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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

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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 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, eg, 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—eg, 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 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).

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 (eg, 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.

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.

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://circ.ahajournals.org/lookup/suppl/doi:10.1161/01.cir.0000441966.31451.3f/-/DC1. 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

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 (eg, 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.

measures within the set. Diagnostics, patient education (including on the topics of prognosis and etiology), treatment, self-management, and 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 the 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] The writing committee also examined available information on gaps in care and the clinical epidemiology of PCI.

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.

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 (eg, 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 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.

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.

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 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.

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 (eg, 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

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]

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. 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 (eg, 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 (ie, treating the right patient). Without existing data on its use in test populations, however, it is difficult to 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 (ie, 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 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 (eg, 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 (eg, 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 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 (eg, 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 (eg, fractional flow reserve, intravascular ultrasound) and noncoronary procedures (eg, 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 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 (eg, 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.

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.

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KEY WORDS: AHA Scientific Statements ■ health policy and outcome research ■ quality indicators ■ ambulatory-level quality ■ hospital quality ■ percutaneous coronary intervention

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

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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
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
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

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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
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.

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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Appendix B. Continued

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

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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
Raymond F. Stainback	Content Reviewer—ACC Appropriate Use Criteria Task Force	None	None	None	None	None	None
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.***

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†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; Aijnomoto†; 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-aventist†; Santaris Pharmaceuticals†; Schering-Plough†; Sciost†; Siemens†; Southwest Oncology Group†; Spectraneticst†; 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.

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 (eg, 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.

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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Author Listing of Comprehensive Relationships With Industry and Other Entities—ACC/AHA/SCAI/AMA-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
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Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
		• Sorin • Essential Pharmaceuticals					
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Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
	Physician						
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Manesh R. Patel	Duke University Medical Center—Assistant Professor of Medicine	None	None	None	• Genzyme	None	None
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Brook Watts	Louis Stokes Cleveland VA Medical Center—	None	None	None	None	None	None

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
	Director, Medical Quality Improvement						

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.

*No financial relationship.
†Significant (greater than $10,000) relationship.
‡Dr. Nallamothu's relationship with Abbott Vascular (attended training for MitraClip) was added shortly prior to finalizing the performance measures, so it was not relevant during the development of the measures.

ABIM indicates American Board of Internal Medicine; ACC, American College of Cardiology; AHA, American Heart Association; AHRQ, Agency for Healthcare Research and Quality; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; BCBS, Blue Shield Blue Cross; CORAL Study, Cardiovascular Outcomes in Renal Atherosclerotic Lesions; DCRI, Duke Clinical Research Institute; DSMB, Data Safety Monitoring Board; GE, General Electric; NIH, National Institutes of Health; NCQA, National Committee for Quality Assurance; PCI, Percutaneous Coronary Intervention; SCAI, Society for Cardiovascular Angiography and Interventions; TRANSLATE trial- Treatment With Adenosine Diphosphate (ADP) Receptor Inhibitors: Longitudinal Assessment of Treatment Patterns and Events After Acute Coronary Syndrome; TIMI- Thrombolysis In Myocardial Infarction; VA, Veterans Affairs.