Performance Measures for Interventional Cardiology: Opportunities and Challenges

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The American College of Cardiology Foundation and American Heart Association (AHA) performance measures are measures of outcomes, processes, and structure that are based on guideline recommendations that reflect clinical care patterns and are suitable for accountability [Bonow RO et al. *J Am Coll Cardiol*. 2011]. Performance measures focus on areas with widely accepted evidence and feasible validation. Some performance measures are appropriate for public reporting, while quality metrics are for internal quality improvement. Kalon K. L. Ho, MD, MS, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA, presented an overview of desirable attributes for performance measures (Table 1).

PERFORMANCE MEASURES FOR PERCUTANEOUS CORONARY INTERVENTION

Performance measures for percutaneous coronary intervention (PCI) have been published by the American College of Cardiology (ACC), AHA, Society for Cardiovascular Angiography and Interventions, American Medical Association–Convened Physician Consortium for Performance Improvement, and the National Committee for Quality Assurance [Nallamothu BK et al. *J Am Coll Cardiol*. 2014]. All their performance measures for PCI were also reviewed by Dr Ho and are summarized in Table 2.

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Table 1. ACCF/AHA Desirable Attributes of Performance Measures

Attribute	Definition
Useful in improving patient outcomes	
Evidence based	The scientific basis of the measure is well established
Interpretable	The results of the measure are interpretable by practitioners
Actionable	The measure addresses an area under the practitioner's control
Measure design	
Denominator	The patient group to whom this measure applies is clinically meaningful
Numerator	The definition of conformance for this measure is clinically meaningful
Face validity	The measure appears to measure what it is intended to measure
Content validity	The measure captures most meaningful aspects of care
Construct validity	The measure correlates well with other measures of the same aspect of care
Reliability	The measure is likely to be reproducible across organizations and delivery settings
Measure implementation	
Feasibility	The data required for the measure are likely to be obtained with reasonable effort and cost and within the period allowed for data collection

ACCF indicates American College of Cardiology Foundation; and AHA, American Heart Association.

Table 2. 2013 ACC/AHA/SCAI/AMA Percutaneous Coronary Intervention Measurement Set

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

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.

*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.

READMISSIONS POST-PCI SERVE AS A PERFORMANCE MEASURE

Since implementation of the Hospital Readmissions Reduction Program of the Affordable Care Act, there has been a focus on readmissions after PCI as a performance measure. In 2005, the Medicare Payment Advisory Commission identified PCI as 1 of 7 conditions and procedures responsible for most readmissions, with nearly 1 in 6 Medicare patients readmitted within 30 days of PCI. The rate is similar for other payers and varies across hospitals. According to Jeptha P. Curtis, MD, Yale School of Medicine, New Haven, Connecticut, USA, there is evidence that providing better care results in lower readmission rates.

The Centers for Medicare and Medicaid Services (CMS) and the ACC developed unplanned readmissions as a performance measure, using registry data to improve risk adjustment and CMS data to identify outcomes. Implementation began in 2013. Hospitals received detailed information about their risk-standardized readmission rates, and 350 hospitals volunteered to report their outcomes. Although the CMS has not continued to publicly report PCI readmissions, the ACC is considering whether to include PCI readmissions as part of its public reporting effort.

A study of readmissions from 2 academic medical centers showed that about 40% of readmissions after PCI were potentially preventable [Wasfy JH et al. *J Am Heart Assoc.* 2014]. Furthermore, according to Dr Curtis, readmission rates across a number of medical conditions have declined since outcomes reporting began in 2010.

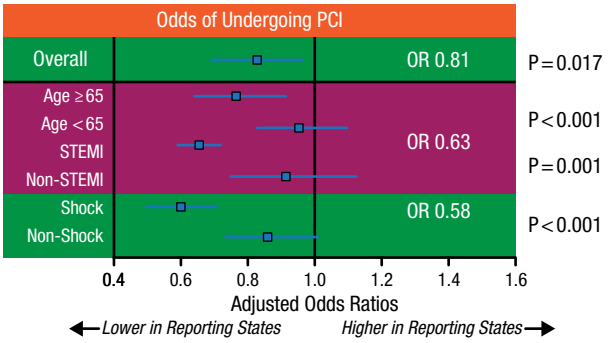
The Translating Outstanding Performance in PCI study, in collaboration with the ACC, surveyed hospitals performing PCI and found 7 strategies that were strongly associated with lower readmission rates: retaining high-quality staff, regularly meeting with care agencies, having a dedicated unit for PCI patients, adopting new technologies early, including pharmacists in the care of all PCI patients, arranging follow-up appointments before discharge, and withholding the discharge summary from patients and family.

PUBLIC REPORTING OF PCI MORTALITY

According to Ken Rosenfield, MD, Massachusetts General Hospital, Boston, Massachusetts, USA, mortality after PCI is easy to measure and is an accepted end point in clinical trials and other health care outcomes assessments, with established benchmarks. However, mortality is highly dependent on the complexity of cases and patient risk profiles. Mortality cannot be adequately risk adjusted due to infrequency and high case variability. Given the low frequency of death after PCI and the low volume of operators, 1 or 2 deaths can skew the percentage for individual operators, which might lead to risk avoidance behavior. This was demonstrated in a study showing that public reporting was associated with reduced PCI rates and increased mortality in patients with acute myocardial infarction not selected for PCI (Figure 1) [Waldo SW et al. *J Am Coll Cardiol.* 2015]. In New York, a public reporting state, selective PCI use led to decreased PCI mortality but increased overall mortality [Apolito RA et al. *Am Heart J.* 2008].

Physician risk aversion can be mitigated by introducing compassionate-use and exceptional-risk criteria and new variables for risk adjustment, such as surgical ineligibility [Waldo SW et al. *Circulation.* 2014; Resnic FS et al. *J Am Coll Cardiol.* 2011]. According to Dr Rosenfield, very high-risk patients perhaps should be excluded from the numerator and denominator of the published report. However, those data should be captured and tracked, and operator reviews should be undertaken to identify issues related to quality and appropriateness. External quality review of outliers can provide context to the statistical report. Finally, Rosenfield supported the concept of independent interfacility peer review of a random sampling of cases to evaluate both quality and appropriateness. Rather than a punitive approach, such a peer review process should be designed to identify potential issues and address them before they become problematic.

Figure 1. PCI Use in Public Reporting vs Nonreporting States



Adjusted odds of undergoing percutaneous revascularization among patients with AMI was significantly lower in public reporting states than in nonreporting states (p = 0.017). These findings were specifically pronounced among older patients, those with Medicare insurance, and those presenting with STEMI or concomitant cardiac arrest or cardiogenic shock (interaction p < 0.001 for each comparison).

PCI, percutaneous coronary intervention.

PERFORMANCE MEASURES FOR PERIPHERAL ARTERY DISEASE

The current most widely used vascular procedure database for outcome analysis is the Vascular Quality Initiative. This initiative involves a collaboration of regional quality groups collecting and analyzing data with the purpose of improving patient care [Vascular Quality Initiative. http://www.vascularqualityinitiative.org/. Accessed May 13, 2015]. The goal of such a database and outcomes analysis is to increase transparency and quality. Mark C. Bates, MD, West Virginia University School of Medicine, Charleston, West Virginia, USA, defined quality as ensuring that the patient has access to the best-quality physicians as documented by objective outcome measures in a facility that is focused on safety and has a patient-centered mind-set.

Table 3. Critical Measures for Management of Peripheral Artery Disease

Before the Procedure	
Clearly defined indications	Lifestyle-limiting claudication (quantified)
	CLI (wound size and severity of disease)
	ALI
Quality of life	Particularly important for claudication patients
Assessments	American Society of Anesthesiology score if surgery planned
	ABI, including toe pressure or perfusion for CLI primary indication
	Walking distance for claudication primary indication; treadmill data is standard
Medications	Antiplatelet therapy
	Statin (low, medium, or high dose depending on cholesterol levels)
	ACE inhibitor or ARB
Annual procedure volumes	Hospital and physician
During the Procedure	
Acute outcomes/ complications	Death
	Emergent surgery or secondary intervention
Operator information	Certification (cardiology, interventional radiology, vascular surgery, vascular medicine)
	Physician name and identifier allows volume to be tracked
Device or conduit	Atherectomy
	Type of stent
	Type of graft
	Others
After the Procedure	
At 30 d	Transfusions
	Death
	Access complications
	Cost of admission
	Hemodynamic, patency, and tissue perfusion assessment
	Amputation
	MI or stroke
	Infection
	Compartment syndrome
	Atheroemboli
Follow-up	
Limb status	Limiting claudication (quantified)
	CLI (wound and limb status)
	ALI (limb status)
Patient	Smoking status (smoking cessation discussed)
	Chronic heart failure
Quality of life	Outcome measures such as walking treadmill
Complications	Venous thromboembolism
	Stroke or MI
	Repeat surgery or intervention (ipsilateral)
Quantification of disease[a]	ABI, including toe pressure if applicable
	Duplex ultrasound
	Magnetic resonance angiography
	Computed tomographic angiography
	Angiogram
	Walking distance
Medications	Antiplatelet therapy
	Statin
	ACE or ARB

ABI, ankle-brachial index; ACE, angiotensin-converting enzyme; ALI, acute limb ischemia; ARB, angiotensin receptor blocker; CLI, critical limb ischemia; MI, myocardial infarction.

[a]Level and severity.

Source: Anderson JL et al. *Circulation*. 2013; Olin JW et al. *Circulation*. 2010.

Performance measures for peripheral artery disease (PAD) are not as well defined as those for PCI, noted Dr Bates. In 2010, several major societies published proposed performance measures for adults with PAD [Olin JW et al. *Circulation*. 2010]. Dr Bates highlighted critical measures based on these performance measures and the guidelines of the American College of Cardiology Foundation and AHA for the management of PAD (Table 3) [Anderson JL et al. *Circulation*. 2013].

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) is holding a meeting in July 2015, at which society representatives can provide input on important data for performance measures. MEDCAC is collecting data on whether PAD interventions result in reduced pain, decreased amputation, improved quality of life and functional capacity, wound healing, and decreased cardiovascular events and all-cause mortality and whether there are associated harms to patients.

The Virginia Vascular Study Group collects data and provides feedback for center and physician outliers. According to Dr Bates, the challenge for the future will be

mastering "big data" and providing personalized objective recommendations based on data from multiple sources funneling into a central database. This database will house the patient's genomic fingerprint proteomic data, hospital records, as well as physician assessments, and all outputs will be framed by comparative data from other centers, expert consensus, relevant literature, and expert consensus.

PERFORMANCE MEASURES FOR TRANSCATHETER AORTIC VALVE REPLACEMENT

No specific performance measures for transcatheter aortic valve replacement (TAVR) have been published. However, facilities that perform TAVR are required to submit data to the Society of Thoracic Surgeons and ACC transcatheter valve therapy registry for transcatheter valve replacement and repair procedures. David L. Brown, MD, The Heart Hospital Baylor, Plano, Texas, USA, discussed the evidence for several proposed performance measures for TAVR, including mortality and stroke, renal injury, vascular complications, paravalvular regurgitation, permanent pacemaker implantation, length of stay, economics, and quality of life.

A transcatheter valve therapy registry study reported favorable overall rates of in-hospital mortality (5.5%) and stroke (2.0%) and 30-day mortality (7.6%) and stroke (2.8%) [Mack MJ et al. *JAMA*. 2013], but 1-year mortality (23.7%) rates were high [Holmes DR Jr et al. *JAMA*. 2015]. Comparing implantation with Sapien vs CoreValve implantation, several studies found no differences in 1-year mortality and 30-day stroke rates in high-risk and inoperable patients.

Major vascular access site complications are associated with impaired clinical outcomes, increased transfusions, prolonged hospital stay, and increased cost. The percutaneous, transfemoral access route is the preferred and most frequently used access site. The incidence of major vascular access site complications has rapidly declined due to lower profile devices and delivery sheaths, as well as learning experience.

In the PARTNER trial, multivariable predictors of permanent pacemaker implantation after TAVR were as follows: existing right bundle branch block ($P < .001$), treatment in a registry ($P = .025$), prosthesis diameter and left ventricular outflow tract diameter ($P = .002$), and left ventricular end-diastolic diameter ($P = .003$) [Nazif TM et al. *J Am Coll Cardiol Intv*. 2015]. Permanent pacemakers increased the risk of hospitalization but not mortality.

From a US societal perspective, TAVR appears to be reasonably cost-effective for both inoperable and high-risk patients, particularly when performed via a transfemoral approach [Reynolds MR et al. *J Am Coll Cardiol.* 2012]. From a hospital perspective, economics depend heavily on geography and case mix. Ongoing reductions in complications should modestly improve the cost-effectiveness of TAVR. The greatest opportunity lies in maximizing efficiency of care for uncomplicated procedures.

Many challenges remain in the development, implementation, and reporting of performance measures for interventional procedures. Implementation of data registries is ongoing and provides an evidence base for performance measures that accurately reflect the quality of interventional care. Physician risk avoidance is a challenge that may be mitigated by instituting compassionate-use criteria and risk adjustment measures where appropriate.

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