severity of comorbid conditions using Deyo modification of CCI (Table II in the online-only Data Supplement). This index contains 17 comorbid conditions with differential weights. The score ranges from 0 to 33, with higher scores corresponding to greater burden of comorbid diseases.[34]

Statistical Analysis

Stata IC 11.0 (Stata-Corp, College Station, TX) and SAS 9.3 (SAS Institute Inc, Cary, NC) were used for analyses, which accounted for the complex survey design and clustering. We stratified our study sample by quartiles of annual operator volume (≤15, 16–44, 45–100, >101).

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Table 3. Adverse Clinical Events* Related to Percutaneous Coronary Intervention by ICD-9 Code, 2005 Through 2009

Complications	Percentage
Death	1.08
Any complications	7.10
Death + Any complications	7.70
Death + Vascular + Stroke + Cardiac+ Requirement of open heart surgery	5.53
Death + Vascular + Stroke + Cardiac + Requirement of open heart surgery + Renal + DVT + Infectious	6.35
Vascular complications	2.01
Postop-hemorrhage requiring transfusion†	0.50
Vascular injury	1.56
Cardiac complications	1.76
Iatrogenic cardiac complications	1.69
Pericardial complications	0.10
Requiring CABG	0.10
Respiratory complications (Post-op resp failure)	1.50
Postop-stroke/TIA	0.99
Renal and metabolic complications	0.20
Acute renal failure requiring dialysis	<0.1
Acute severe metabolic derangement	0.16
Postoperative DVT/PE	0.41
Postoperative infectious complications§	0.61

CABG indicates coronary artery bypass grafting; DVT, deep venous thrombosis; PE, pulmonary embolism; and TIA, transient ischemic attack.

*Details in Table II in the online-only Data Supplement.

†Hemorrhage requiring transfusion was identified as any patient having postoperative hemorrhage and also received transfusion.

‡Infectious complications were identified as composite of postoperative sepsis, septic shock, or catheter-related infection.

All analyses were performed using the designated weighting specified in the data set to minimize biases. Differences in baseline characteristics were examined using 1-way analysis of variance for continuous variables (reported as mean±SD) and χ^2 test for categorical variables (reported as %). *P* value of less than 0.05 was considered significant.

Hierarchical Modeling

Hierarchical mixed effects models were generated to identify the independent multivariate predictors of the primary and secondary outcomes. Hierarchical modeling is designed to analyze data with nested observations and more appropriate to simple regression modeling for an available dataset. The NIS dataset is inherently hierarchical (viz the data has group- [ie, hospital] specific attributes and within each group there are patients which contribute patient-specific attributes to the data). Hierarchical models take into consideration the effect of nesting. Three-level hierarchical models (with patient level factors nested within hospital level factors) were created with the unique hospital identification number and hospital region incorporated as random effects within the model (meaning that patients treated at the same hospital may experience similar outcomes as a result of other processes of care).

We excluded race from the multivariable models because nearly 13.42% of the observations were missing. Because 94.52% of these procedures were performed in urban hospitals, we did not include rural/urban location of hospital in the model. In all multivariate models, we included hospital level variables like annual institutional volume, hospital region (Northeast, South, Midwest with West as referent), teaching versus nonteaching hospital, and patient-level variables like age, sex, Deyo modification of CCI, myocardial infarction, shock, emergent/urgent versus elective admission, admission over the weekend, median household income, primary payer (with Medicare/Medicaid considered as referent; Table III in the online-only Data Supplement), in addition to annual operator procedure volume. All interactions were thoroughly tested. Colinearity was assessed using variance inflation factor.

Model discrimination was assessed using the c-index (Table IV in the online-only Data Supplement). The probability of death was calculated for each patient using the full hierarchical model. Average adjusted probability of death was then calculated for each level of institutional and operator volume. The absolute risk reduction between each level of institutional and operator volume was the absolute difference in average probability of death in each group, which represents possible change in patient mortality risk associated with changing the level of institutional and operator volume for the average patient, after adjusting for all potential confounders as described above.

Subgroups analyses were carried out in Charlson ≥2, emergent admission, myocardial infarction and or shock, and multivessel subgroups. To compare current guideline with previous, we also divided operator volume into 3 groups: ≤50 PCIs/yr, 51 to 75 PCIs/yr, and >75 PCIs/yr. Length of stay and cost of care were not normally distributed in the population and so were converted into logarithmic scale.

Results

Our analysis included 457498 of an estimated total of 2243209 PCI procedures performed in the United States during the study period. The mean age of the study population was 64.56±0.02 years; 66.21% were male and 69.69% were white. Most of the PCIs were performed in urban hospitals (94.52%), during weekdays (86.94%), in an urgent or emergent setting

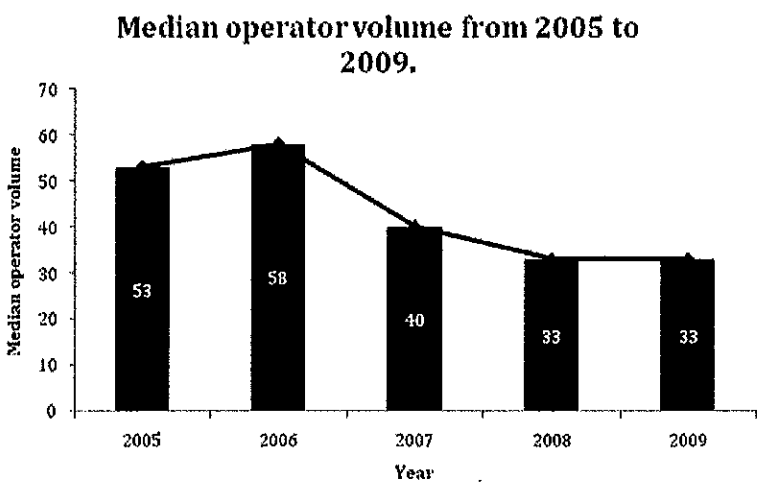

Figure 2. Median operator volume from 2005 to 2009.

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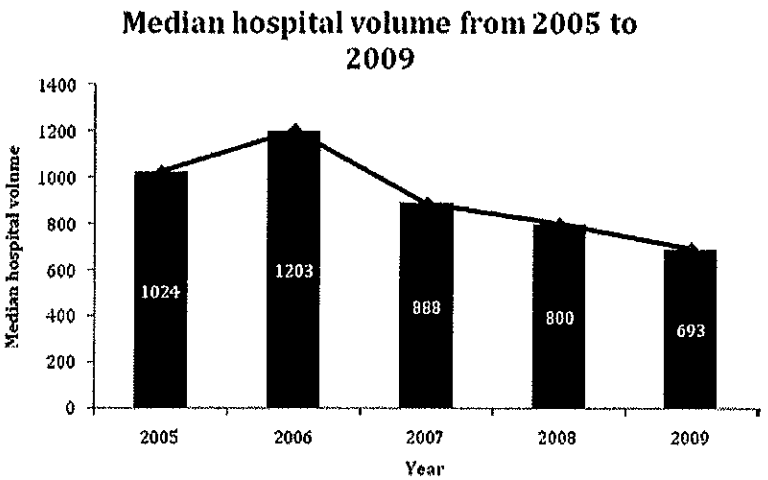

Figure 3. Median institutional volume from 2005 to 2009.

(67.00%). The primary expected payer was Medicare/Medicaid (55.16%). Baseline characteristics of the study population are shown in Tables 1 and 2. Given the large number of procedures used for the analysis, most of the variables were statistically different across operator volume quartiles.

Overall mortality and complication rates were 1.08% and 7.10%, respectively. Vascular complications were reported at 2.01% with vascular injury accounting for 1.56% of total complications. Other frequent complications included iatrogenic cardiac complications (1.69%), postoperative respiratory failure (1.50%), postoperative stroke (0.99%), and acute renal failure requiring dialysis (<0.1%; Table 3).

Median operator PCI volume declined from 53 (2005) to 33 annually (2009; Figure 2). Median institutional PCI volume also declined from 1024 (2005) to 693 annually (2009; Figure 3).

Annual Operator Volume and Outcomes

Crude cumulative mortality and complication rates decreased significantly with increasing quartiles of operator volume (Figure 4). Crude mortality rates were 1.68%, 1.15%, 0.87%, and 0.59% in 1st (≤15 PCIs/yr), 2nd (16–44 PCIs/yr), 3rd (45–100 PCIs/yr), and 4th (>100 PCIs/yr) quartile of operator volume, respectively. Similarly complication rates were 10.12%, 7.17%, 5.96%, and 5.19% with increasing quartiles

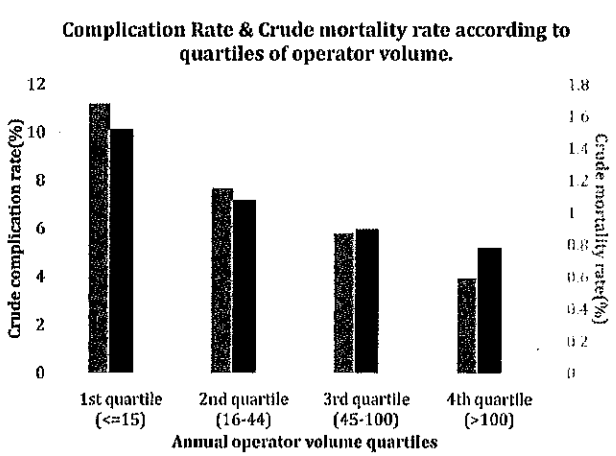

Figure 4. Crude mortality rate and complication rate according to quartiles of operator volume.

of operator volume. The association between operator volume quartile and primary and secondary outcomes persisted even after adjusting for potential confounding factors. Compared with patients treated by lowest quartile of operator volume, adjusted odds ratios of mortality for the patients treated by 2nd, 3rd, and 4th quartile of operator volume were 0.80 (0.74–0.87, $P<0.001$), 0.81(0.74–0.89, $P<0.001$), and 0.65(0.58–0.73, $P<0.001$), respectively (Table 4). Similarly adjusted odds ratios for secondary outcome for the patient treated by 2nd, 3rd, and 4th quartile of operator volume were 0.75 (0.73–0.78, <0.001), 0.67 (0.64–0.69, $P<0.001$), and 0.61 (0.58–0.63, $P<0.001$) respectively, as compared with patient treated by lowest quartile of operator volume.

Spline relationship between operator volume and primary and secondary outcomes is demonstrated in Figure 5. Predicted probability of mortality dropped with increasing operator volume and flattened at ≈300 procedures per year (Figure 5A). A similar relationship was also found between the secondary outcome and annual operator volume (Figure 5B).

The magnitude of change in risk-adjusted rate of mortality with the change in operator volume is represented in Tables 5 and 6. Adjusted risk of mortality in a group of patients treated by an operator performing ≤50 procedures/yr, 50 to 75 procedures/yr, >75 procedures/yr were 1.31%, 0.78%, and 0.54%, respectively (Table 6). Similarly, adjusted risk of secondary outcome in a group of patients treated by an operator performing ≤50 procedures/yr, 50 to 75 procedures/yr, >75 procedures/yr were 9.15%, 6.41%, and 5.73%, respectively (Table 6).

Annual Institutional Volume and Outcomes

Crude cumulative mortality and complication rates decreased significantly with increasing quartiles of institutional volume (Figure 6). Crude mortality rates were 1.54%, 1.15%, 0.94%, and 0.68% in 1st, 2nd, 3rd, and 4th quartile of institutional volume, respectively. Similarly complication rates were 8.06%, 7.07%, 7.29%, and 6.09% with increasing quartiles of institutional volume. The association between institutional volume quartile and primary and secondary outcomes persisted even after adjusting for clinical variables (Table III in the online-only Data Supplement). However, the relationship between institutional

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Table 4. Multivariate Predictors of Primary and Secondary Outcomes

	Primary Outcome		Secondary Outcome	
	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
Age (10-yr increment)	1.60 (1.55–1.65)	<0.001	1.11 (1.10–1.13)	<0.001
Female	1.20 (1.13–1.28)	<0.001	1.27 (1.24–1.30)	<0.001
Shock	14.49 (13.28–15.80)	<0.001	7.67 (7.25–8.11)	<0.001
Myocardial infarction	3.96 (3.58–4.39)	<0.001	1.74 (1.69–1.79)	<0.001
Charlson score*				
0	Referent		Referent	
1	2.33 (1.86–2.92)	<0.001	1.46 (1.40 - 1.53)	<0.001
≥2	3.61 (2.89–4.51)	<0.001	2.77 (2.65 - 2.89)	<0.001
Median household income				
1st quartile	Referent		Referent	
2nd quartile	0.99 (0.91–1.08)	0.817	1.00 (0.97–1.04)	0.904
3rd quartile	1.00 (0.91–1.10)	0.991	1.02 (0.98–1.05)	0.405
4th quartile	0.92 (0.83–1.02)	0.126	0.98 (0.94–1.02)	0.362
Primary payer				
Medicare/Medicaid	Referent		Referent	
Private including HMO	0.77 (0.70–0.85)	<0.001	0.78 (0.76–0.81)	<0.001
Self pay/no charge/other	1.23 (1.08–1.40)	0.002	0.82 (0.78–0.87)	<0.001
Teaching vs nonteaching hospital	1.00 (0.91–1.11)	0.985	1.03 (0.98–1.09)	0.266
Weekend vs weekdays admission	1.06 (0.98–1.14)	0.162	1.00 (0.97–1.03)	0.921
Emergent/urgent vs. elective admission	1.43 (1.29–1.59)	<0.001	1.00 (0.97–1.03)	0.946
Use of assist devise or IABP	3.42 (3.11–3.75)	<0.001	2.69 (2.54–2.85)	<0.001
Annual institutional volume				
1st Quartile (≤542)	Referent		Referent	
2nd Quartile (543–914)	0.95 (0.85–1.06)	0.362	0.98 (0.92–1.04)	0.461
3rd Quartile (917–1641)	0.89 (0.78–1.02)	0.099	1.06 (0.99–1.14)	0.088
4th Quartile (>1641)	0.88 (0.75–1.04)	0.137	1.02 (0.93 –1.12)	0.650
Annual operator volume				
1st Quartile (1–15)	Referent		Referent	
2nd Quartile (16–44)	0.80 (0.74–0.87)	<0.001	0.75 (0.73–0.78)	<0.001
3rd Quartile (45–100)	0.81 (0.74–0.89)	<0.001	0.67 (0.64–0.69)	<0.001
4th Quartile (>100)	0.65 (0.58–0.73)	<0.001	0.61 (0.58–0.63)	<0.001

Three levels hierarchical mixed effects models were generated (patient level factors nested within institutional level factors) with the unique hospital identification number incorporated as random effects. Primary and secondary outcome was adjusted for institutional level variables like annual institutional volume hospital region (Northeast, South, Midwest with West as referent), teaching vs. nonteaching hospital, and patient-level variables like age, sex, Deyo modification of Charlson comorbidity index, myocardial infarction, shock, emergent/urgent vs elective admission, admission over the weekend, median household income, primary payer (with Medicare/Medicaid considered as referent), in addition to annual operator and institutional procedure volume. Operator and institutional volume were calculated based on the unique operator and hospital identification number on year to year basis. CI indicates confidence interval; HMO, health maintenance organization; IABP, intra-aortic balloon pump; and OR, odds ratio.

*Charlson/Deyo comorbidity index was calculated as per Deyo classification.

volume and outcomes became statistically nonsignificant once operator volume was added to the model (Table 4).

Spline relationship between institutional volume and primary and secondary outcomes is demonstrated in Figure 5. Predicted probability of mortality dropped with increasing institutional volume. Hospitals performing ≤750 PCIs per year had significantly higher mortality rate than hospitals performing >750 PCIs per year (Figure 5C). A similar relationship was seen for annual institutional volume and secondary outcome (Figure 5D).

Other Predictors of Outcomes

Other independent predictors of primary and secondary outcomes were increasing age, female sex, increasing Charlson score, presence of myocardial infarction or shock at the time of presentation, emergent/urgent admission, use of assist devices,

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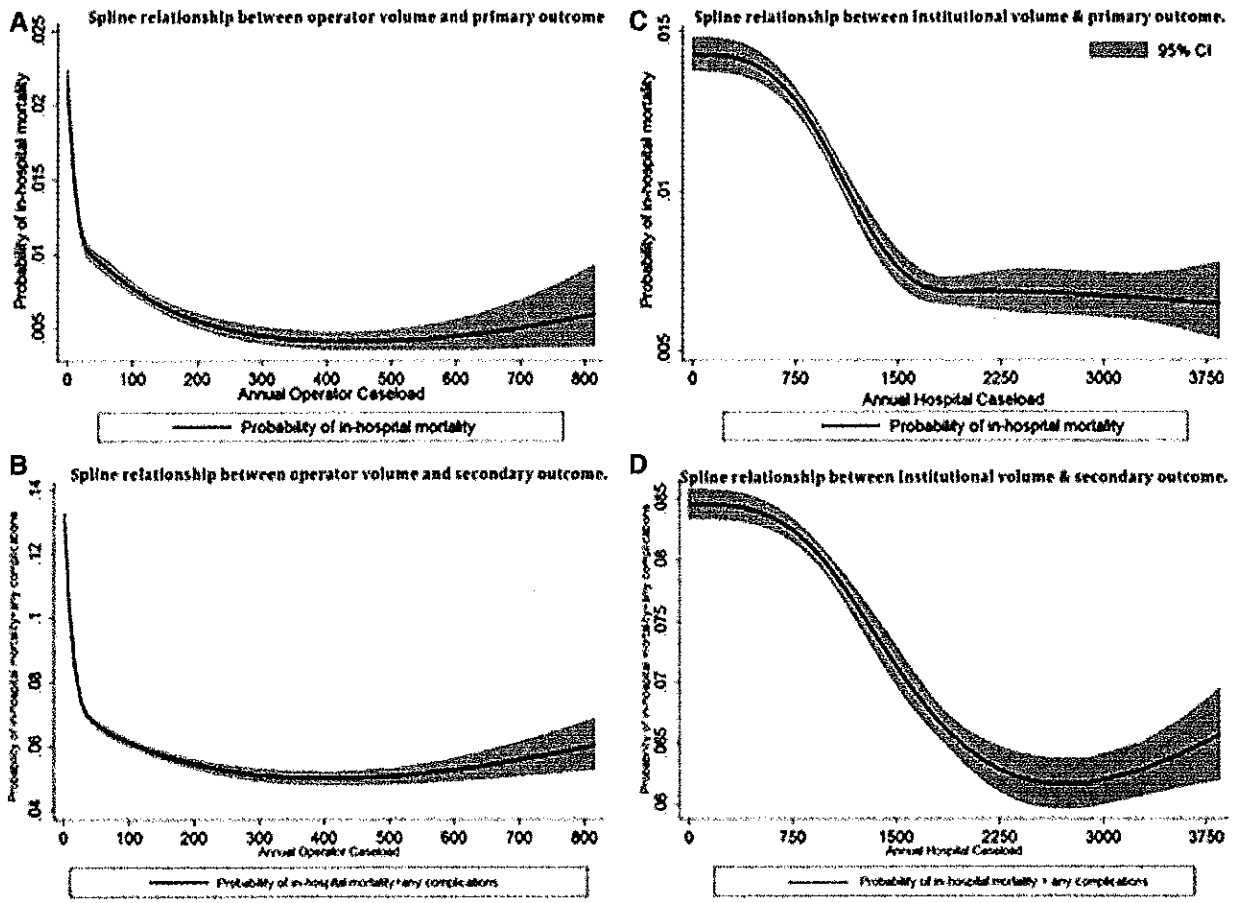

Figure 5. Association between Institutional and operator volume for primary and secondary outcomes. **A**, Spline relationship between operator volume and primary outcome. **B**, Spline relationship between operator volume and secondary outcome. **C**, Spline relationship between Institutional volume and primary outcome. **D**, Spline relationship between Institutional volume and secondary outcome.

and insurance status (self-pay or no insurance versus Medicare/Medicaid). Although increasing quartiles of institutional volume were associated with decreasing in-hospital mortality and secondary outcomes, this association lost statistically significant after adjusting for other confounding factors.

Annual Operator Volume and Outcomes in Selected Subgroups

Procedures performed by operators in the 2nd, 3rd, and 4th quartiles of operator volume were associated with significant reduction in the odds of primary and secondary outcomes across all subgroups except in shock when compared with the procedures performed by operators in the 1st quartile of operator volume. Only highest quartile of operator volume was associated with significant reduction in the odds of primary outcome (Tables 7 and 8)

Length of Stay and Cost of Hospitalization

On multivariable analysis, significant predictors of increased length of hospital stay were presence of shock/myocardial infarction, increasing CCI, emergent/urgent admission, and weekend

Table 5. Adjusted Rates for the Primary and Secondary Outcomes, According to Various Institutional and Operator Quartiles Cutoffs

Institutional Quartiles	Operator Quartiles									
	Primary Outcome					Secondary Outcome				
	Overall	1st Quartile (≤15)	2nd Quartile (16–44)	3rd Quartile (45–100)	4th Quartile (>100)	Overall	1st Quartile (≤15)	2nd Quartile (16–44)	3rd Quartile (45–100)	4th Quartile (>100)
Overall	-	1.62	1.06	0.78	0.48	-	10.94	7.77	6.38	5.52
1st quartile (≤542)	1.46	1.86	1.36	1.06	0.71	8.86	11.08	8.13	6.49	5.66
2nd quartile (543–914)	1.06	1.63	1.08	0.83	0.54	7.74	10.92	7.75	6.25	5.25
3rd quartile (917–1641)	0.84	1.42	0.90	0.75	0.50	7.63	11.08	7.85	6.99	5.80
4th quartile (>1641)	0.59	1.17	0.63	0.56	0.40	6.46	10.41	6.93	5.73	5.42

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Table 6. Adjusted Rates for the Primary and Secondary Outcomes, According to Various Institutional and Operator Volume Cutoffs

Institutional Volume	Operator Volume							
	Primary Outcome				Secondary Outcome			
	Overall	≤50	50–75	>75	Overall	≤50	50–75	>75
Overall	-	1.31	0.78	0.54	-	9.15	6.41	5.73
≤200	1.83	1.88	1.27	0.88	10.01	10.27	6.77	6.07
200–400	1.40	1.55	1.21	0.80	8.72	9.50	6.90	5.95
>400	0.88	1.19	0.73	0.53	7.39	8.96	6.36	5.72

admission whereas length of stay was negatively associated with increased operator volume and institutional volume (Table 9). Similarly, significant predictors of increased cost of care were presence of shock/myocardial infarction, increasing CCI, emergent/urgent admission, and weekend admission whereas increased operator volume and institutional volume were negatively associated with an increased cost of care (Table 9).

Discussion

This study describes one of the largest (a total of 457 498 PCI procedures, representing a total of 2 243 209 procedures across the United States) real-world experiences with PCI over a recent era (2005–2009).We demonstrate a statistically significant decline in the primary and secondary outcomes with increasing annual operator volume of PCIs. This relationship was also seen in subgroups of patients with CCI score ≥2, emergent/urgent admission, myocardial infarction or shock, assist device use, and multivessel disease. The benefit of increasing operator and hospital volume was also noted in decreasing length of stay and cost of hospitalization. Our results are consistent with those based on the NCDR CathPCI Registry (2009), which demonstrated increase in-hospital mortality among patients treated by operators performing <75 PCIs/yr. The NCDR CathPCI data are American College of Cardiology's most comprehensive outcomes-based quality improvement program and NCDR CathPCI Registry is limited to voluntarily participating hospitals. The NIS is the largest publicly available all-payer inpatient care database in the United States, and includes data on ≈20% sample of US community including for nonfederal, short-term, general, and specialty hospitals. Another unique characteristic of the current study is inclusion of end points such as length of stay and cost of hospitalization. The relationship of these outcomes and operator or institutional volume has not been shown earlier.[6–21,35]

Our study demonstrates a statistically significant inverse association between operator volume and outcome (in-hospital mortality and peri-procedural complications) in the current practice. Our results are in agreement with results from previous studies done both in the percutaneous transluminal coronary angioplasty and the stent era.[6–21,35,36] Previous studies have been limited by the number of centers,[12,20] state-based registry data,[8,14,15,18] inclusion of only limited cohorts,[16] lower sample size,[8,9,11–18,20] foreign studies,[11,19,21] and most importantly they lack data from recent era.[6,7,9,16] Previous studies, which have shown a decrease in mortality with increasing operator volume, have failed to reach statistical significance because of low

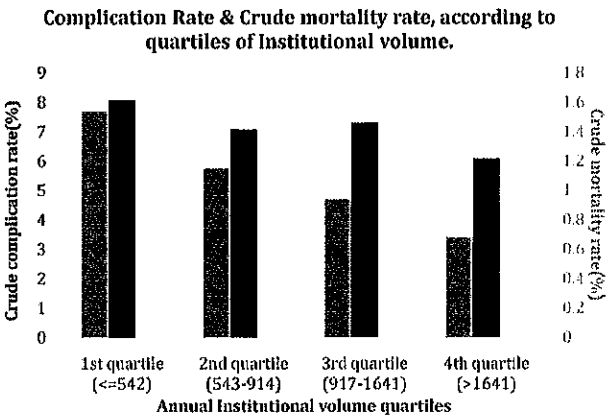

Figure 6. Crude mortality rate and complication rate according to quartiles of Institutional volume.

sample size, large confidence interval, or low procedure related mortality.[15,22–24] Two prior studies have previously evaluated the association of institutional volume and outcome from the NIS database.[10,13] These studies, however, did not evaluate the occurrence of complications and included data from 1998 to 2000 and 2000 to 2003, respectively (pre-COURAGE [Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation trial] period).[10,13] In general, only a limited number of studies have previously evaluated the relationship between PCI volume and complications, with most studies limited to only post-PCI coronary artery bypass graft.[6,16] An additional strength of our study was the comprehensive definition of peri-procedural complications accounting for all major post PCI–related complications similar to previous published analyses.[31]

Over the last decade interventional cardiologists have witnessed a decline in the procedural volume[3,4] (Figures 2 and 3). Some studies have questioned the association between operator/institutional volume and adverse outcome in the current era of technological advancements.[17] The 2011 ACCF/AHA/SCAI PCI guideline recommended that PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high-volume centers (>400 procedures) with onsite cardiac surgery.[2] These volume recommendations were carried over from the 2007ACCF/AHA/SCAI competency statement but downgraded to a Level of Evidence C, recognizing that they represent expert opinion and lack strong and consistent evidence.[1] The current recommendations for interventional cardiologists are to perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) and a hospital minimum of 200 PCI/yr to maintain competency.[5] The 2013 competency statement on PCI recognizes the inherent limitation of the currently available data and states that the current recommendations are primarily established by expert opinion.[5]

We noted that patients undergoing PCI would experience a 0.53% absolute risk reduction in mortality, after adjustment for other clinical variables, in the hands of an operator with annual PCI volume of 50 to 75 procedures/yr as compared with an operator with annual volume of <50 procedures/yr. A further 0.24% absolute risk reduction was noted with operators performing >75 procedures/yr as compared with operators who performed 50 to 75 procedures/yr. We also found that patients undergoing PCI experience a 2.74% absolute risk

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Table 7. Annual Operator Volume and Primary Outcome in Selected Subgroups

	1st Quartile (≤15)	2nd Quartile (16–44) OR (95% CI, *P* Value)	3rd Quartile (45–100) OR (95% CI, *P* Value)	4th Quartile (>100) OR (95% CI, *P* Value)
Charlson score ≥2*	Referent	0.86 (0.78–0.94, 0.001)	0.80 (0.72–0.89, <0.001)	0.68 (0.60–0.78, <0.001)
Emergent/urgent admission	Referent	0.83 (0.76–0.91, <0.001)	0.85 (0.77–0.94, 0.002)	0.70 (0.62–0.78, <0.001)
Myocardial infarction or shock	Referent	0.87 (0.80–0.95, 0.002)	0.89 (0.81–0.98, 0.020)	0.79 (0.67–0.85, <0.001)
Myocardial infarction	Referent	0.88 (0.79–0.97, 0.014)	0.96 (0.76–0.96, 0.010)	0.69 (0.59–0.80, <0.001)
Shock	Referent	0.96 (0.84–1.08, 0.473)	1.06 (0.92–1.22, 0.451)	0.79 (0.66–0.93, 0.006)
Assist devise use	Referent	0.90 (0.79–1.04, 0.166)	0.92 (0.78–1.07, 0.278)	0.66 (0.55–0.80, <0.001)
Multivessel	Referent	0.94 (0.76–1.16, 0.540)	0.94 (0.75–1.20, 0.635)	0.80 (0.62–1.05, 0.105)

CI indicates confidence interval; and OR, odds ratio.
*Charlson/Deyo comorbidity index was calculated as per Deyo classification.

reduction in secondary outcome with operator PCI volume of 50 to 75 procedures/yr as compared with an operator with annual volume of <50 procedures/yr. A further 0.68% absolute risk reduction was noted in the hands of operators performing >75 procedures/yr as compared with operators who performed 50 to 75 procedures/yr (Table 6, Figure I in the online-only Data Supplement).[15]

Another important finding of this study was an increase in-hospital mortality in institutions with <200 PCIs/yr when compared with that of institutions with 200 to 400 and >400 PCIs/yr. Few of the previous studies have reported a combined effect of institutional and operator volume on PCI outcomes.[19,37] These studies have shown contradictory results, with 1 study showing operator volume to be more predictive of outcomes[37] whereas the other did not.[19] We found both the operator and institutional volume to be individually predictive of outcome when not controlled for the other variable (Table 4 and Table III in the online-only Data Supplement).

A large body of evidence supports the existence of a relationship between hospital volume of PCI and outcome, although only a few such studies relate total hospital PCI volume to outcome of acute myocardial infarction.[21,38] Spaulding et al[38] examined the relationship between hospital PCI volume and outcomes after emergency PCI procedures from the French Registry; a clear inverse relationship existed between hospital volume and mortality for emergency PCIs, which persisted after multivariable adjustment. In our study increasing institutional volume was also associated with improved outcomes. In another study by Zahn et al,[21] a small but significant inverse operator volume–outcome relationship existed for in-hospital mortality among patients presenting with acute myocardial infarction. Similarly, Srinivas et al examined the impact of annual hospital and physician volume on risk adjusted mortality in 7321 patients undergoing PCI for acute myocardial infarction from the New York State PCI Registry (2000–2002). High-volume operators performing >10 PPCIs (Primary PCIs)/yr demonstrated a 34% reduction in risk-adjusted mortality, compared with their low-volume counterparts.[37] The 2011 ACCF/AHA/SCAI PCI guideline recommends that PCI for ST–segment-elevation myocardial infarction be performed by experienced operators who perform >11 PPCI procedures per year, and ideally, these procedures should be performed at facilities that perform >36 PPCI procedures annually.[2] Consistent with previous data, on subgroup analysis we also found an association between higher operator volume and outcome (both primary and secondary) in patient with acute myocardial infarction/ shock. We have shown that the volume–outcome relationship still exists in a recent era, and is substantial among high-risk patients undergoing emergency and complex PCI procedures.

Although PCI outcomes have improved and volume has declined over the years,[17] the relationship between PCI volume and outcome still seems intact. One reason for this finding could be higher volume physicians being well versed with clinical practice guidelines, implementing them more often. As evident in the study by Srinivas et al,[37] the higher volume centers were also more likely to follow evidence-based guidelines. Another reason could be familiarity with treating PCI complications and emergencies among higher volume physicians. High-volume hospitals are also likely to have higher-volume operators and, consequently, experience better outcomes.[39]

Table 8. Annual Operator Volume and Secondary Outcome in Selected Subgroups

	1st Quartile (≤15)	2nd Quartile (16–44) OR (95% CI, *P* Value)	3rd Quartile (45–100) OR (95% CI, *P* Value)	4th Quartile (>100) OR (95% CI, *P* Value)
Charlson score ≥2*	Referent	0.74 (0.71–0.78, <0.001)	0.63 (0.60–0.66, <0.001)	0.59 (0.56–0.62, <0.001)
Emergent/urgent admission	Referent	0.79 (0.77–0.82, <0.001)	0.70 (0.67–0.73, <0.001)	0.63 (0.61–0.66, <0.001)
Myocardial infarction or shock	Referent	0.82 (0.78–0.85, <0.001)	0.76 (0.73–0.80, <0.001)	0.71 (0.67–0.76, <0.001)
Myocardial infarction	Referent	0.79 (0.75–0.84, <0.001)	0.72 (0.67–0.76, <0.001)	0.64 (0.59–0.69, <0.001)
Shock	Referent	0.86 (0.76–0.96, 0.008)	0.81 (0.71–0.92, 0.002)	0.68 (0.58–0.80, <0.001)
Assist devise use	Referent	0.80 (0.71–0.90, <0.001)	0.75 (0.65–0.85, <0.001)	0.57 (0.49–0.66, <0.001)
Multivessel	Referent	0.78 (0.72–0.84, <0.001)	0.72 (0.66–0.78, <0.001)	0.64 (0.59–0.70, <0.001)

CI indicates confidence interval; and OR, odds ratio.
*Charlson/Deyo comorbidity index was calculated as per Deyo classification.

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Table 9. Multivariate Predictors of Length of Stay and Cost of Hospitalization

	Logarithmic Scale of Length of Stay		Logarithmic Scale of Cost of Hospitalization	
Variables	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
Age (10-yr increment)	1.00 (1.00–1.01)	<0.001	1.02 (1.02–1.02)	<0.001
Female	0.98 (0.98–0.98)	<0.001	0.99 (0.99–0.99)	<0.001
Shock	1.07 (1.06–1.08)	<0.001	1.35 (1.34–1.37)	<0.001
Myocardial infarction	1.07 (1.07–1.08)	<0.001	1.12 (1.12–1.13)	<0.001
Charlson score				
0	Referent		Referent	
1	1.02 (1.02–1.02)	<0.001	1.03 (1.03–1.03)	<0.001
≥2	1.06 (1.05–1.06)	<0.001	1.13 (1.13–1.14)	<0.001
Primary payer				
Medicare/Medicaid	Referent		Referent	
Private including HMO	1.01 (1.01–1.01)	<0.001	1.00 (1.00–1.00)	0.385
Self pay/no charge/other	0.99 (0.99–1.00)	0.02	0.99 (0.98–0.99)	<0.001
Teaching vs nonteaching hospital	1.03 (1.02–1.04)	<0.001	1.02 (1.01–1.03)	<0.001
Weekend vs weekday admission	1.04 (1.04–1.05)	<0.001	1.08 (1.08–1.08)	<0.001
Emergent/urgent vs elective admission	1.06 (1.06–1.07)	<0.001	1.13 (1.12–1.13)	<0.001
Use of assist devise	1.28 (1.27–1.29)	<0.001	1.42 (1.41–1.44)	<0.001
Institutional volume (quartile)				
1st quartile (≤542)	Referent		Referent	
2nd quartile (543–914)	0.96 (0.95–0.97)	<0.001	0.97 (0.96–0.98)	<0.001
3rd quartile (917–1641)	0.92 (0.91–0.93)	<0.001	0.93 (0.92–0.94)	<0.001
4th quartile (>1641)	0.95 (0.94–0.96)	<0.001	0.97 (0.96–0.99)	<0.001
Operator volume (quartile)				
1st quartile (1–15)	Referent		Referent	
2nd quartile (16–44)	0.97 (0.96–0.97)	<0.001	0.91 (0.91–0.91)	<0.001
3rd quartile (45–100)	0.95 (0.94–0.95)	<0.001	0.88 (0.87–0.88)	<0.001
4th quartile (>100)	0.95 (0.94–0.95)	<0.001	0.87 (0.87–0.87)	<0.001

Three levels hierarchical mixed effects models were generated (patient level factors nested within hospital level factors) with the unique hospital identification number incorporated as random effects. Length of stay was adjusted for hospital-level variables like annual institutional volume, hospital region (Northeast, South, Midwest with West as referent), teaching vs. nonteaching hospital, and patient level variables like age, sex, Deyo modification of Charlson comorbidity index, myocardial infarction, shock, emergent/urgent vs elective admission, admission over the weekend, median household income, primary payer (with Medicare/Medicaid considered as referent), in addition to annual operator and institutional procedure volume. Operator and institutional volume were calculated based on the unique operator and institutional identification number on year to year basis. CI indicates confidence interval; HMO, health maintenance organization; and OR, odds ratio.

Limitations

Although the NIS sampling design is statistically sound and has been previously used in research to estimate national health care trends, the clinical data may have some inaccuracies. It is difficult to validate individual ICD-9 codes because NIS is a deidentified database making it susceptible to errors related to coding. The operator volume data can also be misrepresented because operators could also be performing PCI in hospitals that were not part of the NIS database. In addition, not all hospitals allow the release of operator-specific data. Operator identification numbers were released in only 23 states, which led to exclusion of large number of procedures. The baseline characteristics of excluded subjects were, however, similar to those of included subjects (Table V in the online-only Data Supplement). Although principal diagnosis is accurately coded in administrative data, secondary or comorbid diagnoses are often under-reported, which may explain lower prevalence of comobidities such as anemia, obesity, and congestive heart failure in our study. Finally, we lack hemodynamic, echocardiographic, and postdischarge long-term follow-up data, which could plausibly provide further information regarding safety and efficacy of PCI. Being an observational study, a causal relation between the volume of patients and the outcome of

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treatment cannot be made. Despite these limitations, our study represents real-world experience with a large sample size. It is free from selection bias, which is associated with clinical trials.

In conclusion, we report data from multiple hospitals across the nation on the association of increasing operator volume with a decreasing PCI-related in-hospital mortality, procedural complications, length of stay, and cost of hospitalization.

Disclosures

None.

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CLINICAL PERSPECTIVE

There has been a recent decline in total number of percutaneous coronary interventions (PCIs) performed. Many interventional cardiologists and hospitals have therefore experienced a fall in procedural volumes. The current clinical competency guidelines are primarily based on expert opinion because there is paucity of data regarding effects of operator or institutional volume on outcomes. We assessed the current recommendations in this cross-sectional study consisting of 457 498 PCI procedures (representing a total of 2 243 209 PCIs performed in the United States during 2005–2009) from multiple hospitals across the nation. We found that procedures performed by high-volume operators and at high-volume institutions have significant impact on mortality, complications, length of hospital stay, and hence the total cost of in-hospital care. We also report other patient- and hospital-related factors affecting the outcomes during PCI-related hospitalizations.

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Impact of Annual Operator and Institutional Volume on Percutaneous Coronary Intervention Outcomes: A 5-Year United States Experience (2005–2009)

Apurva O. Badheka, Nileshkumar J. Patel, Peeyush Grover, Vikas Singh, Nilay Patel, Shilpkumar Arora, Ankit Chothani, Kathan Mehta, Abhishek Deshmukh, Ghanshyambhai T. Savani, Achint Patel, Sidakpal S. Panaich, Neeraj Shah, Ankit Rathod, Michael Brown, Tamam Mohamad, Frank V. Tamburrino, Saibal Kar, Raj Makkar, William W. O'Neill, Eduardo De Marchena, Theodore Schreiber, Cindy L. Grines, Charanjit S. Rihal and Mauricio G. Cohen

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APPENDIX 1f

6. Strom, et al., Association Between Operator Procedure Volume and Patient Outcomes in Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis, Circulation: Cardiovascular Quality and Outcomes, Vol. 7, Issue 4 (2014).

Original Article

Association Between Operator Procedure Volume and Patient Outcomes in Percutaneous Coronary Intervention

A Systematic Review and Meta-Analysis

Jordan B. Strom, MD; Neil J. Wimmer, MD, MSc; Jason H. Wasfy, MD, MPhil; Kevin Kennedy, MS; Robert W. Yeh, MD, MSc

Background—The growth of centers capable of performing percutaneous coronary intervention (PCI) has outpaced population growth despite declining incidence of myocardial infarction and prevalence of coronary artery disease, potentially increasing the proportion of operators falling below minimal yearly volume standards set by professional societies.

Methods and Results—Electronic literature search of MEDLINE and the Cochrane Library for English-language articles published between 1977 and November 2012 was performed. Title and abstract review followed by full-text and references review were performed by 2 authors independently to identify studies examining the association between operator volume and outcomes in PCI. Using a standardized form, 2 authors abstracted information on study design, methods, outcomes, statistical methods, and conclusions. Studies were categorized according to methodological quality and outcomes. Meta-analyses were performed by outcome using a random-effects model. Of the 23 studies included in the analysis, 14 (61%) evaluated mortality, 7 (30%) evaluated major adverse cardiac events, and 2 (9%) evaluated angiographic success. In total, the studies evaluated 15 907 operators performing 205 214 PCIs on 1 109 103 patients at 2456 centers with a mean follow-up of 2.8 years. Eleven (48%) were considered higher quality. Studies with higher methodological quality and large sample sizes more often showed a relationship between operator volume and outcomes in PCI. Higher volume was associated with improved major adverse cardiac events at every threshold, regardless of the threshold evaluated.

Conclusions—Mortality and major adverse cardiac events increase as operator volumes decrease in PCI. Among studies showing a relationship, high-volume operators were defined variably, with annual PCIs ranging from >11 to >270, with no clear evidence of a threshold effect within the ranges studied. (***Circ Cardiovasc Qual Outcomes*. 2014;7:560-566.**)

Key Words: percutaneous coronary intervention

Percutaneous coronary intervention (PCI) is the treatment of choice for acute myocardial infarction (MI), as well as a frequently used modality in the treatment of stable, symptomatic coronary artery disease.[1] During the past decade, improvements in primary prevention have led to declines in the prevalence of coronary artery disease and the incidence of acute MI.[2–5] During this same period, clinical trial evidence, notably from the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial, continues to support the use of optimal medical therapy without PCI in many patients with coronary artery disease.[6] Together, these trends have led to declines in rates of PCI in selected populations.[7]

Despite these trends, the number of medical facilities capable of performing PCI grew by 21.2% from 2003 to 2011, likely driven by several factors including the desire to improve timely access to PCI for ST-elevation MI, financial and marketing incentives, and the relaxation of requirements for onsite cardiac surgical backup for elective PCI.[8] The decreasing clinical requirements for coronary revascularization and the expanding availability of centers offering PCI are likely to cause average facility and operator procedural volumes to decrease dramatically in the future.[9,10]

This is of particular relevance, given the adoption of minimal volume standards for competency by several major cardiovascular professional societies.[11] Decreasing average operator volumes may result in an increasing proportion of operators who fall below these minimum standards recommended for competency. The impact that these trends may have on quality of care hinges on the relationship between operator PCI procedure volume and patient outcomes. In this systematic review and meta-analysis, we summarize the current literature examining the relationship between operator-specific PCI volume and patient outcomes and discuss the health policy

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WHAT IS KNOWN

- Percutaneous coronary intervention volumes have decreased, potentially increasing the proportion of interventional cardiologists who do not meet the individual operator volume targets recommended by professional societies.
- Institutional volume is inversely related with mortality, but the relationship between operator volume and outcomes is less clear.

WHAT THE STUDY ADDS

- In this systematic review and meta-analysis, mortality and major adverse cardiovascular events were inversely associated with annual percutaneous coronary intervention operator volume.
- Heterogeneity in the designs of these studies raises questions about study poolability, and the results should be interpreted in context.
- Overall, this study supports that higher annual individual operator percutaneous coronary intervention volumes are associated with better outcomes, but existing study designs preclude evaluation of a specific threshold value.

implications of our findings in light of continuing declines in the average operator PCI volume.

Methods

Data Sources and Search Strategy

We searched MEDLINE and the Cochrane Library for English-language reports published between January 1977 and November 2012. We searched combinations of keywords and Medical Subject Heading terms in the title or abstract related to volume or experience (volume, number, experience), PCI (angioplasty, percutaneous coronary, balloon coronary, PCI), and patient care outcomes (outcome assessment, treatment outcome, outcome) to find relevant studies. A detailed listing of search terms may be found in Table I in the Data Supplement. Institutional review board approval was waived because of the nature of the study.

Study Selection

We identified studies that (1) examined patients undergoing PCI (with or without stent placement), (2) reported the effects of operator-specific volume on patient mortality or morbidity, and (3) evaluated annualized volumes as opposed to career volumes. Two physicians (J.B.S. and N.J.W.) independently reviewed titles and abstracts of articles identified in the initial search for inclusion eligibility. Articles were excluded on the basis of not meeting inclusion criteria, being duplicates, evaluating career volume, and not reporting original research. The reference lists of these studies were manually reviewed for additional studies potentially eligible for inclusion. Studies that addressed both operator and hospital volume were included in the analysis.

Data Extraction

Each article meeting study eligibility was reviewed independently by 2 physicians and the data abstracted using a standardized form with the following prespecified variables: study design, study period and duration of follow-up, procedure (PCI with stent placement versus angioplasty alone), country and region, data source and population, number of patients, number of PCIs, centers, and operators included in the analysis, range and median/mean of procedural volumes per operator per year, primary and secondary outcomes analyzed, as well as time point of these outcomes, adjustment for confounders (such as demographic characteristics and case mix), adjustment for clustering of outcomes within providers or hospitals, correction for time trends, statistical tests used, P values for trend, and overall study conclusion (presence or absence of a relationship between volume and outcomes among operators). For studies dividing operator volume into multiple percentiles, the number of volume percentiles was recorded. Results were compared and reconciled between the 2 reviewers by consensus.

Data Synthesis and Analysis

Study outcomes were grouped into 3 categories: mortality, major adverse cardiovascular events (MACE), or angiographic success. Studies were then further classified by the degree to which they addressed bias and confounding that can be found in observational research, specifically whether or not the investigators (1) accounted for differences in risk, case mix, and patient demographics by adjustment for variables independently related to the outcome of interest; (2) used statistical techniques to account for clustering of outcomes within providers such as random effects, hierarchical models, or generalized estimating equations; (3) accounted for clustering of outcomes by hospital; and (4) used statistical methods to control for time trends and variation of outcomes between years of study. Studies were subsequently grouped by the degree to which they controlled for these potential biases into the following categories: very high-quality studies incorporated all 4 criteria into their study design, high-quality studies incorporated 3 of 4 criteria, good quality studies incorporated 2 of 4 criteria, fair quality studies only incorporated 1 of 4 criteria, and poor studies incorporated none. Study selection for inclusion, as well as classification of studies by quality criteria, was performed independently by the 2 physician reviewers with differences reconciled by consensus.

When available, risk ratios for event rates comparing dichotomized higher volume and lower volume groups were extracted from the data. If these estimates were not presented, they were estimated based on the crude data presented in the original studies. A meta-analysis was performed using a random-effects model to calculate a summary statistic for each outcome. We assessed for heterogeneity between studies by computing I^2 and τ^2 statistics and assessed for publication bias by constructing an Egger funnel plot. Weight was assigned according to each study's sample size. Meta-analyses were secondarily performed separately for studies of higher (defined as very high and high) and lower (defined as good, fair, and poor) quality. All P values were 2-tailed with statistical significance set at 0.05 and confidence intervals (CIs) calculated at the 95% level. Analyses were performed using R version 2.15 (University of Auckland, New Zealand).

Results

Search Results

Our literature search identified 419 citations (Figure 1), of which 54 articles were eligible for inclusion and were retrieved for full-text review. The bibliographies of these articles were queried for other references yielding an additional 9 studies. Of these articles, 31 articles were excluded because they were duplicates (n=2), editorials (n=2), focused on a procedure other than PCI (n=1), evaluated the effect of career volumes on outcome (n=1), or did not address the specific relationship of operator volume to outcome (n=26). Twenty-three[12–34] articles were included in the analysis on the basis of meeting all inclusion criteria with 100% agreement between reviewers.

Characteristics of Included Studies

Table II in the Data Supplement provides summary characteristics, as well as more detailed information about each included study. Studies enrolled patients undergoing PCI from 1990 until 2005. Six studies (26%) enrolled patients undergoing

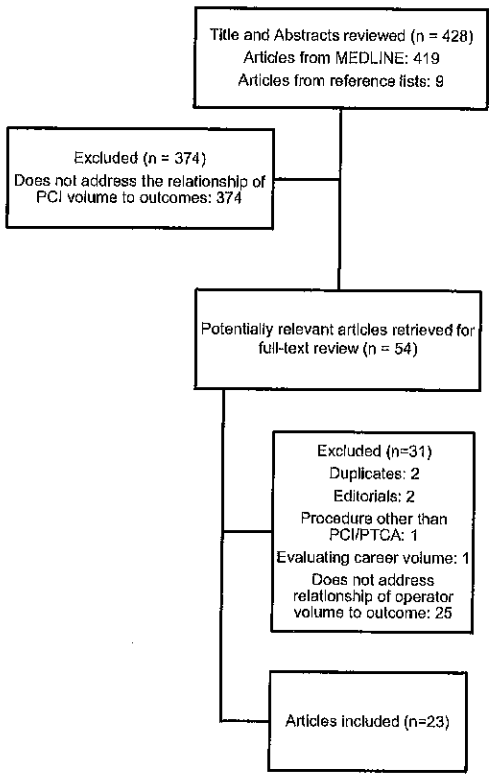

Figure 1. Summary of study selection and exclusions. PCI indicates percutaneous coronary intervention. Summary of study selection and exclusions. PCI indicates percutaneous coronary intervention; and PTCA, percutaneous transluminal coronary angioplasty.

balloon angioplasty alone rather than PCI with stent placement,[12–17] with each of these starting enrollment before 1996. Six studies (26%) were single-center studies,[18–23] with the rest ranging from 2 to 1003 centers per study (mean, 102; median, 12). The number of operators included ranged from 3 to 6534 (mean, 691; median, 108), performing from 5 to 593 PCI procedures per year (mean, 195; median, 112). Study duration ranged from 4 months to 7 years (mean, 2.8 years; median, 3 years). Data sources included mainly hospital-based databases in 9 (39%) studies and regional databases in 10 (43%) studies, with 2 studies (9%) drawing from Medicare claims data[14,28] and 2 (9%) from clinical trial data.[20,29]

Study Methods and Quality

There was considerable variability with which the studies used methods to address potential bias and confounding (Table). No studies were classified as poor quality. Six studies (26%) were classified as fair quality because they met only 1 of 4 criteria,[13,23–27] with 5 only adjusting for baseline demographics and case mix[13,24–27] and 1 only adjusting for clustering of outcomes by hospital.[23] Five studies (22%) were considered very high quality.[15,17,28–30] Overall, 11 studies (48%) were of higher (high or very high) quality.[12,14,15,17,20,21,28–33]

Outcomes of Included Studies

Mortality

Mortality was included as the primary outcome for 13 studies (57%), with 11 (85%) evaluating in-hospital mortality[12,13,15,16,22,23,25,28,30–32] and the rest evaluating mortality at 30 days[26,29] (Figure 2). Among the group of studies rated as high or very high quality,[12,15,28–30,32] most (4 of 6 [67%]) studies showed a significant or strong trend toward reduced mortality with increasing volume compared with 2 of 7 (29%) lower quality studies. Among higher quality studies, effect estimates ranged from a significant reduction in mortality of 57%[15] for operators performing ≥11 versus 1 to 2 percutaneous coronary transluminal angioplasties per year to a nonsignificant increase in mortality of 2%[29] for operators performing ≥100 versus <100 PCIs per year. The summary estimate showed no overall effect of operator volume on mortality, with an odds ratio of 0.96 (95% CI, 0.86–1.08), with significant heterogeneity (I^2 = 61.4%; P=0.0019), and no evidence of publication bias (P=0.55). When the analysis was restricted to very high-quality and high-quality studies (figure not shown), the summary estimate demonstrated a nonsignificant reduction in

Table. Quality Rating and Sample Size of Included Studies

Outcome	Quality Rating*	No. of Studies, n	Total Sample Size, n†	Studies Concluding Existence of Relationship, %
Mortality	Very High	4	197867	50
	High	2	170383	100
	Good	3	129857	33
	Fair	4	55594	0
MACE	Very High	1	452404	100
	High	3	117011	100
	Good	3	17783	67
	Fair	1	6510	0

MACE indicates major adverse cardiac events.

*Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high=accounting for all 4 aforementioned criteria; high=accounting for 3 criteria; good=accounting for 2 criteria; fair=accounting for 1 criterion. No studies accounted for zero criteria.

†Sample size refers to the number of patients. In studies not reporting number of patients, the number of percutaneous coronary interventions included in the analysis was used.

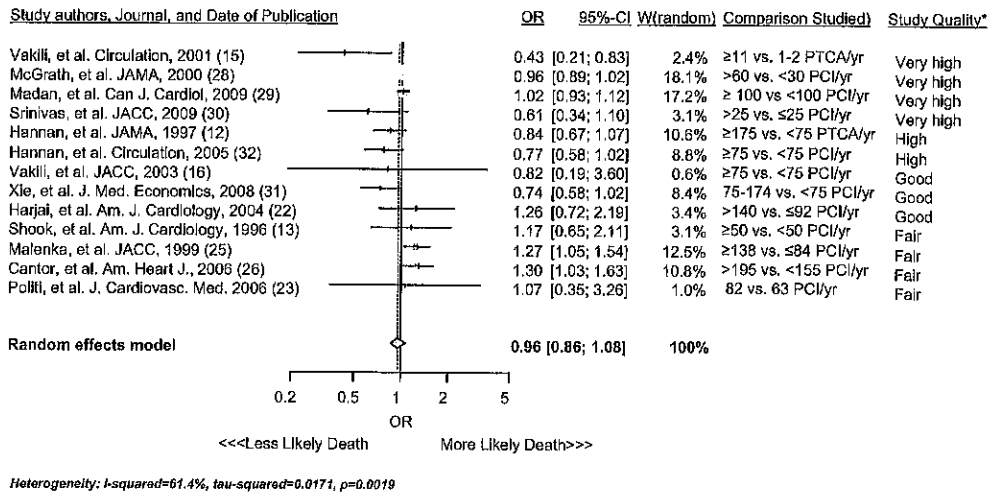

Figure 2. Results of studies evaluating the relationship between annual percutaneous coronary intervention (PCI) operator volume and mortality. *Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high=accounting for all 4 aforementioned criteria; high=accounting for 3 criteria; good=accounting for 2 criteria; fair=accounting for 1 criterion. No studies accounted for zero criteria. CI indicates confidence interval; OR, odds ratio; PCI/yr, number of PCIs per operator per year; and PTCA/yr, number of PTCA per operator per year.

mortality with an odds ratio of 0.90 (95% CI, 0.79–1.01) for higher versus lower volume operators and significant heterogeneity among studies (I^2=60.9%; P=0.0256).

The definitions of lowest and highest volume operators were, however, variable. Studies differed in the number of volume percentiles used, from 1[19] to 5,[12,18,33,34] and in the number of PCIs per operator per year in the lowest percentile, with <75 PCIs per operator per year being most common[12,16,17,27,28] but ranging from <10[15,30] to <155[26] and from ≥11[16] to >195[26] in the highest quintile. Two studies[15,32] described a threshold volume below which mortality worsened, one suggesting a threshold of 10 PCIs per year and the other suggesting a threshold of 75 PCIs per year, although the latter was no longer statistically significant when adjusting for hospital volume.[32]

Major Adverse Cardiac Events

Eight studies (35%) reported MACE as the primary outcome[14,17–19,21,27,33,34] (Figure 3). MACE was variably defined from a composite outcome of death, MI, or emergency coronary artery bypass grafting surgery[18,34] to a composite of death or emergency coronary artery bypass grafting[14,17] or major complications (MI, cardiac tamponade, coronary perforation, emergency bypass surgery, death, or blood transfusions[27]); a composite of death, MI, cardiogenic shock, ventricular tachycardia or fibrillation, or thromboembolism[19]; or a composite of death, MI, or symptom-driven revascularization.[21] Four studies (50%) reported in-hospital outcomes,[14,27] with the rest reporting outcomes at 30 days,[18,21] 1 year,[17] or 3 years.[19]

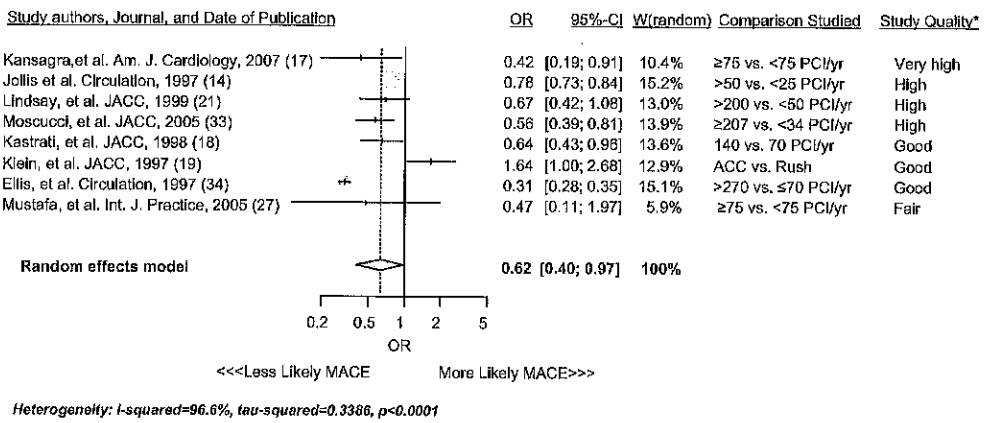

Figure 3. Results of studies evaluating the relationship between annual percutaneous coronary intervention (PCI) operator volume and major adverse cardiac events. *Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high=accounting for all 4 aforementioned criteria; high=accounting for 3 criteria; good=accounting for 2 criteria; fair=accounting for 1 criterion. No studies accounted for zero criteria. ACC indicates American College of Cardiology Registry; CI, confidence interval; OR, odds ratio; PCI/yr, number of PCIs per operator per year; PTCA/yr, number of PTCA per operator per year; and RR, relative risk.

Overall, 5 studies (63%) reported a significant association between lower operator volume and increased risk of MACE. Among the 4 higher quality studies,[14,17,21,33] 3 reported significant reductions in MACE with increasing operator volume, and the fourth showed a strong trend, with risk reductions ranging from 0.42 to 0.78 for higher volume compared with lower volume groups, with a mean reduction in MACE of 39% when comparing highest with lowest volume cohorts. The summary estimate demonstrated a significant reduction in MACE comparing high- with low-volume operators with an odds ratio of 0.62 (95% CI, 0.4–0.97), as well as significant heterogeneity (I^2=96.6%; P=<0.0001) and no publication bias (P=0.88). Restricting the analysis to very high-quality and high-quality studies (figure not shown) did not markedly change the size of the effect with an odds ratio of 0.67 (95% CI, 0.53–0.85), although with improved and nonsignificant heterogeneity (I^2=46.9%; P=0.1297). These studies defined lower and higher volume operators variably, with low-volume cutoffs ranging from <25[14] to 100[18] PCIs per year and high-volume cutoffs ranging from >50[14] to >270[34] PCIs per year. Of studies initiated before the year 2000, 5 of 6 (83%) demonstrated a relationship[14,21] compared with 1 of 2 (50%) after 2000.[33]

Discussion

In a comprehensive systematic review and meta-analysis of the association between operator procedure volume and outcomes in PCI, we found that in the majority of high-quality studies, there was an inverse relationship between yearly operator volume and clinical outcomes, particularly MACE. However, there was significant heterogeneity in the quality and designs of studies included, which preclude the ability to definitively evaluate the magnitude of this effect or the existence of a threshold above which volume differences are no longer meaningful.

Current PCI guidelines dictate a class I indication for PCI operators to perform >50 elective PCIs annually averaged over to years (and >11 primary PCIs) at an institution volume of >200 elective PCIs annually (and >36 primary PCIs).[11] For individuals with an annual case volume <50 PCIs, current guidelines recommend that facilities establish internal review strategies to assess these individuals.[11] Our findings support the recommendations for operators to achieve a higher annual PCI volume, but do not clearly endorse the value 50 as the appropriate threshold. Although the annual recommended case volume was decreased to >50 PCIs from the prior threshold of >75 PCIs to accommodate the growing number of PCI operators performing <50 PCIs per year, our findings support recommendations to achieve a higher annual PCI volume through means such as increasing PCI regionalization and PCI center consolidation.

However, when restricting the meta-analysis to very high-quality and high-quality studies, a significant reduction in MACE was observed with high- versus low-volume operators of 33%. In addition, higher quality studies also suggested a trend for reduction in mortality for high- versus low-volume operators of borderline significance. Although our review of the literature suggests the existence of a relationship between operator volume and clinical outcomes among studies using more rigorous observational study design, most studies[13,16,18,19,22–27,31,34] did not effectively deal with methodological problems that are inherent in observational research. Certain studies failed to adjust for degree of baseline risk and known confounding variables,[23] others failed to address clustering of outcomes by operator[13,14,16,18–27,31,33] or hospital,[13,16,24–27] and still others failed to adjust for time trends.[12,13,18,19,22–27,31,32,34] Future studies accounting for these factors and specifically designed to assess volume thresholds could be a useful addition to the existing literature.

Furthermore, significant variation in study design limited any conclusions that could be made about the existence of a threshold value at which risk decreases more substantially. In general, studies most often created categories of volume and used either the lowest or highest volume range as the reference range for comparison versus analyzing volume as a continuous variable. This variation in design limits conclusions about a threshold value above which outcomes change. However, among high-quality studies, there seemed to be a strong trend toward increased MACE among lower volume operators at cutoffs as high as 50 PCIs per year and for increased mortality at a cutoff of 11 PCIs per year. In future studies, analysis of volume as a continuous variable may permit determination of a threshold effect, should one exist.

Although overall our review suggests a relationship between operator volume and outcomes in PCI, particularly with regard to MACE, temporal trends in PCI performance and technological advances may influence the degree to which operator volume influences outcomes. As noted previously, 3 of 4 (75%) studies evaluating balloon angioplasty alone showed a relationship compared with 2 of 7 (29%) PCI studies, suggesting that operator volumes may have had a larger effect on outcomes in the early stages of development of modern PCI and that refinement in technology, physician training, and standardization and improvement in catheterization laboratory procedures has led to improvement in outcomes across volume ranges. Furthermore, improvements in medical therapy before, during, and after PCI may further confound this relationship.

Our study has several important limitations. Our review included only English-language studies and did not include information from nonindexed journals, conferences, or unpublished abstracts. Furthermore, variability in which studies are indexed under particular search terms may have prevented the inclusion of some eligible studies. Definitive study in this area is difficult for several reasons. First, defining the optimal research question is challenging because there are several reasonable and related questions for consideration. Examples include the following: what is the role of lifetime procedural volume beyond procedural volume in the year under study? What is the modifying relationship between hospital volume and individual clinician volume? Is there a different volume–outcome relationship for primary PCI than for procedures performed on more stable patients? What is the role of operator volume in academic medical centers where trainees are participating in the performance of procedures? Finally, although we chose to conduct a quantitative meta-analysis to synthesize the data, heterogeneity in the designs of these studies raises questions about study poolability. The results should be interpreted in this context.

The existence of a relationship between operator volume and patient outcomes has important implications for patients, as well as structuring of training programs, maintenance of PCI competency, and regionalization of PCI care. In the current economic climate, the growth of PCI centers has outpaced both population growth and rates of coronary artery disease, which in turn have declined.[2–5] With new data supporting the safety of carefully selected, nonemergent PCI in centers without onsite surgical backup and continued economic incentives for growth,[35] it is likely that the number of PCI centers will continue to increase. As a result, PCI operators may perform fewer procedures, and many may fall below the threshold levels for competency as set by professional societies. Trainees at lower volume centers may have insufficient volumes to develop competency in PCI, suggesting the need for low-volume training programs to partner in order for their trainees to develop sufficient volume credentials. The existence of a relationship between operator volume and outcomes in PCI suggests that the addition of more PCI-capable cardiac catheterization laboratories may not lead to improved clinical outcomes or access, particularly in light of recent evidence suggesting that new PCI programs may be duplicative of existing programs.[36] Recognizing that 61% of PCI operators in 2008, accounting for 30% of all PCIs performed nationally, performed ≤40 Medicare fee-for-service PCIs argues for the consolidation rather than addition of cardiac catheterization laboratories and for further regionalization of PCI care.[9] Although other studies have shown an inverse relationship between hospital volume and mortality[37–38], our study is the first meta-analysis to our knowledge to demonstrate a similar association between operator volume and outcomes.

In summary, in high-quality comparative studies, mortality and MACE are inversely associated with annual PCI operator volume, particularly MACE. This finding has important implications for the development of new PCI centers, as well as the training and maintenance of competency of interventional cardiologists. More research is necessary to confirm this finding and elucidate the presence or absence of a threshold effect.

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Disclosures

None.

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APPENDIX 1g

7. Laslett, et al., The Worldwide Environment of Cardiovascular Disease: Prevalence, Diagnosis, Therapy, and Policy Issues: A Report from the American College of Cardiology, Journal of the American College of Cardiology, Vol. 60 Suppl S, No. 25 (2012).

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STATE-OF-THE-ART PAPER

The Worldwide Environment of Cardiovascular Disease: Prevalence, Diagnosis, Therapy, and Policy Issues

A Report From the American College of Cardiology

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Sacramento and Redwood City, California; Hershey, Pennsylvania; Hartford, Connecticut; Chesterfield, Missouri; New York, New York; and Washington, DC

The environment in which the field of cardiology finds itself has been rapidly changing. This supplement, an expansion of a report created for the Board of Trustees, is intended to provide a timely snapshot of the socioeconomic, political, and scientific aspects of this environment as it applies to practice both in the United States and internationally. This publication should assist healthcare professionals looking for the most recent statistics on cardiovascular disease and the risk factors that contribute to it, drug and device trends affecting the industry, and how the practice of cardiology is changing in the United States. (J Am Coll Cardiol 2012;60 Suppl S: S1–S49) © 2012 by the American College of Cardiology Foundation

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Global Burden of Cardiovascular Disease

Cardiovascular disease (CVD) currently accounts for nearly half of noncommunicable diseases (NCDs). NCDs have overtaken communicable diseases as the world's major disease burden, with CVD remaining the leading global cause of death, accounting for 17.3 million deaths per year, a number that is expected to grow to >23.6 million by 2030 (1,2).

Increasingly, the populations affected are those in low- and middle-income countries (LIMC) (Fig. 1), where 80% of these deaths occur, usually at younger ages than in higher income countries, and where the human and financial resources to address them are most limited (2,3).

From 2011 to 2025, the projected cumulative economic losses from all NCD is $7.28 trillion in LIMC. As displayed in Figure 2, CVD accounts for nearly 50% of this projected loss (4). Within LIMC, it is projected that reducing CVD mortality by 10% would result in a $377 billion reduction in economic losses from 2011 to 2025 (5).

Economists project that the cost of not investing in CVD prevention and treatment could amount to as much as $47 trillion worldwide in the next 25 years. This loss is potentially avoidable because the prescribed World Health Organization (WHO) "best buy" interventions only cost $11 billion to $13 billion annually (6). The consequences will be more severe in developing countries, given that 80% of cardiovascular deaths occur in LMIC countries (7).

Cardiovascular disease is responsible for 10% of the disability-adjusted life years (DALYs) lost in LMIC, and for 18% of DALYs lost in high-income countries (8). The cost of CVD to both families and society is related to both a loss of productivity and income of the person who has CVD and of their caregiver, who may have to stop working to care for them. This economic loss is exacerbated in the developing world where CVD affects a high proportion of working-age adults (9).

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Abbreviations and Acronyms

ACA = Affordable Care Act
ACC = American College of Cardiology
ACO = Accountable Care Organization
AHA = American Heart Association
BMI = body mass index
CMS = Centers for Medicare and Medicaid Services
COI = conflict of interest
CVD = cardiovascular disease
CVRN = Cardiovascular Research Network
DALY = disability-adjusted life year
DES = drug-eluting stent
EHR = electronic health record
FDA = Food and Drug Administration
FTE = full-time equivalent
HDL = high-density lipoprotein
LDL = low-density lipoprotein
LMIC = low- to middle-income country
NCD = noncommunicable disease
NIH = National Institutes of Health
PCMH = patient-centered medical home
PGPD = physician group practice demonstration
TAVR = transcatheter aortic valve replacement
YLL = years of lives lost

Heart disease and stroke by country. The SHARE (Survey of Health, Ageing, and Retirement) in 11 European countries, the HRS (Health Retirement Survey) in the United States, and the ELSA (English Longitudinal Study of Aging) survey and collect information regarding the health of the aging population. Table 1 synthesizes the studies and displays comparisons of age-adjusted self-reported prevalence of heart disease and stroke by country. It indicates that the United States has the highest prevalence of heart disease and stroke in both males and females Table 1 (10).

CVD risk factors. OBESITY. Globally, the prevalence of obesity (body mass index [BMI] ≥30 kg/m^2) doubled between 1980 and 2008, and it is estimated that 2.8 million deaths annually are caused by being overweight (BMI ≥25 kg/m^2) or obese. In 2008, 10% of men and 14% of women globally were obese compared with 5% of men and 8% of women in 1980. The Americas had the highest prevalence of overweight (62%) and obese (26%) persons (1,11). Figure 3 and Table 2 display the mean BMI change by WHO region and globally.

HYPERTENSION. Globally, some 40% of people over the age of 25 years have high blood pressure, and the number of people with elevated blood pressure (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) has increased from 600 million in 1980 to a billion in 2008. The global hypertensive percentage has improved over this period; however, some regions have worsened in this respect. A decrease in the proportion of populations with high blood pressure was seen in the Western Pacific, Europe, and the Americas, as shown in Figure 4 and Table 2 (12). Systolic blood pressure is highest in LMIC. Globally, elevated blood pressure is reported to cause 51% of stroke deaths and 45% of coronary heart disease deaths (Table 2) (11).

DYSLIPIDEMIA. Mean total cholesterol levels around the world are highest in high-income countries and have been dropping since 1980 throughout the world. The most drastic decreases have been in high-income countries (5.62 to 5.19 mmol/l), but modest decreases in low-income countries (4.46 to 4.20 mmol/l) and middle-income countries (4.91 to 4.7 mmol/l) have also been seen. Nevertheless, some 39% of the global population still has elevated cholesterol, as do more than one-half of those in higher income countries (Fig. 5) (3).

SMOKING. Smoking rates among adults in the United States have declined by more than one-half over the past 25 years, from 33.5% in 1980 to 15.1% in 2010—thought to be the fourth lowest rate among OECD countries (countries that signed the convention on Organization for Economic Cooperation and Development) after Iceland, Sweden, and Mexico. In contrast, at least 25% of residents living in Greece, Chile, Ireland, Hungary, Estonia, Spain, and Turkey smoke cigarettes, according to the most recent data (Table 3) (13).

Drivers of CVD. AGING AS A GLOBAL PHENOMENON. Populations in the developed world have been aging for decades due to rising life expectancy and falling birth rates. The United Nations has calculated that the proportion of the world's population over the age of 65 years will more than double by 2050, at which point approximately 1 billion people around the world will be over the age of 65 years (Fig. 6).

Problems associated with an aging population are expected to be particularly acute in wealthy, industrialized countries such as Japan, Italy, and Germany, where 20% or more of the population was 65 years of age or older in 2010. In LIMC, the elderly are also expected to become an increasingly large economic burden as they are expected to

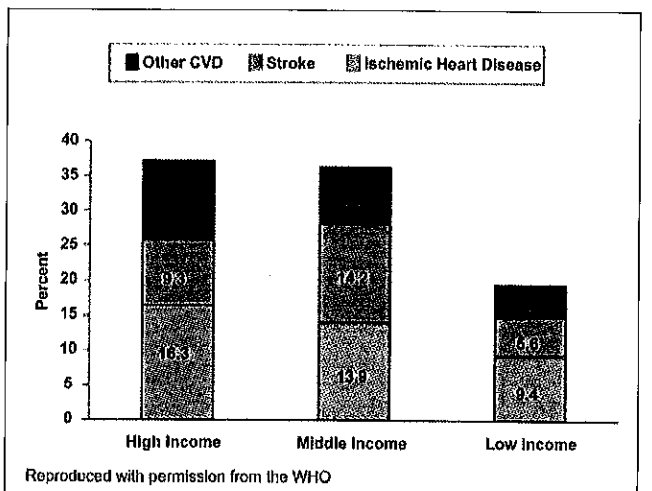

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Figure 1 Crude Data: Proportion of Deaths Due to CVD by Country Income Level

CVD = cardiovascular disease. Source: Sinclair H. CVD Improvements and Challenges of a Global Epidemic; MD Conference Express, November 2010.

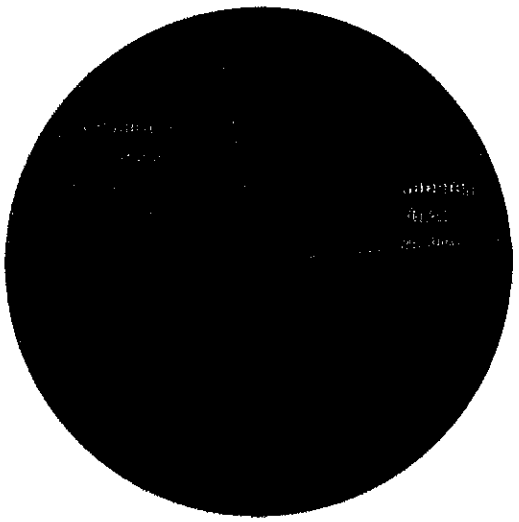

Figure 2 **Economic Loss (Trillions of US$ in 2008) of Noncommunicable Diseases in Low- and Middle-Income Countries, 2011 to 2025**

Source: World Economic Forum and World Health Organization (5).

represent at least 15% of the population in countries in which the per capita income was under $10,000 in 2005 (14). In the absence of targeted policy measures, the aging of the population is expected to lead to significant increases in societal expenditures beginning around 2020 onward, the largest proportion of it going to pensions, followed by health and long-term care.

Life expectancy has been progressively increasing for the last 50 years. Figure 7 shows life expectancy at birth in 2009 (or nearest year available), and the years gained since 1960.

URBANIZATION AND THE CVD RISK FACTOR BURDEN. Living in a city—often a megacity (>10 million people), of which there are now 21 in the world—brings with it a number of predictable hazards (15). Among those that contribute to CVD are heavy environmental pollution, high traffic, no sidewalks, and even the threat of violence outside the home; these factors are major obstacles to physical activity. Additionally, there are very few "green spaces," or open land for public use, contributing to the lack of exercise and sedentary lifestyle (8).

Globalization and urbanization are key factors driving the worldwide increase in obesity and diabetes mellitus (major CVD risk factors), along with hypertension. With urbanization has come the global nutritional transition. This transition includes an increase in consumption of animal-source foods, edible oils, and sugars that has occurred in high-income countries and is progressively occurring in LMICs. This dietary change is influenced by the increasing numbers of supermarkets in developing countries that tend to serve processed foods higher in salt, fat, and added sugar. In Latin America, for example, supermarkets' share of food sales increased from 15% to 60% over a 10-year period (1990 to 2000). Another factor is the decreasing price of animal source foods and grains (11). Low-income countries often face a double burden of nutritional insufficiencies among infants and children combined with greater access to nutrition-poor food later in life. This has been found to increase the risk for CVD later in life (11).

Migrating from rural to urban areas is shown to increase blood pressure due to changing dietary patterns. Figure 8 shows that, on average, urban areas have a higher prevalence of hypertension than rural areas (16). Finally, smoking rates are also increasing among youth in several regions of the world due to urbanization. Tobacco manufacturers aggressively market to cities of LMIC. Unfortunately, children are most affected by these campaigns, as they are more impressionable (8).

Mortality disparities. In comparison to high-income countries, total years of life lost (YLL) to disease are more than 4 times higher in LIMC and more than double in middle-income countries. More than two-thirds of total YLL are caused by communicable diseases, maternal and perinatal conditions, as well as nutritional deficiencies. As the burden of CVD risk factors increases in LMIC countries, the proportion of deaths due to CVD is projected to increase, especially in LMIC countries, as displayed in Figure 9. In contrast, the same causes account for only about one-quarter of lives lost in middle-income countries and fewer than 10% of lives lost in high-income countries (Fig. 10) (11).

STROKE MORTALITY EXCEEDS ISCHEMIC HEART DISEASE MORTALITY. CVD-associated stroke mortality exceeded ischemic heart disease mortality in 74 WHO member countries in a global analysis of WHO cause-specific mortality data and World Bank national income data. China, Africa, and South America had a disproportionately higher burden of stroke (Fig. 11). Specifically, in the country with

Table 1 **Age-Adjusted Prevalence (% of Population) of Heart Disease and Stroke by Sex, 2004**

	Heart Disease		Stroke	
Country	Males	Females	Males	Females
Austria	12.2	7.3	5.2	3.5
Belgium	18.8	11.8	3.9	4.2
Denmark	10.8	7.6	6.5	4.6
France	19.3	9.8	3.7	3.5
Germany	14.3	9.3	5.6	3.1
Greece	14.9	10.7	4.1	3.5
Italy	12.7	9.1	3.8	2.5
Netherlands	14.7	8.9	5.0	4.8
Spain	11.4	10.0	2.4	1.8
Sweden	20.3	13.0	6.3	3.6
Switzerland	9.5	5.4	2.9	2.2
Total SHARE	15.4	9.9	4.5	3.5
United States (HRS)	26.4	19.7	6.6	5.5
England (HRS)	19.0	16.0	3.2	2.5

HRS = Health Retirement Survey; SHARE = Survey of Health, Ageing, and Retirement.

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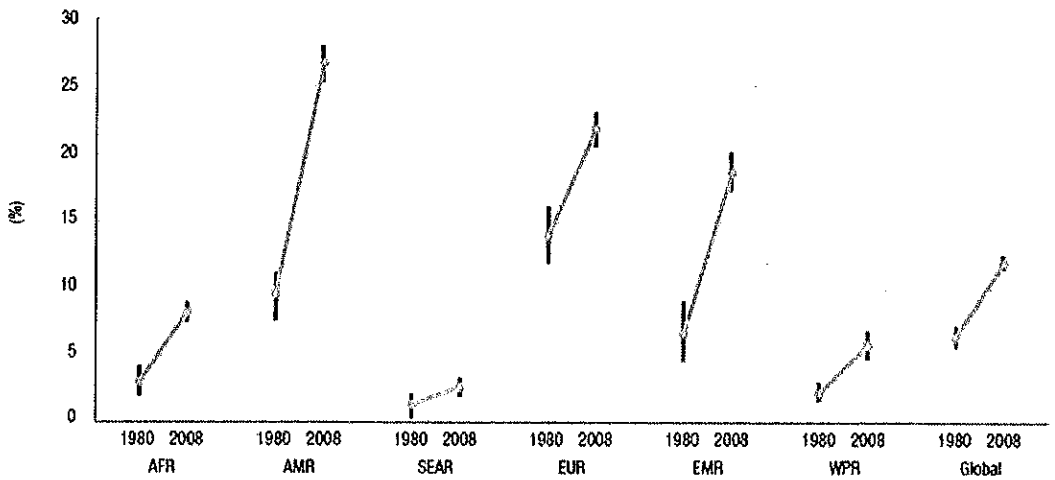

Figure 3 **Change Over Time in Mean BMI by WHO Region, 2009**

AFR = African region; AMR = Americas region; BMI = body mass index; EMR = Eastern Mediterranean region; EUR = European region; SEAR = South-East Asia region; WHO = World Health Organization; WPR = West Pacific region. Source: World Health Organization (11).

the second largest excess, China, stroke mortality rate was 19.9% of total all-cause mortality compared with the 8.0% attributed to ischemic heart disease. Conversely, Australia, much of Europe, North America, and the Middle East experienced a higher burden of ischemic heart disease (Fig. 11) (17).

Global CVD initiatives. As CVD becomes a bigger health concern in the developing world, the United Nations political declaration on NCD resolved to reduce premature death due to NCDs by 25%. To respond to the declaration, a task force consisting of representatives from professional societies (American College of Cardiology Foundation [ACCF], American Heart Association (AHA), World Heart Federation, European Heart Network, and European Society of Cardiology) convened to establish risk factor reduction targets. The targets to be reached by 2025 include the following:

- 10% relative reduction in overall alcohol consumption
- 15% relative reduction in mean proportion of total energy intake from saturated fatty acids
- Stop the increasing obesity prevalence
- 10% relative reduction in the prevalence of insufficient activity
- 25% relative reduction in prevalence of high blood pressure
- 20% relative reduction in high total cholesterol
- 30% relative reduction in mean population intake of salt
- 30% relative reduction in smoking prevalence (2).

Table 2 **World Health Organization Abbreviations**

Abbreviation	WHO Region
AFR	African Region
AMR	Region of the Americas
SEAR	South-East Asia Region
EUR	European Region
EMR	Eastern Mediterranean Region
WPR	Western Pacific Region

WHO = World Health Organization.

The UnitedHealth Chronic Disease Initiative, together with the National Heart, Lung, and Blood Institute, has pledged $34 million over 5 years to support a network of collaborating centers of excellence to help combat chronic diseases, including CVD, in developing countries (18). A research institution in each center within a developing country is paired with at least 1 institution in a developed country, and each center is responsible for carrying out research tailored to local or regional needs (19).

A similar initiative is planned to improve medical education and research capability in Sub-Saharan Africa. The National Institutes of Health and the President's Emergency Plan for AIDS relief collaborated to award funding to the Medical Education Partnership Initiatives to address shortages in specialized training. One clear need is cardiology training in Sub-Saharan Africa. For example, Zimbabwe has 3 trained cardiologists (2 adult cardiologists and 1 pediatric cardiologist). The main medical school in Zimbabwe received a Medical Education Partnership Initiatives–based grant (Cerebrovascular, Heart Failure, Rheumatic Heart Disease Interventions Strategy grant) to integrate modern cardiovascular training within existing medical school education to improve health outcomes and improve CVD research capacity (20).

It should also be noted that access to up-to-date biomedical research within the developing world is a key component to improving CVD care. The Health InterNetwork

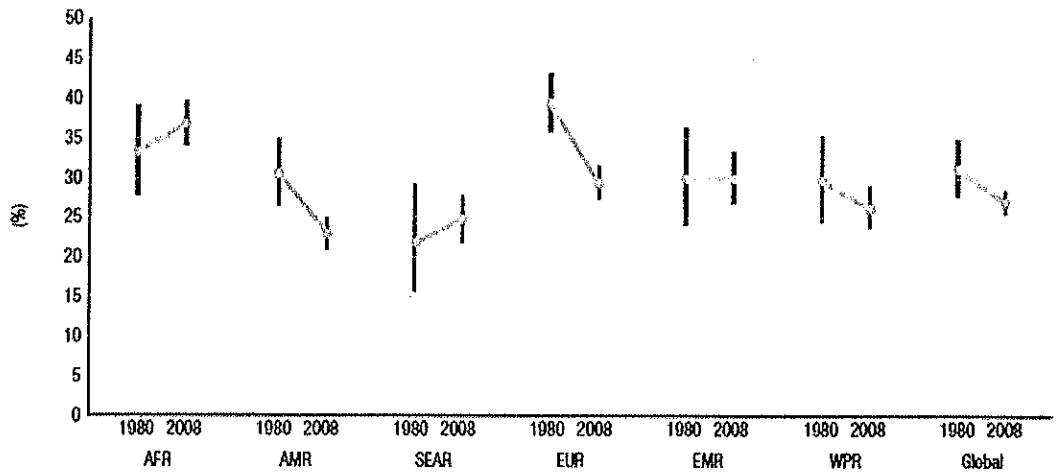

Figure 4 **Prevalence of Elevated Blood Pressure (SBP ≥140 mm Hg or DBP ≥90 mm Hg) Among Adults Over 25 Years by WHO Region, 1980 to 2008**

DBP = diastolic blood pressure; SBP = systolic blood pressure; other abbreviations as in Figure 3. Source: World Health Organization (11).

Access Research Initiative provides free online access to >7,500 journal titles in the biomedical and health literature to 105 academic institutions in developing countries. The project is expected to continue until at least 2015 (21).

Changing Dynamics of Payment and Delivery

Economic pressure is causing the healthcare industry to adopt new paradigms of care that service more people at lower costs. The most recent national spending projections from the Centers for Medicare and Medicaid Services (CMS) estimate that U.S. healthcare spending will grow at an average annual rate of 5.7% from 2011 through 2021, rising from 17.9% of the gross domestic product ($2,495.8 billion) to 19.6% ($4,781.0 billion) (Fig. 12) (22,23).

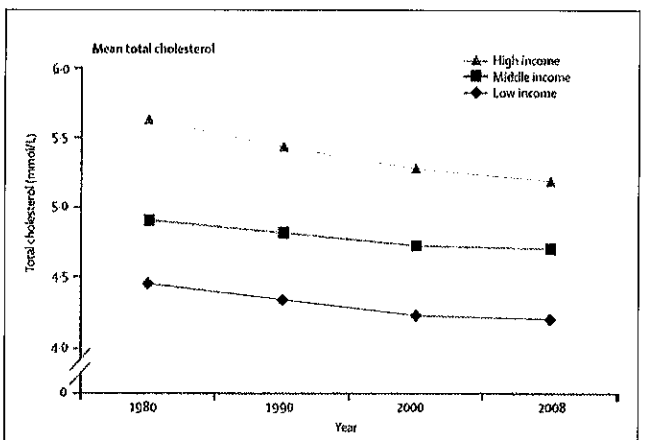

Figure 5 **Change Over Time in Mean Total Cholesterol by Country Income Category**

Green = high income; **red** = middle income; **blue** = low income. Source: Anand et al. Stemming the global tsunami of cardiovascular disease. Lancet 2011 Feb 12.

Mirroring the national trend of increasing costs, the AHA's recent projections show cardiovascular care cost tripling from $272.5 billion in 2010 to an estimated $818.1 billion in 2030 (24). Figure 13 shows the projected direct and indirect costs of all CVD, 2010 to 2030.

Between 2010 and 2030, real (2008$) total direct medical costs of CVD are projected to triple, from $272.5 billion to $818.1 billion (Table 4). Because it has a higher prevalence than other CVD conditions, hypertension is the most expensive component of CVD (24).

Real indirect costs for all CVDs are estimated to increase from $171.7 billion in 2010 to $275.8 billion in 2030, an increase of 61% (Table 4). Congestive heart disease has the highest indirect cost and is expected to continue to account for 40% of all CVD indirect costs (Table 4) (24).

It is important to note that these CVD projections were made under the assumption that the status quo will be maintained in CVD prevention and treatment trends (e.g., no increase in the use of generic drugs).

Roehrig and Rousseau (25) suggest that prior health spending research has overly emphasized so-called treated prevalence, namely, the number of people receiving treatment for a given condition, rather than correctly accounting for the effects of cost per case trends. Examining treated prevalence, clinical prevalence (the number of people with a given disease, treated or not) and cost per case across all medical conditions between 1996 and 2006, they found three-fourths of the increase in real per capita health spending was attributable to growth in cost per case, whereas treated prevalence accounted for about one-fourth of spending growth. They conclude that most of the treated prevalence effect is due to an increase in the share of eligible people being treated rather than to an increase in clinical prevalence of diseases, and suggest that efforts to curb

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Table 3 Proportion of Population in OECD Countries Who Smoke, 2010*

Rank	OECD Countries	2010
1	Greece	31.9
2	Chile	29.8
3	Ireland	29.0
4	Hungary	26.5
5	Estonia	26.2
5	Spain	26.2
7	Turkey	25.4
8	Czech Republic	24.6
9	Poland	23.8
10	France	23.3
11	Austria	23.2
12	Italy	23.1
13	Korea	22.9
14	Germany	21.9
15	United Kingdom	21.5
16	Netherlands	20.9
17	Belgium	20.5
18	Switzerland	20.4
19	Denmark	20.0
20	Japan	19.5
20	Slovak Republic	19.5
22	Finland	19.0
22	Norway	19.0
24	Slovenia	18.9
25	Israel	18.6
25	Portugal	18.6
27	New Zealand	18.1
28	Luxembourg	18.0
29	Canada	16.3
30	Australia	15.1
30	United States	15.1
32	Iceland	14.3
33	Sweden	14.0
34	Mexico	13.3
	OECD average	21.1

*Or nearest available year. Source: OECD Health Data 2012 (13).
OECD = Organization for Economic Cooperation and Development.

health spending should focus more on reining in cost per case (25). Table 5 shows the growth rate in real per capita spending along with cost per case and treated prevalence percentages for cardiovascular conditions between 1996 and 2006 (25).

Addressing rising costs, along with expanding coverage and improving healthcare delivery, is a key focus of the Affordable Care Act (ACA) approved by Congress in 2010 with key provisions, albeit modified concerning the expansion of the Medicaid program, upheld in 2012. Table 6 lists provisions related to cost control enacted by the law (26).

Table 7 lists current CMS Innovation Center initiatives (29,30); Figure 14 shows percentage of total U.S. healthcare spending by payment sources (2010).

Care coordination. Addressing fragmented care through better coordination is considered an approach that may improve healthcare quality. Nonphysician professionals are being seen as a resource to alleviate pressure created by physician shortages. Various healthcare reform efforts are under way to develop teams of allied healthcare practitioners who will be able to provide team-based care for chronically ill patients. Interdisciplinary teams are a key component to provide chronic disease management and transitional care delivered in newer models of care such as accountable care organizations (ACOs).

The most significant model currently undergoing testing and development to understand the dynamics of team-based care is the patient-centered medical home (PCMH) (31,32). The CMS is currently running the federally qualified health center advanced primary care practice demonstration to determine whether the PCMH can improve quality of care, promote better health, and lower costs. As of October 2011, approximately 500 practices were enrolled in the demonstration (33).

In an effort to alleviate potential obstacles in the creation of PCMHs, the CMS Innovation Center has committed funding to multiple PCMH efforts. These include pilot projects aimed at improving quality of care for vulnerable populations and implementation of the PCMH model in medical settings. The CMS has designated these efforts as the Health Care Innovation Awards and recently distributed $122.6 million to 26 health centers in May

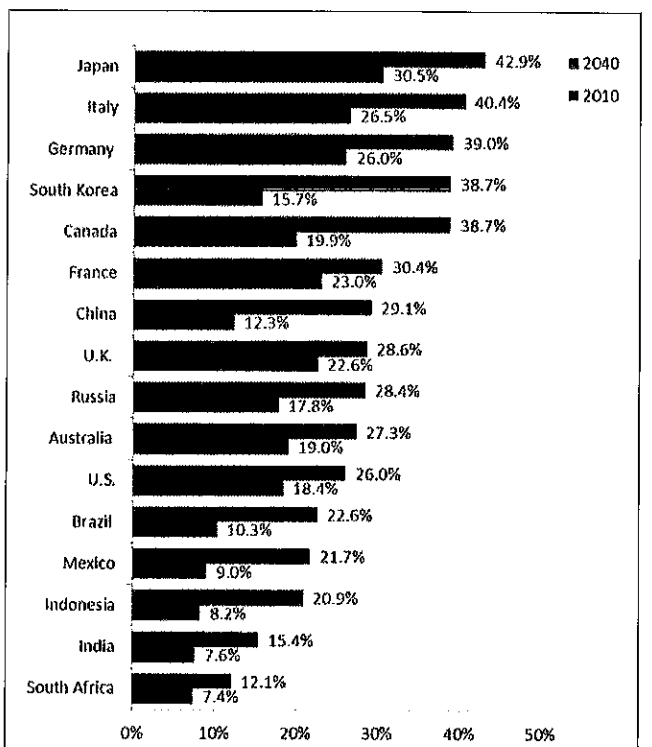

Figure 6 Elderly (Age 60 Years and Older), as Percent of Population in 2010 and 2040

Red bars = 2040; **blue bars** = 2010. Source: UN Population Division, World Population Prospects, 2010 Revision. United Nations, 2011.

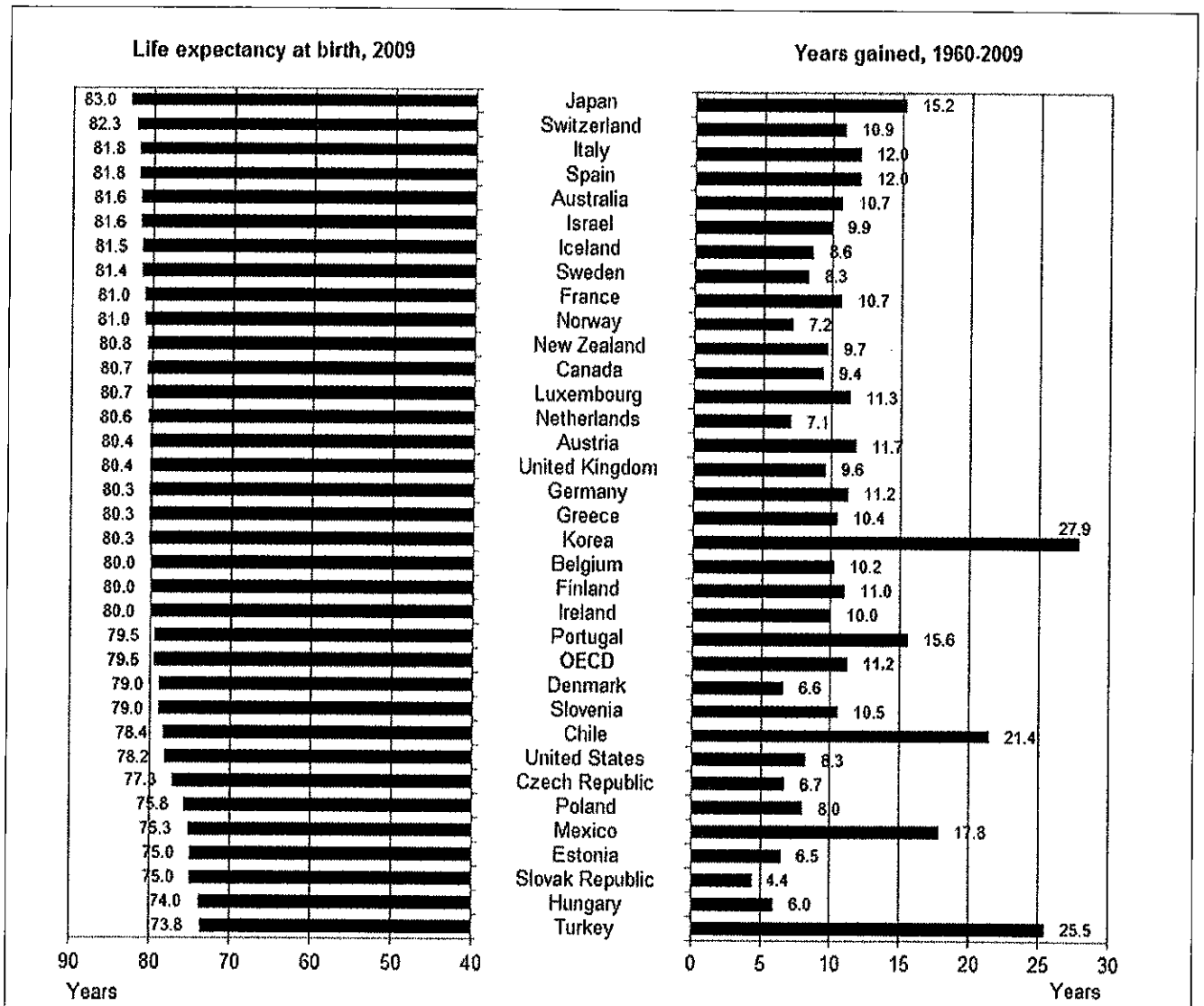

Figure 7 **Life Expectancy at Birth, 2009 (or Nearest Year Available), and Years Gained Since 1960**

OECD = Organization for Economic Cooperation and Development. Source: OECD 2012. OECD Factbook 2011–2012: Economic, Environmental and Social Statistics. OECD Publishing. Available at: http://www.oecd-ilibrary.org/economics/oecd-factbook_18147364.

2012. The CMS Innovation Center budgeted to disperse up to $1 billion to grantees that primarily serve Medicare, Medicaid, and children under the Children's Health Insurance Program who will be transitioning to patient-centered care and dispersed a second batch of funding in June 2012 (34).

Along with the focus of the CMS on underserved populations, the Innovation Center has helped fund a multistate project for 12 Veterans Health Association-affiliated hospitals. These hospitals have been given $20.75 million through the Health Care Innovation Awards endeavor to identify high-risk patients and to improve coordination of care for these patients. Part of the care coordination process will include transitioning primary care practices within targeted communities to PCMHs. Funding will also support employee training and new positions that will be specifically needed in transitions clinics (34).

Accountable care organizations. The ACO program, which involves groups of hospitals, physicians, and other clinicians that are responsible for the range of care of specified groups of patients, requires a significant investment of resources by participating providers and has been the most prominent of the reform efforts. Currently, a pilot program is in place to test the ability of participating institutions to facilitate coordination and cooperation to improve quality of care and reduce costs (35). Participating institutions will be evaluated, and must perform in the top 30th percentile for 70% of the 32 quality measures established in the Medicare physician group practice demonstration (PGPD) (Fig. 15) (36).

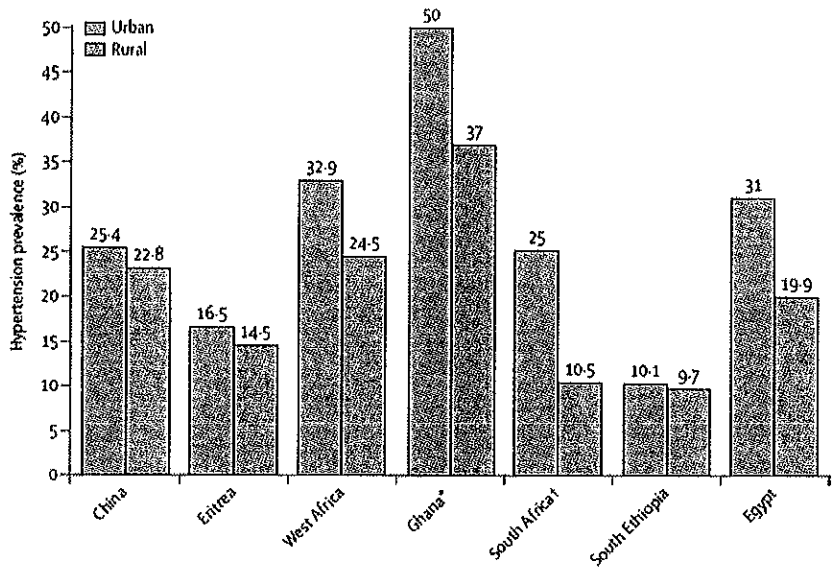

Figure 8 **Difference in Prevalence of Hypertension in Urban and Rural Regions**

Green bars = urban; **lavender bars** = rural. Source: Ibrahim and Damasceno (16).

From 2005 to 2010, CMS conducted the PGPD to model how physician groups could share in savings when they spent less than projected. All 10 organizations that participated in PGPD reached 30 of the 32 quality measures after 5 years for patients with coronary artery disease, congestive heart failure, hypertension, diabetes, and cancer screenings. On average, the PGPD organizations increased their quality scores by 12 percentage points on heart failure, 6 percentage points on coronary heart disease, and 4 percentage points on hypertension (36). Subsequent analysis determined that PGPD organizations saved an average of $114 per Medicare beneficiary and $532 per dually eligible

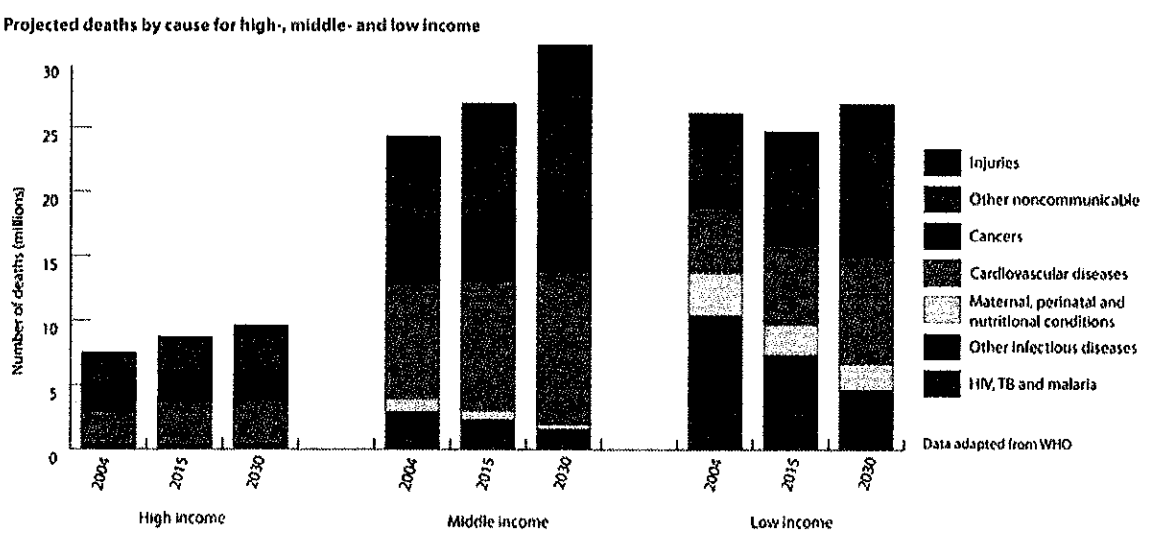

Figure 9 **Project Mortality Trends Globally by Income Category**

Blue = injuries; **taupe** = other noncommunicable diseases; **red** = cancers; **gold** = cardiovascular diseases; **beige** = maternal, perinatal, and nutritional conditions; **brown** = other infectious diseases; and **olive brown** = human immunodeficiency virus, tuberculosis, and malaria. Source: Agyemang C. Cardiovascular diseases in poor resource settings. Available at: http://gm.stijlfabriek.com/issues/issue-10/cardiovascular-diseases-in-poor-resource-settings/. Accessed June 2012.

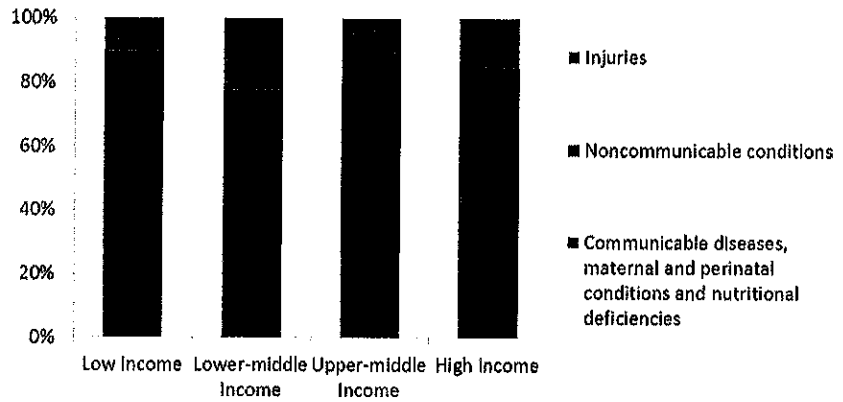

Figure 10 **Proportion of YLL Due to Premature Mortality by Broad Cause and Country-Income Group, 2004**

YLL = years of life lost. Source: World Health Organization. GBD 2004 Summary Tables. 2008. Available at: http://www.who.int/evidence/bod. Accessed October 2012.

beneficiaries annually. However, the savings varied greatly across practices, from a savings of $655 per capita to spending $749 more per capita annually (37).

CMS quality initiatives. In addition to these programs from the Innovation Center, CMS is implementing the value-based purchasing, quality measure, and resource use measurement programs in an effort to move away from the current fee-for-service program (38).

The hospital value-based purchasing program under CMS will begin in the 2013 fiscal year (39). The 2013 year is considered a "dry run" and will generate reports for hospitals on the basis of the quality measures to educate them on the performance methodology but will not have any financial consequences. Eligible hospitals will be evaluated on 12 clinical process of care and 8 hospital consumer assessment of healthcare providers and systems measures, with clinical care measures accounting for 70% of the score. Measures are displayed in Tables 8 and 9 (40).

The Physician Compare website will soon publish physician performance measures, much like Hospital Compare, a CMS-funded website that publically reports hospital performance measures. There are no financial incentives tied to these performance measures but they will be available for the public to review. The physician quality reporting system examines quality measures for services to Medicare beneficiaries and offers incentive payments to high performers, utilizing data from claims, registries, electronic health records (EHR), and the group practice reporting option tool. The CMS intends for these data to be published on

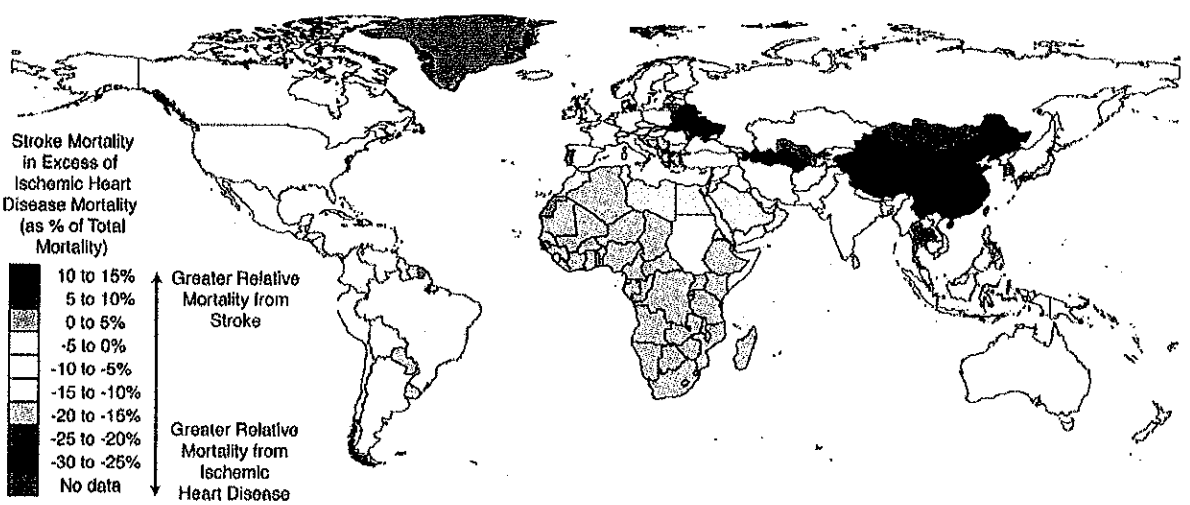

Figure 11 **Geographic Distribution of Relative Mortality From Stroke and Ischemic Heart Disease**

Source: Kim and Johnston (17).

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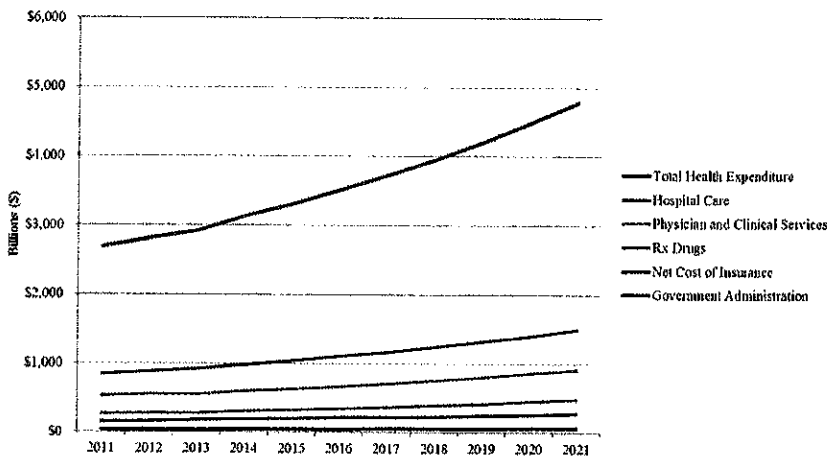

Figure 12 **National Healthcare Expenditure Projections by Expenditure Type, 2011 to 2021**

Red = total health expenditure; **dark brown** = hospital care; **light brown** = physician and clinical services; **gray** = prescription drugs; **black** = net cost of insurance; **dark red** = government administration. Source: Centers for Medicare and Medicaid Services (22).

Physician Compare by January 1, 2013. Beginning in 2015, there will be penalties for physicians who do not report to the website (41).

The physicians resource use measurement and reporting program will be incorporated into the value-based payment modifier program by providing individualized feedback to providers, including how they compare to their peers. The CMS incorporates cost and quality information when calculating potential reimbursements. The CMS will apply a value-based payment modifier based on performance measures beginning in 2015. Beginning in 2017, the value-based payment modifier scheme will be applied to most physicians who submit claims under the Medicare physician fee-for-service schedule (42).

Measure Application Partnership. The Department of Health and Human Services has contracted with the National Quality Forum, a consensus-based organization, to convene Measure Application Partnership as the body that helps coordinate and provide upstream recommendations on performance measure use. Utilizing what is termed "families of measures," this approach is intended to help move the field toward a more patient-driven, integrated, and synchronized approach to measuring healthcare performance by giving implementers a pre-screened group of measures carefully selected to work cohesively in pursuit of specific healthcare improvement goals (43).

For the first series of recommendations, Measure Application Partnership reviewed 676 measures across the topics

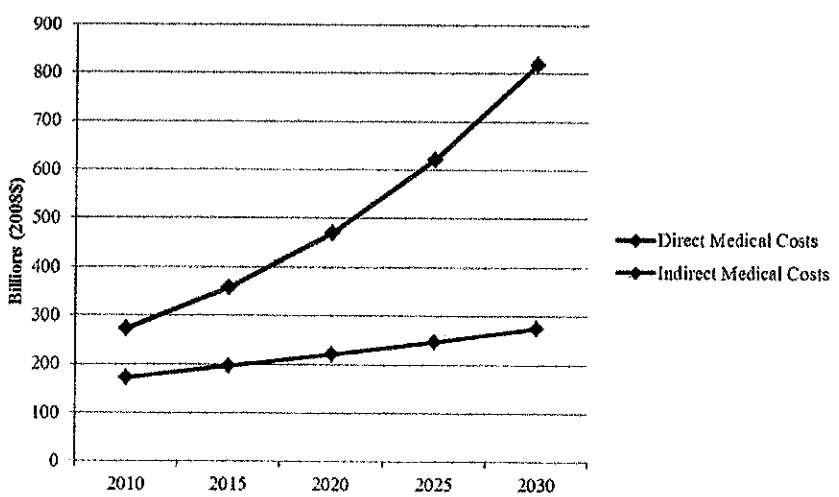

Figure 13 **Projected Direct and Indirect Costs of CVD, 2010 to 2030**

Red = direct medical costs; **brown** = indirect medical costs. CVD = cardiovascular disease. Source: Heidenreich et al. (24).

Table 4 Projected Direct Medical Costs and Indirect (Lost Productivity) Costs of Cardiovascular Disease, 2010 to 2030, United States

	2010	2015	2020	2025	2030
Direct medical cost					
All cardiovascular disease*	272.5	358.0	470.3	621.6	818.1
Coronary heart disease	35.7	46.8	61.4	81.1	106.4
Heart failure	24.7	32.4	42.9	57.5	77.7
Hypertension	69.9	91.4	119.1	155.0	200.3
Hypertension as risk factor	130.7	170.4	222.5	293.6	389.0
Stroke	28.3	38.0	51.3	70.0	95.6
Indirect medical cost					
All cardiovascular disease*	171.7	195.7	220.0	246.1	275.8
Coronary heart disease	73.2	82.8	92.0	101.5	112.3
Heart failure	9.7	11.3	13.0	15.1	17.4
Hypertension	23.6	27.2	31.0	35.1	39.8
Hypertension as risk factor	25.4	29.3	33.3	37.8	42.8
Stroke	25.6	29.7	34.0	38.9	44.4

*Includes hypertension, coronary heart disease, heart failure, stroke, and cardiac dysrhythmias, rheumatic heart disease, cardiomyopathy, pulmonary heart disease, and other or ill-defined heart disease.

of safety, care coordination, cardiovascular conditions, and diabetes; and recommended 55 safety, 62 care coordination, 37 cardiovascular, and 13 diabetes measures for inclusion in the measure families (44). The cardiovascular measures are provided in Table 10.

Cardiovascular procedure trends. In 2010, an estimated 7.5 million inpatient cardiovascular procedures were performed in the United States. Of these procedures, 4.3 million were performed on males and 3.1 million on females (45). Figure 16 displays a detailed breakdown of inpatient procedures from 1993 to 2010 from the Nationwide Inpatient Sample. Figure 17 displays the trends of cardiovascular procedures from 2007 to 2010 based on the National Hospital Discharge Survey. Figure 18 displays a decade of procedure trends for all cardiac stents. From 2000 to the peak in 2006, the number of cardiac stent procedures increased by 52%. The number of stent procedures subsequently declined by 40% from 2006 to 2010.

Medicare data from 1999 to 2008 showed the number of procedures done in cardiovascular care in the United States is growing simultaneously with the rising cost to treat cardiovascular diseases (24). From 1999 to 2009, the number of inpatient cardiovascular procedures increased by 22% (based on the National Center for Health Statistics data) (46). Among Medicare beneficiaries, it was found that invasive procedures (coronary, peripheral vascular, and electrophysiological procedures) did not contribute substantially to the increase of cardiovascular procedures and are, in fact, decreasing. Figure 19 displays the trends of growth of services provided by categories of services. Among noninvasive procedures, nuclear stress testing increased 3.2-fold, peripheral vascular ultrasonography increased 2.8-fold, event monitoring grew 2.6-fold, transthoracic and transesophageal echocardiography grew 90% and 70%, respectively, and electrocardiography increased 28% (47).

Noninvasive procedures (electrophysiological monitoring, resting imaging, transesophageal echocardiography, and stress testing) grew 70% from 1999 to 2008 (47). However, studies indicate the growth rate of noninvasive diagnostic imaging utilization leveled off from 2005 to 2008. From

Table 5 Decomposition of Real Per Capita Health Spending Growth, 1996 to 2006

Exhibit 1

	Nominal Spending (Billions of Dollars)			Component		Subcomponent	
Category/Condition[a]	1996	2006	Real Per Capita Spending Growth (%)	Cost Per Case (%)	Treated Prevalence (%)	Clinical, at 2% Ceiling (%)	Proportion Treated (%)
Circulatory system	115.9	200.4	2.3	0.4	1.8	0.3	1.6
Heart conditions	65.3	93.3	0.3	−0.1	0.5	0.1	0.4
Coronary heart disease	46.3	59.8	−0.7	0.0	−0.7	−0.7	0.0
Congestive heart failure	7.1	15.5	4.6	0.4	4.2	2.0	2.2
Dysrhythmias	9.9	14.0	0.2	−2.0	2.2	1.5	0.7
Cerebrovascular disease	16.1	18.8	−1.7	0.2	−1.8	−2.6	0.7
Hypertension	15.2	38.7	6.3	1.8	4.5	2.0	2.5
Hyperlipidemia[b]	4.5	22.9	14.0	1.1	12.9	2.0	10.9

Source: Roehrig and Rousseau (25). [a]Medical conditions are not all-inclusive, so expenditures by condition sum to less than category totals. [b]Hyperlipidemia is mapped to the endocrine chapter in the International Classification of Diseases-Ninth Revision (ICD-9), but is included under circulatory here.

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Table 6 Patient Protection and Affordable Care Act (P.L. 111–148), Cost Containment Provisions

Cost Containment	Provision
Administrative simplification	• Simplify health insurance administration by adopting a single set of operating rules for eligibility verification and claims status (rules adopted July 1, 2011; effective January 1, 2013), electronic funds transfers and healthcare payment and remittance (rules adopted July 1, 2012; effective January 1, 2014), and health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization (rules adopted July 1, 2014; effective January 1, 2016). Health plans must document compliance with these standards or face a penalty of no more than $1 per covered life. (Effective April 1, 2014.)
Medicare	• Restructure payments to Medicare Advantage (MA) plans by setting payments to different percentages of Medicare fee-for-service (FFS) rates, with higher payments for areas with low FFS rates and lower payments (95% of FFS) for areas with high FFS rates. Phase in revised payments over 3 years beginning in 2011, for plans in most areas, with payments phased in over longer periods (4 years and 6 years) for plans in other areas. Provide bonuses to plans receiving 4 or more stars, based on the current 5-star quality rating system for MA plans, beginning in 2012; qualifying plans in qualifying areas receive double bonuses. Modify rebate system with rebates allocated based on a plan's quality rating. Phase in adjustments to plan payments for coding practices related to the health status of enrollees, with adjustments equaling 5.7% by 2019. Cap total payments, including bonuses, at current payment levels. Require MA plans to remit partial payments to the Secretary if the plan has a medical loss ratio of <85%, beginning 2014. Require the Secretary to suspend plan enrollment for 3 years if the medical loss ratio is <85% for 2 consecutive years and to terminate the plan contract if the medical loss ratio is <85% for 5 consecutive years.
	• Reduce annual market basket updates for inpatient hospital, home health, skilled nursing facility, hospice, and other Medicare providers, and adjust for productivity. (Effective dates vary.)
	• Freeze the threshold for income-related Medicare Part B premiums for 2011 through 2019, and reduce the Medicare Part D premium subsidy for those with incomes >$85,000/individual and $170,000/couple. (Effective January 1, 2011.)
	• Establish an Independent Payment Advisory Board composed of 15 members to submit legislative proposals containing recommendations to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. Beginning April 2013, require the Chief Actuary of the Centers for Medicare and Medicaid Services (CMS) to project whether Medicare per capita spending exceeds the average of Consortium for Performance Improvement (CPI)-U and CPI-M, based on a 5-year period ending that year. If so, beginning January 15, 2014, the Board will submit recommendations to achieve reductions in Medicare spending. Beginning January 2018, the target is modified such that the Board submits recommendations if Medicare per capita spending exceeds gross domestic product per capita plus 1%. The Board will submit proposals to the President and Congress for immediate consideration. The Board is prohibited from submitting proposals that would ration care, increase revenues, or change benefits, eligibility, or Medicare beneficiary cost sharing (including Parts A and B premiums), or would result in a change in the beneficiary premium percentage or low-income subsidies under Part D. Hospitals and hospices (through 2019) and clinical laboratories (for 1 year) will not be subject to cost reductions proposed by the Board. The Board must also submit recommendations every other year to slow the growth in national health expenditures while preserving quality of care by January 1, 2015. The Secretary of Health and Human Services (HHS) is directed to implement the Board's proposals automatically unless Congress affirmatively acts to alter the Board's proposals or to discontinue the automatic implementation of such proposals (27).
	• Reduce Medicare Disproportionate Share Hospital (DSH) payments initially by 75% and subsequently increase payments based on the percent of the population uninsured and the amount of uncompensated care provided. (Effective fiscal year 2014.)
	• Eliminate the Medicare Improvement Fund. (Effective upon enactment.)
	• Allow providers organized as an accountable care organization (ACO) that voluntarily meet quality thresholds to share in the cost savings they achieve for the Medicare program. To qualify as an ACO, organizations must agree to be accountable for the overall care of their Medicare beneficiaries, have adequate participation of primary care physicians, define processes to promote evidence-based medicine, report on quality and costs, and coordinate care. (Shared savings program established January 1, 2012.)
	• Create an Innovation Center within the CMS to test, evaluate, and expand in Medicare, Medicaid, and CHIP different payment structures and methodologies to reduce program expenditures while maintaining or improving quality of care (see Table 7). Payment reform models that improve quality and reduce the rate of cost growth could be expanded throughout the Medicare, Medicaid, and CHIP programs. (Effective January 1, 2011.)
	• Reduce Medicare payments that would otherwise be made to hospitals by specified percentages to account for excess (preventable) hospital readmissions. (Effective October 1, 2012.)
Medicaid	• Reduce Medicare payments to certain hospitals for hospital-acquired conditions by 1%. (Effective fiscal year 2015.)
	• Increase the Medicaid drug rebate percentage for brand name drugs to 23.1 (except the rebate for clotting factors and drugs approved exclusively for pediatric use increases to 17.1%); increase the Medicaid rebate for non-innovator, multiple source drugs to 13% of average manufacturer price. (Effective January 1, 2010.) Extend the drug rebate to Medicaid managed care plans. (Effective upon enactment.)
	• Reduce aggregate Medicaid DSH allotments by $.5 billion in 2014, $.6 billion in 2015, $.6 billion in 2016, $1.8 billion in 2017, $5 billion in 2018, $5.6 billion in 2019, and $4 billion in 2020. Require the Secretary to develop a methodology to distribute the DSH reductions in a manner that imposes the largest reduction in DSH allotments for states with the lowest percentage of uninsured or those that do not target DSH payments, imposes smaller reductions for low-DSH states, and accounts for DSH allotments used for 1115 waivers. (Effective October 1, 2011.)
	• Prohibit federal payments to states for Medicaid services related to healthcare acquired conditions. (Effective July 1, 2011.)
Prescription drugs	• Authorize the Food and Drug Administration to approve generic versions of biologic drugs and grant biologics manufacturers 12 years of exclusive use before generics can be developed. (Effective upon enactment.)
Waste, fraud, and abuse	• Reduce aggregate Medicaid DSH allotments by $.5 billion in 2014, $.6 billion in 2015, $.6 billion in 2016, $1.8 billion in 2017, $5 billion in 2018, $5.6 billion in 2019, and $4 billion in 2020. Require the Secretary to develop a methodology to distribute the DSH reductions in a manner that imposes the largest reduction in DSH allotments for states with the lowest percentage of uninsured or those that do not target DSH payments, imposes smaller reductions for low-DSH states, and accounts for DSH allotments used for 1115 waivers. (Effective October 1, 2011.)
	• Reduce waste, fraud, and abuse in public programs by allowing provider screening, enhanced oversight periods for new providers and suppliers, including a 90-day period of enhanced oversight for initial claims of DME suppliers, and enrollment moratoria in areas identified as being at elevated risk of fraud in all public programs, and by requiring Medicare and Medicaid program providers and suppliers to establish compliance programs. Develop a database to capture and share data across federal and state programs, increase penalties for submitting false claims, strengthen standards for community mental health centers, and increase funding for antifraud activities. (Effective dates vary.)

Data for 2010 show the Centers for Medicare and Medicaid Services (CMS) as the largest single payer entity in the United States, responsible for almost 40% of NHE (Fig. 14) (28). Due to its large share of the payer market, reform efforts implemented by CMS often have the most significant effects on care delivery models.

Table 7 Current Centers for Medicare and Medicaid Innovation Center Initiatives

Initiative	Initiative Start Date	Length	Participants/Locations	Total Funding	Number of Beneficiaries Affected
Primary care transformation					
Comprehensive primary care initiative demonstration	Fall 2012	4 yrs	500 primary care practices in AR, CO, NJ, NY, OH, OK, OR	$322 million	313,00 Medicare
Federally qualified health center (FQHC) advanced primary care practice demonstration	November 2011	3 yrs	500 FQHCs in 44 states	$49.7 million	195,000 Medicare
Multipayer advanced primary care practice demonstration	Phase-in begins July 2011	3 yrs	NC, ME, MI, MN, NY, PA, RI, VT	$283 million*	332,000 Medicare
Independence at home	Summer 2012	3 yrs	15 independent practices and 3 consortia	$15 million*	10,000 Medicare
Bundled payments for care improvement					
Bundled payment for care improvement initiative	2012	3 yrs	TBD	$118 million	Not available
Accountable care organizations					
Pioneer accountable care organization model initiative	January 2012	3 yrs (potential 2-yr extension)	32 ACOs	$77 million	860,000 Medicare
Accelerated development learning sessions	June 2011	3 sessions completed	Available to all developing or existing ACOs	$1.5 million	Not available
Advanced payment accountable care organization model initiative	April or July 2012	Payments end June 2014	Physician-based and rural ACOs in the shared savings program	$175 million	650,000 Medicare
Physician group practice transition demonstration	January 2012	Up to 3 yrs	10 group practices initially, 3 switched to pioneer ACO model	$500,000 (administrative cost)*	87,700 Medicare
Medicare-Medicaid enrollees					
State demonstrations to integrate care for Medicare-Medicaid enrollees	April/May 2011	18 months with extension option	CA, CO, CT, MA, MI, MN, NY, NC, OK, OR, SC, TN, VT, WA, WI	$15 million	Not available
Financial alignment model demonstrations	January 2013	3 yrs	38 states and DC have submitted letters of intent	TBD	2 million Medicare-Medicaid enrollees
Capacity to spread innovation					
Partnership for patients	April 2011	Ongoing	26 hospital engagement networks	$500 million	Not available
Innovation advisors program	January 2012	Ongoing	200 advisors	$5.9 million	Not available
Health care innovation challenge	May 2012	3 yrs	50 states	$1 billion	Not available
Other					
Medicaid emergency psychiatric demonstration	Spring 2012	3 yrs	11 states and DC	$75 million*	Not available
Medicaid incentives for prevention of chronic diseases program	September 2011	5 yrs	10 states	$100 million*	Not available

*Funding based on other statutory authorities. Sources: Centers for Medicare and Medicaid Innovation: one year of innovation, CMS, 2012; and Centers for Medicare and Medicaid Innovation: what we're doing, CMS, 2012.
TBD = to be determined.

2000 to 2005, the growth rate was on average 4.1% and declined to 1.4% from 2005 to 2008 (48). Further evidence indicates that among Medicare beneficiaries volume of imaging services has decreased in 2010 and 2011 (49).

Preventable hospital readmissions have been identified as a significant driver of costs, estimated at $25 billion annually (50). An estimated 20% of Medicare beneficiaries are readmitted to the hospital within 30 days and 34% within 90 days, costing an estimated $17.5 billion annually (51,52). Effective October 1, 2012, CMS implemented the Readmissions Reduction Program, reducing payments to hospitals with excess readmissions (53).

Comparative effectiveness research. Comparative effectiveness research, a controversial topic in the industry, is a main focus of the Patient-Centered Outcomes Research Institute. The Institute has committed approximately $120 million of research funding through the end of 2012 to support its initial research agenda (see the following list), in addition to the $30 million awarded for pilot projects. As of April 2012, 50 pilot projects were approved to receive funding for up to 2 years, at a total of approximately $15 million per year (54).

The Patient-Centered Outcomes Research Institute's Five Priorities are as follows:

1. Assessment of prevention, diagnosis, and treatment options: comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.
2. Improving healthcare systems: comparing health system-level approaches to improving access, supporting patient

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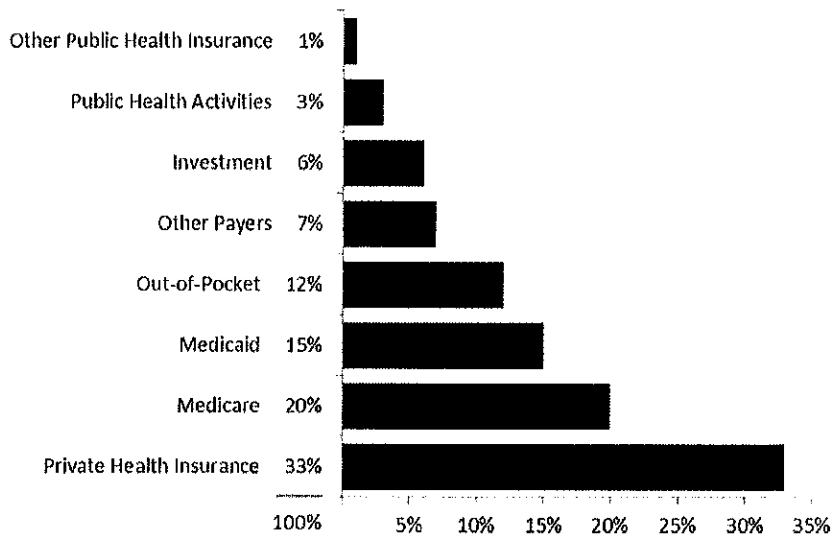

Figure 14 **Percentage of Total U.S. Healthcare Spending by Payment Sources, 2010**

Source: California Health Care Foundation. U.S. Healthcare Spending: Health Care Costs 101. Oakland, CA: California Health Care Foundation, 2012.

self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

3. Communication and dissemination research: comparing approaches to providing comparative effectiveness research information, empowering people to ask for and

Physician Group Practice Demonstration Quality Measures			
Diabetes Mellitus	Congestive Heart Failure	Coronary Artery Disease	Preventive Care
HbAlc Management	Left Ventricular Function Assessment	Antiplatelet Therapy	Blood Pressure Screening
HbAlc Control	Left Ventricular Ejection Fraction Testing	Drug Therapy for Lowering LDL Cholesterol	Blood Pressure Control
Blood Pressure Management	Weight Measurement	Beta-Blocker Therapy –Prior MI	Blood Pressure Control Plan of Care
Lipid Measurement	Blood Pressure Screening	Blood Pressure	Breast Cancer Screening
LDL Cholesterol Level	Patient Education	Lipid Profile	Colorectal Cancer Screening
Urine Protein Testing	Beta-Blocker Therapy	LDL Cholesterol Level	
Eye Exam	Ace Inhibitor Therapy	Ace Inhibitor Therapy	
Foot Exam	Warfarin Therapy for Patients HF		
Influenza Vaccination	Influenza Vaccination		
Pneumonia Vaccination	Pneumonia Vaccination		

Figure 15 **Physician Group Practice Demonstration Quality Measures**

Ace = angiotensin-converting enzyme; Exam = examination; Hb = hemoglobin; HF = heart failure; LDL = low-density lipoprotein; MI = myocardial infarction. Source: Dept Health and Human Services. Medicare Physician Group Practice Demonstration: physicians groups continue to improve quality and generate savings under Medicare physician pay-for-performance demonstration, July 2011.

Table 8 Clinical Process of Care Under Value-Based Purchasing Reimbursement Model

Acute myocardial infarction	
AMI-7a	Fibrinolytic therapy received within 30 min of hospital arrival
AMI-8	Primary PCI received within 90 min of hospital arrival
Heart failure	
HF-1	Discharge instructions
Pneumonia	
PN-3b	Blood cultures performed in the ED prior to initial antibiotic received in hospital
PN-6	Initial antibiotic selection for CAP in immunocompetent patient
Health care associated infections	
SCIP-Inf-1	Prophylactic antibiotic received within 1 h
SCIP-Inf-2	Prophylactic antiobiotic selection for surgical patient
SCIP-Inf-3	Prophylactic antibiotics discontinued within 24 h after surgery
SCIP-Inf-4	Cardiac surgery patients with controlled 6 AM post-operative serum glucose
Surgeries	
SCIP-Card-2	Surgery patients on a beta-blocker prior to arrival that received beta-blocker during the perioperative period
SCIP-VTE-1	Surgery patients with recommended venous thromboembolism prophylaxis ordered
SCIP-VTE-2	Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 h

Source: Centers for Medicare and Medicaid Services (40).
AMI = acute myocardial infarction; Card = cardiac; ED = emergency department; HF = heart failure; Inf = infection; PCI = percutaneous coronary intervention; PN = pneumonia; VTE = venous thromboembolism.

use the information, and supporting shared decision making between patients and their providers.

4. Addressing disparities: identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the health care required to achieve best outcomes in each population.
5. Accelerating patient-centered outcomes research and methodological research: improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients, and other stake holders to participate in this research (55).

Health information technology. The federal government has committed in excess of $27 billion over 10 years to increase the use of EHR. Many physicians and practices agree that EHR can improve clinical decision making and patient outcomes and are already making the transition from paper to EHR use in their practice (56).

MEANINGFUL USE CRITERIA. The use of EHR is encouraged by CMS through an incentive program that provides financial benefits for physicians and care centers that show "meaningful use" of EHR. The primary component of meaningful use is utilizing EHR in a meaningful manner—in other words, to exchange health information electronically to improve care and to submit quality measures. Between 2011 and 2016, each clinician who is eligible under the meaningful use criteria can receive up to $63,750 in total payments for demonstrating meaningful EHR use and may be eligible for both Medicare and Medicaid incentives as well (57).

One aspect of the meaningful use criteria for EHR incentives (both Medicare and Medicaid) is participation in clinical quality measures. Clinical quality measures assess observations, processes, experience, treatment, and outcomes of patient care. Professionals eligible for EHR incentives are required to report 6 clinical quality measures, whereas hospitals and acute care centers are required to report 15 (57).

Hospitals and other providers have until 2015 to utilize electronic medical records before they incur penalties (58). Nearly 46% of clinical sites, ranging from solo practices to hospitals, had adopted EHR as of January 2012 (59). Conversely, only 58% of eligible hospitals and 25% of eligible physicians have enrolled in the meaningful use incentive program, and 16% of eligible hospitals and 6% of eligible professions have received payments thus far (58).

It is admittedly more difficult for smaller practices to adopt EHR and be eligible for meaningful use incentives. Reasons for this vary, but include the financial cost of implementing EHR, concerns about what the return of investment will be once adopted, and the fact that EHR technology may become obsolete. It is, therefore, somewhat surprising that only 21% of small practices reported resistance to EHR adoption compared with 32% of practices with more than 11 physicians (60). Figure 20 displays the disparities in EHR adoption as of 2011 (61).

Certain inpatient providers are not eligible for meaningful use incentives. These include long-term care facilities, rehabilitation hospitals, and psychiatric hospitals, all of which are less likely to adopt EHRs. One study found that only 6% of long-term acute care hospitals, 4% of rehabilitation hospitals, and 2% of psychiatric hospitals had minimum basic EHRs, and obstacles for providers to take advantage of the meaningful use incentive continue (62).

There is a great need for advanced health information technology implementation to achieve quality improvement and patient-centered care. As investigators of a *Health*

Table 9 Patient Experience of Care Measures Under Value-Based Purchasing Reimbursement Model

1. Nurse communication
2. Doctor communication
3. Hospital staff responsiveness
4. Pain management
5. Medicine communication
6. Hospital cleanliness and quietness
7. Discharge information
8. Overall hospital rating

Source: Centers for Medicare and Medicaid Services (40).

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Table 10 Chronic Cardiovascular Conditions Family of Measures by Level of Analysis Along the Patient-Focused Episode of Care

	Primary Prevention		Evaluation and Initial Management		Follow-Up Care
	Outpatient	Inpatient	Outpatient	Inpatient	Outpatient
Clinician group/ individual	Smoking cessation/tobacco use (0028, 1406)*	Smoking cessation/ tobacco use	HF functional status	HF functional status	Afib medications— anticoagulation (1525)*
					HF medications—ACE/ARB (0081)*
	Lifestyle management— weight/obesity (0024, 0421)*				HF medications—beta-blocker (0083)*
	Blood pressure control (0018)*				HF medications—ACE/ARB, beta-blocker persistence
	Lipid control				
	Lifestyle management—diet/nutrition				
	Lifestyle management—activity/ exercise				
	Cardiometabolic risk				
	Resource use (1598 and 1604)*				
Provider/facility	Smoking cessation/tobacco use	Smoking cessation/ tobacco use (1651, 1654)*	HF functional status	HF functional status	HF medications—beta-blocker (0083)*
			Mortality—HF (0229)*	Mortality—HF (0229)*	HF medications—ACE/ARB, beta-blocker persistence
	Lipid control				
	Lifestyle management— weight/obesity				HF early identification of decompensated HF
	Lifestyle management— diet/nutrition				
	Lifestyle management— activity/exercise				
	Cardiometabolic risk				
System	Lifestyle management—weight/obesity (0024)*		Mortality		HF medications—ACE/ARB, beta-blocker persistence
	Blood pressure control (0018)*		HF functional status		
	Smoking cessation/tobacco use				
	Lipid control				
	Blood pressure control				
	Screening				
	Lifestyle management—diet/nutrition				
	Lifestyle management—activity/exercise				
	Cardiometabolic risk				
	Resource use (1598 and 1604)*				
Community	Smoking cessation/tobacco use (1406, 1651, 1654)*		Mortality		HF medications—ACE/ARB, beta-blocker persistence
	Lifestyle management—weight/obesity (0024, 0421)*		HF functional status		
	Blood pressure control (0018)*				
	Cardiometabolic risk				
	Lipid control				
	Lifestyle management—diet/nutrition				
	Lifestyle management—activity/exercise				
	Resource use (1598 and 1604)*				

*High-leverage opportunities represent areas where the task force has identified measures to populate the family; other entries are considered gaps. For additional detail, see National Quality Forum (44).
ACE = angiotensin-converting enzyme; Afib = afibrillation; ARB = angiotensin-receptor blocker; HF = heart failure.

Affairs paper noted (62), continuing medical education is a potential avenue by which to improve HIT competencies and increasing EHR adoption; if offered, continuing medical education could allow more clinicians to be eligible for meaningful use incentives over the next 10 years.

Workforce

Increasing demand, changing business requirements, and provider restructuring have created significant concerns regarding the capacity of the current and future medical workforce to meet the needs of patients. Recent physician surveys found that nearly one-third intend to retire in the next 10 years, and more than three-quarters of physicians are somewhat pessimistic or very pessimistic about the future of the medical profession (63,64).

Physician workforce. In 2010, there were 258.7 active physicians per 100,000 U.S. residents and 219.5 physicians who were active in patient care per 100,000 residents in the

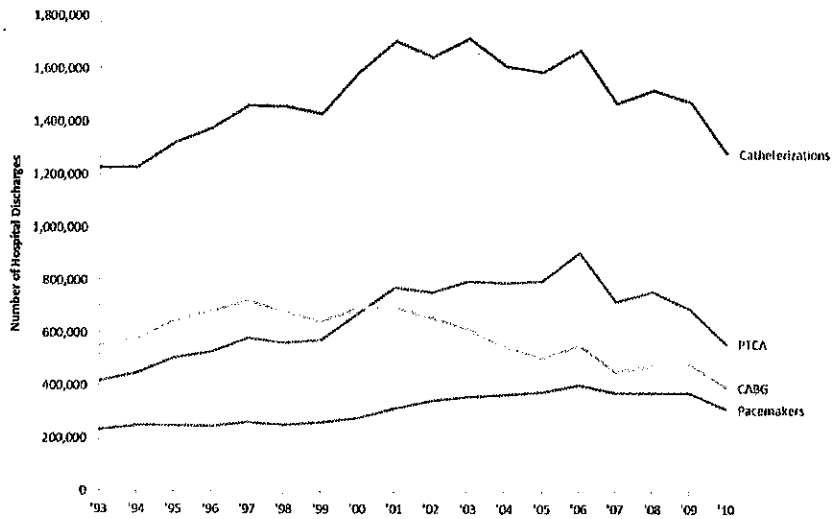

Figure 16 **Trends in Number of Cardiovascular Procedures, United States, 1993 to 2010**

Note: In-hospital procedures only. CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty. Source: Agency for Healthcare Research and Quality. Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project: Nationwide Inpatient Sample, 1993–2010.

United States (65). However, the distribution of physicians was highly variable between states, with a surfeit of physicians being clustered in northeastern states in comparison to the southeast (Table 11, Fig. 21).

On the basis of projections made by the Association of American Medical Colleges, it is expected that the United States will be short 91,500 to 130,600 physicians by 2025 (Fig. 22) (66).

The projections from Figure 22 reflect the current supply and utilization of physicians and disease burdens applied to future population trends. Assumptions in this model are based on speculated utilization shifts due to the ACA. These include increased physician utilization rates for people over 45 years of age; decreased working hours of physicians due to sex and generational trends; growth in medical school graduates; and growth in productivity

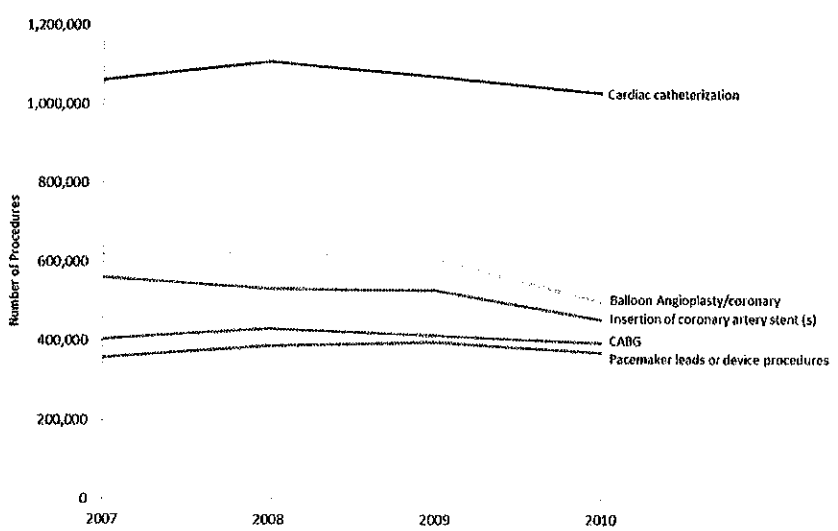

Figure 17 **Number of Discharges From Short-Stay Hospitals by Procedure Category, 2007 to 2010, National Hospital Discharge Survey**

CABG = coronary artery bypass graft surgery. Source: Centers for Disease Control and Prevention. Number of all-listed procedures for discharges from short-stay hospitals by procedure category: United States, 2007–2010. Available at: http://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberproceduresex.pdf. Accessed June 2012.

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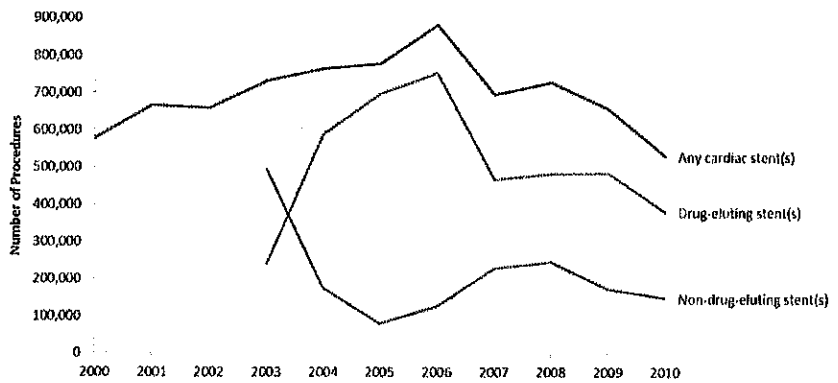
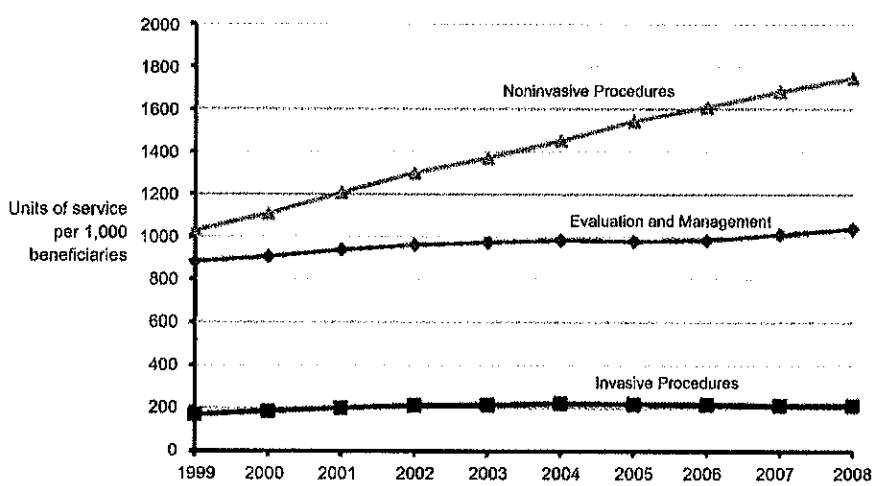


Figure 18 **Trends in Cardiac Stents, United States, 2000 to 2010**

Note: In-hospital procedures only. Source: Agency for Healthcare Research and Quality. Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project: Nationwide Inpatient Sample, 2000–2010. 2012. Available at: http://hcupnet.ahrq.gov/. Accessed October 2012.

(66). The ACA seeks to address the workforce shortage by authorizing the following:

- $250 million to support training of >16,000 new primary care providers for fiscal years 2010 to 2014;
- $320 million over the same period to increase the number of primary care residency positions, to expand training opportunities for physician assistants and nurse practitioners, and to create nurse-managed health clinics;
- A 10% bonus for fiscal years 2011 to 2016 under the Medicare fee schedule for family physicians, internists, geriatricians, nurse practitioners, and physician assistants—aimed at narrowing the income gap between primary care providers and medical specialists;
- A requirement that states increase Medicaid payment rates to Medicare levels in fiscal years 2013 and 2014 for providers who deliver certain primary care services; and
- creation of a 15-member Health Care Workforce Commission, designed to assess the demand for healthcare workers and whether it is being met (67).



Andrus B W. Welch H G Circ Cardiovasc Qual Outcomes 2012;5:31–38

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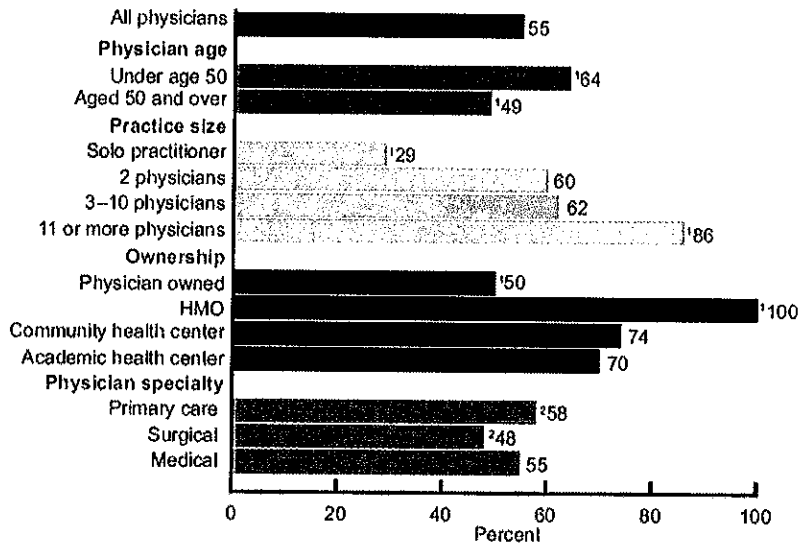
Figure 19 **Trends of Growth of Services Provided by Categories of Services, 1999 to 2008**

Source: Andrus and Welch (47).



[1]Differences in adoption between this category and all others are statistically significant ($p < 0.01$).
[2]Significant difference between primary care and surgical specialists ($p < 0.01$).
NOTES: Adoption consists of physicians who use a health record system that is all or partially electronic (excluding systems solely for billing). The sample includes nonfederal, office-based physicians and excludes radiologists, anesthesiologists, and pathologists. HMO is health maintenance organization.
SOURCE: CDC/NCHS, Physician Workflow study, 2011.

Figure 20 **Percentage of EHR Systems Adoption, by Physician Age, Practice Size, Ownership, and Specialty, 2011**

EHR = electronic health record; HMO = health maintenance organization. Source: Jamoom et al. (61).

The Physician's Foundation survey of 13,575 physicians in 2012 noted the following:

- More than three-quarters of physicians—77.4%—are somewhat pessimistic or very pessimistic about the future of the medical profession.
- More than 84% of physicians agree that the medical profession is in decline.
- The majority of physicians—57.9%—would not recommend medicine as a career to their children or to other young people.
- More than one-third of physicians would not choose medicine if they had their careers to do over.
- Physicians are working 5.9% fewer hours than they did in 2008, resulting in a loss of 44,250 full-time equivalents (FTEs) from the physician workforce.

Table 11 **Highest 5 Rates and Lowest 5 Rates of Active Physicians per 100,000 Population in 2010**

States With Highest Rates		States With Lowest Rates	
Massachusetts	415.5	Utah	197.8
Maryland	368.7	Wyoming	193.0
New York	347.5	Arkansas	189.6
Rhode Island	332.6	Idaho	184.2
Connecticut	331.1	Mississippi	176.4

Data source: AAMC Center for Workforce Studies. 2011 State Physician Workforce Data Book, November 2011. Available at: https://www.aamc.org/download/263512/data/statedata2011.pdf.

- Physicians are seeing 16.6% fewer patients per day than they did in 2008, a decline that could lead to tens of millions of fewer patients seen per year.
- Physicians spend more than 22% of their time on nonclinical paperwork, resulting in a loss of some 165,000 FTEs.
- More than 60% of physicians would retire today if they had the means.
- Physicians are not uniform in their opinions—younger physicians, female physicians, employed physicians, and primary care physicians are generally more positive about their profession than are older physicians, male physicians, practice owners, and specialists.
- More than 52% of physicians have limited the access Medicare patients have to their practices or are planning to do so.
- More than 26% of physicians have closed their practices to Medicaid patients.
- In the next 1 to 3 years, more than 50% of physicians plan to cut back on patients, work part-time, switch to concierge medicine, retire, or take other steps that would reduce patient access to their services.
- More than 59% of physicians indicate passage of the ACA (i.e., "health reform") has made them less positive about the future of health care in America.
- More than 82% of physicians believe doctors have little ability to change the healthcare system.

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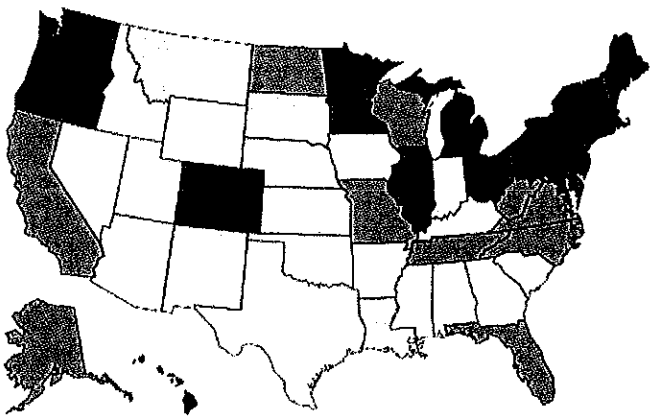

Source: July 1, 2010 population estimates are from the U.S. Census Bureau (Release date: February, 2011). Physician data are from the AMA Physician Masterfile (December 31, 2010).

Figure 21 **Total Active Physicians per 100,000 Population, 2010**

Source: Association of American Medical Colleges. Center for Workforce Studies: 2011 State Physician Workforce Data Book. November 2011. Available at: https://www.aamc.org/download/263512/data/statedata2011.pdf.

- Nearly 92% of physicians are unsure where the health system will be or how they will fit into it 3 to 5 years from now.
- More than 62% of physicians said ACOs are either unlikely to increase healthcare quality and decrease costs or that any quality/cost gains will not be worth the effort.
- Physicians are divided on the efficacy of medical homes, and many (37.9%) remain uncertain about their structure and purpose.
- More than 47% have significant concerns that EHR poses a risk to patient privacy.
- More than 62% of physicians estimate they provide ≥$25,000 each year in uncompensated care (64).

Jackson Healthcare's 2012 physician survey (n = 2,218) found that the majority of physicians surveyed (84%) expect to continue practicing medicine through 2013. The remaining 16% plan to transition to part-time, retire, or leave medicine, or they are considering doing so (Fig. 23) (63). Fourteen percent said they will most likely retire or leave medicine within the next 5 years. Thirty-four percent will do so within the next 10 years. Specialists reported the following (63): oncologists and hematologists, 57% said they would retire by 2022; otolaryngologists, 49% said they would retire in the next decade; general surgeons, 49% said they would retire by 2022; cardiologists, 45% said they would retire in the next decade; and urologists, 42% said they would retire by 2022.

Cardiovascular workforce. The ACC and the Lewin Group's 2009 workforce study (Fig. 24) found that a significant shortage of cardiologists working in the United States exists (Fig. 25), and this shortage is projected to worsen

Year	Supply – All Specialties	Demand – All Specialties	Shortage – All Specialties	Shortage – Primary Care[2]	Shortage – Non-Primary Care[3]
2008	699,100	706,500	7,400	7,400	0
2010	709,700	723,400	13,700	9,000	4,700
2015	735,600	798,500	62,900	29,800	33,100
2020	759,800	851,300	91,500	45,400	46,100
2025	785,400	916,000	130,600	65,800	64,800

Figure 22 **Projected Supply and Demand, FTE Physicians Active in Patient Care, 2008 to 2025**

FTE = full-time equivalent. [2]Primary care includes physicians whose specialty is listed as internal medicine, family medicine or pediatrics in the AMA Masterfile. [3]"Non-primary care" includes physicians in all specialties except primary care specialties. Source: Association of American Medical Colleges. The Impact of Health Care Reform on the Future Supply and Demand for Physicians: Updated Projections Through 2025. June 2010. Available at: https://www.aamc.org/download/158076/data/updated_projections_through_2025.pdf.

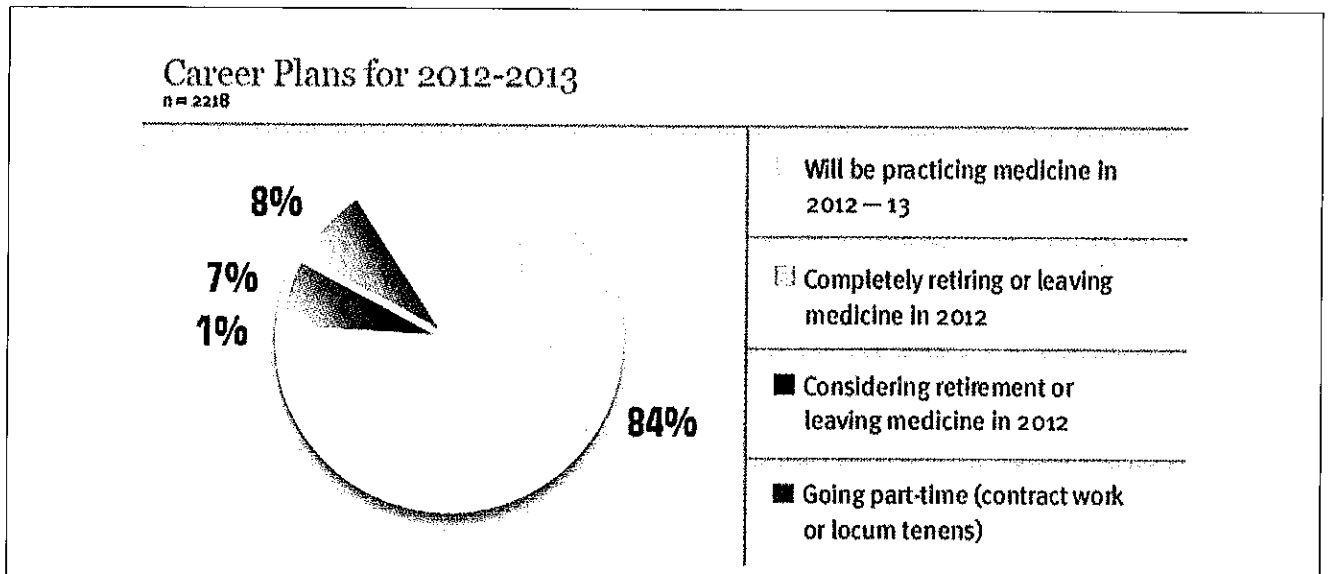

Figure 23 **Physician Career Plans, Jackson Healthcare 2012 Physician Survey**

Source: Jackson Healthcare (63).

over the next 2 decades. These projections are based on the demands of physician lifestyle, demographics, technological advances, healthcare reform, and economic growth (68).

If various measures, including an increase in fellowship training and more efficient use of nonphysician practitioners, are not taken, general cardiology may experience a shortage of >15,000 practitioners by 2025 (Fig. 26). Even with proactive measures taken, it is still projected the field will be approximately 8,000 practitioners short of general cardiology needs. Projections also indicate that by 2025, interventional cardiology will still be short of approximately 2,000 physicians, equal to the current shortage (68).

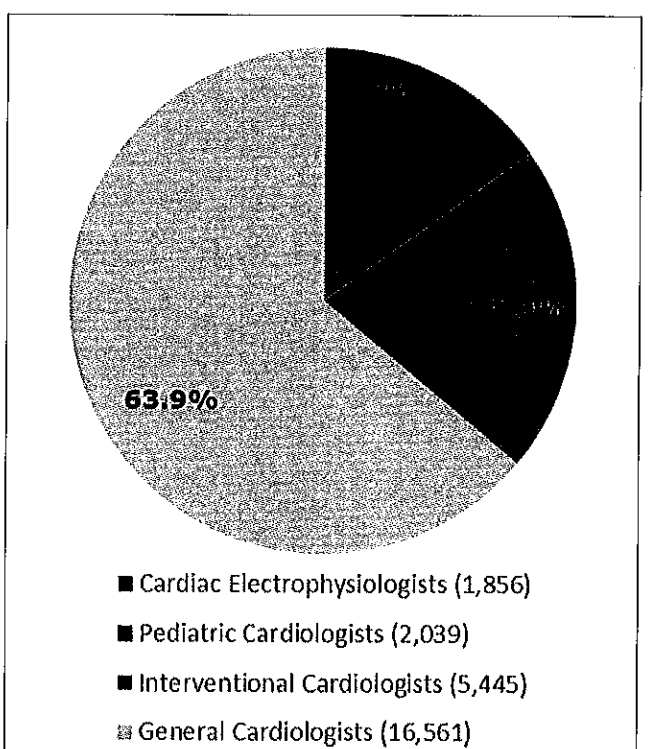

Figure 24 **Cardiologists by Subspecialty, 2008 (n = 25,901)**

Source: The Lewin Group, Inc. and Association of American Medical Colleges (69).

Current shortages of pediatric cardiologists and cardiac electrophysiologists are expected to be eliminated by 2025 (69).

Cardiovascular workforce growth modest. Current growth in the cardiovascular workforce is moderate relative to the overall physician workforce. Between 1995 and 2007, there was a 19.2% increase in cardiologists compared with a 28.6% increase in all physicians. Increases in the ratio of cardiologists per 100,000 older persons were also lower than increases seen for physicians overall (70).

A disparity exists in the geographic distribution of cardiologists, with a lower cardiologist ratio per 100,000 older persons in the western regions of the United States (Fig. 27) (70). In a national survey of rural hospitals, 35% reported a shortage of cardiologists. The region with the highest reported need for cardiologists was the southeast region followed by the southwest region (Fig. 28) (71).

The United States will also be short of approximately 2,000 cardiothoracic surgeons by 2030 (72). The AHA similarly found that the need for cardiothoracic surgeons will increase by 46% from now until 2025, whereas the active supply of cardiothoracic surgeons is projected to decline by 21% (73).

Retirement and workforce supply. Retirement rates will affect the supply of cardiologists in the near future. Currently, 43% of general cardiologists, 31% of pediatric cardiologists, and 21% of interventional cardiologists are over the

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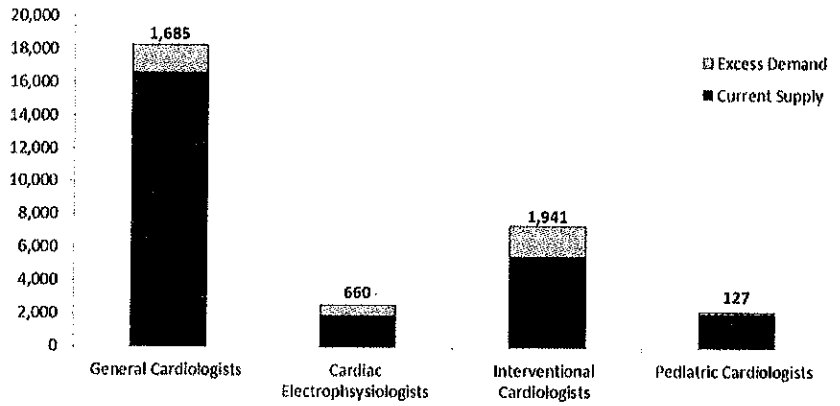

Figure 25 **Excess Demand for Cardiologists by Subspecialty, 2008**

Light teal = excess demand; **dark teal** = current supply. Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

age of 55 years. Some 50% of cardiothoracic surgeons are currently over the age of 55 years as well, and many are expected to retire in the next 10 years (73).

More than one-half of cardiologists today are still clinically active in some fashion, but failing health, professional dissatisfaction, and inadequate compensation often contribute to early retirement. With increasing regulation in medicine—including the need to undergo recertification—additional influences may also factor into a cardiologist's decision to retire early.

Economic pressures may force some older cardiologists to prolong their career. Alternatively, a growing number of physicians may simply reduce the number of hours worked, all of which can influence projected workforce shortages (68).

Medical school enrollment. More than 690,000 first-time and reapplying applicants tried to enroll in U.S. medical schools in 2011 to 2012. Of these, >32,000 were first-time applicants, up by 2.6% from the previous year. The Association of American Medical Colleges also predicts that first-year medical school enrollment will surpass 20,000 in 2014 to 2015, and that by the year 2018, enrollment will increase by 30% compared to 2002 and 2003 (74).

First-year enrollment in Doctor of Osteopathic Medicine (DO) programs is expected to double by 2014 to 2015 compared with 2002. Combined, MD and DO enrollment

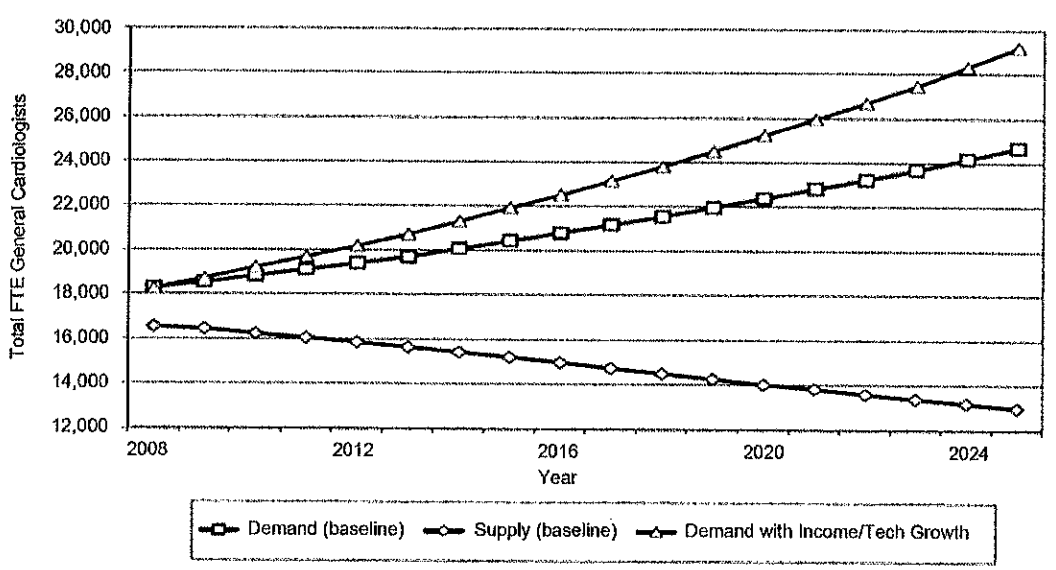

Figure 26 **Baseline Supply and Demand for FTE General Cardiologists**

Red = demand (baseline); **purple** = supply (baseline); **green** = demand with income/technology growth. FTE = full-time equivalent.
Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

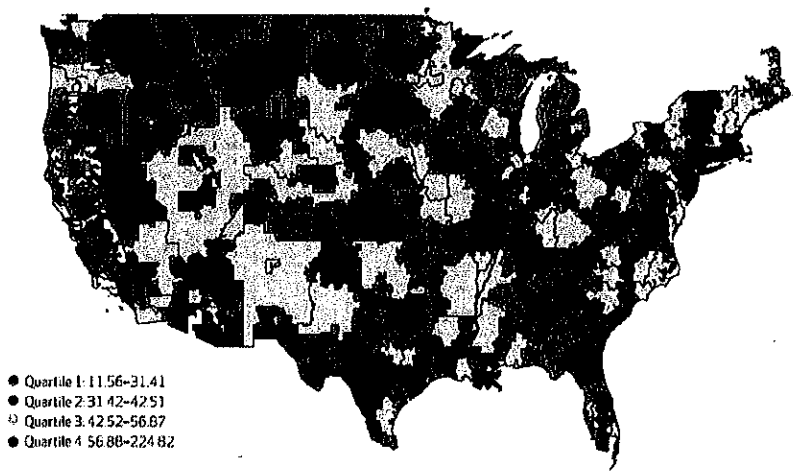

Figure 27 **Ratio of Cardiologists to 100,000 People Ages 65 Years and Older, 2007**

Source: Aneja et al. (70).

is expected to grow by more than one-third over enrollment levels seen in 2002 to 2003 (Table 12).

Over the last 5 academic years, the number of cardiology programs and the fellows they train has increased in the fields of cardiology, interventional cardiology, and pediatric cardiology. Table 13 displays the increasing number of these fellows for each academic year. Conversely, a decrease was seen in the number of fellows in thoracic surgery and cardiac electrophysiology during this same period (75).

Women in cardiovascular medicine. Unlike medicine overall, women currently make up only a small proportion of all cardiologists. However, this may be changing, as representation of women in subspecialty training in cardiology has almost doubled in the past 10 years from 10% in 1996 to 18% in 2004.[68] In 2008, women accounted for 29.0% of pediatric cardiologists, 12.1% of general cardiologists, 9.3% of cardiac electrophysiologists, and 3.4% of interventional cardiologists (Fig. 29) (69). Overall, women accounted for 43% of medical residents in 2010 to 2011; however, the proportion of women among cardiovascular trainees was significantly smaller (Fig. 30) (75).

Minorities in the cardiovascular workforce. Approximately 30% of the population in the United States is either Hispanic or African American (76), but minorities, including black, Hispanic, and Native Americans, account for only 6% of practicing physicians. Black and Hispanic fellows were slightly better represented as 13% of internal medicine residents and 10% of cardiology fellows in 2006 to 2007.

A higher percentage of black trainees are now in cardiology fellowships than in other internal medicine subspecialties, but the proportion is still lower than that for internal medicine graduates as a whole. The proportion of Hispanics completing internal

Most commonly reported specialty physician shortages†	All states (n=343) n (%) 'yes'	New England through Virginia[1] (n=31) n (%) 'yes'	Southeast - east of Mississippi River[2] (n=38) n (%) 'yes'	Upper and Central Midwest[3] (n=102) n (%) 'yes'	Southwest[4] (n=114) n (%) 'yes'	Rocky Mountains[5] (n=16) n (%) 'yes'	West Coast[6] (n=37) n (%) 'yes'	χ^2 test for regional differences
Psychiatry	160 (46.6)	21 (67.7)	17 (44.7)	45 (43.3)	56 (48.7)	4 (25.0)	17 (43.6)	$p = 0.093$
General surgery	137 (39.9)	15 (48.4)	13 (34.2)	38 (48.4)	54 (47.0)	5 (31.3)	12 (30.8)	$p = 0.290$
Neurology	125 (36.4)	10 (32.3)	16 (32.3)	33 (31.7)	53 (46.1)	2 (12.5)	11 (28.2)	$p = 0.043$
Cardiology	120 (35.0)	11 (35.5)	17 (44.7)	26 (25.0)	51 (44.3)	3 (18.8)	12 (30.8)	$p = 0.026$
Obstetrics-gynecology	118 (34.4)	10 (32.3)	8 (21.1)	28 (26.9)	51 (44.3)	6 (37.5)	15 (38.5)	$p = 0.051$

[1]CT, ME, MA, NH, RI, VT, NJ, NY, DE, DC, MD, PA, VA, WV; [2]AL, FL, GA, KY, MS, NC, SC, TN; [3]IL, IN, MI, MN, OH, WI, IA, KS, MO, NE; [4]AR, LA, NM, OK, TX; [5]CO, MT, ND, SD, UT, WY; [6]AZ, CA, HI, NV, AK, ID, OR, WA.

†Frequencies and national percentages for specialties that were less frequently reported as shortages were: 97 emergency medicine (27.3%); 68 pathology (19.2%); 56 orthopedic surgery (15.8%); 83 radiology (23.4%); 55 urology (15.5%); 49 dermatology (13.8%); 44 gastroenterology (12.4%); 39 anesthesiology (11.0%); 32 oncology (10.4%). State not provided by 12/355 respondents.

Figure 28 **Rural Hospital CEO Reponses Regarding Need for Specialist Physicians in Their Community**

National Rural Chief Executive Officer (CEO) Survey, 2008. We wish the response rate would have been higher to increase confidence in the findings (overall response rate of 34.4%), but it is difficult to get even rural hospital CEOs to respond to surveys. Of course, careful assessment of the supply/demand balance, market, and referral characteristics would be important related to assessing need for cardiologist in a particular rural location. You will note our comment in the limitation section that the percents we report are based on CEO perceptions/responses. Source: MacDowell et al. (71).

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Table 12 Medical and Osteopathic Actual and Projected First-Year Enrollment Growth, 2002, 2010, 2015 (Existing Schools)

	2002	2010			2015		
	Enrollment	Enrollment	# Increase	% Increase	Enrollment	# Increase	% Increase
M.D.	16,488	18,665	2,177	13%	20,181	3,693	22%
D.O.	3,079	5,233	2,154	70%	6,222	3,143	102%
Total	19,567	23,898	4,331	22%	26,403	6,836	35%

Source: Center for Workforce Studies. Results of the 2010 Medical School Enrollment Survey, 2011. Available at: https://www.aamc.org/download/251636/data/enrollment2011.pdf. Accessed June 2012.

medicine has increased over the last few years, but not in cardiology. Barriers to pursuing a career in medicine for minorities include the financial burden of paying for education as well as lack of role models (Fig. 31) (68).

International medical graduates. Approximately 30% of the cardiology workforce is now made up of international medical graduates. International medical school graduates recently accounted for 36% of general cardiology fellows, 41% of interventional cardiology fellows, 33% of cardiac electrophysiology fellows, and 22% of pediatric cardiology fellows (75). Unlike minority graduates, international medical graduates appear to be relatively unaffected by specialty compensation or length of training in deciding on cardiology as a career (68). International medical graduates are more likely to remain active in practice than U.S. graduates and to work full-time to an older age, which again is likely to have an impact on potential workforce shortages (Fig. 32).

Global workforce. In 2000, it was estimated that 1.5 million healthcare professionals from developing countries were working in industrialized nations, to the obvious detriment of the poorer countries in which they were trained. Factors behind the migration of healthcare professionals are varied but include low salaries in the country of origin, occupational safety hazards, especially in relation to human immunodeficiency infection, inadequacy of facilities and medicine, and a lack of post-graduate training and continuing professional development (Fig. 33) (77).

At 45%, internal medicine has the largest percentage of international medical graduates now participating in U.S. training programs, but their numbers are increasing in cardiology, and international medical graduates now make up more than half of interventional cardiology fellows (78). Nevertheless, it is plausible that changing conditions globally and in the United States may affect the future supply of international medical graduates.

Economic conditions and increased demand for cardiovascular services in their home country—or a worsening economic climate in the United States—may diminish the attractiveness for international medical graduates to practice in the United States. The loss of trained medical graduates also represents a substantial economic loss to their countries of origin, and regulations may be altered to ensure a greater proportion of international medical graduates either do not leave to begin with or at least return home to practice (68).

Concerns over whether care provided by physicians educated abroad differs from U.S.-trained physicians have been expressed. One study found no differences in mortality rates for patients with heart failure or a heart attack between the 2 care groups (79).

Nursing workforce. In 2001, the national vacancy rate for registered nurses was >10%. Furthermore, in 15% of hospitals, the shortage was >20% (80). Between 2001 and 2008, the number of registered nurses working full time in both hospital and nonhospital settings increased by some 476,000, with the largest growth in FTE registered nurses seen among those between the ages of 50 and 64 years working in hospitals (Fig. 34). Despite this, current projections indicate there will be a shortfall of 260,000 nurses by 2025 (81).

Cardiovascular Drugs and Devices

The pharmaceutical and medical device industries are facing several challenges created by the cost-containment effects of healthcare reform efforts and slow economic activity, a changing regulatory environment, and increasing pressure to show value related to clinical outcomes (82,83).

Table 13 Number of Programs and Fellows by Specialty for the Past 5 Academic Years

	2006–2007		2007–2008		2008–2009		2009–2010		2010–2011	
	Programs	Fellows	Programs	Fellows	Programs	Fellows	Programs	Fellows	Programs	Fellows
Cardiovascular disease	174	2,300	177	2,351	180	2,415	180	2,444	183	2,493
Clinical cardiac electrophysiology	92	168	95	166	97	170	96	174	98	155
Interventional cardiology	128	279	130	285	134	291	134	287	135	290
Pediatric cardiology	48	304	49	304	51	326	50	356	53	378
Thoracic surgery	85	270	81	244	77	223	72	219	69	223
Vascular surgery	95	208	96	215	97	238	101	245	102	251

Source: Accreditation Council for Graduate Medical Education (75).

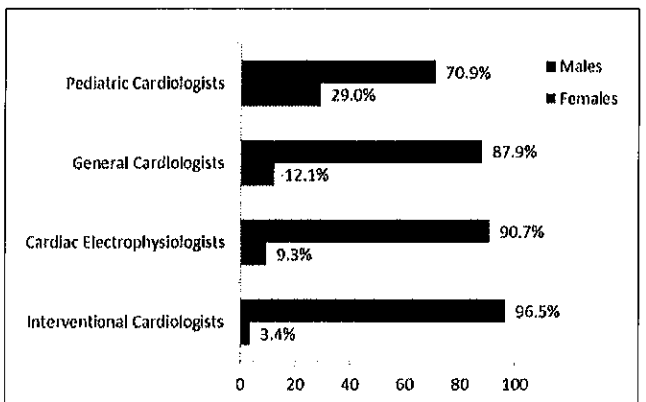

Figure 29 **Cardiologists by Specialty and Sex, 2008**

Dark blue bars = males; **purple bars** = females. Source: The Lewin Group, Inc., and Association of American Medical Colleges (69).

Pharmaceuticals. Worldwide, pharmaceutical sales growth declined to between 4% and 6% in 2010 from the 7% growth rate recorded in 2009. Other global pressures slowing growth of pharmaceutical sales in 2010 were price cuts in Japan—the world's second largest market after the United States—and cuts to publically funded health budgets in Europe (84). The industry is also facing an unprecedented wave of patent expirations, leading to a projected cumulative loss of $78 billion in worldwide sales during 2010 to 2014, with nearly half of this erosion expected to occur due to the loss of patents in 2011 for major blockbuster drugs. (Figure 35 shows the projected replacement ratio for 2012 [85].)

The replacement ratio in a given year is the ratio of revenue from new products (that is, those launched in the previous 5 years) to the revenue lost from declining products (for example, due to generic competition). This ratio is a measure of research and development sufficiency; a ratio of <1 reflects a failure to replace former successful products with new revenue drivers. The data (86) are based on each company's major prescription drug portfolio (the collection of branded drugs, each of which is projected to achieve at least $500 million in annual sales) and were compiled before the mergers of Pfizer and Wyeth, and Merck and Schering-Plough.

Growth in emerging international markets such as China and Brazil will likely offset the generic competition for many of the world's top selling drugs. In 2014, global pharmaceutical sales are projected to approach $1.1 trillion as drug sales in emerging markets are expected to grow by up to 17% (84).

The growth of generic drugs has been beneficial to the consumer, allowing them more access to treatment options and also reducing costs to the system. An IMS analysis found the following related to the use of generics in the United States: the use of generic prescription drugs in place of their brand name counterparts saved the U.S. healthcare system approximately $931 billion over the past decade (2001 through 2010) (Fig. 36); in 2010, generic use generated $158 billion in savings; and savings from newer generic medicines—those that have entered the market since 2001—continue to increase and account for slightly more than one-third of the total savings (Fig. 36) (87).

Within the cardiovascular medicine market, the top drugs in use have come off patent. At the end of 2011, Pfizer stood to lose $10 billion a year when its patent expired on atorvastatin (Lipitor, the world's top-selling drug) (85). The combination of extended-release niacin plus simvastatin (Simcor) as well as fenofibric acid (Trilipix) similarly lost patent protection in 2011. Patent protection also expired on clopidogrel (Plavix) in 2012. In 2010, sales of clopidogrel in the United States alone were >$6 billion (88). Virtually all of the most widely used angiotensin-II receptor antagonists, including losartan (Cozaar/Hyzaar), irbesartan (Avapro), candesartan (Atacand), and valsartan (Diovan), have either already lost or will soon lose patent protection in the United States (89). Table 14 displays key cardiovascular-related patent expirations along with prior patent year sales.

Despite the revenue loss noted and large demand for new drugs, and the projection of heart disease and stroke as the leading cause of death through 2030 (90), there are only approximately 150 new cardiovascular drugs currently (products outlined in Fig. 37) under development compared with some 700 new drugs in development for the treatment of cancer (91).

Additionally, the number CVD-related new molecular entities approved by the Food and Drug Administration (FDA) has declined since 1999, possibly resulting from reduced investment by the industry. This decline is represented in Table 15 (92). In response to the slowing pace of new drug development from industry, the National Insti-

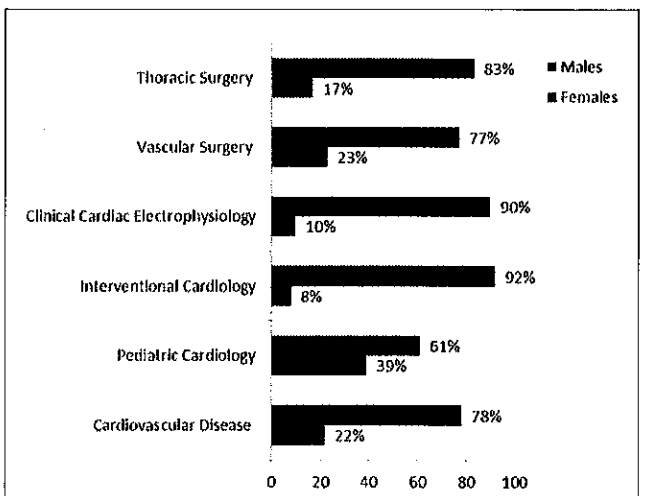

Figure 30 **Trainees by Subspecialty and Sex, 2010 to 2011**

Dark blue bars = males; **purple bars** = females. Number of programs and residents by academic year and specialty and subspecialty, 2010. Source: Accreditation Council for Graduate Medical Education (75).

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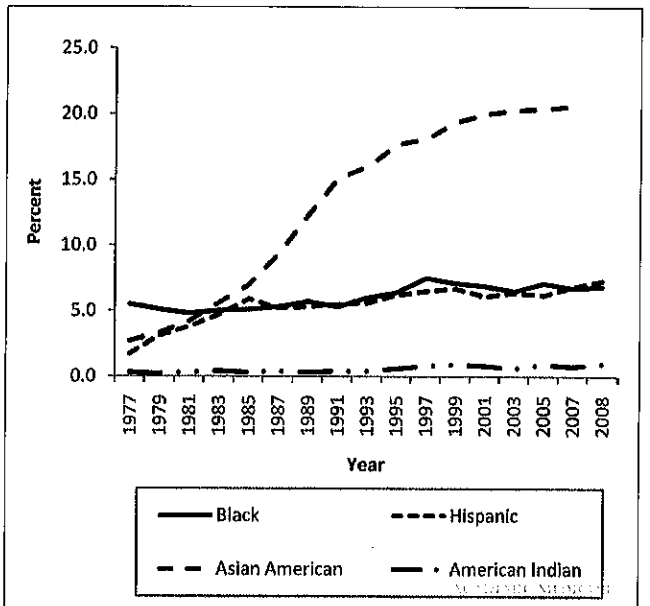

Figure 31 **Minority Graduation Trends in U.S. Medical Schools, 1977 to 2008**

Solid line = black; **dashed line** = Hispanic; **broken line** = Asian American; **dash-dotted line** = American Indian. Source: Sullivan LW, Suez Mittman I. State of diversity in the health professions a century after Flexner. Acad Med 2010;85:193–6.

tutes of Health (NIH) recently proposed a billion-dollar drug development center be established at the agency (93).

It should be noted that the FDA has approved fewer and fewer drugs overall, not just in CVD, whereas spending on industry-wide research and development has nearly doubled over the past decade to $45 billion a year (94). Figure 38 displays the increasing research and development expenditures for both members of the Pharmaceutical Research and Manufacturers of America and the industry from 1995 to 2010.

Medical devices. Lucintel (a market research firm) projects the global cardiovascular device market will reach an estimated $104 billion in 2017 with a compound annual growth rate of 5.2% over the next 5 years (95). A recent pipeline analysis found 114 devices from key manufacturers currently in various phases of development (Fig. 39) (91).

Koncept Analytics projects the coronary stent market to see growth from now through 2015 at a compound annual growth rate of 3.7%, exceeding a total of $8 billion (96). Fourth-generation bioabsorbable stents show the most promise. Results of 3 major trials—ISAR-TEST 3 (Prospective, Randomized Trial of 3 Rapamycin-Eluting Stents With Different Polymer Coating Strategies for the Reduction of Coronary Restenosis), ISAR-TEST 4, and LEADERS (Limus Eluted From a Durable Versus Erodable Stent Coating)—have suggested that the use of biodegradable polymer drug-eluting stents (DES) lead to lower rates of target lesion revascularization, stent thrombosis, and cardiac death and heart attack than DES made of durable polymer (97). Abbott has now initiated the ABSORB II trial in which they will evaluate the safety, efficacy, and performance of the ABSORB bioresorbable vascular scaffold compared with 1 of the company's own DES in patients with heart disease (98).

Several other companies (Medtronic, Biotronic) have also applied for or have received their conformance mark meeting European Union safety and health requirements for their bioabsorbable DES products (99).

Percutaneous devices, including those used to replace aortic and repair mitral valves, entered the U.S. market in 2011 and are projected to account for $1.3 billion of the projected $4.4 billion U.S. cardiovascular surgery market by 2017 (100). Two-year data from Cohort A of the PARTNER (Placement of Aortic Transcatheter Valve Trial) study using the Edwards SAPIEN aortic valve now show comparable mortality rates for patients with transcatheter aortic valve replacement (TAVR) and patients with aortic valves replaced through open-heart surgery in high-risk populations. At 2 years, the difference in stroke risk between the groups became nonsignificant, although valvu-

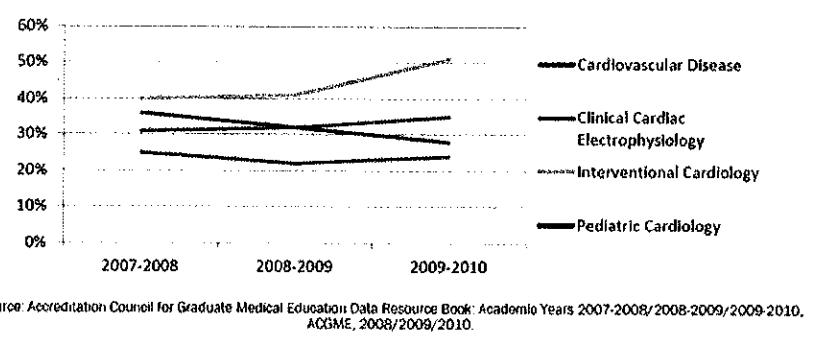

Figure 32 **Percentage of International Medical Graduate Residents, by Cardiovascular Specialty/Subspecialty**

Blue = cardiovascular disease; **red** = clinical cardiac electrophysiology; **green** = interventional cardiology; **purple** = pediatric cardiology. Source: Accreditation Council for Graduate Medicine (78).

Figure 33 **Global Distribution of Physician Workforce (per 10,000 Population), 2000 to 2009**

Source: World Health Statistics 2010, World Health Organization, 2010.

lar regurgitation remained higher in the TAVR group with adverse prognostic significance (101).

In Cohort B of the PARTNER trial, survival and life quality of nonoperable patients treated with TAVR were significantly improved compared with patients treated with medical management only, and readmissions were fewer (102).

Implantation of the Medtronic CoreValve prosthesis was also recently found to be relatively safe as used in a "real-world" clinical population and was associated with an improvement in hemodynamics at 6-month follow-up (97).

Other percutaneous devices include the Evalve MitraClip, which permits double-orifice repair of mitral regurgitation. The Cardiac Dimensions Carrilon system, the Edwards Monarc system, and the Viacor PTMA system are all indirect coronary sinus devices that have been cited for simplicity and ease of use, whereas the Mitralign percutaneous annuloplasty system, as well as the Guided Delivery System, facilitate direct implantation of a device into the mitral annulus and may overcome limitations of the indirect coronary sinus approach.

In contrast, a substantial unmet need remains for medical devices for pediatric interventional cardiology, and off-label use of approved devices is routine in pediatric medicine. Specifically, a study showed that during a 3-year period, some 595 transcatheter interventions were done in approximately 473 pediatric patients, median age 4.1 years. Off-

Employment setting, age, and U.S.- and foreign-born status	Employment growth among FTE RNs, 2001–2008
Total growth	476,000
Age (years)	
Hospital	387,000
Under 35	126,000
35–49	31,000
50–64	230,000
Nonhospital	89,000
Under 35	5,700
35–49	−55,000
50–64	138,000
U.S.-born	321,000
Hospital	268,000
Nonhospital	53,000
Foreign-born	155,000
Hospital	119,000
Nonhospital	35,500

SOURCE: Authors' calculations of data from the Current Population Surveys, 1973–2008.

Figure 34 **Growth in Employment of FTE RNs, by Major Employment Sector, Age, and U.S.- and Foreign-Born Status, 2001 to 2008**

FTE = full-time equivalent; RN = registered nurse. Source: Buerhaus et al. (81).

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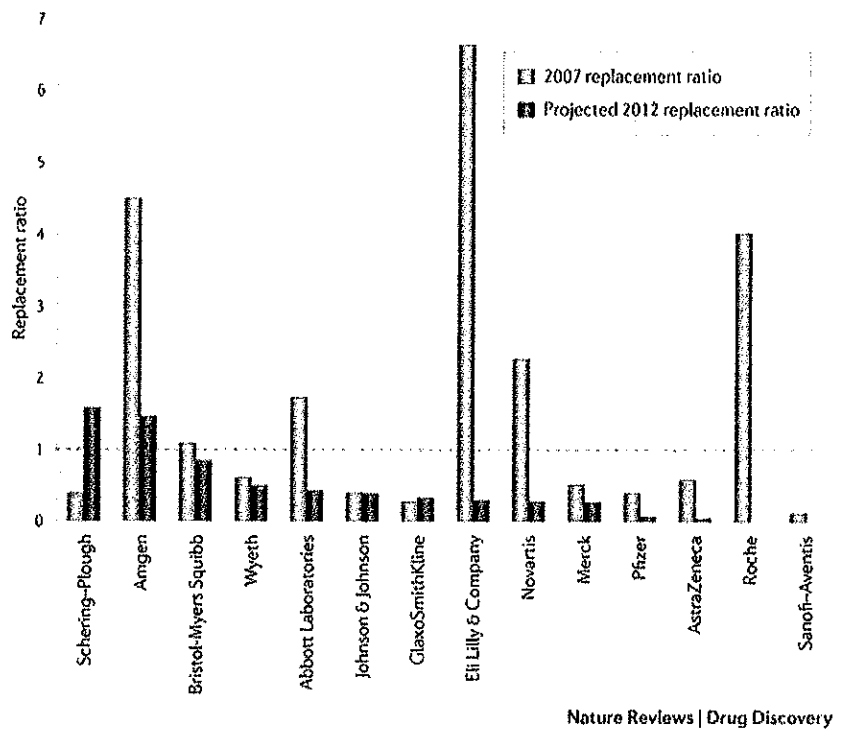

Figure 35 **Projected Replacement Ratio, 2012**

Orange bars = 2007 replacement ratio; **red bars** = projected 2012 replacement ratio. Source: Harrison (85).

label application was used in 63% of all patients and in 99% of stent implantations, 78% of balloon dilations, and 29% of coil embolizations (103).

FDA approval. Review times for drugs and biologics increased by 28% from 2003 to 2008, whereas clearance times for medical devices slowed by >40% over roughly the same period. Premarket approval times have lengthened by 75% (104).

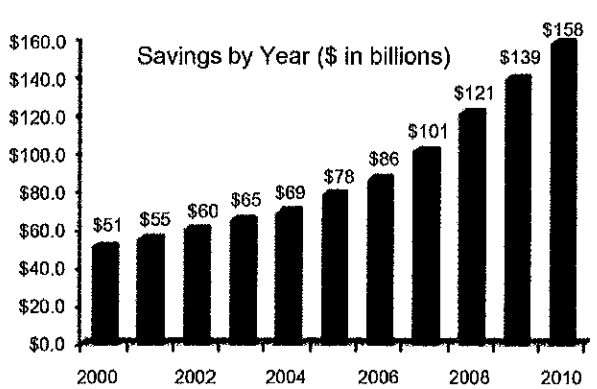

Figure 36 **Savings ($ In Billions) Due to Generic Drug Use by Year**

Source: Generic Pharmaceutical Association (87).

According to 1 study, companies brought products to patients faster and at a much lower cost in Europe than in the United States. In fact, for low- and moderate-risk devices, it took companies 3 months to 2 years longer to navigate the FDA for clearance or approval than it did for similar approval from European regulators; for higher risk devices, the process took 5 times as long in the United States as it did in Europe. There is as yet no evidence that patient safety in Europe has been compromised by a more efficient approval process (105).

Unlike prescription drugs, medical devices are reviewed by the FDA using 2 standards—pre-market approval, which requires clinical testing and inspections, or the so-called "510(k)" process, which requires the device be similar to an

Table 14 **Cardiovascular Disease-Related Patent Expirations ENREF 90**

Drug	Company	Patent Expiration	U.S. Sales In Yr Before Patent Expiration ($ Millions)
Avapro	BMS/sanofi	3/12	$281
Plavix	BMS/sanofi	5/12	$6,895
Diovan	Novartis	9/12	$2,333
Atacand	AZ/Takeda	12/12	$110
Integrilin	Merck	11/14	$288*
Benicar	Sankyo	4/16	$1,066†

*Projections for 2013. †Projections for 2015. Source: Access Communications (91).

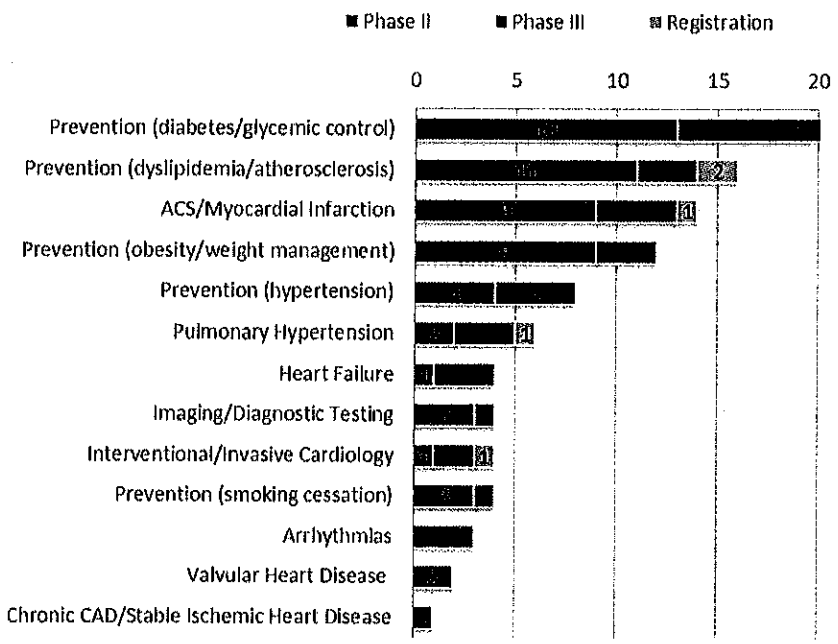

Figure 37 **CV Pipeline Products by ACC-Defined Core Pathway and Phase of Development**

Blue = Phase II; **red** = Phase III; **green** = Registration. ACC = American College of Cardiology; ACS = acute coronary syndrome; CAD = coronary artery disease; CV = cardiovascular. Source: Access Communications (91).

already marketed device. In an analysis of the FDA's list of device recalls from 2005 to 2009, it was determined that 113 recalls during this interval could cause serious health problems or death (106). Only 19% of these devices had been approved through the pre-marketing process, whereas 71% were cleared through the 510(k) process. Seven percent were exempt from any FDA regulation (107).

These findings suggest that those medical devices recalled for life-threatening or very serious hazards in this review were originally cleared for the market using the less stringent 510(k) process and that there is clearly room to reform the regulatory process to ensure patient safety. Despite a modest increase in funding, there was no corresponding increase in FDA approvals for drugs or devices between 2003 and 2008, as indicated in Table 16.

The FDA is taking steps to reduce approval times for drugs and devices, among them a streamlining of the review process for lower risk medical devices, increasing the efficiency and transparency of the review process, and establishing a new Center Science Council made up of senior FDA experts to ensure timely and consistent decision-making. The FDA and CMS are also considering a joint plan for overlapping evaluation of pre-market medical products to shorten the time it takes for newly approved medical products to be covered by third-party payers (107).

Post-market surveillance. Post-market surveillance of medical devices is done passively, meaning that the FDA relies on voluntary reporting of adverse events. As a result, the detection, analysis, and recall for potentially dangerous devices can be slow because of not having an accurate estimate of the adverse impact of a device. Devices like the Riata and Riata ST implantable cardioverter-defibrillator leads, which are prone to high-voltage failure, were not recalled until after their widespread use (108). Although the lead was pulled from the market in 2010 and recalled by the FDA in December of 2011, >79,000 patients in the United

Table 15 **Cardiovascular Disease-Related New Molecular Entities Approved by the Food and Drug Administration**

	Year														
	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
NME*	45	41	43	36	26	30	22	26	32	38	26	35	34	37	23
CVD related NMEs	N/A	N/A	N/A	3	4	4	5	1	1	0	1	3	2	3	1
% CVD related NMEs to total NMEs	N/A	N/A	N/A	8.3	15.3	13.3	22.7	3.8	3.1	0	3.8	8.5	5.8	8.1	4.3

*2004 to 2010 represent applications for new molecular entities (NMEs) filed under New Drug Applications (NDAs) and therapeutic biologics filed under Original Biologic License Applications (BLAs). 2001 to 2003 represent NMEs but not therapeutic biologics. Source: Mehta (92).
CVD = cardiovascular disease.

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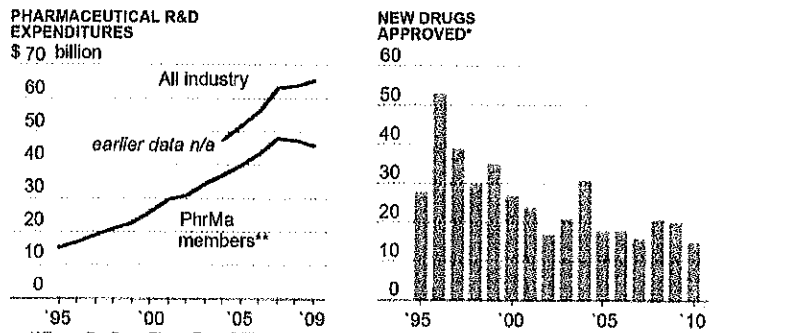

Source: Wilson, D., Drug Firms Face Billions in Losses as Patents End, NY Times, March 6, 2011 (Source Data: FDA).

Figure 38 **Pharmaceutical Companies Have Spent More on Research and Development Over Time, But Have Discovered Fewer Novel Drugs That Gain FDA Approval**

FDA = Food and Drug Administration; n/a = not available; PhrMa = Pharmaceutical Research and Manufacturers of America. Source: Wilson (94).

States still use the implants (109). To improve post-market surveillance, Congress and the FDA are working to utilize data from EHR, claims data, and clinical registries through the Sentinel Initiative to receive more accurate information (110).

Another major effort to improve market surveillance is the Medical Device Epidemiology Network Initiative. This initiative promotes public–private partnerships to collect and share information about devices after they are marketed to ensure patient safety. The partnerships are currently exploring more novel methodologies to study medical devices to track adverse events and improve patient outcomes (111).

One of the major obstacles to surveillance is that medical device identification is not standardized across hospital systems, manufacturers, and distributions. To remedy this, the FDA intends to use a unique device identification system in the upcoming years to identify device failure rates (112). The Sentinel Assurance for Effective Devices Act of 2012 was submitted to Congress in May to establish a system to identify and analyze adverse events among medical devices (113). The FDA has proposed the unique device identification system rollout to begin in 2013 for implantations and other devices that support human life, such as TAVR, pacemakers, and defibrillators. The rollout for equipment such as radiography, pumps, and surgical drapes is said to begin in 2015 (114).

New methods of post-market surveillance. Professional associations and the CMS have begun collaborating to coordinate clinical registries and other relevant databases to track the safety of devices and procedures to enhance post-market surveillance. One example of this collaboration is the transcatheter valve therapy registry that tracks patients undergoing TAVR. Soon after the Edwards SAPIEN transcatheter heart valve was approved by the FDA in 2011, 2 professional associations (the Society of Thoracic Surgeons and ACC) launched the transcatheter valve therapy

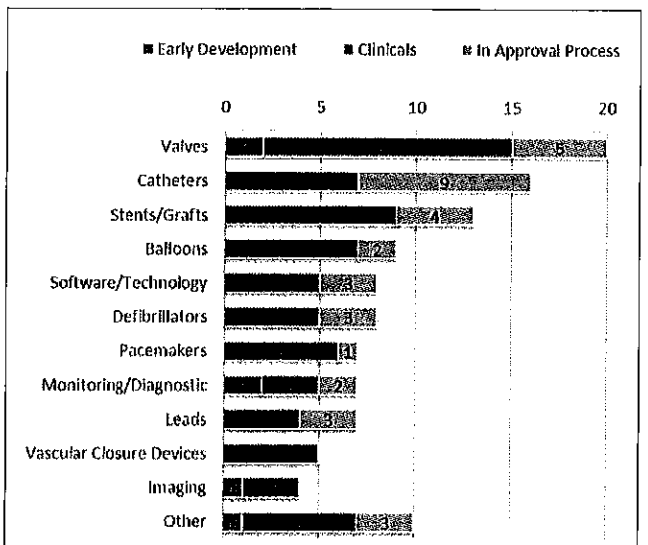

Figure 39 **CV Devices in Development by Key Manufacturers by Category**

Key device manufacturers were defined as those with the largest presence in the cardiovascular (CV) device segment with active pipelines (includes Medtronic, Boston Scientific, St. Jude Medical, Edwards Lifescience, C.R. Bard, Sorin, Cordis, Abbot Vascular, Coviden, GE Healthcare, Philips, Siemens, Toshiba). **Blue** = in early development; **red** = in clinical trials; **green** = in approval process. Source: Access Communications (91).

Table 16 **New Drug and Device Approvals by U.S. Food and Drug Administration, 2003–2008**

Category	2003	2004	2005	2006	2007	2008
New molecular entities	21	31	18	18	16	17
Biologic license applications*		5	2	4	2	3
f41Device premarket application approvals†	33	46	32	38	25	25

*The Food and Drug Administration reported biologic license approvals beginning in 2004.
†Numbers include instruments, implantables, patient monitoring, diagnostic devices, and in vitro tests. Source: Dorsey et al. (130).

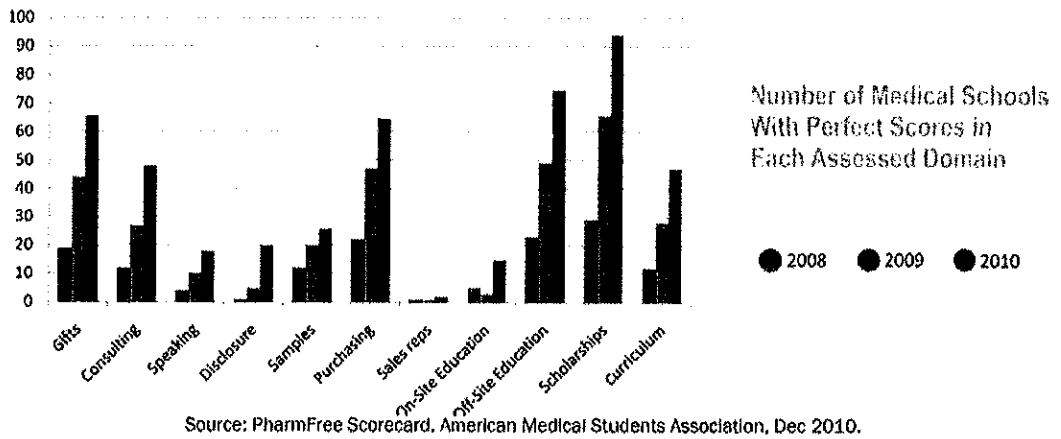

Figure 40 **Number of Medical Schools With Perfect Scores in Each Assessed Domain, 2010**

Red bars = 2008; **blue bars** = 2009; **green bars** = 2010. Source: American Medical Association.

registry to track safety and long-term health outcomes of patients who undergo TAVR (115). Information from the transcatheter valve therapy registry is linked to the Social Security Death Master File as well as to other CMS databases to track the long-term health outcomes and can be utilized by the FDA for post-market surveillance (116).

Similar registries have also been mandated by CMS for coverage determinations and tracking of patient outcomes. For example, patients receiving an implantable cardioverter-debrillator are required to participate in the implantable cardioverter-debrillator registry sponsored by the Heart Rhythm Society and ACCF for Medicare coverage. Registries operated by professional societies for devices with significant expense and risk are gaining value because CMS and other payers are interested in measuring patient outcomes (117).

Additionally, 4 professional associations (American Association for Thoracic Surgery, ACCF, Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons) collaborated to publish an Expert Consensus Document on TAVR to advise payers, providers, and other stake holders on safely incorporating TAVR into their practice (116). To ensure national standards for patients

	Maine		West Virginia	
Type of Effect	Compared With New Hampshire	Compared With Rhode Island	Compared With Kentucky	Compared With Delaware
On percentage of claims that are for brands				
Statins	−0.81 (−1.22 to −0.39)[b]	−5.29 (−5.45 to −5.13)[c]	0.26 (−12.82 to 13.34)	−2.62 (−4.74 to −0.49)[b]
SSRIs	3.73 (3.20 to 4.25)[c]	−0.72 (−1.18 to −0.26)[b]	1.09 (−4.13 to 6.31)	−0.53 (−0.77 to −0.28)[b]
On out-of-pocket prescription costs ($ per 30-d supply)				
Statins	0.77 (−1.94 to 3.48)	0.77 (−3.03 to 4.58)	−2.64 (−9.41 to 4.16)	−2.12 (−8.50 to 4.27)
SSRIs	0.02 (−0.51 to 0.55)	−0.69 (−1.88 to 0.51)	−1.78 (−5.72 to 2.15)	−3.01 (−14.52 to 8.49)
On out-of-pocket costs + insurer payments ($ per 30-d supply)				
Statins	−2.08 (−7.19 to 3.02)	−6.33 (−13.87 to 1.21)	3.06 (−23.39 to 29.52)	−0.11 (−13.83 to 13.61)
SSRIs	0.08 (−0.05 to 0.22)	−2.74 (−4.46 to −1.03)[b]	0.73 (−18.23 to 19.69)	−0.99 (−14.44 to 12.45)

Abbreviation: SSRI, selective serotonin reuptake inhibitors.
[a]Numbers in parentheses indicate the 95% CI. All regressions include dummy variables for exclusivity expiration of brand drugs, dummy variables for seasonality of state claims, state fixed effects, and year fixed effects. Standard errors are clustered by state. There were 156 observations in each set of comparisons.
[b]$P < .05$.
[c]$P < .01$.

Figure 41 **Effect of Physician Payment Disclosure Laws on Prescribing and Expenditures[a]**

SSRI = selective serotonin reuptake inhibitor. Source: Arch Intern Med 2012;172:819–21; doi:10.1001/archinternmed.2012.1210.

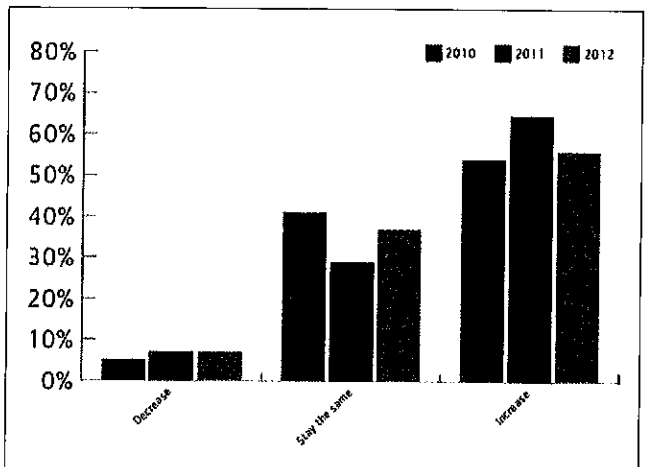

Figure 42 **Expected Change in Investment in Aggregate Spend Reporting and Disclosure Compliance, 2010 to 2012**

Blue bars = 2010; **red bars** = 2011; **green bars** = 2012. Source: Pelletier (125).

undergoing TAVR, a national coverage determination analysis was requested of CMS. In May 2012, CMS approved reimbursement for providers that perform TAVR given the following conditions are met: the valve and implantation system have FDA premarket approval; 2 cardiac surgeons independently evaluate the patient; the patient is under the care of a multidisciplinary heart team at a hospital qualified to perform TAVR; both the interventional cardiologist and cardiac surgeons are involved with the implantation; and the heart team and hospital participate in a TAVR registry (118).

Relationships With Industry

The Physician Payment Sunshine Act, a section of the ACA, was created to disclose payments to physicians from private industry (pharmaceutical and medical device companies). It was scheduled to be implemented in January 1, 2012, but CMS delayed the implementation to 2013 to address logistical issues and data accuracy (119).

A number of academic medical centers and states have implemented new policies that more strictly manage relationships between physicians and industry. For example, in 2010, Harvard's Partners Healthcare capped payments its physicians can receive for serving on corporate boards at $5,000 a day. In the same year, Massachusetts required conflict-of-interest (COI) policies be posted on its public health website, and an increasing number of universities have placed a ban on gifts from pharmaceutical companies (120).

Simultaneously, a number of pharmaceutical companies including GlaxoSmithKline, Lilly, Merck, and Cephalon have been disclosing payments to physicians on their company websites (120). Newly proposed regulations would also compel researchers funded by the NIH to disclose their financial ties to industry and lower the threshold at which a researcher's financial interest requires disclosure to $5,000. Institutions would also be required to create plans to manage all identified financial COIs under the same proposed rules, and every publicly funded institution would similarly have to disclose all significant COIs online. Investigators, in turn, would be required to undergo COI training before engaging in publicly funded research, and training would be required every 2 years thereafter (121).

Most medical schools in the United States have implemented COI policies governing industry interactions at the schools. As a measurement of these interactions, the American Medical Student Association developed a PharmFree Scorecard that grades medical schools according to their COI policies (122). In 2012, 102 of 152 medical schools in the United States received a grade A or grade B for their COI polices, up from 79 in the previous year. The trends of schools achieving perfect grades on the PharmFree Scorecard is displayed in Figure 40 (123). Furthermore, one-third of U.S. medical schools incorporated COI policies into their curriculum (120).

A recent study of physician prescribing habits in Maine and West Virginia, which both enacted payment-disclosure legislation in 2004, found that, in Maine, prescribing of branded selective serotonin reuptake inhibitors was actually 3.7 percentage points higher than in New Hampshire, a state that did not enact them. The prescribing patterns for statins showed little difference across states with the enacted legislation (Maine and West Virginia) compared to those without legislation (Kentucky and Delaware) (Fig. 41) (124).

Responding to this increased pressure for transparency, life science executives (pharmaceutical, biotech, and medical device companies) expect to increase their investment in aggregate

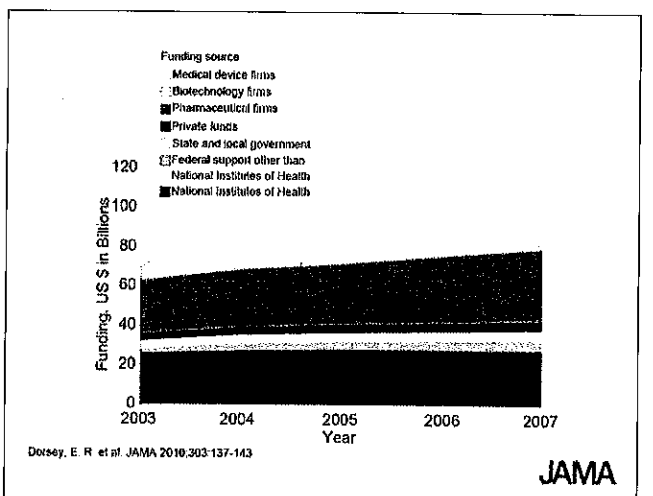

Figure 43 **Funding for Biomedical Research by Source, 2003 to 2007**

Light blue = medical device firms; **medium blue** = biotechnology firms; **deep blue** = pharmaceutical firms; **black** = private funds; **light gray** = state and local government; **medium gray** = federal support other than National Institutes of Health; and **dark gray** = National Institutes of Health. Source: Dorsey et al (130).

spend reporting and disclosure compliance over the next year (Fig. 42). The expected increase is partly due to federal regulations and the trend of global transparency.

Additionally, 88% of attendees surveyed at the Fourth Annual Life Sciences Meeting Management Forum said they already had a system in place to track physician payments, and 76% were already testing their systems (125).

Funding for Biomedical Research

For the 2013 fiscal year, $140.8 billion of President Obama's proposed $3.8 trillion budget has been allocated to research and development (126,127). Funding recommendations for federal research for the fiscal year 2013 include $30.7 billion to the NIH (128), $7.4 billion to the National Science Foundation, and $583 million to the Department of Veterans Affairs medical and prosthetics research program (129).

The NIH is the largest federal contributor to biomedical research, accounting for 84% of total federal funding in 2007 (130,131). In 2011, the NIH allocated a total of $2.1 billion to cardiovascular research. More specifically, $1.2 billion was allocated to heart disease research, $317 million to stroke research, and $437 million to coronary heart disease research (131).

The National Heart, Lung and Blood Institute, an institute within the NIH, has been funding the Cardiovascular Research Network (CVRN), which brings together researchers and databases from 15 integrated health plan members of the NIH health maintenance organization research. This network has access to the EHR of >11 million patients, and the electronic database of the CVRN offers significant potential for a broad array of research opportunities (132).

The NIH awarded >$13 million to the CVRN for research regarding heart failure, atrial fibrillation, and CVD surveillance (133). A $7.2 million grant from the National Heart, Lung, and Blood Institute is supporting the development of an integrated surveillance system that will provide comprehensive information regarding the burden of CVD in the United States (131).

From 2003 to 2007, funding for biomedical research increased by 14%, to a total of $101.1 billion in 2007, a considerably higher annual growth rate than the 7.8% growth reported for the years 1994 and 2003. The growth in

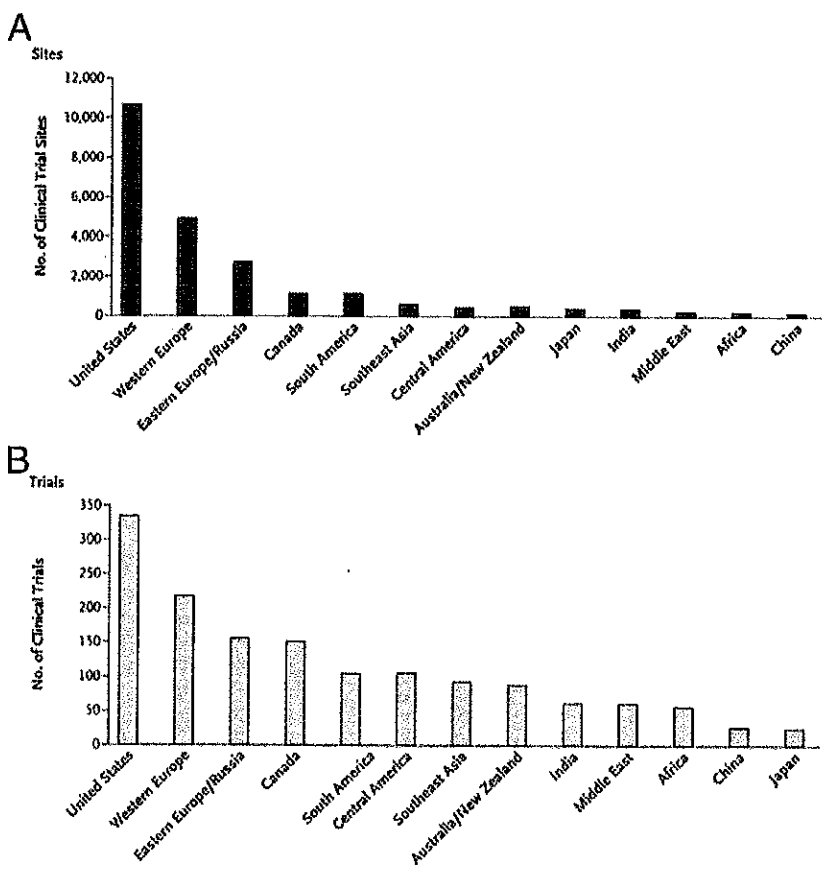

Figure 44 **Open Phase III Clinical Trials Globally in 2007 by the 20 Largest U.S. Pharmaceutical Companies**

(A) Sites. **(B)** Trials. Source: Glickman et al. (136).

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Variable	1993 mean	1993 SD	2005 mean	2005 SD
PUBLIC HEALTH AGENCY CHARACTERISTICS				
Per capita public health spending	$34.68	$33.08	$40.84	$42.52
Agency governed by local board of health	64.41%		57.42%	
Agency operates as centralized unit of state agency	10.27%		7.83%	
COMMUNITY CHARACTERISTICS				
Population size (1,000s)	108.63	340.60	131.44	426.42
Population per square mile (1,000s)	475.08	1,841.46	484.04	1,842.57
Community located within a metropolitan area	51.05%		50.48%	
Percent of:				
Population nonwhite	14.33	17.93	19.27	17.36
Population 65 or older	14.39	3.91	14.07	4.00
Population with college degree	15.85	8.25	19.59	9.53
Population unemployed	6.21	2.42	5.64	2.26
Population below federal poverty level	15.65	7.04	11.92	4.79
Population non-English speaking	1.07	1.77	1.73	2.32
Population uninsured	13.66	4.65	13.52	4.50
MEDICAL CARE RESOURCES				
Active physicians per 100,000 population	138.04	133.83	169.24	159.23
Hospital beds per 100,000 population	384.16	320.51	320.60	372.81
Federally qualified health center serves community	48.33%		46.57%	
HEALTH OUTCOMES				
Infant deaths per 1,000 live births	8.76	3.50	7.03	3.22
Deaths per 100,000 population from:				
Influenza	36.11	17.66	27.28	15.52
Cancer	215.46	56.16	219.49	57.99
Heart disease	225.02	78.87	194.09	76.95
Diabetes	23.47	10.58	28.67	14.41
Total deaths per 100,000 population	1,020.97	256.59	980.62	270.68
Number of observations	2,026		2,300	

SOURCE Authors' analysis of linked data from the National Association of County and City Health Officials' National Profile of Local Health Departments, the Census Bureau's Census of Governments and *Consolidated Federal Funds Report*, the Health Resources and Services Administration's Area Resource File, and the Centers for Disease Control and Prevention's Compressed Mortality File. **NOTE** SD is standard deviation.

Figure 45 **Characteristics of the Study Communities, 1993 and 2005**

Source: Mays and Smith (138).

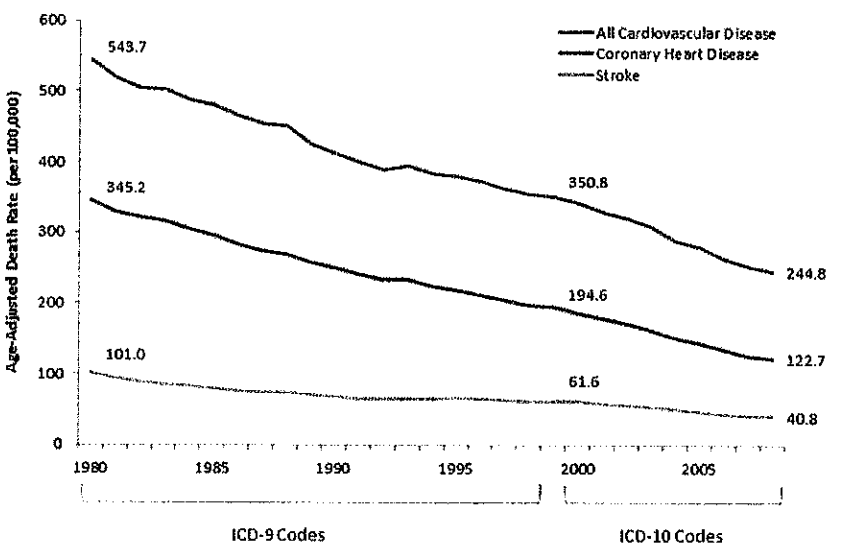

Figure 46 **Age-Adjusted Death Rates for Cardiovascular Disease, Coronary Heart Disease, and Stroke, 1980 to 2008**

Blue line = all cardiovascular disease; **red line** = coronary heart disease; and **green line** = stroke. ICD = International Classification of Diseases. Source: National Institutes of Health, National Heart, Lung and Blood Institute. Morbidity and Mortality: 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases. Available at: http://www.nhlbi.nih.gov/resources/docs/2012_ChartBook_508.pdf.

funding for biomedical research is displayed in Figure 43. Industry was the largest source of funding in 2007, accounting for 58% of the total, followed by the federal government, which accounted for 33%. Taken together, support from pharmaceutical, biotechnology, and medical device companies increased by 25% (adjusted for inflation) from 2003 to 2007, where it peaked at $58.6 billion (130).

The biopharmaceutical industry spent an estimated $67.4 billion on research and development in 2010. Between 2000 and 2010, 333 drugs or biologics were approved by the FDA. Each drug takes 10 to 15 years to be developed and approved, and on average costs approximately $1.3 billion (134).

Although the pharmaceutical industry is sponsoring more research and development, more clinical trials are moving to developing countries (135). A study from the *New England Journal of Medicine* noted that the shift is due to the more cost intensive and complex regulatory environments in the United States and Western Europe. The funding required for clinical trials in the United States often exceeds the federal funding allotted for biomedical research. Figure 44 displays the open phase 3 clinical trials by the number of sites and trials by the top 20 largest U.S. pharmaceutical companies in 2007. The FDA reported that the number of regulated investigations conducted outside of the United States has grown by 15% annually.

There are concerns regarding clinical trials conducted abroad. One concern is ethical oversight. In a study of researchers in developing countries, 56% reported that their studies were reviewed by a local institutional review board or ministry of health. Further concerns regarding the generalizability of the results have been discussed by the FDA relating to potential genetic and socioenvironmental factors that affect treatment efficacy among patient populations in developing countries (Fig. 45) (136).

Cardiovascular Prevention

Cardiovascular prevention efforts are receiving growing attention in an effort to offset the increasing burden of disease and to stem rising healthcare costs. Federal efforts, public agencies, and employers are developing strategies addressing risk factors associated with CVD.

The debate continues around which approach has had the greatest impact on reducing mortality from coronary heart disease: better control of cardiovascular risk factors or the use of medical interventions (137). An analysis of the effect of increased public health spending on mortality found that public health spending is not significantly associated with overall mortality; however, increased public health spending correlated with lower heart disease-related mortality rates (138).

Table 17 Deaths from Coronary Heart Disease That Were Prevented or Postponed as a Result of Changes in Population Risk Factors

	Absolute Level of Risk Factor‡		Change in Risk Factor				Deaths Prevented or Postponed					
Risk Factor†	1980	2000	Absolute Change	Relative Change (%)	Beta Regression Coefficient for Change in Mortality Rate§	Relative Risk	Best Estimate	Minimum Estimate	Maximum Estimate	Best Estimate	Minimum Estimate	Maximum Estimate
							No. of Deaths			Percent of Total Reduction		
Smoking prevalence (%)	36.3	24.6	−11.7	−32.2			39,925	34,955	52,435	11.7	10.2	15.3
Men						2.52						
Women						2.14						
Systolic blood pressure (mm Hg)	129.0	123.9	−5.1	−4.0			68,800	53,730	105,060	20.1	15.7	30.7
Men					−0.0334							
Women					−0.0413							
Total cholesterol (mmol/l)	5.67	5.33	−0.34	−6.1			82,830	58,455	95,570	24.2	17.1	28.0
Men					−0.9458							
Women					−0.9121							
Physical inactivity (%)	29.6	27.3	−2.3	−7.8	—		17,445	8,340	29,035	5.1	2.4	8.5
Men						1.27						
Women						1.33						
BMI	25.6	28.2	+2.6	10.1			−25,905	−14,430	−40,405	−7.6	−4.2	−11.8
Men					0.0297							
Women					0.0297							
Diabetes prevalence (%)	6.5	9.4	+2.9	44.2	—		−33,465	−23,885	−43,330	−9.8	−7.0	−12.7
Men						1.93						
Women						2.59						
Total risk factors							149,635	117,165	198,360	43.8	34.3	58.0

*Percentages may not sum to 100 because of rounding. BMI denotes body-mass index (the weight in kilograms divided by the square of the height in meters). To convert the values for cholesterol to milligrams per deciliter, divide by 0.02586. Data sources are described in the Supplementary Appendix. †The total adult population in 1980 was 177,745,055. For systolic pressure, the numbers of deaths exclude patients receiving treatment for hypertension, and for total cholesterol, the numbers exclude patients receiving statins. ‡Data are from the National Center for Health Statistics, except for data on physical inactivity, which are from the Behavioral Risk Factor Surveillance System. §The change in the mortality rate per unit of measurement for the risk factor is shown. Source: Ford et al. (140).

BMI = body mass index.

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	Framingham[6]	SCORE[7]	ASSIGN-SCORE[8]
Data	Prospective studies: Framingham Heart Study and Framingham offspring study. Latest version includes both	Pooled prospective studies	SHHEC Prospective study
Population	General population in Framingham, Mass. Baselines: 1968–1971, 1971–1975, 1984–1987	12 Prospective studies from 11 European countries. Baselines: 1972–1991	Random sample from general population in Scotland. Baseline 1984–1987
Sample type	Volunteer	Mostly random samples from general population, some occupational cohorts	Random
Sample size	3969 Men and 4522 women	117 098 Men and 88 080 women	6540 Men and 6757 women
Statistical methods	Cox (Weibull; earlier versions[14])	Cox and Weibull	Cox
Calculates	10-Year risk of CHD events originally. Latest version: 10-year risk of CVD events. NCEP ATP III version: 10-year risk of hard coronary events	10-Year risk of CVD mortality	10-Year risk of CVD events
Age range, y	30–75	40–65	30–74
Variables	Gender, age, total cholesterol, HDL cholesterol, SBP, smoking status, diabetes, hypertensive treatment	Gender, age, total cholesterol or total cholesterol/HDL cholesterol ratio, SBP, smoking status. Versions for use in high- and low-risk countries	Gender, age, total cholesterol, HDL cholesterol, SBP, smoking (no. of cigarettes), diabetes, area-based index of deprivation, family history
Formats	Simplified scoring sheets. Color charts have been generated for some guidelines, eg, JBS and New Zealand guidelines. Online calculators. Portable calculators	Color-coded charts. HeartScore: online and CD-based stand-alone electronic versions	Online calculator
Developments	Latest version includes version based on nonlaboratory values only, substituting BMI for lipid measurements	National, updated recalibrations	
Recommended by guidelines	NCEP guidelines,[20] CCS guidelines.[5] Other national guidelines recommend adapted versions, including New Zealand[17]	European guidelines on CVD prevention[7]	Recommended by SIGN[21]
Web site	Online and downloadable risk calculator available at: www.nhlbi.nih.gov/guidelines/cholesterol/index/htm and www.framinghamheartstudy.com	Online and downloadable risk calculators available at: www.HeartScore.org	Online risk calculator available at: www.assign-score.com
Internal validation: discrimination	AUROC: Men 0.76 (0.75–0.78), women 0.79 (0.77–0.81)	AUROC high risk 0.80 (0.80–0.82). AUROC low risk 0.75 (0.73–0.77)	AUROC: Men 0.73, women 0.77
Internal validation: calibration	HL: Men 13.48, women 7.79	Not specified	Observed 10-year CVD incidence rates: Men 11.7%, women 6.4%. Median ASSIGN score: Men 11.7%, women 6.2%
External validation: discrimination	PRIME Study[23]: Belfast 0.68, France 0.66. Dutch study[24]: 0.86 (0.84–0.88). Cleveland Study[25]: 0.57. China[26]: Men 0.75 (0.72–0.78), women 0.79 (0.74–0.85). THIN (UK)[27]: Men 0.74 (0.73–0.74), women 0.76 (0.76–0.76). EPIC Norfolk[28]: 0.71. UK Women (BHHS)[29]: 0.66 (0.62–0.69)	Dutch study[24]: 0.85 (0.83–0.87). Cleveland Study[25]: 0.73. Norwegian Study[30]: Range for different age groups, men 0.66–0.68, women 0.66–0.72. Austrian Study[31]: Men 0.76 (0.74–0.79), women 0.78 (0.74–0.82). Icelandic Study[32]: 0.80 (0.78–0.82). SCORE high 0.80 (0.77–0.82). SCORE low	Not assessed

Figure 47 **Characteristics of Current Risk Estimation Systems**

ATP = Adult Treatment Panel; AUROC = area under receiver-operating characteristic curve; BMI = body mass index; CCS = Canadian Cardiovascular Society; CVD = cardiovascular disease; Hb = hemoglobin; HDL = high-density lipoprotein; hs-CRP = high-sensitivity C-reactive protein; JBS = Joint British Societies; LDL = low-density lipoprotein; MI = myocardial infarction; NCEP = National Cholesterol Education Program; SBP = systolic blood pressure; WHO = World Health Organization. The reference citations throughout this figure related to the original source. Source: Cooney et al. (152).

The NIH, National Heart, Lung and Blood Institute reports that the CVD age-adjusted mortality rate dropped from 543.7 per 100,000 in 1980 to 244.8 per 100,000 in 2008. Figure 46 displays the decline of age-adjusted mortality rates from 1980 to 2008 for CVD, coronary heart disease, and stroke with a designation of the transition from International Classification of Disease-Ninth Edition (in italics) (ICD-9) to ICD-10 mortality coding in 1999 (139). Previous studies found that the decline for coronary heart disease from 1980 to 2000 was attributed fairly equally to improvements in treatment (47%) and risk factor control (44%) (140).

Ford et al. (140) modeled the effects of risk factor control, finding that reductions in major risk factors may have accounted for approximately 44% of the decrease in deaths from coronary heart disease from 1980 to 2000 (Table 17). Earlier U.S. studies suggested a similar contribution of approximately 54% of the reduction in deaths between 1968

QRISK[18] and QRISK2[9]	PROCAM[10]	WHO/ISH[11]	Reynolds Risk Score[12,13]
QRESEARCH database	Prospective study	Methods differ vs other risk estimation functions; not based on prospective data	Randomized controlled trials. Women: Women's Health Study; men: Physician's Health Study II
Data collected from 1993 to 2008	Healthy employees. Baseline: 1978–1995	Not applicable	Women: Health service employees, baseline 1993–1996. Men: Physicians, baseline 1997
Health records of GP attendees; not random	Industrial employee volunteers; not random	Not applicable	Health service employees; volunteer, not random
1.28 Million (QRISK1) and 2.29 million (QRISK2)	18 460 Men and 8515 women	Not applicable	24 558 Women, 10 724 men
Imputation of substantial missing data Cox	Cox and Weibull; exploratory analyses with neural networks also[10]	Relative risks associated with risk factors were taken from the Comparative Risk Assessment Project. These were combined with estimated absolute risks for each WHO subregion based on the Global Burden of Disease Study	Cox
10-Year risk of CVD events	Two separate scores calculate 10-year risks of major coronary events and cerebral ischemic events	10-Year risk of CVD events	10-Year risk of incident MI, stroke, coronary revascularization, or cardiovascular death
35–74	20–75	40–79	45–80
QRISK1: Gender, age, total cholesterol to HDL cholesterol ratio, SBP, smoking status, diabetes, area-based index of deprivation, family history, BMI, antihypertensive treatment. QRISK2 also includes ethnicity and chronic diseases	Age, gender, LDL cholesterol, HDL cholesterol, diabetes, smoking, SBP	Gender, age, SBP, smoking status, diabetes, with or without total cholesterol. Different charts available for worldwide regions	Gender, age, SBP, smoking, hs-CRP, total cholesterol, HDL cholesterol, family history of premature MI (parent <age 60 y), HbA1C if diabetic
Online calculator	Simple scoring sheet and online calculators	Color-coded charts	Online calculator
QRISK2 includes interaction terms to adjust for interactions between age and some variables	Recent change in methods (Weibull) allows extension of risk estimation to women and a broader age range		
NICE guidelines on lipid modification[22]	International Task Force for Prevention of Coronary Disease guidelines	WHO guidelines on CVD prevention[11]	CCS guidelines recommend a choice of either Reynolds or Framingham risk score[1]
Online risk calculator available at: www.qrisk.co.uk	Online calculator available at: www.chd-taskforce.com/calculator	Charts downloadable at: www.who.int/cardiovascular_diseases/guidelines/Pocket_GL_information/en/index.html	Online calculator available at: www.reynoldsriskscore.com
QRISK2: AUROC Men 0.79 (0.79–0.79), women 0.82 (0.81–0.82)	AUROC 0.82 for coronary events, 0.78 for cerebral ischemic events	Not specified	Women: AUROC 0.808, men: AUROC 0.708
Good correlation between observed and predicted risks in both men and women, presented graphically only, in each decile of risk	Not specified	Not specified	Women 0.62, men 12.9
THIN database (UK)[22]: QRISK1 AUROC, men 0.76 (0.76–0.77), women 0.79 (0.79–0.79)	PRIME Study[23]: Belfast 0.61, France 0.64	Not assessed	Not assessed

Figure 47 **Continued**

and 1976 (141), and approximately 50% between 1980 and 1990 (142). The investigators note that "most of the changes in treatments and risk factors between 1980 and 2000 led to reductions in deaths from coronary heart disease with 2 major exceptions: increases in BMI accounted overall for about 26,000 additional deaths from coronary heart disease in 2000 and increases in the prevalence of diabetes for about 33,500 additional deaths" (140).

Despite mixed evidence on the optimal mix of prevention approaches, it is clear that they each have positive effects on CVD. Thus, the ACA allocated $15 billion in federal funding to prevention efforts related to CVD (143). Under these provisions, an estimated 54 million Americans will receive preventive services. Reimbursement rates will also be increased for preventive services for Medicare and Medicaid beneficiaries (144).

The U.S. Preventive Services Task Force developed the following CVD-specific recommendations that will be covered under Medicare, Medicaid, and non-grandfathered insurance plans (plans established after March 23, 2010):

- Aspirin to prevent CVD in men (ages 45 to 79 years) and women (ages 55 to 79 years)
- High blood pressure screening for all adults
- Cholesterol screening for men (over age 35 years) and women (over age 45 years)
- Type 2 diabetes screening for adults with sustained high blood pressure (135/80 mm Hg)
- Healthy diet counseling (intensive behavioral dietary counseling) for adults with risk factors for CVD
- Obesity screening and counseling for adults and children (behavioral interventions to promote weight loss)

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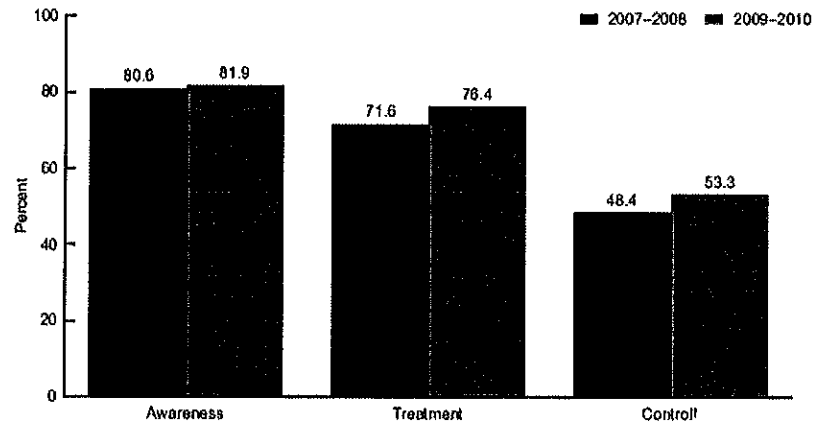


[1]Significant difference between the two time periods.
NOTE: Access data table for Figure 2 at http://www.cdc.gov/nchs/data/databriefs/db107_tables.pdf#2
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

Figure 48 **Age-Adjusted Awareness, Treatment, and Control of Hypertension Among Adults With Hypertension: United States, 2007 to 2010**

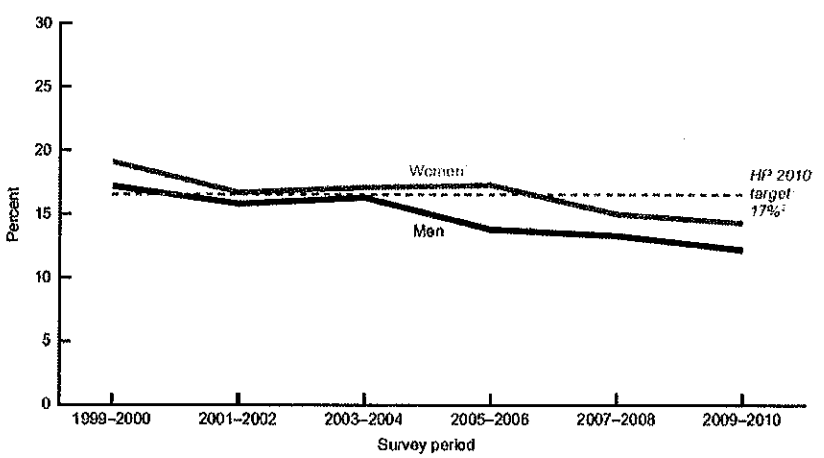
Blue bars = 2007 to 2008; **green bars** = 2009 to 2010. Source: Yoon et al. (156).

- Tobacco use counseling for pregnant and nonpregnant adults (counseling varies by status) (145).

Non-grandfathered insurance plans are required to fully cover specified preventive health services on the premise that people are more likely to take advantage of preventive care practices if they are not responsible for copays or other deductibles (146,145).

Employers have shown interest in addressing risk factors at the workplace. Studies of workplace wellness programs suggest that healthcare costs are reduced and health outcomes improve when risk factors are reduced (147).

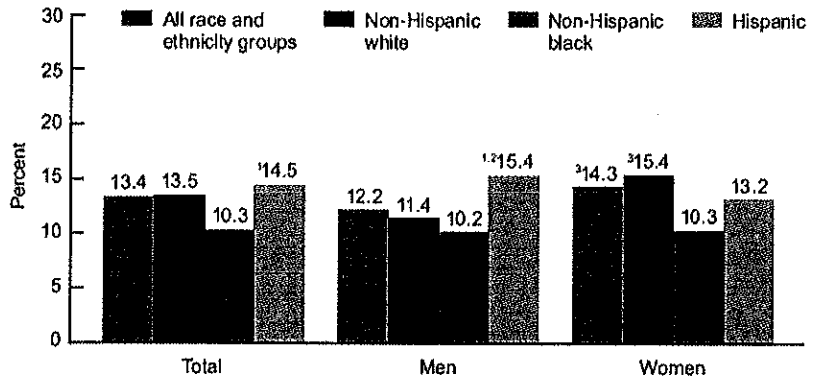
Risk estimation frameworks. Cooney et al. (148–151) report that all current CVD prevention guidelines stress the need to consider the likely impact of all risk factors before making clinical management decisions and, in most cases, to recommend a system of evaluating combined risk factor effects. They go on to provide a comparison of the Framingham system, the best known both nationally and interna-



[1]Significant decreasing trend ($p < 0.005$)
[2]Healthy People 2010 Objective (12-14)
NOTE: High total cholesterol is serum total cholesterol level equal to or greater than 240 mg/dL. Estimates were age adjusted by the direct method to U.S. Census 2000 population estimates using age groups 20–39, 40–59, and 60 and over. Access data table for Figure 2 at http://www.cdc.gov/nchs/data/databriefs/db92_tables.pdf#2.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Surveys, 1999–2010.

Figure 49 **Trends in Percentage of Adults Age 20 Years and Older With High Total Cholesterol: United States, 1999 to 2010**

HP = Healthy People. Source: Carroll et al. (160).



[1]Significantly different from non-Hispanic black population.
[2]Significantly different from non-Hispanic white population.
[3]Significantly different from men in the same racial and ethnic group.
NOTES: High total cholesterol is serum total cholesterol equal to or greater than 240 mg/dL. Estimates were age adjusted by the direct method to U.S. Census 2000 population estimates using age groups 20–39, 40–59, and 60 and over.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey, 2009–2010.

Figure 50 **Percentage of Adults Age 20 Years and Older With High Total Cholesterol, by Sex, Race, and Ethnicity: United States, 2009 to 2010**

Green bars = all race and ethnicity groups; **dark blue bars** = non-Hispanic white; **dark gray bars** = non-Hispanic black; and **medium gray bars** = Hispanic. Source: Carroll et al. (160).

tionally and the most commonly used framework, to other commonly used systems recommended by guidelines on CVD prevention (Fig. 47) (152).

Risk factor control. HYPERTENSION. Uncontrolled hypertension is the leading attributable risk factor for CVD (i.e., stroke, myocardial infarction, heart failure, renal failure) and mortality worldwide (153–155). Hypertension is a prevalent condition affecting approximately 1 in 3 adults in the United States (28.6%) (Fig. 48) (156). Among adults with hypertension in 2009 to 2010, 81.9% were aware of their hypertension, and 76.4% reported currently taking prescribed medication to lower their blood pressure (Fig. 48). There was no change from 2007 to 2008 in the awareness and treatment of hypertension (Fig. 48) (156).

Resistant hypertension, defined as blood pressure that remains above goal (>140/90 mm Hg) despite the concurrent use of 3 different classes of antihypertensive agents at optimal doses, including a diuretic) (155), is estimated to affect approximately 12% of the population according to analysis of National Health and Nutrition Examination Survey data between 2003 and 2006 (157). As the U.S. population ages and the incidence and prevalence of obesity rises, the prevalence of resistant hypertension is projected to increase to 15% to 30% (154,158).

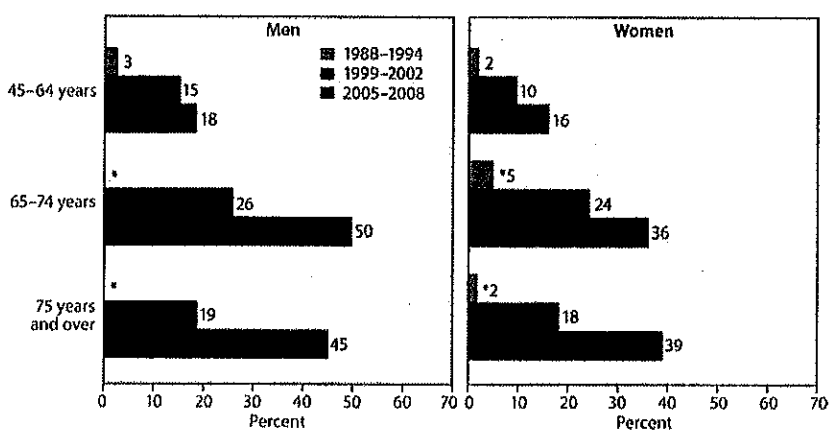


Figure 51 **Statin Drug Use in Past 30 Days Among Adults ≥45 Years of Age, by Sex and Age**

Statin drug use in the past 30 days among adults ≥45 years of age, by sex (men **[left panel]**; women **[right panel]**) and age, in United States, 1988 to 1994 **(gold bars)**, 1999 to 2002 **(teal bars)**, and 2005 to 2008 **(purple bars)**. *Estimates are considered unreliable. Source: National Center for Health Statistics (161).

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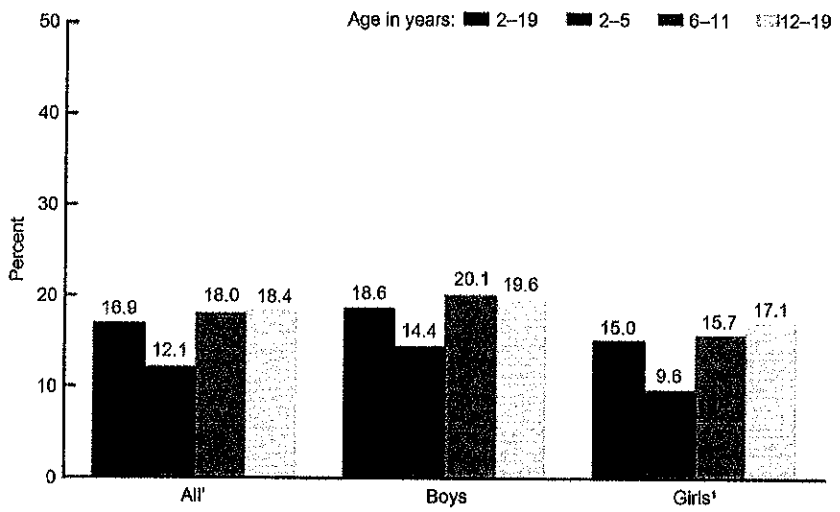

Figure 52 **Prevalence of Obesity Among Children and Adolescents Ages 2 to 19 Years, by Sex and Age: United States 2009 to 2010**

Dark blue bars = 2 to 19 years; **dark-medium blue bars** = 2 to 5; **medium-light blue bars** = 6 to 11; **light blue bars** = 12 to 19. Source: National Center for Health Statistics (161).

Renal denervation is a potentially important emerging option for managing resistant hypertension and is currently available in the European Union and Australia. The procedure utilizes a radiofrequency catheter that is inserted into the renal artery to disrupt the renal sympathetic nervous system. Medtronic has developed a Symplicity catheter system for this procedure and is the first company to receive FDA approval to study the technique in the United States. Catheter systems are also being developed by several other device companies and numerous studies of this therapy are in progress. As of August 2012, clinicaltrials.gov lists 45 studies on renal denervation: completed, 1; active, not recruiting, 9; recruiting, 31; and not yet recruiting, 4.

DYSLIPIDEMIA. There is a growing recognition that a target-based approach to lipids may not be the best strategy and is not strongly based on trial evidence. Not all drugs that reduce low-density lipoprotein (LDL) have been shown to reduce patient risk—and some have paradoxically increased risk. Moreover, no large trial tested a target strategy—they were trials of fixed doses of specific drugs. Also, the benefit of statins has generally been shown to be consistent across initial levels of LDL. As a result, some experts are advocating statins over a target that may be reached with a variety of drugs, including those that have not been shown to improve outcomes. Also, some experts are advocating a strategy to treat based on patient risk rather

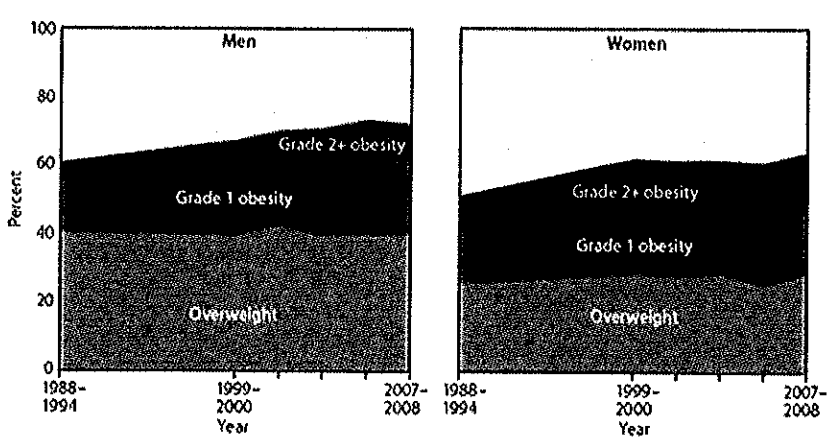

Figure 53 **Overweight and Obesity Among Adults ≥20 Years of Age, by Sex: United States, 1988 to 1994 Through 2007 to 2008**

(Left panel) Men. **(Right panel)** Women. Source: National Center for Health Statistics (161).

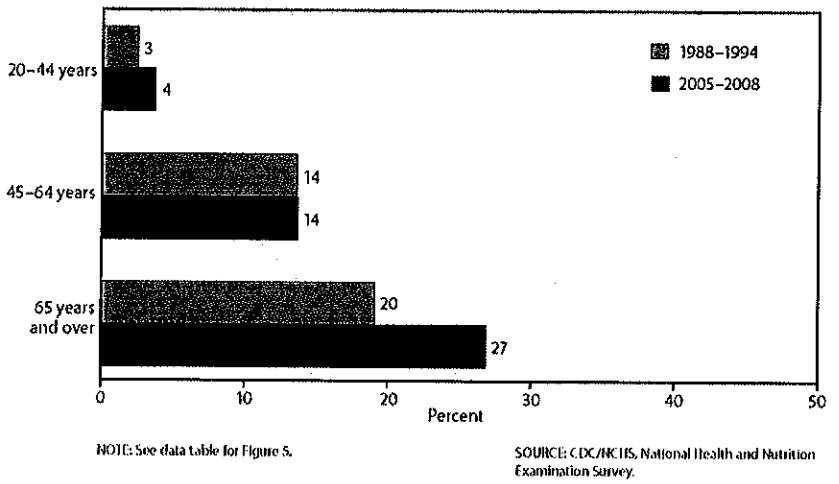

Figure 54 **Diabetes Prevalence Among Adults ≥20 Years of Age, by Age: United States, 1988 to 1994 and 2005 to 2008**

Gold bars = 1988 to 1994; **blue bars** = 2005 to 2008. Source: National Center for Health Statistics (161).

than lipid levels because the absolute benefit is predicated on the risk not the lipid level (159).

Lipid levels among U.S. adults are declining. Between 1999 and 2000, 18.3% of men and women had high total cholesterol count—defined as 240 mg/dl or higher. This dropped to 13.4% in 2009 to 2010 (displayed in Fig. 49). The U.S. Hispanic population is reported to have the highest percentage of adults (over 20 years of age) with high total cholesterol levels (Fig. 50) (160).

STATINS AND LDL CHOLESTEROL REDUCTION. There is substantial evidence supporting the use of statin therapy to reduce LDL cholesterol and subsequent risk of coronary heart disease. From 1988 to 1994 through to 2005 and 2008, the use of statin therapy in U.S. adults 45 years of age increased 12-fold, from 2% to 25% (Fig. 51). The documented decline in total cholesterol in the U.S. population is likely attributable to increased use of the statins at least in part (161). There is, however, disagreement on the use of statins for primary prevention of coronary heart disease for persons at high-risk but who show no symptoms (162,163).

The ACCORD (Action to Control Cardiovascular Risk in Diabetes) trial and the Fenofibrate Intervention and Event Lowering in Diabetes trial found that that fenofibrate did not reduce cardiovascular morbidity or mortality over that produced by a statin alone (164). However, the ACCORD trial and other previous research indicated there is potential benefit to men to include fibrate treatment for those with elevated triglycerides and low high-density lipoprotein (HDL) cholesterol after using statin therapy to reduce LDL

Cohort	1997–1998	1999–2000	2001–2002	2003–2004	Rate difference of cohort 2003–2004 vs. 1997–1998	*P* for trend	Multivariate HRR for cohort 2003–2004 vs. 1997–1998
CVD mortality							
DM (age-adjusted)	9.5 (7.8–11.3)	7.0 (5.7–8.3)	8.3 (6.4–10.3)	5.6 (4.5–6.7)†	−4.0 (−6.0 to −1.9)	0.001	0.60 (0.46–0.77)
No DM (age-adjusted)	3.7 (3.4–4.0)	3.3 (3.0–3.6)	3.2 (2.9–3.5)	3.3 (2.9–3.6)	−0.4 (−0.9 to 0.1)	0.07	0.89 (0.78–1.03)
Age-adjusted difference (DM vs. no DM)	5.8 (4.1–7.6)	3.7 (2.4–5.0)	5.1 (3.1–7.1)	2.3 (1.2–3.4)			
HRR (DM vs. no DM)	2.38 (2.97–3.89)	2.04 (1.68–2.47)	2.35 (1.87–2.96)	1.64 (1.32–2.06)			
All-cause mortality							
DM (age-adjusted)	20.3 (17.6–22.9)	17.9 (15.5–20.4)	21.1 (18.5–23.7)	15.1 (13.2–17.1)*	−5.2 (−8.5 to −1.8)	0.02	0.77 (0.65–0.90)
No DM (age-adjusted)	9.5 (9.0–10.0)	8.7 (8.2–9.2)	9.1 (8.5–9.6)	9.0 (8.5–9.6)	−0.5 (−1.3 to 0.3)	0.36	0.97 (0.89–1.05)
Age-adjusted difference (DM vs. no DM)	10.8 (8.1–13.4)	9.2 (6.8–11.7)	12.0 (9.4–14.7)	6.1 (4.0–8.2)			
HRR (DM vs. no DM)	1.94 (1.70–2.20)	1.86 (1.62–2.13)	2.02 (1.79–2.28)	1.54 (1.35–1.77)			
Cancer mortality							
DM (age-adjusted)	3.3 (2.4–4.2)	3.5 (2.6–4.4)	4.5 (2.9–6.1)	3.0 (2.2–3.8)	−0.3 (−1.5 to 0.9)	0.93	0.95 (0.66–1.37)
No DM (age-adjusted)	2.6 (2.4–2.9)	2.4 (2.1–2.7)	2.7 (2.3–3.0)	2.6 (2.4–2.9)	0.0 (−0.4 to 0.4)	0.58	1.03 (0.89–1.20)
Age-adjusted difference (DM vs. no DM)	0.7 (−0.3 to 1.6)	1.1 (0.2–2.0)	1.8 (0.2–3.4)	0.4 (−0.5 to 1.2)			
HRR (DM vs. no DM)‡	1.24 (0.94–1.65)	1.47 (1.11–2.96)	1.36 (1.04–1.78)	1.16 (0.86–1.57)			

Data are deaths per 1,000 person-years except where indicated as HRR (95% CI). DM, diabetes. *P value for test of heterogeneity across years, by diabetes status: <0.05. †P value for test of heterogeneity across years, by diabetes status: <0.01. ‡Age, sex, race/ethnicity, education (analyses across years, within diabetes status also controlled for diabetes duration).

Figure 55 **All-Cause and CVD-Related Mortality Rates (Deaths per 100,000 Person-Years), by Cohort and DM Status**

CVD = cardiovascular disease; CI = confidence interval; DM = diabetes mellitus; HRR = hazard rate ratio. Source: Gregg et al. (177).

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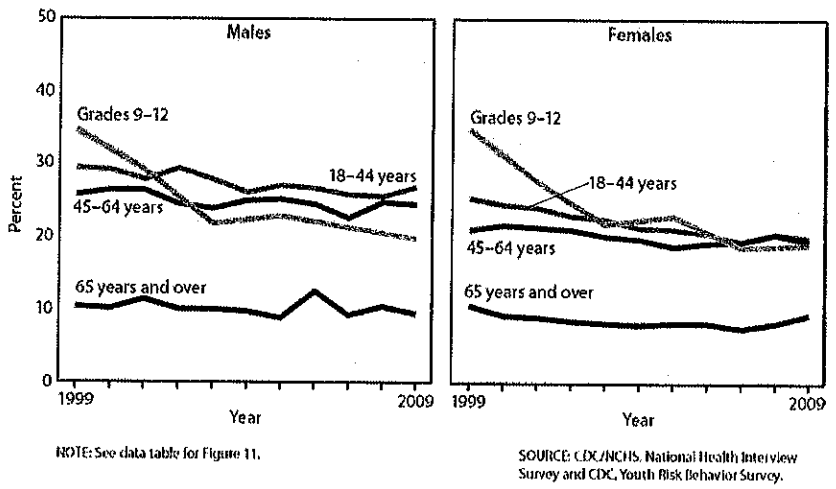


Figure 56 **Cigarette Smoking Among Students in Grades 9 to 12 and Adults ≥18 Years of Age, by Sex, Grade, and Age: United States, 1999 to 2009**

(Left panel) Males. **(Right panel)** Females. Source: National Center for Health Statistics (161).

cholesterol (165). Further efforts have been directed toward the development of drugs that raise HDL cholesterol, reducing LDL cholesterol at the same time.

The first version of cholesteryl ester transfer protein inhibitors, torcetrapib, proved to cause excess deaths. A new version, anacetrapib, has not be shown to increase the risk of cardiovascular events, and the drug was associated with a 138% rise in HDL cholesterol and a 40% drop in LDL in 1 clinical trial (166). Based on early data, some 30,000 patients were to receive anacetrapib starting in 2011 to test whether adding the drug to a statin further reduces morbidity and mortality (167). Another version of transfer protein inhibitors, dalcetrapib, was tested but in mid 2012 phase III clinical trials ended because it was not found to significantly increase HDL cholesterol and lower LDL cholesterol (168).

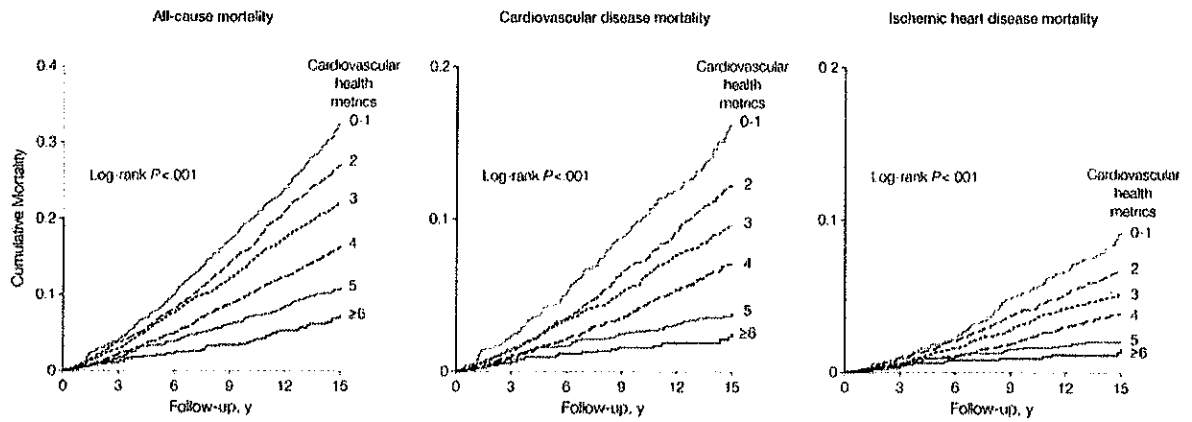
OBESITY. Obesity is usually defined by BMI, where persons with a BMI of ≥30 kg/m^2 are considered to be obese and those with a BMI >35 kg/m^2 are grade 2 obese (161). Excess body weight is associated with excess morbidity and mortality from CVD (169), and grade 2+ obesity significantly increases mortality risk (170). From 1999 to 2000 through 2009 to 2010, the prevalence of obesity increased from 13.8% to 15.0% among girls and from 14% to 18.6% among boys in the United States. Figure 52 displays the current prevalence by age group among adolescents.

Among women in the same time period, there was an increase in the prevalence of obesity (33.4% to 35.8%). In 1999, the prevalence of obesity in men was approximately 27.5%; 10 years later, that number had risen to 35.5%. In terms of numbers, this means 12.5 million children, 40.6 million women, and 37.5 million men were obese in 2009 to 2010 (171,172). Figure 53 displays obesity rates among men and women.

DIABETES MELLITUS. Approximately 8% of the population or 18.8 million people in the United States have been diagnosed with diabetes, the great majority of them with type 2 diabetes (173). Another 7 million people have undiagnosed diabetes, and some 79 million have pre-diabetes (174).

Type 2 diabetes is also affecting younger and younger people. It is now estimated that 215,000 children and adolescents under the age of 20 years have diabetes (174). The incidence of diabetes is also increasing in the United States, in parallel with increasing obesity rates (173). By 2050, the Centers for Disease Control and Prevention predict as many as 1 in 3 adults in the United States could have diabetes if current trends continue (175). Figure 54 depicts the increasing prevalence of type 2 diabetes among U.S. adults.

Approximately two-thirds of persons with diabetes die from heart disease or stroke (173). Those with diabetes also have triple the risk of stroke compared with persons who have normal blood sugar levels (176). However, as the death rates of CVD decreases for the general population, the proportion of CVD-related deaths among diabetic patients has decreased, as shown in Figure 55. According to Gregg et al. (177), among diabetic adults, the CVD death rate declined by 40%, and all-cause mortality declined by 23% between 1997 and 2006. There was no difference in the rates of decline in mortality between diabetic men and women. The excess CVD mortality rate associated with diabetes (i.e., compared with nondiabetic adults) decreased by 60% (from 5.8 to 2.3 CVD deaths per 1,000), whereas the excess all-cause mortality rate declined by 44% (from 10.8 to 6.1 deaths per 1,000) (177).



Y-axis segments shown in blue indicate range from 0 to 0.2. CVD indicates cardiovascular disease; IHD, ischemic heart disease; NHANES, National Health and Nutrition Examination Survey.

Figure 57 **Trends in CV Health Metrics and Associations With All-Cause and CVD Mortality Among U.S. Adults**

The Y-axis segments shown in **blue** indicate range from 0 to 0.2. Source: Yang Q et al. (187).

Careful glycemic control is currently considered the cornerstone of diabetes management, and research has shown that reaching and maintaining treatment goals can result in a decreased risk of diabetes-related complications, lower costs, and less healthcare utilization (174,178). The ADA and the Academy of Clinical Endocrinology/American Association of Clinical Endocrinologists have published specific glycemic goals for managing adult, nonpregnant patients with diabetes (174,179), which emphasize the importance of an individualized approach to the management of type 2 diabetes by selecting agents and regimens tailored to the unique needs of patients (178).

However, although there has been some recent improvement in the percentage of people with diabetes who have achieved treatment goals over the last few years (180), <50% of people with diabetes achieve the ADA's recommended hemoglobin A1c goal of <7.0% (176), and 67% do not achieve the American Association of Clinical Endocrinologists' A1c goal of ≤6.5% (181).

SMOKING. It is estimated that 40% of all heart disease is related to smoking (46). Smoking is also a major risk factor for stroke, approximately doubling the risk for ischemic stroke and increasing the risk of subarachnoid hemorrhage by twofold to fourfold (182). Smoking rates have been declining since the 1960s when the Surgeon General first warned of the health effects of cigarettes. In 1965, 41.7% of adults smoked; in 2010, that number had dropped to 19.3%. Figure 56 shows declining smoking rates across different age groups.

Table 18 **"ABCS" Indicators—Comparison of 2017 Million Hearts' Goals With 2011 PINNACLE Registry Data Submitting Practices**

Indicator	Definition	Baseline	2017 Goal	Comparable PINNACLE Measure*	SD
Aspirin	People with increased risk of CVD who take aspirin	47%	65%	83%	±15.3
Blood pressure	People with HTN who have controlled BP	46%	65%	69%	NA
Cholesterol	People diagnosed with high cholesterol who have it properly controlled	33%	65%	98%	±2.5
Smoking	Decrease population of smokers	19%	17%	41%	±34.9
Sodium intake	Decrease average sodium intake	3.5 g/day	20% reduction	NA	NA
Artificial transfat consumption	Decrease amount of artificial transfat consumption	1% of calories/day	50% reduction	NA	NA

*Total across all practices, year ending second quarter 2011. Source: American Heart Association. Million Hearts Campaign and the Role of the American Heart Association. Available at: http://www.telligenhitrec.org/c/document_library/get_file?uuid=d1ff5a8f-d86c-45e1-8cac-3616dcb39496&groupId=10309. Accessed June 2012.

ABCS = aspirin for people at risk, blood pressure control, cholesterol management, and smoking cessation; BP = blood pressure; CVD = cardiovascular disease; HTN = hypertension; NA = not available; PINNACLE = Practice Innovation And Clinical Excellence.

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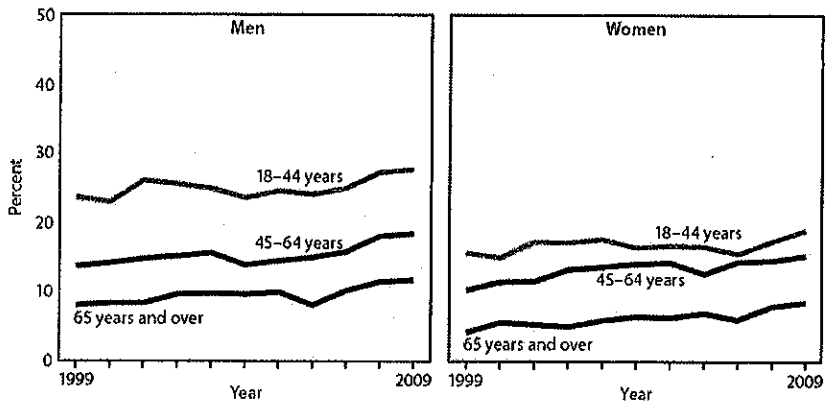
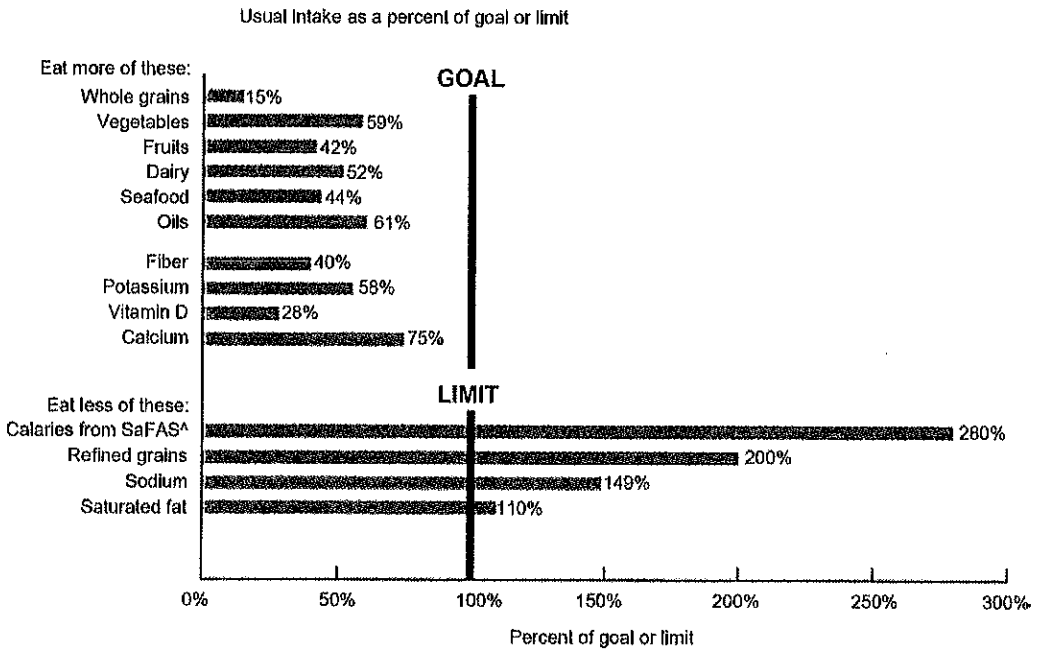


Figure 58 **Participation in Leisure-Time Aerobic and Muscle-Strengthening Activities Meeting 2008 Federal Physical Activity Guidelines for Adults ≥18 Years of Age, by Sex and Age: United States, 1999 to 2009**

(Left panel) Men. **(Right panel)** Women. Source: National Center for Health Statistics (161).

A 2008 study of patients hospitalized for coronary artery disease, heart failure, and nonvalvular atrial fibrillation (or any combination of the 3), reported that 10.6% were current smokers and 36.5% of them were former smokers (183). Another study found that approximately 13% of patients with coronary artery disease were current smokers (184). Smoking has also been shown to diminish the benefits of statins, worsen hypertension, and contribute to CVD morbidity and mortality (185).



^SoFAS-solid fats and added sugars.
Note Bars show average intakes for all individuals (ages 1 or 2 years or older, depending on the data source) as a percent of the recommended intake level or limit. Recommended intakes for food groups and limits for refined grains and solid fats and added sugars are based on amounts in the USDA 2000 calorie food pattern. Recommended intakes for fibre, potassium, vitamin D, and calcium are based on the highest AI or RDA for ages 14 to 70 years. Limits for sodium are based on the UL and for saturated fat on 10% of calories. The protein foods group is not shown here because, on average, intake is close to recommended levels.

Based on data from: U.S. Department of Agriculture, Agricultural Research Service and U.S. Department of Health and Human services, Centers for Disease Control and Prevention. What we eat in America, NHANES 2001-2004 or 2005-2006.

Figure 59 **How Do Typical American Diets Compare to Recommended Intake Levels or Limits?**

AI = adequate intake level; RDA = recommended daily allowance; SoFAS = solid fats and added sugars; UL = upper limit; USDA = U.S. Department of Agriculture.
Source: USDA. Choose My Plate: Guidelines. Available at: www.mypyramid.gov/guidelines/policydoc.pdf. Accessed June 2012.

Million Hearts Initiative. A significant public private campaign launched in 2011 targeting cardiovascular prevention is the Million Hearts Initiative, the goal of which is to prevent 1 million cardiovascular events over the next 5 years. Through improved management of the 4 "ABCS" indicators—aspirin for people at risk, blood pressure control, cholesterol management, and smoking cessation—the Million Hearts Initiative hopes to reduce the current annual heart attack and stroke rate by 10% (Table 18) (173).

The ACC is moving forward with its participation in the Million Hearts Initiative. The College has offered comments on the blood pressure control and lipid management measures. Concerns were raised that pushing all patients to the 140/90 mm Hg blood pressure target may put some at risk due to the potential for unintended consequences, and that the lipid management measure should not be based solely on a target LDL (<100 mg/dl) and may be too simplistic based on recent evidence.

To improve the measures, the ACC/AHA Task Force on Performance Measures has offered to commission 1 or more studies to compare the effectiveness of these different measures. If the ACC/AHA/Physician Consortium for Performance Improvement blood pressure and lipid measures are superior to the Healthcare Effectiveness Data and Information Set measures when used at the physician and practice levels, then it would be demonstrated with actual evidence of impact on clinical outcomes of interest at the population level (186).

IDEAL CVD HEALTH BEHAVIORS. The great majority of the population does not meet ideal cardiovascular health metrics, as defined by the AHA. These 7 behaviors or health metrics include not smoking; being physically active; having normal blood pressure, blood glucose levels, total cholesterol, and weight; and eating a healthy diet. According to the latest National Health and Nutrition Examination Survey, only 1.2% of a representative sample of 44,959 U.S. adults achieved all 7 health metrics, whereas only 8.8% of the same cohort achieved 6 or more (187).

For the select proportion of persons who did meet 6 or more of the AHA's health metrics, all-cause mortality was 51% lower than for persons who achieved 1 or fewer cardiovascular health metrics; and CVD mortality was 76% lower for the highest achievers versus the lowest achievers. Mortality from ischemic heart disease was 70% lower, again in favor of the highest health metric achievers versus the lowest.

These findings support prevention strategies aimed at improving CVD risk factors as a highly significant way in which to reduce morbidity and mortality caused by CVD (173). Figure 57 depicts the differences in morbidity and mortality according to the health metrics achieved.

INCREASE REGULAR PHYSICAL ACTIVITY. The AHA also defines "ideal" levels of physical activity as either ≥150 min/week of moderate intensity activity or ≥75 min/week of vigorous intensity activity or ≥150 min/week of moderate and vigorous activity combined (173).

On the same survey, 45.2% of the population achieved ideal levels of physical activity, whereas another 22.9% achieved AHA-defined levels of intermediate activity, namely, 1 to 149 min/week of moderately intense activity or the same amount of moderate and vigorous activity combined, or 1 to 74 min/week of vigorous activity. Some 31.9% of the population reported no levels of physical activity in 2010 (173). Figure 58 shows trends in physical activity across different age groups out to 2009.

The prevalence of physical activity has marginally increased among U.S. adults since the late 1980s (188), but the majority of adults are still not physically active enough to meet the guidelines for optimal health (187). Inadequate amounts of physical activity are widely acknowledged to be a major contributor to the rising rates of obesity in the United States (189).

HEALTHY DIETARY CHANGES CRITICAL. The AHA measures how healthy a person's diet is by assigning 1 point to each specific dietary component for a score of 0 to 5. Components include consumption of fruits and vegetables ≥4 cups a day; fish, ≥2 3.5-oz servings/week; fiber-rich whole grains ≥3 1-oz equivalent servings per day; sodium ≤1,500 mg/day, and sugar-sweetened beverages ≤36 oz/week. According to National Health and Nutrition Examination Survey data, 22.3% of the population had a healthy diet score of ≥2 components from 2005 to 2010, a 3.1% increase from 1999 to 2004 (187). Figure 59 shows how a typical American diet compared with recommended intake levels of various food components.

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Key Words: cardiology economic environment ▪ cardiology political environment ▪ cardiology practice trends ▪ cardiology social environment ▪ cardiology statistics.

APPENDIX

For a table on chronic cardiovascular conditions family of measures, please see the online version of this article.

APPENDIX 1h

8. Maroney, et al., Current Operator Volumes of Invasive Coronary Procedures in Medicare Patients: Implications for Future Manpower Needs in the Catheterization Laboratory, Catheterization and Cardiovascular Interventions, Volume 81, Issue 1 (2013).

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Current Operator Volumes of Invasive Coronary Procedures in Medicare Patients: Implications for Future Manpower Needs in the Catheterization Laboratory

Justin Maroney,[1] MD, Saba Khan,[1] MD, Wayne Powell,[2] MPS, and Lloyd W. Klein,[1*] MD, FSCAI

Objectives: We seek to assess the per-operator volume of diagnostic catheterizations and percutaneous coronary interventions (PCI) among US cardiologists, and its implication for future manpower needs in the catheterization laboratory. **Background:** The number of annual Medicare PCIs peaked in 2004 and has trended downward since, however the total number of catheterization laboratories nationwide has increased. It is unknown whether these trends have resulted in a dilution of per-operator volumes, and whether the current supply of interventional cardiologists is appropriate to meet future needs. **Methods:** We analyzed the Centers for Medicare and Medicaid Services 2008 Medicare 5% sample file, and extracted the total number of Medicare fee-for-service (Medicare FFS) diagnostic catheterizations and PCIs performed in 2008. We then determined per-physician procedure volumes using National Provider Identifier numbers. **Results:** There were 1,198,610 Medicare FFS diagnostic catheterizations performed by 11,029 diagnostic cardiologists, and there were 378,372 Medicare FFS PCIs performed by 6,443 interventional cardiologists in 2008. The data reveal a marked difference in the 2008 distribution of diagnostic catheterizations and PCIs among operators. Just over 10% of diagnostic catheterizations were performed by operators performing 40 or fewer Medicare FFS diagnostic catheterizations, contrasted with almost 30% of PCIs performed by operators with 40 of fewer Medicare FFS PCIs. A significant majority of interventional cardiologists (61%) performed 40 or fewer Medicare FFS PCIs in 2008. **Conclusions:** There is a high percentage of low-volume operators performing PCI, raising questions regarding annual volume recommendations for procedural skill maintenance, and the future manpower requirements in the catheterization laboratory. © 2012 Wiley Periodicals, Inc.

Key words: diagnostic cardiac catheterization; percutaneous coronary intervention; angiography—coronary angiography

INTRODUCTION

Over the past decade, progressive technical improvements have led to improved outcomes and expanded indications for both diagnostic catheterizations and percutaneous coronary intervention (PCI). A rational plan for the future of interventional cardiology [1] requires a firm comprehension of the number of invasive and interventional cardiologists currently practicing, accurately ascertaining the number of interventions currently being performed by these physicians, and then extrapolating how many procedures will be performed at a future date based on an assessment of population growth and advancement in the field.

According to the Agency for Healthcare Research and Quality (AHRQ), there were 1,475,602 inpatient diagnostic catheterizations and 693,315 inpatient PCI procedures performed in the United States in 2009 [2].

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Conflict of interest: One of the authors, Mr. Wayne Powell, is a staff member of the Society for Cardiovascular Angiography and Interventions in the Department of Advocacy and Guidelines. The authors have no other conflicts of interest or industry relationships to disclose.

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Most recently, data from the Centers for Medicare and Medicaid Services (CMS) has shown that yearly Medicare PCI volumes peaked in 2004 and have trended downward since [3]. The cause for this trend is likely multi-factorial, including cardiologists' response to the negative results of several recent clinical trials (COURAGE, OAT etc.) [4,5], as well as reduced rates of in-stent restenosis with the increasing usage of drug-eluting stents, and longer periods of dual antiplatelet drug therapy after PCI. Despite the downward trend in PCI volumes, the number of hospitals performing PCI has increased substantially, estimated to have increased from 1,223 in 2001 to 1,637 by 2008 [6]. The number of active invasive and interventional cardiologists in the United States is more difficult to ascertain with accuracy. According to the American Board of Internal Medicine there are currently 23,696 active board certified cardiologists, but there are no accurate estimates of how many perform PCI. There are 5,196 individuals with active interventional cardiology certificates and as many as an additional 1,000 individuals who have not recertified [7].

In this study, we use the CMS 2008 Medicare 5% sample file to estimate aggregate volumes and per-physician yearly averages of diagnostic cardiac catheterizations and PCIs among US cardiologists. We evaluate the 2008 volume distribution among practitioners and identify its implications regarding future manpower needs.

METHODS

To obtain accurate information for operator volume, this study analyzes the CMS procedure billing data from 2008 to report physician practice trends in diagnostic cardiac catheterization and PCI (both angioplasty and stenting). Data obtained from the CMS for the year 2008 through the Medicare utilization statistics data set, Part B (Medicare Standard Analytic Files) were analyzed. The Standard Analytic Files contain all inpatient, outpatient, skilled nursing, physician, and supplier claims for a 5% random sample of fee-for-service Medicare beneficiaries. Beneficiaries enter the sample on the basis of their beneficiary identification number and remain in the sample until they leave the Medicare program. The 2008 Medicare 5% sample data was summarized to show the count of all services and the count of interventional and diagnostic catheterizations. Using billed American Medical Association Current Procedural Terminology (CPT) codes from 2008, the total number of diagnostic catheterizations (CPT codes 93508–93529), and PCIs were compiled. PCI was broken down into stenting (CPT code 92980) and angioplasty (CPT code 92982) used as a primary treatment modality, not in combination with other therapies.

Diagnostic cardiac catheterization and PCI volume was summarized by National Provider Identifier (NPI), which uniquely identifies individual physicians. All providers and all billed procedures in the 2008 Medicare 5% sample were identified. All diagnostic catheterizations and PCIs were then identified per physician provider. The NPI summary was tabulated by the volume of procedures reported for each NPI using the CPT codes.

A skewed distribution was observed in the 2008 Medicare 5% sample file, and using the "binomial distribution," or "repeated Bernoulli trial," the original distribution of procedure volumes in the year 2008 was inferred. Using the statistical correction, the result is a parametric estimate of the distribution of actual procedure volumes in the universe of beneficiaries, based on what was observed in the 2008 Medicare 5% sample data. When necessary, a simple linear interpolation between exact percentiles to obtain data for round-number percentiles for display purposes was utilized. Estimated 2008 volumes are presented, which were calculated using a multiplicative factor of 20.

It should be noted that the absolute volumes reported include only Medicare fee-for-service (Medicare FFS) procedures. The data presented is the estimated total 2008 Medicare FFS volume based on the 5% sampling data. The results show the distribution of these Medicare FFS diagnostic catheterization and PCI services among physicians performing any Medicare FFS procedures.

Furthermore, the underlying claims only reflect Medicare FFS data, and we did not convert these numbers into an estimated total volume of diagnostic catheterizations and PCIs for all payers. To convert the Medicare FFS volume to total volume for all payer types, a multiplicative factor of 2 would be a reasonable approximation based on the 2009 AHRQ data, where Medicare accounted for an estimated 51.4% of all diagnostic catheterizations, and 51.3% of all PCIs, respectively [2]. In this analysis, this conversion is not utilized in the results section but is referred to in the discussion section. The resulting procedure volume distributions presented here, based on the Medicare FFS data only, should be a reasonable proxy for the distribution of all diagnostic catheterization and PCI services among physicians.

RESULTS

In 2008, there were 1,198,610 Medicare FFS diagnostic catheterizations performed by 11,029 diagnostic-only and/or dual-diagnostic and interventional cardiologists. There were 378,372 Medicare FFS PCIs performed by 6,443 interventional cardiologists. The mean 2008

Medicare FFS procedural volume per-operator was 109 diagnostic cardiac catheterizations and 59 PCIs, respectively (see Table I).

There was an uneven distribution of Medicare FFS diagnostic catheterizations and PCIs among cardiologists. For diagnostic catheterizations, 123,567 Medicare FFS procedures were performed by cardiologists whose total 2008 Medicare FFS diagnostic volume was 40 cases or fewer. Conversely, 187,741 Medicare FFS diagnostic catheterizations were performed by a very small group of high-volume cardiologists (359 total), each of whom performed >400 Medicare FFS procedures in 2008 (see Fig. 1).

Dividing diagnostic-only and/or dual-diagnostic and interventional cardiologists into three categories based on Medicare FFS procedural volume for 2008 (those performing 40 or fewer, 41–200, and >200 Medicare FFS diagnostic procedures in 2008), there were 4,009 cardiologists who performed 40 or fewer Medicare FFS diagnostic catheterizations in 2008. This cohort represents 36.3% of all diagnostic-only and/or dual-diagnostic and interventional cardiologists, and their aggregate volume represents 10.3% of the total Medicare FFS diagnostic catheterizations performed in 2008. There were 1,449 cardiologists who performed >200 Medicare FFS diagnostic catheterizations, representing 41.6% of the total Medicare FFS diagnostic procedures performed in 2008 (see Table II).

For PCI, 112,679 Medicare FFS procedures were performed by interventional cardiologists whose total 2008 Medicare FFS interventional volume was 40 cases or fewer. Conversely, 3,911 Medicare FFS PCIs were performed by a very small group of high-volume interventional cardiologists (nine total), each of whom performed >400 Medicare FFS PCIs in 2008 (see Fig. 2).

Dividing interventional cardiologists into three categories based on Medicare FFS procedural volume for 2008 (those performing 40 or fewer, 41–200, and >200 Medicare FFS PCIs in 2008), there were 3,929 interventional cardiologists who performed 40 or fewer Medicare FFS PCIs in 2008. This cohort represents 61.0% of all interventional cardiologists, and their aggregate volume represents 29.8% of the total Medicare FFS PCI procedures performed in 2008. There were 185 interventional cardiologists who performed >200 Medicare FFS PCIs, representing 13.8% of the total Medicare FFS PCI procedures performed in 2008 (see Table III). The low-volume cohort (interventional cardiologists performing 40 or fewer Medicare FFS PCIs in 2008) per-physician Medicare FFS procedure average is 29, whereas the

TABLE I. 2008 Medicare fee-for-service Diagnostic Catheterization and PCI[a] Data

	Diagnostic catheterizations	PCI
Total procedure volume	1,198,610	378,372
Total cardiologists performing procedures	11,029	6,443
Average procedure volume per cardiologist	109	59

[a]PCI, percutaneous coronary intervention.

TABLE II. 2008 Medicare fee-for-service Diagnostic Catheterizations by Physician Procedure Volume Cohort

Diagnostic catheterization volume	Physicians in cohort	% Total	Aggregate diagnostic catheterizations performed by cohort	% Total	Cohort average volume
1–40	4,009	36.3	123,567	10.3	31
41–200	5,571	50.5	576,145	48.1	103
>200	1,449	13.1	498,898	41.6	344
	11,029		1,198,610		

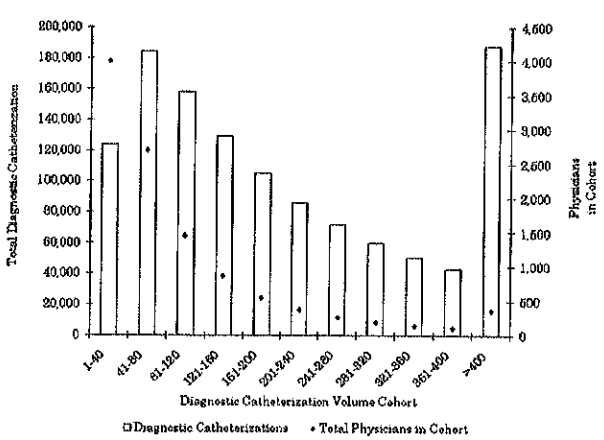

Fig. 1. Total Medicare fee-for-service diagnostic catheterizations by 2008 physician volume cohort.

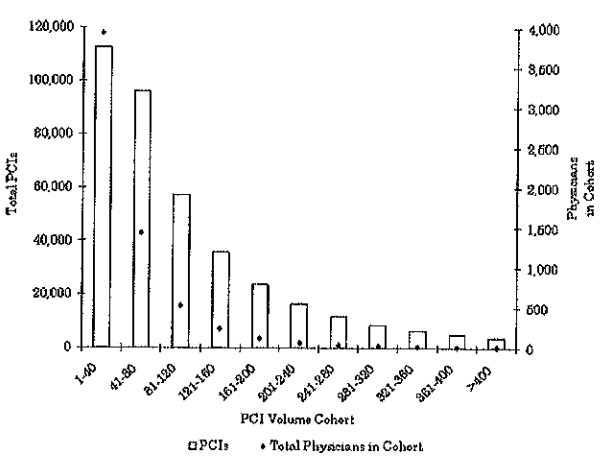

Fig. 2. Total Medicare fee-for-service PCI by 2008 physician volume cohort.

TABLE III. 2008 Medicare fee-for-service PCI[a] by Physician Procedure Volume Cohort

PCI volume	Physicians in cohort	% Total	Aggregate PCI performed by cohort	% Total	Cohort average volume
1–40	3,929	61.0	112,679	29.8	29
41–200	2,329	36.1	213,345	56.4	92
>200	185	2.9	52,348	13.8	283
	6,443		378,372		

[a]PCI, percutaneous coronary intervention.

mid- and high-volume cohorts averaged 92 and 283 Medicare FFS PCI procedures in 2008, respectively (see Table III). This "skew" in the distribution of procedure volume is substantial, and the distribution is clearly not a Normal or Gaussian distribution. Consequently, calculation of an overall average per-physician procedure volume is highly misleading. This explains why even though 61% of all physicians performed 40 or fewer Medicare FFS PCIs in 2008, the calculated average procedure volume for all physicians is 59 (see Table I).

DISCUSSION

In the United States over the last decade, the general direction of invasive procedures has been toward fewer procedures and revascularizations per capita [6]. In contrast, the supply of interventional cardiologists has increased over this same time frame, with significant implications for the manpower requirements in the field over the coming decade. In this study, we report the number of interventional cardiologists performing Medicare FFS procedures was 6,443 in 2008. Based on self-reported numbers from the last workforce assessment from ACC, the number of cardiologists performing PCI may be closer to 8,000–9,000 [8].

Current ACC/AHA/SCAI guidelines suggest that interventional cardiologists perform 75 or more PCIs yearly to maintain their procedural proficiency. With 693,315 inpatient PCIs performed in the US in 2009, the ACC/AHA/SCAI guidelines imply an upper bound for the optimal total number of practicing interventional cardiologists nationwide of 9,244. This crude estimate assumes a uniform distribution of procedures across interventional cardiologists, ignoring real-world dynamics like variations in operator volume relating to individual practice structure, population density, and the presence (or absence) of regional referral centers for advanced cardiac care. The skew in the distribution of volume per operator seen in the 2008 CMS data clearly demonstrates that anticipating future manpower needs is far more complex than a simple calculation of this type.

The 2008 Medicare FFS data for diagnostic catheterizations and PCIs presented here, when segregated by yearly operator volume, reveals a marked difference in the distribution of the two respective procedures among operators. Just over 10% of diagnostic catheterizations were performed by operators with 40 or fewer Medicare FFS diagnostic catheterizations in 2008, contrasted with almost 30% of PCIs performed by operators with 40 of fewer Medicare FFS PCIs that same year. Indeed, a significant majority of interventional cardiologists (61%) performed 40 or fewer Medicare FFS PCIs in 2008, compared to only 36.3% of diagnostic-only and/or dual-diagnostic and interventional cardiologists performing 40 or fewer Medicare FFS diagnostic catheterizations. Given the correlation between higher operator volume and improved patient outcomes, this data raises questions regarding whether the current distribution of PCIs across interventional cardiologists is rational [9].

The percentage of interventional cardiologists performing 40 or fewer Medicare FFS PCIs in 2008 may reflect the increasing number of facilities offering PCI nationwide, the expanding geographic coverage of PCI capability, and the increasing necessity to staff catheterization laboratories with 24 hour-per-day, 7 day-per-week coverage to meet guideline door-to-balloon times. From a heuristic standpoint, "24/7" catheterization laboratory staffing requires approximately five operators per laboratory. With 1,637 laboratories operating nationwide in 2008, simple arithmetic suggests that 8,185 interventional cardiologists would be an appropriate "equilibrium" level, independent of individual physician yearly volume. With acute myocardial infarction representing a growing percentage of PCI volume, it should be expected that increasing geographic coverage for PCI capability will necessarily dilute operator volumes as the procedure follows a natural migration from population-dense, high-volume centers into lower population-density exurban and rural communities.

There are a number of limitations to the data analysis presented. The data presented captures only Medicare FFS diagnostic catheterizations and PCIs performed in 2008. This excludes the entire universe of non-Medicare procedures. While Medicare patients accounted for roughly 51.3% of total PCIs performed based on the 2009 AHRQ data, we cannot be certain that simply "grossing up" the yearly Medicare FFS volume by a factor of 2 for each of the cohorts listed in Tables II and III represent an accurate estimate of total yearly volumes [2]. In addition, the data presented represents a nationwide estimate of procedure volumes. Any conclusions regarding per-operator volumes would result in an over-estimate of "true" per-operator volumes in states with older average populations

(e.g., Florida), and an under-estimate in younger states (e.g., Colorado). Similarly, areas with differing rates of Medicare patients in the Medicare FFS program (as opposed to managed care) also skews the data.

Furthermore, with regard to the PCI data, fewer PCIs performed does not necessarily correlate with fewer advanced interventional procedures performed. The Medicare FFS data presented captures only coronary interventions, it does not include procedures where the use of intravascular ultrasound or fractional flow reserve technologies result in foregoing an intervention. Nor does it include transcatheter valvular procedures, percutaneous closure device placements, or peripheral interventions such as lower extremity or carotid artery percutaneous interventions. As the role of the interventional cardiologist evolves to include more non-coronary interventions it will be appropriate to include these procedures as part of their total annual volumes [1].

Finally, the data presented reflects the most recently available CMS Medicare 5% sample file, that for 2008. We are unable to present year-over-year procedure volume trends since CMS releases the Medicare 5% sample file data only periodically, with the next most recent 5% sample dating back to 2005.

The 2008 Medicare FFS data reveals a significant difference in the distribution of diagnostic catheterizations versus PCIs across physicians, with lower-volume operators representing over 60% of the universe of interventional cardiologists, versus lower-volume diagnostic-only and/or dual-diagnostic and interventional cardiologists representing just over 36% of the diagnostic universe. This analysis, however, only scratches the surface of current diagnostic and PCI volumes nationwide, and the implications for future manpower needs in the catheterization laboratory. Recent reports suggest that as the obesity epidemic increases, there will be a 30% increase in the number of coronary artery disease diagnoses, many of whom will require invasive and interventional procedures [10]. This data suggests that the number of interventional cardiologists currently being trained is adequate to meet that challenge, as long as the per-physician procedure distribution narrows. If the current variation in per-physician procedure distribution continues, or even widens, then many more interventional cardiologists will need to be trained, with many of those not performing an acceptable minimum of cases.

The main problem identified by this analysis is that the per-physician volume distribution of PCI, based on the 2008 Medicare FFS data, is concerning because there is a very high percentage of low-volume operators. Certainly this finding raises questions in connection with the necessary operator volume for technical and cognitive skill maintenance. Moreover, the fact that the incidence of coronary artery disease is likely to increase will offset some of the recent trends in regard to the volume and appropriateness of invasive procedures. A key factor in determining the overall manpower requirements for PCI in the future is whether or not the per-physician procedure distribution observed in this study, with its skew toward low-volume operators, will persist or normalize. The data presented suggests that clinical cardiologists who perform limited numbers of diagnostic and interventional procedures may have an increasingly difficult time maintaining their skills. The skew in the 2008 Medicare FFS PCI per-physician procedure volume distribution suggests that many interventional and invasive cardiologists in the US do not currently meet the minimum criteria traditionally set by the AHA/ACC/SCAI guidelines [11]. Notably, the most recent quality statements of the SCAI suggest moving away from a minimum volume criterion [12].

This study highlights the need for better data aggregation and surveillance regarding the total number of catheterization laboratories operating nationwide, the total number of physicians staffing these laboratories, the demographics, population density, and geographic areas they serve, and the clinical scenarios under which both diagnostic catheterizations and PCI are performed, to more accurately predict future manpower needs in the catheterization laboratory.

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APPENDIX 1i

9. Riley, et al., Trends in Coronary Revascularization in the United States from 2001 to 2009: Recent Declines in Percutaneous Coronary Intervention Volumes, Circulation: Cardiovascular Quality and Outcomes, Vol. 4, Issue 2 (2011).

Trends in Coronary Revascularization in the United States From 2001 to 2009

Recent Declines in Percutaneous Coronary Intervention Volumes

Robert F. Riley, MD; Creighton W. Don, MD, PhD; Wayne Powell, MPS; Charles Maynard, PhD; Larry S. Dean, MD

Background—There is speculation that the volume of percutaneous coronary interventions (PCIs) has been decreasing over the past several years. Published studies of PCI volume have evaluated regional or hospital trends, but few have captured national data. This study describes the use of coronary angiography and revascularization methods in Medicare patients from 2001 to 2009.

Methods and Results—This retrospective study used data from the Centers for Medicare & Medicaid Services from 2001 to 2009. The annual number of coronary angiograms, PCI, intravascular ultrasound, fractional flow reserve, and coronary artery bypass graft (CABG) surgery procedures were determined from billing data and adjusted for the number of Medicare recipients. From 2001 to 2009, the average year-to-year increase for PCI was 1.3% per 1000 beneficiaries, whereas the mean annual decrease for CABG surgery was 5%. However, the increase in PCI volume occurred primarily from 2001 to 2004, as there was a mean annual rate of decline of 2.5% from 2004 to 2009; similar trends were seen with diagnostic angiography. The use of intravascular ultrasound and fractional flow reserve steadily increased over time.

Conclusions—This study confirms recent speculation that PCI volume has begun to decrease. Although rates of CABG have waned for several decades, all forms of coronary revascularization have been declining since 2004. (***Circ Cardiovasc Qual Outcomes*. 2011;4:193-197.**)

Key Words: angiography ■ catheterization ■ epidemiology ■ angioplasty ■ revascularization

Since the development of coronary angioplasty >3 decades ago, there have been several studies that have cited both an increase in percutaneous coronary intervention (PCI) and a decrease in coronary artery bypass graft (CABG) surgery volumes in the treatment of coronary artery disease within the United States and abroad.[1–10] There has been speculation that the volume of PCIs has started to decline recently, however, in light of the increasing use of drug-eluting stents (DES), advances in medical therapy, and the publication of data from the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial demonstrating that coronary revascularization does not reduce the risk of major cardiovascular events over and above optimal medical therapy in patients with stable angina.[11,12] We analyzed Centers for Medicaid & Medicare Services procedure billing data from 2001 to 2009 to report trends in cardiac catheterizations (diagnostic and interventional), use of PCI (angioplasty and stents), CABG surgeries, and the use of intravascular ultrasound (IVUS) and fractional flow reserve (FFR) during angiography.

Methods

This retrospective study used data from the Centers for Medicare & Medicaid Services from 2001 to 2009 through the Medicare utilization statistics data set, Part B. Using billed American Medical Association *Current Procedural Terminology* (CPT) codes from that period, the total number of diagnostic catheterizations (CPT codes 93508 to 93529), PCIs, and CABG (CPT codes 33510 to 33536) surgeries were compiled. PCI was broken down into angioplasty (CPT codes 92982 and 92984; used as a primary treatment modality, not in combination with other therapies) and stenting (both single [CPT code 92980] and multivessel [CPT code 92981] stenting). Diagnostic catheterizations were defined as procedures in which only coronary angiography was performed; the angiographic component of PCI procedures was not included in this number. Diagnostic catheterization and PCI rates for a given year were then combined into a category called "total catheterizations." The total CABG and PCI rates for a given year comprised the category "total coronary revascularizations."

For reimbursement purposes, Medicare recognizes 3 coronary arteries: right coronary, left circumflex coronary, and left anterior descending coronary. In multivessel PCI, it is possible that a physician may report up to 3 percutaneous interventions if an intervention is performed in each of the 3 coronary arteries or their branches. The first reported procedure must use a primary

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code (CPT codes 92980 and 92982) corresponding to the most complex procedure performed. The procedures performed in the other 1 or 2 coronary arteries (including their branches) are reported with the CPT add-on codes (CPT codes 92981 and 92984). Therefore, multivessel PCI, as per Medicare billing guidelines, was defined as intervention in a vessel different from the vessel in which an initial stent was placed, billed separately and in addition to the initial vessel that received intervention. This definition differentiated multivessel stenting from both single-vessel stenting and multiple stents being placed within a single vessel (which was billed as single-vessel stenting).

WHAT IS KNOWN

- In prior decades, diagnostic and interventional coronary catheterization rates have increased, whereas there has been a concurrent decrease in coronary artery bypass graft (CABG) surgery rates in the United States.
- Several factors, such as the publication of the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial, may have influenced rates of diagnostic and interventional coronary catheterization in recent years.

WHAT THE STUDY ADDS

- Diagnostic and interventional coronary catheterization rates within the Medicare population have steadily declined since 2004.
- Rates of intravascular ultrasound and fractional flow reserve use per catheterization have steadily been increasing within the Medicare population over the past several years.
- Given the declines in both CABG surgery and percutaneous coronary intervention since 2004, the use of percutaneous coronary intervention does not appear to entirely explain recent declines in CABG surgery rates.

The total number of annual fee-for-service Medicare beneficiaries during this period was gathered from the Annual Reports of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds during this period. Using these numbers as denominators, each procedure was reported per 1000 Medicare beneficiaries for each given year to account for annual changes in this population. Similar data on the use of IVUS (CPT codes 92978 and 92979) and FFR (CPT codes 93571 and 93572) during angiography also was collected on the basis of billing codes. Notably, data on IVUS use during 2004 was not available because Medicare only released data for high-volume procedures for that year; thus, IVUS did not qualify. Because this research used a limited data set with deidentified information, the University of Washington Institutional Review Board waived the formal application for approval to perform human subject research for this project.

Results

The total number of coronary procedures billed each year between 2001 and 2009 in the Medicare population are shown in the Table; procedures per 1000 Medicare beneficiaries are shown in Figure 1. The year-to-year percent change in procedures per 1000 beneficiaries is shown in Figure 2. Although the overall number of diagnostic catheterizations per 1000 Medicare beneficiaries increased by only 0.8% in 2009 compared to 2001, the year-to-year trends clearly demonstrate a marked increase in the number of catheterizations from 2001 to 2004, with an average increase of 5.1% per year per 1000 patients, followed by a mean decrease of 2.7% per year between 2004 and 2009 (Table).

From 2001 to 2009, the use of PCI with stenting increased from 10.2 to 12.4 per 1000 beneficiaries. Similar to the temporal trend seen with diagnostic catheterizations between 2001 and 2004, the mean year-to-year change in coronary stenting increased 11.3% per year per 1000 patients, but from 2004 to 2009, there was a mean annual decrease of 2.4% (Figure 2). PCI using balloon angioplasty alone decreased steadily between 2002 and 2005 and remained at roughly 1 per 1000 beneficiaries for the remainder of the period (Figure 1). Overall, the average annual increase in PCI (stenting and angioplasty alone) per 1000 beneficiaries was 1.3% over the 9-year period. The increase in volume primarily was seen between 2001 and 2004, whereas a mean annual rate of decline of 2.5% was seen between 2004 and 2009 (Figure 2).

The use of coronary angiography and PCIs increased annually from 2001 and peaked in 2004, whereas there were notable percentage decreases in 2005 and 2007. In 2009, the number of diagnostic catheterizations and PCI procedures increased slightly compared to 2008, but were still well below the 2004 levels. In contrast, CABG procedures declined consistently from 2001 to 2008 by ≈4% to 7% per year followed by a slight increase in CABG procedures per beneficiary in 2009. The ratio of PCI to CABG procedures performed increased steadily from 1.05 in 2001 to 1.72 in 2009, demonstrating that the rate of decline in CABG was greater than PCI over the entire period. The number of multivessel stenting procedures remained relatively constant over time at ≈12% of PCIs using stents (Table).

IVUS and FFR use per catheterization during this time period are shown in Figure 3. Data within the Medicare population was available starting in 2003 for IVUS and in 2005 for FFR. Total IVUS procedures doubled from 0.77 in 2003 to 1.53 per 1000 beneficiaries in 2009. FFR was used less frequently than IVUS during this time, but increased from 0.22 to 0.41 per 1000 beneficiaries (Table), with the percentage of catheterizations using FFR increasing by 101% from 2005 to 2009 (Figure 3).

Discussion

The most recent epidemiological data from 2007 showed that the overall death rate from cardiovascular disease in the United States was 204.3 per 100 000 persons, making it the leading cause of death in both men and women.[13] However, the age-adjusted death rate for coronary heart disease has been steadily decreasing since the 1980s, likely as a result of improved risk factor modification and cardiovascular therapies.[14] The trends in coronary catheterization volumes observed in our study from 2001 to 2004 are consistent with previous reports that showed steady increases in PCI volumes during that period.[15] Our data also show that the total and per-beneficiary numbers of diagnostic and interventional catheterizations in the Medicare population have been decreasing steadily since 2004. Although there was stabilization

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Table. Total Coronary Diagnostic and Treatment Procedures Billed in the Medicare Population From 2001 to 2009

	2001	2002	2003	2004	2005	2006	2007	2008	2009
Diagnostic catheterizations	1 075 623	1 180 899	1 201 590	1 315 515	1 193 200	1 166 972	1 063 429	1 040 274	1 047 945
PCI using angioplasty	57 114	59 830	54 659	36 972	28 564	27 492	28 134	27 790	28 100
PCI using stents	275 037	309 829	346 711	399 558	383 888	379 280	322 884	319 567	322 034
Multivessel stenting	32 034	36 915	39 952	47 320	49 738	50 088	38 128	37 609	38 053
Total PCIs	332 151	369 659	401 370	436 530	412 452	406 772	351 018	347 357	350 134
Total catheterizations	1 407 774	1 550 558	1 602 960	1 752 045	1 605 652	1 573 744	1 414 447	1 387 631	1 398 079
CABG surgeries	316 951	311 096	305 240	283 818	262 396	240 252	218 594	199 358	203 025
Total coronary revascularizations	649 102	680 755	706 610	720 348	674 848	647 024	569 612	546 715	553 159
IVUS	N/A	N/A	21 746	N/A	30 781	35 251	35 532	40 368	40 767
FFR	N/A	N/A	N/A	N/A	6 176	7 930	8 572	10 606	10 811
Fee-for-service population	26 959 000	27 686 000	28 232 000	28 440 000	28 443 000	27 614 000	26 933 000	26 319 000	26 064 000

in the number of catheterizations in 2009, the overall trend from 2004 to 2009 remained in decline, with the total number of coronary revascularizations (PCI and CABG combined) declining over the 9-year period studied. The rate of decline in CABG surgeries continued to outpace that of the decline in PCI.

There are numerous possible explanations about why coronary catheterization rates have started to decline over the past several years. One explanation might be increased treatment of atherosclerotic risk factors over the past decade. It has been previously estimated that 44% of the reduction in US deaths due to coronary heart disease from 1980 to 2000 was due to risk factor modification.[14] The Centers for Disease Control and Prevention recently published a report that showed that the prevalence of smoking among US adults decreased by 3.5% from 1998 to 2008.[16] There also are data showing that an increasing percentage of the US population is achieving target blood pressure and cholesterol goals.[17,18] The Medical Expenditure Panel Survey published a report in 2008 that showed nearly a doubling in statin prescriptions from 2000 to 2005 (89.7 versus 173.7 million) in the US population.[19] There is also evidence for increasing prescriptions for β-blockers among patients with known coronary artery disease.[20]

Another possible explanation for these trends could be the increasing use of DES during this period. After their initial approval by the US Food and Drug Administration in 2003, DES were used in as many as 90% of all PCIs in the United States by 2006.[21] In a similar Medicare population, it was reported that the use of bare-metal stents in PCI decreased from 89% in 2001 to 19% in 2004. Similarly, the use of DES increased to 75% of all stents placed in this population in 2008. Concurrently, significant reductions were found in the need for repeat revascularization in this population over that period.[15] The reduction of in-stent restenosis from the use of DES could have led to fewer repeat angiograms and repeat revascularization procedures. On the other hand, the concerns for increased stent thrombosis of DES in the latter part of this period also may have contributed to the decrease in PCI seen after 2004.[22]

Additionally, it is possible that more patients with stable angina are being primarily medically managed or evaluated with noninvasive imaging before diagnostic catheterization or

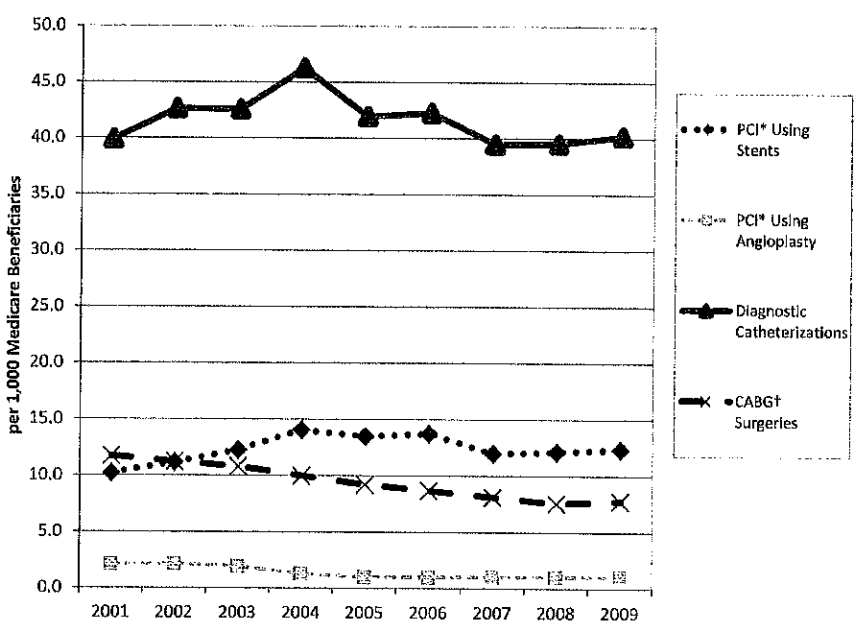

Figure 1. Trends in total coronary procedures per 1000 Medicare beneficiaries from 2001 to 2009.

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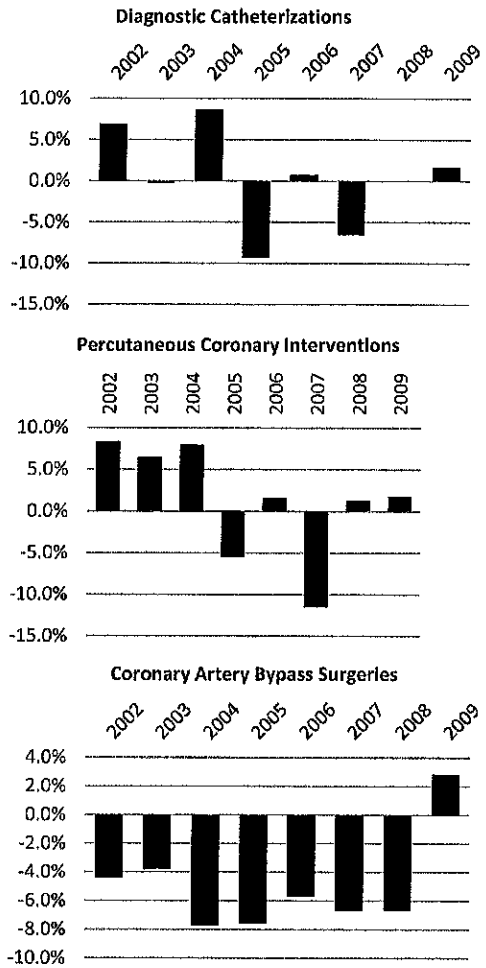

Figure 2. Year-to-year percent change in coronary procedures per 1000 Medicare beneficiaries.

coronary revascularization. In a recent single-center study, patients referred for angiography following publication of the COURAGE trial were more often treated with aggressive disease-modifying agents before referral for catheterization than were pre-COURAGE patients. In the same study, it also was noted that patients with stable angina and significant coronary artery disease on angiography were more likely to receive medical therapy rather than revascularization as

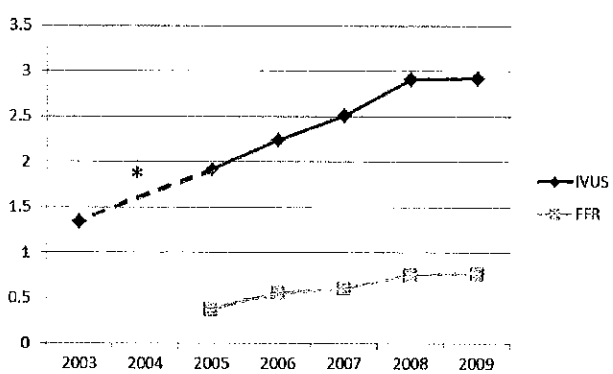

Figure 3. Percentage of total catheterizations in which IVUS and FFR were used in the Medicare population from 2003 to 2009. *2004 data were not available for IVUS.

initial treatment management post-COURAGE.[20] An increased use of primary medical management along with an increasing use of noninvasive coronary imaging[23] likely have contributed to decreasing catheterization and revascularization rates, although the COURAGE trial itself would not explain our results because it was not published until 2007.

During the same period in which PCI rates have been decreasing, the rates of IVUS and FFR use per catheterization have been steadily increasing within the Medicare population. This increased use could be related to the increased complexity of coronary artery disease being managed percutaneously. Conversely, the increased hemodynamic assessment of coronary lesions using FFR and anatomic assessment using IVUS could have contributed to the decrease in PCI. However, these changes in procedure volume were comparatively small, and their contribution to the overall changes in revascularization volumes was likely trivial.

There are several limitations to our study. First, patient-level data, the indication for each type of procedure, procedure priority (emergent versus nonemergent), and stent type (bare metal versus drug eluting) were not available for our study population, making it difficult to evaluate the contribution of these factors on the observed trends. Another limitation, inherent to studies based on physician billing codes, is that we were unable to account for the contribution of improper billing on our results. Underbilling due to accidental physician omission or overbilling for multivessel PCI (eg, billing for multivessel PCI when stenting the left anterior descending coronary artery plus a diagonal artery, which should be billed as single-vessel PCI) are 2 such examples. Finally, the older population within Medicare may not reflect the patient population of the United States as whole because trends in the use of diagnostic and interventional cardiac procedures may differ between older and younger patients. Nevertheless, Medicare is the largest insurance carrier in the United States and is likely representative of national trends.[15]

In summary, the use of diagnostic and interventional coronary catheterizations within the Medicare population has been steadily declining since 2004. Although there was some stabilization of these trends in 2009, they are reminiscent of the decline in CABG rates that started in the late 1980s, which was initially attributed to the expanding use of PCI. Given the declines in both CABG and PCI since 2004, the use of PCI does not appear to entirely explain the decline in CABG rates. Potentially, the decline in CABG surgery volume was simply the canary in the coal mine that signaled larger-scale reductions in the need for coronary revascularization as risk factor modification and cardiovascular therapeutics continue to improve.

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Disclosures

None.

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Trends in Coronary Revascularization in the United States From 2001 to 2009: Recent Declines in Percutaneous Coronary Intervention Volumes

Robert F. Riley, Creighton W. Don, Wayne Powell, Charles Maynard and Larry S. Dean

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APPENDIX 1j

10. Concannon, et al., Comparative Effectiveness of ST-Segment-Elevation Myocardial Infarction Regionalization Strategies, Circulation: Cardiovascular Quality and Outcomes, Vol. 3, Issue 5 (2010).

Comparative Effectiveness of ST-Segment–Elevation Myocardial Infarction Regionalization Strategies

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Background—Primary percutaneous coronary intervention (PCI) is more effective on average than fibrinolytic therapy in the treatment of ST-segment–elevation myocardial infarction. Yet, most US hospitals are not equipped for PCI, and fibrinolytic therapy is still widely used. This study evaluated the comparative effectiveness of ST-segment–elevation myocardial infarction regionalization strategies to increase the use of PCI against standard emergency transport and care.

Methods and Results—We estimated incremental treatment costs and quality-adjusted life expectancies of 2000 patients with ST-segment–elevation myocardial infarction who received PCI or fibrinolytic therapy in simulations of emergency care in a regional hospital system. To increase access to PCI across the system, we compared a base case strategy with 12 hospital-based strategies of building new PCI laboratories or extending the hours of existing laboratories and 1 emergency medical services–based strategy of transporting all patients with ST-segment–elevation myocardial infarction to existing PCI-capable hospitals. The base case resulted in 609 (95% CI, 569–647) patients getting PCI. Hospital-based strategies increased the number of patients receiving PCI, the costs of care, and quality-adjusted life years saved and were cost-effective under a variety of conditions. An emergency medical services–based strategy of transporting every patient to an existing PCI facility was less costly and more effective than all hospital expansion options.

Conclusion—Our results suggest that new construction and staffing of PCI laboratories may not be warranted if an emergency medical services strategy is both available and feasible. (***Circ Cardiovasc Qual Outcomes*. 2010;3:506-513.**)

Key Words: cost-benefit analysis ■ fibrinolysis ■ percutaneous coronary intervention ■ ST-segment–elevation myocardial infarction ■ thrombolysis

For patients with ST-segment–elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI), if administered in a timely manner, is better than fibrinolytic therapy (FT) at reducing mortality.[1–3] However, PCI is available only at hospitals with cardiac catheterization laboratories, and FT remains the standard of care in the majority of US hospitals.[4] One recent study indicates that 80% of the US population lives within a 1-hour drive of a PCI facility, but empirical estimates suggest that far fewer than 80% of eligible patients with STEMI actually receive PCI.[5,6]

Editorial see p 441

To increase access to PCI, there is considerable interest in regional planning for the procedure,[7,8] but few opportunities are available to evaluate regionalization strategies in head-to-head comparisons. In the present study, we used our recently developed triage and allocation model[9] to compare the incremental benefits and costs of 2 approaches for increasing patient access to PCI: (1) hospital-based strategies, in which new PCI capacity is added to a region through hospital laboratory construction and staffing, and (2) an emergency medical service (EMS)–based strategy, in which patients with STEMI are transported by EMS to existing PCI-capable hospitals.

Methods

To estimate the costs and effectiveness of alternative strategies for increasing access to PCI, we compared a strategy of standard emergency resources and transport procedures (the base case) with 13 scenarios in which hospital PCI capability was expanded (the hospital-based strategies) and 1 scenario in which EMS was used to transport all patients with suspected STEMI to an existing PCI-capable hospital (the EMS strategy). The strategies and scenarios are presented in Table 1. The base case (A) assumed that EMS providers transport patients to the closest hospital, regardless of which reperfusion method is available at the time of arrival. This scenario assumed no new PCI laboratory construction and no new staffing of existing PCI laboratories. In the base case, 2 hospitals were capable of performing PCI full time, 12 were capable of doing so part-time

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WHAT IS KNOWN

- For patients with STEMI, PCI is better than FT, but PCI is available only at a minority of US hospitals. Detection of patients with STEMI in the EMS system setting and diversion to PCI-capable hospitals have been shown to be both safe and effective.

WHAT THE STUDY ADDS

- This article estimates the comparative benefits and costs of building new PCI capability at US hospitals versus diverting patients with STEMI to existing PCI-capable hospitals. In EMS systems wherein STEMI detection and diversion are feasible, such a strategy may be more effective and less costly than construction and staffing of new hospital PCI capability. Construction and staffing of new PCI hospitals may not be warranted if an EMS strategy is both available and feasible.

(Monday through Friday, 7 AM to 5 PM), and 2 were capable of providing FT only. In scenario B, a high-volume hospital that was capable of providing FT only was selected for PCI expansion. This hospital built and staffed a part-time PCI laboratory and operated it Monday through Friday, 7 AM to 5 PM. In this scenario, we assumed that back-up coronary artery bypass graft (CABG) surgery could be provided off-site, saving the cost of building and staffing a new suite dedicated to the procedure. In scenario C, we added a CABG suite to the costs in scenario B. All new construction scenarios were tested both with and without a new on-site CABG suite (D and E, G and H, I and J, K and L, M and N). One scenario (F) involved only an increase in staffing hours at 2 existing PCI-capable hospitals, and therefore, construction of a new PCI laboratory and CABG suite were not necessary. The EMS strategy (O) involved EMS transport of patients with suspected STEMI to existing PCI-capable hospitals. In this scenario, we used the regional configuration of hospital PCI capability that existed in scenario A.

We simulated EMS transport, reperfusion strategy, clinical outcomes, and costs for 2000 patients, representing ≈1 year of STEMIs in a municipal area the size of Dallas County, Texas. We bootstrapped the simulation 500 times and estimated the bootstrap mean and confidence intervals at the 2.5 and 97.5 percentiles.

Patients

Patient data were sampled from the Atlantic Cardiovascular Patient Outcomes Research Team Trial.[10] The Atlantic Cardiovascular Patient Outcomes Research Team Trial was a randomized, controlled trial of 451 patients with STEMI conducted from July 1996 through June 1999 that compared PCI and FT at 11 community-based hospitals in Maryland and Massachusetts. Clinical data needed for the mortality predictive model were available for 408 of the 451 subjects recruited into the Atlantic Cardiovascular Patient Outcomes Research Team Trial. All hospital-, EMS-, and patient-level variables were used in or computed from a model of Dallas County that was built by using ArcGIS version 9.1 (Environmental Systems Research Institute, Redlands, Calif). The model is described further in a previous work.[9]

Outcomes

We used the PCI–Thrombolytic Predictive Instrument to predict 30-day mortality for each patient.[11,12] For individual patients, the PCI–Thrombolytic Predictive Instrument trades off the incremental mortality benefit of PCI over FT with delays to treatment. Rates of post MI stroke, congestive heart failure, and reinfarction at 30 days

Table 1. STEMI Regionalization Strategies

		Hospital Capabilities		
Scenario	Strategy	Full-Time PCI Hospitals	Part-Time PCI Hospitals	FT-Only Hospitals
Base case				
A	No new construction or staffing	2	12	2
Hospital strategies				
B	One new part-time lab*	2	13	1
C	One new part-time lab and CABG suite	2	13	1
D	One new full-time lab†	3	12	1
E	One new full-time lab and CABG suite	3	12	1
F	Night and weekend staffing for 2 part-time labs	4	10	2
G	Night and weekend staffing for 2 part-time labs and one new part-time lab	4	11	1
H	Night and weekend staffing for two part-time labs and 1 new part-time lab and CABG suite	4	11	1
I	Night and weekend staffing for 2 part-time labs and 1 new full-time lab	5	10	1
J	Night and weekend staffing for 2 part-time labs and 1 new full-time lab and CABG suite	5	10	1
K	Night and weekend staffing for 2 part-time labs and 2 new part-time labs	4	12	0
L	Night and weekend staffing for 2 part-time labs and 2 new part-time labs and CABG suites	4	12	0
M	Night and weekend staffing for 2 part-time labs and 2 new full-time labs	6	10	0
N	Night and weekend staffing for 2 part-time labs and 2 new full-time labs an CABG suites	6	10	0
EMS strategy				
O	No new construction or staffing: EMS transports only to PCI-capable hospitals	2	12	2

*Staffed Monday through Friday 7 AM to 5 PM.
†Staffed 24 hours/day, 7 days/week.

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Table 2. Follow-Up Events, Quality of Life Estimates, and Event Rates

Event	Quality of Life (Lower)	Quality of Life (Upper)	Event Rates (PCI)	Event Rates (FT)
Mortality				
In-hospital			0.04[13]	0.063[13]
4–6 weeks			0.05[1]	0.07[1]
6–18 months			≈0.095[1]	≈0.135[1]
Nonfatal reinfarction	0.73[14]	0.91[14]		
In-hospital			0.025[13]	0.064[13]
4–6 weeks			0.03[1]	0.07[1]
6–18 months			≈0.05[1]	≈0.1[1]
Total stroke	0.60[15]	0.85[16]		
In-hospital			0.0022[13]	0.0145[13]
4–6 weeks			0.01[1]	0.02[1]
6–18 months			0.022[10]	0.04[10]
Rescue PCI				
In-hospital			0.133[17]	0.63[17]
4–6 weeks			0.19[10]	0.49[10]
6 months			0.236[10]	0.496[10]
CABG				
In-hospital			0.082[17]	0.12[17]
4–6 weeks			0.124[10]	0.186[10]
6 months			Flat	Flat
CHF	0.63[18]	0.85[19]		
In-hospital			Flat	0.18[20]
4–6 weeks			0.152[21]	Flat
6 months			Flat	Flat

CHF indicates congestive heart failure. Other abbreviations are as defined in text. Superscripted numbers refer to References in text.

and 6 months were taken from the outcomes literature (Table 2[1,10,13–21]). Survival for each additional year was stochastically estimated from rates published in 2007 National Center for Health Statistics age- and sex-adjusted actuarial tables. We assumed a small additional mortality risk due to MI up to 5 years after the initial event, an approach that has been shown in previous work[22] to calibrate well with 5-year survival rates after STEMI.[23] In our main analysis, we added a 0.005 risk of mortality for patients treated with PCI and a 0.015 risk for patients treated with FT. In a sensitivity analysis, we added a 0.01 risk to both groups to explore how results would change if longer-term mortality were equal in the 2 treatment groups.

For every year survived, we adjusted for reduced quality of life from complications related to the index event or to the mode of reperfusion. Utility estimates for stroke, congestive heart failure, and reinfarction were drawn from the Cost Effectiveness Analysis Registry[24] (Table 2). We used high and low estimates from a search of the registry to estimate the upper and lower bounds for each utility measure. We assumed the higher bound in our main analysis and the lower bound in a sensitivity analysis. Future years were discounted at 3% per year in our main analysis and at 5% in sensitivity analyses.

Our main analysis thus assumed unequal risk of death in the 2 treatment groups at year 1 after the index event, a high quality of life after complications, and a 3% discount for future years. In sensitivity analyses, we changed these assumptions individually and simultaneously to account for uncertainty surrounding survival, quality of life, and discounting.

Costs

We updated a previously developed framework for hospital operations and costs[25] to 2008 US dollars by using the National Income and Product Accounts GDP deflator.[26] We assumed that newly purchased laboratory equipment and facilities would be in use for 10 years.

In randomized, controlled trials comparing PCI and FT, the initial costs of PCI have been higher typically, but additional complication and procedure rates in the FT arm have been found to yield similar cumulative costs.[27–29] Two studies from the mid-1990s drew different conclusions: 1 that used registry data found lower costs in the FT group[30] and another that used administrative data found lower costs in the PCI group.[31] Our base case assumed equal costs for PCI and FT over the lifetime of patients. In each successive scenario, we added costs when new construction, staffing, in-hospital CABG back-up, or diverted transport was needed. SAS version 9.1 (SAS Institute, Cary, NC) was used for all statistical analyses.

Results

Table 3 shows the number of new PCI patients, total costs, quality-adjusted life-years (QALYs) saved, and cost per QALY for each of the 14 scenarios. In the base case (A), 609 (95% CI, 569 to 647) primary PCI procedures, representing 30.4% of all patients with STEMI, were performed annually in 14 hospitals. Roughly 250 of these were performed during weekdays at a time when elective procedures would otherwise be scheduled. With 14 PCI laboratories operating on 260 weekdays per year, we assumed that the demand for elective PCI was already being met and that no additional elective procedures would be performed as a result of new capacity. In this context, new construction and staffing costs could not be defrayed with elective procedures.

The costs and effectiveness of each successive scenario (B through O) were compared with the base case (A). An additional 82 patients had access to PCI after construction of a new part-time laboratory in a hospital seeing >200 patients with STEMI annually (B). This scenario resulted in nearly $4.8 million additional costs in 10 years, and the additional 82 PCI procedures performed during this period saved 157.4 QALYs. The cost per QALY saved was $30 399, well below the costs of other accepted life-saving therapies. When that same hospital built a new laboratory and staffed it full time (D), an additional 272 PCI treatments could be performed in a year, and the cost per QALY saved dropped to $14 765. If a new program of on-site CABG back-up was needed for this new laboratory, costs increased to $85 032 per QALY saved in the part-time scenario (C) and to $31 021 in the full-time scenario (E). Building a new laboratory was most cost-effective if it could be opened full time and if a new on-site CABG back-up program was unnecessary (D). Costs per QALY saved are graphed for each scenario in the Figure.

Expansion of PCI capability in the 2 highest-volume hospitals that already had a part-time PCI laboratory in place (F) resulted in 304 additional procedures and 605.2 QALYs saved at a cost of $10 000 per QALY saved. This expansion, involving only the additional costs of night and weekend on-call staff, was the most cost-effective of hospital-based scenarios. We explored a series of combinations involving new laboratory construction and expansion of part-time PCI laboratories to full-time hours (G through N). When compared with the base case, each scenario cost <$100 000 per QALY saved.

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Table 3. Cost-Effectiveness of Strategies to Increase Access to PCI

Scenario	Strategy	PCI Patients, N=2000, % (SD)	New PCI Patients, n	Costs in 2008 Dollars, 1000s	QALYs Saved (95% CI)	Cost per QALY (95% CI)
Base case						
A	No new construction or staffing	30.4 (1.0)				
EMS strategy						
O	No new construction or staffing: EMS transports only to PCI-capable hospitals	100 (0.0)	1391	1391	2749.8 (2678.4–2936.6)	506 (474–519)
Hospital strategies						
F	Night and weekend staffing for 2 part-time labs	45.6 (1.1)	304	6052	605.2 (550.8–788.8)	10 000 (7673–10 988)
I	Night and weekend staffing for 2 part-time labs and 1 new full-time lab	59.2 (1.1)	576	13 863	1125.6 (1109.4–1210.6)	12 316 (11 451–12 496)
G	Night and weekend staffing for 2 part-time labs and 1 new part-time lab	49.7 (1.1)	385	10 837	754.0 (719.2–877.0)	14 373 (12 357–15 068)
D	One new full-time lab	44.0 (1.1)	272	7811	529.0 (544.8–650.2)	14 765 (12 013–14 337)
M	Night and weekend staffing for 2 part-time labs and 2 new full-time labs	61.3 (1.1)	617	21 674	1247.0 (1147.2–1356.0)	17 381 (15 984–18 893)
K	Night and weekend staffing for 2 part-time labs and 2 new part-time labs	50.3 (1.1)	398	15 622	788.6 (803.0–1039.0)	19 810 (15 035–19 454)
J	Night and weekend staffing for 2 part-time labs and 1 new full-time lab and CABG suite	59.2 (1.1)	576	22 462	1125.6 (1109.4–1210.6	19 956 (18 555–20 247)
H	Night and weekend staffing for 2 part-time labs and 1 new part-time lab and CABG suite	49.7 (1.1)	385	19 436	754.0 (719.2–877.0)	25 778 (22 162–27 025)
B	One new part-time lab	34.5 (1.0)	82	4785	157.4 (37.2–302.8)	30 399 (15 802–128 623)
E	One new full-time lab and CABG suite	44.0 (1.1)	272	16 410	529.0 (544.8–650.2)	31 021 (25 239–30 122)
N	Night and weekend staffing for 2 part-time labs and 2 new full-time labs and CABG suites	61.3 (1.1)	617	38 873	1247.0 (1147.2–1356.0	31 173 (28 667–33 885)
L	Night and weekend staffing for 2 part-time labs and 2 new part-time labs and CABG suites	50.3 (1.1)	398	32 820	788.6 (803.0–1039.0)	41 619 (31 588–40 872)
C	One new part-time lab and CABG suite	34.5 (1.0)	82	13 384	157.4 (37.2–302.8)	85 032 (44 201–359 787)

Incremental cost-effectiveness ratios are presented in the last column, measured as the cost in 2008 dollars per QALY saved. Strategies are presented in order from least to most cost-effective. Results assume that the risk of death is unequal for the 2 treatment groups through 5 years after treatment; an upper bound for health-related quality of life if survival with STEMI is followed by stroke, congestive heart failure, or reinfarction; and future years discounted at 3%.

Finally, we estimated the incremental costs and effectiveness of 1 EMS strategy for increasing access to PCI (O). In this scenario, EMS personnel identified patients with STEMI before hospital arrival and transported directly to PCI-capable hospitals. Because our previous work on EMS triage strategies for PCI[9] showed that this approach achieved the largest reduction in short-term mortality, we selected direct transport as the EMS strategy of interest for the present study. A strategy of interhospital transfer performed almost as well in our previous work and is of interest for our future work. For the present study, we assumed that the EMS transport strategy would cost an additional $1000 per diverted patient.

In 2000 patients, this strategy resulted in 1391 diversions at a cost of nearly $1.4 million and a cost per QALY saved of $506. Because it was less costly and more effective than any of the hospital-based strategies, we considered the EMS strategy to be dominant. It would no longer be the most cost-effective strategy if the average cost per diverted patient rose to more than $19 769 (a 20-fold increase). Alternatively, it would no longer be the most cost effective strategy if the most favorable hospital-based scenario (F) cost <$306 231 (a 20-fold decrease).

We assumed 100% adherence to each tested strategy, including the assumption that all patients called 911 for emergency assistance. This assumption could lead to an overestimate of benefit for the EMS strategy in an actual regional emergency system, wherein nearly half of all patients with STEMI arrive at the hospital by transportation other than EMS.[32] Evidence suggests that patients who arrive by EMS are older, at higher risk, and more likely to benefit from PCI than are those who arrive by other means.[32] To test the sensitivity of our results to 100% adherence, we iteratively reduced the EMS strategy's total benefit by the average benefit per diverted patient until the strategy was no longer more effective than the next most effective hospital strategy. This method would indicate how many walk-ins would be

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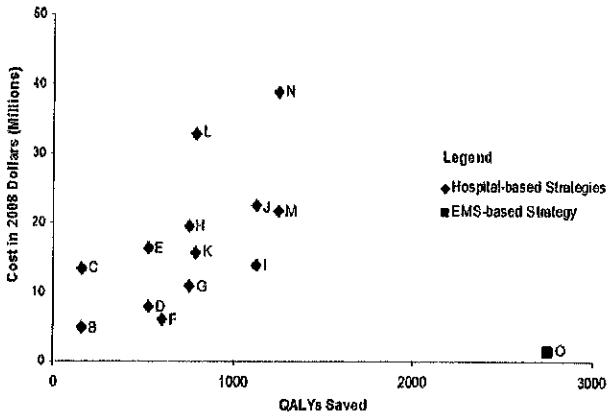

Figure. STEMI regionalization strategies: cost per QALY. QALYs saved are presented on the *x* axis, and cost in 2008 dollars, on the *y* axis. The base strategy is positioned at (0,0). Hospital strategies (B–N) are depicted with a diamond. The EMS strategy (O) is depicted with a square.

needed until the EMS strategy was no longer dominant. In the EMS strategy (O), 1391 patients were diverted, producing a total benefit of 2749.8 QALYs, or an average benefit of 1.98 QALYs per diverted patient. The next most beneficial strategy (M) produced 1247.0 QALYs. To fall below this level of benefit, 762 of 1391 diversions (55%) would have to be replaced by walk-ins. The EMS strategy would therefore continue to be more effective and less costly than the next best hospital strategy if at least 45% of all patients with STEMI were to call 911 for assistance. Below that number, the EMS strategy would continue to be more cost-effective but would not dominate hospital strategies. This calculation is conservative if patients who are more likely to benefit from PCI are more likely to call 911, as the evidence suggests they are.

Conclusions

To increase access to PCI in our model of a large urban, suburban, and rural region, an EMS strategy of transporting all patients to existing PCI-capable hospitals was more effective and less costly than 13 hospital-based strategies of new construction and staffing. Whereas hospital strategies were cost-effective under a variety of conditions, the EMS strategy dominated in all of the scenarios that we tested and in multivariate sensitivity analyses. Our results strongly suggest that construction and staffing of new PCI hospitals may not be warranted if an EMS strategy is both available and feasible. Demonstration programs have shown that EMS detection and diversion of patients with STEMI for delayed PCI are both safe and effective.[33,34] Our results suggest that, in EMS systems where STEMI detection and diversion are feasible, such a strategy is more effective and less costly than hospital-based regionalization alternatives. This finding persisted even when the estimated new cost of an EMS strategy was multiplied by a factor of nearly 20 or when its expected benefits were decreased by 55% or more.

Expansion of access to timely PCI is widely considered to be critical for improving outcomes after STEMI. To accomplish this goal, a range of regionalization approaches have been reviewed or evaluated in the research literature.[35–39] To understand the potential of STEMI regionalization strategies in their full context, however, it is critical that the benefits, risks, and costs of all hospital and EMS strategies be compared in head-to-head match-ups. Although the preferred method to compare such strategies might be a randomized effectiveness trial,[39] such an approach would not likely be feasible, given the large numbers needed to measure rare outcomes after heart attack, as well as the ethical problem of randomizing patients to receive FT when timely PCI is known to be superior.

In this context, the use of mathematical modeling to compare predicted outcomes from PCI expansion strategies is a promising approach. The model we used combined empirical data from clinical, health systems, and geographic sources with clinical predictive instruments to perform head-to-head comparisons of regionalization strategies. Our model for estimating outcomes was sensitive to the number of new PCI treatments resulting from an expansion strategy and therefore, to the regional population's baseline rate of access to PCI. In our model of Dallas County, we estimated a baseline access rate of 30.4%. Two aspects of our model explain why our baseline rate was 50 percentage points lower than a recent national estimate indicating that 80% of the population lives within a 1-hour drive of a PCI-capable hospital.[4] First, patients in our base case were transported to the closest hospital even when PCI was available within a 1-hour drive. Second, the 80% estimate assumes that hospitals with a PCI laboratory operate the laboratory 24 hours per day, 7 days per week. Of the 16 hospitals in our model of a large county, 14 had a PCI laboratory but only 2 operated the laboratory full time. In the base case, we operated the part-time PCI laboratories from Monday through Friday, 7 AM to 5 PM. Two classic articles on the circadian and weekly patterns of heart attack onset estimate that ≈39% begin during these weekday hours.[40,41] We used these estimates to stochastically estimate STEMI onset day and time. In our model, therefore, ≈61% of patients with STEMI onset in locations served by a part-time laboratory received immediate FT in the local hospital or delayed PCI after transport to a more-distant, full-time laboratory. We believe that our method of accounting for the part-time operation of PCI laboratories is reflective of actual operations in a region that has not yet introduced regionalization measures. Assuming full-time operation at all hospitals would have led to a significant overestimate of the true baseline access rate.

Nevertheless, in regions with a higher baseline rate of access to primary PCI, we would expect that an EMS strategy would fare better and the hospital strategies would fare worse than in our model. In a hospital strategy, the high fixed costs of construction can be defrayed only by increasing the number of patients with newly created access to PCI. In an EMS strategy, new costs are substantially lower and vary with the number of new transports that are needed. This relatively low variable cost is the primary advantage of an EMS strategy. A second advantage was explored in our previous work: the opportunity to select for transport to existing PCI hospitals only those patients who are predicted to benefit most from PCI. We did not exploit this opportunity in the present study; we transported every patient with

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suspected STEMI directly to a PCI-capable hospital regardless of predicted benefit. The EMS strategy dominated hospital strategies on the basis of its low variable costs and its potential to reach every patient with STEMI, but we believe an even stronger case could be made for a strategy that involves selective transport of only those patients who are individually predicted to benefit from delayed PCI.

Public policy remains unsettled on the optimal strategy to increase access to PCI. In some states, certificate-of-need laws are used to control the widespread diffusion of high cost and volume-sensitive procedures such as PCI. In 2008, these laws existed in 36 states, but only 23 had provisions for cardiac catheterization services review.[42] From 2001 through 2006, American Hospital Association data show a steady increase of 50 to 125 new hospitals with PCI capability in the United States each year, in both urban and rural areas.[43,44] There is substantial contradictory activity in the public arena that is aimed both at curtailing and at sustaining the diffusion of PCI laboratories. We believe our approach to comparing alternative strategies can help clarify the impact of such decisions.

For several reasons, Dallas County represents an ideal place to test our model. First, Dallas has a diversity of urban, suburban, and rural areas. The majority of census tracts in Dallas County are designated as urban (comprising 69.7% of the county's dry land area), but a substantial portion of the county is suburban and rural. Second, there is significant variation in PCI capability at hospitals inside the county. Our model showed that just 30.4% of the county's population lived closest to a PCI-capable hospital, leaving room for growth in the availability of PCI. Third, Dallas is bordered to the north, east, and south by sparsely populated areas and to the west by Dallas–Fort Worth Airport, creating natural and manmade barriers to EMS transport outside the county's borders. These factors allowed us to test the EMS strategy inside a diverse yet nearly closed emergency system.

Although Dallas County offered an excellent choice for the first test of our model, large and less densely populated regions are of great interest for further testing. In rural areas where access to PCI is lowest, the need for further study is especially urgent. Empirical evidence suggests that new hospital PCI capability results in modest new access to PCI.[45] To answer the question about what works best in urban, suburban, and rural counties, head-to-head comparisons of all available strategies are needed. Our triage and allocation model can help planners and policy makers decide on the approach that best fits the specific features of a county or region.

Our main finding, that an EMS strategy is more effective and less costly than any hospital strategy, was based on the estimated societal impact of alternative regional planning strategies in the care of patients with STEMI. The implications for individual hospitals are less clear. However, if it were recast to take in the hospital perspective, our model could help to inform the business case for regional planning. This would lend a great deal of clarity to discussion about the implications of our main finding.

In some circumstances, we recognize that a hospital strategy may be warranted even when it is dominated by an EMS strategy. First, resource constraints may preclude EMS strategies from being considered. Ambulance staff must be able to identify patients with STEMI accurately, the vehicles must be equipped with electrocardiograms, and EMS-hospital handoff should be organized to prenotify receiving hospitals. Second, hospital expansion may be particularly important in some suburban and rural settings, where the risks of exceptionally lengthy drive times to PCI hospitals can be prohibitive. Third, hospital strategies may be acceptable or desirable if the geographic distribution of PCI hospitals is inequitable and hospital expansion could lead to outcome improvements for a presently underserved population.

Our study has limitations. First, there are limitations inherent to simulations, insofar that they incorporate empirical data from multiple sources and resort to assumptions where empirical data are unavailable. Our simulation was no different in this regard. However, we conducted a wide range of multivariate sensitivity analyses, and the results were robust to all potential changes. Perhaps the strongest assumptions made concerned the costs of EMS transport and hospital laboratory construction, which were estimated from a study of new construction and staffing at US hospitals from the mid-1990s. We chose this model because it allowed us to compare a range of hospital costs in discrete categories and thus to compare 13 alternative hospital strategies with each other and with the EMS strategy. We updated the cost model by using the most reliable index for inflation of medical care and construction costs, the National Income Products Account GDP deflator. In a sensitivity analysis, our main finding was robust to changes in baseline costs by a factor of nearly 20 across the board. A second important assumption included adherence to the tested strategies. We assumed that 100% of patients use 911, an assumption that would lead to overestimates of benefit in the EMS strategy in locales where hospital walk-ins occur at a high rate. In a post hoc sensitivity analysis, our findings were robust until 55% or more of patients arrived at the hospital by means other than EMS. A third important set of assumptions included the utility weights for quality adjustment. In sensitivity analyses, we used high and low estimates from a search of the Cost Effectiveness Analysis Registry to estimate the upper and lower bounds for each utility measure in our model. Quality adjustment had minor effects on the ordering of preferred hospital strategies but did not change the main result, showing that the EMS strategy was both more effective and less costly than all hospital strategies.

A second limitation was that we conducted the study in a single county. We selected Dallas County for its size, diversity, and composition of urban, suburban, and rural districts, but the primary advantage of this setting was its self-contained emergency system. Further research is planned in a broadly representative sample of US counties.

In summary, while expansion of hospital PCI capability can be cost-effective for improving quality-adjusted survival after STEMI, a strategy of EMS transport to existing PCI-capable hospitals was dominant in a regional hospital system with 30% baseline access to PCI. Further inquiry is needed into the relation of regional health system characteristics and optimal strategies for increasing access to PCI, and we have

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begun a 5-year research project funded by the Agency for Healthcare Research and Quality to explore these relations. Our results suggest that regional planners should consider EMS strategies for increasing access to PCI before adopting strategies involving new construction or increased staffing of PCI hospitals.

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Disclosures

None.

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Comparative Effectiveness of ST-Segment–Elevation Myocardial Infarction Regionalization Strategies

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APPENDIX 1k

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PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

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Preamble

The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, up-

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dating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force (1). The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the Class III recommendations to delineate if the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another have been added for COR I and IIa, LOE A or B only.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term *guideline-directed medical therapy (GDMT)* to represent optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I). This new term, GDMT, will be used herein and throughout all future guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and be involved in shared decision making whenever feasible, particularly for COR IIa and IIb, where the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing committee. All writing committee members and peer reviewers of the guideline are required to disclose all such current relationships, as well as those existing 12 months previously. In December 2009, the ACCF and AHA implemented a new policy for relationships with industry and other entities (RWI) that requires the writing committee chair plus a minimum of 50% of the writing committee to have no *relevant* RWI (Appendix 1 for the ACCF/AHA definition of relevance). These statements

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Table 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT				
	CLASS III *Benefit >> Risk* Procedure/Treatment SHOULD NOT be performed/administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED		
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective ■ Consistent evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses		
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective ■ Single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies		
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective ■ Only opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care		
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/administered/other is not useful/beneficial/effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/administered/other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B			

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. †For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee and are updated as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members are not permitted to write, and must recuse themselves from voting on, any recommendation or section to which their RWI apply. Members who recused themselves from voting are indicated in the list of writing committee members, and section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI) without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a

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focus on summary and evidence tables (with references linked to abstracts in PubMed), and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011 the Institute of Medicine released 2 reports: *Finding What Works in Health Care: Standards for Systematic Reviews and Clinical Practice Guidelines We Can Trust* (2,3). It is noteworthy that the ACCF/AHA guidelines are cited as being compliant with many of the proposed standards. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Alice K. Jacobs, MD, FACC, FAHA
Chair, ACCF/AHA Task Force on Practice Guidelines

1. Introduction

1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. An extensive evidence review was conducted through November 2010, as well as selected other references through August 2011. Searches were limited to studies, reviews, and other evidence conducted in human subjects and that were published in English. Key search words included but were not limited to the following: *ad hoc angioplasty, angioplasty, balloon angioplasty, clinical trial, coronary stenting, delayed angioplasty, meta-analysis, percutaneous transluminal coronary angioplasty, randomized controlled trial, percutaneous coronary intervention (PCI) and angina, angina reduction, antiplatelet therapy, bare-metal stents (BMS), cardiac rehabilitation, chronic stable angina, complication, coronary bifurcation lesion, coronary calcified lesion, coronary chronic total occlusion, coronary ostial lesions, coronary stent (BMS and drug-eluting stents [DES]; and BMS versus DES), diabetes, distal embolization, distal protection, elderly, ethics, late stent thrombosis, medical therapy, microembolization, mortality, multiple lesions, multivessel, myocardial infarction, non–ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor, return to work, same-day angioplasty and/or stenting, slow flow, stable ischemic heart disease (SIHD), staged angioplasty, STEMI, survival, and unstable angina (UA).* Additional searches cross-referenced these topics with the following subtopics: *anticoagulant therapy, contrast nephropathy, PCI-related vascular complications, unprotected left main PCI, multivessel coronary artery disease (CAD), adjunctive percutaneous interventional devices, percutaneous hemodynamic support devices, and secondary prevention.* Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

Because the executive summary contains only the recommendations, the reader is encouraged to consult the full-text guideline (4) for additional detail on the recommendations and guidance on the care of the patient undergoing PCI.

1.2. Organization of the Writing Committee

The committee was composed of physicians with expertise in interventional cardiology, general cardiology, critical care cardiology, cardiothoracic surgery, clinical trials, and health services research. The committee included representatives from the ACCF, AHA, and SCAI.

1.3. Document Review and Approval

This document was reviewed by 2 official reviewers nominated by the ACCF, AHA, and SCAI, as well as 21 individual content reviewers (including members of the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All information on reviewers' RWI was distributed to the writing committee and is published in this document (Appendix 2). This document was approved for publication by the governing bodies of the ACCF, AHA, and SCAI.

1.4. PCI Guideline Scope

The evolution of the PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, intravascular ultrasound (IVUS) and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. The 2011 iteration of the guideline continues this process, addressing ethical aspects of PCI, vascular access considerations, CAD revascularization including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support devices, no-reflow therapies, and vascular closure devices. Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations. The focus of this guideline is the safe, appropriate, and efficacious performance of PCI. The risks of PCI must be balanced against the likelihood of improved survival, symptoms, or functional status. This is especially important in patients with SIHD.

In a major undertaking, the STEMI, PCI, and coronary artery bypass graft (CABG) surgery guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing greater collaboration between the different writing committees on topics such as PCI in STEMI and revascularization strategies in patients with CAD (including unprotected left main PCI, multivessel disease revascularization, and hybrid procedures).

In accordance with direction from the Task Force and feedback from readers, in this iteration of the guideline, the text has been shortened, with an emphasis on summary statements rather than detailed discussion of numerous individual trials.

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Online supplemental evidence and summary tables have been created to document the studies and data considered for new or changed guideline recommendations.

2. CAD Revascularization: Recommendations

Recommendations and text in this section are the result of extensive collaborative discussions between the PCI and CABG writing committees, as well as key members of the SIHD and UA/NSTEMI writing committees. Certain issues, such as older versus more contemporary studies, primary analyses versus subgroup analyses, and prospective versus post hoc analyses, have been carefully weighed in designating COR and LOE; they are addressed in the appropriate corresponding text (4). The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms. The following text contains recommendations for revascularization to improve survival and symptoms, and they are presented in Tables 2 and 3.

Revascularization recommendations in this section are predominantly based on studies of patients with symptomatic SIHD and should be interpreted in this context. As discussed later in this section, recommendations on the type of revascularization are, in general, applicable to patients with UA/NSTEMI. In some cases (e.g., unprotected left main CAD), specific recommendations are made for patients with UA/NSTEMI or STEMI.

2.1. Heart Team Approach to Revascularization Decisions

CLASS I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD (5–7). *(Level of Evidence: C)*

CLASS IIa

1. Calculation of the Society of Thoracic Surgeons and SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) scores is reasonable in patients with unprotected left main and complex CAD (7–14). *(Level of Evidence: B)*

2.2. Revascularization to Improve Survival

Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis (15–21). *(Level of Evidence: B)*

CLASS IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., Society of Thoracic Surgeons–predicted risk of operative mortality ≥5%) (8,10,11,22–40,106) *(Level of Evidence: B)*
2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG (11,27,29–31,36, 37,39–41). *(Level of Evidence: B)*
3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis in Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG (24,42,43). *(Level of Evidence: C)*

CLASS IIb

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; Society of Thoracic Surgeons–predicted risk of operative mortality >2%) (8,10,11,22–40,44). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG (8,10,11,15–23). *(Level of Evidence: B)*

Non–Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal left anterior descending [LAD]) or in the proximal LAD plus 1 other major coronary artery (17,21,45–48). *(Level of Evidence: B)*
2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. *(CABG Level of Evidence: B* [49–51]; *PCI Level of Evidence: C* [49])

CLASS IIa

1. CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium (52–55). *(Level of Evidence: B)*
2. CABG to improve survival is reasonable in patients with mild-moderate left ventricular systolic dysfunction (ejection fraction 35% to 50%) and significant (≥70% diameter stenosis) multivessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization (21,56–60). *(Level of Evidence: B)*
3. CABG with a left internal mammary artery graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia (21,48,61,62). *(Level of Evidence: B)*

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Table 2. Revascularization to Improve Survival Compared With Medical Therapy

Anatomic Setting	COR	LOE	References
UPLM or complex CAD			
CABG and PCI	I—Heart team approach recommended	C	(5–7)
CABG and PCI	IIa—Calculation of STS and SYNTAX scores	B	(7–14)
UPLM*			
CABG	I	B	(15–21)
PCI	IIa—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score of ≤22, ostial or trunk left main CAD) • Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%)	B	(8,10,11,22–40,106)
	IIa—For UA/NSTEMI if not a CABG candidate	B	(11,27,29–31,36,37,39–41)
	IIa—For STEMI when distal coronary flow is TIMI flow grade <3 and PCI can be performed more rapidly and safely than CABG	C	(24,42,43)
	IIb—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of ≤33, bifurcation left main CAD) • Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality <2%)	B	(8,10,11,22–40,44)
	III: Harm—for SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	B	(8,10,11,15–23)
3-vessel disease with or without proximal LAD artery disease*			
CABG	I	B	(17,21,45–48)
	IIa—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) who are good candidates for CABG.	B	(23,38,48,63,64)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
2-vessel disease with proximal LAD artery disease*			
CABG	I	B	(17,21,45–48)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
2-vessel disease without proximal LAD artery disease*			
CABG	IIa—With extensive ischemia	B	(52–55)
	IIb—Of uncertain benefit without extensive ischemia	C	(48)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
1-vessel proximal LAD artery disease			
CABG	IIa—With LIMA for long-term benefit	B	(21,48,61,62)
PCI	IIb—Of uncertain benefit	B	(17,45,48,74)
1-vessel disease without proximal LAD artery involvement			
CABG	III: Harm	B	(21,45,52,53,86–90)
PCI	III: Harm	B	(21,45,52,53,86–90)
LV dysfunction			
CABG	IIa—EF 35% to 50%	B	(21,56–60)
CABG	IIb—EF <35% without significant left main CAD	B	(21,56–60,75,76)
PCI	Insufficient data		N/A
Survivors of sudden cardiac death with presumed ischemia-mediated VT			
CABG	I	B	(49–51)
PCI	I	C	(49)
No anatomic or physiologic criteria for revascularization			
CABG	III: Harm	B	(21,45,52,53,86–90)
PCI	III: Harm	B	(21,45,52,53,86–90)

***In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI (54,66–73) (Class IIa; LOE: B).**

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; COR, class of recommendation; EF, ejection fraction; LAD, left anterior descending; LIMA, left internal mammary artery; LOE, level of evidence; LV, left ventricular; N/A, not applicable; PCI, percutaneous coronary intervention; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; STS, Society of Thoracic Surgeons; SYNTAX, Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery; TIMI, Thrombolysis in Myocardial Infarction; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; UPLM, unprotected left main disease; and VT, ventricular tachycardia.

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Table 3. Revascularization to Improve Symptoms With Significant Anatomic (≥50% Left Main or ≥70% Non–Left Main CAD) or Physiological (FFR≤0.80) Coronary Artery Stenoses

Clinical Setting	COR	LOE	References
≥1 significant stenoses amenable to revascularization and unacceptable angina despite GDMT	I–CABG I–PCI	A	(74,91–100)
≥1 significant stenoses and unacceptable angina in whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences	IIa–CABG IIa–PCI	C	N/A
Previous CABG with ≥1 significant stenoses associated with ischemia and unacceptable angina despite GDMT	IIa–PCI	C	(78,81,84)
	IIb–CABG	C	(85)
Complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery and a good candidate for CABG	IIa–CABG preferred over PCI	B	(23,38,48,63,64)
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb–TMR as an adjunct to CABG	B	(101–105)
No anatomic or physiologic criteria for revascularization	III: Harm–CABG III: Harm–PCI	C	N/A

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COR, class of recommendation; FFR, fractional flow reserve; GDMT, guideline-directed medical therapy; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and TMR, transmyocardial laser revascularization.

4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery who are good candidates for CABG (23,38,48,63,64). *(Level of Evidence: B)*
5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a left internal mammary artery graft can be anastomosed to the LAD artery (54,66–73). *(Level of Evidence: B)*

CLASS IIb

1. The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia (48). *(Level of Evidence: C)*
2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease (17,45,48,74). *(Level of Evidence: B)*
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe left ventricular systolic dysfunction (ejection fraction <35%) whether or not viable myocardium is present (21,56–60,75,76). *(Level of Evidence: B)*
4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing (77–85). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non–left main coronary artery stenosis, fractional flow reserve >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium (21,45,52,53,86–90). *(Level of Evidence: B)*

2.3. Revascularization to Improve Symptoms

CLASS I

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT (74,91–100). *(Level of Evidence: A)*

CLASS IIa

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. *(Level of Evidence: C)*
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT (78,81,84). *(Level of Evidence: C)*
3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG (23,38,48,63,64). *(Level of Evidence: B)*

CLASS IIb

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT (85). *(Level of Evidence: C)*
2. Transmyocardial laser revascularization performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting (101–105). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% left main or ≥70% non–left main stenosis) or physiological (e.g., abnormal fractional flow reserve) criteria for revascularization. *(Level of Evidence: C)*

2.4. Clinical Factors That May Influence the Choice of Revascularization

2.4.1. Dual Antiplatelet Therapy Compliance and Stent Thrombosis

CLASS III: HARM

1. PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with dual antiplatelet therapy (DAPT) for the appropriate duration of treatment based on the type of stent implanted (107–110). *(Level of Evidence: B)*

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Table 4. Summary of Recommendations for Preprocedural Considerations and Interventions in Patients Undergoing PCI

Recommendations	COR	LOE	References
Contrast-induced AKI			
Patients should be assessed for risk of contrast-induced AKI before PCI.	I	C	(118,119)
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	I	B	(120–123)
In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.	I	B	(124–126)
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	A	(127–131)
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	I	B	(132–135)
In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.	III: No Benefit	C	(136–138)
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.	IIa	A: Statin naive	(139–145)
		B: Chronic statin therapy	(146)
Bleeding risk			
All patients should be evaluated for risk of bleeding before PCI.	I	C	N/A
CKD			
In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.	I	B	(147–149)
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	I	B	(150–153)
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	I	B	(150,152,153)

AKI indicates acute kidney injury; CKD, chronic kidney disease; COR, class of recommendation; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; and PCI, percutaneous coronary intervention.

2.5. Hybrid Coronary Revascularization

CLASS IIa

1. Hybrid coronary revascularization (defined as the planned combination of left internal mammary artery-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following (111–117) *(Level of Evidence: B)*:
   a. Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);
   b. Lack of suitable graft conduits;
   c. Unfavorable LAD artery or PCI (i.e., excessive vessel tortuosity or chronic total occlusion).

CLASS IIb

1. Hybrid coronary revascularization (defined as the planned combination of left internal mammary artery-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures. *(Level of Evidence: C)*

3. Preprocedural Considerations: Recommendations

Table 4 contains recommendations for preprocedural considerations and interventions in patients undergoing PCI.

3.1. Radiation Safety

CLASS I

1. Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. *(Level of Evidence: C)*

3.2. Contrast-Induced Acute Kidney Injury

CLASS I

1. Patients should be assessed for risk of contrast-induced acute kidney injury before PCI (118,119). *(Level of Evidence: C)*
2. Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration (120–123). *(Level of Evidence: B)*
3. In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized (124–126). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced acute kidney injury (127–131). *(Level of Evidence: A)*

3.3. Anaphylactoid Reactions

CLASS I

1. Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration (132–135). *(Level of Evidence: B)*

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Table 5. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	I	A	(155,175–178)
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B	(179,180)
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B	(181,182)
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A	(183–187)
Coronary angiography before hospital discharge			
Stable patients	IIb	C	N/A
Coronary angiography at any time			
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	C	N/A

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

CLASS III: NO BENEFIT

1. In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial (136–138). *(Level of Evidence: C)*

3.4. Statin Treatment

CLASS IIa

1. Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural myocardial infarction. *(Level of Evidence: A for statin-naïve patients* [139–145]*; Level of Evidence: B for those on chronic statin therapy* [146]*)*

3.5. Bleeding Risk

CLASS I

1. All patients should be evaluated for risk of bleeding before PCI. *(Level of Evidence: C)*

3.6. PCI in Hospitals Without On-Site Surgical Backup

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (155,156). *(Level of Evidence: B)*

CLASS IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (156–158). *(Level of Evidence: B)*

CLASS III: HARM

1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

4. Procedural Considerations: Recommendations

4.1. Vascular Access

CLASS IIa

1. The use of radial artery access can be useful to decrease access site complications (159–167). *(Level of Evidence: A)*

4.2. PCI in Specific Clinical Situations

4.2.1. Unstable Angina/Non–ST-Elevation Myocardial Infarction

CLASS I

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures) (168–170). *(Level of Evidence: B)*
2. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events (169–172). *(Level of Evidence: A)*
3. The selection of PCI or CABG as the means of revascularization in the patient with acute coronary syndrome (ACS) should generally be based on the same considerations as those without ACS (45,170,173,174). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (e.g., liver or pulmonary failure, cancer) in whom *(Level of Evidence: C)*
   a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,
   b. There is a low likelihood of ACS despite acute chest pain, or
   c. Consent to revascularization will not be granted regardless of the findings.

4.2.2. ST-Elevation Myocardial Infarction

Table 5 contains indications for coronary angiography in STEMI.

4.2.2.1. CORONARY ANGIOGRAPHY STRATEGIES IN STEMI

CLASS I

1. A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for:
   a. Patients who are candidates for primary PCI (155,175–178). *(Level of Evidence: A)*

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b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization (179,180). *(Level of Evidence: B)*

CLASS IIa

1. A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis (181,182). *(Level of Evidence: B)*
2. A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame (183–187). *(Level of Evidence: A)*

CLASS IIb

1. A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care. *(Level of Evidence: C)*

4.2.2.2. PRIMARY PCI OF THE INFARCT ARTERY

CLASS I

1. Primary PCI should be performed in patients within 12 hours of onset of STEMI (175–178). *(Level of Evidence: A)*
2. Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal (188,189). *(Level of Evidence: B)*
3. Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal (190–192). *(Level of Evidence: B)*
4. Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay (179,180). *(Level of Evidence: B)*
5. Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for less than 12 hours (193,194). *(Level of Evidence: B)*

CLASS IIa

1. Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset (195–197). *(Level of Evidence: B)*

CLASS IIb

1. Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. *(Level of Evidence: C)*

CLASS III: HARM

1. PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise (198–202). *(Level of Evidence: B)*

4.2.2.3. DELAYED OR ELECTIVE PCI IN PATIENTS WITH STEMI

CLASS IIa

1. PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion (181,182). *(Level of Evidence: B)*
2. PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy (186,187). *(Level of Evidence: B)*
3. PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing (203,204). *(Level of Evidence: B)*

CLASS IIb

1. PCI of a hemodynamically significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy (205–209). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia (210–212). *(Level of Evidence: B)*

Table 6 contains indications for PCI in STEMI.

4.2.3. Cardiogenic Shock

CLASS I

1. PCI is recommended for patients with acute myocardial infarction who develop cardiogenic shock and are suitable candidates (180,213–215). *(Level of Evidence: B)*
2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (180,216–219). *(Level of Evidence: B)*

4.2.4. Revascularization Before Noncardiac Surgery

CLASS IIa

1. For patients who require PCI and are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable (220–226). *(Level of Evidence: B)*
2. For patients with DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period (222,227). *(Level of Evidence: C)*

CLASS III: HARM

1. Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery (228,229). *(Level of Evidence: B)*
2. Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively (107,225, 230,231). *(Level of Evidence: B)*

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Table 6. Indications for PCI in STEMI

Indications	COR	LOE	References
Primary PCI*			
STEMI symptoms within 12 h	I	A	(175–178)
Severe heart failure or cardiogenic shock	I	B	(179,180)
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B	(193,194)
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B	(195–197)
Asymptomatic patients presenting between 12 and 24 h after symptom onset and higher risk	IIb	C	N/A
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B	(198–202)
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B	(181,182)
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B	(186,187)
Ischemia on noninvasive testing	IIa	B	(203,204)
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	IIb	B	(205–209)
Totally occluded infarct artery >24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B	(210–212)

*Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability (188,189) (Class I; LOE: B) and within 120 min when the patient presents to a hospital without PCI capability (190–192) (Class I; LOE: B).

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

4.3. Coronary Stents

CLASS I

1. Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT (232). *(Level of Evidence: C)*
2. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT *(Level of Evidence: A* for elective PCI [233–237]; *Level of Evidence: C* for UA/NSTEMI [235]; *Level of Evidence: A* for STEMI [235,236,238–240]).
3. Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted (107,241–243). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT (107–110). *(Level of Evidence: B)*
2. DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation (107,241–243). *(Level of Evidence: B)*

4.4. Adjunctive Diagnostic Devices

4.4.1. Fractional Flow Reserve

CLASS IIa

1. Fractional flow reserve is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD (89,244–247). *(Level of Evidence: A)*

4.4.2. Intravascular Ultrasound

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (248–250). *(Level of Evidence: B)*
2. IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information (251–253). *(Level of Evidence: B)*
3. IVUS is reasonable to determine the mechanism of stent restenosis (254). *(Level of Evidence: C)*

CLASS IIb

1. IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) (248,255,256). *(Level of Evidence: B)*
2. IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting (249,254,257). *(Level of Evidence: B)*
3. IVUS may be reasonable to determine the mechanism of stent thrombosis (254). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. *(Level of Evidence: C)*

4.5. Adjunctive Therapeutic Devices

4.5.1. Coronary Atherectomy

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (258,259). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis (260–263). *(Level of Evidence: A)*

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4.5.2. Thrombectomy

CLASS IIa

1. Aspiration thrombectomy is reasonable for patients undergoing primary PCI (264–266). *(Level of Evidence: B)*

4.5.3. Laser Angioplasty

CLASS IIb

1. Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (267). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Laser angioplasty should not be used routinely during PCI (260,262,268). *(Level of Evidence: A)*

4.5.4. Cutting Balloon Angioplasty

CLASS IIb

1. Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (269). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Cutting balloon angioplasty should not be performed routinely during PCI (260,269,270). *(Level of Evidence: A)*

4.5.5. Embolic Protection Devices

CLASS I

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible (271–274). *(Level of Evidence: B)*

4.6. Percutaneous Hemodynamic Support Devices

Table 7 contains recommendations for antiplatelet and antithrombin pharmacotherapy at the time of PCI.

CLASS IIb

1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. *(Level of Evidence: C)*

4.6.1. Oral Antiplatelet Therapy

CLASS I

1. Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI (150–153). *(Level of Evidence: B)*
2. Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI (150,152,153). *(Level of Evidence: B)*
3. After PCI, use of aspirin should be continued indefinitely (275-278). *(Level of Evidence: A)*
4. A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting (279–283) *(Level of Evidence: A)*. Options include
   a. Clopidogrel 600 mg (ACS and non-ACS patients) (279–281). *(Level of Evidence: B)*
   b. Prasugrel 60 mg (ACS patients) (282). *(Level of Evidence: B)*
   c. Ticagrelor 180 mg (ACS patients) (283). *(Level of Evidence: B)*
5. The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy (280,284). *(Level of Evidence: C)*
6. Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT (107). *(Level of Evidence: C)*
7. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (285), prasugrel 10 mg daily (282), and ticagrelor 90 mg twice daily (283). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding (107,232,286). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (107,287). *(Level of Evidence: B)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (151,288–291). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation (282,283). *(Level of Evidence: C)*

CLASS III: HARM

1. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack (282). *(Level of Evidence: B)*

4.6.2. Intravenous Antiplatelet Therapy

STEMI

CLASS IIa

1. In patients undergoing primary PCI treated with unfractionated heparin (UFH), it is reasonable to administer a glycoprotein (GP) IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel (292–298). *(For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel, Level of Evidence: A; for GP IIb/IIIa inhibitor administration in patients pretreated with clopidogrel, Level of Evidence: C)*

CLASS IIb

1. In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab (297,299–312). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Routine precatheterization laboratory (e.g., ambulance or emergency room) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial (313–320). *(Level of Evidence: B)*

UA/NSTEMI

CLASS I

1. In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) not treated with bivalirudin and not adequately pre-

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Table 7. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	I	B	(150–153,275–278)	N/A
$P2Y_{12}$ inhibitors	I	A	(279–283)	• A loading dose of a $P2Y_{12}$ inhibitor should be given to patients undergoing PCI with stenting.
• Clopidogrel	I	B	(279–281)	• 600-mg loading dose now recommended.
• Prasugrel	I	B	(282)	• Contraindicated in patients with prior TIA/CVA: ***Class III: Harm; LOE: B.*** • Generally not recommended in patients >75 years of age (see Section 5.7.2 in full text). • Consideration of using a lower maintenance dose in persons weighing <60 kg suggested by FDA (Section 5.7.2 in full text).
• Ticagrelor	I	B	(283)	• Issues of patient compliance may be especially important.
GP IIb/IIIa inhibitors (abciximab, double-bolus eptifibatide, high-bolus dose tirofiban)				
• No clopidogrel pretreatment	STEMI: IIa	A	(292–298)	• UA/NSTEMI recommendation applies to those with high-risk features. • GPI use in STEMI may be most appropriate in those with large anterior MI and/or large thrombus burden. • IC abciximab administration in STEMI: ***Class IIb; LOE: B.*** • Precatheterization laboratory GPI administration in STEMI: ***Class III: No Benefit; LOE: B.*** • Recommendations apply to those not at high risk for bleeding complications.
	UA/NSTEMI: I	A	(321–326)	
	SIHD: IIa	B	(327–329)	
• Clopidogrel pretreatment	STEMI: IIa	C	(292–298)	
	UA/NSTEMI: IIa	B	(324,327)	
	SIHD: IIb	B	(327,330–332)	
Antithrombin agents				
UFH	I	C	N/A	• Dosing based on whether or not GPI was administered
Bivalirudin	I	B	(333–342)	• Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.
Enoxaparin	IIb	B	(343–347)	• Recommendations apply to administration of IV enoxaparin at the time of PCI for those who have not received prior antithrombin therapy or who have received "upstream" SC enoxaparin therapy for UA/NSTEMI. • An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic SC doses (e.g., 1 mg/kg) or received the last SC enoxaparin dose 8 to 12 h before PCI: ***Class I; LOE: B.*** • Patients treated with SC enoxaparin within 12 h of PCI should not receive additional treatment with UFH during PCI ("stacking"): ***Class III: Harm; LOE: B.***
Anti-Xa inhibitors				
Fondaparinux	III: Harm	C	(348,349)	• PCI should not be performed with fondaparinux as the sole antithrombin agent in patients treated with upstream fondaparinux. An additional anticoagulant with anti-IIa activity should be administered.

ACT indicates activated clotting time; COR, class of recommendation; CVA, cerebrovascular accident; FDA, U.S. Food and Drug Administration; GP, glycoprotein; GPI, glycoprotein IIb/IIIa inhibitor; IC, intracoronary; IV, intravenous; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; and UFH, unfractionated heparin.

treated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH (321–326). *(Level of Evidence: A)*

CLASS IIa

1. In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (324,327). *(Level of Evidence: B)*

SIHD

CLASS IIa

1. In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (327–329). *(Level of Evidence: B)*

CLASS IIb

1. In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (327,330–332). *(Level of Evidence: B)*

4.6.3. Anticoagulant Therapy

4.6.3.1. USE OF PARENTERAL ANTICOAGULANTS DURING PCI

CLASS I

1. An anticoagulant should be administered to patients undergoing PCI. *(Level of Evidence: C)*

4.6.3.2. UNFRACTIONATED HEPARIN

CLASS I

1. Administration of IV UFH is useful in patients undergoing PCI. *(Level of Evidence: C)*

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4.6.3.3. ENOXAPARIN

CLASS I

1. An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received fewer than 2 therapeutic subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI (346,350–353). *(Level of Evidence: B)*

CLASS IIb

1. Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/NSTEMI or who have not received prior antithrombin therapy and are administered IV enoxaparin at the time of PCI (343–347). *(Level of Evidence: B)*

CLASS III: HARM

1. UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin (346,354). *(Level of Evidence: B)*

4.6.3.4. BIVALIRUDIN AND ARGATROBAN

CLASS I

1. For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH (333–342). *(Level of Evidence: B)*
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH (355,356). *(Level of Evidence: B)*

4.6.3.5. FONDAPARINUX

CLASS III: HARM

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis (348,349). *(Level of Evidence: C)*

4.6.4. No-Reflow Pharmacological Therapies

CLASS IIa

1. Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI (357–372). *(Level of Evidence: B)*

4.7. PCI in Specific Anatomic Situations

4.7.1. Chronic Total Occlusions

CLASS IIa

1. PCI of a chronic total occlusion in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise (373–377). *(Level of Evidence: B)*

4.7.2. Saphenous Vein Grafts

CLASS I

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible (271–274). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during saphenous vein graft PCI (232,286,378,379). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI is not recommended for chronic saphenous vein graft occlusions (380–382). *(Level of Evidence: C)*

4.7.3. Bifurcation Lesions

CLASS I

1. Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium (383–386). *(Level of Evidence: A)*

CLASS IIa

1. It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low (387–390). *(Level of Evidence: B)*

4.7.4. Aorto-Ostial Stenoses

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (391,392). *(Level of Evidence: B)*
2. Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis (393,394). *(Level of Evidence: B)*

4.7.5. Calcified Lesions

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (258,259,395). *(Level of Evidence: C)*

4.8. PCI in Specific Patient Populations

4.8.1. Chronic Kidney Disease

CLASS I

In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted (147–149). *(Level of Evidence: B)*

4.9. Periprocedural Myocardial Infarction Assessment

CLASS I

1. In patients who have signs or symptoms suggestive of myocardial infarction during or after PCI or in asymptomatic patients with significant *persistent* angiographic complications (e.g., large side-branch occlusion, flow-limiting dissection, no-reflow phenomenon, or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured. *(Level of Evidence: C)*

CLASS IIb

1. Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable. *(Level of Evidence: C)*

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4.10. Vascular Closure Devices

CLASS I

1. Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment. *(Level of Evidence: C)*

CLASS IIa

1. The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression (396–399). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding (396–401). *(Level of Evidence: B)*

5. Postprocedural Considerations: Recommendations

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 8. Some recommendations and text regarding DAPT in Section 5.7.2 of the full-text guideline (4) are intentionally repeated in this section for reader ease of use.

5.1. Postprocedural Antiplatelet Therapy

CLASS I

1. After PCI, use of aspirin should be continued indefinitely (275–278). *(Level of Evidence: A)*
2. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (285), prasugrel 10 mg daily (282), and ticagrelor 90 mg twice daily (283). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding (107,232,286). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (287). *(Level of Evidence: B)*
3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist (107). *(Level of Evidence: C)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (151,288–291). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of clopidogrel, prasugrel or ticagrelor beyond 12 months may be considered in patients undergoing placement of DES (282,283). *(Level of Evidence: C)*

5.1.1. Proton Pump Inhibitors and Antiplatelet Therapy

CLASS I

1. Proton pump inhibitors should be used in patients with a history of prior gastrointestinal bleeding who require DAPT (402). *(Level of Evidence: C)*

CLASS IIa

1. Use of proton pump inhibitors is reasonable in patients with an increased risk of gastrointestinal bleeding (e.g., advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT (402). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine use of a proton pump inhibitor is not recommended for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy (402). *(Level of Evidence: C)*

5.1.2. Clopidogrel Genetic Testing

CLASS IIb

1. Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel (434). *(Level of Evidence: C)*
2. When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (e.g., prasugrel or ticagrelor) might be considered (434). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (434). *(Level of Evidence: C)*

5.1.3. Platelet Function Testing

CLASS IIb

1. Platelet function testing may be considered in patients at high risk for poor clinical outcomes (434). *(Level of Evidence: C)*
2. In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered (434). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of platelet function testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (434). *(Level of Evidence: C)*

5.2. Restenosis

CLASS I

1. Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT (435). *(Level of Evidence: B)*
2. Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient

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Table 8. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations		COR	LOE	References
Aspirin				
After PCI, use of aspirin should be continued indefinitely.		I	A	(275–278)
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.		IIa	B	(151,288–291)
$P2Y_{12}$ inhibitors				
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.		I	B	(282,283,285)
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.		I	B	(107,232,286)
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).		I	B	(287)
Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.		I	C	(107)
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.		I	C	(402)
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.		IIa	C	N/A
Use of PPIs is reasonable in patients with an increased risk of GI bleeding (e.g., advanced age, concomitant use of warfarin, steroids, NSAIDs, *Helicobacter pylori* infection) who require DAPT.		IIa	C	(402)
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.		IIb	C	(282,283)
Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.		III: No Benefit	C	(402)
Exercise testing				
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.		IIa	C	N/A
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.		III: No Benefit	C	(403)
Cardiac rehabilitation				
Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for patients at moderate to high risk for whom supervised exercise training is warranted.		I	A	(404–412)
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy Guideline) (413)				
Lipid management with lifestyle modification and lipid-lowering pharmacotherapy	Lifestyle modification	I	B	(414,415)
	Statin therapy	I	A	(414,416–419,419a)
	Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	I	C	(414–419,419a)
	Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	IIa	C	(416–418,419a,420–422)
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)	Lifestyle modification	I	B	(423–427)
	Pharmacotherapy	I	A	(423,428,429)
Diabetes management (e.g., lifestyle modification and pharmacotherapy) coordinated with the patient's primary care physician and/or endocrinologist		I	C	N/A
Complete smoking cessation		I	A	(430–433)

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides ≥200 mg/dL plus non–HDL-cholesterol ≥130 mg/dL with low HDL-cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

ACS indicates acute coronary syndromes; BMS, bare-metal stent(s); COR, class of recommendation; DAPT, dual antiplatelet therapy; DES, drug-eluting stent(s); GI, gastrointestinal; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LOE, level of evidence; N/A, not applicable; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; and PPI, proton pump inhibitor.

is able to comply with and tolerate DAPT (436–438). *(Level of Evidence: A)*

CLASS IIa

1. IVUS is reasonable to determine the mechanism of stent restenosis (254). *(Level of Evidence: C)*

CLASS IIb

1. Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT (254). *(Level of Evidence: C)*

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5.2.1. Exercise Testing

CLASS IIa

1. In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed (403). *(Level of Evidence: C)*

5.2.2. Cardiac Rehabilitation

CLASS I

1. Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted (404–412). *(Level of Evidence: A)*

6. Quality and Performance Considerations: Recommendations

6.1. Quality and Performance

CLASS I

1. Every PCI program should operate a quality-improvement program that routinely 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews. *(Level of Evidence: C)*
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms. *(Level of Evidence: C)*

6.2. Certification and Maintenance of Certification

CLASS IIa

1. It is reasonable for all physicians who perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program. *(Level of Evidence: C)*

6.3. Operator and Institutional Competency and Volume

CLASS I

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery (439,440). *(Level of Evidence: C)*
2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. *(Level of Evidence: C)*
3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year (439,441–444). *(Level of Evidence: C)*

CLASS IIa

1. It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery (439). *(Level of Evidence: C)*
2. It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures. *(Level of Evidence: C)*

CLASS IIb

1. The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (<11 PCIs for STEMI per year) is not well established. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service (439). *(Level of Evidence: C)*

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Key Words: ACCF/AHA Practice Guidelines ■ acute coronary syndromes ■ anticoagulants ■ antiplatelet agents ■ arrhythmias, cardiac ■ coronary angiography ■ coronary artery revascularization interventions: stents ■ drug therapy ■ heart diseases ■ myocardial revasularization ■ platelet aggregation inhibitor ■ ultrasound.

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Glenn N. Levine *(Chair)*	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates *(Vice Chair)*	University of Michigan—Professor of Medicine	• Bristol-Myers Squibb • Daiichi-Sankyo • Datascope • Eli Lilly • Merck • Sanofi-aventis	None	None	None	None	None	5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 6.1 6.1.2 6.1.3
James C. Blankenship *(Vice Chair)*	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratories	None	None	None	• Abiomed • AstraZeneca • Boston Scientific • Conor Medsystems • Kai Pharmaceutical • Schering-Plough	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.4.1 5.4.2 5.8.4 6.3
Steven R. Bailey	University of Texas Medical Center—Professor of Medicine and Radiology	• Volcano	None	None	• Boston Scientific	None	None	5.4.1 5.4.2
John A. Bittl	Munroe Heart—Interventional Cardiologist	None	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center—Director, Coronary Care Unit	None	None	None	None	None	None	None

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Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Charles E. Chambers	Penn State Milton S. Hershey Medical Center—Professor of Medicine and Radiology	None	None	None	None	None	None	None
Stephen G. Ellis	Cleveland Clinic Foundation—Section Head, Invasive and Interventional Cardiology	• Abbott Vascular • Boston Scientific • Cordis • Daiichi-Sankyo • Eli Lilly	None	None	• Abbott Vascular	None	None	2.2 2.11 5.7.2 6.1
Robert A. Guyton	Emory Clinic, Inc.—Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.5.5 6.2 6.3
Steven M. Hollenberg	Cooper University Hospital—Director, Coronary Care Unit	• Eisai	None	None	None	None	None	5.7.4.3
Umesh N. Khot	CV Research Innovations, LLC—President/CEO	None	None	• Merck†	None	None	None	4.6 5.7.3
Richard A. Lange	University of Texas Health Science Center at San Antonio—Professor of Medicine	None	None	None	None	None	None	None
Laura Mauri	Brigham and Women's Hospital—Associate Professor of Medicine, Harvard Medical School	• Abbott • Conor Medsystems (Johnson & Johnson) • Cordis • Medtronic	None	None	• Lutonix	• Abbott • Ablomed • Boston Scientific • Bristol-Myers Squibb • Conor Medsystems • Cordis • Daiichi-Sankyo • Eli Lilly • Medtronic Cardiovascular • Sanofi-aventis	• Defendant, Conor, interpretation of clinical trial results, 2010	2.9.7 5.2.3 5.3 5.4.2 5.5.1 5.5.2 5.5.4 5.5.5 5.6 5.7.2 5.7.3 5.8.2 5.8.4 5.8.5 5.11 6.1 6.1.2 6.1.3 6.2
Roxana Mehran	Columbia University Medical Center—Associate Professor of Medicine; Director, Data Coordinating Analysis Center	• Abbott Vascular • Ablomed • AlphaMedical • AstraZeneca • Bracco • BMS/sanofi-aventis • DataScope • Eli Lilly/Daichii-Sankyo • Guerbet • The Medicines Company • Medtronic Vascular • St. Jude	None	None	None	None	None	4.7 5.1 5.2.4 5.3 5.4.1 5.4.2 5.5.1 5.5.2 5.6 5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 5.8.3 5.8.4 5.11 6.1 6.1.1 6.1.2 6.1.3

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Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Issam D. Moussa	Mayo Clinic—Professor of Medicine; Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
Brahmajee K. Nallamothu	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

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*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply. Section numbers apply to the full-text guideline. †Significant relationship.

APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt	Official Reviewer—AHA	None	None	None	• AstraZeneca* • Bristol-Myers Squibb* • Eisai* • Eli Lilly • Ethicon* • The Medicines Company* • PLx Pharma† • Sanofi-aventis*	None	None
Mauricio G. Cohen	Official Reviewer—AHA	• AstraZeneca* • Momenta Pharma • Xoma	• Terumo Medical	None	• Invitrox*	None	None
John P. Erwin III	Official Reviewer—ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kirk Garratt	Official Reviewer—SCAI	• Boston Scientific • Cordis/Johnson & Johnson • The Medicines Company	• Boston Scientific • BMS/sanofi-aventis* • Daiichi-Sankyo/Eli Lilly* • Medtronic • The Medicines Company	• Abbott Vascular • Boston Scientific	None	None	None
Steven L. Goldberg	Official Reviewer—SCAI	• AGA	• Bristol-Myers Squibb • Sanofi-aventis	None	None	None	• Plaintiff, patient litigation, 2010

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Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Alice K. Jacobs	Official Reviewer—ACCF/ AHA Task Force on Practice Guidelines	None	None	• Wyeth*	• Abbott Vascular* • Abiomed* • Accumetrics* • Cardiovascular Research Foundation (DSMB)† • Harvard Clinical Research Institute† • TIMI Study Group (DSMB)†	None	None
G.B. John Mancini	Official Reviewer—ACCF Board of Governors	• GlaxoSmithKline • Merck • Pfizer • Sanofi-aventis	None	None	• Merck*	None	None
W. Douglas Weaver	Official Reviewer—ACCF Board of Trustees	None	None	None	• Boehringher Ingelheim (DSMB) • Boston Scientific (DSMB) • Duke Clinical Research Institute (Johnson & Johnson/Schering Plough)* • GlaxoSmithKline • NHLBI (DSMB) • TIMI Study Group (Johnson & Johnson/Bayer-DSMB)	None	None
Thomas M. Bashore	Content Reviewer	None	None	None	None	None	None
Christopher E. Buller	Content Reviewer	• Abbott Vascular • Toshiba Medical	None	None	• Novartis • Regado Biosciences	None	None
James A. Burke	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
John G. Byrne	Content Reviewer—ACCF Surgeons' Scientific Council	• Edwards Lifesciences	None	None	None	None	None
T. Bruce Ferguson	Content Reviewer—ACCF Surgeons' Scientific Council	None	None	None	• Novadaq Technologies*	None	None
Victor A. Ferrari	Content Reviewer	None	None	None	• NHLBI (DSMB)† • National Institute for Aging/NIH (DSMB)†	None	None
John G. Harold	Content Reviewer	None	None	None	None	None	None
Biswajit Kar	Content Reviewer	None	None	None	• AstraZeneca† • Boston Scientific† • Medtronic†	• Veterans Affairs Cooperative Study†	None

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Spencer B. King III	Content Reviewer	• Celonova Biosciences†	None	None	• Merck (DSMB) • Wyeth (DSMB)	None	None
Frederick G. Kushner	Content Reviewer	None	None	None	• Novartis†	None	None
David J. Maron	Content Reviewer	None	None	• Cardiovascular Care Affiliates*	None	None	• Plaintiff, acute coronary syndrome, 2010
Douglass A. Morrison	Content Reviewer	None	None	None	None	None	None
Thomas C. Piemonte	Content Reviewer—ACCF Board of Governors	None	None	None	None	None	• Defendant, stent perforation, 2010
Peter K. Smith	Content Reviewer	• Eli Lilly	None	None	None	None	None
Sidney C. Smith	Content Reviewer	None	None	None	None	None	None
Richard W. Snyder	Content Reviewer—ACCF Board of Governors	None	None	None	None	• Hospital Corporation of America	None
Patrick L. Whitlow	Content Reviewer	• Edwards Lifesciences* • eValve* • Medtronic*	None	None	None	• ICON	None
David O. Williams	Content Reviewer	• Light Lab/St. Jude Medical	None	None	None	None	None
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According to the ACCF/AHA, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or c) The *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.

*Significant relationship. †No financial benefit.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; DSMB, data safety and monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis in Myocardial Infarction.

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