ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures, the American College of Radiology, the Society for Cardiac Angiography and Interventions, the Society for Interventional Radiology, the Society for Vascular Medicine, the Society for Vascular Nursing, and the Society for Vascular Surgery (Writing Committee to Develop Clinical Performance Measures for Peripheral Artery Disease)

Developed in Collaboration With the American Association of Cardiovascular and Pulmonary Rehabilitation; the American Diabetes Association; the Society for Atherosclerosis Imaging and Prevention; the Society for Cardiovascular Magnetic Resonance; the Society of Cardiovascular Computed Tomography; and the PAD Coalition

Endorsed by the American Academy of Podiatric Practice Management

WRITING COMMITTEE MEMBERS

Jeffrey W. Olin, DO, FACC, FAHA, Chair; David E. Allie, MD*; Michael Belkin, MD†; Robert O. Bonow, MD, MACC, FAHA‡; Donald E. Casey, Jr, MD, MPH, MBA, FACP§; Mark A. Creager, MD, FACC, FAHA; Thomas C. Gerber, MD, PhD, FACP, FACC, FAHA‖; Alan T. Hirsch, MD, FACC, FAHA¶; Michael R. Jaff, DO, FACC, FAHA#; John A. Kaufman, MD, FAHA; Curtis A. Lewis, MD, MBA, JD**; Edward T. Martin, MD, FACC, FACP, FAHA††; Louis G. Martin, MD, FSIR‡‡; Peter Sheehan, MD§§; Kerry J. Stewart, EdD, FAACVPR, FAHA, FACSM‖‖; Diane Treat-Jacobson, PhD, RN, FAHA¶¶; Christopher J. White, MD, FACC, FAHA, FSCAI##; Zhi-Jie Zheng, MD, PhD***

*Society of Cardiovascular Computed Tomography Representative.
†Society for Vascular Surgery Representative.
‡ACCF/AHA Task Force on Performance Measures Liaison.
§American College of Physicians Representative.
‖Society for Atherosclerosis Imaging and Prevention Representative.
¶Recused from voting on Measure 4 (Antiplatelet Therapy).
#Society for Vascular Medicine Representative.
**American College of Radiology Representative.
††Society for Cardiovascular Magnetic Resonance Representative.
‡‡Society for Interventional Radiology Representative.
§§American Diabetes Association and the PAD Coalition Representative.
‖‖American Association of Cardiovascular and Pulmonary Rehabilitation Representative.
¶¶Society for Vascular Nursing Representative.
##Society for Cardiac Angiography and Interventions Representative.
***National Heart, Lung, and Blood Institute.
†††Immediate Past Task Force Chair.

This document was approved by the American College of Cardiology Board of Trustees in July 2010 and the American Heart Association Science Advisory and Coordinating Committee in August 2010, by the American College of Radiology in August 2010, by the Society for Cardiac Angiography and Interventions in August 2010, by the Society for Interventional Radiology in August 2010, by the Society for Vascular Medicine in August 2010, by the Society for Vascular Nursing in August 2010, and by the Society for Vascular Surgery in August 2010.

The American Heart Association requests that this document be cited as follows: Olin JW, Allie DE, Belkin M, Bonow RO, Casey DE Jr., Creager MA, Gerber TC, Hirsch AT, Jaff MR, Kaufman JA, Lewis CA, Martin ET, Martin LG, Sheehan P, Stewart KJ, Treat-Jacobson D, White CJ, Zheng Z-J. ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 performance measures for adults with peripheral artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures, the American College of Radiology, the Society for Cardiac Angiography and Interventions, the Society for Interventional Radiology, the Society for Vascular Medicine, the Society for Vascular Nursing, and the Society for Vascular Surgery (Writing Committee to Develop Performance Measures for Peripheral Artery Disease). *Circulation*. 2010;122:2583–2618.

This article has been copublished in *Journal of the American College of Cardiology*, the *Journal of Vascular Nursing*, the *Journal of Vascular Surgery*, and the *Vascular Medicine Journal*.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (www.cardiosource.org) and the American Heart Association (my.americanheart.org). A copy of the document is also available at http://www.americanheart.org/presenter.jhtml?identifier=3003999 by selecting either the "topic list" link or the "chronological list" link (No. KB-0110). To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.

(***Circulation*. 2010;122:2583-2618**)

***Circulation* is available at http://circ.ahajournals.org** **DOI: 10.1161/CIR.0b013e3182031a3c**

ACCF/AHA TASK FORCE ON PERFORMANCE MEASURES
Frederick A. Masoudi, MD, MSPH, FACC, FAHA, Chair; Robert O. Bonow, MD, MACC, FAHA†††; Elizabeth DeLong, PhD; John P. Erwin III, MD, FACC; David C. Goff, Jr, MD, PhD, FAHA, FACP; Kathleen Grady, PhD, RN, FAHA, FAAN; Lee A. Green, MD, MPH; Paul A. Heidenreich, MD, FACC, FAHA; Kathy J. Jenkins, MD, MPH, FACC; Ann R. Loth, RN, MS, CNS; Eric D. Peterson, MD, MPH, FACC, FAHA; David M. Shahian, MD, FACC

Table of Contents

Preamble

Over the past decade, there has been an increasing awareness that the quality of medical care delivered in the United States is variable. In its seminal document dedicated to characterizing deficiencies in delivering effective, timely, safe, equitable, efficient, and patient-centered medical care, the Institute of Medicine described a quality "chasm".[1] Recognition of the magnitude of the gap between the care that is delivered and the care that ought to be provided has stimulated interest in the development of measures of quality of care and the use of such measures for the purposes of quality improvement and accountability.

Consistent with this national focus on healthcare quality, the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have taken a leadership role in developing measures of the quality of care for cardiovascular disease (CVD) in several clinical areas (Table 1). The ACCF/AHA Task Force on Performance Measures was formed in February 2000 and was charged with identifying the clinical topics appropriate for the development of performance measures and with assembling writing committees composed of clinical and methodological experts. When appropriate, these committees have included representation from other organizations involved in the care of patients with the condition of focus. The committees are informed about the methodology of performance measure development and are instructed to construct measures for use both prospectively and retrospectively, to rely upon easily documented clinical criteria, and where appropriate, to incorporate administrative data. The data elements required for the performance measures are linked to existing ACCF/AHA

Table 1. ACCF/AHA Performance Measure Sets

Topic	Original Publication Date	Partnering Organizations	Status
Chronic heart failure[2]	2005	ACC/AHA—inpatient measures	Currently undergoing update
		ACC/AHA/PCPI—outpatient measures	Currently undergoing update
Chronic stable coronary artery disease[3]	2005	ACC/AHA/PCPI	Currently undergoing update
Hypertension[4]	2005	ACC/AHA/PCPI	Currently undergoing update
ST-elevation and non–ST-elevation myocardial infarction[5]	2006	ACC/AHA	Updated 2008[6]
Cardiac rehabilitation[7]	2007	AACVPR/ACC/AHA	Updated 2010 (referral measures only)[7a]
Atrial fibrillation[8]	2008	ACC/AHA/PCPI	
Primary prevention of cardiovascular disease[9]	2009	ACCF/AHA	
Peripheral artery disease	2010*	ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS	
Percutaneous coronary intervention	2011*	ACCF/AHA/SCAI/PCPI/NCQA	Under development

*Planned publication date.

AACVPR indicates American Association of Cardiovascular and Pulmonary Rehabilitation; ACC, American College of Cardiology; ACCF, American College of Cardiology Foundation; ACR, American College of Radiology; AHA, American Heart Association; NCQA, National Committee for Quality Assurance; PCPI, American Medical Association–Physician Consortium for Performance Improvement; SCAI, Society for Cardiac Angiography and Interventions; SIR, Society for Interventional Radiology; SVM, Society for Vascular Medicine; SVN, Society for Vascular Nursing; and SVS, Society for Vascular Surgery.

clinical data standards to encourage uniform measurements of cardiovascular care. The writing committees are also instructed to evaluate the extent to which existing nationally recognized performance measures conform to the attributes of performance measures described by the ACCF/AHA and to strive to create measures aligned with acceptable existing measures when this is feasible.

The initial measure sets published by the ACCF/AHA focused primarily on processes of medical care, or actions taken by healthcare providers, such as the prescription of a medication for a condition. These process measures are founded on the strongest recommendations contained in the ACCF/AHA clinical practice guidelines, delineating actions taken by clinicians in the care of patients, such as the prescription of a particular drug for a specific condition. Specifically, the writing committees consider as candidates for measures those processes of care that are recommended by the guidelines either as Class I, which identifies procedures and/or treatments that should be administered, or Class III, which identifies procedures and/or treatments that should not be administered (Table 2). Class II recommendations are not considered as candidates for performance measures. The methodology guiding the translation of guideline recommendations into process measures has been explicitly delineated by the ACCF/AHA, providing guidance to the writing committees.[10]

Although they possess several strengths, processes of care are limited as the sole measures of quality. Thus, current ACCF/AHA Performance Measures writing committees are instructed to consider measures of structures of care, outcomes, and efficiency as complements to process measures. In developing such measures, the committees are guided by methodology established by the ACCF/AHA.[11] Although implementation of measures of outcomes and efficiency is currently not as well established as that of process measures, it is expected that such measures will become more pervasive over time.

Although the focus of the performance measures writing committees is on measures intended for quality improvement efforts, other organizations may use these measures for external review or public reporting of provider performance. Therefore, it is within the scope of the writing committee's task to comment, when appropriate, on the strengths and limitations of such external reporting for a particular CVD state or patient population. Thus, the metrics contained within this document are categorized as either performance measures or test measures. Performance measures are those metrics that the committee designates as appropriate for use for both quality improvement and external reporting. In contrast, test measures are those appropriate for the purposes of quality improvement but not for external reporting until further validation and testing are performed.

All measures have limitations and pose challenges to implementation that could result in unintended consequences when used for accountability. The implementation of measures for purposes other than quality improvement requires field testing to address issues related but not limited to sample size, frequency of use of an intervention, comparability, and audit requirements. The manner in which these issues are addressed is dependent on several factors, including the method of data collection, performance attribution, baseline performance rates, incentives, and public reporting methods. The ACCF/AHA encourages those interested in implementing these measures for purposes beyond quality improvement to work with the ACCF/AHA to consider these complex issues in pilot implementation projects, to assess limitations and confounding factors, and to guide refinements of the measures to enhance their utility for these additional purposes.

By facilitating measurements of cardiovascular healthcare quality, ACCF/AHA performance measurement sets may serve as vehicles to accelerate appropriate translation of scientific evidence into clinical practice. These documents are intended to provide practitioners and institutions that deliver care with tools to measure the quality of their care and identify opportunities for

Table 2. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT: **CLASS I** *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	**CLASS IIa** *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	**CLASS IIb** *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	**CLASS III** *No Benefit* or **CLASS III** *Harm*
				Procedure Test / Treatment
				COR III: No benefit — Not Helpful / No Proven Benefit
				COR III: Harm — Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care

Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be done is not useful/ beneficial/ effective	COR III Harm potentially harmful causes harm associated with excess morbidity/mortality should not be done
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preferance to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B			

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence: A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

improvement. It is our hope that application of these performance measures will provide a mechanism through which the quality of medical care can be measured and improved.

Frederick A. Masoudi, MD, MSPH, FACC, FAHA
Chair, ACCF/AHA Task Force on Performance Measures

1. Introduction

The ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS Peripheral Artery Disease Performance Measures Writing Committee was charged to develop performance measures for peripheral artery disease (PAD). These performance measures address lower extremity and abdominal aortic disease, as covered by the ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) (hereafter, "PAD guidelines").[12] The measures are intended for adults (age ≥18 years) evaluated in the outpatient setting. The writing committee acknowledges that the field is rapidly evolving due to the contributions of observational research, registries, and clinical trials. Hence, modifications to these performance measures for PAD will be necessary as the field advances. In addition, there has been a recent change in the nomenclature for vascular diseases.[13] The term *atherosclerotic vascular disease* refers to disease of the arteries (other than the coronary arteries) caused by atherosclerosis.[14] We have

incorporated this new terminology into this document where it is feasible to do so.

1.1. Scope of the Problem

The PAD guidelines[12] state that:

> the term "peripheral arterial disease" includes a diverse group of disorders that lead to progressive stenosis or occlusion, or aneurysmal dilation, of the aorta and its noncoronary branch arteries, including the carotid, upper extremity, visceral, and lower extremity arterial branches. Peripheral arterial disease is the preferred clinical term that should be used to denote stenotic, occlusive, and aneurysmal diseases of the aorta and its branch arteries, exclusive of the coronary arteries (page e7).

For the purposes of these performance measures, the term *peripheral artery disease* in the title is used to denote atherosclerotic stenosis or occlusion of the aorta and arteries supplying the lower extremities and abdominal aortic aneurysms (AAAs).[13,14]

PAD is a marker of systemic atherosclerosis. It has been estimated that approximately 8 million persons in the United States are afflicted with PAD.[15] The prevalence of PAD is approximately 12% of the adult population, with men being affected slightly more than women.[16,17] However, this percentage is age dependent. Almost 20% of adults over the age of 70 years have PAD.[18] Findings from a national cross-sectional survey of PARTNERS (PAD Awareness, Risk, and Treatment: New Resources for Survival) found that PAD afflicts 29% of patients who are age ≥70 years, age 50 to 69 years with at least a 10–pack-per-year history of smoking, or age 50 to 69 years with a history of diabetes.[19] Despite the strikingly high prevalence of PAD, this disease is underdiagnosed because it often presents with atypical symptoms or no ischemic symptoms related to the legs at all. More than 70% of primary care providers in the PARTNERS study whose patients were screened were unaware of the presence of PAD in those with the disease.[19]

The clinical presentation of PAD may vary from no symptoms to intermittent claudication, atypical leg pain, rest pain, ischemic ulcers, or gangrene. Claudication is the typical symptomatic expression of PAD. However, asymptomatic disease may occur in up to 50% of all patients with PAD.[12] The Walking and Leg Circulation Study evaluated the symptoms in patients with PAD. Of the 460 patients with PAD, 19.8% had no exertional leg pain, 28.5% had atypical leg pain, 32.6% had classic intermittent claudication, and 19.1% had pain at rest.[20] The results of these and other studies make it readily apparent that more patients with PAD are asymptomatic or have atypical leg symptoms than have classic intermittent claudication.

PAD has 2 major consequences: The first is a decrease in overall well-being and quality of life due to claudication and atypical leg pain.[21–25] This often leads to patients becoming sedentary and limiting the amount of walking they do because of pain and discomfort. This may be associated with depression.[26] The second is a markedly increased cardiovascular morbidity (myocardial infarction and stroke) and mortality (cardiovascular and all-cause). Treatment should be directed at each of these facets.

PAD is most often diagnosed by an ankle-brachial index (ABI) ≤0.9. A low ABI is an independent predictor of increased mortality.[27–32] In the Framingham Study, mortality in patients with intermittent claudication was 2–3 times higher than in age- and sex-matched control patients, with 75% of PAD patients dying from cardiovascular events. In a 15-year review of patients with claudication, over 66% of mortality was attributable to CVD.[17] In a 10-year prospective study by Criqui et al,[33] PAD patients both with and without a history of CVD had significantly increased risk of dying from cardiovascular and coronary heart disease compared with age-matched control patients. The all-cause mortality was 3.1 times greater and the CVD mortality was 5.9 times greater in patients with PAD compared with patients without PAD. The risk of cardiovascular events has been found to be similar between PAD patients with claudication and PAD patients without symptoms.[34] The extremely high morbidity and mortality in the PAD population is due to myocardial infarction and stroke.[35,36] Both the Edinburgh Artery Study and the ARIC (Atherosclerosis Risk in Communities) study correlated an increased risk of stroke and transient ischemic attack with increased PAD severity.[34,37] The combination of known coronary or cerebrovascular disease with PAD has been shown to increase mortality risk. The BARI (Bypass Angioplasty Revascularization Investigation) trial demonstrated that patients with multivessel coronary artery disease (CAD) and PAD had a 4.9 times greater relative risk of death compared with those individuals without PAD.[38] In addition, in a pooled analysis of 8 randomized prospective trials involving 19,867 patients undergoing percutaneous coronary intervention, the 1-year mortality was 5% in patients with PAD and coronary disease compared with 2.1% in patients with coronary disease alone ($P<0.001$).[39]

Despite the overwhelming evidence that patients with PAD are at a markedly increased risk of myocardial infarction, stroke, and death, these patients are often undertreated, in that they do not receive antiplatelet therapy or statins with the same frequency as do patients with coronary artery disease.[19]

Thus, these PAD performance measures are directed at strategies to improve diagnosis and treatment of patients with PAD with an overall goal of improving patients' walking distance and speed, improving their quality of life, and decreasing cardiovascular event rates.

1.2. Structure and Membership of the Writing Committee

The members of the writing committee included experienced clinicians and specialists in vascular medicine, cardiology, vascular surgery, exercise physiology, vascular and interventional radiology, interventional cardiology, endocrinology, and epidemiology. The writing committee also included representatives from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR); the American College of Physicians (ACP); the American College of Radiology (ACR); the American

Diabetes Association (ADA); the National Heart, Lung, and Blood Institute (NHLBI); the PAD Coalition; the Society for Atherosclerosis Imaging and Prevention (SAIP); the Society for Cardiac Angiography and Interventions (SCAI); the Society of Cardiovascular Computed Tomography (SCCT); the Society for Cardiovascular Magnetic Resonance (SCMR); the Society for Interventional Radiology (SIR); the Society for Vascular Medicine (SVM); the Society for Vascular Nursing (SVN); and the Society for Vascular Surgery (SVS).

1.3. Disclosure of Relationships With Industry

The work of the writing committee was supported exclusively by the ACCF and AHA. Committee members volunteered their time, and there was no commercial support for the development of these performance measures. Meetings of the writing committee were confidential and attended only by committee members and staff. Writing committee members were required to disclose in writing all financial relationships with industry relevant to this topic according to standard ACCF and AHA reporting policies and verbally acknowledged these relationships to the other members at each meeting (see Appendix A). A confidential final vote was conducted on each measure proposed for inclusion in this set. Committee members with relationships relevant to a specific measure did not participate in the voting regarding that measure but were allowed to participate in the discussion after disclosing the relationship. In addition, Appendix B includes relevant relationships with industry information for all peer reviewers of this document.

1.4. Review and Endorsement

Between July 20, 2009, and August 18, 2009, this performance measure document underwent a 30-day public comment period, during which ACCF and AHA members and other health professionals had an opportunity to review and comment on the text in advance of its final approval and publication. Sixteen public responses were received.

The official peer and content review of the document was conducted simultaneously with the 30-day public comment period, with 2 peer reviewers nominated by the ACCF, 2 nominated by the AHA, and 2 peer reviewers nominated by each of the other partnering organizations (ACR, SCAI, SIR, SVM, SVN, and SVS) and by each collaborating organization (AACVPR, ADA, PAD Coalition, SAIP, SCCT, and SCMR). Additional comments were sought from clinical content experts and performance measurement experts, and 8 individual content reviewer responses were received. All peer and content reviewer relationships with industry information was collected and distributed to the writing committee and is published in this document. (See Appendix B for details.)

The ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease was adopted by the respective Boards of Directors of the ACCF and AHA in August 2010. These measures will be reviewed for currency once annually and updated as needed. They should be considered valid until either updated or rescinded by the ACCF/AHA Task Force on Performance Measures.

2. Methodology

The development of performance systems involves identification of a set of measures targeting a specific patient population observed over a particular time period. To achieve this goal, the ACCF/AHA Task Force on Performance Measures has outlined 5 mandatory sequential steps. Sections 2.1 through 2.5 outline how the writing committee addressed these elements.

2.1. Target Population and Care Period

The target population consists of patients age ≥18 years. The writing committee developed exclusion criteria specific to each measure to further specify the target population.

2.2. Dimensions of Care

Given the multiple potential domains of treatment that can be measured, the writing committee identified the relevant dimensions of care that should be evaluated. We placed each potential performance measure into the relevant dimension of care categories. Performance measures and test measures selected for inclusion in the final set and their dimensions of care are summarized in Table 3. Appendix C provides the detailed specifications for each measure.

Although the writing committee considered a number of additional measures that focus on equally important aspects of care, length and complexity considerations did not allow their inclusion in the set. Some of the reasons for this are discussed later in this paper.

2.3. Literature Review

The writing committee used the PAD guidelines as the primary source for deriving these measures.[12] In addition, the writing committee also reviewed guidelines in "Transatlantic Inter-Societal Consensus for the Management of Peripheral Arterial Disease (TASC II)"[40] and the "AACVPR/ACC/AHA 2007 Performance Measures on Cardiac Rehabilitation for Referral to and Delivery of Cardiac Rehabilitation/Secondary Prevention Services".[7]

2.4. Definition of Potential Measures

Explicit criteria exist for the development of performance measures that accurately reflect quality of care. These criteria include: 1) defining the numerators and denominators of potential measures, and 2) evaluating their applicability, interpretability, and feasibility. To select measures for inclusion in the performance measurement set, the writing committee prioritized the recommendations from the PAD guidelines.[12]

2.5. Selection of Measures for Inclusion in the Performance Measure Set

From analysis of these recommendations, the writing committee identified potential measures relevant to adults with PAD and then independently evaluated their potential for use as performance measures using 9 exclusion criteria adapted

from the ACCF/AHA Attributes of Performance Measures (Table 4) and the Performance Measure Survey Form and Exclusion Criteria Definitions (Appendix D). Member ratings of all the potential measures were collated and discussed by the full committee so that members could reach consensus about which measures should advance for inclusion in the final measure set. There were 37 potential measures initially advanced for full specification to assess their suitability as performance measures. Through an iterative process of repeated surveys within the writing committee, these potential measures were eventually reduced to 7 final performance measures and 2 test measures. After additional discussion and refinement of measure specifications, the writing committee conducted a confidential vote on whether to include each measure and whether to designate any of the measures as test measures in the final set. Writing committee members were required to recuse themselves from voting on any measures for which they had significant relevant relationships with industry.

3. Peripheral Artery Disease Performance Measures

3.1. Definition of Peripheral Artery Disease and Abdominal Aortic Aneurysm

Atherosclerotic vascular disease encompasses a range of noncoronary arterial syndromes that are caused by the altered structure and function of the arteries that supply the brain, visceral organs, and the limbs. Numerous pathophysiologic processes can contribute to the creation of stenosis or aneurysms of the noncoronary arterial circulation, but atherosclerosis remains the most common disease process affecting the aorta and its branch arteries.

3.2. Brief Summary of the Measurement Set

Table 5 summarizes the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measurement Set—those measures with the highest level of evidence and support among the writing committee members. Appendix C provides the detailed specifications for each performance measure, including the numerator, denominator, period of assessment, method of reporting, sources of data, rationale, clinical recommendations, recommended level of attribution and/or aggregation, and challenges to implementation.

3.3. Data Collection

These performance measures for PAD are ideally intended for prospective use to enhance the quality improvement process but may also be applied retrospectively. We recommend use of a data collection instrument to aid compilation (see Appendix E). Individual institutions may modify the sample instrument or develop a different tool based on local practice and standards.

3.4. Exclusion Criteria and Challenges to Implementation

The writing committee added exclusion criteria, recognizing that there are justifiable reasons for not meeting the performance measures. These reasons should be recorded on the data collection form. Documentation of such factors should be encouraged because this will provide data for future research and facilitate in-depth quality improvement in situations in which there are apparent outliers with respect to the number of patients with medical or patient-centered reasons for exclusion.

Challenges to implementation of the measures are discussed, where applicable. In general, the initial challenge facing any measurement effort is inadequate documentation. Discussion of these challenges is not an argument against any individual measure. Rather, it is a cautionary note that draws attention to areas where additional research may enhance the value of the measures.

4. Discussion

The performance measures that were chosen fulfilled the criteria, as outlined in Table 4:

1. They are useful in improving patient outcomes and are based on Class I evidence: interpretable and actionable.
2. The measure design is precisely defined and valid in face, content, and construct.
3. The measure can be implemented with reasonable effort and cost and in a reasonable time period.

The writing committee examined all Class I and Class III recommendations from the PAD guidelines and considered only those guideline recommendations that could be translated into measures that met the criteria stated above. Many potential performance measures did not meet these 3 criteria and thus were not included in this set of measures. Reasons for some of these omissions are discussed in section 4.7. In summary, the final selection of performance measures was based on the evidence base for a given measure, the ease and/or complexity of measurement, and whether the measurement was covered in previously published measurement sets.

Assessment of care remains challenging in all areas of medicine but is particularly so in patients with PAD. PAD is underdiagnosed, undertreated, and poorly understood by many practicing clinicians.[19] Although the PAD guidelines[12] provide a good first step for many clinicians to establish their clinical expertise, continuing research upon which to base future measurement is important, and continuing modification of the guidelines will be necessary to keep up to date with current knowledge and improve patient outcomes.

Potential performance measures for which the challenges to implementation were considered too difficult to overcome were not included in this data set. In general, the requirements for documentation are an important challenge of any measurement effort. The acknowledgment of these challenges is not an argument against measurement. They are listed to make the reader aware of the potential obstacles that may occur in any measurement set.

4.1. Attribution and/or Aggregation

Clinical performance measures are used to assess quality of care provided by individual physicians. Hence, caution must be exercised if several physicians are actively involved at once with a particular episode of care. Given the nature and

Table 3. ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measurement Set: Dimension of Care Measures Matrix

Measure Name	Risk Assessment	Diagnostics	Patient Education	Treatment	Self-Management/ Compliance	Monitoring of Disease Status
1. Ankle brachial index	✓	✓				
2. Cholesterol-lowering medications (statin)				✓		
3. Smoking cessation			✓	✓	✓	
4. Antiplatelet therapy				✓		
5. Supervised exercise			✓	✓	✓	✓
6. Lower extremity vein bypass graft surveillance		✓				✓
7. Monitoring of abdominal aortic aneurysms						✓
T-1. Vascular review of systems for lower extremity PAD*	✓	✓				
T-2. PAD "at risk" population pulse examination*	✓	✓				

*Test measure (T-1 and T-2): This measure has been designated for use in internal quality improvement programs only. It is not appropriate for any other use (e.g., pay for performance, physician ranking, or public reporting programs).

ACCF indicates American College of Cardiology Foundation; ACR, American College of Radiology; AHA, American Heart Association; PAD, peripheral artery disease; SCAI, Society for Cardiac Angiography and Interventions; SIR, Society of Interventional Radiology; SVM, Society for Vascular Medicine; SVN, Society of Vascular Nursing; and SVS, Society for Vascular Surgery.

clinical course of PAD, most patients require longitudinal follow-up by physicians of different specialties. It is likely that the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease will be utilized by the Centers for Medicare and Medicaid Services and other third-party payers to assess each individual physician caring for patients with PAD. Therefore, it is critical that physicians effectively document in the patient's medical records all clinical data necessary for each PAD performance measure. More important is the need for all clinicians who are participating in a patient's care to share this information consistently so that data collection for performance measures attributable to all involved can be readily available. Such information sharing will also improve communication and coordination of care among physicians caring for patients with PAD.

Table 4. ACCF/AHA Attributes of Performance Measures

Consideration	Attribute
Useful in improving patient outcomes	Evidence-based
	Interpretable
	Actionable
Measure design	Denominator precisely defined
	Numerator precisely defined
	Validity type
	• Face • Content • Construct
	Reliability
Measure implementation	Feasibility
	• Reasonable effort • Reasonable cost • Reasonable time period for collection
Overall assessment	Overall assessment of measure for inclusion in measurement set

Adapted from Normand et al.[41]

For the first time in an ACCF/AHA performance measure set, attribution and/or aggregation is listed in each measure. Attribution indicates which clinicians and/or practices should report a given measure (ie, all clinicians and/or practices managing patients with CVD versus only vascular specialists). The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance. Healthcare providers from many different specialties (primary care, internal medicine, cardiovascular medicine, vascular medicine, interventional radiology, vascular surgery, and endocrinology) may care for patients with PAD, yet not all specialists should be responsible for each performance measure. For example, for lower extremity bypass graft surveillance (Performance Measure 6) only vascular specialists should be held accountable. In addition, the writing committee believes it is now beyond the scope of practice to expect vascular surgeons and interventional radiologists to manage cholesterol-lowering medications (Performance Measure 2). However, vascular surgeons and interventional radiologists should communicate with the primary care physician about the use of statin and antiplatelet therapy in patients with PAD and document such communication and medication use in the chart.

4.2. Overlap With Existing National Performance Measure Sets

All individuals with PAD, regardless of symptom status, ABI, or efficacy of revascularization, face as high (or higher) a short-term risk of a morbid or mortal ischemic event (myocardial infarction, stroke, or death) as that suffered by patients with any other CVD[12,42] Nevertheless, although the published peer-reviewed evidence base—as documented in the PAD guidelines[12]—unambiguously documents that impressive risk reductions are achieved by use of proven pharmacological and lifestyle interventions, individuals with PAD in clinical practice are known to less consistently receive these treatments.[19,43–45] Furthermore, physicians often do not recognize

Table 5. ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measurement Set

Measure Name	Description	Attribution
Performance Measures		
1. ABI	Measurement of ABI in patients at risk for PAD	All clinicians managing patients with cardiovascular disease
2. Cholesterol-Lowering Medications (Statin)	Drug therapy for lowering low-density lipoprotein cholesterol in patients with PAD	All primary care and cardiovascular medicine physicians
3. Smoking Cessation	Smoking-cessation intervention for active smoking in patients with PAD	All clinicians managing patients with cardiovascular disease
4. Antiplatelet Therapy	Antiplatelet therapy to reduce the risk of myocardial infarction, stroke, or vascular death in patients with a history of symptomatic PAD	All clinicians managing patients with cardiovascular disease
5. Supervised Exercise	Supervised exercise training for patients with intermittent claudication	All clinicians managing patients with cardiovascular disease
6. Lower Extremity Vein Bypass Graft Surveillance	ABI and Duplex ultrasound of lower extremity vein bypass site	Vascular specialists only
7. Monitoring of Abdominal Aortic Aneurysms	Monitoring of asymptomatic abdominal aortic aneurysms between 4.0 and 5.4 cm in diameter	All clinicians managing patients with cardiovascular disease
Test Measures		
T-1. Vascular Review of Systems for Lower Extremity PAD*	Medical or personal history of walking impairment, claudication or ischemic rest pain, and nonhealing wounds in patients at risk for lower extremity PAD	All clinicians managing patients with cardiovascular disease
T-2. PAD "At Risk" Population Pulse Examination*	Measurement of pulses in the lower extremities in patients at risk for PAD	All clinicians managing patients with cardiovascular disease

*Test measure (T-1 and T-2): This measure has been designated for use in internal quality improvement programs only. It is not appropriate for any other use (e.g., pay for performance, physician ranking, or public reporting programs).

ABI indicates ankle brachial index; ACCF, American College of Cardiology Foundation; ACR, American College of Radiology; AHA, American Heart Association; PAD, peripheral arterial disease; SCAI, Society for Cardiac Angiography and Interventions; SIR, Society of Interventional Radiology; SVM, Society for Vascular Medicine; SVN, Society of Vascular Nursing; and SVS, Society for Vascular Surgery.

the cardiovascular risk of PAD. This is a major reason that they do not consistently prescribe such risk-reduction medications for patients with PAD, as they do for individuals with coronary artery disease.[46,47] These facts are evident even though other cardiovascular treatment guidelines for lipid lowering, hypertension, and smoking have long included PAD as a "very high risk" patient cohort.

These PAD performance measures therefore provide a critical disease-based opportunity to improve PAD clinical care and outcomes, which can be accomplished only if the use of risk-reduction interventions are measured (as they have been for acute coronary syndromes and heart failure) and thus permit incremental improvement to be systematically achieved.

One measure would evaluate use of statin therapy for lowering lipoprotein cholesterol (LDL-C) in patients with PAD by measuring the fraction of eligible patients with PAD who were prescribed a statin and whose LDL-C is <100 mg/dL. The second measure would evaluate the use of smoking-cessation interventions for active smoking in patients with PAD by documenting the fraction of patients with PAD identified as current smokers who have received smoking-cessation intervention. The third measure would evaluate use of antiplatelet therapy to reduce the risk of myocardial infarction, stroke, or cardiovascular death in patients with a history of symptomatic PAD. Each of these measures should be achievable by any physician, advanced practice nurse, practice, or healthcare system that is dedicated to improving health outcomes for individuals with PAD.

4.3. Ankle Brachial Index

Individuals with PAD are at significant risk for cardiovascular ischemic events, including myocardial infarction, stroke, and death.[12,48] Epidemiological studies have shown that even asymptomatic patients suffer mortality rates significantly higher than individuals who do not have PAD. PAD can easily be diagnosed with an ABI ≤ 0.90[12,27,29,32,33,35] The ABI is measured with a handheld continuous wave Doppler ultrasound device and a blood pressure cuff. The higher systolic pressure measured from either the posterior tibial or dorsalis pedis artery (in each leg) is compared with the higher brachial artery pressure taken from either arm. Diagnosis of PAD provides the physician the opportunity to initiate treatment to reduce cardiovascular risk and therefore decrease morbidity and mortality. This is particularly important for those individuals who have not previously been diagnosed with an atherosclerotic disease.

The ABI is a simple, inexpensive, noninvasive test that can be easily performed in most clinical settings and has a sensitivity of 79% to 95% and a specificity of 95% to 100%.[12] Numerous studies have demonstrated that an abnormal ABI correlates with a significantly increased risk of coronary heart disease, stroke, and cardiovascular death. Most recently, a 2008 meta-analysis demonstrated that a low ABI (<0.90) was associated with approximately twice the 10-year total mortality, cardiovascular

mortality, and major coronary event rate compared with the overall rate in each Framingham Risk Score category. Including the ABI in cardiovascular risk stratification using the Framingham Risk Score would result in reclassification of the risk category and modification of treatment recommendations in approximately 19% of men and 36% of women.[49] The writing committee recognizes that reimbursement for the ABI in the office setting is incomplete and that requiring an ABI in persons at risk for PAD adds a burden to busy primary care clinicians. Despite this, the weight of the evidence of the utility of the ABI to predict cardiovascular morbidity and mortality and all-cause mortality and to facilitate initiation of treatment to reduce cardiovascular events has led this writing committee to support the measurement of the ABI in patients at risk (see Performance Measure 1 for definition of at risk) for PAD. It is the writing committee's belief that this measure will also be useful in better documenting current practice patterns of physician office evaluation and in identifying potential opportunities for quality improvements for patients with PAD.

4.4. Antiplatelet Therapy

In the PAD guidelines[12] and the "Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)",[40] antiplatelet therapy is recommended for the treatment of patients with PAD. Several documents in the past year have questioned the efficacy of aspirin in patients with asymptomatic PAD.[50,51] The role of antiplatelet therapy in asymptomatic patients is addressed in the upcoming ACCF/AHA focused update to the 2005 PAD guidelines; thus, we have included only patients with a history of symptomatic PAD in this performance measure.

4.5. Supervised Exercise

The PAD guidelines recommend supervised exercise to treat patients with PAD who have claudication because of its proven efficacy and safety.[12] Any performance measure that is intended to measure the "appropriateness" of care offered to individuals with PAD and claudication would rightly measure the applied use of this treatment care standard.

Nevertheless, the writing committee is aware that, as for many performance measures, real-world barriers exist that limit actual use of a treatment. The efficacy and safety of PAD exercise rehabilitation for the treatment of claudication is a uniformly recommended, evidence-based, consensus-driven therapy that has a Class I (Level of Evidence: A) recommendation in the 2005 PAD guidelines.[12] There is currently incomplete reimbursement for, and therefore a lack of broad availability of, supervised exercise programs, which makes this PAD performance measure difficult to carry out. However, the data supporting the ability of supervised exercise to increase walking capability in patients with claudication are so strong[52] that we feel including this treatment modality as a performance measure may help to move it into more general use. Another limiting factor for the low use of exercise rehabilitation is the lack of counseling about and prescription of this therapy by many healthcare professionals. The writing committee believes that more patients would choose a trial of exercise, as they do in other rehabilitative therapies (eg, cardiac rehabilitation, pulmonary rehabilitation, and orthopedic rehabilitation), if they were made aware that this is an efficacious treatment option, or if they were prescribed this option, and especially if it were carried out in a supervised setting.

Patients with PAD should be counseled about all of their treatment options in order to engage them fully in the decision-making process about their care. This counseling and discussion of treatment options should include use of supervised exercise, pharmacological management, and/or the various percutaneous or open surgical revascularization techniques. Inasmuch as exercise rehabilitation has not to date been routinely recommended by clinicians, it is impossible to define what percentage of patients would choose supervised exercise as the first-line therapy if they were made aware of this option and if this treatment modality were reimbursed by third-party payers. Thus, the inclusion of supervised exercise in the PAD performance measures will assure the following: 1) that this evidence-based therapeutic modality will be provided as a component of informed decision making about the various treatment strategies for patients with PAD; 2) that data can be collected to evaluate current claudication treatment recommendation practice patterns; and 3) that these data will be able to be tracked over time as PAD rehabilitation programs, and possible insurance reimbursement, become more widely available. A variety of supervised exercise protocols have been published.[53] Practices should create individual options for patients that mirror these protocols in physiologic effectiveness.

It should be noted that ongoing advocacy efforts are under way to align future Centers for Medicare and Medicaid Services and other health payer reimbursement to the current PAD guideline evidence base and thus to include reimbursement for PAD exercise rehabilitation programs. It is anticipated that this essential performance measure will permit patients, healthcare providers, and health payers to be able to make incremental improvements that will assure patient access to all proven claudication therapies. Most current cardiac rehabilitation programs, which are broadly available, are poised to provide PAD exercise rehabilitation. This performance measure provides data that can help translate evidence-based PAD knowledge into real-world care improvements.

4.6. Test Measures

Although it is common sense that one should obtain an accurate vascular history and perform a good vascular examination in all patients suspected of having PAD, the writing committee chose to include measures T-1 and T-2 as test measures only. This decision was made because of the desire to limit the number of performance measures to a reasonable number. We also believe that these measures would be difficult and time consuming to track and would require additional resources for monitoring that may not be available. As test measures, their use should be for internal quality improvement programs only. They are not appropriate for other uses, such as pay for performance, physician ranking, or public reporting programs.

4.7. Potential Measures Considered But Not Included in This Set

4.7.1. Lower Extremity Endovascular Revascularization Surveillance

Although there has been some controversy in the literature there have been several good studies (Class I, Level of Evidence: A) demonstrating that surveillance for vein bypass is an effective way to preserve the long-term function of the bypass and to identify and correct problems before the bypass thromboses.[54–56] There are no such studies available in patients who have undergone endovascular revascularization, yet it makes intuitive sense that if a problem (eg, restenosis) can be identified, the problem may be correctable before the artery occludes. However, the PAD guidelines gave this a Class IIa designation, thus we were unable to include this as a performance or test measure.

4.7.2. Chronic Critical Limb Ischemia and Acute Limb Ischemia

The writing committee considered numerous potential measures that would focus on the surgical as well as endovascular management of patients with chronic and acute limb ischemia. Although the management of chronic and acute limb ischemia is considered extremely important by the writing committee, specific measures were not included in this area for a variety of reasons. One of the important reasons is that the goal of the writing committee was to develop performance measures that would be relevant to as many clinicians and as many patients as possible. Patients with chronic limb ischemia and acute limb ischemia needing surgical or endovascular therapy represent a small minority of all patients with PAD. Furthermore, the clinicians who actively manage these problems represent a small subset of clinicians who manage patients with PAD. As such, the writing committee felt that the scope of any performance measures adopted in these areas would not be relevant to enough patients and clinicians to justify their inclusion.

Another reason for not including measures in these areas is the complexity of any metrics that might be developed to measure the performance of care. These patients present with very complex symptoms, with multiple comorbidities and significant anatomic variations, which render simple metrics impractical. Finally, the level of evidence for establishing specific guidelines and measures in these areas is not sufficiently rigorous to justify specific performance measures for the management of chronic or acute limb ischemia.

4.7.3. Renal and Mesenteric Artery Disease

There are no performance measures related to renal or mesenteric artery disease included in this report. While renal artery disease is a common cardiovascular condition, the PAD guidelines contain no Class I recommendations related to this disease, and no randomized controlled trials of sufficiently high caliber exist to guide clinicians in the optimal management of patients with renal artery disease. In addition, a considerable controversy remains among "experts" as to the most effective therapy to manage this group of patients. Until the results of the CORAL (Cardiovascular Outcomes in Renal Atherosclerotic Lesions) trial[57] are reported, healthcare providers will continue to manage this group of patients according to their interpretation of the available literature.

Likewise, there is even less scientific information on mesenteric artery disease available, and thus no performance measures were deemed appropriate for this topic.

4.7.4. Exercise Treadmill Testing

Exercise treadmill testing can assist clinicians in the evaluation of the functional status of PAD patients. A decrease in the postexercise ankle pressures can confirm a diagnosis of PAD in symptomatic patients who have a normal ABI at rest. In addition, exercise treadmill testing allows quantification of a patient's baseline and/or postprocedure functional limitation or improvement.

Despite the potential benefits of this procedure, the writing committee agreed both that this measure would be difficult to implement and that there were other measures with higher priority; thus, we decided not to include this measure.

4.7.5. Computed Tomographic Angiography and Magnetic Resonance Angiography

It has been clearly shown that computed tomographic angiography and magnetic resonance angiography are useful imaging strategies to delineate the anatomy and help plan percutaneous and surgical revascularization.[12] However, this potential performance measure did not meet the criteria for a good performance measures as outlined in Table 4.

4.7.6. Management of Hypertension and Diabetes

It is very important to control blood pressure and diabetes to goal levels in patients with PAD. Excellent performance measures already exist on the diagnosis and management of hypertension and diabetes mellitus, and the reader is referred to those.[4,58,59]

4.7.7. Screening for Abdominal Aortic Aneurysm

This was the most difficult measure to exclude. However, the PAD guidelines assigned this only a Class IIa designation. Because only Class I designations are considered for performance measures, screening for abdominal aortic aneurysm was excluded. However, the U.S. Preventive Task Force[60] and the Societies for Vascular Medicine and Surgery[61] recommend screening for AAA in the following patient populations:

- Men age ≥60 years with a history of AAA in a parent or sibling.
- Men age 65 to 75 years who have ever smoked >100 cigarettes in their lifetime.

Screening this patient population has been shown to decrease aneurysm-related mortality.[61–64] A meta-analysis of 4 large randomized prospective controlled trials[65] evaluated the midterm (3.5 to 5 years) and long-term (7 to 15 years) results as related to aneurysm-related mortality and total mortality. Heterogeneity between the studies was assessed by the chi-square test. In cases of heterogeneity, random effect models were used. The pooled midterm analysis demonstrated a reduction in AAA-related mortality (odds ratio [OR], 0.56, 95% confidence interval [CI], 0.44 to 0.72). Overall mortality was nonsignificantly reduced

(OR, 0.94, 95% CI, 0.86 to 1.02). The long-term results also showed a reduction in AAA-related mortality (OR, 0.47, 95% CI, 0.25 to 0.90) and a significant reduction in overall mortality (OR, 0.94, 95% CI, 0.92 to 0.97). The conclusion of this meta-analysis was that population screening for AAA reduces AAA-related and overall mortality but local differences may influence the cost-effectiveness of screening.

Kim and associates[66] showed that the benefit derived at 4 years was maintained at 7 years of follow-up, with a relative risk reduction of aneurysm-related death of 47%. They also showed that there is a substantial cost-benefit to screening, which is estimated on the basis of AAA-related mortality as U.S. $19,500 per life-year gained. The mortality curves diverge at a constant rate after 1 year, and the area between the curves is greater at years 5 to 7 than years 1 to 4. Thus, the cost per life-year gained decreases in the later years.[67] Therefore, when the PAD guideline is revised, if screening for AAA becomes a Class I recommendation, creation of an associated performance measure will be considered.

4.7.8. Outcome Measures

The writing committee recognizes that the most interpretable and potentially important performance measures are outcome measures; however, there are a number of significant limitations to their use for provider accountability or public reporting.[11] Outcome measures are therefore currently best suited for use as tools to assist providers in understanding their own performance.

Krumholz et al.[6] have eloquently described the importance of assessing outcomes in addition to measuring performance on key processes of care, per se:

> Although measures focusing on processes of care have substantial appeal as a means of reflecting quality, such measures assess only a small proportion of all of the care delivered and apply to only subsets of the population with a particular condition. Furthermore, while determining whether a particular process of care was delivered, such measures do not convey information on the effectiveness of the process. Finally, although patients presumably care about the processes of care that they receive, this interest reflects an assumption that better processes of care ultimately result in better outcomes. For these reasons, outcomes measures have been proposed as a means of complementing process measurement as a reflection of quality (p. 2054).

A recent multidisciplinary AHA Scientific Statement, which is endorsed by the ACCF, identified 7 attributes of outcomes measures suitable for public reporting.[11] These attributes include: 1) a clear and explicit definition of an appropriate patient sample; 2) clinical coherence of model adjustment variables; 3) sufficiently high-quality and timely data; 4) designation of an appropriate reference time before which covariates are derived and after which outcomes are measured; 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; and 7) disclosure of the methods used to compare outcomes, including disclosure of performance of risk-adjustment methodology in derivation and validation samples.

While the writing committee recognizes the importance of developing scientifically valid, effective, and useful measures of clinical outcomes for PAD, we are not yet at the point to do so with the data available. Outcome measurements, however, should be considered in future revisions of the PAD performance measures.

Staff

American College of Cardiology Foundation

Ralph G. Brindis, MD, MPH, FACC, FSCAI, President

John C. Lewin, MD, Chief Executive Officer

Charlene May, Senior Director, Clinical Policy and Documents

Melanie Shahriary, RN, BSN, Associate Director, Performance Measures and Data Standards

Jensen S. Chiu, MHA, Specialist, Clinical Performance Measurement

Erin A. Barrett, MPS, Senior Specialist, Clinical Policy and Documents

American Heart Association

Nancy Brown, Chief Executive Officer

Rose Marie Robertson, MD, FACC, FAHA, Chief Science Officer

Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations

Dwight Randle, PhD, Science and Medicine Advisor

References

1. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
2. Bonow RO, Bennett S, Casey DE Jr., et al. ACC/AHA clinical performance measures for adults with chronic heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Heart Failure Clinical Performance Measures). J Am Coll Cardiol. 2005;46:1144–78.
3. American Medical Association Physician Consortium for Performance Improvement. Clinical performance measures: chronic stable coronary artery disease. Available at: http://www.ama-assn.org/ama1/pub/upload/mm/370/cadminisetjune06.pdf. Accessed January 5, 2010.
4. American Medical Association Physician Consortium for Performance Improvement. Clinical performance measures: hypertension. Available at: http://www.ama-assn.org/ama1/pub/upload/mm/370/hypertension-8-05.pdf. Accessed January 5, 2010.
5. Krumholz HM, Anderson JL, Brooks NH, et al. ACC/AHA clinical performance measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Performance Measures on ST-Elevation and Non–ST-Elevation Myocardial Infarction). J Am Coll Cardiol. 2006;47:236–65.
6. Krumholz HM, Anderson JL, Bachelder BL, et al. ACC/AHA 2008 performance measures for adults with ST-elevation and non–ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Performance Measures for ST-Elevation and Non–ST-Elevation Myocardial Infarction). J Am Coll Cardiol. 2008;52:2046–99.
7. Thomas RJ, King M, Lui K, et al. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services. J Am Coll Cardiol. 2007;50:1400–33.

7a. Thomas RJ, King M, Lui K, et al. AACVPR/ACCF/AHA 2010 update: performance measures on cardiac rehabilitation for referral to cardiac rehabilitation/secondary prevention services. J Am Coll Cardiol. 2010; 56:1159–67.

8. Estes NA 3rd, Halperin JL, Calkins H, et al. ACC/AHA/Physician Consortium 2008 clinical performance measures for adults with nonvalvular atrial fibrillation or atrial flutter: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation). J Am Coll Cardiol. 2008;51:865–84.
9. Redberg RF, Benjamin EJ, Bittner V, et al. ACCF/AHA 2009 performance measures for primary prevention of cardiovascular disease in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Performance Measures for Primary Prevention of Cardiovascular Disease). J Am Coll Cardiol. 2009;54:1364–405.
10. Spertus JA, Eagle KA, Krumholz HM, et al. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol. 2005;45:1147–56.
11. Krumholz HM, Brindis RG, Brush JE, et al. Standards for statistical models used for public reporting of health outcomes: an American Heart Association scientific statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Circulation. 2006;113:456–62.
12. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease). J Am Coll Cardiol. 2006;47:e1–192.
13. Creager MA, White CJ, Hiatt WR, et al. Atherosclerotic Peripheral Vascular Disease Symposium II: executive summary. Circulation. 2008;118:2811–25.
14. Hiatt WR, Goldstone J, Smith SC Jr., et al. Atherosclerotic Peripheral Vascular Disease Symposium II: nomenclature for vascular diseases. Circulation. 2008;118:2826–9.
15. Rosamond W, Flegal K, Furie K, et al. Heart disease and stroke statistics—2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation. 2008;117:e25–146.
16. Criqui MH, Fronek A, Barrett-Connor E, et al. The prevalence of peripheral arterial disease in a defined population. Circulation. 1985;71:510–5.
17. Kannel WB, McGee DL. Update on some epidemiologic features of intermittent claudiation: the Framingham Study. J Am Geriatr Soc. 1985;33:13–8.
18. Regensteiner JG, Hiatt WR. Current medical therapies for patients with peripheral arterial disease: a critical review. Am J Med. 2002;112:49–57.
19. Hirsch AT, Criqui MH, Treat-Jacobson D, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA. 2001;286:1317–24.
20. McDermott MM, Greenland P, Liu K, et al. The ankle brachial index is associated with leg function and physical activity: the Walking and Leg Circulation Study. Ann Intern Med. 2002;136:873–83.
21. Barletta G, Perna S, Sabba C, et al. Quality of life in patients with intermittent claudication: relationship with laboratory exercise performance. Vasc Med. 1996;1:3–7.
22. Khaira HS, Hanger R, Shearman CP. Quality of life in patients with intermittent claudication. Eur J Vasc Endovasc Surg. 1996;11:65–9.
23. Pell JP. Impact of intermittent claudication on quality of life. The Scottish Vascular Audit Group. Eur J Vasc Endovasc Surg. 1995;9:469–72.
24. Ponte E, Cattinelli S. Quality of life in a group of patients with intermittent claudication. Angiology. 1996;47:247–51.
25. Treat-Jacobson D, Halverson S, Ratchford A, et al. A patient-derived perspective of health-related quality-of-life in peripheral arterial disease. Journal of Nursing Scholarship. 2002;34:55–60.
26. Smolderen KG, Aquarius AE, de Vries J, et al. Depressive symptoms in peripheral arterial disease: a follow-up study on prevalence, stability, and risk factors. J Affect Disord. 2008;110:27–35.
27. Vogt MT, Cauley JA, Newman AB, et al. Decreased ankle/arm blood pressure index and mortality in elderly women. JAMA. 1993;270:465–9.
28. McKenna M, Wolfson S, Kuller L. The ratio of ankle and arm arterial pressure as an independent predictor of mortality. Atherosclerosis. 1991;87:119–28.
29. Newman AB, Shemanski L, Manolio TA, et al. Ankle-arm index as a predictor of cardiovascular disease and mortality in the Cardiovascular Health Study. Arterioscler Thromb Vasc Biol. 1999;19:538–45.
30. Criqui MH, Coughlin SS, Fronek A. Noninvasively diagnosed peripheral arterial disease as a predictor of mortality: results from a prospective study. Circulation. 1985;72:768–73.
31. Newman AB, Tyrrell KS, Kuller LH. Mortality over four years in SHEP participants with a low ankle-arm index. J Am Geriatr Soc. 1997;45:1472–8.
32. Resnick HE, Lindsay RS, McDermott MM, et al. Relationship of high and low ankle brachial index to all-cause and cardiovascular disease mortality: the Strong Heart Study. Circulation. 2004;109:733–9.
33. Criqui MH, Langer RD, Fronek A, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med. 1992;326:381–6.
34. Leng GC, Lee AJ, Fowkes FG, et al. Incidence, natural history and cardiovascular events in symptomatic and asymptomatic peripheral arterial disease in the general population. Int J Epidemiol. 1996;25:1172–81.
35. Criqui MH, Denenberg JO, Langer RD, et al. The epidemiology of peripheral arterial disease: importance of identifying the population at risk. Vasc Med. 1997;2:221–6.
36. Ness J, Aronow WS. Prevalence of coexistence of coronary artery disease, ischemic stroke, and peripheral arterial disease in older persons, mean age 80 years, in an academic hospital-based geriatrics practice. J Am Geriatr Soc. 1999;47:1255–6.
37. Zheng ZJ, Sharrett AR, Chambless LE, et al. Associations of ankle-brachial index with clinical coronary heart disease, stroke and preclinical carotid and popliteal atherosclerosis: the Atherosclerosis Risk in Communities (ARIC) Study. Atherosclerosis. 1997;131:115–25.
38. Burek KA, Sutton-Tyrrell K, Brooks MM, et al. Prognostic importance of lower extremity arterial disease in patients undergoing coronary revascularization in the Bypass Angioplasty Revascularization Investigation (BARI). J Am Coll Cardiol. 1999;34:716–21.
39. Saw J, Bhatt DL, Moliterno DJ, et al. The influence of peripheral arterial disease on outcomes: a pooled analysis of mortality in eight large randomized percutaneous coronary intervention trials. J Am Coll Cardiol. 2006;48:1567–72.
40. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:1–75.
41. 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.
42. Steg PG, Bhatt DL, Wilson PW, et al. One-year cardiovascular event rates in outpatients with atherothrombosis. JAMA. 2007;297:1197–206.
43. Diehm C, Lange S, Darius H, et al. Association of low ankle brachial index with high mortality in primary care. Eur Heart J. 2006;27:1743–9.
44. Selvin E, Hirsch AT. Contemporary risk factor control and walking dysfunction in individuals with peripheral arterial disease: NHANES 1999–2004. Atherosclerosis. 2008;201:425–33.
45. Feringa HH, van Waning VH, Bax JJ, et al. Cardioprotective medication is associated with improved survival in patients with peripheral arterial disease. J Am Coll Cardiol. 2006;47:1182–7.
46. McDermott MM, Hahn EA, Greenland P, et al. Atherosclerotic risk factor reduction in peripheral arterial diseasea: results of a national physician survey. J Gen Intern Med. 2002;17:895–904.
47. McDermott MM, Mandapat AL, Moates A, et al. Knowledge and attitudes regarding cardiovascular disease risk and prevention in patients with coronary or peripheral arterial disease. Arch Intern Med. 2003;163:2157–62.
48. Perlstein TS, Creager MA. The ankle-brachial index as a biomarker of cardiovascular risk: it's not just about the legs. Circulation. 2009;120:2033–5.
49. Fowkes FG, Murray GD, Butcher I, et al. Ankle brachial index combined with Framingham Risk Score to predict cardiovascular events and mortality: a meta-analysis. JAMA. 2008;300:197–208.
50. Berger JS, Krantz MJ, Kittelson JM, et al. Aspirin for the prevention of cardiovascular events in patients with peripheral artery disease: a meta-analysis of randomized trials. JAMA. 2009;301:1909–19.
51. Fowkes FG, Price JF, Stewart MC, et al. Aspirin for prevention of cardiovascular events in a general population screened for a low ankle

brachial index: a randomized controlled trial. JAMA. 2010;303:841–8.
52. Hiatt WR. Medical treatment of peripheral arterial disease and claudication. N Engl J Med. 2001;344:1608–21.
53. Stewart KJ, Hiatt WR, Regensteiner JG, et al. Exercise training for claudication. N Engl J Med. 2002;347:1941–51.
54. Bandyk DF, Schmitt DD, Seabrook GR, et al. Monitoring functional patency of in situ saphenous vein bypasses: the impact of a surveillance protocol and elective revision. J Vasc Surg. 1989;9:286–96.
55. Lundell A, Lindblad B, Bergqvist D, et al. Femoropopliteal-crural graft patency is improved by an intensive surveillance program: a prospective randomized study. J Vasc Surg. 1995;21:26–33.
56. Davies AH, Hawdon AJ, Sydes MR, et al. Is Duplex surveillance of value after leg vein bypass grafting? Principal results of the Vein Graft Surveillance Randomised Trial (VGST). Circulation. 2005;112:1985–91.
57. Cooper CJ, Murphy TP, Matsumoto A, et al. Stent revascularization for the prevention of cardiovascular and renal events among patients with renal artery stenosis and systolic hypertension: rationale and design of the CORAL trial. Am Heart J. 2006;152:59–66.
58. National Diabetes Quality Improvement Alliance. Performance measurement set for adult diabetes. Available at: http://www-nehc.med.navy.mil/bumed/diabetes/document%20folders/diabetes/cpg/dqia.msrs.pdf. Accessed January 5, 2010.
59. National Quality Forum. National voluntary consensus standards for ambulatory care: diabetes care measures. Available at: http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_Ambulatory_Care%E2%80%93Part_2.aspx. Accessed December 24, 2009.
60. Fleming C, Whitlock EP, Beil TL, et al. Screening for abdominal aortic aneurysm: a best-evidence systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2005;142:203–11.
61. Kent KC, Zwolak RM, Jaff MR, et al. Screening for abdominal aortic aneurysm: a consensus statement. J Vasc Surg. 2004;39:267–9.
62. Screening for abdominal aortic aneurysm: recommendation statement. Ann Intern Med. 2005;142:198–202.
63. Ashton HA, Gao L, Kim LG, et al. Fifteen-year follow-up of a randomized clinical trial of ultrasonographic screening for abdominal aortic aneurysms. Br J Surg. 2007;94:696–701.
64. Cosford PA, Leng GC. Screening for abdominal aortic aneurysm. Cochrane Database Syst Rev. 2007;CD002945.
65. Lindholt JS, Norman P. Screening for abdominal aortic aneurysm reduces overall mortality in men. A meta-analysis of the mid- and long-term effects of screening for abdominal aortic aneurysms. Eur J Vasc Endovasc Surg. 2008;36:167–71.
66. Kim LG, Scott RAP, Ashton HA, et al. A sustained mortality benefit from screening for abdominal aortic aneurysm. Ann Intern Med. 2007;146:699–706.
67. Olin JW. Long-term outcomes and cost-effectiveness of screening for abdominal aortic aneurysm. Nat Clin Pract Cardiovasc Med. 2007;4:650–1.
68. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet. 2002;360:7–22.
69. Smith SC, Jr., Allen J, Blair SN, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update. J Am Coll Cardiol. 2006;47:2130–9.
70. The Vascular Disease Foundation (VDF) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). P.A.D. exercise training toolkit: a guide for health care professionals. Available at: http://www.vdf.org/professionals/exercisetoolkit.php. Accessed May 25, 2010.
71. American College of Sports Medicine. ACSM's Guidelines for Exercise Testing and Prescription. 7th ed. Baltimore, Md: Lippincott Williams & Wilkins; 2006.
72. Penchansky R, Thomas JW. The concept of access: definition and relationship to consumer satisfaction. Med Care. 1981;19:127–40.

KEY WORDS: AHA Scientific Statements ■ abdominal aortic aneurysm ■ ankle brachial index ■ peripheral arterial disease ■ secondary prevention ■ supervised exercise

Appendix A. Author Relationships With Industry and Other Entities—ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease

Committee Member	Employer/Title	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jeffrey W. Olin, *Chair*	Mt. Sinai School of Medicine/Director, Vascular Medicine Program	• Bristol-Myers Squibb/Sanofi • Genzyme • Schering-Plough • Takeda	None	None	• Genzyme • Sanofi	None	• Cleveland Clinic Foundation* • Johnson & Johnson
David E. Allie	Cardiovascular Institute of the South—Lafayette/Chief of Cardiothoracic and Endovascular Surgery	• ev3* • Flowmedica* • Spectranetics* • Toshiba/Bracco*	• Spectranetics	None	None	None	None
Michael Belkin	Brigham and Women's Hospital, Harvard Medical School/ Vascular Surgery Fellowship Program Director	• Aastrom Biosciences, Inc. • AGA Medical	None	Merck	None	None	None
Robert O. Bonow	Northwestern University Feinberg School of Medicine/Goldberg Distinguished Professor; Chief, Division of Cardiology	None	• Edwards Lifesciences*	None	None	None	None
Donald E. Casey	Atlantic Health/Vice President, Quality and Chief Medical Officer	None	None	None	None	None	None
Mark A. Creager	Brigham and Women's Hospital Cardiovascular Division/Professor of Medicine (Cardiology)	• ActivBiotics • Biomarin • Genzyme • Kos Pharmaceuticals • Sanofi-Aventis • Sigma Tau	• Bristol-Myers Squibb	• Merck	• Sanofi-Aventis	None	None
Thomas C. Gerber	Mayo College of Medicine, Mayo Clinic Division of Cardiovascular Diseases/Associate Professor of Medicine and Radiology	None	None	None	None	None	None

(*Continued*)

Appendix A. Continued

Committee Member	Employer/Title	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Alan T. Hirsch	University of Minnesota School of Public Health/ Professor of Epidemiology and Community Health	• Kos Pharmaceuticals • Pifzer* • Roche*	• Bristol-Myers Squibb/Sanofi-Aventis	None	• Abbott Vascular • AstraZeneca • Bristol-Myers Squibb/Sanofi-Aventis • Kos Pharmaceuticals* • Omron • PreMD • SonoSite	None	None
Michael R. Jaff	Massachusetts General Hospital/ Director, Vascular Diagnostic Lab	• Abbott Vascular • Arsenal Medical • Atheromed • Bacchus Vascular • Baxter Healthcare • Boston Scientific • Cortis • FlexStent • HCRI* • Hypermed • I.C. Sciences • Medical Simulation Corporation • Medtronic • Micell • Nexeon MedSystems • Pathway Medical • Proteon • Takeda Pharmaceuticals	None	None	• Access Closire • Icon Interventional • Sadra Medical • Setagon • Square One	• Vascular Therapies • VIVA Physicians, Inc.*	None
John A. Kaufman	Dotter Interventional Institute Oregon Health and Science University/Professor of Radiology	None	None	None	None	None	None
Curtis A. Lewis	The Grady Health System/Chief of Staff and Sr. Vice President of Medical Affairs	None	None	None	None	None	None
Edward T. Martin	Oklahoma Heart Institute/Director, Cardiovascular MRI Center	• Astellas • Siemens	• GE Healthcare*	None	• Siemens	• Astellas • Siemens	None
Louis G. Martin	Emory University School of Medicine/ Professor, Department of Radiology	None	None	None	None	None	None

(*Continued*)

Appendix A. Continued

Committee Member	Employer/Title	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Peter Sheehan	Mount Sinai School of Medicine/Senior Faculty	None	• Bristol-Myers Squibb/Sanofi* • Edwards Lifesciences* • FoxHollow*	None	• Genzyme* • Nissan*	None	None
Kerry J. Stewart	Johns Hopkins University School of Medicine Johns Hopkins Bayview Medical Center/ Professor of Medicine and Director, Clinical and Research Exercise Physiology	None	None	None	None	None	None
Diane Treat-Jacobson	University of Minnesota School of Nursing/ Assistant Professor	• Kos Pharmaceuticals*	• Bristol-Myers Squibb/Sanofi-Aventis	None	• National Heart, Lung, and Blood Institute*	None	None
Christopher J. White	Ochsner Clinic Foundation/Chairman, Department of Cardiology	None	• Baxter • Boston Scientific	None	None	None	None
Zhi-Jie Zheng	Center for the Application of Research Discoveries National Heart, Lung and Blood Institute/Senior Medical Epidemiologist	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were reported by authors 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% or more of the voting stock or share of the business entity, if the interest represents ownership of $10 000 or more 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 in this table are modest unless otherwise noted.

*Significant relationship.

Appendix B. Peer Reviewer Relationships With Industry and Other Entities—ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease

Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Herbert Aronow	Official Reviewer—SVM	• Cordis • Medtronic	• Bristol-Myers Squibb/Sanofi-Aventis • Pfizer*	None	None	None	None
Robert M. Bersin	Official Reviewer—SCAI	• Abbott Vascular* • Boston Scientific* • Bristol-Myers Squibb • Cordis Endovascular* • Daiichi Sankyo • Eli Lilly • ev3* • Medtronic Vascular • Palmaz Scientific • ReVascular Therapeutics • Sanofi-Aventis • Vascular Solutions • W.L. Gore*	• Boston Scientific* • Bristol-Myers Squibb • Cordis Endovascular* • Daiichi Sankyo • Eli Lilly • The Medicines Co. • Sanofi-Aventis	• Boston Scientific* • Cordis Endovascular*	None	None	None
Alain T. Drooz	Official Reviewer—SIR	• Possis Medical	• Peripheral Angioplasty & All that Jazz – May 2007	None	• Invatec INTENSE Trial DSMB	None	None
Gordon Fung	Official Reviewer—ACCF Board of Governors	None	• Abbott Cardiovascular • GlaxoSmithKline	None	• Roche Pharmaceuticals	• AHA/LWW • UCSF(Vice Chair, Committee on Human Research) • UCSF School of Medicine (Director, Clinical Faculty Affairs)	None
Bertrand Janne d'Othee	Official Reviewer—ACR	None	None	None	None	None	None
Debra Kohlman-Trigoboff	Official Reviewer—SVN	None	None	None	None	None	None
Sanjoy Kundu	Official Reviewer—SIR	None	None	None	None	None	None
Frank W. LoGerfo	Official Reviewer—SVS	None	None	None	None	None	None
James O. Menzoian	Official Reviewer—SVS	None	None	None	None	None	None

(*Continued*)

Appendix B. Continued

Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Sanjay Misra	Official Reviewer—AHA	None	None	None	• National Center for Research Resources (part of NIH)*	None	None
Issam Moussa	Official Reviewer—SCAI	None	None	None	None	None	None
Martha J. Radford	Official Reviewer—ACCF/AHA Task Force on Performance Measures Lead Reviewer	None	None	None	None	None	None
Anne C. Roberts	Official Reviewer—AHA and ACR	None	None	None	None	• ACR Board of Chancellors	None
George P. Rodgers	Official Reviewer—ACCF Board of Trustees	• United Health	None	• Biophysical*	None	• Paragon Health	• For defendent (injury on treadmill)
Nakela Cook	Organizational Reviewer—NHLBI	None	None	None	None	None	None
Ricardo C. Cury	Organizational Reviewer—SCCT	• Astellas Pharma	• Siemens	None	• Astellas Pharma* • Pfizer Inc.*	• SCCT Board Member	None
James M. Galloway	Organizational Reviewer—ADA	None	None	None	None	None	None
Jerry Goldstone	Organizational Reviewer—PAD Coalition	• Vascutek, a TERUMO company	None	None	None	None	None
Marjorie L. King	Organizational Reviewer—AACVPR	None	None	None	None	None	None
M. Sue Kirkman	Organizational Reviewer—ADA	None	None	None	None	None	None
Christopher Kramer	Organizational Reviewer—SAIP	• Siemens Medical Solutions	• Merck • Schering-Plough	None	• Astellas* • GlaxoSmithKline* • Siemens Medical Solutions*	None	None
John R. Lesser	Organizational Reviewer—SCCT	• Vital Images	• Siemens Medical Solutions	None	None	None	None
Keith Michl	Organizational Reviewer—ACP	None	None	None	None	None	None
Diane Reid	Organizational Reviewer—NHLBI	None	None	None	None	None	None

(*Continued*)

Appendix B. Continued

Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Carolyn Robinson	Organizational Reviewer—PAD Coalition	None	None	None	None	None	None
Frank Rybicki	Organizational Reviewer—SCMR	None	• Vital Images	None	• Bracco Diagnostics • Toshiba Medical Systems	None	None
Ray Squires	Organizational Reviewer—AACVPR	None	None	None	None	None	None
Allen Taylor	Organizational Reviewer—SAIP	None	• Abbott*	None	• Abbott	None	None
Steven D. Wolff	Organizational Reviewer—SCMR	• GE Healthcare*	None	• NeoCoil, LLC • NeoSoft, LLC	None	None	None
Elizabeth Delong	Content Reviewer—ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kathleen Grady	Content Reviewer—ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Hitinger Gurm	Content Reviewer—ACCF Peripheral Vascular Disease Committee	• Icon Interventional Systems	None	None	• Blue Cross Blue Shield of Michigan*	None	None
William Hiatt	Content Reviewer—Individual	None	None	None	• Bristol-Myers Squibb/Sanofi-Aventis* • Otsuka Japan*	None	None
Loren F. Hiratzka	Content Reviewer—ACC/AHA 2005 PAD Clinical Practice Guideline Writing Committee	None	• AHA	None	None	None	None

(*Continued*)

Appendix B. Continued

Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
David J. Malenka	Content Reviewer—ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS PAVD Data Standards Writing Committee	None	None	None	• Abbott Vascular* • St. Jude Medical Foundation*	None	None
Richard Milani	Content Reviewer—Individual	None	• Astra-Zeneca • Bristol-Myers Squibb* • Pfizer • Sanofi-Aventis	None	None	None	• For plaintiff (suit alleging owners of boat-diving company failed to provide timely medical care for a passenger who suffered acute MI)
Timothy Murphy	Content Reviewer—Individual	• Bristol-Myers Squibb*	None	None	• Abbott Vascular* • Boston Scientific* • Cordis/Johnson & Johnson* • Otsuka Pharmaceuticals*	None	None

This table represents the relevant relationships with industry and other entities that were disclosed by reviewers at the time of peer review. 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% or more of the voting stock or share of the business entity, if the interest represents ownership of $10 000 or more 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 in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation in the peer review process does not imply endorsement of this document.

*Significant relationship.

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACR, American College of Radiology; AHA, American Heart Association; DSMB, data safety monitoring board; LWW, Lippincott, Williams, & Wilkins; NHLBI, National, Heart, Lung, and Blood Institute; NIH, National Institutes of Health; PAD, peripheral arterial disease; PAVD, peripheral atherosclerotic vascular disease; SCAI, Society for Cardiac Angiography and Interventions; SCCT, Society of Cardiovascular Computed Tomography; SIR, Society of Interventional Radiology; STS, Society of Thoracic Surgeons; SVM, Society for Vascular Medicine; SVN, Society of Vascular Nursing; SVS, Society for Vascular Surgery; and UCSF, University of California, San Francisco.

Appendix C. ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease Performance Measurement Set Specifications

1. ABI	
Measurement of ABI in patients at risk for PAD	
Numerator	Patients in whom measurement and numerical results of an ABI* are documented at least once in the last 5 y.
Denominator	All patients: ▪ Age ≥18 y with walking impairment or claudication or lower extremity nonhealing wounds **OR** ▪ Age 50–69 y with a history of smoking or diabetes **OR** ▪ Age ≥70 y **Exceptions:** ▪ Patients with known atherosclerosis in any other location (eg, coronary, carotid, or renal artery disease). ▪ Medical reason(s) documented by a physician, advanced practice nurse, or physician assistant for not performing an ABI (eg, amputation or limited life expectancy).
Period of Assessment	5-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

The ABI is a very specific and sensitive measure for the detection of PAD. It can be performed in the office setting and predicts morbidity and mortality. PAD is considered a CHD risk equivalent, and documentation of PAD changes the management of risk factors such as hypertension and dyslipidemia.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]

Class I

Individuals with asymptomatic lower extremity PAD should be identified by examination and/or measurement of the ABI so that therapeutic interventions known to diminish their increased risk of myocardial infarction, stroke, and death may be offered. (*Level of Evidence: B*)

The resting ABI should be used to establish the lower extremity PAD diagnosis in patients with suspected lower extremity PAD, defined as individuals with exertional leg symptoms, with nonhealing wounds, who are 70 years or older or who are 50 years or older with a history of smoking or diabetes. *(Level of Evidence: C)*

TASC-II[40]

Recommendation 12

Recommendations for ABI screening to detect peripheral arterial disease in the individual patient.

An ABI should be measured in:

- All patients who have exertional leg symptoms [B].
- All patients age 50 to 69 y and who have a cardiovascular risk factor (particularly diabetes or smoking) [B].
- All patients age ≥70 y regardless of risk factor status [B].
- All patients with a Framingham Risk Score 10%–20% [C].

Attribution/Aggregation

This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.

Method of Reporting

Per patient:

Whether an ABI was performed at least once in the last 5 y.

Per patient population:

Percentage of patients for whom ABI was performed at least once in the last 5 y.

Challenges to Implementation

- Lack of uniform reimbursement for ABI performed according to evidence-based guidelines.
- Lack of equipment to perform this measurement in the physician's office.
- Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.

ABI indicates ankle-brachial index; CHD, coronary heart disease; and PAD, peripheral artery disease.

*ABI is the ratio of the systolic ankle arterial pressure to the systolic brachial arterial pressure. The higher of the brachial pressures is used as the denominator for both right and left ratios, and the higher of the 2 ankle pressures (posterior tibial or dorsalis pedis) is used as the numerator for each leg.

(*Continued*)

Appendix C. Continued

2. Cholesterol-Lowering Medications (Statin)	
Drug therapy for lowering LDL-C in patients with PAD	
Numerator	Patients who ▪ Were prescribed a statin and whose LDL-C is <100 mg/dL **OR** ▪ Were prescribed a statin at maximal dose* **OR** ▪ Whose LDL-C is <100 mg/dL without a statin **OR** ▪ Whose LDL-C ≥100 mg/dL and who had a medical or patient reason that a statin at maximal dose* was not prescribed documented by a physician, advanced practice nurse, or physician assistant.
Denominator	All patients age ≥18 y with PAD. PAD is defined as the presence of 1 or more of the following: ▪ Claudication ▪ Critical limb ischemia (ischemic rest pain, nonhealing ischemic ulcers, gangrene) ▪ History of vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities ▪ Amputation for critical limb ischemia ▪ Abnormal noninvasive test (eg, ankle brachial index, ultrasound, magnetic resonance, or computed tomography imaging demonstrating stenosis in any peripheral artery; ie, aorta, iliac, femoral, popliteal, tibial, peroneal). **Exceptions:** None
Period of Assessment	1-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

Treatment of dyslipidemia reduces the risk of adverse cardiovascular events in patients with atherosclerosis. Cholesterol-lowering therapy with an HMG coenzyme-A reductase inhibitor (statin) reduces the risk of myocardial infarction, stroke, and cardiovascular death in patients with coronary artery disease. In the Heart Protection Study, statins reduced the risk of myocardial infarction, stroke, or cardiovascular death by 24% in patients with PAD.[68] Despite the proven efficacy of effective lipid-lowering therapy in patients with PAD, these patients are undertreated when compared to patients with coronary artery disease.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]

Class I

Treatment with a HMG coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with PAD to achieve a target LDL-C level of <100 mg/dL. *(Level of Evidence: B)*

Class IIa

Treatment with an HMG coenzyme-A reductase inhibitor (statin) medication to achieve a target LDL-C level of <70 mg/dL is reasonable for patients with lower extremity PAD at very high risk of ischemic events. *(Level of Evidence: B)*

AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2006 Update[69]

For lipid management:

Assess fasting lipid profile in all patients, and within 24 hr of hospitalization for those with an acute cardiovascular or coronary event. For hospitalized patients, initiate lipid-lowering medication as recommended below before discharge according to the following schedule:

- LDL-C should be <100 mg/dL (Class I, *Level of Evidence: A*), and
- Further reduction of LDL-C to <70 mg/dL is reasonable. (Class IIa, *Level of Evidence: A*)
- If baseline LDL-C is ≥100 mg/dL, initiate LDL-lowering drug therapy.† (Class I, *Level of Evidence: A*)
- If on-treatment LDL-C is ≥100 mg/dL, intensify LDL-lowering drug therapy (may require LDL-lowering drug combination‡). (Class I, *Level of Evidence: A*).

Attribution/Aggregation

This measure should be reported by all primary care physicians or primary care practices and cardiovascular medicine physicians or cardiovascular medicine practices. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.

(*Continued*)

Appendix C. Continued

Method of Reporting
Per patient:
Whether patient
▪ Was prescribed a statin and had LDL-C <100 mg/dL **OR**
▪ Was prescribed a statin at maximal dose* **OR**
▪ Had LDL-C <100 mg/dL without a statin **OR**
▪ Had LDL-C ≥100 mg/dL and had a medical or patient reason that a statin at maximal dose* was not prescribed documented by a physician, advanced practice nurse, or physician assistant.
Per patient population:
Percentage of all patients who
▪ Were prescribed a statin and had LDL-C <100 mg/dL **OR**
▪ Were prescribed a statin at maximal dose* **OR**
▪ Had LDL-C <100 mg/dL without a statin **OR**
▪ Had LDL-C ≥100 mg/dL and had a medical or patient reason that a statin at maximal dose* was not prescribed documented by a physician, advanced practice nurse, or physician assistant.
Challenges to Implementation
Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.

LDL-C indicates low-density lipoprotein cholesterol; PAD, peripheral artery disease; and HMG, hydroxymethyl glutaryl.

*Maximal dosing for currently available statins:

- Atorvastatin=80 mg/d
- Fluvastatin=80 mg/d
- Lovastatin=80 mg/d
- Pravastatin=80 mg/d
- Rosuvastatin=40 mg/d
- Simvastatin=80 mg/d

†When LDL-lowering medications are used, obtain at least a 30% to 40% reduction in LDL-C levels. If LDL-C <70 mg/dL is the chosen target, consider drug titration to achieve this level, to minimize side effects and cost. When LDL-C <70 mg/dL is not achievable because of high baseline LDL-C levels, it generally is possible to achieve reductions of >50% in LDL-C levels by either statins or LDL-C–lowering drug combinations.

‡Standard dose of statin with ezetimibe, bile acid sequestrate, or niacin.

(*Continued*)

Appendix C. Continued

3. Smoking Cessation	
Smoking-cessation intervention for active smoking in patients with PAD	
Numerator	Patients identified as tobacco users who have received cessation intervention. Cessation intervention may include smoking-cessation counseling (eg, verbal advice to quit, referral to smoking-cessation program or counselor) and/or pharmacologic therapy.* The type of intervention should be explicitly captured.
Denominator	All patients age ≥18 y at the start of the measurement period with PAD who are identified as tobacco users. PAD is defined as the presence of 1 or more of the following: ▪ Claudication ▪ Critical limb ischemia (ischemic rest pain, nonhealing ischemic ulcers, gangrene) ▪ History of vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities ▪ Amputation for critical limb ischemia ▪ Abnormal noninvasive test (eg, ankle brachial index, ultrasound, magnetic resonance, or computed tomography imaging demonstrating stenosis in any peripheral artery; ie, aorta, iliac, femoral, popliteal, tibial, peroneal). **Exceptions:** None
Period of Assessment	2-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record
Rationale	
Tobacco smoking is the most potent modifiable risk factor for development of PAD. Continued use of tobacco affects disease progression and graft patency. Smoking status should be assessed at each encounter: patients should be strongly advised to quit, and resources to assist in quitting should be offered. (The 6 *A* factors should be included: ask, assess, advise, assure, arrange [a follow-up], and applaud).	
Clinical Recommendation(s)	
ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12] Class I Individuals with lower extremity PAD who smoke cigarettes or use other forms of tobacco should be advised by each of their clinicians to stop smoking and should be offered comprehensive smoking-cessation interventions, including behavior modification therapy, nicotine replacement therapy, or bupropion. *(Level of Evidence: B)**	
Attribution/Aggregation	
This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.	
Method of Reporting	
Per patient: Whether the PAD patient identified as a tobacco user, received cessation intervention, and the type of cessation intervention that was provided as documented in the medical records. ***Per patient population:*** Percentage of PAD patients identified as tobacco users who received cessation intervention and a breakdown of the type of cessation intervention that was provided as documented in the medical record.	
Challenges to Implementation	
▪ Lack of documentation or consistency of description of interventions in medical record. ▪ Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.	

PAD indicates peripheral artery disease.

*Recent evidence supports the use of varenicline as an adjunct therapy for smoking cessation. For purposes of this measure, use of varenicline, nicotine replacement therapy, or bupropion should all be considered pharmacologic therapy for smoking cessation.

(*Continued*)

Appendix C. Continued

4. Antiplatelet Therapy	
Antiplatelet therapy to reduce the risk of myocardial infarction, stroke, or vascular death in patients with a history of symptomatic PAD	
Numerator	Patients who were prescribed an antiplatelet agent (aspirin or clopidogrel)
Denominator	All patients age ≥18 y with a history of symptomatic PAD. History of symptomatic PAD is defined as the presence of the following: ▪ Claudication **OR** ▪ Critical limb ischemia (ischemic rest pain, nonhealing ischemic ulcers, gangrene) **OR** ▪ History of vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities **OR** ▪ Amputation for critical limb ischemia. **Exceptions:** ▪ Medical reason(s) documented by a physician, advanced practice nurse, or physician assistant for not prescribing an antiplatelet agent (eg, allergy or intolerance to both aspirin and clopidogrel, risk of bleeding, noncompliance, use of warfarin, or other medical reason). ▪ Documentation of patient reason(s) for not prescribing an antiplatelet agent (eg, patient refusal).
Period of Assessment	1-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

Administration of antiplatelet agents to patients with symptomatic atherosclerotic lower extremity PAD is well documented to reduce the risk of myocardial infarction, stroke, or vascular death.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]

Class I

1. Antiplatelet therapy is indicated to reduce the risk of myocardial infarction, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. *(Level of Evidence: A)*
2. Aspirin, in daily doses of 75 to 325 mg, is recommended as safe and effective antiplatelet therapy to reduce the risk of myocardial infarction, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. *(Level of Evidence: A)*
3. Clopidogrel (75 mg/d) is recommended as an effective alternative antiplatelet therapy to aspirin to reduce the risk of myocardial infarction, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. *(Level of Evidence: B)*

Attribution/Aggregation

This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.

Method of Reporting

Per patient:

Whether a patient with a history of symptomatic PAD was prescribed aspirin or clopidogrel.

Per patient population:

Percentage of all patients with a history of symptomatic PAD who were prescribed aspirin or clopidogrel.

Challenges to Implementation

Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.

PAD indicates peripheral artery disease.

(*Continued*)

Appendix C. Continued

5. Supervised Exercise	
Supervised exercise training for patients with intermittent claudication	
Numerator	Patients who were ▪ Offered a supervised exercise training program as an option (preferred) **OR** ▪ Given explicit written or verbal instructions for unsupervised exercise (acceptable alternative if no supervised program is accessible*) **AND** had a medical, patient, or system reason documented by a physician, advanced practice nurse, or physician assistant that they could not be offered a supervised program. Note: Exercise training should be performed for a minimum of 30 to 45 min, at least 3 times/wk, for a minimum of 12 wks.[70]
Denominator	Patients age ≥18 y with intermittent claudication **Exceptions:** Medical reason(s) documented by a physician, advanced practice nurse, or physician assistant that patient was not offered a supervised exercise training program as an option, such as ▪ Critical limb ischemia (ischemic rest pain, nonhealing ischemic ulcers, gangrene) ▪ Unstable angina or recent myocardial infarction ▪ Decompensated heart failure ▪ Uncontrolled cardiac arrhythmias ▪ Severe or symptomatic valvular disease ▪ Other conditions that could be aggravated by exercise including, but not limited to, severe joint disease, uncontrolled diabetes, uncontrolled hypertension, or severe pulmonary disease.
Period of Assessment	1-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

A supervised claudication exercise program is known to result in an increase in the speed, distance, and duration walked in a high fraction of candidates, with decreased claudication symptoms at each workload or distance. In addition, exercise programs achieve significant systemic risk-reduction benefits (lowered blood pressure, improved glycemic control, and improved lipid profile). These functional and biochemical benefits accrue gradually and become evident over 4 to 8 wks and increase progressively over ≥12 wks. The biological mechanisms underlying the exercise improvements are complex, and there is inadequate evidence to attribute this functional benefit, as is often believed, to the growth of new collaterals (angiogenesis). Although the mechanism(s) by which exercise improves walking is unknown, studies have suggested that 1 or more of the following may play a role: alterations in skeletal muscle metabolism, reduced inflammation, improvement in endothelial function and hemorheology, carnitine metabolism, or altered gait. Adverse events, although possible, are rare, and the risk can be further reduced with appropriate medical screening before starting a program.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]

Class I

Individuals with intermittent claudication who are offered the option of endovascular or surgical therapies should be provided information regarding supervised claudication exercise therapy and pharmacotherapy.

1. A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication. *(Level of Evidence: A)*
2. Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least 3 times per week, for a minimum of 12 weeks. *(Level of Evidence: A)*

Class IIb

The usefulness of unsupervised exercise programs is not well established as an effective initial treatment modality for patients with intermittent claudication. *(Level of Evidence: B)*

TASC-II[40]

Recommendation 14

Exercise therapy in intermittent claudication:

- Supervised exercise should be made available as part of the initial treatment for all patients with peripheral arterial disease [A].
- The most effective programs employ treadmill or track walking that is of sufficient intensity to bring on claudication, followed by rest, over the course of a 30 to 60-min session. Exercise sessions are typically conducted 3 times a week for 3 months [A].

American College of Sports Medicine Guidelines for Exercise Testing and Prescription, 7th ed, 2006[71]

Initial enrollment in a medically supervised program with ECG, heart rate, and BP monitoring is encouraged.

Attribution/Aggregation

This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.

(*Continued*)

Appendix C. Continued

Method of Reporting
Per patient: Whether patient was offered the option of a supervised exercise program, if accessible, or given explicit instructions for an unsupervised program if a supervised program is not accessible. Documentation should include whether a supervised exercise training program is available in the local community.
Per patient population: Percentage of patients who were offered the option of an exercise program either supervised, if accessible, or given explicit instructions for an unsupervised program if a supervised program is not accessible. Documentation should include whether a supervised exercise training program is available in the local community.

Challenges to Implementation
■ Locating information in the medical record.
■ Access to supervised exercise training records if the program is located at another facility.
■ Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.

ECG indicates electrocardiogram; BP, blood pressure.

*Inaccessible means that no program is available in the patient's area, or is affordable by insurance or by pricing within the patient's economic means, or will accommodate the patient's work hours or other fixed schedule barriers.[72]

(*Continued*)

Appendix C. Continued

6. Lower Extremity Vein Bypass Graft Surveillance	
ABI and Duplex ultrasound of lower extremity vein bypass site	
Numerator	Patients who had an ABI and Duplex ultrasound of their infrainguinal vein bypass graft revascularization site at least once during the 1-y measurement period.
Denominator	All patients age ≥40 y who have undergone arterial bypass with autologous vein graft surgery for infrainguinal revascularization. **Exceptions:** ▪ Patients with synthetic bypass grafts ▪ Patients with medical reason(s) documented by a physician, advanced practice nurse, or physician assistant for not performing ABI and Duplex ultrasound (eg, patients who have undergone major lower limb amputation remote from their revascularization procedure) ▪ Documented patient reasons that ABI and Duplex ultrasound could not be performed (eg, patient refusal)
Period of Assessment	1-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record, vascular laboratory data reports

Rationale

Infrainguinal venous bypass grafts are at risk for developing stenoses, which, if unrecognized, may result in graft thrombosis. Once thrombosed, the secondary patency rates of these grafts are poor. Performing physical examination and ABI testing are insufficient methods of determining whether a stenosis is present. Routine Duplex scan surveillance has been demonstrated to identify vein grafts at risk for failure. Although there is some conflict in the literature, identification and revision of these grafts has been shown to improve long-term results. Synthetic grafts may also develop stenoses; however, graft thrombosis is relatively easily managed with surgical thrombectomy, and secondary patency rates are similar to those of primary assisted patency.
Similar data do not exist in infrainguinal endovascular intervention; however, if the revascularization was complex, and the challenges of restoring patency after failure of the intervention are great, it is intuitive that surveillance in a manner similar to that of infrainguinal venous bypass grafts be employed.
The durability of suprainguinal bypass grafts and endovascular interventions are superior to those of infrainguinal interventions, and given the challenges of Duplex ultrasound surveillance in iliac arteries, routine surveillance is not recommended.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]
Class I
Long-term patency of infrainguinal bypass grafts should be evaluated in a surveillance program, which should include an interval vascular history, resting ABIs, physical examination, and a Duplex ultrasound at regular intervals if a venous conduit has been used. *(Level of Evidence: B)*
Duplex ultrasound is recommended for routine surveillance after femoral-popliteal and femoral-tibial-pedal bypass with a venous conduit. Minimum surveillance intervals are approximately 3, 6, and 12 months, and then yearly after graft placement. *(Level of Evidence: A)*

Attribution/Aggregation

This measure should be reported by vascular specialists or vascular specialist practices only. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.

Method of Reporting

Per patient:
Whether ABI and Duplex ultrasound of the revascularization site was performed at least once during the measurement period.
Per patient population:
Percentage of patients for whom ABI and Duplex ultrasound of the revascularization site was performed at least once during the measurement period.

Challenges to Implementation

- This requires a vascular laboratory skilled in performance of lower extremity arterial Duplex ultrasonography, as well as having a method to schedule surveillance testing of patients with infrainguinal lower extremity revascularization.
- Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.

ABI indicates ankle-brachial index.

(Continued)

Appendix C. Continued

7. Monitoring of AAA	
Monitoring of asymptomatic AAA between 4.0 and 5.4 cm in diameter	
Numerator	Patients whose AAA diameter was measured at least once within the last year.
Denominator	All patients age ≥18 y and over with asymptomatic abdominal aortic aneurysm between 4.0 and 5.4 cm at the start of the measurement period. **Exceptions:** ▪ Patients with known symptomatic AAA ▪ Patients with AAA diameter <4.0 cm or ≥5.5 cm ▪ Patients who have had elective repair of their AAA ▪ Medical reason(s) documented by a physician, advanced practice nurse, or physician assistant, for not measuring AAA diameter, for example: Patients who are not candidates for AAA repair of any type due to comorbidities or surgical risk (eg, metastatic cancer, dementia, severe cardiopulmonary disease). ▪ Documented patient reason(s) for not measuring AAA diameter (eg, patient refusal).
Period of Assessment	1-y measurement period
Sources of Data	Electronic medical records, retrospective paper records, and prospective flow sheets
Rationale	
Aneurysm size remains the single most important predictor not only for aneurysm rupture but also for death from other cardiovascular events. Prospective studies have indicated that small aneurysms (<5.5 cm) have a low risk of rupture and may be safely monitored with annual or semiannual imaging.	
Clinical Recommendation(s)	
ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12] Class I 1. Patients with infrarenal or juxtarenal AAAs measuring 5.5 cm or larger should undergo repair to eliminate the risk of rupture. *(Level of Evidence: B)* 2. Patients with infrarenal or juxtarenal AAAs measuring 4.0 to 5.4 cm should be monitored by ultrasound, computerized tomography imaging, or magnetic resonance every 6 to 12 months to detect expansion. *(Level of Evidence: A)*	
Attribution/Aggregation	
This measure should be reported by all clinicians and/or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend upon the availability of adequate sample sizes to provide stable estimates of performance.	
Method of Reporting	
Per patient: Whether the patient's abdominal aortic aneurysm diameter was measured. ***Per patient population:*** Percentage of patients whose abdominal aortic aneurysm diameter was measured.	
Challenges to Implementation	
Sample size may preclude reporting of reliable performance estimates, particularly at the clinician level.	

AAA indicates abdominal aortic aneurysms.

(Continued)

Appendix C. Continued

T-1. Vascular Review of Systems for Lower Extremity PAD*

Medical or personal history of walking impairment, claudication, or ischemic rest pain and nonhealing wounds in patients at risk for lower extremity PAD

Numerator	All patients for whom a vascular review of systems is documented at least once in the last 2 years. Vascular review of systems must include assessment of ALL of the following: ▪ Walking impairment or claudication ▪ Ischemic rest pain ▪ Lower extremity nonhealing wounds
Denominator	All patients age ≥18 y who are "at risk" for PAD. *At risk* is defined as the presence of 1 or more of the following: ▪ Age <50 y, with diabetes and 1 or more other atherosclerosis risk factors (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia); ▪ Age 50–69 y, with a history of smoking or diabetes; ▪ Age ≥70 y; ▪ Known atherosclerosis in any other location (eg, coronary, carotid, or renal artery disease). **Exceptions:** None
Period of Assessment	2-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

There is a high prevalence (about 30%) of PAD in this "at risk" population. Because the symptoms of PAD may be confused with arthritis, or simply aging, it is advisable to specifically ask about symptoms of claudication or critical limb ischemia.

Clinical Recommendation(s)

ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12]

Class I

Individuals at risk for lower extremity PAD (see Section 2.1.1, Table 2) should undergo a vascular review of symptoms to assess walking impairment, claudication, ischemic rest pain, and/or the presence of nonhealing wounds. *(Level of Evidence: C)*

Table 2 (Section 2.1.1) Individuals at Risk for Lower Extremity Peripheral Arterial Disease:

- Age <50 y, with diabetes and one other atherosclerosis risk factor (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia)
- Age 50–69 y and history of smoking or diabetes
- Age ≥70 y
- Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- Abnormal lower extremity pulse examination
- Known atherosclerotic coronary, carotid, or renal artery disease

A history of walking impairment, claudication, ischemic rest pain, and/or nonhealing wounds is recommended as a required component of a standard ROS for adults age ≥50 y who have atherosclerosis risk factors and for adults age ≥70 y. *(Level of Evidence: C)*

TASC-II

Recommendation 1.1[40]

History and physical examination in suspected PAD:

- Individuals with risk factors for PAD, limb symptoms on exertion, or reduced limb function should undergo a vascular history to evaluate for symptoms of claudication or other limb symptoms that limit walking ability [B].

Attribution/Aggregation

This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend on the availability of adequate sample sizes to provide stable estimates of performance.

Method of Reporting

Per patient:

Whether a vascular review of systems was recorded.

Per patient population:

Percentage of all patients who had a vascular review of systems recorded.

Challenges to Implementation

- Identifying the population "at risk" for PAD.
- Sample sizes may preclude reporting of reliable performance estimates, particularly at the clinician level.

PAD indicates peripheral artery disease.

*This measure has been designated for use in internal quality improvement programs only. It is not appropriate for any other use (eg, pay for performance, physician ranking, or public reporting programs).

(Continued)

Appendix C. Continued

T-2. PAD "At Risk" Population Pulse Examination*	
Measurement of pulses in the lower extremities in patients at risk for PAD	
Numerator	Patients in whom a lower extremity pulse examination was documented at least once in the last 2 years. The pulse examination should include the femoral, popliteal, dorsalis pedis, and posterior tibial pulses.
Denominator	All patients age ≥18 y who are "at risk" for PAD. *At risk* is defined as the presence of 1 or more of the following: ▪ Age <50 y, with diabetes and 1 or more other atherosclerosis risk factors (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia); ▪ Age 50–69 y, with a history of smoking or diabetes; ▪ Age 70 ≥y; ▪ Walking impairment or claudication, ischemic rest pain, or lower extremity nonhealing wounds ▪ Known atherosclerosis in any other location (eg, coronary, carotid, or renal artery disease). **Exceptions:** Medical reason(s) documented by a physician, advanced practice nurse, or physician assistant for not performing a lower extremity pulse examination (eg, amputation).
Period of Assessment	2-y measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record
Rationale	
Examination of the pulses is important to document the presence of peripheral artery disease, determine the location of obstruction, and detect the presence of aneurysms.	
Clinical Recommendation(s)	
ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease[12] Class I Individuals at risk for lower extremity PAD (see Section 2.1.1, Table 2, of the full-text guidelines) should undergo comprehensive pulse examination and inspection of the feet. *(Level of Evidence: C)* Table 2 (Section 2.1.1) Individuals at Risk for Lower Extremity Peripheral Arterial Disease: ▪ Age <50 y, with diabetes and 1 other atherosclerosis risk factor (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia) ▪ Age 50–69 y and history of smoking or diabetes ▪ Age ≥70 y ▪ Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain ▪ Abnormal lower extremity pulse examination ▪ Known atherosclerotic coronary, carotid, or renal artery disease TASC-II Recommendation 1.1[40] History and physical examination in suspected PAD: • Patients at risk for PAD or patients with reduced limb function should also have a vascular examination evaluating peripheral pulses [B].	
Attribution/Aggregation	
This measure should be reported by all clinicians or practices managing patients with cardiovascular disease. The level of "aggregation" (clinician versus practice) will depend on the availability of adequate sample sizes to provide stable estimates of performance.	
Method of Reporting	
Per patient: Whether a lower extremity pulse examination was performed. ***Per patient population:*** Percentage of patients for whom a lower extremity pulse examination was performed.	
Challenges to Implementation	
Identifying the population "at risk" for PAD. Sample sizes may preclude reporting of reliable performance estimates, particularly at the clinician level.	

PAD indicates peripheral artery disease.

*This measure has been designated for use in internal quality improvement programs only. It is not appropriate for any other use (eg, pay for performance, physician ranking, or public reporting programs).

(Continued)

Appendix D. Sample Performance Measure Survey Form and Exclusion Criteria Definitions

SAMPLE SURVEY FORM

	PERFORMANCE MEASURE SURVEY Please see the definition for each of the criteria below in the attached Performance Measure Survey Guide. Indicate your selection by marking X in the appropriate field											
ACC/AHA PAD GUIDELINE RECOMMENDATIONS	A. Insufficient evidence	B. Uninterpretable	C. Not actionable	D. Unclear patient population	E. Not clinically meaningful	F. Uncertain reliability across settings	G. Uncertain feasibility due to data collection effort	H. Uncertain feasibility due to cost of data collection	I. Uncertain data collection period	Other, specify	Potential measure? Y/N/Other	Comment
Recommendation from guideline to be considered as potential measure*												

**Example:* The resting ABI should be used to establish the lower extremity PAD diagnosis in patients with suspected lower extremity PAD, defined as individuals with exertional leg symptoms, with nonhealing wounds, who are age ≥70 or who are age ≥50 y with a history of smoking or diabetes. *(Level of Evidence: C).*

ABI indicates ankle-brachial index; ACC, American College of Cardiology; AHA, American Heart Association; PAD, peripheral artery disease.

(Continued)

Appendix D. Continued

Potential Challenge to Implementation	Considerations
Useful in Improving Patient Outcomes	
1. Insufficient evidence: The scientific basis for the recommendation is not well established.	Considering level of evidence, mark this as a potential challenge to implementation if you believe it is inappropriate to consider as a potential performance measure.
2. Not interpretable: The results of the (potential) measure are not interpretable by practitioners	This is your assessment of the degree to which a provider can clearly understand what the results of a measure based on this recommendation mean and can take action if necessary.
3. Not actionable: The recommendation addresses an area that is not under the practitioner's control.	This is your assessment of the degree to which a provider is empowered and can influence the activities of the healthcare system toward improvement.
Measure Design	
4. Unclear patient population	This is your assessment of whether the patient group to whom this recommendation applies (denominator) can be explicitly defined using criteria that are clinically meaningful.
5. Not clinically meaningful	The recommendation does not capture clinically meaningful aspects of care.
6. Uncertain reliability across settings	The recommendation is not likely to be applicable across organizations and delivery settings.
Measure Implementation	
7. Uncertain feasibility due to data collection effort: The data required to measure successful implementation of recommendation cannot be obtained with reasonable effort.	From your perspective, the required data can be typically abstracted from patient charts or there are national registries or other databases readily available.
8. Uncertain feasibility due to cost of data collection: The data required to measure successful implementation of recommendation cannot be obtained at reasonable cost.	
9. Uncertain data collection period: The data required to measure successful implementation of recommendation cannot be obtained within the period allowed for data collection.	
Overall Assessment	
10. Overall assessment: Considering your assessment of this recommendation on all dimensions above, rate this recommendation for inclusion in the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measure set.	Consider a balance in the continuum of care. Consider overall purpose of the measurement set and the intended user. On the survey form enter: **YES:** This recommendation **should** be considered for further development into a performance measure and inclusion in the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measure set. **NO:** This recommendation should **not** be considered for further development into a performance measure or inclusion in the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS PAD Performance Measure set.

Appendix E. Sample Prospective Data Collection Flowsheet

ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS Peripheral Artery Disease Performance Measurement Set

Visit Date: _____ /_____ /_____ **Physician Evaluating Patient:** _____

1. Demographics/Patient Information

Patient Last Name: _____ **Patient First Name**: _____ **Patient Middle Name/Initial**: _____

Sex: ☐ Male ☐ Female **Date of Birth**: ____ /____ /____ **Age:** _____ years

2. History/Diagnoses *(Check all that apply)*

☐ Peripheral Artery Disease (PAD)	☐ Claudication	☐ **Optional: Hyperhomocysteinemia**
☐ Diabetes	☐ Walking Impairment	☐ **Optional: Hypertension**
☐ Atherosclerosis other than PAD (coronary, carotid, or renal artery disease)	☐ Lower Extremity Nonhealing Wounds	☐ **Optional: Dyslipidemia**
	☐ Critical limb ischemia (ischemic rest pain, nonhealing ischemic ulcers, gangrene)	☐ **Optional: Ischemic Rest Pain**

☐ Infrainguinal vein bypass graft revascularization

→ *If yes, and patient is age >40 y, also complete section 7 below*

Abdominal Aortic Aneurysm (AAA): ☐ Yes ☐ No

→ *Complete if patient has a history of AAA:* ☐ **Elective repair of AAA performed**

→ *Complete if no elective repair has been performed:* Most recent **AAA diameter**: _____cm Date diameter measured: ____ /____ /____

→ *Complete if AAA diameter not measured:*

Medical or patient reason(s) AAA diameter was not measured *(MD, DO, APN or PA only):* _____

Tobacco Use: ☐ Never smoked ☐ Former smoker: Date Quit: ____ /_____ (month, if known/year) ☐ Current Smoker

→ ***Complete if patient is a current smoker:***

☐ Advised to quit smoking ☐ Referred for smoking-cessation counseling ☐ Medication prescribed: _____ (eg, bupropion, varenicline, nicotine patches, gum, or lozenges) ☐ **Other** _____

3. Laboratory Assessments

LDL-Cholesterol _____mg/dL

4. Medications (Current and Prescribed)

Medication Allergy/Intolerance: ☐ Aspirin ☐ Clopidogrel ☐ Statin Medications

	Medication Category	Prescribed: Yes	Prescribed: No				
A	**Aspirin**	☐	☐	→ ***Complete if neither aspirin nor clopidogrel prescribed:***			
	Clopidogrel	☐	☐	**Medical or patient reason(s) neither aspirin nor clopidogrel prescribed** *(MD, DO, APN, or PA only):* _____			
B	**Statin Medication**	☐	☐	→ **If Yes, enter name, dosage, and frequency of statin medication**	Statin Name	Statin Dosage	Statin Frequency

→ ***Complete if no statin medication prescribed:***

Medical or patient reason(s) statin not prescribed or reason statin could not be prescribed at maximal dosage*
(MD, DO, APN, or PA only): _____

(Continued)

APPENDIX E. Continued

5. Optional: Lower Extremity Pulse Examination

Complete if patient is:

☐ Age <50 y, with a history of diabetes and 1 or more of the following: smoking, dyslipidemia, hypertension, or hyperhomocysteinemia

OR

☐ Age 50–69 y, with a history of smoking or diabetes

OR

☐ Age ≥70 y

OR

☐ Has a history of walking impairment or claudication, ischemic rest pain, or lower extremity nonhealing wounds

OR

☐ Has known atherosclerosis in any other location (e.g., coronary, carotid, or renal artery disease).

Pulse location	Pulse examination performed		→ *If yes, record* **Narrative or Numeric Assessment** *(eg, present or absent, or graded on scale [0 = absent, 1=diminished, 2=normal, 3=bounding])*
	Yes	No	
Femoral	☐	☐	
Popliteal	☐	☐	
Dorsalis pedis	☐	☐	
Posterior tibial	☐	☐	

→ ***Complete if any of the pulses above was not examined:***

Medical reason(s) for not performing lower extremity pulse examination *(MD, DO, APN, or PA only):*

_____

6. Ankle Brachial Index

Complete if patient is:

☐ Age ≥ 18 y, with a history of walking impairment or claudication or lower extremity nonhealing wounds

OR

☐ Age 50–69 y, with a history diabetes or smoking

OR

☐ Age ≥70 y

Ankle Brachial Index (ABI) performed		→ *If yes, enter*	→ *Complete if no ABI performed:*
☐ Yes	☐ No	**Numerical result:** **(R)** _____ **(L)** _____	**Medical reason(s) for not performing an ABI** *(MD, DO, APN, or PA only):*_____

7. Other Diagnostic Tests (Revascularization Surveillance)

Complete if patient is age ≥40 y and has history of infrainguinal vein bypass graft revascularization or infrainguinal endovascular revascularization. (Optional for endovascular revascularization)

Duplex ultrasound of revascularization site performed		→ *Complete if no Duplex ultrasound performed:*
☐ Yes	☐ No	**Medical or patient reason(s) for not performing Duplex ultrasound of revascularization site** *(MD, DO, APN, or PA only):* _____
ABI of revascularization site performed		→ *Complete if no ABI performed:*
☐ Yes	☐ No	**Medical or patient reason(s) for not performing ABI of revascularization site** *(MD, DO, APN, or PA only):*_____

8. Therapeutic Recommendations

Complete if patient has a history of claudication

Patient offered a supervised exercise training program	Yes	No
	☐	☐
→ *Complete if no supervised exercise program is accessible:* **Patient given explicit written or verbal instruction for unsupervised exercise**	☐	☐

→ *Complete if only written or verbal instructions given:*

Reason supervised exercise program could not be offered: _____

→ *Complete if patient was not offered a supervised exercise training program or given explicit written or verbal instructions for unsupervised exercise:*

Medical reason(s) patient was not offered a supervised exercise training program or given explicit written or verbal instructions for unsupervised exercise *(MD, DO, APN or PA only):* _____

***Maximal dosing for currently available statins:**

Atorvastatin =80 mg/d	Pravastatin =80 mg/d
Fluvastatin =80 mg/d	Rosuvastatin=40 mg/d
Lovastatin =80 mg/d	Simvastatin =80 mg/d

ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures, the American College of Radiology, the Society for Cardiac Angiography and Interventions, the Society for Interventional Radiology, the Society for Vascular Medicine, the Society for Vascular Nursing, and the Society for Vascular Surgery (Writing Committee to Develop Clinical Performance Measures for Peripheral Artery Disease)

Jeffrey W. Olin, David E. Allie, Michael Belkin, Robert O. Bonow, Donald E. Casey, Jr, Mark A. Creager, Thomas C. Gerber, Alan T. Hirsch, Michael R. Jaff, John A. Kaufman, Curtis A. Lewis, Edward T. Martin, Louis G. Martin, Peter Sheehan, Kerry J. Stewart, Diane Treat-Jacobson, Christopher J. White and Zhi-Jie Zheng

Circulation. 2010;122:2583-2618; originally published online November 29, 2010;
doi: 10.1161/CIR.0b013e3182031a3c
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0009-7322. Online ISSN: 1524-4539