Russ Myers, FACHE
President, Chief Executive Officer
russmyers@yvmh.org

March 14, 2016

Tami Thompson, Rules Coordinator
Washington State Department of Health
Tami.Thompson@doh.wa.gov

Dear Ms. Thompson:

Pursuant to RCW 34.05.330 and chapter 82-05 WAC, Yakima Valley Memorial Hospital respectfully petitions the Washington State Department of Health to undertake rule-making to amend current certificate of need rules concerning elective percutaneous coronary interventions in order to update minimum volume standards for hospitals and physicians to reflect current evidence.

As we understand, RCW 34.05.330 allows any person to petition a state agency to adopt, repeal, or amend any rule within its authority. We further understand that the Department of Health staff will respond to this petition within one business day acknowledging receipt of the petition, after which the Department has 60 days to respond to the petition.

We appreciate your consideration of this petition, and are prepared to answer any questions the Department may have.

Sincerely,

Russ Myers
Chief Executive Officer
russmyers@yvmh.org
(509) 575-8001

2811 Tieton Drive
Yakima, WA 98902

509-575-8000
yakimamemorial.org

Petition to amend certificate of need rules concerning elective percutaneous coronary interventions

1. Name and Address of Petitioner.

Yakima Valley Memorial Hospital
Russ Myers, CEO
2811 Tieton Drive
Yakima, WA 98902

509-575-8144
russmyers@yvmh.org

2. Name and Address of Agency Responsible for Administering the Rule.

Washington State Department of Health, Certificate of Need Program
111 Israel Rd. S.E.
Tumwater, WA 98501
P. O. Box 47852
Olympia, WA 98504-7852

The Department is the state agency authorized and directed to implement the Health Planning and Development Act, chapter 70.38 RCW (the "Act") in the state of Washington. The Department has adopted the rules set forth in chapter 246-310 WAC to assist it in implementing the Act.

3. Rationale for Amendment of the Rule.

Legislation in 2007 directed the Department of Health (Department) to adopt rules establishing criteria for the issuance of a certificate of need (CON) for the performance of elective percutaneous coronary interventions (PCIs) at hospitals that do not otherwise provide on-site cardiac surgery. The rules subsequently adopted in December 2008 (Chapter 246-310 WAC) require a hospital receiving a CON to annually perform no fewer than 300 PCI, with each physician performing no fewer than 75.

As discussed below, amendments to the Department's 2008 rules are now needed for two reasons: the rules' volume standards no longer reflect published research, and they are not being met by most hospitals in this state performing elective PCI. Absent the requested amendments, their CON could be subject to revocation or other agency action, despite current research and the fact that these hospitals are otherwise meeting quality standards.

In an August 18, 2015 letter (included as Attachment 1) regarding possible changes to the list of CON reviewable tertiary services, the Department itself stated (citing the "Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures")[1]:

> *The current volume standards are three hundred (300) and seventy-five (75), respectively… there is academic research that supports reconsidering those volume standards.*

Without amendments to reflect current research, the Department faces a significant compliance issue based on requirements contained in WAC 246-310-755 ("Ongoing compliance with standards"), which reads in part:

> *If the department issues a certificate of need (CON), it will be conditioned to require ongoing compliance with the CON standards. Failure to meet the standards may be grounds for revocation or suspension of a hospital's CON, or other appropriate licensing or certification actions.*
>
> *(1) Hospitals granted a certificate of need must meet:*
> *(a) The program procedure volume standards within three years from the date of initiating the program;*

Since adoption of the rules in 2008, nine hospitals have received CON approval to establish an elective PCI Program. Each of these programs has been in operation for more than three years. Eight of the nine, despite meeting quality standards, operate below the 300 case threshold. The volumes for each hospital are detailed in Attachment 3 to this petition.

In addition to these eight hospitals not otherwise providing on-site cardiac surgery, another five hospitals in the state that otherwise do provide on-site cardiac surgery fall below the 300 case threshold for elective services. Again, these hospitals operate with quality outcomes. **In total, of the 26 hospitals in Washington currently providing elective PCI, the majority are allowed to operate – without problem – below the 300 case threshold.**

The Department should amend the elective PCI rules to reflect current research and practice by updating the hospital and physician minimum volume standards in WACs 246-310-715, 246-310-720, 246-310-725 and 246-310-745.

The specific amendments being requested are included as Attachment 4 to this petition.

[1] SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup. Catheterization and Cardiovascular Interventions 2014; and ACC/AHA/SCAI/AMA – Convened PCPI/NCQA 2013 Performance Measure for Adults Undergoing Percutaneous Coronary Intervention. JACC: 63;7;722-745;2014. Complete copies of these reports are included as Attachment 2 to this petition.

Attachment 1
Department of Health Letter
August 18, 2015

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

TO: Martin Mueller, Assistant Secretary, Health Services Quality Assurance

FROM: Certificate of Need Tertiary Services Review Team[1]

SUBJECT: 2015 tertiary services review

DATE: August 18, 2015

EXECUTIVE SUMMARY

Beginning in January 2015, the Department conducted a review of proposed changes to its list (the "List")[2] of tertiary services. This memorandum represents the end of the process as laid out in rule and therefore, the conclusion of the Review Team's work.

External input revolved around two services: first, there were proposals to add Neonatal intensive care nursery and/or obstetric services level IV ("NICU Level IV") to the List; second, there were proposals to both remove elective therapeutic cardiac catheterization (Elective PCI) from the List and reduce minimum volume standards for institutions and individual providers that perform Elective PCI.

The services and procedures that fall under NICU Level IV fit all of the Department's criteria for tertiary services. Additionally, the Department adopted Level of Care Guidelines in 2013 that recommended the addition of Level IV to the pre-existing levels. Finally, there was no external opposition to the addition of Level IV to the List.

[1] Participation in the review was sought from all divisions. The review team consisted of Steve Saxe, Community Health Systems; Bart Eggen, Construction Review/Certificate of Need Program; Janis Sigman, Certificate of Need Program; Blake Maresh, Health Professions and Facilities; Katherine Hoffman, Office of the Assistant Secretary; Kyle Karinen, Office of Legal Services; and Laurie Soine, ARNP, Nursing Care Quality Assurance Commission (Commission member).

[2] For ease of reference, we will be using informal designations throughout. In the body of the memorandum, where appropriate, there will be an initial citation to the relevant statute or rule.

The services and procedures that fall under Elective PCI fit a majority of the Department's criteria for tertiary services. Elective PCI was the focus of a majority of the external input and the Team discussion. The proposals for removal of Elective PCI and against removal could not be reconciled. After review of the material submitted, the Review Team concluded the while the clinical landscape around Elective PCI has changed since the initial adoption of the List in 1991, a majority of the factors for inclusion remain.

In summary, the Review Team recommends:

1. NICU Level 4 should be added to the List; and

2. No other changes should be made to List.

Part I of this memorandum describes the process used by the Team and briefly lays out the statutory and administrative rule structure that underlies tertiary services. Part II describes the input received regarding NICU Level 4 and Team's conclusions regarding adding it to the List. Part III describes the input received regarding elective PCI and the team's conclusions regarding removing it from the List.

Part I – Process and underlying statutes and rules

In addition to construction, development, or other establishment of new health care facilities, the Department has been charged by the Legislature with implementing rules that guide the provision of tertiary services.[3] The Legislature defines tertiary services in statute 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."[4] The Department identifies specific services and procedures using a set of seven base factors that are identified in rule:

(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;

[3] RCW 70.38.105(4)f).
[4] RCW 70.38.025(14).

(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 a significant risk or consequence.[5]

(Hereinafter, the Criteria)

The seven factors listed are not conjunctive and the rule does not call for one factor to be weighted more heavily than the others. Therefore, the Team considered one factor alone could mean the service was tertiary even if the other factors did not.

The Certificate of Need Program (Program) is required to periodically conduct a review of the services it has identified as tertiary services.[6] By rule, the review has three phases. The first period announces to interested parties that a review will to be conducted and offers an opportunity to submit materials for the Department to consider. This period is two months in length and ended on February 27.

Four groups submitted materials. The materials largely focused on two areas: (1) adding NICU Level IV; and (2) either removing Elective PCI or reducing the volume thresholds necessary for a Certificate of Need. The Program disseminated the materials received via the Program listserv and on the DOH website to interested parties shortly after February 27.

Beginning March 16, Program accepted comments on the materials submitted over a thirty-day period. (This is referred to as the "comment period" in rule.)

There were nine comments submitted. Eight of the nine revolved around Elective PCI.[7]

Between April 16 and June 15, the Team conducted an internal review of all materials submitted to the Department. (This is referred to as the "consideration period" in rule.) All seven members reviewed the materials submitted along with the relevant statutes, rules and two pieces of supplemental reference material.[8] The Team also regarded this period as an opportunity to correspond with interested parties to clarify unresolved issues. As detailed in Part III, there was a short exchange with a group who advocate removing Elective PCI from the List.

The time period after June 15 until now has been dedicated to finishing the review, meeting to make sure all members were in consensus and preparing this memorandum.

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[5] WAC 246-310-035(2). The Department is required by rule to review these factors at least every three years to make ensure they continue to accurately define tertiary services.

[6] WAC 246-310-035(3).

[7] The ninth was submitted by the Washington State Hospital Association (WSHA). WSHA did not take a substantive position regarding either NICU Level IV or Elective PCI, but endorsed the Program's review of tertiary services and the process the Program chose to use.

[8] Respectively: (i) Washington State Level of Care Guidelines for Perinatal and Neononatal Care, February 2013; and (ii) Chapter 14: Certificate of Need, Washington Health Law Manual, 3rd edition, 2010.

Part II – NICU Level 4

The List currently contains two services that relate to neonatal and obstetric care: Level II and Level III.[9] In 2013, the Department through the Perinatal Advisory Committee convened a technical workgroup to review the level of care guidelines for perinatal and neonatal care.[10] That workgroup was precipitated by an American Academy of Pediatrics recommendation to use uniform, nationally applicable definitions and consistent standards of service. The resulting guidelines essentially split Level III into two parts, the latter of which was designated Level IV. Currently, there are thirteen institutions that are designated Level III providers. Of those, the Program has determined four are also providing services that would fit under the Level IV designation.

The guidelines are self-explanatory, but the most concise summary is that a Level IV institution is a Level III institution with certain additions that allow for care of the small population of the most ill neonates.

Specifically, a Level IV institution must have: (a) an on-site roster of pediatric medical and surgical subspecialists as well as pediatric anesthesiologists; (b) a multi-disciplinary team for management of orthopedic and neurological anomalies; (c) surgical capabilities that contemplate repair of complex conditions that may require cardiopulmonary bypass, extracorporeal membrane oxygenation (ECMO), dialysis, tracheostomy and similar procedures; (d) a neuro-developmental follow-up program; (e) quality improvement program with comparison to national benchmarks for other Level IV institutions; and (f) a training and educational relationship with referring hospitals.

In applying the factors to determine whether NICU Level IV is a tertiary service, it is important to note that all of the care provided under NICU Level IV is already a tertiary service under the current Level III. However, a brief review showed that this care fits the Criteria:

a. Dependent on skills and coordination of specialty and subspecialty providers. No less than twenty-two medical subspecialties and no less than thirteen surgical subspecialties could be involved in NICU Level IV care.

b. Acute care hospital access. NICU Level IV care always requires immediate access to a hospital.

[9] WAC 246-310-020(1)(d)(i)(B), (C).
[10] Note the 2013 Guidelines did not add a Level IV for obstetrics.

c. Few providers. Only four institutions in Washington are currently providing care equivalent to NICU Level IV.

d. Service broader than a procedure. The advocates for inclusion of NICU Level IV interpret this factor to rely on diagnosis –related groups, and the Team endorsed that approach. The primary advocate for inclusion conducted a survey of its "recent Level IV cases." The survey revealed less than seventeen separate DRGs. Without further data, it is not possible to verify this result as a representative sample. However, the wide range of medical and surgical subspecialties that fall under the Guideline definitions make this at the very least a plausible representative sample. Therefore, NICU Level IV is broader than a procedure.

e. Low use rate. Data submitted indicates a volume of approximately 1.4% of all births in 2013 meet criteria for NICU Level IV. While the definition of "low" in the Criteria is vague, the Team believed 1.4% of all births represents a commonsense threshold for a low use rate.

f. Volume correlated to structure, process and outcomes. This factor was non-conclusive. There does not appear to be consensus or published research.

g. Significant risk or consequence. Data submitted indicates a mortality rate of 15% which is slightly less than double the next highest tertiary service mortality rate, heart transplants. "Significant risk or consequence" is not more specifically defined in rule. Additionally, there is no quantitative factor of how often a specific risk or consequence must occur in order to be relevant to a discussion of significance. Even with those limitations in mind, the Team believed a 15% mortality rate would be toward the far end of a more specific definition.

The Team regards the addition of NICU Level IV as an administrative housekeeping item. The adoption of the 2013 Guidelines was non-controversial and the Program already has the technical capability to add this item. Potential rule-making to add NICU Level IV will also require some revision of the Level III as parts of the definition will no longer be applicable.

Part III Elective PCI

The List includes Elective PCI as part of a larger definition that includes open heart surgery:

> "Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous translumenal coronary angioplasty (PTCA). Open heart surgery includes the care of patients who have surgery requiring the use of a heart lung bypass machine. Therapeutic cardiac catheterization means passage of a tube or other device into the coronary arteries or the

> heart chambers to improve blood flow. PTCA means the treatment of a narrowing of a coronary artery by means of inflating a balloon catheter at the site of the narrowing to dilate the artery[.]"[11]

No party submitted material concerning open heart surgery and therefore the Team did not consider open heart surgery as part of its review. Additionally, there were several comments received in both the initial phase of the review and the comment period that endorsed a reduction in institutional and individual practitioner volume standards. The current volume standards are three hundred (300)[12] and seventy-five (75)[13], respectively. While there is academic research that supports reconsidering those volume standards[14], the Team believed this issue fell outside the scope of whether the service should be on the List generally.

Elective PCI is by its very definition an outlier on the List because an institution does not need a Certificate of Need in order to perform PCI on emergent cases. Emergent cases are arguably more complex than those deemed elective. The Department's rationale when the List was originally put into rule in 1991 was the risk of transport in emergent cases outweighed the benefit in requiring an institution to have a Certificate of Need in order to provide the care. So while it may not seem intuitive to require a Certificate of Need for arguably more complex cases, there is an underlying rationale and the Team endorses absent compelling clinical data to the contrary.

Notably, unlike any other tertiary service, there are both statutes and rules that apply to Elective PCI and no other tertiary service. As outlined above, tertiary services require a Certificate of Need. Removal from the List would normally remove the legal requirement to receive a Certificate of Need from the Program in order to provide Elective PCI. However, in 2007, the Legislature added a statute that requires a Certificate of Need for Elective PCI without regard to tertiary service designation in hospitals that do not otherwise provide on-site cardiac surgery.[15] This consideration did not directly impact the Team's application of the Criteria to Elective PCI, but it is worth noting as another way in which Elective PCI is different than other tertiary services.

Application of the Criteria:

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[11] WAC 246-310-020(1)(d)(i)(E).
[12] WAC 246-310-720(1).
[13] WAC 246-310-725.
[14] See Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures, Journal of the American College of Cardiology, Vol. 62, No. 4 (2013), Section 2.8.3, page 374.
[15] RCW 70.38.128.

a. Dependent on skills and coordination of specialty and subspecialty providers. Elective PCI requires a highly specialized team of interventional cardiologists, nurses, lab technicians and imaging staff. The advocates for removal stressed that this factor was applicable to many acute care services and some of those services were considered tertiary and some were not. The Team acknowledged that may be the case, however the plain language of the factor is easily met nonetheless in the case of Elective PCI.

b. Acute care hospital access. All parties that applied the factors acknowledged that Elective PCI requires access to an acute care hospital and the Team agreed.

c. Few providers. Currently, ten of Washington's hospitals are performing Elective PCI without also performing open heart surgery. No matter how the data is reviewed, applying a standard definition of "few", there are not few providers of Elective PCI in Washington State.

d. Service broader than a procedure. Here it is important to note the List refers specifically to "elective therapeutic cardiac catheterization." The Department has adopted rules that define "percutaneous coronary interventions" as "invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

(a) Bare and drug-eluting stent implantation;

(b) Percutaneous transluminal coronary angioplasty (PTCA);

(c) Cutting balloon atherectomy;

(d) Rotational atherectomy;

(e) Directional atherectomy;

(f) Excimer laser angioplasty;

(g) Extractional thrombectomy.

The Team interpreted this latter definition to be a subset of the broader definition found in the List. Advocates for and against both agreed that, at a minimum, six DRGs applied to Elective PCI. Advocates for maintaining Elective PCI on the List felt that another twelve DRGs also applied and those DRGs represented a minimum of fourteen separate ICD-9 procedure codes. In reviewing the submitted material, the Team again believed DRGs were an adequate way to gauge the variety in the service and when coupled with ICD-9 procedure codes and the need for substantial coordination between multi-disciplinary providers both pre- and post-procedure, there was sufficient support to say the service was broader than a procedure.

e. Low use rate. Material submitted differed on what could be categorized as a low use rate. No matter which statistical method is chosen, the parties agreed that PCI is used at a rate higher than four of the other tertiary services, but lower than two of the other tertiary services. If the number of discharges is adjusted to only represent truly elective procedures, the use rate falls further. Again, the Criteria does not offer much guidance, but the Team felt that so long as the use rate was in line with other tertiary services, it was appropriate to say Elective PCI has a low use rate.

f. Volume correlated to structure, process and outcomes. There is substantial and conclusive research that supports the conclusion that volume standards are a necessary aspect to maintain structure, process and outcomes of care.[16]

g. Significant risk or consequence. Elective PCI carries a lower mortality risk than almost all other tertiary services. However, it is an interventional cardiac procedure associated with significant life-threatening risks including stroke, heart attack, rupture of a coronary artery. As detailed previously, this factor does not call for an evaluation of how often a risk or consequence must occur to count. However, the risks to a patient are certainly significant and therefore the Team believed this factor was also met. Additionally, the Team noted the lifelong consequences of Elective PCI in the lives of patients, including use of antiplatelet medications as support for this factor.

Six of the factors from the Criteria were clearly met. There are valid, substantive arguments on both sides of the issue. However, in light of the Program's statutory mandate to "promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources while controlling increases in costs, and recognize prevention as a high priority in health programs,"[17] the Team found that the first, second and seventh factors were particularly important in the case of Elective PCI. All of those factors support inclusion. Therefore, the Team concluded there was substantial support for leaving Elective PCI on the List.

[16] Id. Fn 14.
[17] RCW 70.38.015(1).

Attachment 2
Referenced Articles

Catheterization and Cardiovascular Interventions 00:00–00 (2014)

Clinical Decision Making

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

Gregory J. Dehmer,[1*] MD, James C. Blankenship,[2] MD, Mehmet Cilingiroglu,[3] MD, James G. Dwyer,[4] MD, Dmitriy N. Feldman,[5] MD, Timothy J. Gardner,[6] MD, Cindy L. Grines,[7] MD, and Mandeep Singh,[8] MD, MPH

Key words: angioplasty; coronary artery bypass surgery; consensus

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

[1]Baylor Scott & White Health, Central Texas, Temple, TX. SCAI Writing Committee Member and Chair
[2]Geisinger Health System, Danville, PA. SCAI Writing Committee Member
[3]Arkansas Heart Hospital, Little Rock, AR. SCAI Writing Committee Member
[4]Heart and Vascular Center of Northern Arizona, Flagstaff, AZ. SCAI Writing Committee Member
[5]New York Presbyterian Hospital, New York, NY. SCAI Writing Committee Member
[6]Christiana Care Health System, Newark, DE. AHA Writing Committee Member
[7]Detroit Medical Center, Detroit, MI. SCAI Writing Committee Member
[8]Mayo Clinic, Rochester MN. ACC Writing Committee Member

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Conflict of interest: See Appendix 1.

*Correspondence to: Gregory J. Dehmer, Cardiology Division, [MS 33 ST156], BaylorScott & White Health, Central Texas 2401 South 31st Street, Temple, TX 76513. E-mail: gdehmer@sw.org

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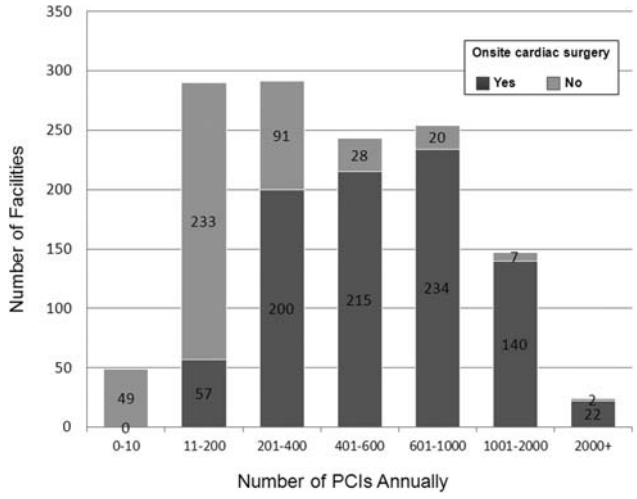

Fig. 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref [8] with permission. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Coronary Artery Interventional Procedures have been published [3,4].

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

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents related to PCI without on-site surgery and summarize all relevant information into a single resource document;
4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30% [5]. Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria [5,6]. As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually [7]. Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed $\leq$400 PCIs and 26% performed $\leq$200 PCIs annually (Fig. 1) [8]. Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of $\leq$200 PCI procedures. F1

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states. Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial [9]. Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being revaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration [10]. F2

Recent Literature on PCI Without On-site Surgery

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

Primary PCI without on-site surgery. Seven studies and 2 meta-analyses of primary PCI showed no

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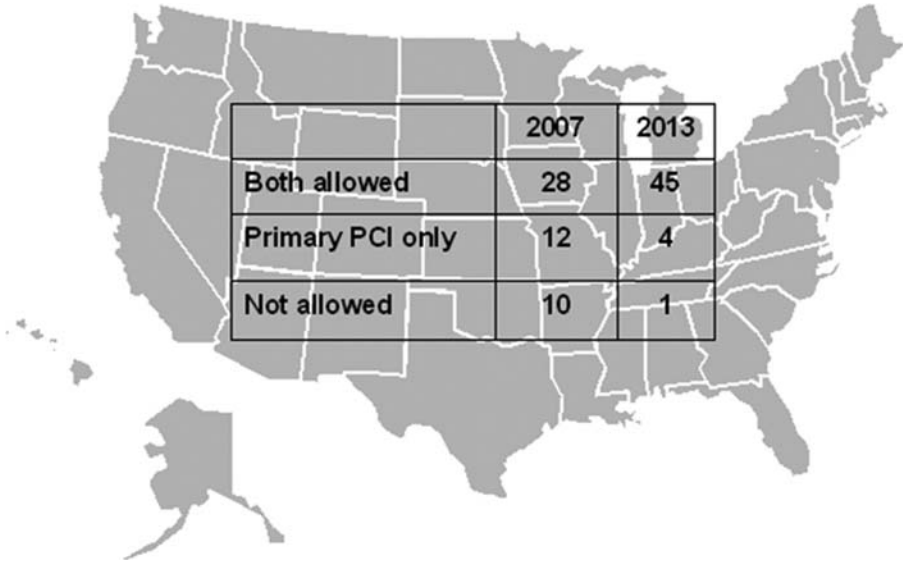

Fig. 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table I). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79) [20].

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

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000 patients in a 1 : 3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively [9]. High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($P = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($P = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals [11]. The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P < 0.001$ for noninferiority) and 17.3% and 17.8%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P < 0.001$ for noninferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery [19,20,23]. Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $P = 0.04$) [20]. However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials [9,11]. Therefore, based on these

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TABLE I. Studies on Primary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) [12]	Multicenter SCAAR Registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007) [13]	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008) [14]	Multicenter Portuguese Registry	No	1214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1470	4.0		2.7		
Kutcher (2009) [15]	Multicenter NCDR Registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009) [16]	Multicenter NRMI Database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009) [17]	Multicenter New York State Database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009) [18]	3 sites Mayo Clinic experience	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
		Yes	667	3.1		0.6		
Meta-analyses								
Zia [2011] [19]		No	8703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97386	7.6		3.4		
Singh M [2011] [20]		No	16489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107585	7.2		1.03		

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

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TABLE II. Studies on Nonprimary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) [12]	Multicenter SCAAR	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
	Registry	Yes	20,930	0.66		0.2		
Frutkin (2008) [21]	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008) [14]	Multicenter Portuguese	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
	Registry	Yes	5584	0.7		2.1		
Kutcher (2009) [15]	Multicenter NCDR	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
	Registry	Yes	268,312	0.8		0.3		
Pride (2009) [22]	Multicenter NRMI	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
	Registry	Yes	1,282	1.3				
Singh (2009) [18]	3 sites Mayo clinic	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
	Experience	Yes	1,842	0.4		0.2		
Aversano (2012) [9]	Multicenter Randomized Trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013) [11]	Multicenter Randomized Trial	No	2774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011) [19]		No	28552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881261	2.1		0.9		
Singh M (2011) [20]		No	30423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883865	0.8		0.29		
Singh PP (2011) [23]		No	1812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4039	0.72		0.02		

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

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recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

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

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

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery [2]. Primary PCI was assigned a class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a class IIb recommendation. Elective PCI, previously assigned a class III recommendation, was given a class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document [1]. New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document [4]. In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery [26].

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

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

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

In addition to defining numerous requirements for operator competency, new operator, and facility PCI

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

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

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

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

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

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

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

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand

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

AHA Policy Statement on PCI Without Surgical Backup

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

Mission Lifeline

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

Door-to-Balloon Alliance

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

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population ($\geq$18 years of age) who lived within 60 min of a PCI hospital [46]. An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to only 79.9%, with the median driving time reduced by <1 min to 10.5 min [47]. Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan

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where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population [48]. Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access [49]. In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

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

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

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

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

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TABLE III. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in $\leq$30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery*. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral*.	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data [via T-1 transmission line] as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required*. Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table V).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories [both primary and elective PCI, with and without on-site cardiac surgery] performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility for a STEMI patient is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

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TABLE III. *Continued*

General Recommendations	Source
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including:	2009 PCI-GL
• Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes.	2011 PCI-GL
• A process for prehospital identification and activation.	
• Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center.	ML D2B
• A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers.	
• Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis:	ML
a. Door-to-first device time, nontransfer patients	
b. STEMI Referral Hospital ED door-to-balloon [first device used] time	
c. First medical contact to balloon inflation [first device used] time, nontransfer patients	
d. First medical contact to balloon inflation [first device used] time, transfer patients	
e. Proportion of eligible patients receiving reperfusion therapy	
f. Proportion of eligible patients administered guideline-based class I therapies	
g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who	
i. do not undergo acute catheterization because of misdiagnosis	
ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h	
h. In-hospital mortality	

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

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

Italics font: New or modified recommendation in the document.

Recommendations

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

TABLE IV. Personnel Requirements for PCI Programs Without On-Site Surgery

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

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

Italics font: New or modified recommendation in the document.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document (4) (Table III). Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access [46–49]. If the transfer time is ≤30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

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

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

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

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

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their

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TABLE VI. Patient and Lesion Characteristics That Could be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

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

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

performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistically certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized [67,68]. Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence [ACE] are recommended as resources for improving quality [69,70].

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site

surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and
T4 >36 primary PCI procedures annually (Table IV). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardi-
T5 ologists and cardiac surgeons are listed in Table V. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table V, and criteria for identifying high-risk lesions
T6 and patients are contained in Table VI. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery [18,71]. However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

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

REFERENCES

1. Dehmer GJ, Blankenship J, Wharton TP Jr, Seth A, Morrison DA, DiMario C, Muller D, Kellett M, Uretsky BF. The current status and future direction of percutaneous coronary intervention without on-site surgical backup: An expert consensus document from the Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv 2007;69:471–478.
2. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. A report of the American College of Cardiology Foundation/

American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol 2011;58:e44–e122.

3. Bashore TM, Balter S, Barac A, Byrne JG, Cavendish JJ, Chambers CE, Hermiller JB Jr, Kinlay S, Landzberg JS, Laskey WK, McKay CR, Miller JM, Moliterno DJ, Moore JWM, Oliver-McNeil SM, Popma JJ, Tommaso CL. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update. J Am Coll Cardiol 2012;59:2221–2305.
4. Harold JG, Bass TA, Bashore TM, Brindis RG, Brush JE, Burke JA, Dehmer GJ, Deychak YA, Jneid H, Jollis JG, Landzberg JS, Levine GN, McClurken JB, Messenger JC, Moussa ID, Muhlestein JB, Pomerantz RM, Sanborn TA, Sivaram CA, White, CJ, Williams ES. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A report of the American College of Cardiology Foundation/American Heart Assocation/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol 2013;62:357–396.
5. Laslett LJ, Alagona P, Clark BA, Drozda JP, Saldivar F, Wilson SR, Poe C, Hart M. The worldwide environment of cardiovascular disease: Prevalence, diagnosis, therapy, and policy issues. J Am Coll Cardiol 2012;60:S1–S49.
6. Yeh RW, Sidney S, Chandra M, Sorel M, Selby JV, Go AS. Population trends in the incidence and outcomes of acute myocardial infarction. N Engl J Med 2010;362:2155–2165.
7. Maroney J, Khan S, Powell W, Klein LW. Current operator volumes of invasive coronary procedures in medicare patients: Implications for future manpower needs in the catheterization laboratory. Catheter Cardiovasc Interv 2013;81:34–39.
8. Dehmer GJ, Weaver D, Roe MT, Milford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, Brindis RG. A contemporary view of diagnostic cardiac catheterization and percutaneous coronary intervention in the United States: A report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011. J Am Coll Cardiol 2012;60:2017–2031.
9. Aversano T, Lemmon CC, Liu L;Atlantic CPORT Investigators. Outcomes of PCI at hospitals with or without on-site cardiac surgery. N Engl J Med 2012;366:1792–1802.
10. Personal communication. John Rumsfeld, MD PhD. National Director of Cardiology, U.S. Veterans Health Administration.
11. Jacobs AK, Normand SL, Massaro JM, Cutlip DE, Carrozza JP Jr, Marks AD, Murphy N, Romm IK, Biondolillo M, Mauri L; the MASS COMM Investigators. Nonemergency PCI at hospitals with or without on-site cardiac surgery. New Eng J Med 2013;368:1498–1508.
12. Carlsson J, James SN, Ståhle E, Höfer S, Lagerqvist B. Outcome of percutaneous coronary intervention in hospitals with and without on-site cardiac surgery standby. Heart 2007;93:335–338.
13. Peels HO, de Swart H, Ploeg TV, Hautvast RW, Cornel JH, Arnold AE, Wharton TP, Umans VA. Percutaneous coronary intervention with off-site cardiac surgery backup for acute myocardial infarction as a strategy to reduce door-to-balloon time. Am J Cardiol 2007;100:1353–1358.
14. Pereira H, da Silva PC, Gonçalves L, José B;Investigadores do Registo Nacional de Cardiologia de Intervenção. Elective and primary angioplasty at hospitals without on-site surgery versus with on-site surgery: results from a national registry. Rev Port Cardiol 2008;27:769–782.
15. Kutcher MA, Klein LW, Ou FS, Wharton TP Jr, Dehmer GJ, Singh M, Anderson HV, Rumsfeld JS, Weintraub WS, Shaw RE, Sacrinty MT, Woodward A, Peterson ED, Brindis RG;National Cardiovascular Data Registry. Percutaneous coronary interventions in facilities without cardiac surgery on site: A report from the National Cardiovascular Data Registry (NCDR). J Am Coll Cardiol 2009;54:16–24.
16. Pride YB, Canto JG, Frederick PD, Gibson CM;NRMI Investigators. Outcomes among patients with ST-segment-elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. Circ Cardiovasc Qual Outcomes 2009;2:574–582.
17. Hannan EL, Zhong Y, Racz M, Jacobs AK, Walford G, Cozzens K, Holmes DR, Jones RH, Hibberd M, Doran D, Whalen D, King SB III. Outcomes for patients with ST-elevation myocardial infarction in hospitals with and without onsite coronary artery bypass graft surgery: the New York State experience. Circ Cardiovasc Interv 2009;2:519–527.
18. Singh M, Gersh BJ, Lennon RJ, Ting HH, Holmes DR Jr, Doyle BJ, Rihal CS. Outcomes of a system-wide protocol for elective and nonelective coronary angioplasty at sites without on-site surgery: The Mayo Clinic experience. Mayo Clin Proc 2009;84:501–508.
19. Zia MI, Wijeysundera HC, Tu JV, Lee DS, Ko DT. Percutaneous coronary intervention with vs without on-site cardiac surgery backup: A systematic review. Can J Cardiol 2011;27:664.e9–16.
20. Singh M, Holmes DR Jr, Dehmer GJ, Lennon RJ, Wharton TP, Kutcher MA, Aversano T, Rihal CS. Percutaneous coronary intervention at centers with and without on-site surgery: A meta-analysis. JAMA 2011;306:2487–2494.
21. Frutkin AD, Mehta SK, Patel T, Menon P, Safley DM, House J, Barth CW III, Grantham JA, Marso SP. Outcomes of 1,090 consecutive, elective, nonselected percutaneous coronary interventions at a community hospital without onsite cardiac surgery. Am J Cardiol 2008;101:53–57.
22. Pride YB, Canto JG, Frederick PD, Gibson CM;NRMI Investigators. Outcomes among patients with non-ST-segment elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. JACC Cardiovasc Interv 2009;2:944–952.
23. Singh PP, Singh M, Bedi US, Adigopula S, Singh S, Kodumuri V, Molnar J, Ahmed A, Arora R, Khosla S. Outcomes of nonemergent percutaneous coronary intervention with and without on-site surgical backup: A meta-analysis. Am J Ther 2011;18:e22–e28.
24. Kushner FG, Hand M, Smith SC Jr, King SB 3rd, Anderson JL, Antman EM, Bailey SR, Bates ER, Blankenship JC, Casey DE Jr, Green LA, Hochman JS, Jacobs AK, Krumholz HM, Morrison DA, Ornato JP, Pearle DL, Peterson ED, Sloan MA, Whitlow PL, Williams DO. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update): A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2009;54:2205–2241.
25. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG,

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Creager MA, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–e140.

26. Hillis L, Smith PK, Anderson JL, Bittl JA, Bridges CR, Byrne JG, Cigarroa JE, DiSesa VJ, Hiratzka LF, Hutter AM Jr, Jessen ME, Keeley EC, Lahey SJ, Lange RA, London MJ, Mack MJ, Patel MR, Puskas JD, Sabik JF, Selnes O, Shahian DM, Trost JC, Winniford MD, Jacobs AK, Anderson JL, Albert N, Creager MA, Ettinger SM, Guyton RA, Halperin JL, Hochman JS, Kushner FG, Ohman EM, Stevenson W, Yancy CW. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. J Am Coll Cardiol 2011;58:e123–e210.
27. Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS);European Association for Percutaneous Cardiovascular Interventions (EAPCI), Wijns W, Kolh P, Danchin N, Di Mario C, Falk V, Folliguet T, Garg S, Huber K, James S, Knuuti J, Lopez-Sendon J, Marco J, Menicanti L, Ostojic M, Piepoli MF, Pirlet C, Pomar JL, Reifart N, Ribichini FL, Schalij MJ, Sergeant P, Serruys PW, Silber S, Sousa Uva M, Taggart D. Guidelines on myocardial revascularization. Eur Heart J 2010;31:2501–2555.
28. Steg PG, James SK, Atar D, Badano LP, Blömstrom-Lundqvist C, Borger MA, Di Mario C, Dickstein K, Ducrocq G, Fernandez-Aviles F, Gershlick AH, Giannuzzi P, Halvorsen S, Huber K, Juni P, Kastrati A, Knuuti J, Lenzen MJ, Mahaffey KW, Valgimigli M, van 't Hof A, Widimsky P, Zahger D. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012;33:2569–2619.
29. Widimsky P, Wijns W, Fajadet J, de Belder M, Knot J, Aaberge L, Andrikopoulos G, Baz JA, Betriu A, Claeys M, Danchin N, Djambazov S, Erne P, Hartikainen J, Huber K, Kala P, Klinceva M, Kristensen SD, Ludman P, Ferre JM, Merkely B, Milicic D, Morais J, Noc M, Opolski G, Ostojic M, Radovanovic D, De Servi S, Stenestrand U, Studencan M, Tubaro M, Vasiljevic Z, Weidinger F, Witkowski A, Zeymer U. Reperfusion therapy for ST elevation acute myocardial infarction in Europe: Description of the current situation in 30 countries. Eur Heart J 2010;31:943–957.
30. Gershlick AH, Banning AP, Myat A, Verheugt FWA, Gersh BJ. Reperfusion therapy for STEMI: Is there still a role for thrombolysis in the era of primary percutaneous coronary intervention? Lancet 2013;382:624–632.
31. Dawkins KD, Gershlick T, de Belder M, Chauhan A, Venn G, Schofield P, Smith D, Watkins J, Gray HH,Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society. Coronary angioplasty: Guidelines for good practice and training. Heart 2005;91(Suppl VI):vi1–vi27.
32. Guidelines on Support Facilities for Coronary Angiography and Percutaneous Coronary Intervention (PCI) including Guidelines on the Performance of Procedures in Rural Sites. The Cardiac Society of Australia and New Zealand (2011). Available at: http://www.csanz.edu.au/LinkClick.aspx?fileticket=XwJu1B7jn9k%3d&tabid=170 Accessed August 19, 2013.
33. Oliveras EE, Hernández Antolín RA, Bescós LL, Burgos JM, Moya-Prats JLP. Requirements to perform coronary interventions at hospitals without coronary surgery. Guidelines of the Spanish Society of Cardiology. Rev Esp Cardiol 1999;52:5–12.
34. Fernández-Avilés F, Alonso Martín J, María Augé Sanpera J, García Fernández E, Macaya de Miguel C, Melgares Moreno R, Valdés Chavarri M. Continuous practice and advanced training in interventional cardiology. Recommendations for the assessment and maintenance of proficiency in interventional cardiology. A statement for physicians and advanced training units from the Section of Hemodynamics and Interventional Cardiology of the Spanish Society of Cardiology. Rev Esp Cardiol 2000;53:1613–1625.
35. Morís De La Tassa C, Cequier Fillat AR, Moreu Burgos J, Pérez Hernández H, Aguirre Salcedo JM;Sociedad Española de Cardiología. Guidelines of the Spanish Society of Cardiology on requirements and equipment in hemodynamic and interventional cardiology. Rev Esp Cardiol 2001;54:741–750.
36. Moura AV, Gottschall CA, Costa EA, Falcao FC, Prudente ML, Furtado RJC. Sociedade Brasileira de Cardiologia. Guidelines for the indications and use of percutaneous interventions and intracoronary stent in clinical practice. Arq Bras Cardiol 2003; 80:1–14.
37. Deutsche Gessellschaft fur Herz- und Kreislaufforschung. Kommission fur Klinische Kardiologie (unter Mitwirking der Arbeits- gruppe Transluminale Angioplastie): Empfehlungen fur die Durchfuhrung der Perkutanen Transluminalen Koronarangioplas- tie (PTCA). Z Kardiol 1987;76:382–385.
38. Tebbe U, Hochadel M, Bramlage P, Kerber S, Hambrecht R, Grube E, Hauptmann KE, Gottwik M, Elsässer A, Glunz HG, Bonzel T, Carlsson J, Zeymer U, Zahn R, Senges J. In-hospital outcomes after elective and non-elective percutaneous coronary interventions in hospitals with and without on-site cardiac surgery backup. Clin Res Cardiol 2009;98:701–707.
39. Legrand V, Wijns W, Vandenbranden F, Benit E, Boland J, Claeys M, De Scheerder I, Eemans T, Hanet C, Heyndrickx G, Lafontaine P, Materne P, Taeymans Y, Vrints C, Vrolix M. Belgian Working Group on Invasive Cardiology. Guidelines for percutaneous coronary intervention by the Belgian Working Group on Invasive Cardiology. Acta Cardiol 2003;58:341–348.
40. Percutaneous Coronary Intervention (PCI) without Surgical Back-up Policy Guidance March 7, 2012. Available at: www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_437472.pdf Accessed June 19, 2013.
41. Jacobs AK, Antman EM, Faxon DP, Gregory T, Solis P. Development of systems of care for ST-elevation myocardial infarction patients: Executive summary. Circulation 2007;116:217–230.
42. Jacobs AK, Antman EM, Ellrodt G, Faxon DP, Gregory T, Mensah GA, Moyer P, Ornato J, Peterson ED, Sadwin L, Smith SC. Recommendation to develop strategies to increase the number of ST-segment-elevation myocardial infarction patients with timely access to primary percutaneous coronary intervention. Circulation 2006;113:2152–2163.
43. Mission Lifeline Program. http://www.heart.org/HEARTORG/HealthcareResearch/MissionLifelineHomePage/Mission-Lifeline-Home-Page_UCM_305495_SubHomePage.jsp. Accessed March 31, 2013.
44. D2B Alliance. Available at: http://www.d2balliance.org Accessed August 16, 2013.
45. Bradley EH, Nallamothu BK, Herrin J, Ting HH, Stern AF, Nembhard IM, Yuan CT, Green JC, Kline-Rogers E, Wang Y, Curtis JP, Webster TR, Masoudi FA, Fonarow GC, Brush JE Jr, Krumholz HM. National efforts to improve door-to-balloon time

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results from the Door-to-Balloon Alliance. J Am Coll Cardiol 2009;54:2423–2429.
46. Nallamothu BK, Bates ER, Wang Y, Bradley EH, Krumholz HM. Driving times and distances to hospitals with percutaneous coronary intervention in the United States: Implications for prehospital triage of patients with ST-elevation myocardial infarction. Circulation 2006;113:1189–1195.
47. Concannon TW, Nelson J, Goetz J, Griffith JL. A percutaneous coronary intervention lab in every hospital? Circ Cardiovasc Qual Outcomes 2012;5:14–20.
48. Buckley JW, Bates ER, Nallamothu BK. Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in Michigan: A geographic information systems analysis. Am Heart J 2008;155:668–672.
49. Horwitz JR, Nichols A, Nallamothu BK, Sasson C, Iwashyna TJ. Expansion of invasive cardiac services in the United States. Circulation 2013;128:803–810.
50. Kinlay S. The trials and tribulations of percutaneous coronary intervention in hospitals without on-site CABG surgery. JAMA 2011;306:2507–2509.
51. Album D, Westin S. Do diseases have a prestige hierarchy? A survey among physicians and medical students. Soc Sci Med 2008;66:182–188.
52. O'Neill WW. A case against low volume percutaneous coronary intervention centers. Circulation 2009;120:546–548.
53. Rittenhouse DR. Primary care and accountable care- two essential elements of delivery-system reform. N Engl J Med 2009; 361:2301–2303.
54. Greaney TL. Accountable care organizations—The fork in the road. N Engl J Med 2011;364:e11.
55. Ho V, Meei-Hsiang K-G, Jollis JG. Certificate of need (CON) for cardiac care: Controversey over the contributions of CON. Health Serv Res 2009;44:483–500.
56. Ross JS, Ho V, Wang Y, Cha SS, Epstein AJ, Masoudi FA, Nallamothu BK, Krumholz HM. Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. Circulation 2007;115:1012–1019.
57. Vaughan-Sarrazin MS, Hannan EL, Gornley CJ. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulations. JAMA 2002;288:1859–1866.
58. Topol EJ, Kereiakes DJ. Regionalization of care for acute ischemic heart disease. Circulation 2003;107:1463–1466.
59. Canto JG, Every NR, Magid DJ, Rogers WJ, Malmgren JA, Frederick PD, French WJ, Tiefenbrunn AJ, Misra VK, Kiefe CI, Barron HV. The volume of primary angioplasty procedures and survival after acute myocardial infarction. N Engl J Med 2000; 342:1573–1580.
60. Srinivas VS, Hailpern SM, Koss E, Monrad ES, Alderman MH. Effect of physician volume on the relationship between hospital volume and mortality during primary angioplasty. J Am Coll Cardiol 2009;53:574–579.
61. Ho V. Evolution of the volume-outcome relation for hospitals performing coronary angioplasty. Circulation 2000;101:1806–1811.
62. Nallamothu BK, Wang Y, Magid DJ, McNamara CV, Krumholz HM. Relation between hospital specialization with primary percutaneous coronary intervention and clinical outcomes in ST-segment elevation myocardial infarction. Circulation 2006;113: 222–229.
63. Hannan EL, Wu C, Walford G, King SB 3rd, Holmes DR Jr, Ambrose JA, Sharma S, Katz S, Clark LT, Jones RH. Volume-outcome relationships for percutaneous coronary interventions in the stent era. Circulation 2005;112:1171–1179.
64. Lieu TA, Gurley RJ, Lundstrom RJ, Ray GT, Fireman BH, Weinstein MC, Parmley WW. Projected cost-effectiveness of primary angioplasty for acute myocardial infarction. J Am Coll Cardiol 1997;30:1741–1750.
65. Long KH, McMurtry EK, Lennon RJ, Chapman AC, Singh M, Rihal CS, Wood DL, Holmes DR Jr, Ting HH. Elective percutaneous coronary intervention without on-site cardiac surgery: clinical and economic implications. Med Care 2006;44:406–413.
66. Kontos MC, Wang Y, Chaudhry SI, Vetrovec GW, Curtis J, Messenger J; on behalf ofthe NCDR. Lower hospital volume is associated with higher in-hospital mortality in patients undergoing primary percutaneous coronary intervention for ST-segment-elevation myocardial infarction: A report from the NCDR. Circ Cardiovasc Qual Outcomes 2013;6:659–667.
67. Klein LW, Uretsky BF, Chambers C, Anderson HV, Hillegass WB, Singh M, Ho KK, Rao SV, Reilly J, Weiner BH, Kern M, Bailey S;Society of Cardiovascular Angiography and Interventions. Quality assessment and improvement in interventional cardiology: A position statement of the Society of Cardiovascular Angiography and Interventions, part 1: Standards for quality assessment and improvement in interventional cardiology. Catheter Cardiovasc Interv 2011;77:927–935.
68. Klein LW, Ho KK, Singh M, Anderson HV, Hillegass WB, Uretsky BF, Chambers C, Rao SV, Reilly J, Weiner BH, Kern M, Bailey S;Society of Cardiovascular Angiography and Interventions. Quality assessment and improvement in interventional cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions, Part II: public reporting and risk adjustment. Catheter Cardiovasc Interv 2011;78:493–502.
69. SCAI Quality Improvement Toolkit [SCAI-QIT]. Available at: http://www.scai.org/QIT/Default.aspx Accessed June 3, 2013.
70. Accreditation for Cardiovascular Excellence. Available at: http://www.cvexcel.org/default.aspx Accessed June 4, 2013.
71. Brennan JM, Curtis JP, Dai D, Fitzgerald S, Khandelwal AK, Spertus JA, Rao SV, Singh M, Shaw RE, Ho KK, Krone RJ, Weintraub WS, Weaver WD, Peterson ED;National Cardiovascular Data Registry. Enhanced Mortality Risk Prediction With a Focus on High-Risk Percutaneous Coronary Intervention: Results From 1,208,137 Procedures in the NCDR (National Cardiovascular Data Registry). JACC Cardiovasc Interv 2013;6:790–799.

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

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

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

*No financial benefit.

†Significant relationship.

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

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PERFORMANCE MEASURES

ACC/AHA/SCAI/AMA–Convened PCPI/NCQA 2013 Performance Measures for Adults Undergoing Percutaneous Coronary Intervention

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures, the Society for Cardiovascular Angiography and Interventions, the American Medical Association–Convened Physician Consortium for Performance Improvement, and the National Committee for Quality Assurance

Developed in Collaboration With the American Association of Cardiovascular and Pulmonary Rehabilitation and Mended Hearts

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and Mended Hearts

WRITING COMMITTEE MEMBERS

Brahmajee K. Nallamothu, MD, MPH, FACC, FAHA, *Co-Chair**; Carl L. Tommaso, MD, FACC, FAHA, FSCAI, *Co-Chair*†; H. Vernon Anderson, MD, FACC, FAHA, FSCAI*; Jeffrey L. Anderson, MD, FACC, FAHA, MACP*; Joseph C. Cleveland, Jr, MD‡; R. Adams Dudley, MD, MBA; Peter Louis Duffy, MD, MMM, FACC, FSCAI†; David P. Faxon, MD, FACC, FAHA*; Hitinder S. Gurm, MD, FACC; Lawrence A. Hamilton, Neil C. Jensen, MHA, MBA; Richard A. Josephson, MD, MS, FACC, FAHA, FAACVPR§; David J. Malenka, MD, FACC, FAHA*; Calin V. Maniu, MD, FACC, FAHA, FSCAI†; Kevin W. McCabe, MD; James D. Mortimer, Manesh R. Patel, MD, FACC*; Stephen D. Persell, MD, MPH; John S. Rumsfeld, MD, PhD, FACC, FAHA‖; Kendrick A. Shunk, MD, PhD, FACC, FAHA, FSCAI*; Sidney C. Smith, Jr, MD, FACC, FAHA, FACP¶; Stephen J. Stanko, MBA, BA, AA#; Brook Watts, MD, MS

*ACC/AHA Representative. †Society of Cardiovascular Angiography and Interventions Representative. ‡Society of Thoracic Surgeons Representative. §American Association of Cardiovascular and Pulmonary Rehabilitation Representative. ‖ACC/AHA Task Force on Performance Measures Liaison. ¶National Heart Lung and Blood Institute Representative. #Mended Hearts Representative.

The measure specifications were approved by the American College of Cardiology Board of Trustees, American Heart Association Science Advisory and Coordinating Committee, in January 2013 and the American Medical Association–Physician Consortium for Performance Improvement in February 2013.

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ACC/AHA TASK FORCE ON PERFORMANCE MEASURES
Eric D. Peterson, MD, MPH, FACC, FAHA, *Chair*;
Paul A. Heidenreich, MD, MS, FACC, FAHA, *Chair-Elect*; Nancy M. Albert, PhD, CCNS, CCRN, FAHA;
Paul S. Chan, MD, MSc, FACC; Lesley H. Curtis, PhD; T. Bruce Ferguson, Jr, MD, FACC;
Gregg C. Fonarow, MD, FACC, FAHA; Marjorie Funk, RN, PhD, FAHA, FAAN;
P. Michael Ho, MD, PhD, FACC, FAHA; Kathy J. Jenkins, MD, MPH, FACC;
Sean O'Brien, PhD; Paul D. Varosy, MD, FACC; Henry H. Ting, MD, MBA, FACC, FAHA

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Preamble

American College of Cardiology (ACC)/American Heart Association (AHA) performance measure sets can serve as vehicles to accelerate appropriate translation of scientific evidence into clinical practice. These documents are intended to provide practitioners and institutions that deliver cardiovascular services with tools to measure the

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quality of their care and identify opportunities for improvement.

The present set of measures breaks important ground for performance measurement. Here, the writing committee was charged with developing measures to benchmark and improve the quality of one of cardiology's most common and important procedures: percutaneous coronary intervention (PCI). In this task, the ACC/AHA Task Force on Performance Measures partnered with representatives from several other organizations, including the Society for Cardiovascular Angiography and Interventions (SCAI), the American Medical Association (AMA)–Convened Physician Consortium for Performance Improvement® (PCPI), and the National Committee for Quality Assurance (NCQA). These bodies provided invaluable input in the development and review of these measures.

The writing committee was instructed to follow the methodology of performance measure development (1,2) and to assure that the measures developed were aligned with national standards so as to promote harmony across measures. The writing committee was also charged with constructing measures that maximally capture multiple important aspects of quality (timeliness, safety, effectiveness, efficiency, equity, and patient-centeredness) while minimizing the reporting burden imposed on participants.

As in other cases, all selected measures pose potential challenges to implementation that could result in unintended consequences. The manner in which these issues are addressed is dependent on several factors, including the measure design, data collection method, performance attribution, baseline performance rates, reporting methods, and incentives linked to these reports. These implementation challenges are appropriately discussed in individual sections dedicated to each of the measures.

These new performance measures for PCI are notable for several reasons. First, the writing committee considered the key initial question of whether performing the procedure was "appropriate," in line with a growing body of evidence in this area. Determining procedural appropriateness of PCI is complex and requires comprehensive documentation of the procedure's priority, the presence and severity of angina symptoms, the use of antianginal medical therapies, and the presence and severity of stenosis (as documented by angiography or other metrics of lesion severity, e.g., intravascular ultrasound or fractional flow reserve). The present PCI performance measure set represents the first time in the cardiology literature that a specific performance measure has been constructed to address procedural appropriateness.

Next, the writing committee listed important tasks to be done by the care team before the procedure, including determining whether the patient can and would be likely to take dual-antiplatelet therapy on an ongoing basis (an important requirement if drug-eluting stents are to be used), as well as documenting the patient's renal function (which can influence both the patient's candidacy for the procedure and procedural strategies—e.g., amount of iodinated contrast). Many procedural and postprocedural factors that can affect patient outcomes are considered in this measure set, such as the use of embolic protection devices and the documentation of ionized radiation and iodinated contrast dosage. The writing committee also put the procedure in the context of patients' longitudinal disease process. Specifically, they considered that procedural quality must extend beyond the laboratory and should involve implementation of appropriate secondary prevention cardiac rehabilitation and medications to modify long-term risk. Finally, the writing committee considered other indicators of quality related to the interventionalist and the institution. These measures include such factors as procedural volume and whether the institution routinely tracks and benchmarks their care relative to others in clinical registries.

Combined, these PCI metrics break important new ground. As noted by the authors, the field of quality assessment and performance measurement in PCI is maturing, and many advances are still needed. Nevertheless, this initial metric set provides a solid foundation for quality improvement in the field and sets the stage for future advancement.

Eric D. Peterson, MD, MPH, FACC, FAHA
Chair, ACC/AHA Task Force on Performance Measures

1. Introduction

The ACC/AHA/SCAI/AMA-PCPI/NCQA Percutaneous Coronary Interventions Performance Measures Writing Committee (the writing committee) was charged with creating the first performance measure set in this area. In this measure set, the writing committee presents 11 measures, which are intended for ambulatory and hospital (inpatient) settings. The measure set is summarized in Table 1.

1.1. Scope of the Problem

The ACC/AHA/SCAI/AMA-PCPI/NCQA 2013 PCI performance measurement set, which is available on the PCPI Web site at http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi?submit=PCPI, discusses in detail the scope of the problem and opportunities for improving the quality of care provided to patients undergoing PCI.

1.2. Structure and Membership of the Writing Committee

The members of the writing committee included clinicians specializing in interventional cardiology, general cardiology, internal medicine, cardiac surgery, and cardiac rehabilitation, as well as individuals with expertise in guideline development and performance measure development, implementation, and testing. The writing committee also included patient/consumer representatives and a payer

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Table 1. 2013 ACC/AHA/SCAI/AMA-PCPI/NCQA Percutaneous Coronary Intervention Measurement Set

Measure	Description*
1. Comprehensive Documentation of Indications for PCI†	Percentage of patients aged ≥18 years for whom PCI is performed with comprehensive documentation of the procedure. This documentation includes, at a minimum, the following elements: 1. Priority (acute coronary syndrome, elective, urgent, emergency/salvage); 2. Presence and severity of angina symptoms (e.g., Canadian Cardiovascular Society classification system); 3. Use of antianginal medical therapies within 2 weeks before the procedure, if any; 4. Presence, results, and timing of noninvasive stress test, fractional flow reserve, or intravascular ultrasound, if performed; and 5. Significance of angiographic stenosis (may be quantitative or qualitative) on coronary angiography for treated lesion.
2. Appropriate Indication for Elective PCI‡	Percentage of patients aged ≥18 years for whom elective PCI is performed in a native coronary artery who have an appropriate indication for the procedure that suggests its overall benefits outweigh its risks.
3. Assessment of Candidacy for Dual-Antiplatelet Therapy†	Percentage of patients aged ≥18 years for whom PCI is performed who have documentation in the medical record that an assessment of candidacy for initiation and duration of dual-antiplatelet therapy was performed prior to the procedure.
4. Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease‡	Percentage of patients aged ≥18 years for whom saphenous vein graft PCI is performed who received an embolic protection device during the procedure.
5. Documentation of Preprocedural Glomerular Filtration Rate and Contrast Dose Used During the Procedure‡	Percentage of patients aged ≥18 years for whom PCI is performed who have both preprocedural estimated glomerular filtration rate or an indication that the patient is on dialysis AND the administered contrast dose documented in the catheterization report or procedure notes.
6. Radiation Dose Documentation‡	Percentage of patients aged ≥18 years for whom PCI is performed who have the administered radiation dose documented in the catheterization report or procedure notes.
7. Postprocedural Optimal Medical Therapy Composite†	Percentage of patients aged ≥18 years for whom PCI is performed who are prescribed optimal medical therapy at discharge.
8. Cardiac Rehabilitation Patient Referral†	Percentage of patients aged ≥18 years for whom PCI is performed who have been referred to an outpatient cardiac rehabilitation / secondary prevention program.
9. Regional or National PCI Registry Participation†	Participation in a national or multisystem geographic regional PCI registry that provides regular performance reports based on benchmarked data.
10. Annual Operator PCI Volume‡	Average annual volume of PCIs performed by an operator over the previous 2 calendar years.
11. Annual Hospital PCI Volume†	Annual volume of PCIs performed by a hospital over the previous calendar year.

*For comprehensive information on these measures, including measure exceptions, please refer to the complete ACC/AHA/AMA-PCPI/NCQA/SCAI performance measurement specifications through the PCPI Web site (http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi?submit=PCPI).

†These measures have been designated *performance measures*. Performance measures are process, structure, efficiency, or outcome measures that have been developed with ACCF/AHA methodology, including the process of public comment and peer review, and have been specifically designated as performance measures by the ACC/AHA Task Force on Performance Measures. These measures not only are intended for internal quality improvement but also may be considered for purposes of public reporting or other forms of accountability.

‡Indicated in shading, these measures have been designated *quality metrics*. Quality metrics are measures that have been developed to support self-assessment and quality improvement at the provider, hospital, or healthcare system level. These metrics are valuable tools to aid clinicians and hospitals in improving quality of care and enhancing patient outcomes but might not meet all specifications of formal performance measures and are, therefore, not appropriate for any use other than internal quality improvement.

ACC indicates American College of Cardiology; AHA, American Heart Association; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; NCQA, National Committee for Quality Assurance; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

representative. The writing committee had representation from the American Association of Cardiovascular and Pulmonary Rehabilitation, Mended Hearts, SCAI, and the Society for Thoracic Surgeons (STS).

1.3. Disclosure of Relationships With Industry and Other Entities

The ACC/AHA Task Force on Performance Measures makes every effort to avoid actual, potential, or perceived conflicts of interest that could arise as a result of relationships with industry or other entities (RWI). Detailed information on the ACC/AHA policy on RWI can be found at http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx. All members of the writing committee, as well as those selected to serve as peer reviewers of this document, were required to disclose all current relationships and those existing within the 12 months before the initiation of this writing effort. ACC/AHA policy also requires that the writing committee co-chairs and at least 50% of the writing committee have no *relevant* RWI.

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Any writing committee member who develops new RWI during his or her tenure on the writing committee is required to notify staff in writing. These statements are reviewed periodically by the Task Force and by members of the writing committee. Author and peer reviewer RWI relevant to the document are included in the appendices: Please see Appendix A for relevant writing committee RWI and Appendix B for relevant peer reviewer RWI. Additionally, to ensure complete transparency, the writing committee members' comprehensive disclosure information, including RWI not relevant to the present document, is available online at http://jaccjacc.cardiosource.com/DataSupp/ACCF/2013_Comprehensive_RWI_WC.pdf. Disclosure information for the Task Force is also available online at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx.

The work of the writing committee was supported exclusively by the ACC, the AHA, and the AMA, without commercial support. Members of the writing committee volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by committee members and staff from the ACC, AHA, SCAI, AMA-PCPI, and NCQA.

2. Methodology

The development of performance measurement systems involves identification of a set of measures targeting a specific patient population observed over a particular time period. To achieve this goal, the ACC/AHA Task Force on Performance Measures has outlined a set of mandatory sequential steps (1). The following sections outline how these steps were applied by the present writing committee.

2.1. Identifying Clinically Important Outcomes

To guide the selection of measures for inclusion in the measure set, the writing committee sought to identify structures, processes, and outcomes that are most meaningful to patients undergoing PCI, as recommended by recent guidelines and appropriate use criteria (AUC). A key aspect was to determine outcomes that are most relevant for patients. A complete list of the desirable outcomes identified by the writing committee and how they relate to the proposed process measures is included in the measure specifications that can be found at http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi?submit=PCPI.

2.2. Dimensions of Care

Given the multiple measurable domains of providing care, the writing committee identified and explicitly articulated the relevant dimensions of care that should be evaluated. As part of the methodology, each potential performance measure was categorized into its relevant dimension of care (Table 2). Classification into dimensions of care facilitated identification of areas in which evidence was lacking and prevented duplication of measures within the set. Diagnostics, patient education (including on the topics of prognosis and etiology), treatment, self-management, and

Table 2. 2013 ACC/AHA/SCAI/AMA-PCPI/NCQA Percutaneous Coronary Intervention Performance Measure Set: Dimensions of Care Measures Matrix*

Measure Name	Diagnostics	Patient Education	Treatment	Self-Management	Monitoring of Disease Status
1. Comprehensive Documentation of Indications for PCI†	✓				
2. Appropriate Indication for Elective PCI‡	✓		✓		
3. Assessment of Candidacy for Dual-Antiplatelet Therapy†	✓	✓	✓		
4. Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease‡			✓		
5. Documentation of Preprocedural Glomerular Filtration Rate and Contrast Dose Used During the Procedure‡	✓		✓		
6. Radiation Dose Documentation‡			✓		
7. Postprocedural Optimal Medical Therapy Composite†			✓		
8. Cardiac Rehabilitation Patient Referral†		✓	✓	✓	✓
9. Regional or National PCI Registry Participation†			✓		
10. Annual Operator PCI Volume‡			✓		
11. Annual Hospital PCI Volume†			✓		

*For comprehensive information on these measures, including measure exceptions, please refer to the complete ACC/AHA/AMA-PCPI/NCQA/SCAI performance measurement set through the PCPI Web site (http://www.ama-assn.org/apps/listserv/x-check/qmeasure.cgi?submit=PCPI).

†These measures are performance measures.

‡Indicated in shading, these measures have been designated *quality metrics* and are for use in internal quality-improvement programs only. They are not appropriate for any other use (e.g., pay-for-performance, physician ranking, public reporting programs).

ACC indicates American College of Cardiology; AHA, American Heart Association; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; NCQA, National Committee for Quality Assurance; PCI Percutaneous Coronary Intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

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monitoring of disease status were selected as the relevant dimensions of care for PCI performance measures.

In addition, to ensure the measure set would be as comprehensive as possible, the writing committee evaluated the potential measures against the Institute of Medicine domains of healthcare quality (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity) (3). The writing committee focused primarily on processes of care, but they also considered structural and outcome measures for PCI. Although the writing committee cannot endorse specific measures developed by others and believes that many measures are needed to quantify the full spectrum of relevant healthcare dimensions of quality, the measures proposed in the present set are intended to complement existing National Quality Forum–endorsed PCI measures.

2.3. Literature Review

The practice guidelines and other clinical guidance documents that provided the basis for these measures can be seen in Table 3.

2.4. Definition and Selection of Measures

The writing committee reviewed both recent guidelines and other clinical guidance documents, such as the "ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization" (11).

Table 3. Associated Guidelines and Other Clinical Guidance Documents

ACCF/AHA/SCAI 2011 Guideline for Percutaneous Coronary Intervention (4)
ACCF/AHA 2013 Guideline for the Management of ST-Elevation Myocardial Infarction (5)
ACC/AHA 2007 Guidelines for the Management of Patients with Unstable Angina/Non–ST-Elevation Myocardial Infarction (6)
ACCF/AHA 2011 Focused Update of the Guidelines for the Management of Patients with Unstable Angina/Non–ST-Elevation Myocardial Infarction (updating the 2007 guideline) (7)
ACCF/AHA 2012 Focused Update of the Guideline for the Management of Patients with Unstable Angina/Non-ST-Elevation Myocardial Infarction (updating the 2007 guideline and replacing the 2011 focused update) (8)
AHA/ACCF 2011 Secondary Prevention and Risk Reduction Therapy for Patients with Coronary and other Atherosclerotic Vascular Disease: 2011 Update (9)
ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization (10)
ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update (11)
ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization (12)

AATS indicates American Association for Thoracic Surgery; ACC, American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ASE, American Society of Echocardiography; ASNC, American Society of Nuclear Cardiology; HFSA, Heart Failure Society of America; HRS, Heart Rhythm Society; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; SCCM, Society of Critical Care Medicine; SCCT, Society of Cardiovascular Computed Tomography; SCMR, Society for Cardiovascular Magnetic Resonance; STEMI, ST-elevation myocardial infarction; and STS, Society of Thoracic Surgeons.

The writing committee also examined available information on gaps in care and the clinical epidemiology of PCI.

All measures were designed to assess quality of care in patients undergoing PCI across a variety of ambulatory and hospital settings to support achievement of the desirable outcomes identified. The measures also were designed to allow for the exclusion of patients with contraindications or other valid reasons for exclusion from the measure. In defining the measure exceptions, the writing committee was guided by the AMA-PCPI Recommendations for Specification and Categorization of Measure Exclusions (13), as discussed further below.

The writing committee evaluated the potential measures against the ACC/AHA attributes of performance measures (Table 4) to reach consensus on which measures should be advanced for inclusion in the final measure set; the Summary Analysis Table (Appendix C) captures this evaluation process. After the peer review and public comment period, the writing committee reviewed and discussed the comments received, and further refinements were made in the measure set.

3. ACC/AHA/SCAI/AMA-PCPI/NCQA 2013 Percutaneous Coronary Intervention Measures

3.1. Target Population and Care Period

The target population for the measures consists of all patients undergoing PCI for coronary artery disease. That said, a large focus of the writing committee was on measures aimed at patients coming to the cardiac catheterization laboratory for elective procedures—that is, those originating as outpatients. Patients arriving from the inpatient setting or emergency department and those with acute coronary syndromes were considered secondarily. The writing committee decided on this approach for 2 reasons. First, in patients with acute coronary syndromes, abundant data indicate that revascularization with PCI is beneficial, and prior measure sets focused on this disease condition have included measures targeting these patients (e.g., door-to-balloon time in ST-elevation myocardial infarction). Second, in selected patients undergoing elective procedures, such as those with chronic stable angina, there is greater controversy as to the best therapy that should be used. Patients referred to the cardiac catheterization laboratory in these settings usually have stable angina that is no longer controlled with medications or have high-risk findings on a noninvasive stress test. The benefit of PCI in these patients is primarily symptom reduction, and data on a mortality rate benefit for this group are limited (14–16).

3.2. Avoiding Overlap and Ensuring Alignment With Existing Measure Sets and Guidelines

The writing committee made every effort to avoid overlap with existing measure sets and to harmonize these

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Table 4. ACC/AHA Task Force on Performance Measures: Attributes for Performance Measures

1. Evidence Based	
High-impact area that is useful in improving patient outcomes	a) For structural measures, the structure should be closely linked to a meaningful process of care that in turn is linked to a meaningful patient outcome. b) For process measures, the scientific basis for the measure should be well established, and the process should be closely linked to a meaningful patient outcome. c) For outcome measures, the outcome should be clinically meaningful. If appropriate, performance measures based on outcomes should adjust for relevant clinical characteristics through the use of appropriate methodology and high-quality data sources.
2. Measure Selection	
Measure definition	a) The patient group to whom the measure applies (denominator) and the patient group for whom conformance is achieved (numerator) are clearly defined and clinically meaningful.
Measure exceptions and exclusions	b) Exceptions and exclusions are supported by evidence.
Reliability	c) The measure is reproducible across organizations and delivery settings.
Face validity	d) The measure appears to assess what it is intended to.
Content validity	e) The measure captures most meaningful aspects of care.
Construct validity	f) The measure correlates well with other measures of the same aspect of care.
3. Measure Feasibility	
Reasonable effort and cost*	a) The data required for the measure can be obtained with reasonable effort and cost.
Reasonable time period	b) The data required for the measure can be obtained within the period allowed for data collection.
4. Accountability	
Actionable*	a) Those held accountable can affect the care process or outcome.
Unintended consequences avoided	b) The likelihood of negative unintended consequences with the measure is low.

ACC indicates American College of Cardiology; AHA, American Heart Association.

Adapted from: Normand SL, McNeil BJ, Peterson LE, et al. Eliciting expert opinion using the Delphi technique: identifying performance indicators for cardiovascular disease. Int J Qual Health Care. 1998;10:247–60.

performance measures with other ACC/AHA/AMA-PCPI performance measure sets when possible. For example, the writing committee did not explore door-to-balloon time as a performance measure, given that this would overlap with performance measures for acute myocardial infarction already constructed and endorsed by numerous organizations. An example of harmonization within the measure set is the postprocedural optimal medical therapy composite measure in the present document, which is aligned with the similar National Quality Forum–endorsed ACCF facility-level measure.

4. General Discussion

4.1. Process Measures

Process measures have several advantages. They are more readily under the control of clinicians than are structural or outcome measures and also are actionable targets for quality improvement. Performance measures of processes are most useful when 1) they are directly linked to improved clinical outcomes through robust evidence, and 2) true gaps in care exist. Expending resources to measure processes that are already conducted at uniformly high rates is not justified, particularly when burdensome chart abstraction is required. An acknowledged limitation of process measures is that they might not always indicate how well the process was done. For example, measure 4 (use of embolic protection devices in the treatment of saphenous vein bypass graft disease) measures use of the embolic protection device during PCI but does not capture the technical skill with which it was deployed. We considered including measures assessing technical care processes performed in the cardiac catheterization laboratory but did not include any such measures because of the lack of feasible, nonsubjective measurement criteria. This should be an area of future investigation.

Two areas in which the writing committee tried to advance process measures were in patient selection measures and patient education/shared decision-making measures. Given the novelty of these topics, these are discussed in greater detail in the subsequent sections.

4.1.1. Patient Selection Measures

As with many procedures, evaluating patient selection and determining appropriateness is a crucial first step in ensuring high-quality clinical care. Nevertheless, this has not been done previously in performance measures for procedures. Ideally, this evaluation would revolve around both patients undergoing PCI and patients who are deferred from the procedure, to ensure that underutilization of potentially beneficial treatments is not occurring (17). Moreover, the indication (or reason) for the revascularization is attributable to several providers, including the referring physician and interventional cardiologist, as well as their discussions with the consenting patient. To date, the "ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary

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Revascularization" (11) and the "ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization" (12) represent the professional societies' attempt at providing a framework for evaluating the appropriateness of procedures in the cardiac catheterization laboratory (18). Prior research demonstrated that the indication for revascularization can be captured and evaluated for appropriateness, although high rates of incomplete data collection were noted (19). These criteria propose that emergency or urgent revascularization for patients with acute coronary syndromes is generally considered appropriate. However, for elective revascularization, several important features should be considered in determining appropriateness of cases, including symptom status, degree of ischemia, anatomy, and current medical therapy. These elements are central to the data that should be captured as the indication for most revascularization procedures. Therefore, the initial goal of measure 1 (comprehensive documentation of indications for PCI) and measure 2 (appropriate indication for elective PCI) is to ensure that adequate information for assessing the indication for revascularization procedures is captured and reported, so that continued evaluation and feedback to improve both the AUC ratings and clinical care can occur.

4.1.2. Patient Education/Shared Decision-Making Measures

Although the aforementioned factors highlight the difficulty of determining when PCI is clinically indicated, reaching a high-quality decision goes beyond meeting the AUC. In an area in which decision making is so complex, performance measurement ideally also would address *how* the decision was made. This is necessary because patient preferences can play an important role in many cases, especially with regard to elective PCI. For example, some patients whose medical history and diagnostic testing results suggest PCI is indicated might still want to consider other options. Conversely, there will be patients for whom it is equivocal whether PCI is indicated, but the patient nonetheless expresses a strong preference to undergo PCI.

The ideal approach to decision making is to involve the patient to the extent he or she wishes to be involved. Performance measurement should reflect this process as much as possible. Many patients will want to be involved in these crucial decisions, and physicians' performance with these patients ideally would be assessed in part by surveying patients about whether their input was solicited and their preferences drove or at least influenced the decision. Alternatively, some patients will prefer that their physician make their decisions for them, and physicians who do so in such instances should be regarded as giving patient-centered care.

In addition, all patients should be educated about their options. This education can be very brief in urgent settings, such as when a patient is having an ST-elevation myocardial infarction with cardiogenic shock. However, if any uncertainty exists about the superiority of PCI versus optimal medical therapy or surgical revascularization (as is usually the case with elective PCI), then the patient should be provided an opportunity to learn about the relative risks and benefits of therapies under consideration.

The writing committee struggled with whether to include process measures that focused on decision making and education through patient surveys. Surveys might be able to address general quality of decisions and ask patients about whether they were involved as much or as little as they desired. Survey results could then be shared at the physician and hospital levels, so both individual clinicians and institutions could understand and improve their decision-making processes. However, there are as yet no validated instruments addressing these domains, nor have other critical details been worked out. These limitations left the writing committee less enthusiastic about supporting a measure at the present time, but this should be a priority area for future investigation.

4.2. Outcome Measures

If the focus of process measures reflects the journey, outcome measures shed light on the destination—the end, rather than the means. Outcome measures offer the potential advantage of providing readouts on entire populations, rather than smaller population subsets, and they focus on the "end results" of care that are most important to clinicians and patients. The challenges with outcome measures are primarily in the risk-adjustment modeling methods, which, though never perfect, can substantially enhance the ability to compare outcomes across different delivery teams, settings, locations, and systems (20). Krumholz et al. (20) have described 7 preferred attributes of models used for outcomes that are publicly reported (Table 5), which this the writing committee strongly believes should remain at the core of any performance measure that includes outcomes.

Table 5. Preferred Attributes of Models Used for Publicly Reported Outcomes

1. Clear and explicit definition of an appropriate patient sample
2. Clinical coherence of model variables
3. Sufficient high-quality and timely data
4. Designation of an appropriate reference time before which covariates are derived and after which outcomes are derived
5. Use of an appropriate outcome and a standardized period of outcome assessment
6. Application of an analytical approach that takes into account the multilevel organization of data
7. Disclosure of the methods used to compare outcomes, including disclosure of performance or risk-adjustment methodology in derivation and validation samples

Reprinted with permission from Krumholz et al. (20).

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4.2.1. Level of Attribution/Aggregation

Contributions of multiple healthcare providers across multiple settings are reflected in outcomes associated with any particular episode of care, and this can be especially true in the case of PCI. In addition, various data sources and data systems are the window into that episode, such that the ability to aggregate data at the level of an individual clinician versus a broader grouping (e.g., practice or hospital) will depend on the types of data available and the outcomes being evaluated. Although data are increasingly available, most sources of information, like administrative claims data, generally lack adequate granularity to be of meaningful use for attribution of outcomes performance at the level of the individual provider, which makes aggregation of PCI outcomes more appropriate for the health system or hospital.

4.2.2. Infrequently Occurring Complications

Certain outcomes could be of inarguable importance in PCI but occur rarely. Such outcomes are difficult to interpret at the individual-provider level simply because of the fact that low-frequency events in a small sample size will produce unreliable estimates of provider performance. For this reason, certain measures are appropriately applied only to larger aggregated provider groupings where sample sizes are larger. These principles have substantial implications for PCI outcomes because the rates of major complications, such as death and the need for emergency coronary artery bypass surgery, have decreased significantly in recent years.

4.2.3. Death/Readmission

Death is perhaps the most important and least ambiguous outcome measure. Proper risk adjustment is—and will remain—a mandatory cornerstone of mortality monitoring for PCI. However, the writing committee also recognized that even the best risk-adjustment model cannot correct for potentially unmeasured confounders, and most risk-adjustment models perform less well at the extremes of risk. This requires a careful design of outcome measures to avoid the unintended consequence of either penalizing facilities or clinicians who take on more difficult cases or rewarding those who avoid certain high-risk patients requiring treatment. In this context, the writing committee did not believe it was necessary to reproduce existing National Quality Forum–endorsed measures that are already available in the public realm on in-hospital and 30-day mortality rate after PCI.

The writing committee also considered a potential measure of 30-day readmission after PCI, given reportedly high rates of readmission and recent interest in this outcome by payers and policymakers. As in the case of mortality rate, risk-adjusted measures of 30-day readmission after PCI have been developed, and we point interested readers toward those measures (21–23).

4.2.4. Patient Surveys

Patient survey data have been used to compare the care provided across health systems and providers. For example, the Mended Hearts pilot program conducted surveys of patients 6 months after PCI, asking a range of questions: "What type of procedure did you have?," "Are you following your medication regimen?," and "What can be done to improve knowledge of medications?" Medicare Health Outcome Surveys also have been administered, as have a NCQA-HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) and system-level survey. In addition, many individual hospital systems have developed and implemented diagnosis-related group-based postdischarge surveys. Such surveys might be appropriate for measuring certain outcomes, including subjective functional status, symptoms, knowledge, and overall satisfaction with the care process. However, critics point out that such measures can be disproportionately weighted by items unrelated to care, including availability of channels on the hospital television, food menu choices, and parking convenience. In addition, standardized tools for symptom measurement and for patient subsets are generally lacking. For example, the response to the question, "Did this procedure save your life?" could be different for a patient undergoing PCI with an acute myocardial infarction and a patient with stable angina. In addition, validated risk-adjustment models for patient survey data do not currently exist. Although the writing committee believes that patient surveys are an important area for future development (see also Section 4.1.2: Patient Education/Shared Decision Making Measures), these limitations raised concerns about their inclusion in the present document.

4.3. Structural Measures

For PCI, measures to evaluate process and outcomes are more clearly substantiated by an evidence base than are structural measures. Still, compared with many clinically important process and outcome measures, it is easier to assess structural measures and, importantly, to track changes longitudinally without need for risk adjustment. Given these considerations, as well as interest in and evidence on registries and the role of case volume in outcomes, we elected to include 3 measures of structure: measure 9 (regional or national PCI registry participation), measure 10 (annual operator PCI volume) (quality improvement only), and measure 11 (annual hospital PCI volume). It is the consensus of the writing committee that these structural measures can provide important contributions to the assessment of care equity and safety without imposing undue data collection burden on hospitals or practitioners. For both of the PCI case volume–specific structural measures, existing standards encourage reporting (24). However, although the experience of the operator and the hospital performing PCI has been associated with improved outcomes, it is not clear what specific threshold volume of PCI cases represents a true clinically important indicator. Thus, the intent of these case-volume measures is to encourage data collection rather than specific targets.

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In addition, the writing committee recognizes the unique challenges of accurately documenting operator volume because some data systems cannot capture data for operators who work at multiple sites, and self-reporting can have limitations. Given the challenges in capturing the required data, the limitations of the evidence supporting a specific threshold for operator volume, and the potential for unintended consequences, the writing committee designated the operator volume metric for use only in internal quality improvement because it does not comply with all the desirable attributes required (see Table 4 and footnotes to Table 1). The writing committee believes it is important to encourage tracking of operator volume, but it would not be appropriate to evaluate operators on the basis of volume of procedures alone, so this measure should not be used in accountability or public reporting programs.

5. Measures Included in This Set

5.1. Comprehensive Documentation of Indications for PCI

Comprehensive documentation of the indication for PCI is an absolute requirement for performing the procedure. This should include an appropriate description of the key features of the clinical presentation, along with documentation of noninvasive stress testing and functional assessments (if clinically indicated and performed) and the severity of angiographic stenosis for the treated lesion. PCIs are performed to improve symptoms or survival. Documentation of these elements allows for an evaluation of the patient's indication for the procedure and also provides prognostic utility. This ultimately permits an appropriate risk/benefit ratio to be inferred for the procedure. In addition, fulfillment of this measure will enable assessment of other important quality indicators derived from the ACC/AHA/SCAI guideline for PCI (4) and the appropriate use criteria for coronary revascularization documents (11,12). The documentation for many PCIs performed in the United States lacks essential data to determine the procedure's appropriateness, making this a measure with a possibly important gap in care (19). A potential concern is that several of the features pertaining to the indication for PCI are attributable to both the physician referring the patient for PCI and the physician performing the procedure, which leads to challenges with attribution. Nonetheless, the writing committee's opinion is that compiling all the required elements at the level of the therapeutic intervention is a process of care that is linked to desirable outcomes for patients undergoing PCI. It is therefore the ultimate responsibility of the physician performing the PCI and of the physician's institution to accurately document key features.

5.2. Appropriate Indication for Elective PCI

There has been considerable discussion among the writing committee members about this performance measure in the context of the recently published AUC for coronary revascularization (11), which include assessments of both coronary artery bypass surgery and PCI, and the well-documented variation (25) in practice of PCI across the United States (11,12). Furthermore, prior attempts to construct performance measures have not relied heavily on AUC, so this represents one of the more innovative and unexplored aspects of this performance measure set. The writing committee therefore approached the creation of this measure cautiously to maximize its value to users without leading to unintended consequences that could be harmful to patients.

Several key aspects of this measure deserve to be highlighted. To optimize our opportunity to improve care, we focused on elective PCIs that occur in nonacute settings, inasmuch as analyses of PCIs performed in acute settings have shown that the vast majority of these procedures are classified as appropriate according to AUC (19). In addition, even though we aimed to harmonize the document with recently published guidelines and AUC, this performance measure is not completely superimposable on their definitions for 2 reasons. First, it is acknowledged that the AUC cannot possibly include every conceivable patient presentation of appropriateness. The AUC are created via a modified Delphi approach, in which experts reach consensus after being presented with specific clinical scenarios that focus on coronary anatomy, symptoms, current medical therapy, and noninvasive studies. Thus, subtle differences between the AUC and guidelines do exist, particularly for PCI. For example, the guidelines for PCI categorize the usefulness of these procedures for survival benefit in asymptomatic patients to be "uncertain in patients with 2- or 3-vessel [coronary artery disease] (with or without involvement of the proximal [left anterior descending] artery) or 1-vessel proximal [left anterior descending] disease" (Class IIb recommendation), on the basis of insufficient data. However, the AUC, as rated by experts, vary in their assessments of the usefulness of PCI in this setting from uncertain to appropriate, on the basis of the additional factors described previously (e.g., current medical therapy, noninvasive studies). Second, the criteria for the AUC are becoming a frequent part of daily clinical practice and of quality-improvement efforts, but they are not entirely noncontroversial (26). We therefore created a measure that more broadly captured appropriate use of PCI, using both the guidelines and the AUC as tools.

Finally, the writing committee considered that, at the present time, the current measure does not entirely meet the strict criteria for accountability measures as put forth by Chassin et al. (27) and the ACC/AHA Task Force on Performance Measures (28). For example, the measurement of appropriateness of PCI is certainly consistent with 2 criteria, in that it is based on a strong foundation of research and captures a process proximate to a desired outcome (i.e., treating the right patient). Without existing data on its use in test populations, however, it is difficult to

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know whether the current measure accurately captures "appropriateness" (as opposed to encouraging gaming) or whether it will lead to unintended consequences by discouraging operators from taking on difficult or high-risk procedures where, although the risk is high, the benefit could be great (i.e., whether the measure will promote underuse). Concern for this last issue is evident in the evolving processes of the AUC, which have undergone significant changes since their early iterations (see below). For these reasons, we designated this measure for internal quality improvement only (see Appendix C for a summary of the writing committee's evaluation).

The writing committee also considered addressing the *inappropriate* indications for elective PCI, as this has been one of the most important features of the AUC. However, the AUC documents specifically underscore the pivotal role of clinical judgment in determining whether revascularization is indicated for an individual patient. The rating of a revascularization as inappropriate by any schematic should not preclude a provider from performing PCI when patient- and condition-specific data support that decision (11,12). This is reflected in new language; "inappropriate" has been changed to "rarely appropriate." Nevertheless, documentation of the reasons for performing a PCI should still be mandatory. Because the criteria for appropriate indications for elective PCI appear to be, in general, less prone to various interpretations, the writing committee decided to focus on appropriate procedures at the present time. It is certainly possible that measurement of rarely appropriate indications for elective PCI might become part of future performance measures.

5.3. Assessment of Candidacy for Dual-Antiplatelet Therapy

Dual-antiplatelet therapy is integral to preventing stent thrombosis in patients treated with stents during PCI. Current guidelines recommend dual-antiplatelet therapy for 4 weeks in patients who are treated with bare metal stents and 1 year in patients who are treated with a drug-eluting stent, though it is recognized that this recommendation is in flux (4). In any case, considerable data suggest that premature cessation of dual-antiplatelet therapy is associated with an increased risk of stent thrombosis and resultant myocardial infarction or death (29,30). It is therefore important that an assessment of tolerability of and adherence with long-term dual-antiplatelet therapy be made before the procedure and that the importance of dual-antiplatelet therapy be discussed with the patient before and after the procedure. For example, this might include (but not be limited to) questions about scheduled or anticipated surgeries. Ideally, this discussion should be part of the informed consent process, and the intended duration of dual-antiplatelet therapy should be documented clearly before the procedure. It is recognized that ascertainment of candidacy for dual-antiplatelet therapy might not be feasible during emergencies or when a patient is unresponsive, and these patients have been excluded from the measure.

5.4. Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease

It is the opinion of the writing committee that, when technically feasible, embolic protection devices should be used during saphenous vein graft PCIs. This is consistent with current (2011) ACCF/AHA/SCAI guidelines, which made embolic protection device use during saphenous vein graft intervention a Class I recommendation (4). Of course, the writing committee recognizes that it might not be technically feasible to use an embolic protection device in all cases, depending on such factors as vessel tortuosity, lesion location and severity, vessel size, and Thrombolysis in Myocardial Infarction (TIMI) flow. If an embolic protection device is not used during saphenous vein graft PCI, the writing committee believes that documentation of technical reasons, unsuitable anatomy, or patient refusal of the device should be provided. This measure was designated for internal quality improvement only because a potential unintended consequence of this measure could be that it might inappropriately encourage use of embolic protection devices by operators without sufficient experience in their use.

5.5. Documentation of Preprocedural Glomerular Filtration Rate and Contrast Dose Used During the Procedure

Assessment of renal function should be a standard part of the preprocedural work-up of patients undergoing coronary angiography and intervention. It is well recognized that serum creatinine concentration by itself is a poor surrogate for renal function and that estimated glomerular filtration rate (GFR) should be calculated for each patient (4). Renal function (as estimated by calculated GFR) is important for dosing medications (including anticoagulants) and contrast media. An excess of bleeding events has been reported in patients who do not receive appropriately adjusted dosing of anticoagulation in the setting of renal dysfunction (31,32). Furthermore, current guidelines recommend use of preprocedural hydration in patients who have a reduced GFR (33,34). Estimated GFR should be calculated as close to the day of the procedure as possible and should be documented in the medical record, ideally as part of the preprocedural checklist.

The writing committee also recommends that the total amount of contrast volume administered to a patient should be documented clearly in the procedure report. The risk of contrast-induced renal injury increases with increasing volume of contrast administered, and physicians should follow a principal of "as low as reasonably possible," especially in patients who have preexisting renal dysfunction (35). Although recent studies suggested an association between high total contrast dose (or GFR-based

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contrast dose) and contrast-induced acute kidney injury, we do not believe that the current evidence is robust enough to support a specific contrast threshold that should not be exceeded under any circumstance (4,32). In addition, no evidence indicates that simply documenting the dose is linked to improved patient outcomes. For these reasons, the writing committee designated this measure only for internal quality improvement at the present time. Of course, individual circumstances during a case often will dictate whether the use of additional contrast is worthwhile for the safety of the procedure. Nevertheless, recording the total volume of contrast used for each case, as required by the measure, should serve as the first step toward understanding and modifying patterns of contrast use in cardiac catheterization laboratories.

5.6. Radiation Dose Documentation

Current guidelines recommend that procedural radiation dose should be recorded for all patients and should be limited to "as low as reasonably achievable," according to clinical circumstances. Measures of radiation dose include total air kerma at the interventional reference point, air kerma area product, fluoroscopy time, and number of cine images (4). Furthermore, it is recommended that every catheterization laboratory define thresholds, with corresponding follow-up protocols, for patients who receive a high procedural radiation dose. It is most typical to report total fluoroscopy time, but the writing committee recognized that this is a limited measure of total radiation exposure and dose. All contemporary interventional x-ray systems report the total air kerma area product (in Gray [Gy]) and air kerma area product (in $Gycm^2$). When available, one or both of these measures should be documented in the procedure report in addition to fluoroscopy time. At the present time, the writing committee designated this measure for internal quality improvement only to avoid potential unintended consequences, such as operators feeling a need to limit additional imaging even when it would be clinically useful (see Appendix C for a summary of the analysis).

5.7. Postprocedural Optimal Medical Therapy Composite

Medical therapy, including aspirin, $P2Y_{12}$ inhibitors, and statins, has been proved to reduce all-cause mortality and cardiovascular morbidity in multiple studies. These medications should be prescribed to all patients who are eligible for them after PCI, except for the rare circumstances in which the life expectancy of the patient is limited or the patient has a known allergy or intolerance. Despite the strong endorsement from the guidelines and their robust evidence base, the use of these medications is less than optimal, particularly for statin therapy. Recently, Borden and colleagues (36) evaluated the use of optimal medical therapy in patients undergoing PCI for stable disease who were enrolled in the National Cardiovascular Data Registry CathPCI Registry. Statins were prescribed to 83% of patients who were discharged alive after PCI, after exclusion of patients with a contraindication to or history of intolerance of statins. Thus, opportunity remains for substantial improvement in the use of these medications in patients undergoing PCI (36). Incorporating these medications into the standard post-PCI order sets and having a detailed discussion of their benefits can be very effective at ensuring patient adherence, particularly with statin therapy (37). This measure harmonizes closely with the corresponding facility-level postprocedural optimal medical therapy composite measure from the ACC (38).

5.8. Cardiac Rehabilitation Patient Referral

Cardiac rehabilitation is a multidisciplinary exercise-based outpatient service that has been proved to provide patient benefit in terms of improved functional status, quality of life, medical resource use, and, ultimately, mortality rate reduction (39–46). Patients with coronary artery disease treated with PCI are at high risk of recurrent events and are particularly suitable for risk reduction via cardiac rehabilitation. Unfortunately, cardiac rehabilitation is a vastly underutilized service, with available data indicating that less than half of eligible patients ultimately enroll in a program (47). There are numerous barriers to referral, entry, and completion of cardiac rehabilitation by patients. Although some of these barriers are financial or system related (e.g., lack of a geographically convenient program), physician referral is a modifiable barrier. Explicit physician referral of patients to cardiac rehabilitation has been shown to substantially increase the likelihood of patient enrollment (47,48). Although it could be argued that referral is the responsibility of a patient's primary physician or other members of the healthcare team, the writing committee believes that cardiac rehabilitation referral should be part of the comprehensive care of a patient undergoing PCI and should be the responsibility of the providers involved with that procedure, in a manner similar to treatment of dyslipidemia. Referral during the index hospitalization for PCI is therefore optimal. The performance measure takes into account appropriate exclusions, such as medical nonsuitability (e.g., history of comorbidities), patient preference, and lack of availability of a suitable program. This performance measure harmonizes closely with the corresponding measure from the ACCF/AHA/PCPI coronary artery disease performance measure set. In the future, broadening this measure to assess levels of participation on the basis of attendance, rather than simply referral, might be examined.

5.9. Regional or National PCI Registry Participation

The writing committee believed strongly that every catheterization laboratory should participate in a national or regional PCI registry for benchmarking purposes. The benefits of participating in a registry include the ability to

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compare the catheterization laboratory's outcomes with those of similar laboratories of comparable volumes, so that the laboratory staff understands their outcomes in relation to national or regional standards. We believe this measure will encourage more cardiac catheterization laboratories to participate in large multicenter databases and collaboratives to improve the evidence base to support quality efforts in PCI.

5.10. Annual Operator and Hospital PCI Volume

The writing committee designated the operator procedure volume as appropriate for internal quality improvement only, as indicated in Appendix C. It is well recognized that operator volume, though useful, is a limited surrogate for quality. This is due partly to the difficulty of collecting volume data for individual operators, who can practice across numerous facilities and even states. The volume of the catheterization laboratory in which an operator works seems to be a more trustworthy surrogate for quality than does individual operator volume. Although updated recommendations exist for operator and institutional volumes (24), they are still based on observational studies that looked at a variety of facility volume thresholds. However, the preponderance of evidence suggests that facilities that perform <200 PCIs per year have worse outcomes than facilities that perform more procedures. Given the limitations of the evidence base, the writing committee felt strongly that no specific threshold should be required for these measures, though it did see value in collecting these data for institutional and operator quality assurance. The writing committee also recognized the potential challenges of operators who are recently out of training or who transiently cease performing procedures because of job changes or health reasons (e.g., pregnancy). A potential unintended consequence of this measure that was discussed by the writing committee is that an operator might perform unnecessary procedures to achieve a threshold level. Future iterations of this measure will need to also address whether adjunctive coronary procedures (e.g., fractional flow reserve, intravascular ultrasound) and noncoronary procedures (e.g., transcatheter aortic valve replacement) should be included in these assessments of operator and institutional volume, given that these techniques require overlapping technical skills.

6. Potential Measures Considered But Not Included in This Set

6.1. Process Measures

The writing committee considered several additional process measures for inclusion. A longitudinal measure assessing use of dual-antiplatelet therapy at 30 days and 1 year was considered. Although such a measure has a greater likelihood of improving care, the logistical challenges of collecting longitudinal drug data on an outpatient basis made it difficult to implement this measure at the present time. We are hopeful that advances in information technology, electronic health records, and outpatient registries will make reliably collecting these data possible in the future.

We also examined additional measures related to ad hoc PCI (PCI performed during the same session as diagnostic angiogram) and multivessel PCI. These measures focused on examining the core question of whether the PCI was appropriate in the context of additional therapeutic options, like medical therapy and coronary artery bypass surgery. This was an area of great interest and much discussion for the writing committee. However, in the end the group felt limited in our ability to construct feasible measures that could be applied reliably in clinical practice. We decided that these topics were ultimately beyond the charge of a writing committee focused on PCI. Our greatest barriers were the lack of definitive data on the risks and benefits of ad hoc PCI and multivessel PCI and their role in shared decision making by patients and providers (49,50). The writing committee, therefore, decided that this topic might be considered in future updates of these measures or might be better handled by a writing committee focused entirely on developing performance measures for coronary revascularization (rather than just PCI).

6.2. Outcome Measures

As noted previously, outcome measures are highly desirable but often difficult to incorporate into performance measure sets because of vulnerability to influences outside the provider's control. Thus, outcome measures, particularly those intended for use in accountability, should be supported by strong data and should address risk-adjustment concerns. For example, the writing committee considered a measure of the incidence of dialysis after PCI. However, this was ultimately not included because the need for unexpected dialysis after PCI is extremely rare, and when dialysis does occur after PCI, it is often in patients with marginal renal function before the PCI for whom the possibility of dialysis was discussed previously. Creating a measure in this area might dissuade these patients, who are often at high risk for coronary artery disease, from undergoing PCI. Several members of the writing committee supported the inclusion of a related measure of acute kidney injury after PCI that would depend on laboratory assessments of renal function. However, controversy exists about the diagnosis of acute kidney injury in this setting, and in many patients, it would require multiple blood tests that are otherwise not indicated.

Similarly, the writing committee considered a measure assessing rates of blood transfusion after PCI. This was not included as a measure because the writing committee felt that it is currently challenging to adequately account for all the factors related to the decision to transfuse patients after PCI, some of which might be related only indirectly to the procedure. Emergency coronary artery bypass surgery after

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PCI was also considered as a measure, but in an era of widespread use of stents, the incidence is extremely small, which would make it an unreliable measure. Finally, a measure of periprocedural infarction based on cardiac biomarkers after PCI was considered. However, standardized collection of cardiac biomarkers after PCI is still a variable practice, and this strongly influences rates of periprocedural infarction. Given these concerns and that standardized collection of cardiac biomarkers after PCI is not a Class I recommendation in recent PCI guidelines, this measure was not included.

Three outcome measures, in particular, were considered strongly by the writing committee, and these are reviewed in detail in the following sections.

6.2.1. Angina

The writing committee considered a measure of assessment of angina. Given that one of the primary reasons for performing PCI is to reduce angina, the concept of assessing anginal class in a structured way before PCI, and reassessing it in the same way after PCI, has intuitive appeal. However, the writing committee noted several challenges. First, it was recognized that angina/ischemia can present in different ways, and there was little agreement on how to account for unusual symptoms presenting as an "anginal equivalent." Second, it was recognized that rigorous, standardized anginal class assessment (e.g., the Seattle Angina Questionnaire), though standard in clinical trials, is not typically performed in the clinical setting, and that more common systems, like the Canadian Classification System, have poor reliability and are too subjective. These issues created a tension between the feasibility of a measure related to angina assessment and its usefulness. For these reasons, the writing committee decided not to include an assessment of angina in the present set, but it believes this should be an area of future development.

6.2.2. Thirty-Day Mortality Rate

The writing committee considered a mortality measure, and the 30-day endpoint was discussed in particular, because this was identified as the time point (as opposed to 1 year) at which outcomes would be most closely related to the index procedure. For the reasons discussed in Section 4.2, death as an outcome measure has obvious appeal. It is overall an unambiguous and unarguable endpoint and, along with stroke, is generally considered one of the worst possible outcomes of a PCI procedure. The challenges to using 30-day mortality rate as a performance measure relate primarily to risk-adjustment issues, and 2 main sentiments prevailed: 1) There was a strong desire to avoid penalizing operators for taking difficult cases. This arose from recognition that risk adjustment is less robust at the extremes of risk, as well as from acknowledgment of some of the unintended negative consequences that could result from focus on this outcome, at the individual-operator level, in terms of avoidance of difficult cases altogether or an undesirable displacement of them to nearby regions and operators subject to lesser scrutiny. 2) It was recognized that mortality rate has been a component of numerous prior efforts, and there was a desire to avoid duplicative efforts. For these reasons, the writing committee opted not to include a measure related to 30-day mortality rate.

6.2.3. Revascularization

The occurrence of a negative outcome after PCI, such as restenosis or stent thrombosis, was also considered as an outcome measure. The writing committee generally agreed that restenosis and stent thrombosis are negative outcomes but was not in agreement that all of the factors that contribute to these outcomes are understood, or at least there was some lack of consensus about the extent to which these outcomes are related to factors within the operator's direct control. More importantly, restenosis and stent thrombosis are both now relatively low-frequency events for any individual operator. In addition, presentation with either restenosis or thrombosis is not always to the same medical center where the index procedure was performed, which creates a challenge to accurately ascertaining the incidence of these outcomes at the individual-operator or center level. For these reasons, the writing committee did not include any outcome measures related to restenosis or thrombosis.

6.3. Structural Measures

Two additional structural measures related to use of standardized protocols were carefully considered by the writing committee. However, these structural measures were determined to be inappropriate for inclusion in the measure set at the present time. In both cases, use of protocols has been advocated as a way to potentially mitigate risk for patients in developing complications from PCI.

First, given the high potential for morbidity and mortality associated with use of antiplatelet and anticoagulation therapy, the writing committee considered a measure to assess use of a standardized protocol for these agents. However, despite their extensive use of these protocols, there is scant evidence to link their use of a protocol to improved patient outcomes. Dosing guidelines exist for specific agents; however, there is a wide range of variability even in the guidelines to account for important clinical considerations, including adjustments for renal impairment, concomitant warfarin anticoagulation, and other clinical factors. Thus, the writing committee decided that the proposed measure offered little added value to quality care assessment at the present time, given the complexity required for its effective implementation. The writing committee does encourage development and implementation of protocols for antiplatelet and anticoagulant therapy as appropriate on a local basis, and reconsideration of this measure might occur in future iterations of this measure set as the evidence base evolves.

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Second, the writing committee considered use of a protocol for managing contrast-related nephropathy before and during PCI but decided that the evidence base is not substantive enough to support inclusion of such a measure at the present time. However, as discussed in Section 5.1, the writing committee did elect to include documentation of preprocedural estimated GFR and contrast dose as internal quality-improvement measures in this set. There is a tight linkage between GFR and contrast dose and development of contrast-related nephropathy. The writing committee felt that these measures should capture, with sufficient granularity, important data to guide local improvement efforts. As the evidence base to guide the management of contrast-related nephropathy continues to evolve, consideration for inclusion might be appropriate in future iterations of this measure set.

7. Areas for Further Research

The writing committee identified 4 areas of interest for further investigation. Although the areas are relevant to performance measures in general, the writing committee felt they would have particularly important implications for measurement with regard to PCI. Some of these have been discussed throughout the present document in relevant sections but are highlighted here for additional emphasis.

7.1. Documentation of Prescription of Drugs Versus Filling of Drug Prescriptions and Optimal Dosing of Drugs

The writing committee felt that it will be important in future work to examine moving beyond documentation of only the prescription of drugs to the actual filling of drug prescriptions and the optimal dosing of drugs. Unfortunately, using existing data collection systems to measure these is currently too difficult, expensive, and prone to error to serve as a useful quality measure. Additionally, a patient could be seen by several practitioners who have different standards for optimal dosing.

7.2. Limitations of Current Data Systems for PCI

Administrative claims data are used for a large number of analyses focused on PCI utilization. Although valuable for capturing use and costs, these data are inadequate as a source for quality measures. For example, the Dartmouth Atlas has suggested for several years that substantial regional differences exist in PCI utilization, leading to concerns that PCI is overutilized (25). A thorough understanding of the reasons for regional variation in these procedures and their value for outcomes, such as improvements in angina and quality of life, however, is still lacking. In addition, hospital-based systems for collecting data on PCI are increasingly incomplete because most elective procedures are now done with an outpatient or observational status rather than an inpatient status.

7.3. Shared Accountability

Most patients who have undergone a PCI have come into contact with more than one physician before receiving their procedure from an interventional cardiologist. These can include a primary care physician, emergency physician, hospitalist, intensivist, noninvasive cardiologist, and clinical cardiologist. Accountability for quality needs to occur throughout the process and should be shared by all the providers who care for the patient. Although accountability and subsequent outcomes lie primarily with the interventionist, many steps in the process that occurred before the PCI can contribute to optimizing patient care. This is equally true for care that happens after the PCI.

7.4. Patient Surveys

The writing committee suggests that hospitals survey their PCI patients about their level of knowledge, level of education, and perception of outcomes of their procedures. This is an exciting and important method of ascertaining and ensuring patient education with regard to their perceived outcomes of PCI. The writing committee did not support including this as a measure because the outcomes of PCI vary according to presenting symptoms; for example, patients with an acute myocardial infarction could have an improved risk of mortality as a result of their PCI, but patients undergoing elective PCI for chronic stable angina probably have no improvement in their outcome other than symptom relief.

Staff

American College of Cardiology
John Gordon Harold, MD, MACC, FAHA, President
Shalom Jacobovitz, Chief Executive Officer
William J. Oetgen, MD, MBA, FACC, Executive Vice President, Science, Education, and Quality
Charlene L. May, Senior Director, Science and Clinical Policy
Melanie Shahriary, RN, BSN, Director, Performance Measures and Data Standards

American College of Cardiology/American Heart Association
Naira Tahir, MPH, Specialist, Clinical Performance Measures

American Heart Association
Mariell Jessup, MD, FACC, FAHA, President
Donna Arnett, PhD, MSPH, FAHA, President
Nancy Brown, Chief Executive Officer
Rose Marie Robertson, MD, FACC, FAHA, FESC, Chief Science Officer
Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations
Melanie B. Turner, MPH, Science and Medicine Advisor, Office of Science Operations

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Jody Hundley, Production Manager, Scientific Publishing, Office of Science Operations

American Medical Association—Physician Consortium for Performance Improvement

Mark Antman, DDS, MBA, Director, Measure Development Operations

Kendra Hanley, MS, Project Manager II, Measure Specifications, Standards, and Informatics

Karen Kmetik, PhD, Vice President, Performance Improvement

Marjorie Rallins, DPM, Director, Measure Specifications, Standards, and Informatics

Samantha Tierney, MPH, Project Manager II, Measure Development Operations

Gregory Wozniak, PhD, Director, Measure Analytics and Economic Evaluation

Society for Cardiovascular Angiography and Interventions

Wayne Powell, Senior Director for Advocacy & Guidelines

Joel Harder, MBA, Director of Quality Initiatives and Clinical Documents

References

1. Spertus JA, Eagle KA, Krumholz HM, et al. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol 2005;45:1147–56.
2. Spertus JA, Bonow RO, Chan P, et al. ACCF/AHA new insights into the methodology of performance measurement: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2010;56:1767–82.
3. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
4. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol 2011;58:e44–122.
5. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–140.
6. Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non–ST-Elevation Myocardial Infarction). J Am Coll Cardiol 2007;50:e1–157.
7. Wright RS, Anderson JL, Adams CD, et al. 2011 ACCF/AHA focused update of the guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2011;57:1920–59.
8. Jneid H, Anderson JL, Wright RS, et al. 2012 ACCF/AHA focused update of the guideline for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline and replacing the 2011 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2012;60:645–81.
9. Smith SC Jr., Benjamin EJ, Bonow RO, et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation. Circulation 2011;124:2458–73.
10. Patel MR, Dehmer GJ, Hirshfeld JW, et al. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 appropriateness criteria for coronary revascularization: a report by the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology. J Am Coll Cardiol 2009;53:530–53.
11. Patel MR, Dehmer GJ, Hirshfeld JW, et al. ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 appropriate use criteria for coronary revascularization focused update: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography. J Am Coll Cardiol 2012;59:857–81.
12. Patel MR, Bailey SR, Bonow RO, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012;59:1995–2027.
13. Physician Consortium for Performance Improvement. *Specification and Categorization of Measure Exclusions: Recommendations to PCPI Work Groups*. American Medical Association; 2008Available at: http://www.ama-assn.org/resources/doc/cqi/exclusions053008.pdf. Accessed May 7, 2013.
14. Boden WE, O'Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med 2007;356:1503–16.
15. Trikalinos TA, Alsheikh-Ali AA, Tatsioni A, et al. Percutaneous coronary interventions for non-acute coronary artery disease: a quantitative 20-year synopsis and a network meta-analysis. Lancet 2009;373:911–8.
16. Wijeysundera HC, Nallamothu BK, Krumholz HM, et al. Meta-analysis: effects of percutaneous coronary intervention versus medical therapy on angina relief. Ann Intern Med 2010;152:370–9.
17. Ko DT, Guo H, Wijeysundera HC, et al. Assessing the association of appropriateness of coronary revascularization and clinical outcomes for patients with stable coronary artery disease. J Am Coll Cardiol 2012;60:1876–84.
18. Patel MR, Wolk MJ, Allen JM, et al. The privilege of self-regulation: the role of appropriate use criteria. J Am Coll Cardiol 2011;57:1557–9.
19. Chan PS, Patel MR, Klein LW, et al. Appropriateness of percutaneous coronary intervention. JAMA 2011;306:53–61.
20. Krumholz HM, Brindis RG, Brush JE, et al. Standards for statistical models used for public reporting of health outcomes: an American Heart Association scientific statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group. Circulation 2006;113:456–62.
21. Curtis JP, Schreiner G, Wang Y, et al. All-cause readmission and repeat revascularization after percutaneous coronary intervention in a cohort of Medicare patients. J Am Coll Cardiol 2009;54:903–7.
22. Hannan EL, Zhong Y, Krumholz H, et al. 30-Day readmission for patients undergoing percutaneous coronary interventions in New York State. J Am Coll Cardiol Intv 2011;4:1335–42.
23. Khawaja FJ, Shah ND, Lennon RJ, et al. Factors associated with 30-day readmission rates after percutaneous coronary intervention. Arch Intern Med 2012;172:112–7.

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24. Harold JG, Bass TA, Bashore TM, et al. ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol 2013;62:357–96.
25. Brownlee S, Wennberg JE, Barry MJ, et al., for the Dartmouth Institute for Health Policy and Clinical Practice. *Improving Patient Decision-Making in Health Care: A 2011 Dartmouth Atlas Report Highlighting Minnesota*. Hanover, NH: Dartmouth Institute for Health Policy and Clinical Practice; 2011. Available at: http://www.dartmouthatlas.org/downloads/reports/Decision_making_report_022411.pdf. Accessed October 11, 2013.
26. Marso SP, Teirstein PS, Kereiakes DJ, et al. Percutaneous coronary intervention use in the United States: defining measures of appropriateness. J Am Coll Cardiol Intv 2012;5:229–35.
27. Chassin MR, Loeb JM, Schmaltz SP, et al. Accountability measures–using measurement to promote quality improvement. N Engl J Med 2010;363:683–8.
28. Bonow RO, Masoudi FA, Rumsfeld JS, et al. ACC/AHA classification of care metrics: performance measures and quality metrics: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2008;52:2113–7.
29. Grines CL, Bonow RO, Casey DE Jr., et al. Prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents: a science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians. J Am Coll Cardiol 2007;49:734–9.
30. Iakovou I, Schmidt T, Bonizzoni E, et al. Incidence, predictors, and outcome of thrombosis after successful implantation of drug-eluting stents. JAMA 2005;293:2126–30.
31. Melloni C, Peterson ED, Chen AY, et al. Cockcroft-Gault versus modification of diet in renal disease: importance of glomerular filtration rate formula for classification of chronic kidney disease in patients with non-ST-segment elevation acute coronary syndromes. J Am Coll Cardiol 2008;51:991–6.
32. Gurm HS, Dixon SR, Smith DE, et al. Renal function-based contrast dosing to define safe limits of radiographic contrast media in patients undergoing percutaneous coronary interventions. J Am Coll Cardiol 2011;58:907–14.
33. Schweiger MJ, Chambers CE, Davidson CJ, et al. Prevention of contrast induced nephropathy: recommendations for the high risk patient undergoing cardiovascular procedures. Catheter Cardiovasc Interv 2007;69:135–40.
34. Stacul F, van der Molen AJ, Reimer P, et al. Contrast induced nephropathy: updated ESUR Contrast Media Safety Committee guidelines. Eur Radiol 2011;21:2527–41.
35. Mehran R, Aymong ED, Nikolsky E, et al. A simple risk score for prediction of contrast-induced nephropathy after percutaneous coronary intervention: development and initial validation. J Am Coll Cardiol 2004;44:1393–9.
36. Borden WB, Redberg RF, Mushlin AI, et al. Patterns and intensity of medical therapy in patients undergoing percutaneous coronary intervention. JAMA 2011;305:1882–9.
37. Fonarow GC, Gawlinski A, Moughrabi S, et al. Improved treatment of coronary heart disease by implementation of a Cardiac Hospitalization Atherosclerosis Management Program (CHAMP). Am J Cardiol 2001;87:819–22.
38. National Cardiovascular Data Registry. Measures and Metrics. Available at: https://www.ncdr.com/WebNCDR/home/metrics-and-measures. Accessed May 10, 2013.
39. Goel K, Lennon RJ, Tilbury RT, et al. Impact of cardiac rehabilitation on mortality and cardiovascular events after percutaneous coronary intervention in the community. Circulation 2011;123:2344–52.
40. Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med 2004;116:682–92.
41. Giannuzzi P, Temporelli PL, Marchioli R, et al. Global secondary prevention strategies to limit event recurrence after myocardial infarction: results of the GOSPEL study, a multicenter, randomized controlled trial from the Italian Cardiac Rehabilitation Network. Arch Intern Med 2008;168:2194–204.
42. Witt BJ, Jacobsen SJ, Weston SA, et al. Cardiac rehabilitation after myocardial infarction in the community. J Am Coll Cardiol 2004;44:988–96.
43. Thompson PD. Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease. Arterioscler Thromb Vasc Biol 2003;23:1319–21.
44. Clark AM, Hartling L, Vandermeer B, et al. Meta-analysis: secondary prevention programs for patients with coronary artery disease. Ann Intern Med 2005;143:659–72.
45. Thomas RJ, King M, Lui K, et al. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services. J Am Coll Cardiol 2007;50:1400–33.
46. Walther C, Möbius-Winkler S, Linke A, et al. Regular exercise training compared with percutaneous intervention leads to a reduction of inflammatory markers and cardiovascular events in patients with coronary artery disease. Eur J Cardiovasc Prev Rehabil 2008;15:107–12.
47. Balady GJ, Ades PA, Bittner VA, et al. Referral, enrollment, and delivery of cardiac rehabilitation/secondary prevention programs at clinical centers and beyond: a presidential advisory from the American Heart Association. Circulation 2011;124:2951–60.
48. Barber K, Stommel M, Kroll J, et al. Cardiac rehabilitation for community-based patients with myocardial infarction: factors predicting discharge recommendation and participation. J Clin Epidemiol 2001;54:1025–30.
49. Nallamothu BK, Krumholz HM. Putting ad hoc PCI on pause. JAMA 2010;304:2059–60.
50. Blankenship JC, Gigliotti OS, Feldman DN, et al. Ad hoc percutaneous coronary intervention: a consensus statement from the Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv 2013;81:748–58.

Key Words: ACC/AHA/SCAI/AMA-PCPI/NCQA Performance Measures ■ health policy and outcome research ■ quality indicators ■ ambulatory-level quality ■ hospital quality ■ percutaneous coronary intervention.

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Appendix A. Author Listing of Relationships With Industry and Other Entities (Relevant)—ACC/AHA/SCAI/AMA-Convened PCPI/NCQA 2013 Performance Measures for Adults Undergoing Percutaneous Coronary Intervention

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Brahmajee K. Nallamothu, Co-Chair	Ann Arbor VAMC Center for Clinical Management Research University of Michigan—Associate Professor	• Prescription Solutions*	None	None	• BCBS Foundation of Michigan*	• Abbott Vascular†	None
Carl L. Tommaso, Co-Chair	NorthShore University HealthSystem—Associate Professor, Rush Medical College Physician	None	None	None	None	None	None
H. Vernon Anderson	University of Texas Health Science Center–Houston—Professor, Department of Medicine	None	• Bristol-Myers Squibb • Sanofi-Aventis	None	• MedPace (DSMB) • DCRI‡ • Novartis • Eli Lilly	None	None
Jeffrey L. Anderson§	Intermountain Medical Center—Associate Chief of Cardiology	• AstraZeneca • Sanofi-Aventis	None	None	• Atherotech • GlaxoSmithKline	None	None
Joseph C. Cleveland, Jr.	University of Colorado at Denver—Professor of Surgery and Surgical Director, Cardiac Transplant and MCS	• Baxter Biosurgery	None	None	None	None	None
R. Adams Dudley	Institute for Health Policy Studies—Professor of Medicine and Health Policy	None	None	None	None	None	None
Peter Louis Duffy	FirstHealth of the Carolinas—Medical Director, Cardiovascular Service Line at Reid Heart Center, Interventional Cardiology	None	• Volcano	None	• Volcano	None	None
David P. Faxon	Brigham and Women's Hospital—Vice Chair of Medicine, Cardiology	• Johnson & Johnson	None	• Reva Medical	• Biotronik (DSMB)‡ • Medtronic (DSMB)‡ • Direct Flow (DSMB) • Boston Scientific (DSMB)	None	None
Hitinder S. Gurm	University of Michigan Cardiovascular Center—Associate Professor	None	None	None	• BCBS of Michigan‖*	None	None
Lawrence A. Hamilton	Kaiser Permanente, Northern California—Regional Director, Cardiac and Renal Services	None	None	None	None	None	None
Neil C. Jensen	United Healthcare—Director, Cardiology Network	None	None	None	None	None	None
Richard A. Josephson	University Hospitals of Cleveland Medical Group—Professor of Medicine, Case Western Reserve University School of Medicine	None	None	None	None	None	None
David J. Malenka	Dartmouth-Hitchcock Medical Center—Professor of Medicine, Division of Cardiology	• Wellpoint*	None	None	• Abbott Vascular	None	None

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Appendix A. Continued

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Calin V. Maniu	Bon Secours Health System, Suffolk, Virginia—Physician	None	None	None	None	None	None
Kevin W. McCabe	S.C. Johnson & Son, Inc.—Director of Occupational and Preventive Medicine	None	None	None	None	None	None
James D. Mortimer	Jim Mortimer Consulting—Consultant	None	None	None	None	None	None
Manesh R. Patel	Duke University Medical Center—Assistant Professor of Medicine	None	None	None	• Genzyme	None	None
Stephen D. Persell	Feinberg School of Medicine, Northwestern University—Assistant Professor of Medicine	None	None	None	None	None	None
John S. Rumsfeld¶	U.S. Veterans Health Administration—National Director of Cardiology; Chief Science Officer, National Cardiovascular Data Registry	• United Healthcare*	None	None	None	None	None
Kendrick A. Shunk	San Francisco VA Medical Center—Director of Interventional Cardiology	• Revascular Therapeutics	None	• Revascular Therapeutics	• Siemens Medical Systems‖ • Abbott Vascular‖ • IntraRedx‖ • Gilead	None	None
Sidney C. Smith, Jr.	University of North Carolina at Chapel Hill—Professor of Medicine	None	None	None	None	None	None
Stephen J. Stanko	The Mended Hearts, Inc.—National Cath Patient Outreach Chair	None	None	None	None	None	None
Brook Watts	Louis Stokes Cleveland VA Medical Center—Associate Professor of Medicine, Case Western Reserve University	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.

According to the ACC/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*.

*At the time that this committee was convened, third-party payers were not deemed relevant.

†Dr. Nallamothu's relationship with Abbott Vascular (attended training for MitraClip) was added shortly before finalization of the performance measures, so it was not relevant during the development of the measures.

‡No financial relationship.

§Recused from voting on measure 7.

‖Significant (greater than $10,000) relationship.

¶Recused from voting on measures 9 and 11.

ACC indicates American College of Cardiology; AHA, American Heart Association; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; BCBS, Blue Shield Blue Cross; DCRI, Duke Clinical Research Institute; DSMB, Data Safety Monitoring Board; NCQA, National Committee for Quality Assurance; SCAI, Society for Cardiovascular Angiography and Interventions; VA, Veterans Affairs.

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Appendix B. Reviewer Relationships With Industry and Other Entities (Relevant)—ACC/AHA/SCAI/AMA-Convened PCPI/NCQA 2013 Performance Measures for Adults Undergoing Percutaneous Coronary Interventions

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Nancy Albert	Content Reviewer—ACC/AHA Task Force on Performance Measures	• Merck* • BG Medicine • Medtronic	None	None	None	None	None
Joseph M. Allen	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	None	None	None	None
Steven R. Bailey	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	• Biostar	• Palmaz Scientific • Boston Scientific (DSMB)	None	None
Justin M. Bachmann	Official Reviewer—ACC Board of Governors	None	None	None	None	None	None
Biykem Bozkurt	Content Reviewer—ACC/AHA Task Force on Data Standards	None	None	None	• Forest Pharmaceuticals—PI† • NIH—PI†	• NIH—Co-Investigator†	None
Nakela L. Cook	Organizational Reviewer— NHLBI	None	None	None	None	None	None
Pamela S. Douglas	Content Reviewer—ACC Appropriate Use Criteria Task Force	• Pappas Ventures	None	None	• Roche* • Bristol-Myers Squib* • Abiomed* • Novartis* • Miracor* • Edwards Lifesciences* • Atritech*	None	None
Thomas C. Gerber	Content Reviewer—ACC/AHA/ACR/AMA-PCPI/NCQA Cardiac Imaging Writing Committee Content Reviewer—AHA	None	None	None	None	None	None
Robert C. Hendel	Content Reviewer—ACC Appropriate Use Criteria Task Force	• Bayer • Adenosine Therapeutics	None	None	None	None	None
Kalon K.L. Ho	Official Reviewer—SCAI Content Reviewer—ACC NCDR Science and Quality Oversight Committee	None	None	None	None	• Boston Scientific*	None
Hani Jneid	Content Reviewer—AHA	None	None	None	None	None	None
Christopher M. Kramer	Content Reviewer—ACC Appropriate Use Criteria Task Force	• Synarc	None	None	• Novartis† • Siemens	None	None
Carl J. Lavie Jr.	Organizational Reviewer—AACVPR	• Abbott • Boehringer Ingelheim • GlaxoSmithKline† • Pfizer† • Upsher Smith • Amarin* • AstraZeneca	None	None	None	None	None
Alice M. Mascette	Organizational Reviewer—NHLBI	None	None	None	None	None	None

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Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Frederick A. Masoudi	Content Reviewer—ACC NCDR Science and Quality Oversight Committee Content Reviewer—AHA	None	None	None	None	None	None
Laura Mauri	Official Reviewer—AHA	• Abbott • Cordis • Johnson & Johnson • Medtronic	None	None	• Abbott† • Abiomed† • Boston Scientific† • Bristol-Myers Squibb† • Cordis† • Daiichi Sankyo† • Eli Lilly† • Johnson & Johnson† • Medtronic† • Sanofi-Aventis† • Harvard Clinical Research Institute†	None	None
James K. Min	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	• GE Healthcare	• TC3*	• Phillips Healthcare* • Arineta*	None	None
Manesh R. Patel	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	None	None	None	None
Eric D. Peterson	Official Reviewer—ACC/AHA Task Force on Performance Measures	• Boehringer Ingelheim • Genentech • Janssen Pharmaceuticals • Johnson & Johnson • Merck	None	None	• Eli Lilly† • Johnson & Johnson† • Janssen Pharmaceuticals†	• DCRI‡	None
Sunil V. Rao	Official Reviewer—SCAI	• AstraZeneca • Bristol-Myers Squibb • Cordis • Daiichi Sankyo • Terumo Medical • The Medicines Company	None	None	• Sanofi-Aventis • Abbott Vascular*	None	None
Matthew T. Roe	Content Reviewer—ACC NCDR Science and Quality Oversight Committee	• KAI Pharmaceuticals† • Daiichi Sankyo† • GlaxoSmithKline • Janssen Pharmaceuticals† • Eli Lilly	• Bristol-Myers Squibb† • Sanofi-Aventis†	None	• AstraZeneca† • Bristol-Myers Squibb† • Eli Lilly† • Merck† • Roche Pharmaceuticals† • Sanofi-Aventis† • AstraZeneca*	• AstraZeneca—lectures performed within DCRI	None
Frank Rybicki	Content Reviewer—ACC/AHA/ACR/AMA-PCPI/NCQA Cardiac Imaging Writing Committee	None	None	None	• Bracco Diagnostics† • Toshiba Medical Systems†	None	None
Leslee Shaw	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	None	• Bracco Diagnostics	None	None
Marc Shelton	Content Reviewer—ACC Board of Governors	None	None	None	None	None	None
John Spertus	Content Reviewer—ACC Appropriate Use Criteria Coronary Revascularization	• Genentech • United Healthcare Scientific Advisory Board • Amgen	None	None	• Eli Lilly†	• CV Outcomes*	None
Raymond F. Stainback	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	None	None	None	None

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Appendix B. Continued

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Eric Stecker	Content Reviewer—ACC Clinical Quality Committee	None	None	None	• Biotronik† • Medtronic† • Boston Scientific†	None	None
James E. Tcheng	Content Reviewer—ACC/AHA Task Force on Data Standards	None	None	None	• Philips Medical Systems†	None	None
Randal J. Thomas	Organizational Reviewer—AACVPR	None	None	None	None	None	None
Thomas T. Tsai	Content Reviewer—ACC NCDR Science and Quality Oversight Committee	None	None	None	None	None	None
Thad Waites	Official Reviewer—ACC Board of Trustees	None	None	None	None	None	None
Tracy Y. Wang	Content Reviewer—ACC/AHA Task Force on Data Standards	• AstraZeneca • Medco Health Solutions	None	None	• Bristol-Myers Squibb • Canyon Pharmaceuticals • Daiichi Sankyo • Eli Lilly • Heartscape • Merck • Sanofi-Aventis • The Medicines Company • Gilead	None	None
Michael J. Wolk	Content Reviewer—ACC Appropriate Use Criteria Task Force	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.

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

*No financial relationship.

†Significant (greater than $10,000) relationship.

‡DCRI has numerous grants and contracts sponsored by industry. These include the following: Aastrom Biosciences†; Abbott†; Abiomed†; Acom Cardiovascular†; Adolor Corp.†; Advanced Cardiovascular Systems†; Advanced Stent Technologies†; Adynnx; Ajinomoto†; Allergan†; Amgen†; Alnylam Pharma†; Alpharma†; Amylin Pharmaceuticals†; Anadys†; Anesiva†; Angel Medical Systems†; ANGES MG†; Angiomedtrix†; APT Nidus Center†; ASCA Biopharma†; Astellas Pharma†; Asklepios†; AstraZeneca†; Atritech†; Attention Therapeutics†; Aventis†; Baxter†; Bayer†; Berlex†; BG Medicine†; Biogen†; Biolex Therapeutics†; Biomarker Factory†; Biosite†; Boehringer Ingelheim Biogen†; Boston Scientific†; Bristol-Myers Squibb†; BMS Pfizer†; Carbomed†; CardioDx†; CardioKinetix†; Cardiovascular Systems†; Cardiovax†; Celsion Corp.†; Centocor†; Cerexa†; Chase Medical†; Conatus Pharmaceuticals†; Conor Medsystems†; Cortex†; Corgentech†; CSL Behring†; CV Therapeutics†; Daiichi Pharmaceuticals†; Daiichi Sankyo†; Daiichi Sankyo Lilly†; Datascope; Dendreon†; Dainippon†; Dr. Reddy's Laboratories; Eclipse Surgical Technologies†; Edwards Lifesciences†; Eisai†; Endicor†; EnteroMedics†; Enzon Pharmaceuticals†; Eli Lilly†; Ethicon†; Ev3†; Evalve†; F2G†; Flow Cardia†; Fox Hollow Pharmaceuticals†; Fujisawa†; Genetech†; General Electric†; General Electric Co.†; General Electric Healthcare†; General Electric Medical Systems†; Genzyme Corp.†; Genome Canada†; Gilead Sciences†; GlaxoSmithKline†; Guidant Corp.†; Heartscape Technologies†; Hoffman-LaRoche†; Hospira†; Idera Pharmaceuticals†; Ikaria†; Imcor Pharmaceuticals†; Immunex†; INFORMD†; Inimex†; Inspire Pharmaceuticals†; Ischemix†; Janssen†; Johnson and Johnson†; Jomed†; Juventus Therapeutics†; KAI Pharmaceuticals†; King Pharmaceuticals†; Kyowa Pharma†; Luitpold†; Mardil†; MedImmune†; Medscape†; Medtronic Diabetes†; Medtronic†; Medtronic Vascular†; Merck Group†; MicroMed Technology†; Millennium Pharmaceuticals†; Mitsubishi Tanabe†; Momenta†; Nabriva†; Neuron Pharmaceuticals†; NitroMed; NovaCardia Inc†; Novartis AG Group†; Novartis Pharmaceuticals†; Oncura†; Orexigen†; Ortho-McNeil-Janssen†; OSI Eyetech†; OSI Pharmaceuticals†; Pfizer†; Pharmacyclics†; Pharmasset†; Pharmos†; Phyxius Pharmaceuticals; Pharsight†; Pluristen Therapeutics†; Portola Pharmaceuticals†; Proventys†; Radiant†; Regado Biosciences†; Rengeneron Pharmaceuticals†; Roche Molecular Systems†; Roche Group†; Roche Diagnostic†; Salix Pharmaceuticals†; Sanofi-Pasteur, Inc; Sanofi-aventis†; Santaris Pharmaceuticals†; Schering-Plough†; Scios†; Siemens†; Southwest Oncology Group†; Spectranetics†; Summit†; Sunovion Pharmaceuticals†; TAP Pharmaceutical Products†; Tengion†; The Medicines Company†; Theravance†; TherOx†; Tethys Bioscience†; Theregen†; Three Rivers Pharmaceuticals†; The EMMES Corporation†; UCB†; Valentis†; Valleylab†; Vertex†; Viacor†; and Wyeth†.

AACVPR indicates American Association of Cardiovascular and Pulmonary Rehabilitation; ACC, American College of Cardiology; ACR, American College of Radiology; AHA, American Heart Association; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; CV, Cardiovascular; DCRI, Duke Clinical Research Institute; DSMB, Data Safety Monitoring Board; NCDR, National Cardiovascular Data Registry; NCQA, National Committee for Quality Assurance; NHLBI, National Heart, Lung, and Blood Institute; SCAI, Society for Cardiovascular Angiography and Interventions.

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Appendix C. ACC/AHA/SCAI/AMA-PCPI/NCQA 2013 Percutaneous Coronary Interventions Performance Measures: Summary Analysis Table

	Completely Fulfills Attribute*	Partially Fulfills or Does Not Fulfill Attribute*	Summary Comments§
Measures included in the performance measure set			
Comprehensive Documentation of PCI†	1,2,3,4		
Appropriate Indication for Elective PCI‡	1,2,3b,4	3a	Lack of existing data on use in test populations makes it difficult to know whether the current measure accurately captures "appropriateness" (as opposed to encouraging gaming) or whether it will lead to unintended consequences by punishing providers.
Assessment of Candidacy for Dual-Antiplatelet Therapy†	1,2,4	3	ACCF National Cardiovascular Data Registry CathPCI Registry is unable to measure this. It will require additional chart documentation and abstraction.
Use of Embolic Protection Devices in the Treatment of Saphenous Vein Bypass Graft Disease‡	2,3b,4	1b, 3a	The guideline Class of Recommendation is 1, and Level of Evidence is only B.
Documentation of Preprocedural Glomerular Filtration Rate and Contrast Dose Used During the Procedure‡	2,3,4	1	There are few potential unintended consequences, given that there are no thresholds specified in this measure. However, evidence indicates that doses are inconsistently documented. Therefore, although this measure is expected to have limited impact because it requires only documentation, it is an intermediate step to a more meaningful performance measure.
Radiation Dose Documented‡	2,3,4	1	There are few potential unintended consequences given that there are no thresholds specified in this measure. However, evidence indicates that doses are inconsistently documented. Therefore, although this measure is expected to have limited impact because it requires only documentation, it is an intermediate step to a more meaningful performance measure.
Postprocedural Optimal Medical Therapy Composite†	1,2,3,4		Registry data are currently limited, making it unfeasible to capture specific medical, patient, or system exceptions.
Cardiac Rehabilitation Patient Referral†	1,2,3,4		
Regional or National PCI Registry Participation†	2,3,4	1	The guideline Class of Recommendation is 1, but Level of Evidence is only C.
Annual Operator PCI Volume‡	2,3b	1,3a,4	• There are potential unintended consequences because operators might be more inclined to intervene when the procedure is not indicated. • This measure could pose a feasibility challenge if a person works at multiple sites.
Annual Hospital PCI Volume†	2,3	1,4	Smaller hospitals might be more inclined to intervene when the procedure is not indicated, to achieve higher volumes.
Measures considered but not included in the performance measure set			
Assessment of patient knowledge of benefits and risks of PCI	1,4b	2,3,4a	• Limited availability of validated surveys. • Limited existing literature on patient education or actionable methods to improve it.
Postprocedural dialysis	1	2,3,4	• Dialysis might not be related to PCI. • Long measurement period is needed to capture data, given it is a rare event.
Postprocedural blood transfusion	1	3,4	Bleeding might occur outside interventionalists' locus of control.
Measurement of cardiac biomarkers	N/A	1,2,3,4	Evidence is still controversial.
Periprocedural angina assessment	1,2	3,4	This is a potentially high-impact area with validated instruments, yet little data exist on how to best incorporate validated instruments into routine practice without excessive effort or costs.
Aspirin/thienopyridine at discharge	3,4	1,2	There is little room for major impact or improvement, given existing evidence of already high compliance rates.

*Corresponding numbers and letters are linked to the ACC/AHA Task Force on Performance Measures Attributes for Performance Measures. Numbers indicate the entire attribute, and letters indicate specific attribute subcriteria.

†These measures are performance measures.

‡Indicated in shading, these measures have been designated *quality metrics*. Quality metric are designated for use in internal quality-improvement programs only. These measures are not appropriate for any other purpose (e.g., pay-for-performance, physician ranking, or public reporting programs).

§Where applicable, the writing committee provided summary comments about why certain measures were included or not included in the final measure set. For all attributes noted as "partially or does not fulfill attribute," the writing committee provided summary comments.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; GFR, glomerular filtration rate; and PCI, percutaneous coronary intervention.

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Attributes and subcriteria key:

1. **Evidence based:**
   - **1a.** For structural measures, the structure should be closely linked to a meaningful process of care that in turn is linked to a meaningful patient outcome.
   - **1b.** For process measures, the scientific basis for the measure is well established, and the process should be closely linked to a meaningful patient outcome.
   - **1c.** For outcome measures, the outcome should be clinically meaningful. If appropriate, performance measures based on outcomes should adjust for relevant clinical characteristics through the use of appropriate methodology and high-quality data sources.
2. **Measure selection:**
   - **2a.** The patient group to whom the measure applies (denominator) and the patient group for whom conformance is achieved (numerator) are clearly defined and clinically meaningful.
   - **2b.** Exceptions and exclusions are supported by evidence.
   - **2c.** The measure is reproducible across organizations and delivery settings.
   - **2d.** Face validity—The measure appears to assess what it is intended to.
   - **2e.** Content validity—The measure captures most meaningful aspects of care.
   - **2f.** Construct validity—The measure correlates well with other measures of the same aspect of care.
3. **Measure feasibility:**
   - **3a.** The data required for the measure can be obtained with reasonable effort and cost.
   - **3b.** The data required for the measure can be obtained within the period allowed for data collection.
4. **Accountability:**
   - **4a.** Actionable—Those held accountable can affect the care process or outcome.
   - **4b.** The likelihood of negative unintended consequences with the measure is low.

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Attachment 3
Volume Levels of Existing Facilities

Current CN Approved Elective PCI Programs
2014 Procedure Volumes

Current CN Approved Elective PCI Programs - received CN approval in 2008	2014 CHARS Inpatient Procedures, Age 15+	2014 Outpatient Procedures, Age 15+	Total
MultiCare Auburn Regional	93	8	101
Capital Medical Center	56	23	79
Evergreen Health	250	168	418
Good Samaritan	246	29	275
Peacehealth St. John	99	-	99
Skagit Valley MC	202	86	288
St. Francis Hospital	149	80	229
Swedish Edmonds	157	70	227
Valley Medical Center	214	49	263

Source: Inpatient from WA State CHARS Database, Age 15+, PCI defined as MSDRGs 250, 251, 248, 249, 246, 247)
Outpatient data from 2015 DOH individual hospital surveys (Dated April to September, 2015)

Attachment 4
Proposed Rule Revisions

Proposed Rule Revisions

WAC 246-310-715--General requirements

The applicant hospital must:

(1) Submit a detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington, and allow the university an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.

(2) Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington annual PCI volume standards **((~~three~~))** **two** hundred by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of **((~~seventy-five~~))** **fifty** PCIs per year. If an applicant hospital fails to meet annual volume standards, the department may conduct a review of certificate of need approval for the program under WAC 246-310-755.

(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively affecting existing staffing at PCI programs in the same planning area.

(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparatus, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.

(6) If an existing CON approved heart surgery program relinquishes the CON for heart surgery, the facility must apply for an amended CON to continue elective PCI services. The applicant must demonstrate ability to meet the elective PCI standards in this chapter.

WAC 246-310-720--Hospital Volume Standards

(1) Hospitals with an elective PCI program must perform a minimum of **((~~three~~))** **two** hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

WAC 246-310-725--Physician volume standards

Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of **((~~seventy-five~~))** **fifty** PCIs per year. Applicant hospitals must provide documentation that physicians performed **((~~seventy-five~~))** **fifty** PCI procedures per year for the previous three years prior to the applicant's CON request.

WAC 246-310-745--Need forecasting methodology.

For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:

(1) "Base year" means the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the department's CHARS reports or successor reports.

(2) "Current capacity" means the sum of all PCIs performed on people (aged fifteen years of age and older) by all CON approved adult elective PCI programs, or department grandfathered programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the department will measure the volume of that hospital as the greater of:

(a) The actual volume; or

(b) The minimum volume standard for an elective PCI program established in WAC 246-310-720.

(3) "Forecast year" means the fifth year after the base year.

(4) "Percutaneous coronary interventions" means cases as defined by diagnosis related groups (DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.

(5) "Use rate" or "PCI use rate," equals the number of PCIs performed on the residents of a planning area (aged fifteen years of age and older), per one thousand persons.

(6) "Grandfathered programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules, that continue to operate a heart surgery program. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be grandfathered.

(7) The data sources for adult elective PCI case volumes include:

(a) The CHARS data from the department, office of hospital and patient data;

(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and

(c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(8) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

(9) The data used for evaluating applications submitted during the concurrent review cycle must be the most recent year end data as reported by CHARS or the most recent survey data available through the department or COAP data for the appropriate application year. The forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from CHARS. In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and COAP.

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

(a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.

Step 3. Compute the planning area's current capacity.

(a) Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or

(c) Calculate the difference between total PCI procedures by CON approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

Step 4. Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than **((~~three~~))** **two** hundred, the department will not approve a new program,

Step 5. If Step 4 is greater than **((~~three~~))** **two** hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by **((~~three~~))** **two** hundred. Round the results down to identify the number of needed programs. For example: **((~~575/300 = 1.916 or 1 program~~))** **375/200 = 1.875 or 1 program.**