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DATA STANDARDS

2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS Key Data Elements and Definitions for Peripheral Atherosclerotic Vascular Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Peripheral Atherosclerotic Vascular Disease)

Developed in Collaboration With the American Association of Cardiovascular and Pulmonary Rehabilitation, American Academy of Neurology, American Association of Neurological Surgeons, American Diabetes Association, Society of Atherosclerosis Imaging and Prevention, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Vascular Disease Foundation

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ACCF/AHA TASK FORCE ON CLINICAL DATA STANDARDS
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Preamble

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) support their members' goal to improve the prevention and care of cardiovascular diseases through professional education, research, and development of guidelines and standards and by fostering policy that supports optimal patient outcomes. The ACCF and AHA recognize the importance of the use of clinical data standards for patient management, to assess outcomes, and conduct research and the importance of defining the processes and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality improvement initiatives.

Hence, clinical data standards strive to define and standardize data relevant to clinical topics in cardiology, with the primary goal of assisting data collection by providing a platform of data elements and definitions applicable to various conditions. Broad agreement on a common vocabulary with reliable definitions used by all is vital to pool and/or compare data across studies to promote interoperability of electronic health records and to assess the applicability of research to clinical practice. The increasing national focus on adoption of certified electronic health records along with financial incentives for providers to demonstrate "meaningful use" of those electronic health records to improve healthcare quality render even more imperative and urgent the need for such definitions and standards. Therefore, the ACCF and AHA have undertaken to define and disseminate clinical data standards: sets of standardized data elements and corresponding definitions to collect data relevant to cardiovascular conditions. The ultimate purpose of clinical data standards is to contribute to the infrastructure necessary to accomplish the ACCF/AHA's missions of fostering optimal cardiovascular care and disease prevention and building healthier lives, free of cardiovascular diseases and stroke, respectively.

The specific goals of clinical data standards are

1. To establish a consistent, interoperable, and universal clinical vocabulary as a foundation to both clinical care and clinical research
2. To promote the ubiquitous use of electronic health records and facilitate the exchange of data across systems through harmonized, standardized definitions of key data elements
3. To facilitate the further development of clinical registries, quality and performance improvement programs, outcomes evaluations, and clinical research, including the comparison of results within and across these initiatives

The key elements and definitions are a compilation of variables intended to facilitate the consistent, accurate, and reproducible capture of clinical concepts; standardize the terminology used to describe cardiovascular diseases and procedures; create a data environment conducive to the assessment of patient management and outcomes for quality and performance improvement and for clinical and translational research; and increase opportunities for sharing data across disparate data sources. The ACCF/AHA Task Force on Clinical Data Standards selects cardiovascular conditions and procedures that will benefit from creating a data standard set. Experts in the subject are selected to examine/consider existing standards and develop a comprehensive, yet not exhaustive, data standard set. When undertaking a data collection effort, only a subset of the elements contained in a

clinical data standards listing may be needed, or, conversely, users may want to consider whether it may be necessary to collect some elements not listed. For example, in the setting of a randomized clinical trial of a new drug, additional information regarding study procedures and drug therapies would likely be required.

The ACCF and AHA recognize that there are other national efforts to establish clinical data standards, and every attempt is made to harmonize newly published standards with existing standards. Writing committees are instructed to consider adopting or adapting existing nationally recognized data standards if the definitions and characteristics are useful and applicable to the set under development. In addition, the ACCF and AHA are committed to continually expanding their portfolio of data standards and will create new standards and update existing standards as needed to maintain their currency and promote harmonization with other standards as health information technology and clinical practice evolve.

The Health Insurance Portability and Accountability Act (HIPAA) privacy regulations, which went into effect in April 2003, have heightened all practitioners' awareness of our professional commitment to safeguard patients' privacy. The HIPAA privacy regulations (1) specify which information elements are considered "protected health information." These elements may not be disclosed to third parties (including registries and research studies) without the patient's written permission. Protected health information may be included in databases used for healthcare operations under a data use agreement. Research studies using protected health information must be reviewed by an institutional review board or a privacy board.

We have included identifying information in all clinical data standards to facilitate uniform collection of these elements when appropriate. For example, a longitudinal clinic database may contain these elements, because access is restricted to the patient's caregivers. On the other hand, registries may not contain protected health information unless specific permission is granted by each patient. These fields are indicated as protected health information in the data standards.

The ACCF/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group were required to submit a disclosure form showing all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the ACCF/AHA Task Force on Clinical Data Standards, reported orally to all members of the writing panel at the first meeting, and updated as changes occur. Writing committee members' relationships with industry or other entities (RWI) are listed in Appendix 1. Official peer reviewers' RWI are listed in Appendix 2.

In clinical care, caregivers communicate with each other through a common vocabulary. In an analogous fashion, the integrity of clinical research depends on firm adherence to prespecified procedures for patient enrollment and follow-up; these procedures are guaranteed through careful attention to definitions enumerated in the study design and case report forms. When data elements and definitions are standardized across studies, comparisons, pooled analysis, and meta-analysis are enabled, thus deepening our understanding of individual studies.

The recent development of quality performance measurement initiatives, particularly those for which comparison of providers is an implicit or explicit aim, has further raised awareness about the importance of data standards. Indeed, a wide audience, including nonmedical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes. To understand and compare care patterns and outcomes, the data elements that characterize them must be clearly defined, consistently used, and properly interpreted, now more than ever before.

Robert C. Hendel, MD, FACC, FASNC, FAHA
Chair, ACCF/AHA Task Force on Clinical Data Standards

1. Introduction

Atherosclerotic vascular disease refers to disorders of the arteries caused by atherosclerosis (2). This document provides data standards for peripheral atherosclerotic vascular diseases (PAVDs), including lower extremity peripheral artery disease (PAD), abdominal aortic aneurysm (AAA), renal and mesenteric artery disease, and extracranial carotid artery disease. It may serve as a companion to the "2005 ACC/AHA Guidelines for the Management of Patients With Peripheral Arterial Disease" (3), the "2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease" (4), and the "2010 ACCF/AHA Performance Measures for Adults With Peripheral Artery Disease" (5). Coronary artery disease is outside the scope of this document. Multiple disciplines are engaged in the evaluation and management of patients with PAVDs, and developments in relevant research and technology are emerging rapidly. Therefore, to ensure optimal documentation and communication among healthcare providers, researchers, policy makers, payers, and industry, the establishment of a uniform set of data elements and definitions for PAVDs could not be more timely and compelling.

The data standards covered in this document are divided into 6 distinct tables. The first table covers general data elements common to all PAVDs, including demographic information, atherosclerotic risk factors, concurrent atherosclerotic diseases, comorbid conditions, medications, the cardiovascular examination, and relevant blood chemistries and hematology. The remaining tables cover data standards specific for lower extremity PAD, AAA, renal artery disease, mesenteric artery disease, and extracranial carotid and vertebral artery disease, respectively. Each of the disease-specific tables includes the following data elements: medical history, physical examination, laboratory testing, diagnostic procedures, invasive therapeutic procedures (both endovascular and open surgical), pharmacological therapy, follow-up, and outcomes.

2. Methodology

2.1. Writing Committee Composition

The ACCF/AHA Task Force on Clinical Data Standards selected members for the Writing Committee to Develop Clinical Data Standards for Peripheral Atherosclerotic Vascular Disease. The writing committee consisted of 23 members who are well versed in the epidemiology, clinical evaluation, medical management, invasive therapy, and/or outcomes assessment of patients with vascular disease and included members with expertise in patient care, clinical investigation, and healthcare services research and delivery. The writing committee included representatives from a broad range of cardiovascular professional societies and organizations to ensure that the content of this document is widely applicable. All partnering and collaborating organizations nominated people to serve on the writing committee.

2.2. Relationships With Industry and Other Entities

The ACCF/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual, potential, or perceived conflicts of interest that may arise as a result of RWI among members of the writing committee. Specifically, all members of the writing group, as well as peer reviewers of the document, were required to disclose all current relationships and those that existed 24 months before initiation of this writing effort that might be perceived as *relevant*. These statements were reviewed by the ACCF/AHA Task Force on Clinical Data Standards and by all members during each conference call or meeting of the writing committee and updated when changes occurred. This writing effort was initiated before the implementation of the updated ACCF and AHA policy on RWI, which requires that the writing committee chair plus a majority of the writing committee have no relevant RWI. Relevant RWI disclosed by writing committee members and peer reviewers are listed in Appendixes 1 and 2, respectively. Comprehensive disclosure information for the Task Force is available online at available online at www.cardiosource.org/ACC/About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF and AHA (and the other partnering organizations) without commercial support. Writing committee members volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by committee members and staff.

2.3. Review of Literature and Existing Data Definitions

The nomenclature used in this document to designate specific PAVDs, including lower extremity PAD, AAA, renal and mesenteric artery disease, and extracranial carotid artery disease, is derived from an AHA conference proceeding (2). The "Peripheral Atherosclerotic Vascular Disease Data Standards" are intended to provide data elements that parallel and complement existing data fields previously reported in ACCF and AHA data standards documents (6–11), along with those used as fields within existing registries, such as those developed by the ACC National Cardiovascular Disease Registry (12). The writing committee also reviewed the "2007 ACC/AHA Methodology for the Development of Clinical Data Standards" (13), the reporting standards formulated by the Society for Vascular Surgery/International Society for Cardiovascular Surgery; the "AHA Guidelines for the Reporting of Renal Artery Revascularization in Clinical Trials" (14); the National Heart, Lung, and Blood Institute CLEVER (Claudication: Exercise Vs Endoluminal Revascularization) Study (15,16); CORAL (Cardiovascular Outcome in Renal Atherosclerotic Lesions) trials (17,18); National Institute of Neurological Disorders and Stroke Common Data Elements (19); and the AHA Get With The Guidelines–Stroke Program (20).

2.4. Defining Data Elements

The definitions of the data elements developed by the writing committee are broad enough for use in various aspects of data collection but specific enough to promote uniform and simplified interpretation of data. Some elements will require an additional level of specificity by the end user for implementation, which is beyond the scope of this document. Data definitions were linked whenever possible to the evidence-based national guidelines.

To ensure consistency across ACCF/AHA data standards, the writers used existing ACCF/AHA definitions. The writing committee chose not to develop an all-inclusive list of every possible data element that may be used for all aspects of PAVD. Rather, the committee focused on common elements that cross vascular specialty disciplinary boundaries. It is anticipated that some data definitions and elements will need further delineation, likely by subspecialty societies and groups. The purpose of this document is to attempt to harmonize as many common data fields as possible.

2.5. Relation to Other Standards

As previously noted, the writing committee reviewed other standards, including those developed for heart failure, atrial fibrillation, electrophysiology, acute coronary syndromes, and cardiac imaging. It was thought that members of the writing committee possessed the key levels of expertise needed to address issues relating to PAVD in a consistent manner.

2.6. Consensus Development

These ACCF/AHA data standards, like other documents developed by the ACCF and AHA, were developed and written as a team effort based on the judgments of experts. The writing committee met >10 times, by telephone and in person, to define and refine the data elements. Throughout the process, consensus was developed through extensive in-person discussion, teleconferences, and e-mail messages.

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Table 1. General Elements

Element Name	Definition
Demographics	
Sex	Indicate the patient's sex at birth. Choose 1 of the following: • Male • Female
Date of birth	Indicate the patient's date of birth (mo/d/y).
Race	Indicate the patient's race as determined by the patient/family: • American Indian or Alaska Native • Asian • Black or African American • Native Hawaiian or Other Pacific Islander • White • Other (specify)
Hispanic ethnicity	Is the patient Spanish, Hispanic, or Latino? Choose 1 of the following: • Yes • No
Patient zip code	Indicate the zip code of the residence where the patient typically lives.
Institution	Coded identification and location of the healthcare facility.
Insurance payer	Indicate the patient's primary insurance payer for this admission. Choose 1 of the following: • Government: Refers to patients who are covered by government-reimbursed care. In the United States this includes – Medicare – Medicaid (including all state or federal Medicaid-type programs) – Veterans Health Administration – Department of Defense – Other federal group (specify) • Commercial: Refers to all indemnity (fee-for-service) carriers and PPOs • HMO: Refers to a health maintenance organization characterized by coverage that provides healthcare services for members on a prepaid basis • None: Refers to patients with limited or no health insurance; thus, the patient is the payer regardless of ability to pay. Only mark "None" when "self" or "none" is denoted as the first insurance in the medical record.
Presentation to Healthcare Facility	
Presentation to healthcare facility	Indicate the date and time the patient presented to the healthcare facility.
Type of encounter	• Emergency admission for stroke • Emergency admission for TIA • Emergency admission for limb ischemia • Emergency admission for other cardiovascular problem • Emergency admission for noncardiovascular problem • Planned admission for evaluation/treatment of carotid artery disease • Planned admission for evaluation/treatment of PAD • Planned admission for evaluation/treatment of aortic aneurysm • Planned admission for evaluation/treatment of renal/mesenteric artery disease • Planned admission for other cardiovascular problem • Planned admission for noncardiovascular problem • Regularly scheduled outpatient visit • Urgent or other unscheduled outpatient visit
Primary reason for encounter	• Symptoms related to carotid artery disease • Symptoms related to PAD • Symptoms related to aortic aneurysmal disease • Symptoms related to renal artery disease • Symptoms related to mesenteric artery disease • Symptoms related to other cardiovascular disease • Noncardiovascular symptoms
Admission location	• ICU/stroke unit • Step-down unit • Unmonitored hospital floor • Observation/holding unit in emergency department • Outpatient

(*Continued*)

Table 1. Continued

Element Name	Definition
Means of transport	• Self/family/friend/caregiver • Taxi/public transportation • Ambulance • Mobile ICU • Air or ambulance transfer from another facility
Location of encounter (21)	Indicate the location of encounter: • Air or ambulance transfer from another facility • Caregiver office: primary care or specialist • Urgent care facility • Inpatient hospital • Outpatient hospital • Emergency department • Ambulatory surgery center • Inpatient rehabilitation facility • SNF • Mobile unit
Patient History	
Risk Factors for Atherosclerosis	
Hypertension	Indicate if the patient has a current or previous diagnosis of hypertension as defined by any of the following: • History of hypertension diagnosed and treated with medication, diet, and/or exercise • On at least 2 occasions, documented blood pressure >140 mm Hg systolic and/or 90 mm Hg diastolic in patients without diabetes or chronic kidney disease; >130 mm Hg systolic or 80 mm Hg diastolic in patients with diabetes or chronic kidney disease • Currently on pharmacological therapy for treatment of hypertension *More than 1 of the above may apply. The year of onset (first diagnosis) may be helpful.*
Diabetes (22)	History of diabetes diagnosed and/or treated by a physician. The American Diabetes Association criteria include documentation of the following: • Hemoglobin A1c >6.5%; or • Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L); or • Two-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test; or • In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose >200 mg/dL (11.1 mmol/L). This does not include gestational diabetes. Indicate the following: 1. Type 1 or type 2 diabetes 2. Year of onset (if known)
Dyslipidemia	Current or previous diagnosis of dyslipidemia per the National Cholesterol Education Program criteria (23), defined as any 1 of the following: • Total cholesterol >200 mg/dL (5.18 mmol/L) • LDL ≥130 mg/dL (3.37 mmol/L) • HDL <40 mg/dL (1.04 mmol/L) in men and <50 mg/dL (1.30 mmol/L) in women Treatment is also initiated if LDL is >100 mg/dL (2.59 mmol/L) in patients with known coronary artery disease or CHD equivalent, and this would qualify as hypercholesterolemia.
History of smoking (24)	History confirming cigarette smoking in the past. Choose from the following categories: • Current every day smoker • Current some days smoker • Former smoker • Never smoker • Smoker, current status unknown • Unknown if ever smoked For current or former smokers, total pack years may be useful.
Alcohol consumption	Specify the patient's history of alcohol consumption. Choose from the following categories: • None • ≤1 alcoholic drinks/wk • 2–7 alcoholic drinks/wk • 8–13 alcoholic drinks/wk • 14–20 alcoholic drinks/wk • ≥21 alcoholic drinks/wk

(*Continued*)

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Table 1. Continued

Element Name	Definition
	Specify alcohol-dependency history. Choose all that apply: Documented alcohol dependency Medical sequelae of alcohol consumption (alcoholic hepatitis, cirrhosis, alcohol neuropathy, Wernicke-Korsakoff syndrome) Treatment for alcohol dependency *For patients with alcohol dependency, note treatment for dependency, cessation of use, or continued use.*
Illicit drug use	Indicate history of current, recent, or remote abuse of any illicit drug (e.g., cocaine, methamphetamine, marijuana) or controlled substance. Choose 1 of the following: ● Yes ● No
Evidence of Atherosclerosis	
History of MI	The term *myocardial infarction* should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Under these conditions, any 1 of the following criteria meets the diagnosis for MI: ● Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least 1 value above the 99th percentile of URL together with evidence of myocardial ischemia with at least 1 of the following: – Symptoms of ischemia – Electrocardiographic changes indicative of new ischemia (new ST-T changes or new LBBB) – Development of pathological Q waves in the ECG – Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality ● Sudden unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation or new LBBB and/or evidence of fresh thrombus by coronary angiography a time before the appearance of cardiac biomarkers in the blood. ● For PCI in patients with normal baseline indicative of periprocedural myocardial necrosis. By convention, increases of biomarkers $>3\times$99th percentile URL have been designated as PCI-related MI. A subtype related to a documented stent thrombosis is recognized. ● For CABG in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of periprocedural myocardial necrosis. By convention, increases of biomarkers $>5\times$99th percentile URL plus either new pathological Q waves or new or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related MI. ● Pathological findings of an acute MI.
MI within the past 6 wk	Indicate if the patient had an MI within 6 wk prior to the index procedure as evidenced by the following: 1. Acute MI ($\leq$7 d) manifested as a rise and fall of cardiac biomarkers (preferably troponin) with at least 1 value above the range of normal for your laboratory (above the 99th percentile of the URL) together with evidence of myocardial ischemia with at least 1 of the following: a. Ischemic symptoms b. Electrocardiographic changes indicative of new ischemia (new ST-T and/or T-wave changes or new LBBB) c. Development of pathological Q waves on the ECG d. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality 2. Recent MI ($>$7 d) manifested by a. An MI meeting the criteria for an acute MI as documented in the medical record, or b. By any 1 of the following: 1. Development of new pathological Q waves with or without symptoms 2. Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract 3. In the absence of a nonischemic cause
History of angina	History of angina may include ● Stable angina – Indicate CCS class ● Unstable angina ● Prior angina; currently asymptom1atic Dates should be sought for the onset of either stable or unstable angina.
Previous CABG surgery	Indicate history of prior CABG surgery, including the date or year of surgery. The total number of CABG procedures and the year of the most recent procedure may be helpful.
Previous PCI	Prior PCI of any type (balloon angioplasty, atherectomy, stent, or other)Total number of PCI procedures and dates (years)

(*Continued*)

Table 1. Continued

Element Name	Definition
History of PAD	Indicate if the patient has a history of lower extremity PAD (from iliac to tibials). Excludes renal, coronary, cerebral, and mesenteric vessels and aneurysm. Major symptoms can include ● Asymptomatic (confirmed by noninvasive diagnostic test) ● Claudication relieved by rest ● Ischemic rest pain ● Tissue loss (including ischemic ulcer and/or gangrene) ● Amputation for critical limb ischemia ● Vascular reconstruction, bypass surgery, or percutaneous revascularization in the arteries of the lower extremities ● Positive noninvasive test (e.g., ABI $\leq$0.90, ultrasound, MR or CT imaging demonstrating $>$50% diameter stenosis in any peripheral artery, ie, aorta, iliac, femoral, popliteal, tibial, peroneal)
History of aortic aneurysm	Indicate if the patient has a history of aortic aneurysm. This can include ● Thoracic aneurysm ● Thoracoabdominal aneurysm ● AAA Confirmed by ultrasound, CT, and/or MR imaging.
History of renal or mesenteric artery disease	Indicate if the patient has a history of renal or mesenteric artery disease. This can include an abnormal imaging study such as duplex ultrasonography, MRA, CTA, or catheter-based contrast angiography demonstrating $>$50% diameter stenosis in the renal artery, celiac trunk, SMA, or IMA.
TIA (25)	Indicate if the patient has a documented history of TIA consisting of a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia without acute infarction. Note the following: ● Right retinal ● Right hemispheric ● Left retinal ● Left hemispheric ● Vertebrobasilar ● Unknown distribution
Prior stroke	Indicate whether the patient has a history of stroke, which is defined as an acute episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. If present, record the type of stroke (26,27): ● Ischemic ● Intracerebral hemorrhage ● Subarachnoid hemorrhage ● Unknown If ischemic, list the most likely etiologies: ● Large-artery atherosclerosis of the extracranial vessels (e.g., carotid) ● Large-artery atherosclerosis of the intracranial vessels (e.g., middle cerebral artery stenosis) ● Cardioembolism ● Small-vessel occlusion (lacunar) ● Ischemic stroke of other determined etiology (e.g., arterial dissection) ● Ischemic stroke of undetermined etiology
Congestive Heart Failure	
CHF	Indicate if the patient has a previous history of CHF. This includes a previous hospital admission with a principal diagnosis of CHF. CHF is defined as documentation or report of any 2 of the following Framingham major criteria of heart failure: orthopnea/paroxysmal nocturnal dyspnea; or the description of rales, jugular venous distention, hepatojugular reflux, S_3 gallop, or pulmonary edema on chest x-ray; or 1 of the major criteria plus 2 Framingham minor criteria, including dyspnea on exertion, nocturnal cough, ankle edema, pleural effusion, or tachycardia. A low ejection fraction without clinical evidence of heart failure does not qualify as heart failure. Include the year of onset if known.
NYHA classification scale (28)	To classify symptoms or signs in patients with suspected or presumed heart failure per the NYHA classification scale: ● Class I: without limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea. ● Class II: slight limitation of physical activity. The patient is comfortable at rest. Ordinary physical activity results in fatigue, palpitations, or dyspnea. ● Class III: marked limitation of physical activity. The patient is comfortable at rest. Less than ordinary activity causes fatigue, palpitations, or dyspnea. ● Class IV: inability to carry on any physical activity without discomfort. Heart failure symptoms are present even at rest or with minimal exertion.

(*Continued*)

Table 1. Continued

Element Name	Definition
Pulmonary insufficiency	Indicate if the patient has a history of pulmonary insufficiency. Pulmonary insufficiency is defined as Pao_2 of $<$60 mm Hg while breathing air or $Paco_2$ of $>$50 mm Hg.
Chronic kidney disease (29)	Current or previous history of chronic kidney disease. Chronic kidney disease is defined as either kidney damage or GFR $<$60 mL/min/1.73 m^2 for $\geq$3 mo. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies. Indicate the patient's stage of disease: • Stage 0: No known kidney disease • Stage 1: Kidney damage with normal or high GFR $\geq$90 mL/min/1.73 m^2 • Stage 2: Kidney damage with mildly decreased GFR—60–89 mL/min/1.73 m^2 • Stage 3: Moderately decreased GFR—30–59 mL/min/1.73 m^2 • Stage 4: Severely decreased GFR—15–29 mL/min/1.73 m^2 • Stage 5: Kidney failure—GFR $<$15 mL/min/1.73 m^2 or on dialysis *Note:* GFR may be estimated using the serum creatinine MDRD formula: eGFR$=186\ (\text{serum creatinine})^{-1.154}\ (\text{age})^{-0.203}\ (0.742\ [\text{if female}])\ (1.210\ [\text{if black}])$ Year of onset (first diagnosis) may be helpful.
Patient Assessment: Physical Evaluation	
Height	Patient's height in centimeters. To be converted from conventional units if needed *Note:* May be measured or reported by the patient.
Weight	Patient's measured actual weight in kilograms. To be converted from conventional units if needed *Note:* Must be measured during encounter. It is advisable to standardize clothing worn (i.e., whether shoes are worn).
BMI	BMI is calculated according to the following formula: the patient's weight in kilograms, divided by height in meters squared. Obesity is defined as a BMI $\geq$30 kg/m^2.
Blood pressure (right and left arm)	Systolic and diastolic blood pressure (mm Hg) in both the right and left arms recorded closest to the time of presentation at the healthcare facility. The patient's position (supine, sitting, other) may be noted.
Heart rate	Number of heart beats over 1 min. Note: Recorded closest to the time of presentation at the healthcare facility and/or on discharge (for inpatient). Specify whether the heart rate is regular or irregular. Heart rate may be ascertained from the ECG or record of physical examination.
Cardiac rhythm	Indicate if the patient has any of the following: • Normal sinus rhythm • Atrial fibrillation • Other
Complete vascular examination	Carotid, upper, lower extremity pulses, auscultation of the neck for carotid bruits, auscultation of the abdomen and femoral arteries for bruits, palpation of the abdomen and popliteal fossa for aneurysms
Complete cardiac examination	Palpation and auscultation of the heart, assessing rate, rhythm, presence of murmur, presence of gallop (e.g., S_3 suggesting left ventricular dysfunction; S_4 suggesting noncompliant left ventricle), notation of location of point of maximal intensity
Limb edema	Note the presence/absence of lower extremity (less commonly, upper extremity) edema, including location, extent, and pitting versus nonpitting.
Laboratory Testing	
CBC	Include RBC, WBC, and platelet counts: 1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Hemoglobin	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Hematocrit	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Glucose	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
BUN	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Creatinine	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
GFR	Indicate estimated or actual GFR in milliliters per minute per 1.73 meters squared.
Sodium	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper and lower limit of normal when appropriate)
Potassium	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper and lower limit of normal when appropriate)
Hemoglobin A1C	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Prothrombin time	Measured in seconds. Report INR as ratio.
Partial thromboplastin time	Indicate whether activators used (aPTT) or not (PTT). Measured in seconds.
Total cholesterol	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)

(*Continued*)

Table 1. Continued

Element Name	Definition
LDL	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
HDL	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Triglycerides	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
hs-CRP	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
ESR	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Calcium	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper and lower limit of normal when appropriate)
Phosphorus	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper and lower limit of normal when appropriate)
Magnesium	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper and lower limit of normal when appropriate)
TSH	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
BNP or N-terminal BNP	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
AST	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
ALT	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
CK	The upper limit of normal of total CK as defined by individual hospital laboratory standards. Units of CK and type of units should be noted (e.g., IU, ng/dL, kCat/L).
	All CK values during hospitalization should be noted; include units, date, and time.
Troponin	Indicate which type: T or I.
	Indicate the upper limit of normal (usually the 99th percentile of a normal population) and units (e.g., ng/dL).
	All troponin T or I values during hospitalization should be noted; include units, date, and time.
Homocysteine	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Vitamin B_{12}	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Folate	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Prothrombin 20210 gene mutation	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Protein C activity	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Protein S activity	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Antithrombin III	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Anticardiolipin antibody	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Lupus anticoagulant	1) value, 2) unit of measurement, 3) date, and 4) normal range (upper limit of normal when appropriate)
Current Pharmacologic Therapy to Manage Cardiovascular Disease	
Antiplatelet Drugs	
Aspirin	Note specific dose.
Clopidogrel	Note specific dose.
Prasugrel	Note specific dose.
Other P2Y12 antagonists	Note specific drug and dose.
Dipyridamole	Note specific dose.
Others	Note specific drug and dose.
Anticoagulant Drugs	
Unfractionated heparin	Note specific dose.
Low–molecular-weight heparin	Note specific drug and dose.
Fondaparinux	Note specific dose.
Other factor Xa inhibitor	Note specific drug and dose.
Direct thrombin inhibitor	Note specific drug and dose.
Warfarin	Indicate whether this drug has been prescribed; note INR.
Others	Note specific drug and dose.
Drugs to Control Cardiovascular Risk Factors	
Antihypertensive drugs	Note specific drug and dose.
Statins and lipid-control agents	Note specific drug and dose.
Drugs for diabetes	Note specific drug and dose.
Drugs to aid in smoking cessation	Note specific drug and dose.

(*Continued*)

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Table 1. Continued

Element Name	Definition
Drugs for Coexisting Cardiovascular Conditions	
Antiarrhythmic drugs	Note specific drug and dose.
Heart failure medications	Note specific drug and dose.
Drugs for symptoms of PAD	Note specific drug and dose.
Noncardiovascular medications	Note the specific drug and dose.
Other Elements Related to Pharmacological Therapy to Manage Cardiovascular Disease	
Medication allergy	Specify the medication and type of reaction.
Medication side effect	Describe the side effect and whether the medication was stopped.

AAA indicates abdominal aortic aneurysm; ABI, ankle brachial index; ALT, alanine aminotransferase; aPTT, activated partial thromboplastin time; AST, aspartate aminotransferase; BMI, body mass index; BNP, B-type natriuretic peptide; BUN, blood urea nitrogen; CABG, coronary artery bypass graft; CBC, complete blood count; CCS, Canadian Cardiovascular Society; CHD, coronary heart disease; CHF, congestive heart failure; CK, creatine kinase; CT, computed tomography; ECG, electrocardiogram; ESR, erythrocyte sedimentation rate; GFR, glomerular filtration rate; HDL, high-density lipoprotein; HMO, health maintenance organization; hs-CRP, high-sensitivity C-reactive protein; ICU, intensive care unit; IMA, inferior mesenteric artery; INR, international normalized ratio; LBBB, left bundle-branch block; LDL, low-density lipoprotein; MDRD, modification of diet in renal disease; MI, myocardial infarction; MR, magnetic resonance; MRA, magnetic resonance angiography; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PPO, preferred provider organization; PTT, partial thromboplastin time; RBC, red blood cell; SMA, superior mesenteric artery; SNF, skilled nursing facility; TIA, transient ischemic attack; TSH, thyroid stimulating hormone; URL, upper reference limit; and WBC, white blood cell.

2.7. Peer Review, Public Review, and Board Approval

This set of standards and definitions for PAVD was independently reviewed by official appointees from the ACCF, AHA, American College of Radiology, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, and the ACCF/AHA Task Force on Clinical Data Standards, as well as experts from collaborating organizations, namely, the American College of Physicians; American Association of Cardiovascular and Pulmonary Rehabilitation; American Academy of Neurology; American Diabetes Association; National Heart, Lung, and Blood Institute; Society of Atherosclerosis Imaging and Prevention; Society of Cardiovascular Computed Tomography; Society for Cardiovascular Magnetic Resonance; and Vascular Disease Foundation. To increase its applicability, this document was posted on the ACC Web site for a 30-day public comment period from September 1, 2010, through October 1, 2010. The document was then approved by the ACCF Board of Trustees and the AHA Science Advisory and Coordinating Committee in June 2011; American Association of Cardiovascular and Pulmonary Rehabilitation, American Academy of Neurology, American Diabetes Association, Society of Atherosclerosis Imaging and Prevention, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, Society of Interventional Radiology, Society of Thoracic Surgeons, Society for Vascular Medicine, Society for Vascular Nursing, and Vascular Disease Foundation in October 2011; the American College of Radiology and Society for Cardiovascular Angiography and Interventions in November 2011; and the Society for Vascular Surgery in December 2011.

The writing committee anticipates that these data standards will require review and updating, as with the ACCF/AHA guidelines, performance measures, and appropriate use criteria. At the anniversary of publication, the writing committee will review the data standards to ascertain whether modifications should be considered.

2.8. Intended Use

The writing committee anticipates that the "Key Data Elements and Definitions for Peripheral Atherosclerotic Vascular Disease" will prove useful in several settings:

1. *Clinical programs* in which providers and health plans work in concert to achieve optimal use of procedures pertinent to PAVD. Data standards will assist in the development of structured reporting systems and the organization and design of electronic medical information systems, including clinical database and decision support tools.
2. *Clinical research,* including prospective registries and randomized controlled trials. Meta-analyses will be particularly strengthened by the use of standardized data for key variables.
3. *Quality assessment/performance measurement.* Data standards will especially facilitate interpretation for nonmedical users, including payers, regulators, and consumers.

3. PAVD Data Standard Elements and Definitions

3.1. General Table of Data Elements

The general elements listed in Table 1 are applicable to all of the PAVDs included in this document. These include demographic elements, such as sex, age, race, ethnicity, and payer information; elements related to the patient's presentation, such as the primary reason for the encounter and its location; risk factors for atherosclerosis, such as hypertension, dyslipidemia, diabetes mellitus, and cigarette smoking; and evidence of previously established atherosclerotic conditions, such as coronary artery disease, lower extremity PAD,

Table 2. Lower Extremity PAD Elements and Definitions

Element Name	Definition
Patient Assessment: Signs and Symptoms	
Asymptomatic	The patient has no symptoms of claudication, no symptoms of ischemic pain, and no limitation in walking distance.
Claudication: characteristics	Indicate claudication as determined by the discomfort: • Exertional • Reproducible • Resolves within 10 min of rest
Claudication: description	Describe the discomfort. Choose all that apply: • Cramping • Aching • Fatigue • Other
Claudication: location	Indicate the limb (right leg, left leg, both) with discomfort and the location of the discomfort. Choose all that apply: • Buttock • Hip • Thigh • Calf • Foot
Claudication: walking	When describing walking, indicate the following: • Pain-free walking distance (ft/m/blocks) • Maximum walking distance (ft/m/blocks) • Typical walking speed – Slow – Normal – Fast • Flat surface versus incline
Claudication: onset of symptoms	Indicate the following: • Date of onset • Duration of symptoms
Claudication: stability of symptoms	Indicate if symptoms • Improved • Stabilized • Worsened
Atypical symptoms	Describe the characteristics of atypical symptoms.
Ischemic rest pain	Indicate if the pain and discomfort • Are characterized by aching or burning at rest or with elevation • Are relieved by dependency • Interfere with sleep Also indicate the following: • Location (right or left leg or both) – Forefoot – Toes • Date of onset • Duration of symptoms • Frequency of occurrence – Intermittent – Constant
Tissue loss	To report a nonhealing wound, indicate the following: • Location • Onset/duration
Acute Limb Ischemia	
Characteristics	Indicate if there is sudden onset of • Pain • Paresthesia
Location	Indicate the specific location of pain.
Symptom onset	Indicate the onset and duration of symptoms.

(*Continued*)

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Table 2. Continued

Element Name	Definition
Patient Assessment: Physical Evaluation	
Pulses	Indicate the characteristics of pulses in the following locations: ● Femoral ● Popliteal ● Dorsalis pedis ● Posterior tibial Indicate if pulses are: ● 0: Absent ● 1: Diminished ● 2: Normal ● 3: Bounding
Bruits	Indicate the presence or absence of bruits on auscultation in the following: ● Carotid ● Abdominal ● Femoral ● Subclavian
Elevation pallor	Indicate the presence of pallor of the forefoot after elevating the leg 60° for 1 min.
Reperfusion delay	Reperfusion delay (>40 s)
Dependent rubor	Indicate if rubor of the foot is present when held in dependence after an elevation pallor maneuver.
Acute limb ischemia	Acute limb ischemia is characterized by ● Pallor ● Pulselessness ● Poikilothermia ● Paralysis – One of the following categories should be assigned: ○ I: Viable—Limb is not immediately threatened; no sensory loss; no muscle weakness; audible arterial and venous Doppler ○ II: Threatened—Mild to moderate sensory or motor loss; inaudible arterial Doppler; audible venous Doppler ○ III: Irreversible—Major tissue loss or permanent nerve damage inevitable; profound sensory loss, anesthetic; profound muscle weakness or paralysis (rigor); inaudible arterial and venous Doppler
Tissue loss (ischemic wound or gangrene): characteristics	Tissue loss is characterized by ● Dryness ● Necrosis ● Granulation
Tissue loss (ischemic wound or gangrene): affected limb	Indicate the affected extremity/extremities. Choose 1 of the following: ● Left ● Right ● Bilateral
Tissue loss (ischemic wound or gangrene): location	Specify the location of tissue loss. Choose all that apply: ● Distal aspect of leg or foot ● Over bony prominence ● Toe ● Others
Tissue loss (ischemic wound or gangrene): wound area	Indicate the measured area of the wound in centimeters.
Tissue loss (ischemic wound or gangrene): infection	Indicate the presence or absence of infection. Choose 1 of the following: ● Yes ● No
Tissue loss (ischemic wound or gangrene): type	Indicate the type of tissue loss. Choose 1 of the following: ● Minor: nonhealing ulcer, focal gangrene with diffuse pedal ischemia ● Major: extending above transmetatarsal level; functional foot no longer salvageable
Tissue loss (ischemic wound or gangrene): depth/Wagner grade	Indicate the Wagner grade of the wound/gangrene. Choose 1 of the following: ● Grade 0: Pre- or postulcerative lesion ● Grade 1: Partial/full thickness ulcer ● Grade 2: Probing to tendon or capsule ● Grade 3: Deep with osteitis ● Grade 4: Partial foot gangrene ● Grade 5: Whole foot gangrene

(*Continued*)

Table 2. Continued

Element Name	Definition
Diagnostic Testing: Noninvasive Procedures	
Ankle Brachial Index/Toe Brachial Index	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Ankle systolic pressure	Indicate the ankle systolic pressure of the right and left legs and whether it is recorded from the posterior tibial or dorsalis pedis arteries.
ABI value	Indicate the ABI value for each leg. Choose 1 of the following: • Normal (ABI 1.00–1.40) • Abnormal (ABI $<$0.90) • Borderline (ABI 0.91–0.99) • Noncompressible arteries (ABI $>$1.40)
Great toe systolic pressure	Indicate the right and left great toe systolic pressures.
TBI value	Indicate the TBI value for each leg. A TBI value of $\leq$0.7 is abnormal.
Exercise Testing: Treadmill Exercise	
Date of procedure	Indicate the date exercise testing was performed (mo/d/y).
Protocol	Specify the symptom-limited exercise protocol used (constant load/graded).
Postexercise ankle pressure and/or ABI	Indicate if immediate postexercise ankle pressure and/or ABI measurement were performed. Choose 1 of the following: • Yes. If so, indicate value. • No
Walking time	Indicate the following walking time in minutes: • Claudication onset time • Peak walking time
Distance	Indicate the walking distance in meters or feet: • Claudication-onset walking distance • Peak walking distance
METS	1 MET is defined as 3.5 mL $O_2 \cdot kg^{-1} \cdot min^{-1}$. Indicate METS at peak exercise.
Alternative method	A 6-min walk is the distance walked in 6 min on flat surface using standardized measurement procedures. It is reported in meters or feet.
Segmental Pressure Examination	
Date of examination	Indicate the date the segmental pressure examination was performed (mo/d/y).
Segmental pressure measurements	• Right and left brachial pressures • Right and left thigh pressures • Right and left low thigh pressures • Right and left thigh calf pressures • Right and left dorsalis pedis pressures • Right and left posterior tibial pressures Indicate if there is a $>$20 mm Hg drop between the contiguous segments of the same leg, which can suggest the location of stenosis.
Pulse Volume Recording	
Date of recording	Indicate the date PVR was taken (mo/d/y).
Amplitude reduction	Indicate the leg and location of PVR: • Right/left high thigh • Right/left low thigh • Right/left calf • Right/left ankle • Right/left metatarsal Choose 1 of the following to describe pulse wave amplitude: • Normal • Abnormal • Mildly reduced • Moderately reduced • Severely reduced
Transcutaneous Oxygen Pressure	
Date of measurement	Indicate the date of measurement (mo/d/y).
$TcPo_2$ measured	Measurement of the pressure of oxygen on the surface of the skin. Indicate the following: • Right foot • Left foot
Value of $TcPo_2$	Indicate the $TcPo_2$ value in the right foot and left foot.

(*Continued*)

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Table 2. Continued

Element Name	Definition
Duplex Ultrasound	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Artery imaged	Indicate the artery imaged. Choose all that apply: • Aorta • Right/left CIA • Right/left EIA • Right/left common femoral artery • Right/left proximal profunda femoris artery • Right/left superficial femoral artery • Right/left popliteal artery • Right/left tibioperoneal trunk • Right/left anterior tibial artery • Right/left posterior tibial artery • Right/left peroneal artery
Peak systolic velocity	Specify for • Aorta • Right/left CIA • Right/left EIA • Right/left common femoral artery • Right/left proximal profunda femoris artery • Right/left superficial femoral artery • Right/left popliteal artery • Right/left tibioperoneal trunk • Right/left anterior tibial artery • Right/left posterior tibial artery • Right/left peroneal artery
Category of stenosis	Specify for • Aorta • Right/left CIA • Right/left EIA • Right/left common femoral artery • Right/left proximal profunda femoris artery • Right/left superficial femoral artery • Right/left popliteal artery • Right/left tibioperoneal trunk • Right/left anterior tibial artery • Right/left posterior tibial artery • Right/left peroneal artery Indicate the category of stenosis (30): • Normal • 1%–49% • 50%–99% • Occlusion
Bypass graft	Indicate location of proximal and distal anastomosis and type (e.g., in situ saphenous vein, reverse saphenous vein, PTFE).
Peak systolic velocity of bypass graft	Indicate peak systolic velocity at proximal anastomosis, along conduit, and at distal anastomosis.
Ratios of peak systolic velocities along bypass graft	Indicate ratio of peak systolic velocity of 2 contiguous segments at proximal anastomosis, along conduit, and at distal anastomosis.
Category of bypass graft stenosis	Bypass graft stenosis percentage. Indicate location and choose 1 of the following: • 0%–49% • 50%–99% • Occluded
Magnetic Resonance Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast use	Indicate if gadolinium was used. Choose 1 of the following: • Yes • No

(*Continued*)

Table 2. Continued

Element Name	Definition
Artery imaged	Indicate the artery imaged. Choose all that apply: ● Abdominal aorta ● Right/left iliac (common, internal, external) artery ● Right/left femoral (common, superficial, deep) artery ● Right/left popliteal (above knee, below knee, both) artery ● Right/left tibial/peroneal (anterior tibial, posterior tibial, peroneal) arteries
Lesion location	Specify the location of the lesion.
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Reconstitution	Indicate if reconstitution was seen. Choose 1 of the following: ● Yes ● No
CT Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast used	Indicate the type of contrast used. Choose 1 of the following: ● Ionic contrast ● Nonionic contrast; specify: – Monomer – Dimer
Contrast volume	Indicate the volume of contrast used in milliliters.
Slice thickness	Indicate the slice thickness in millimeters.
Format: raw images	Indicate if raw images were reviewed. Choose 1 of the following: ● Yes ● No
Format: reconstructed images	Indicate if reconstructed images were reviewed. Choose 1 of the following: ● Yes. If yes, specify – Shaded surface images – Maximum intensity projection ● No
Artery imaged	Indicate the artery imaged. Choose all that apply: ● Abdominal aorta ● Right/left iliac (common, internal, external) artery ● Right/left femoral (common, superficial, deep) artery ● Right/left popliteal (above knee, below knee, both) artery ● Right/left tibial/peroneal (anterior tibial, posterior tibial peroneal) arteries
Lesion location	Specify the location of the lesion.
Calcification	Indicate if calcification is present. If present, specify the location. Choose 1 of the following: ● None ● Mild ● Moderate ● Severe
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Reconstitution	Indicate if reconstitution was seen. Choose 1 of the following: ● Yes ● No
Diagnostic Testing: Invasive Procedures	
Catheter Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator name	Last name, first, middle
Anesthesia	Indicate the type of anesthesia used. Choose 1 of the following: ● General ● Local – Indicate if sedation was used. Choose 1 of the following: ○ Yes ○ No ● Regional – With sedation – Without sedation

(*Continued*)

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Table 2. Continued

Element Name	Definition
Vascular access site	Specify the vascular access site.
Contrast agent	Indicate the contrast agent used: ● Iodinated – Ionic – Nonionic ○ Monomer ○ Dimer ● Noniodinated (CO_2)
Contrast volume	Specify the contrast volume given.
Field size	Indicate the field size in centimeters or inches.
Frame rate	Indicate the FPS.
Image type	Indicate the image type. Choose 1 of the following: ● Cine ● Digital images
Digital subtraction	Indicate if digital subtraction was done. Choose 1 of the following: ● Yes ● No
Fluoroscopy time	Indicate total fluoroscopy time recorded to the nearest 0.10 min. The time recorded should include the total time for the procedure.
Artery imaged	Indicate the artery imaged. Choose all that apply: ● Abdominal aorta ● Right/left iliac (common, internal, external) artery ● Right/left femoral (common, deep, superficial) artery ● Right/left popliteal (above knee, below knee, or both) artery ● Right/left tibial/peroneal (anterior tibial, posterior tibial, peroneal) arteries
Lesion location	Specify the location of the lesion (ostial, proximal third, middle third, and distal third).
Calcification	Indicate if calcification is present. If present, specify the location. Choose 1 of the following: ● None ● Mild ● Moderate ● Severe
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Reconstitution	Indicate if the artery is reconstituted by collaterals. Choose 1 of the following: ● Yes – If yes, indicate level. ● No
Translesional pressure gradient	Indicate the pressure measured proximal to the stenosis minus the pressure measured distal to the stenosis. Also indicate the following: ● Baseline pressure gradient – Systolic – Mean – Diastolic ● Enhanced (hyperemic, postvasodilator) pressure gradient – Systolic – Mean – Diastolic ● Measurement timing – Simultaneous – Pullback
Complications	Indicate any technical complications encountered during the diagnostic procedure: Choose all that apply: ● Pseudoaneurysm ● Atrioventricular fistula ● Hematoma ● Dissection ● Vessel thrombosis ● Vessel perforation ● Atheromatous embolization

(*Continued*)

Table 2. Continued

Element Name	Definition
	● Contrast nephropathy ● Contrast hypersensitivity ● Requirement of intervention to prevent permanent impairment/damage
Pharmacological Therapy for Symptoms of Claudication	
Cilostazol	Indicate if cilostazol has been prescribed for the patient. Choose 1 of the following: ● Yes – If yes, indicate the following: ○ Dose ○ Duration of treatment ● No
Pentoxifylline	Indicate if pentoxifylline has been prescribed for the patient. Choose 1 of the following: ● Yes – If yes, indicate the following: ○ Dose ○ Duration of treatment ● No
Exercise Rehabilitation for Intermittent Claudication	
Exercise Program Assessment	
Functional status/quality of life	Document functional ability at initiation and completion of the exercise program based on the following: ● Claudication onset walking distance ● Peak walking distance ● METS achieved at peak exercise ● 6-min walking test ● Questionnaires
Total exercise time	Document the total exercise time during the exercise session at initiation and completion of the exercise program.
Total rest time	Document the total rest time spent during the exercise session at initiation and completion of the exercise program.
Walking time	Document the duration of walking time at initiation and completion of the exercise program.
Exercise Prescription	
Place	Indicate the place where exercise is done. Choose 1 of the following: ● Supervised facility ● Home based
Mode of exercise	Indicate the mode of exercise prescribed. Choose 1 of the following: ● Treadmill – Indicate initial speed and grade – Indicate final speed and grade ● Track walking – Indicate initial speed – Indicate final speed ● Cycling – Indicate initial speed and watts – Indicate final speed and watts
Progression	Indicate the recommendation for progression of exercise.
Intensity level	Indicate the recommended claudication pain intensity level before resting.
RPE	Indicate the recommended range of RPE.
Duration of session	Indicate the duration of the exercise session in minutes.
Frequency of session	Indicate the number of days of exercise session per week
Duration of prescription	Indicate how long the exercise prescription should be performed in number of sessions or number of weeks
Therapeutic Procedures: Endovascular and Open Surgical Revascularization	
Endovascular	
Date	Indicate the date the procedure was performed (mo/d/y).
Operator name	Last name, first, middle
Limb revascularized	Indicate which limb was revascularized. Choose 1 of the following: ● Right ● Left ● Both

(*Continued*)

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Table 2. Continued

Element Name	Definition
Procedure	Indicate the procedure performed. Choose 1 or more of the following: ● Balloon angioplasty ● Cutting balloon ● Stent — Indicate if stent is drug eluting. Choose 1 of the following ○ Yes – If so, specify the type of drug-eluting stent. ○ No ● Stent graft ● Atherectomy ● Laser ● Cryoplasty
Vessel	Indicate the target vessel for revascularization. Choose all that apply: ● Aorta ● CIA ● EIA ● IIA ● Common femoral artery ● Superficial femoral artery ● Deep femoral artery ● Popliteal (above the knee) ● Popliteal (below the knee) ● Anterior tibial artery ● Posterior tibial artery ● Peroneal artery ● Pedal arteries
Manufacturer	Indicate the manufacturer of the device.
Model	Indicate the model number of the device.
Diameter	Indicate the maximum diameter of the device in millimeters.
Length	Indicate the maximum length of the device in millimeters.
Time arrived in catheterization lab	Indicate the time of patient arrival in the catheterization lab in hours:minutes.
Last catheter removed	Indicate the date (mo/d/y) and time (h:min) the last catheter was removed.
Thrombolytic agent	Indicate the thrombolytic agent used. Specify the following: ● Specific thrombolytic agent used ● Route of delivery ● Dosage ● Duration of infusion
Antithrombotic agent	Indicate the antithrombotic agent used. Specify the following: ● Specific antithrombotic agent used. Choose 1 of the following: — Unfractionated heparin — Low–molecular-weight heparin — Fondaparinux — Direct thrombin inhibitor ● Route of delivery ● Dosage ● Duration of infusion
Antiplatelet agent	Indicate the antiplatelet agent used. Specify the following: ● Dosage
Closure device	Indicate if a closure device was used. Choose 1 of the following: ● Yes. Specify the following: — Manufacturer — Model ● No
Contrast	Indicate type of contrast used. Choose 1 of the following: ● Iodinated — Ionic — Nonionic — Monomer ○ Dimer ● Noniodinated (CO_2)

(*Continued*)

Table 2. Continued

Element Name	Definition
Device utilization	Indicate the devices used for the procedure. Choose all that apply: ● Guidewires ● Guiding catheters ● Intravascular ultrasound ● Angioplasty balloons ● Cutting balloon ● Infusion catheter ● Laser catheter ● Thrombectomy device ● Atherectomy device ● Reentry device ● Thermal balloon ● EPD ● Stent ● Drug-eluting stent ● Stent graft
Technical outcome	Indicate the technical outcome of the procedure. Specify the following: ● Postprocedure translesional gradient ● Residual percent stenosis
Technical complication	Indicate any technical complications encountered during the procedure: Choose all that apply: ● Vessel perforation ● Embolization (loss of runoff vessel) ● Dissection ● Vasospasm ● Access site bleeding
Open Surgery	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator name	Last name, first, middle
Location	Indicate which limb the procedure was done. Choose 1 of the following: ● Right ● Left ● Both
Procedure type	Indicate the type of procedure performed. Choose 1 of the following: ● Primary/secondary ● Bypass – Inflow/outflow – Anatomic/extra-anatomic ● Endarterectomy ● Thrombectomy ● Graft revision
Proximal anastomotic site	Indicate the proximal anastomotic site and side. Choose 1 of the following: ● Thoracic aorta ● Abdominal aorta ● CIA ● EIA ● Common femoral artery ● Proximal superficial femoral artery ● Distal superficial femoral artery ● Profunda femoral artery ● Proximal popliteal artery ● Distal popliteal artery ● Tibioperoneal artery ● Proximal anterior tibial artery ● Distal anterior tibial artery ● Proximal posterior tibial artery ● Distal posterior tibial artery ● Proximal peroneal artery ● Distal peroneal artery ● Dorsalis pedis/tarsal artery

(*Continued*)

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Table 2. Continued

Element Name	Definition
Distal anastomotic site	Indicate the distal anastomotic site. Choose 1 of the following: ● CIA ● EIA ● Common femoral artery ● Proximal superficial femoral artery ● Distal superficial femoral artery ● Profunda femoral artery ● Proximal popliteal artery ● Distal popliteal artery ● Tibioperoneal artery ● Proximal anterior tibial artery ● Distal anterior tibial artery ● Proximal posterior tibial artery ● Distal posterior tibial artery ● Proximal peroneal artery ● Distal peroneal artery ● Dorsalis pedis/tarsal artery
Graft material	Indicate the type of graft material used for the procedure. Choose 1 of the following: ● Autogenous – Specify the harvest site. Choose 1 of the following: ○ Left ○ Right – Specify the vein used. Choose 1 of the following: ○ Great saphenous vein, in situ ○ Great saphenous vein, nonreversed ○ Great saphenous vein, reversed ○ Arm vein ○ Small saphenous vein ○ Composite vein ○ Vein patch ● Autogenous-prosthetic composite ● Prosthetic – Specify the type. Choose 1 of the following: ○ PTFE ○ Heparin-coated PTFE ○ Dacron ○ Other (specify)
Graft diameter	Specify graft diameter: ● Prosthetic ● Vein
Anesthesia	Indicate type of anesthesia used. Choose 1 of the following: ● General ● Local – Indicate if sedation was used. Choose 1 of the following: ○ Yes ○ No ● Regional – Epidural – Spinal – Indicate if sedation was used. Choose 1 of the following: ○ Yes ○ No
Technical outcome	Indicate the technical outcome of the procedure. Specify the following: ● Postprocedure translesional gradient ● Residual percent stenosis
Completion study	Indicate the type of study performed after the procedure. Choose 1 of the following: ● Angiogram ● Duplex ultrasound

(*Continued*)

Table 2. Continued

Element Name	Definition
Estimated blood loss	Indicate the estimated amount of blood loss in milliliters.
Transfused blood products	Indicate the blood products transfused to the patient. Choose all that apply: ● Auto transfused blood (specify volume used) ● Packed RBCs ● Fresh frozen plasma ● Platelets ● Other (specify)
Operative time	Indicate the total time of the procedure in hours:minutes.
Outcomes of Endovascular/ Open Surgery Procedures	
Time point	Indicate the period at which outcome measures are assessed. Choose all that apply: ● Periprocedure (24 h) ● Procedure related (30 d) ● 3 mo ● 6 mo ● 1 y
Serious adverse event	Indicate major clinical complications arising from the management or treatment of the disease. Choose 1 of the following: ● Yes — *Specify the serious adverse event. Choose all that apply:* ○ Hospitalization/prolonged hospitalization ○ Loss of limb or function of organ system ○ Persistent or significant disability or incapacity ○ Death ● No
Complications of endovascular procedure	Indicate postoperative clinical events or conditions associated with the endovascular procedure. Choose all that apply: ● Pseudoaneurysm ● AV fistula ● Hematoma ● Dissection ● Vessel thrombosis ● Vessel perforation ● Atheromatous embolization ● Contrast nephropathy ● Contrast hypersensitivity ● Infection ● Requirement of intervention to prevent permanent impairment/damage
Complications of open surgery	Indicate complications of open surgery. Choose all that apply: ● Major complication — Death — Shock (cardiogenic or septic) — MI — Stroke (ischemic, hemorrhagic, unknown type) — Renal failure — Prolonged hospitalization — Infection — Coagulopathy — Thrombosis — Compartment syndrome — Acute graft failure ● Minor complication (specify)
Clinical Outcomes	
Limb-Related Outcomes	
Time point	Indicate the period at which outcome measures are assessed. Choose all that apply: ● 1 mo ● 3 mo ● 6 mo ● 1 y

(*Continued*)

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Table 2. Continued

Element Name	Definition
Limb-related outcomes: symptoms	• Claudication – None – Unchanged – Improved – Worsened • Ischemic rest pain • Ischemic tissue loss • Amputation
Limb-related outcomes: functional capacity	Walking ability • Pain-free walking distance (in meters) or time (in minutes) • Maximum walking distance (in meters) or time (in minutes) Functional status/quality of life • Questionnaire assessment – Community-based walking (PAD specific): Walking Impairment Questionnaire, others – Generic health status: SF-36, Nottingham Health Profile, EuroQol, Sickness Impact Profile, and others – PAD-specific quality of life: VascuQOL Questionnaire, PADQOL, and others • Patient anecdote
Noninvasive assessment of outcome	• Limb perfusion pressure and/or ABI • Graft scan • Other imaging (CTA or MRA)
Procedure-related outcomes	Patency • Primary • Assisted • Secondary
Limb-related outcomes: wound healing	Wound healing characteristics. Complete all that apply: • Description of dressing • 1-wk change in area • 4-wk change in area • Presence and amount of granulation tissue • Presence of reepithelialization • Presence of fibrin slough
Cardiovascular Outcomes	
Cardiovascular outcomes	New cardiovascular ischemic event: • Angina • MI • Coronary artery revascularization • CHF • TIA • Stroke (ischemic, hemorrhagic, unknown type) • Carotid artery revascularization • Death

ABI indicates ankle brachial index; CHF, congestive heart failure; CIA, common iliac artery; CT, computed tomography; CTA, computed tomographic angiography; EIA, external iliac artery; EPD, embolic protection device; FPS, frame rate per second; IIA, internal iliac artery; METS, metabolic equivalent of task score; MI, myocardial infarction; MRA, magnetic resonance angiography; PAD, peripheral artery disease; PTFE, polytetrafluoroethylene; PVR, pulse volume recording; QoL/QOL, quality of life; RBC, red blood cell; RPE, rating of perceived exertion; SF-36, Short Form 36 Health Survey; TBI, toe-brachial index; $TcPo_2$, transcutaneous partial pressure of oxygen; and TIA, transient ischemic attack.

renal/mesenteric artery disease, AAAs, and cerebrovascular disease; and comorbid conditions, such as congestive heart failure, pulmonary insufficiency, and chronic kidney disease. More detailed data elements for each PAVD are provided in the subsequent tables. The general elements table also lists components of the physical examination, such as height, weight, body mass index, vital signs, and aspects of the cardiac and vascular examination. Detailed elements of the examination are provided in subsequent tables as applicable to each PAVD. Common laboratory values are also included, such as the complete blood count, renal and hepatic function tests, lipid levels, cardiac enzymes, markers of inflammation, and tests for inherited and acquired thrombophilia. Additional general elements include current pharmacotherapy, such as antiplatelet/anticoagulant drugs, medications to treat atherosclerotic risk factors, and drugs for comorbid cardiovascular conditions.

3.2. Lower Extremity PAD Table of Data Elements

Lower extremity PAD is defined as atherosclerotic disease that affects the arteries supplying the legs (2). Affected blood vessels may include the aorta and the iliac, femoral, popliteal, tibial, and peroneal arteries and their major branches. The data elements defined in Table 2 enable detailed documentation of symptomatic status, vascular examination, and sever-

Table 3. Abdominal Aortic Aneurysm Elements and Definitions

Element Name	Definition
History	
History of present illness	Indicate if the patient has been having any of the following symptoms and specify duration. Choose all that apply: ● No symptoms ● Abdominal pain ● Back pain ● Groin pain ● Leg pain
Past medical history	Indicate if the patient has any of the following past medical history. Choose all that apply: ● Aneurysms or dissection – Indicate location(s) and extent ● Prior aneurysm surgery ● Marfan syndrome ● Ehlers-Danlos syndrome ● Aortic surgery or endovascular repair – Indicate location(s), type, and extent of repair ● Aortitis ● Other inflammatory or infectious disorders: – Giant cell arteritis – Takayasu's arteritis – Behçet's syndrome – Infection
Family history	Indicate if the patient has any of the following family history. Choose all that apply: ● Aneurysms or dissections – Indicate location(s) ● Marfan syndrome ● Ehlers-Danlos syndrome ● Loeys-Dietz syndrome ● Other
Physical Assessment	
Abdominal Aorta	
Body habitus	Indicate the patient's body habitus. Choose 1 of the following: ● Thin ● Normal ● Obese
Aortic pulsations	Indicate the presence or absence of palpable abdominal aortic pulsations. Choose 1 of the following: ● Absent ● Present
Aortic pulsation characteristics	Indicate the characteristics of aortic pulsation. Choose 1 of the following: ● Normal ● Expansile
Aortic diameter	Estimate the diameter of AAA by palpation in inches or centimeters.
Abdominal bruit	Indicate the absence or presence of abdominal bruit. Choose 1 of the following: ● Absent ● Present
Abdominal aortic area tenderness	Indicate the absence or presence of tenderness in the abdominal aortic area. Choose 1 of the following: ● Absent ● Present
Abdominal tenderness	Indicate the absence or presence of abdominal tenderness in areas other than the abdominal aortic area. Choose 1 of the following: ● Absent ● Present
Abdominal tenderness location	Indicate location of abdominal tenderness.
Lumbar spinal tenderness	Indicate the absence or presence of lumbar spinal tenderness. Choose 1 of the following: ● Absent ● Present
Pulses	Indicate the characteristics of pulses in the following locations: ● Femoral ● Popliteal ● Dorsalis pedis ● Posterior tibial

(*Continued*)

Table 3. Continued

Element Name	Definition
	Indicate if pulses are: ● 0: Absent ● 1: Diminished ● 2: Normal ● 3: Bounding or expansile
Diagnostic Procedures: Noninvasive	
Ultrasonography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Aneurysm: type	Indicate the type of aneurysm. Choose 1 of the following: ● Fusiform ● Saccular ● Pseudoaneurysm
Aneurysm: size	Indicate the size of the aneurysm in millimeters in anteroposterior, transverse, and longitudinal dimensions.
Aneurysm: distance	Indicate the distance from the most proximal portion of the aneurysm to its most distal portion in millimeters.
Thrombus	Indicate if thrombus is present. Choose 1 of the following: ● Yes ● No
Dissection	Indicate if dissection is present. Choose 1 of the following: ● Yes ● No
Leak	Indicate if leak is present. Choose 1 of the following: ● Yes ● No
Magnetic Resonance Imaging	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Method of MRA	Indicate the method of MRA used. Choose 1 of the following: ● Contrast-enhanced MRA: White blood angiogram obtained by lowering the T1 relaxation time of blood below the surrounding tissue ● Time-of-flight MRA: White blood angiogram generated by using the in-flow effect
Contrast used	Indicate if gadolinium was used. Choose 1 of the following: ● Yes ● No
Aneurysm: location	Indicate location of the aneurysm. Choose any of the following: ● Thoracoabdominal: – Type 1 – Type 2 – Type 3 – Type 4 ● Abdominal – *Indicate the proximal extent of the aneurysm:* ○ Suprarenal ○ Juxtarenal ○ Infrarenal – *Indicate whether the distal extent of the aneurysm is the aorta or whether it involves the iliac arteries.* ○ Aorta ○ Aortoiliac – Bi-iliac – Left iliac – Right iliac
Aneurysm: type	Indicate the type of aneurysm. Choose 1 of the following: ● Fusiform ● Saccular ● Pseudoaneurysm
Aneurysm: size	Indicate the size of the aneurysm in millimeters by recording the maximum axial dimension measured from outer margin to outer margin. The axial dimension should be perpendicular to blood flow.

(*Continued*)

Table 3. Continued

Element Name	Definition
Aneurysm: distance	Indicate the distance from the most proximal portion of the aneurysm to the most distal portion in millimeters.
Thrombus	Indicate if thrombus is present. Choose 1 of the following: ● Yes ● No
Dissection	Indicate if dissection is present. Choose 1 of the following: ● Yes ● No
Leak	Indicate if leak is present. Choose 1 of the following: ● Yes ● No
Characteristics of other arteries	Indicate other arteries imaged and indicate the patency or severity of stenosis. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric femoral artery ● Right renal artery ● Left renal artery ● Right/left CIA ● Right/left external iliac artery ● Right/left common femoral artery
Computed Tomography	
CT method	Indicate method of CT. Choose 1 of the following: ● Standard ● Spiral (helical) ● Electron beam
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast used	Indicate the type of contrast used. Choose 1 of the following: ● Ionic ● Nonionic; specify: – Monomer – Dimer
Contrast volume	Indicate the volume of contrast used in milliliters.
Slice thickness	Indicate the slice thickness in millimeters.
Format: raw images	Indicate if raw images were reviewed. Choose 1 of the following: — Yes — No
Format: reconstructed images	Indicate if reconstructed images were reviewed. Choose 1 of the following: ● Yes. If yes, specify: — Shaded surface images — Maximum intensity projection ● No
Aneurysm: location	Indicate location of the aneurysm. Choose any of the following: ● Thoracoabdominal: – Type 1 – Type 2 – Type 3 – Type 4 ● Abdominal – *Indicate the proximal extent of the aneurysm:* ○ Suprarenal ○ Juxtarenal ○ Infrarenal – *Indicate whether the distal extent of the aneurysm is the aorta or whether it involves the iliac arteries:* ○ Aorta ○ Aortoiliac – Bi-iliac – Left iliac – Right iliac

(*Continued*)

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Table 3. Continued

Element Name	Definition
Aneurysm: type	Indicate the type of aneurysm. Choose 1 of the following: ● Fusiform ● Saccular ● Pseudoaneurysm
Aneurysm: size	Indicate the size of the aneurysm in millimeters by recording the maximum axial dimension from outer margin to outer margin. The axial dimension should be perpendicular to blood flow.
Aneurysm: distance	Indicate the distance from the most proximal portion of the aneurysm to the most distal portion in millimeters.
Aortic neck morphology	Indicate each of the following: ● Presence or absence of calcification ● Presence or absence of thrombus within the neck ● Degree of angulation in the neck ● Diameter of the neck ● Length of the neck from the lowest renal artery to the origin of the aneurysm
Thrombus	Indicate if thrombus is present. Choose 1 of the following: ● Yes ● No
Dissection	Indicate if dissection is present. Choose 1 of the following: ● Yes ● No
Leak	Indicate if leak is present. Choose 1 of the following: ● Yes ● No
Characteristics of other arteries	Indicate other arteries imaged and the patency or severity of stenosis. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric femoral artery ● Right renal artery ● Left renal artery ● Right/left CIA ● Right/left external iliac artery ● Right/left common femoral artery
Diagnostic Procedures: Invasive	
Catheter Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast	Indicate the contrast used. Specify the following: ● Type ● Amount in milliliters
Fluoroscopy time	Indicate the total fluoroscopy time recorded to the nearest 0.10 min. Time recorded should include the total time for the procedure.
Aneurysm: location	Indicate the location of the aneurysm. Choose any of the following: ● Thoracoabdominal: – Type 1 – Type 2 – Type 3 – Type 4 ● Abdominal – *Indicate the proximal extent of the aneurysm:* ○ Suprarenal ○ Juxtarenal ○ Infrarenal – *Indicate whether distal extent of aneurysm is the aorta or whether it involves the iliac arteries:* ○ Aorta ○ Aorto-iliac – Bi-iliac – Left iliac – Right iliac

(*Continued*)

Table 3. Continued

Element Name	Definition
Aneurysm: type	Indicate type of aneurysm. Choose 1 of the following: ● Fusiform ● Saccular ● Pseudoaneurysm
Aneurysm: size	Indicate the size of aneurysm in millimeters by recording the maximum axial dimension measured from outer margin to outer margin. The axial dimension should be perpendicular to blood flow.
Aneurysm: distance	Indicate the distance from the most proximal portion of the aneurysm to the most distal portion in millimeters.
Thrombus	Indicate if thrombus is present. Choose 1 of the following: ● Yes ● No
Dissection	Indicate if dissection is present. Choose 1 of the following: ● Yes ● No
Leak	Indicate if leak is present. Choose 1 of the following: ● Yes ● No
Characteristics of other arteries	Indicate other arteries imaged and the patency or severity of stenosis. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric femoral artery ● Right renal artery ● Left renal artery ● Right/left CIA ● Right/left external iliac artery ● Right/left internal iliac artery ● Right/left common femoral artery
Treatment: *Invasive Therapeutic Procedures*	
Open AAA Repair	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator name	Last name, first, middle
Extent of aneurysm	Indicate the extent of aneurysm in the following areas: ● Thoracoabdominal: – Type 1 – Type 2 – Type 3 – Type 4 ● Associated dissection – Yes – No Infrarenal: ● Aorta ● Aortoiliac – Bi-iliac – Left iliac – Right iliac
Clamping site: proximal	Specify the proximal clamping site (or proximal control). This may include the following: Thoracoabdominal: ● Above the mesenteric arteries ● Descending thoracic aorta ● Hypothermic circulatory arrest (no clamp) ● Distal to left subclavian artery ● Proximal to left subclavian artery Infrarenal: ● Infrarenal ● Supraceliac ● Suprarenal

(*Continued*)

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Table 3. Continued

Element Name	Definition
Clamp time	Indicate the following: ● Proximal time ● Time to restoration of visceral flow ● Total clamp time
Clamping site: distal	Specify the distal clamping site. This may include the following: Thoracic: ● Clamp site ● Segmental clamping – Yes – No Infrarenal: ● Aorta ● CIA ● EIA and IIA
Neuroprotection technique (thoracoabdominal)	Indicate neuroprotection techniques used. Choose all that apply: ● Clamp and sew (no protection) ● Preoperative imaging of spinal perfusion ● Retrograde perfusion – Atrial-femoral bypass – Axillo-femoral bypass – Femoro-femoral bypass – Shunt – Others: specify ● Neurologic monitoring ● CSF drainage ● Systemic cooling ● Epidural cooling ● Reimplantation of intercostal arteries – Specify how many
Graft	Indicate type of graft used for procedure. Choose 1 of the following: ● Polyester woven ● Polyester knitted ● PTFE Infrarenal: ● Tube graft ● Bifurcated graft ● Site of distal anastomoses (iliac or femoral arteries)
Management of visceral segment for thoracoabdominal	Indicate how visceral segment was managed. Choose 1 of the following: ● Visceral patch, including celiac artery, SMA, right renal artery, and left renal artery. ● Visceral patch, including celiac artery, SMA, and right renal artery with left renal artery either bypassed or implanted into aortic graft separately ● Individual bypasses to visceral and renal arteries. ● Indicate if visceral organ protection was used – If so, specify type (perfusion, cold infusion)
Management of inferior mesenteric artery	Indicate how inferior mesenteric artery was managed. Choose 1 of the following: ● Chronically occluded ● Oversewn ● Reimplanted
Intraoperative Details for Open AAA Repair	
Additional procedures	Indicate other procedures performed. Choose all that apply: ● Renal artery bypass/endarterectomy ● Visceral artery procedure (specify) ● Other (specify)
Intraoperative complications	Indicate if there were any intraoperative complications. Choose 1 of the following: ● Yes (specify) ● No

(*Continued*)

Table 3. Continued

Element Name	Definition
Endovascular AAA Repair	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator name	Last name, first, middle
Aortic and iliac diameters and lengths	Indicate aortic and iliac diameters and lengths ● Aortic diameter at lowest renal artery ● Aortic diameter 1.5 cm below lowest renal artery ● Aortic diameter at terminal aorta ● Maximum diameter of right CIA ● Maximum diameter of left CIA ● Minimum diameter of right EIA ● Minimum diameter of left EIA ● Length of aorta from lowest renal artery to aortic bifurcation ● Length from aortic bifurcation to right IIA ● Length from aortic bifurcation to left IIA
Graft	Indicate type of graft used. Choose 1 of the following: ● Fixation – Infrarenal – Suprarenal ● Unibody ● Bifurcated – 1 docking limb – 2 docking limbs
Hypogastric arteries excluded	Indicate number of hypogastric arteries excluded. Choose 1 of the following: ● 0 ● 1 ● 2
Management of inferior mesenteric artery	Indicate how inferior mesenteric artery was managed. Choose 1 of the following: ● Chronically occluded/covered ● Coil occluded
Extension used	Indicate extension used. Choose 1 of the following: ● Distal – Number and size placed – Landing zone ○ CIA ○ EIA ● Proximal – Number and size placed
Adjunctive procedures	Indicate the adjunctive procedures used. Choose 1 of the following: ● Adjunctive angioplasty or stent required. Specify the following: – Side: indicate left or right – Location: CIA, IIA, EIA – Indication ● Conduit used for insertion of endograft. Specify the following: – Side: indicate left or right – Size and type of graft material of conduit – Indication ● Accessory renal artery management. Specify the following: – Side: indicate left or right – Site of artery – Size of artery – Treatment: ○ Embolization ○ Coverage ● Iliac embolization. Specify the following: – Side: indicate left or right – Size: balloon or stent – Indication
Endograft configuration	Indicate the configuration of the endograft: ● Aorto–bi-iliac ● Aorto–uni-iliac graft with femoral artery to femoral artery bypass and iliac artery occlusion

(*Continued*)

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Table 3. Continued

Element Name	Definition
Aortic neck morphology	Indicate each of the following: ● Presence or absence of calcification ● Presence or absence of thrombus within neck ● Degree of angulation in the neck. Specify C-arm correction angle in degrees. ● Diameter of the neck ● Length of the neck from the lowest renal artery to the origin of the aneurysm
Intraoperative Details for Endovascular AAA Repair	
Endoleak present	Indicate the type of endoleak present at the end of the case. Choose 1 of the following: ● Type I ● Type II ● Type III ● Type IV ● Undetermined
Limb kinking	If present, specify the following: ● Site ● Size ● How it was resolved
Patency of arteries	Indicate the patency of the arteries. Specify the following: ● Right/left renal arteries: – Number ● Right/left accessory renal arteries – Number ● Right/left common/external iliac arteries
Intraoperative complications	Indicate if there were any intraoperative complications. Choose 1 of the following: ● Yes. If yes, choose all that apply: – Arterial injury ○ Indicate right or left side ○ Indicate artery injured – Embolization ○ Indicate site – Inadvertent covering of artery ○ Indicate site ● No
Invasive Therapeutic Procedures: Other Operative Details	
Estimated blood loss	Indicate the total amount of blood loss in milliliters.
Transfused blood products	Indicate the blood products transfused to the patient. Choose all that apply: ● Auto transfused blood (specify volume) ● Packed RBCs ● Fresh frozen plasma ● Platelets ● Other (specify)
Operative time	Indicate the total time of procedure in hours:minutes.
Invasive Therapeutic Procedures: Postprocedure Details	
Time to extubation	Indicate when the patient was extubated post procedure. Choose 1 of the following: ● Immediate ● Postoperative day (specify day number)
Oral intake	Indicate the day of oral intake.
Length of stay in ICU	Indicate the length of stay in the ICU. Specify the number of days or indicate not applicable.
Length of stay in step-down unit	Indicate the length of stay in a step-down unit. Specify the number of days or indicate not applicable.
Postoperative complications	Indicate postoperative complications. Choose all that apply: ● Bleeding ● Cardiac ● Infections ● Pulmonary

(*Continued*)

Table 3. Continued

Element Name	Definition
	• Renal • Neurological • Reoperation • Other (specify)
Total length of stay	Indicate total length of stay in the hospital in number of days.
Discharge status (21)	Indicate the patient's discharge status. Choose 1 of the following: • Discharged to home or self-care: – This includes discharge to home; jail or law enforcement; home on oxygen if DME only; any other DME only; group home, foster care, and other residential care arrangements; outpatient programs such as partial hospitalization or outpatient chemical dependency programs; assisted living facilities that are not state designated. • Discharged/transferred to short-term general hospital for inpatient care • Discharged/transferred to SNF with Medicare certification in anticipation of skilled care • Discharged/transferred to ICF • Discharged/transferred to standard rehabilitation facility • Discharged/transferred to ventilator rehabilitation facility • Discharged/transferred to another type of healthcare institution other than the above • Patient died
Patient Education/Counseling	
Medication instruction	Verbal and written medication instructions provided to patient and/or family
Recognition of new or worsening symptoms	Verbal and written instructions provided to patient and/or family (by physician or nurse) about new or worsening symptoms and when to call the physician
Diet counseling	Advice given or discussion held with patient and/or family about the importance of diet in relation to lowering cardiovascular risk. May include • Sodium restriction • Fluid restriction • Referral to dietitian for weight management and/or advanced nutritional instruction • Other (specify)
Smoking cessation counseling	Advice given or discussion held with patient (by physician, nurse, or other personnel) about the importance of stopping smoking. May include • Counseling (may be basic or advanced) • Written materials • Referral to smoking cessation program • Drugs to help with smoking cessation
Activity counseling	Advice given or discussion held with patient and/or family about activity level and restrictions in activity and/or exercise recommendations
Follow-Up	
Open repair	Documentation of follow-up evaluation of patient 2 to 4 wk after discharge should include • Physical examination • Duplex ultrasound to check integrity of repair CT scan of chest, abdomen, and pelvis should be considered within 5 y to evaluate for synchronous aneurysms.
Endovascular/hybrid approach	Documentation of follow-up evaluation of patient 4 wk after discharge should include • Physical examination • CT scan of abdomen and pelvis • Plain film of abdomen to access stent integrity and migration
Outcomes of Open AAA and Endovascular Repair	
Time point	Indicate the period at which outcome measures are assessed. Choose all that apply: • Periprocedure (24 h) • Procedure related (30 d) • 3 mo • 6 mo • 1 y • Other
Serious adverse event	Indicate major clinical complications arising from management or treatment of the disease. • Yes – Specify serious adverse event from complication list below. • No

(*Continued*)

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Table 3. Continued

Element Name	Definition
Complications of endovascular repair	Indicate postoperative clinical events or conditions associated with endovascular procedure. Choose all that apply: ● Major complication – Death – MI (also see cardiovascular complications below): ○ Prolonged hospitalization ○ Loss of limb or function of organ system ○ Persistent or significant disability or incapacity ○ Dissection ○ Pseudoaneurysm ○ Vessel thrombosis ○ Vessel rupture – Stroke ○ Cerebral ○ Spinal cord stroke – Other life-threatening major complication (specify) ○ Seroma ○ Hematoma ○ Mesenteric ischemia ○ Renal failure ○ Pneumonia ○ Atheromatous embolization ○ DVT ○ Contrast nephropathy ○ Contrast hypersensitivity ○ Infection ○ Requirement for intervention to prevent permanent impairment/damage ○ Postimplant syndrome ● Minor complication (specify)
Complications of open repair	Indicate complications of open surgery. Choose all that apply: ● Major complication – Death – MI (also see cardiovascular complications below): ○ Prolonged hospitalization ○ Loss of limb or function of organ system ○ Persistent or significant disability or incapacity ○ Dissection ○ Pseudoaneurysm ○ Vessel thrombosis ○ Vessel rupture – Stroke ○ Cerebral ○ Spinal cord stroke – Other life-threatening major complication (specify) ○ Seroma ○ Hematoma ○ Mesenteric ischemia ○ Renal failure ○ Pneumonia ○ Atheromatous embolization ○ DVT ○ Contrast nephropathy ○ Contrast hypersensitivity ○ Infection ○ Requirement for intervention to prevent permanent impairment/damage ○ Postimplant syndrome ● Minor complication (specify)
Clinical Outcomes	
Time point	Indicate period at which outcome measures are assessed. Choose all that apply: ● 1 mo ● 3 mo ● 6 mo ● 1 y

(*Continued*)

Table 3. Continued

Element Name	Definition
Graft or Endograft-Related Outcomes	
Graft or endograft-related outcomes	• Patency – Primary – Assisted – Secondary • Ischemic rest pain • Ischemic tissue loss • Amputation
Cardiovascular Outcomes	
Cardiovascular outcomes	New cardiovascular ischemic event • Angina • MI • Coronary artery revascularization • CHF • TIA • Ischemic stroke • Hemorrhagic stroke • Stroke (unknown if ischemic or hemorrhagic) • Death
Outcomes Assessment	
Noninvasive assessment of outcome	• Pulse examination • ABI
Long-Term Outcomes of Open AAA Repair and Endovascular AAA Repair	
Open AAA repair: long-term outcomes	• Infection • Aortoenteric fistulae • Second aneurysm formation (remote from open AAA repair) • Paragraft aneurysm formation (close or near old aneurysm repair) • Need for secondary procedure
Endovascular AAA repair: long-term outcomes	• Infection • Aortoenteric fistulae • Secondary aneurysm formation (remote from open AAA repair) • Paragraft aneurysm formation (close or near old aneurysm repair) • Endoleak • Need for secondary procedure

AAA indicates abdominal aortic aneurysm; ABI, ankle brachial index; CHF, congestive heart failure; CIA, common iliac artery; CSF, cerebrospinal fluid; CT, computed tomography; DME, durable medical equipment; DVT, deep venous thrombosis; EIA, external iliac artery; ICF, intermediate care facility; ICU, intensive care unit; IIA, internal iliac artery; MI, myocardial infarction; MRA, magnetic resonance angiography; PTFE, polytetrafluoroethylene; RBC, red blood cell; SMA, superior mesenteric artery; SNF, skilled nursing facility; and TIA, transient ischemic attack.

ity of limb ischemia. The table includes data elements used in physiologic diagnostic tests, such as the ankle brachial index, treadmill exercise test, limb segmental pressure measurements, and pulse volume recordings. It also provides detailed elements of imaging tests, including duplex ultrasonography, magnetic resonance angiography, computed tomographic angiography, and catheter-based radiocontrast angiography, such as the artery imaged and the location and severity of stenoses. Data elements relevant to treatment include pharmacotherapy and exercise rehabilitation for claudication. Table 2 also includes detailed data elements for both endovascular and open surgical revascularization such as the target vessel, the specific procedure, outcomes, and complications.

3.3. AAA Table of Data Elements

Table 3 provides a list and definition of data elements relevant to AAAs. Atherosclerosis is associated with the degenerative changes found in the aortic wall of AAA, though it is not necessarily causal. For this reason, it is included in this document as a PAVD, although there are other much less common causes of AAA, such as aortitis, infection, aortic dissection, and inherited disorders of connective tissue. The data elements defined in Table 3 enable documentation of symptoms, relevant medical history, and the physical assessment of AAA. The table comprises detailed elements of diagnostic imaging tests, including ultrasonography, magnetic resonance imaging, and computed tomography, such as aneurysm type, size, location, and other characteristics. Additional elements relate to endovascular and open surgical repair and include details of the procedures, outcomes, and complications.

3.4. Renal and Mesenteric Artery Disease Table of Data Elements

In the context of this document, renal artery disease is defined as atherosclerotic disease that causes stenosis or occlusion of arteries supplying the kidneys (2). Other causes of renal

Table 4. Renal Artery Disease Elements and Definitions

Element Name	Definition
History	
Hypertension suggestive of renal artery disease	• New-onset hypertension in those <30 or >55 y of age • Accelerated hypertension • Refractory hypertension • Hypertension and concomitant atherosclerotic disease in other vascular territories • Hypertension urgency/emergency
History of acute renal insufficiency	History of reduced renal function for <3 mo (see "chronic kidney disease" element). Year of occurrence of and precipitant for acute renal insufficiency (e.g., following treatment with angiotensin-converting enzyme inhibitor or angiotensin receptor blocker) may be specified.
Chronic kidney disease	Current or previous history of chronic kidney disease. Chronic kidney disease is defined as either kidney damage or GFR > 60 mL/min/1.73 m^2 for ≥3 mo. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies. Indicate the patient's stage of disease: • Stage 0: No known kidney disease • Stage 1: Kidney damage with normal or high GFR: ≥90 mL/min/1.73 m^2 • Stage 2: Kidney damage with mildly decreased GFR: 60–89 mL/min/1.73 m^2 • Stage 3: Moderately decreased GFR: 30–59 mL/min/1.73 m^2 • Stage 4: Severely decreased GFR: 15–29 mL/min/1.73 m^2 • Stage 5: Kidney failure: GFR <15 mL/min/1.73 m^2 or on dialysis *Note:* GFR may be estimated using the serum creatinine MDRD formula: eGFR=186 (serum creatinine)$^{-1.154}$ (age)$^{-0.203}$ (0.742 [if female]) (1.210 [if black]) Year of onset (first diagnosis) may be helpful.
Cause of chronic kidney disease (if present)	• Glomerular disease • Tubular/interstitial disease • Obstructive uropathy • Polycystic kidney disease • Other (specify) • Unknown
Other kidney disorder	• Single kidney • Cancer • Nephrectomy • Past trauma • Other
Recurrent "flash" pulmonary edema without coronary ischemia/left ventricular dysfunction	Episodes of heart failure or pulmonary edema in the absence of a clear-cut cardiac cause such as • Active coronary ischemia • Systolic dysfunction on echocardiography
Other cardiovascular disease related to renal artery disease	Coronary artery disease, PAD, carotid artery disease, AAA
Noninvasive Diagnostic Procedures	
Duplex Ultrasound	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Artery imaged	Indicate artery imaged: • Right renal artery • Left renal artery
Peak systolic velocity	• Aorta • Proximal, mid-, distal right renal artery • Proximal, mid-, distal left renal artery
Ratio of renal to aortic peak systolic velocities	Record ratio for right and left renal arteries.
	Specify for right and left renal arteries. Choose 1 of the following (31): • 0%–59% • 60%–99% • Occluded
Location of stenosis	Indicate side (right or left) and location of stenosis. Choose all that apply: • Proximal • Mid • Distal
Kidney size	Indicate maximum pole-to-pole renal length in centimeters.

(*Continued*)

Table 4. Continued

Element Name	Definition
Resistive index	(peak systolic velocity−end diastolic velocity)/peak systolic velocity • Specify for right and left kidney
Assessment of aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Magnetic Resonance Angiography	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Contrast use	Indicate if gadolinium was used. Choose 1 of the following: • Yes • No
Location of stenosis	Indicate side (right or left) and location of stenosis. Choose all that apply: • Proximal • Mid • Distal
Location of stenosis: specific location in renal artery	Indicate side (right or left) and location of stenosis. Choose all that apply: • Main renal artery ostium • Main renal artery postostium (>1 cm from ostium) • Segmental renal artery • Intrarenal renal artery
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Kidney size	Indicate the maximum pole-to-pole renal length in centimeters.
Symmetry of renal perfusion	Consistency and equality of renal blood flow in both kidneys
Symmetry of renal excretion	Symmetry of rate of excretion of contrast agent from kidney
Renal artery morphology	• FMD • Atherosclerosis
Computed Tomographic Angiography	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Contrast used	Indicate the type of contrast used. Choose 1 of the following: • Ionic contrast • Nonionic contrast; specify: – Monomer – Dimer
Contrast volume	Indicate the volume of contrast used in milliliters.
Location of stenosis: specific location in renal artery	Indicate the side (right or left) and location of stenosis. Choose all that apply: • Main renal artery ostium • Main renal artery postostium (>1 cm from ostium) • Segmental renal artery • Intrarenal renal artery
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Kidney size	Indicate the maximum longitudinal renal length in centimeters.
Symmetry of renal perfusion	Consistency and equality of renal blood flow in both kidneys
Symmetry of renal excretion	Symmetry of rate of excretion of contrast agent from kidney
Renal artery morphology	• FMD • Atherosclerosis
Captopril Renography	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Operator	Last name, first, middle
Symmetry	Indicate whether there is equal uptake and excretion of radiotracer within kidneys.
Renogram curve	Absolute time-activity curves pre- and postcaptopril, including peak and time to half-activity after peak The time activity curve consists of the • Vascular phase • Secretory or functional phase • Excretory phase

(*Continued*)

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Table 4. Continued

Element Name	Definition
Invasive Diagnostic Procedure	
Catheter-Based Angiography	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Operator name	Last name, first, middle
Vascular access site	Specify the vascular access site.
Contrast agent	Indicate the contrast agent used: ● Iodinated – Ionic – Nonionic ○ Monomer ○ Dimer • Noniodinated (CO_2)
Contrast volume	Specify contrast volume given.
Fluoroscopy time	Indicate the total fluoroscopy time recorded during the procedure to the nearest 0.10 min.
Catheter position	● Selective ● Nonselective
Renal perfusion	Were all renal arteries identified (i.e., are there unexplained perfusion defects in the nephrogram phase)?
Location of stenosis: specific location in renal artery	Indicate the side (right or left) and location of stenosis. Choose all that apply: ● Main renal artery ostium ● Main renal artery postostium (>1 cm from ostium) ● Segmental renal artery ● Intrarenal renal artery
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Kidney size	Maximum longitudinal renal length in centimeters
Symmetry of renal perfusion	Assess the consistency and equality of renal blood flow in both kidneys.
Renal artery morphology	● FMD ● Atherosclerosis
Complications	Indicate complications related to the diagnostic procedure. If a concurrent endovascular procedure is performed, report under endovascular complications. Choose all that apply: ● Pseudoaneurysm ● AV fistula ● Hematoma ● Dissection ● Vessel thrombosis ● Vessel perforation ● Atheromatous embolization ● Contrast nephropathy ● Contrast hypersensitivity ● Requirement of intervention to prevent permanent impairment/damage ● None
Medical Therapies	
Antihypertensive therapy	Indicate name, dose, frequency of specific antihypertensive agent(s) used; address the use of angiotensin-converting enzyme inhibitors/angiotensin II receptor antagonists.
Antilipidemic therapy	Indicate the name, dose, and frequency of specific lipid-lowering agent(s) used.
Antiplatelet therapy	Indicate the name, dose, and frequency of specific antiplatelet agent(s) used.
Invasive Therapeutic Procedures	
Renal Artery Angioplasty/Stenting	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator	Last name, first, middle
Angioplasty/stenting	Choose 1 of the following: ● Balloon angioplasty alone ● Stent
Balloon length	Indicate the length of the balloon used in millimeters.
Nominal balloon diameter	Indicate the diameter of the balloon at initial inflation and final inflation in millimeters.
Target renal artery	Indicate whether the target vessel for the procedure is the right or left renal artery.

(*Continued*)

Table 4. Continued

Element Name	Definition
Current procedure part of clinical trial	Indicate whether the procedure is part of a clinical trial. Choose one: • Yes If yes, indicate the trial type: — IDE — Postmarket approval — Other (specify) • No
Anesthesia	Indicate if the patient received general anesthesia, conscious sedation, local anesthesia, or no anesthesia during the current procedure.
Procedure Indications and Anatomic Variables	
Clinical indications	• Hypertension • Renal insufficiency • CHF/pulmonary edema • Angina pectoris
Restenosis in target vessel after prior renal stent	Note if the indication for the current procedure is restenosis in the target renal artery that was previously treated with angioplasty and/or a stent. • *Renal artery restenosis is defined as >50% diameter stenosis at or adjacent to the site previously treated with balloon angioplasty or a stent.*
Contrast volume	Indicate the volume of iodinated contrast injected during the procedure in milliliters.
Fluoroscopy time	Indicate the total fluoroscopy time recorded during the procedure to the nearest 0.10 min. The time recorded should include the total time for the procedure.
Contralateral renal artery occlusion	Indicate if there is known 100% occlusion of the patient's contralateral renal artery.
Spontaneous aortic or renal artery dissection	Indicate if the patient has had a spontaneous renal artery dissection before the current procedure.
Procedure arterial access site	Indicate the primary arterial access site used to perform the renal artery stenting procedure. Note the location (right/left): • Femoral • Brachial • Radial • Axillary
Arterial access closure method	• List methods and devices in chronological order of closure. • Indicate the method used to achieve hemostasis: – Device – Nondevice (such as manual compression)
Lesions	
Target lesion location	List the following: • Ostial • Proximal • Mid • Distal • Intrarenal
Visible thrombus present	Indicate if the target lesion contains thrombus as assessed by baseline angiography and implied by the presence of filling defect.
Calcification	Indicate if calcification is present. If present, specify the location. Choose 1 of the following: • None • Mild • Moderate • Severe
Lesion length	Indicate the length of the target lesion in millimeters as assessed by baseline angiography.
Minimal luminal diameter	Indicate the MLD of the target lesion in millimeters as assessed by baseline angiography. *Minimal luminal diameter is defined as the minimum luminal diameter derived from the angiographic view that shows the tightest point of the stenosis.*
Diameter of distal renal artery	Indicate the diameter of the nontapering distal segment of the renal artery measured at the intended landing zone of the distal edge of the stent.
Preprocedure percent stenosis of renal artery	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment

(*Continued*)

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Table 4. Continued

Element Name	Definition
Lesion treatment incomplete or aborted	Indicate if the lesion treatment was incomplete or aborted. Choose 1 of the following: ● Yes – If yes, note the reasons: ○ Failure to gain vascular access ○ Failure to engage ostium with guide catheter ○ Unable to cross with guidewire ○ Unable to deploy stent ○ Failure to confirm significant stenosis ○ Unable to cross balloon ○ Cardiac ischemia ○ Unable to deploy device ○ Hypotension ○ Hypertension ○ Unable to deliver stent ○ Other ● No
Embolic protection attempted	Indicate if the operator tried to use an EPD. Choose 1 of the following: ● Yes – If yes, indicate if predilatation before the balloon or stent was performed or not. – If yes, list EPD in chronological order. Note if successfully deployed. ● No
Stent malposition	Indicate if the stent was deployed in a location or position other than that for which it was intended.
Final MLD	Indicate the final residual lumen diameter in millimeters.
Final percent stenosis of renal artery	Indicate the percent stenosis post procedure by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Device	
Number of stents used (per artery)	● 1 ● >1
Stent type	Indicate the type of stent used. Choose all that apply: ● Balloon expandable ● Self-expanding ● Drug eluting ● Covered
Stent brand name	Indicate the brand name of the stent used.
Stent model	Indicate the model number of the stent used.
Stent manufacturer	Indicate the manufacturer of the stent used.
Stent length	Indicate the length of the stent used in millimeters.
Stent diameter	Indicate the diameter of the stent used in millimeters.
Renal Artery Surgical Revascularization	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Indications for the procedure	Consider indications for renal artery revascularization. Choose all that apply: ● Clinical indications – Hypertension – Renal insufficiency – CHF/pulmonary edema – Angina pectoris ● Surgery-specific indications – Repetitive failure of renal artery angioplasty/stent – Need for aortic surgery (i.e., AAA repair)
Surgical procedures	Indicate the surgical revascularization procedure: ● Renal artery endarterectomy ● Aortorenal bypass with either saphenous vein or synthetic material ● Extra-anatomic bypass: hepatorenal, splenorenal, ileorenal
Outcomes of Endovascular/ Open Surgical Procedures	
Time points	Indicate the period at which outcome measures are assessed. Choose all that apply: ● Periprocedure (24 h) ● Procedure related (30 d) ● 3 mo

(*Continued*)

Table 4. Continued

Element Name	Definition
	• 6 mo • 1 y
Complications of endovascular procedure	Indicate postoperative clinical events or conditions associated with the endovascular procedure. Choose all that apply: • Pseudoaneurysm • AV fistula • Hematoma • Dissection • Vessel thrombosis • Vessel perforation • Atheromatous embolization • Contrast nephropathy • Contrast hypersensitivity • Requirement of intervention to prevent permanent impairment/damage • Other (specify) • None
Complications of open surgery	Indicate complications of open surgery. Choose all that apply: • Major complication – Death – MI (also see cardiovascular complications below): ○ Prolonged hospitalization ○ Loss of limb or function of organ system ○ Persistent or significant disability or incapacity ○ Vessel thrombosis ○ Vessel rupture – Stroke ○ Cerebral ○ Spinal cord stroke – Other life-threatening major complication (specify) ○ Seroma ○ Hematoma ○ Mesenteric ischemia ○ Renal failure ○ Pneumonia ○ Atheromatous embolization ○ DVT ○ Graft thrombosis ○ Atheromatous embolization ○ Contrast nephropathy ○ Contrast hypersensitivity ○ Infection ○ Requirement for intervention to prevent permanent impairment/damage – Minor complication (specify)
Total length of stay	Indicate the length of stay in the hospital in number of days.
Discharge status	Indicate the patient's discharge status. Choose 1 of the following: • Discharged to home or self-care – This includes discharge to home; jail or law enforcement; home on oxygen if DME only; any other DME only; group home, foster care, and other residential care arrangements; outpatient programs such as partial hospitalization or outpatient chemical dependency programs; assisted living facilities that are not state designated. • Discharged/transferred to short-term general hospital for inpatient care • Discharged/transferred to SNF with Medicare certification in anticipation of skilled care • Discharged/transferred to ICF • Discharged/transferred to standard rehabilitation facility • Discharged/transferred to ventilator rehabilitation facility • Discharged/transferred to another type of healthcare institution other than the above • Patient died
Patient Education/Counseling	
Medication instruction	Verbal and written medication instructions provided to patient and/or family
Recognition of new or worsening symptoms	Verbal and written instructions provided to patient and/or family (by physician or nurse) regarding new or worsening symptoms and when to call the physician

(*Continued*)

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Table 4. Continued

Element Name	Definition
Diet counseling	Advice given or discussion held with the patient and/or family about diet counseling in relation to lowering cardiovascular risk. May include ● Sodium restriction ● Fluid restriction ● Referral to dietitian for weight management and/or advanced nutritional instruction ● Other (specify)
Smoking cessation counseling	Advice given or discussion held with patient (by physician, nurse, or other personnel) about the importance of stopping smoking. May include ● Counseling (may be basic or advanced) ● Written materials ● Referral to smoking cessation program ● Drugs to help with smoking cessation
Activity counseling	Advice given or discussion held with patient and/or family about activity level and restrictions in activity and/or exercise recommendations
Follow-Up	
Open repair	Documentation of evaluation of the patient after discharge. Indicate all of the following that apply: ● Physical examination ● Imaging (e.g., ultrasound, MR, CT)
Endovascular	Documentation of evaluation of the patient after discharge. Indicate all of the following that apply: ● Physical examination ● Imaging (e.g., ultrasound, MR, CT)
Clinical Outcomes	
Time points	Indicate the period at which outcome measures are assessed. Choose all that apply: ● 1 mo ● 3 mo ● 6 mo ● 1 y
Blood pressure	● Indicate systolic and diastolic blood pressure ● Categories of blood pressure – Reduction in systolic blood pressure by 20 mm Hg – Reduction in diastolic blood pressure by 10 mm Hg – Normotensive versus hypertensive ● Indicate changes in the number of antihypertensive medications (specify medications)
Renal function	Monitor creatinine and estimated/calculated GFR: ● Improvement: Change of at least 1 stage for the better (e.g., going from stage 3 to stage 2) ● Stable: No change in stage ● Decline: Change for the worse of at least 1 stage (e.g., going from stage 3 to stage 4)
Morbidity/mortality	● MI ● CHF ● Stroke ● Other adverse cardiovascular event ● Hospitalization/prolonged hospitalization ● Loss of function of organ system ● Persistent or significant disability or incapacity ● Death (indicate causes)

AAA indicates abdominal aortic aneurysm; AV, atrioventricular; CHF, congestive heart failure; CT, computed tomography; DME, durable medical equipment; DVT, deep venous thrombosis; eGFR, estimated glomerular filtration rate; EPD, embolic protection device; FMD, fibromuscular dysplasia; GFR, glomerular filtration rate; ICF, intermediate care facility; IDE, investigational device exemption; MDRD, modification of diet in renal disease; MI, myocardial infarction; MLD, minimal luminal diameter; MR, magnetic resonance; PAD, peripheral artery disease; and SNF, skilled nursing facility.

artery disease include thrombosis, embolism, and fibromuscular dysplasia. Mesenteric artery disease refers to atherosclerotic stenosis or occlusion of the celiac trunk, superior mesenteric artery, and/or inferior mesenteric artery. Other causes include thrombosis, embolism, vasculitis, and extrinsic compression. The data elements defined in Table 4 include symptoms and clinical findings that occur in patients with renal artery disease. Table 4 also provides detailed elements of renal imaging tests, including duplex ultrasonography, magnetic resonance angiography, computed tomographic angiography, and catheter-based angiography, In addition, there are detailed data elements for renal artery angioplasty and stenting, including specific elements concerning the procedure, target lesion location, results and complications, and similarly for surgical revascularization of renal artery stenoses. In addition, data elements are defined for clinical outcomes following medical and revascularization therapy. The data elements defined in Table 5 include symptoms and clinical findings that occur in patients with mesenteric artery disease. Table 5 also provides detailed elements of mesenteric

Table 5. Chronic Mesenteric Artery Disease Elements and Definitions

Element Name	Definition
History	
Risk Factors	
Atherosclerosis	Known atherosclerosis in any vascular territory
Patient Assessment: Symptoms	
Indicate if any of the symptoms listed below are present	
Symptoms suggestive of mesenteric ischemia	• Abdominal fullness, bloating, discomfort after eating that ultimately results in "fear of food" • Weight loss, anorexia, failure to thrive • All associated with presence of atherosclerosis in other vascular beds or the presence of cardiac dysrhythmia (i.e., atrial fibrillation) or severe left ventricular dysfunction
Postprandial abdominal pain	Pain, bloating, early satiety following ingestion of food and/or liquids
Fear of eating	Avoidance of eating because of predictable abdominal pain, often resulting in more frequent eating of small amounts of food
Weight loss	Specify amount of weight loss in pounds or kilograms.
Malnutrition	The patient manifests malnutrition because of inadequate caloric intake to meet metabolic demands, as well as dehydration.
Malabsorption/steatorrhea	• Diarrhea • Oily stool • Floating stool
Physical Examination	
Complete Abdominal Examination	
Body habitus	Describe the patient's body habitus. Choose one of the following: • Thin • Normal • Obese
Aortic diameter	Estimate abdominal aortic diameter by palpation in inches or centimeters.
Abdominal bruit	Indicate the absence or presence of abdominal bruit. Choose 1 of the following: • Absent • Present
Rectal Exam	
Digital rectal examination	Examine the lower rectum to check for abnormalities in the rectum and stool (hemoccult).
Stool testing for occult blood	Occult blood present or absent?
Laboratory Testing	
Amylase, lipase	Indicate the following: • Date of test • Value • Unit of measurement • Normal range
Stool fat content	• Microscopic: Indicate the number of stainable lipid globules per high-powered microscope field. • Gravimetric: Indicate the collection period (number of days), reference range, and test result in grams of lipid per 24 h. • Titrimetric
Fecal occult blood	Occult blood present or absent?
Noninvasive Diagnostic Procedures	
Mesenteric Artery Duplex Ultrasound	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Operator	Last name, first, middle
Peak systolic velocity measurements	• Aorta • Celiac artery • Superior mesenteric artery • Inferior mesenteric artery
Ratio of mesenteric artery to aorta peak systolic velocities	Record ratio for celiac, superior mesenteric, and inferior mesenteric arteries.
Location of stenosis	Indicate the location of the stenosis. Choose all that apply: • Celiac artery • Superior mesenteric artery • Inferior mesenteric artery

(*Continued*)

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Table 5. Continued

Element Name	Definition
Category of stenosis	Specify for celiac, superior mesenteric, and inferior mesenteric arteries. Choose 1 of the following: ● 0–69% ● 70%–99% ● Occlusion
Computed Tomographic Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast used	Indicate the type of contrast used. Choose 1 of the following: ● Ionic contrast ● Nonionic contrast; specify: – Monomer – Dimer
Contrast volume	Indicate volume of contrast used in milliliters.
Artery imaged	Indicate artery imaged. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric artery
Location of stenosis	Indicate the location of the stenosis.
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aneurysm	Dilation of a mesenteric artery to a diameter ≥1.5 times the nondilated diameter
Small and large bowel	Indicate if there is thickening of the small or large bowel wall. Choose 1 of the following: ● Yes ● No
Free air in the abdomen	Indicate the presence of free air in the abdomen. Choose 1 of the following: ● Yes ● No
Mesenteric venous thrombosis	Patent venous opacification of the superior mesenteric vein and portal vein
Pneumatosis coli	Indicate the presence of pneumatosis coli: ● Yes ● No
Magnetic Resonance Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Contrast use	Indicate if gadolinium was used. Choose 1 of the following: ● Yes ● No
Artery imaged	Indicate the artery imaged. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric artery
Location of stenosis	Indicate the location of the stenosis.
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Small and large bowel	Indicate if there is thickening of the small or large bowel wall. Choose 1 of the following: ● Yes ● No
Free air in the abdomen	Indicate the presence of free air in the abdomen. Choose 1 of the following: ● Yes ● No
Mesenteric venous thrombosis	Patent venous opacification of the superior mesenteric vein and portal vein
Pneumatosis coli	Indicate the presence of pneumatosis coli: ● Yes ● No
Diagnostic Procedure: Invasive	
Catheter-Based Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator	Last name, first, middle

(*Continued*)

Table 5. Continued

Element Name	Definition
Artery imaged	Indicate the artery imaged. Choose all that apply: ● Celiac artery ● Superior mesenteric artery ● Inferior mesenteric artery
Artery stenosis	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Aorta	Identify atherosclerosis, stenosis, occlusion, and/or aneurysm of the abdominal aorta.
Diffuse vasospasm	Indicate the presence or absence of vasospasm consistent with nonocclusive mesenteric ischemia.
Mesenteric venous thrombosis	Indicate whether the superior mesenteric vein and portal vein are patent or occluded by thrombus.
Invasive Therapeutic Procedures: Catheter Based	
Mesenteric Artery Angioplasty Stenting	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator	Last name, first, middle
Angioplasty/stenting	Choose one: ● Balloon angioplasty alone ● Stent
Balloon length	Indicate the length of balloon used in millimeters.
Nominal balloon diameter	Indicate the diameter of the balloon at initial inflation and final inflation in millimeters.
How many stents used (per artery)?	● 1 ● >1
Stent type	Indicate type of stent used. Choose all that apply: ● Balloon expandable ● Self-expanding ● Drug eluting ● Covered
Stent brand name	Identify the brand name of the stent used.
Stent model	Identify the model number of the stent used.
Stent manufacturer	Identify the manufacturer of the stent used.
Stent length	Indicate the length of the stent used in millimeters.
Stent diameter	Indicate the diameter of the stent used in millimeters.
Target mesenteric artery	Indicate whether the target vessel for the procedure is the celiac, superior mesenteric, and/or inferior mesenteric artery.
Current procedure part of clinical trial	Indicate whether the procedure is part of a clinical trial. Choose 1 of the following: ● Yes – If yes, indicate the trial type: ○ IDE ○ Postmarket approval ○ Other (specify) ● No
Anesthesia	Indicate if the patient received general anesthesia, conscious sedation, local anesthesia, or no anesthesia during the current procedure.
Procedure Indications and Anatomic Variables	
Clinical indication	● Symptoms of mesenteric ischemia ● Weight loss ● Malnutrition ● Other
Restenosis in target vessel after prior mesenteric artery stent	Note if the indication for the current procedure is restenosis in the target mesenteric artery that was previously treated with angioplasty and/or a stent.
Contrast volume	Indicate the volume of iodinated contrast injected during the procedure in milliliters.
Fluoroscopy time	Indicate the total fluoroscopy time recorded during the procedure to the nearest 0.10 min. The time recorded should include the total time for the procedure.

(*Continued*)

Table 5. Continued

Element Name	Definition
Procedure arterial access site	Indicate the primary arterial access site used to perform the mesenteric artery stenting procedure. Note the location (right/left): ● Femoral ● Brachial ● Radial ● Axillary
Arterial access closure method	● List methods and devices in chronological order of closure. ● Indicate the method used to achieve hemostasis: – Device – Nondevice (such as manual compression)
Lesions	
Target lesion location	Indicate the location of the target lesion.
Visible thrombus present	Indicate if the target lesion contains thrombus as assessed by baseline angiography and implied by the presence of filling defect.
Calcification	Indicate if calcification is present. If present, specify the location. Choose 1of the following: ● None ● Mild ● Moderate ● Severe
Lesion length	Indicate the length of the target lesion in millimeters as assessed by baseline angiography.
Minimal luminal diameter	Indicate the MLD of the target lesion in millimeters as assessed by baseline angiography.
Diameter of distal mesenteric artery	Indicate the diameter of the nontapering distal segment of the mesenteric artery measurement at the intended landing zone of the distal edge of the stent.
Preprocedure percent stenosis of mesenteric artery	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
Lesion treatment incomplete or aborted	Indicate if the lesion treatment was incomplete or aborted. Choose 1 of the following: ● Yes – If yes, note reasons: ○ Failure to gain vascular access. ○ Failure to engage ostium with guide catheter ○ Unable to cross with guidewire ○ Unable to deploy stent ○ Failure to confirm significant stenosis ○ Unable to cross balloon ○ Cardiac ischemia ○ Unable to deploy device ○ Hypotension ○ Hypertension ○ Unable to deliver stent ○ Other ● No
Embolic protection attempted	Indicate if the operator tried to use an EPD: ● Yes – If yes, indicate if predilatation before balloon or stent was performed or not. – If yes, list EPD in chronological order. Note if successfully deployed. ● No
Stent malposition	Indicate if the stent was deployed in a location or position other than that for which it was intended.
Final minimal luminal diameter	Indicate the final residual lumen diameter in millimeters.
Final percent stenosis of mesenteric artery	Indicate the severity of stenosis by quantitative analysis using the formula 100×(1−minimum lumen diameter)/maximum diameter of reference segment
How many stents used (per artery)?	● 1 ● >1
Invasive Therapeutic Procedure: Surgical Revascularization	
Aortomesenteric Bypass Graft Surgery	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Proximal anastomosis	Indicate the location of proximal anastomosis with graft (i.e., supraceliac aorta, iliac artery).

(*Continued*)

Table 5. Continued

Element Name	Definition
Distal anastomosis	Indicate the location of distal anastomosis with graft (i.e., mid-celiac artery, mid-SMA).
Conduit	Indicate the type of graft material used for bypass (e.g., synthetic, autologous).
Mesenteric Endarterectomy	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Outcomes of Endovascular/ Open Surgery Procedures	
Time points	Indicate the period at which outcome measures are assessed. Choose all that apply: ● Periprocedure (24 h) ● Procedure related (30 d) ● 3 mo ● 6 mo ● 1 y
Complications of endovascular procedure	Indicate postoperative clinical events or conditions associated with an endovascular procedure. Choose all that apply: ● Pseudoaneurysm ● AV fistula ● Hematoma ● Dissection ● Vessel thrombosis ● Vessel perforation ● Atheromatous embolization ● Contrast nephropathy ● Contrast hypersensitivity ● Infection ● Requirement of intervention to prevent permanent impairment/damage
Complications of open surgery	Indicate complications of open surgery. Choose all that apply: ● Major complication: – Death – MI (also see cardiovascular complications below) – Stroke (ischemic, hemorrhagic, unknown type) ● Other life-threatening major complication (specify): – Prolonged hospitalization – Persistent or significant disability or incapacity – Vessel thrombosis – Vessel rupture – Seroma – Hematoma – Renal failure – Bowel infarction – Other end-organ damage – Pneumonia – DVT – Graft thrombosis – Atheromatous embolization – Requirement of intervention to prevent permanent impairment/damage – Infection ● Minor complication (specify)
Total length of stay	Indicate the length of stay in the hospital in number of days.
Discharge status	Indicate the patient's discharge status. Choose 1 of the following: ● Discharged to home or self-care – This includes discharge to home; jail or law enforcement; home on oxygen if DME only; any other DME only; group home, foster care, and other residential care arrangements; outpatient programs such as partial hospitalization or outpatient chemical dependency programs; assisted living facilities that are not state designated. ● Discharged/transferred to short-term general hospital for inpatient care ● Discharged/transferred to an SNF with Medicare certification in anticipation of skilled care ● Discharged/transferred to an ICF ● Discharged/transferred to standard rehabilitation facility ● Discharged/transferred to ventilator rehabilitation facility ● Discharged/transferred to another type of healthcare institution other than the above ● Patient died

(*Continued*)

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Table 5. Continued

Element Name	Definition
Patient Education/Counseling	
Medication instruction	Verbal and written medication instructions provided to patient and/or family
Recognition of new or worsening symptoms	Verbal and written instructions provided to patient and/or family (by physician or nurse) regarding new or worsening symptoms and when to call the physician
Diet counseling	Advice given or discussion held with patient and/or family about diet counseling in relation to lowering cardiovascular risk. May include ● Sodium restriction ● Fluid restriction ● Referral to dietitian for weight management and/or advanced nutritional instruction. ● Other (specify)
Smoking cessation counseling	Advice given or discussion held with patient (by physician, nurse, or other personnel) about the importance of stopping smoking. May include ● Counseling (may be basic or advanced) ● Written materials ● Referral to smoking cessation program ● Drugs to help with smoking cessation
Activity counseling	Advice given or discussion held with patient and/or family about activity level and restrictions in activity and/or exercise recommendations
Follow-Up	
Open repair	Documentation of evaluation of patient following discharge. Indicate all of the following that apply: ● Physical examination ● Imaging (e.g., ultrasound, MR, CT)
Endovascular	Documentation of evaluation of patient after discharge. Indicate all of the following that apply ● Physical examination ● Imaging (e.g., ultrasound, MR, CT)
Clinical Outcomes	
Time points	Indicate the period at which outcome measures are assessed. Choose all that apply: ● 1 mo ● 3 mo ● 6 mo ● 1 y
Patient assessment	Assess recurrent signs and symptoms of mesenteric disease: ● Appetite ● Caloric intake ● Nutritional status ● Presence or absence of postprandial abdominal pain ● Food avoidance/tolerance ● Weight loss/gain
Adverse events	● Recurrent bowel ischemia/infarction ● Repeat revascularization ● Bowel resection ● MI ● Stroke (ischemic, hemorrhagic, unknown type) ● Other adverse event ● Death

AV indicates atrioventricular; CT, computed tomography; DME, durable medical equipment; DVT, deep venous thrombosis; EPD, embolic protection device; ICF, intermediate care facility; IDE, investigational device exemption; MI, myocardial infarction; MLD, minimal luminal diameter; MR, magnetic resonance; SMA, superior mesenteric artery; and SNF, skilled nursing facility.

artery imaging tests, including duplex ultrasonography, magnetic resonance angiography, computed tomographic angiography, and catheter-based angiography. In addition, there are detailed data elements for mesenteric artery angioplasty and stenting, including specific elements concerning the procedure, target lesion location, results and complications, and similarly for surgical revascularization of mesenteric artery disease. In addition, data elements are defined for clinical outcomes following medical and revascularization therapy.

3.5. Extracranial Carotid and Vertebral Artery Disease Table of Data Elements

In the context of this document, extracranial carotid artery disease is defined as a cerebral artery atherosclerotic disease that causes stenosis or occlusion of the cervical portion of the carotid arteries (2). Other causes of carotid artery disease include fibromuscular dysplasia, arteritis, radiation-induced arteriopathy, dissection, and restenosis following carotid artery revascularization procedures. Extracranial vertebral

Table 6. Extracranial Carotid and Vertebral Artery Disease Elements and Definitions

Element Name	Definition
Patient History	
Asymptomatic	Indicate if the patient is asymptomatic. No prior stroke or TIA
Symptomatic	Indicate the onset and duration of symptoms.
Previous stroke	Previous stroke is defined as an acute loss of neurological function caused by an ischemic or hemorrhagic event with residual symptoms for at least 24 h or symptoms for <24 h with evidence of acute infarction (e.g., by CT or MRI). If present, record stroke type: • Ischemic • Intracerebral hemorrhage • Subarachnoid hemorrhage • Unknown If ischemic, list the most likely etiologies: • Large-artery atherosclerosis of the extracranial vessels (e.g., carotid) • Large-artery atherosclerosis of the intracranial vessels (e.g., middle cerebral artery stenosis) • Cardioembolism • Small-vessel occlusion (lacunar) • Ischemic stroke of other determined etiology (e.g., arterial dissection) • Ischemic stroke of undetermined etiology
Transient ischemic attack (TIA)	Documented history of TIA consisting of a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction Note the following: • Right retinal • Right hemispheric • Left retinal • Left hemispheric • Vertebrobasilar • Unknown distribution Date of first and most recent episode
ASA grade	Choose 1 of the following: • Grade I: Normal, healthy • Grade II: Mild systemic disease that does not limit activity • Grade III: Severe systemic disease that limits activity but is not incapacitating • Grade IV: Incapacitating systemic disease that is constantly life threatening • Grade V: Moribund; not expected to survive 24 h with or without surgery
History of dementia	History of dementia, Alzheimer's disease, chronic confusion (at least 1 mo in duration), or senility *Year of onset (first diagnosis) may be helpful.*
Seizures	Indicate if the patient has a documented history of epilepsy.
Hemorrhage	Indicate if the patient has a hemorrhage. Choose all that apply: • Intraparenchymal • Intraventricular • Subarachnoid • Subdural
Cause of carotid/vertebral stenosis	Select any of the following that apply • Atherosclerosis • FMD • Dissection • Vasculitis (Takayasu's or giant cell arteritis) • Irradiation • Restenosis following CEA • Restenosis following CAS • Restenosis following vertebral angioplasty/stenting
Anatomic High-Risk Conditions	
Previous neck radiation	Indicate if the patient had previous radiation therapy to the neck before the current admission or procedure.
Previous neck surgery (other than CEA)	Indicate if the patient had a previous extensive (i.e., radical) neck dissection (other than CEA) before the current admission or procedure.
Previous carotid intervention	Yes or no. If yes, within <30 d, 31–180 d, or >180 d? Note: • Right CEA • Right CAS • Left CEA • Left CAS

(*Continued*)

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Table 6. Continued

Element Name	Definition
Previous vertebral intervention	Yes or no. If yes, within <30 d, 31–180 d, or >180 d? Note: • Left • Right • Proximal • Distal
Previous ipsilateral CEA	Yes or no
Tracheostomy present	Indicate if the patient has an open tracheostomy at the time of the current procedure.
Cranial nerve palsy (32,33)	Indicate if patient has a history of cranial nerve palsy/palsies. Choose 1 of the following: • Yes – If yes, indicate all nerves involved: ○ Recurrent laryngeal or its parent nerve, the vagus nerve ○ Hypoglossal ○ Facial ○ Other • No
Comorbid Cardiopulmonary Conditions	
History of chronic lung disease	History of chronic lung disease (e.g., chronic obstructive pulmonary disease, chronic bronchitis, emphysema, restrictive lung disease) or currently receiving long-term treatment with inhaled or oral pharmacological therapy (e.g., beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid) *Year of onset (first diagnosis) may be helpful.*
On home oxygen	Indicate if, before the current procedure, the patient has been receiving home oxygen therapy for treatment of chronic lung disease.
NYHA class III or IV in last 6 wk	Indicate if the patient's highest NYHA cardiac functional class has been class III or IV at any time within 6 wk before the current procedure. Patients in NYHA classes III and IV have anginal or heart failure symptoms at rest and/or resulting in marked limitation of physical activity. NYHA classes III and IV are formally defined as follows: • Class III: Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. However, less than ordinary physical activity (e.g., walking 1 to 2 level blocks or climbing 1 flight of stairs) causes fatigue, palpitations, dyspnea, or anginal pain. • Class IV: Patient has dyspnea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased. *Note:* For patients without cardiac disease or patients with NYHA class I or II, code No.
Patient Assessment	
Carotid bruits	Indicate if carotid bruits are present. Choose 1 of the following: • Yes – Left – Right – Bilateral • No • Not assessed
Supraclavicular bruits	Indicate if supraclavicular bruits are present. Choose 1 of the following: • Yes – Left – Right – Bilateral • No • Not assessed
NIH Stroke Scale score	Indicate if the NIHSS was used. Choose 1 of the following: • Yes – Indicate scores done before the procedure, immediately after the procedure, before discharge, and other. • No

(*Continued*)

Table 6. Continued

Element Name	Definition
Modified Rankin Stroke Scale score	Indicate the patient's score: Score Description 0 No symptoms at all 1 No significant disability despite symptoms; able to carry out all usual duties and activities 2 Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance 3 Moderate disability; requiring some help but able to walk without assistance 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance 5 Severe disability; bedridden, incontinent, and requiring constant nursing care and attention 6 Death
Barthel Index	Indicate if the Barthel Index was measured. Choose 1 of the following: ● Yes — Indicate scores done before the procedure, immediately after the procedure, before discharge, and other. ● No
Specific neurologic findings	Indicate the presence or absence of the following: ● Hemiparesis ● Upper motor neuron facial weakness ● Lower motor neuron facial weakness ● Dysphasia ● Hemisensory loss ● Visuospatial neglect ● Branch retinal artery occlusion ● Central retinal artery occlusion ● Dysarthria ● Gait ataxia ● Disconjugate gaze ● Tongue deviation ● Nystagmus
Diagnostic Procedures	
Carotid Duplex Ultrasound	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Location of measurement	Measure each of the following in the right CCA, right ICA, left CCA, and left ICA.
Plaque characteristics	Indicate if any of the following are present: ● No plaque ● Homogeneous plaque (stable) ● Heterogeneous plaque (unstable) ● Surface irregularity
Intima-media thickness	Indicate intima-media thickness in millimeters.
CCA systolic velocity	Measure systolic velocity in proximal, mid, and distal segments of CCA. Measure velocity in centimeters per second.
CCA diastolic velocity	Measure diastolic velocity in proximal, mid, and distal segments of CCA. Measure velocity in centimeters per second.
ICA systolic velocity	Measure systolic velocity in proximal, mid, and distal segments of ICA. Measure velocity in centimeters per second.
ICA diastolic velocity	Measure diastolic velocity in proximal, mid, and distal segments of ICA. Measure velocity in centimeters per second.
Peak ICA: distal CCA systolic velocity ratio	Indicate systolic velocity radio measured in centimeters per second. Choose 1 of the following: ● <2.0 ● 2.0–4.0 ● >4.0
Degree of stenosis	Indicate range of stenosis: ● Normal ● 1%–49% ● 50%–69% ● 70%–99% ● Complete occlusion

(*Continued*)

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Table 6. Continued

Element Name	Definition
Carotid stent stenosis	Indicate the range of stenosis after carotid stenting: ● Normal ● 1%–49% ● 50%–69% ● 70%–99% ● Complete occlusion
Carotid bifurcation location	Indicate the location of carotid bifurcation. Choose 1 of the following: ● Normal ● High
Vertebral artery flow direction	Indicate the direction of artery flow for the right and left vertebral artery. Choose 1 of the following: ● Forward ● Reversed ● No flow detected
CT Angiography	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Radiologist	Last name, first, middle
Location of measurement	Measure each of the following in the right CCA, right ICA, left CCA, and left ICA.
Luminal diameter of CCA	Measure diameter in millimeters.
Luminal diameter of ICA	Measure diameter in millimeters.
Degree of stenosis	Use the NASCET method for measurement of stenosis defined by the formula % stenosis=100×(1−minimum luminal diameter at the lesion site)/diameter of nontapering segment of distal ICA
Nonobstructed diameter of ICA	Measure diameter in millimeters.
Plaque characteristics	Indicate if any of the following are present: ● Calcifications ● Ulceration ● Tandem lesion
Intracranial atherosclerotic disease	Indicate if intracranial atherosclerotic disease (>50% stenosis) is present in the distribution in either the right or left ICAs: Yes or no.
Other vascular abnormality	Indicate if another vascular abnormality is present, including aneurysm, AVM, etc.
Magnetic Resonance Angiography	
Date of procedure	Indicate the date of the procedure (mo/d/y).
Location of measurement	Measure each of the following in the right CCA, right ICA, left CCA, and left ICA.
Diameter of CCA	Measure diameter in millimeters.
Diameter of ICA	Measure diameter in millimeters.
Degree of stenosis	Use the NASCET method for measurement of stenosis defined by the formula % stenosis=100×(1−minimum luminal diameter at the lesion site)/diameter of nontapering segment of distal ICA
Nonobstructed diameter of ICA	Measure diameter in millimeters.
Plaque	Indicate if any of the following are present and describe: ● Fibrous cap thickness in millimeters ● Fibrous cap disruption ● Intraplaque lipid content ● Intraplaque hemorrhage
Tandem lesion	Indicate yes or no.
Other vascular abnormality	Indicate if another vascular abnormality is present, including aneurysm, AVM, etc.
Intracranial atherosclerotic disease	Indicate if intracranial atherosclerotic disease (>50% stenosis) is present in the distribution of either the right or left ICA: Yes or no.
Invasive Therapeutic Procedures: Carotid and Vertebral Artery Stenting	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Target carotid vessel	Indicate whether the target vessel is the right or left carotid artery for the current procedure: Right or left.
Target vertebral artery	Indicate whether the target vessel is the right or left vertebral artery for the current procedure: Right or left.
Is the current procedure part of a clinical trial?	Yes or no. If yes, note trial type: ● Postmarket surveillance ● Premarket approval ● IDE ● Other (specify)

(*Continued*)

Table 6. Continued

Element Name	Definition
Anesthesia	Indicate if the patient received general anesthesia, local anesthesia, or no anesthesia during the current procedure. If >1 method was used, code it General.
Procedure Indications and Anatomic Variables	
Target lesion symptomatic within past 6 mo	Indicate if the patient has had neurologic symptoms related to the target lesion in the past 6 mo.
Restenosis in target vessel after prior CAS	Note if the indication for the current procedure is restenosis in the target carotid artery that was previously treated with angioplasty and/or a stent. Carotid artery restenosis is defined as >50% diameter stenosis at or adjacent to the site previously treated with balloon angioplasty or a stent.
Restenosis of target vessel after prior CEA	Note if the indication for the current procedure is restenosis in the target carotid artery that was previously treated with carotid artery endarterectomy. Restenosis is defined as renarrowing within or adjacent to a prior endarterectomy site, evidenced by >50% diameter stenosis.
Carotid lesion difficult to access surgically	Indicate if the lesion is difficult to access surgically for CEA. Yes or no Note: Lesions that are difficult to access include those that are high in the neck (e.g., at or above the level of C2) and those that are within the proximal one half or one third of the CCA, at or below the clavicle, rendering endarterectomy either difficult or impossible.
Vertebral lesion difficult to access surgically	Indicate if the lesion is difficult to access surgically. Yes or no
Aortic arch type	Indicate the patient's aortic arch type configuration. The 3 types of aortic arch are based on the relationship of the innominate artery to the aortic arch. The more inferior the origin of the target artery (i.e., type II or III aortic arch), the greater the difficulty in gaining access to the carotid artery. Category: ● Type I ● Type II ● Type III
Contrast volume	Indicate the volume of iodinated contrast injected during the procedure in milliliters.
Fluoroscopy time	Indicate the total fluoroscopy time recorded during the procedure to the nearest 0.10 min. The time recorded should include the total time for the procedure.
Contralateral carotid occlusion	Indicate if there is known 100% occlusion of the patient's contralateral carotid artery.
Contralateral vertebral occlusion	Indicate if there is known 100% occlusion of the patient's contralateral vertebral artery.
Bovine arch	Indicate if the patient's aortic arch is bovine, in which the right brachiocephalic and left carotid arteries share a common trunk from the aortic arch.
Procedure arterial access site	Indicate the primary arterial access site used to perform the CAS procedure. Note the location: ● Femoral ● Direct carotid puncture ● Direct vertebral puncture ● Brachial ● Radial ● Axillary exposure ● Carotid cut down ● Vertebral cut down
Arterial access closure method	List methods and devices in chronological order of closure. Indicate the method used to achieve hemostasis. Methods should include devices and nondevices such as manual compression.
Tandem lesions	Indicate if there is evidence of tandem lesions. Choose 1 of the following: ● Yes – Specify location(s) ● No
Intracranial stenosis	Indicate if there is evidence of intracranial lesions. Choose 1 of the following: ● Yes – Specify location(s) ● No
Other intracranial pathology	Indicate if there is evidence of other intracranial pathology. Choose 1 of the following: ● Yes – Specify type ● No

(*Continued*)

Table 6. Continued

Element Name	Definition
Lesions and Devices	
Target lesion location	List the following: ● Isolated CCA ● Isolated ICA ● Bifurcation ● Vertebral ostia ● Vertebral artery ostia ● Midcervical vertebral
Visible thrombus present	Indicate if the target lesion contains thrombus as assessed by baseline angiography and implied by the presence of filling defect.
Ulceration	Indicate if the target lesion is ulcerated as assessed by baseline angiography.
Calcification	Indicate if calcification is present. If present, specify the location. Choose 1 of the following: ● None ● Mild ● Moderate ● Severe
Lesion length	Indicate the length of the target lesion in millimeters as assessed by baseline angiography.
Minimal luminal diameter	Indicate the MLD of the target lesion in millimeters as assessed by baseline angiography. The MLD is defined as the minimum luminal diameter derived from the angiographic view that shows the tightest point of the stenosis.
Diameter of distal ICA	Indicate the diameter of the nontapering distal segment of the ICA for NASCET measurement at the intended landing zone of the distal edge of the stent (where the vessel is no longer tapered and the walls become parallel). *Note:* NASCET was a randomized clinical trial that compared the safety and efficacy of CEA to medical therapy for the prevention of stroke in symptomatic patients.
Preprocedure percent stenosis of the carotid artery	Indicate the percent stenosis preprocedure, which is calculated as follows: 1. When the tightest stenosis is in the ICA or at the carotid bifurcation, use the NASCET method. Percent diameter stenosis is calculated as 1−(minimum luminal diameter at the lesion site/diameter of nontapering segment of the distal ICA). The nontapering site is where the walls of the ICA become parallel. 2. Do not use the NASCET method if the distal lumen collapses from a low-flow situation. In such cases, enter 99% because the stenosis may be graded as a near-occlusion. 3. For stenosis localized to the CCA, percent diameter stenosis is calculated as 1−(minimum luminal diameter/diameter of the adjacent normal segment of the CCA).
Preprocedure percent stenosis of the vertebral artery	Indicate preprocedure percent stenosis calculated as follows: When the tightest stenosis is in the cervical vertebral artery (origin to dural entry), percent diameter stenosis is calculated as 1−(minimum luminal diameter of the nontapering segment of the distal vertebral artery). The nontapering site is where the walls of the vertebral artery become parallel.
Lesion treatment incomplete or aborted	Indicate if the lesion treatment was incomplete or aborted: Yes or no. If yes, note the reason(s): ● Failure to gain vascular access ● Unable to cross with guidewire ● Unable to cross with balloon ● Unable to deploy stent ● Arrhythmia ● Failure to confirm significant stenosis ● Difficult to access because of tortuosity ● Cardiac ischemia ● Hypotension ● Hypertension ● Unable to deliver stent ● Acute neurological event ● Other
Embolic protection attempted	Indicate if the operator tried to use an EPD: ● Yes — Indicate if predilatation was done before balloon or stent. — List EPD devices in chronological order. — Note if successfully deployed. ● No If yes, indicate if predilatation was done before balloon or stent. ● Yes ● No If yes, list EPD devices in chronological order.

(*Continued*)

Table 6. Continued

Element Name	Definition
Predilatation	Indicate if predilatation was performed before the attempted stent implantation or after EPD: Yes or no
Stents implanted	Were stents implanted? Yes or no. If yes, list stents in chronological order with the following information: • Stent • Brand • Model • Manufacturer
Stents tapered	Yes or no
Stent(s) diameter	Indicate the diameter of the stent. If a tapered stent was used, indicate the smallest diameter of the tapered stent in millimeters.
Stent(s) length	Indicate the length of the stent in millimeters.
Stent(s) malposition	Indicate if the stent was deployed in a location or position other than that for which it was intended.
Postdilatation performed	Was postdilatation performed? Yes or no. If yes, note the following: • Nominal balloon diameter in millimeters • Maximum inflation pressure in atmospheres
Final MLD	Indicate the final residual lumen diameter in millimeters.
Final percent stenosis for carotid artery	Indicate percent stenosis postprocedure, calculated as follows: 1. For an ICA site, use NASCET methodology. Percent diameter stenosis is calculated as 1−(minimum residual luminal diameter within the treated site/diameter of the nontapering segment of the distal ICA). The nontapering site is where the walls of the ICA become parallel. 2. For a lesion and interventional site localized to the CCA, percent diameter stenosis is calculated as 1−(minimum residual luminal diameter/diameter of the adjacent normal segment of the CCA).
Final percent stenosis for vertebral artery	Value is dependent on the largest stenosis using essentially similar NASCET criteria for vertebral disease.
Invasive Therapeutic Procedures: Carotid Endarterectomy	
Date of procedure	Indicate the date the procedure was performed (mo/d/y).
Operator	Last name, first, middle
Is the current procedure part of a carotid trial?	Yes or no. If yes, note the type of trial: • Postmarket surveillance • Premarket approval • IDE • Other (specify)
Target carotid vessel	Indicate whether the target vessel is the right or left carotid artery for the current procedure: • Right • Left • Common • Bifurcation • Distal internal
Anesthesia	Indicate if the patient received general anesthesia, local anesthesia, or no anesthesia during the current procedure. If >1 method of anesthesia was given, code it General.
Endarterectomy technique	Standard or eversion
Procedure Indications and Anatomic Variables	
Target lesion symptomatic within past 6 mo	Indicate if the patient has had neurologic symptoms related to the target lesion in the past 6 mo.
Target lesion symptomatic within past 3 mo	Yes or no
Target lesion symptomatic within past 6 wk	Yes or no
Restenosis in target vessel after prior CEA	Note if the indication for the current procedure is restenosis in the target carotid artery that was previously treated with CEA. Restenosis is defined as renarrowing within or adjacent to a prior endarterectomy site, evidenced by >50% diameter stenosis.
Contralateral carotid artery occlusion	Indicate if there is known 100% occlusion of the patient's contralateral carotid artery.
Contralateral carotid artery stenosis	Yes or no

(*Continued*)

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Table 6. Continued

Element Name	Definition
Spontaneous carotid artery dissection	Indicate if the patient has had a spontaneous carotid artery dissection before the current procedure: Yes or no. If yes, note the location: ● Common carotid ● Carotid bifurcation ● Distal internal
Tandem lesions	Yes or no. If yes, note the location.
Intracranial stenosis	Yes or no. If yes, note the location.
Other intracranial pathology	Yes or no. If yes, note the type.
Intraprocedural Information	
Patch utilization	Standard technique? ● Yes — If yes, indicate the type of patch (e.g., Dacron, PTFE, bovine pericardium, vein). ● No
Thrombus present on direct visual inspection	Indicate if a thrombus (blood clot) was present on direct visual inspection intraoperatively during the CEA procedure.
Monitoring technique used	Note the following: ● Awake monitoring ● Selective monitoring based on EEG, stump pressure, SSEP, motor-evoked potential, anatomic, or other factor (describe).
Shunting used	Indicate if a shunt was used. If yes, note the following: ● Selective shunt based on EEG, stump pressure, SSEP, motor-evoked potential, anatomic, or other factor (describe) ● Was a shunt indicated but not technically possible?
Surgical procedure terminated	Indicate if the CEA procedure was terminated: Yes or no. If yes, note the reason(s): ● Hypotension ● Hypertension ● Nerve compromise ● Excessive scar tissue ● Carotid artery thrombosis ● Difficulty with anesthesia ● Difficulty with suction ● ICA string sign or atresia ● Cardiac instability ● Inability to implement shunting ● Excessive bleeding ● Inability to access lesion because of anatomical lesions ● Other (specify)
Intraoperative completion evaluation	Check all that apply: ● None ● Standard Doppler ● Arteriogram (include findings) ● Duplex scan (include findings)
Intraoperative complications	Indicate any of the following: ● Reopening of carotid artery (note indication and findings) ● Technical difficulties (describe)
Patient outcome	● Normal neurologic exam ● Deficit (describe)
Medications	
Antiplatelet therapy, aspirin	Yes or no. If yes, note type.
Contraindicated clopidogrel	Yes or no
Contraindicated ticlopidine	Yes or no
Contraindicated other	Yes or no
Intraoperative anticoagulation	Indicate the drug and dose used
Procedural Outcomes	
Intraprocedural/intraoperative adverse events	Indicate adverse event(s) that occurred during or after the procedure. Specify time of occurrence relative to procedure: ● Abrupt closure ● Spasm requiring treatment ● Loss of external carotid ● Distal intracranial embolization ● Embolization (systemic)

(*Continued*)

Table 6. Continued

Element Name	Definition
	• Embolization (carotid) • Thrombosis • Occlusive untreated dissection • Arrhythmia requiring treatment • Hypotension requiring treatment • Hypertension requiring treatment • Stroke (ischemic, hemorrhagic, unknown type) • TIA • Amaurosis fugax • Seizure • Puncture site complications • Death (or death in lab) • Intubation or resuscitation • Stent malposition • Embolic protection retrieval • Intracranial hemorrhage • Other (specify)
Results	• Procedure technical failure—unable to deploy stent • Procedure terminated for stenosis <70% • Procedure terminated because of complication before deployment • Procedure technical success without complications • Procedure technical success with complications
Acute occlusion	Indicate if there is acute occlusion <24 h after the procedure.
Residual stenosis	Note: • Right • Left • Bilateral
Right-side percent stenosis	Indicate right-side percent stenosis.
Left-side percent stenosis	Indicate left-side percent stenosis.
Stent migration/deformation	Stent located in planned landing zone with complete lesion coverage
Distal embolization	Occlusion of cerebral arteries or periprocedural neurologic deficit resulting from dislodgment of atheromatous debris or thrombus from the procedural site
Postprocedural complications in hospital	Indicate if any of the following occurred: • None • Arrhythmia requiring treatment • Hypotension requiring treatment • Hypertension requiring treatment • MI • New unstable angina • Electrocardiographic changes • Cardiac enzyme elevations • Pulmonary embolism • Stroke (ischemic, hemorrhagic, unknown type) • Deterioration in Modified Rankin Scale score • TIA • Amaurosis fugax • Seizure • Intracranial hemorrhage • Hyperperfusion syndrome • Other neurologic complication (specify) • Secondary carotid intervention (specify) • Vessel thrombosis or ischemia of extremity • Puncture site complications • Pseudoaneurysm • Pseudoaneurysm vascular repair • Hematoma (local or retroperitoneal) (indicate if transfusion required) • Other bleeding (indicate if transfusion required) • Access site infection • Creatinine increase >1.0 mg/dL • Hemodialysis

(*Continued*)

Table 6. Continued

Element Name	Definition
	• Pneumonia • Urinary tract infection • Sepsis • Death • Other (specify)
Patient Education/Counseling	
Medication instruction	Verbal and written medication instructions provided to patient and/or family
Recognition of new or worsening symptoms	Verbal and written instructions provided to patient and/or family (by physician or nurse) regarding new or worsening symptoms and when to call the physician
Diet counseling	Advice given or discussion held with the patient and/or family about diet counseling related to lowering cardiovascular risk. May include • Sodium restriction • Fluid restriction • Other (specify)
Referral to dietician for diet counseling	Referral to dietitian for weight management and/or advanced nutritional instruction
Activity counseling	Advice given or discussion held with the patient and/or family about activity level and restrictions in activity and/or exercise recommendations.
Smoking cessation counseling	Advice given or discussion held with the patient (by physician, nurse, or other personnel) about the importance of stopping smoking. May include • Counseling (may be basic or advanced) • Written materials • Referral to smoking cessation program • Drugs to assist for smoking cessation
Plan for follow-up care	Documentation of plan for follow-up care with physician and/or nurse Should include date of follow-up
Patient referral	Patient referred to other care such as neurology, neurosurgery, vascular surgery, cardiology clinic/office. Transitional care (specify duration): • Home health care • Nurse case manager • Hospice or palliative care • Home telemonitoring • Ambulatory cardiac telemetric monitoring (e.g., mobile cardiac outpatient telemetry) • Period of time enrolled in the program and/or qualitative characterization of the level of the patient's success/participation in the program(s) may be specified.
Discharge status	Indicate the following: • Discharge NIHSS score • Discharge Modified Rankin Scale score • Discharge Barthel Index • Cranial nerve injury • Technical defects requiring revision • Stroke (ischemic, hemorrhagic, unknown type)—note date • TIA (single or multiple)—note date • Amaurosis fugax • MI (Q wave or non–Q wave)—note date
Outcomes	
Time points	Indicate the period at which outcome measures are assessed. Choose all that apply: • 1 mo • 3 mo • 6 mo • 1 y
Follow-up visit	Documentation of follow-up evaluation for patients with established carotid/vertebral arterial disease should include • Patient history • Functional status • Physical examination • Laboratory or other tests
Date of visit	Indicate the date of visit (mo/d/y).
Follow-up NIHSS	(See scale above.)

(*Continued*)

Table 6. Continued

Element Name	Definition
Repeat duplex ultrasound performed	Indicate if repeat duplex ultrasound was performed in any of the following time frames: • Before discharge – Yes – No • 3 mo – Yes – No • 6 mo – Yes – No • Annually – Yes – No
Right-side percent stenosis	Indicate right-side percent stenosis.
Left-side percent stenosis	Indicate left-side percent stenosis.
MRA or CTA performed	Indicate if MRA or CTA was performed in any of the following time frames: • Before discharge – Yes – No • 3 mo – Yes – No • 6 mo – Yes – No • Annually – Yes – No
Right-side percent stenosis	Indicate right-side percent stenosis.
Left-side percent stenosis	Indicate left-side percent stenosis.
Follow-up Modified Rankin Scale score	(See scale above.)
Follow-up Barthel Index	(See scale above.)
Stroke	Indicate stroke type: • Ischemic • Hemorrhagic • Unknown
	Indicate whether or not the patient was hospitalized.
Reason for termination	Indicate the reason for termination.
Death	Note the following: • Date • Cause • Date of the last visit in which the patient was evaluated • Death within 30 d of last visit • Death 30 d after last visit
Repeat Hospitalization	
Date of admission	Indicate the date of admission (mo/d/y).
Primary reason for readmission	Stroke, TIA, MI, other
Repeat duplex ultrasound performed?	Yes or no
Right-side percent stenosis	Indicate right-side percent stenosis.
Left-side percent stenosis	Indicate left-side percent stenosis.
Was repeated MRA, CTA, or conventional angiogram performed?	Yes or no
Target lesion revascularization	Indicate whether CAS was performed.
Target vessel revascularization	Indicate whether CEA or CAS was performed.

(*Continued*)

Table 6. Continued

Element Name	Definition
Stent patency	Indicate whether the stent is patent and if restenosis is present: ● Right-side percent stenosis ● Left-side percent stenosis

ASA indicates American Society of Anesthesiologists; AVM, arteriovenous malformation; CAS, carotid artery stenting; CCA, common carotid artery; CEA, carotid endarterectomy; CT, computed tomography; CTA, computed tomographic angiography; EEG, electroencephalogram; EPD, embolic protection device; FMD, fibromuscular dysplasia; ICA, internal carotid artery; IDE, investigational device exemption; MI, myocardial infarction; MLD, minimal luminal diameter; MRA, magnetic resonance angiography; MRI, magnetic resonance imaging; NASCET, North American Symptomatic Carotid Endarterectomy Trial; NIH, National Institutes of Health; NIHSS, National Institutes of Health Stroke Scale; NYHA, New York Heart Association; PTFE, polytetrafluoroethylene; SSEP, somatosensory evoked potential; and TIA, transient ischemic attack.

and intracranial cerebral artery diseases are outside the scope of this document. The data elements defined in Table 6 include symptoms and clinical findings related to ischemic strokes and transient ischemic attacks that occur in patients with carotid artery disease. Also included are data elements that define anatomic high-risk conditions and comorbid cardiopulmonary conditions that are used to assess risk of carotid revascularization procedures. Table 6 provides detailed elements of carotid artery imaging tests, including duplex ultrasonography, magnetic resonance angiography, computed tomographic angiography, and catheter-based angiography. In addition, there are detailed data elements for carotid artery stenting, including specific elements concerning the procedure, target lesion location, results and complications, and similarly for carotid endarterectomy. In addition, data elements are defined for clinical outcomes following carotid revascularization.

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References

1. Health Insurance Portability and Accountability Act of 1996. Public Law 104-191. 1996.
2. Hiatt WR, Goldstone J, Smith SC Jr., et al. Atherosclerotic Peripheral Vascular Disease Symposium II: nomenclature for vascular diseases. Circulation. 2008;118:2826–9.
3. 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): executive summary: 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;47:1239–312.
4. Rooke T, Hirsch A, Misra S, et al. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2010;58:2020–45.
5. Olin JW, Allie DE, Belkin M, et al. 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). J Am Coll Cardiol. 2010;56:2147–81.
6. Buxton AE, Calkins H, Callans DJ, et al. ACC/AHA/HRS 2006 key data elements and definitions for electrophysiological studies and procedures: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (ACC/AHA/HRS Writing Committee to Develop Data Standards on Electrophysiology). J Am Coll Cardiol. 2006;48:2360–98.
7. Cannon CP, Battler A, Brindis RG, et al. American College of Cardiology key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes: a report of the American College of Cardiology Task Force on Clinical Data Standards (Acute Coronary Syndromes Writing Committee). J Am Coll Cardiol. 2001;38:2114–30.
8. Hendel RC, Budoff MJ, Cardella JF, et al. ACC/AHA/ACR/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SIR 2008 key data elements and definitions for cardiac imaging: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Cardiac Imaging). J Am Coll Cardiol. 2009;53:91–124.
9. McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). J Am Coll Cardiol. 2004;44:475–95.
10. Radford MJ, Arnold JM, Bennett SJ, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with chronic heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Heart Failure Clinical Data Standards). Circulation. 2005;112:1888–916.
11. Weintraub WS, Karlsberg RP, Tcheng JE, et al. ACCF/AHA 2011 key data elements and definitions of a base cardiovascular vocabulary for electronic health records: a report of the American College of Cardiology

Foundation/American Heart Association Task Force on Clinical Data Standards. J Am Coll Cardiol. 2011;58:202–22.
12. National Cardiovascular Data Registry. Available at: http://www.ncdr.com/webncdr/common/. Last updated January 1, 2011. Accessed February 4, 2011.
13. Radford MJ, Heidenreich PA, Bailey SR, et al. ACC/AHA 2007 methodology for the development of clinical data standards: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. J Am Coll Cardiol. 2007;49:830–7.
14. Rundback JH, Sacks D, Kent KC, et al. Guidelines for the reporting of renal artery revascularization in clinical trials. Circulation. 2002;106:1572–85.
15. Murphy TP, Hirsch AT, Ricotta JJ, et al. The Claudication: Exercise Vs. Endoluminal Revascularization (CLEVER) study: rationale and methods. J Vasc Surg. 2008;47:1356–63.
16. Murphy TP, Hirsch AT, Cutlip DE, et al. Claudication: Exercise Vs. Endoluminal Revascularization (CLEVER) study update. J Vasc Surg. 2009;50:942–5.
17. 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.
18. Murphy TP, Cooper CJ, Dworkin LD, et al. The Cardiovascular Outcomes with Renal Atherosclerotic Lesions (CORAL) study: rationale and methods. J Vasc Interv Radiol. 2005;16:1295–300.
19. National Institute of Neurological Disorders and Stroke Common Data Elements. Available at: http://www.ninds.nih.gov/research/clinical_research/toolkit/common_data_elements.htm. Accessed June 10, 2011.
20. Get With The Guidelines Stroke Program. Available at: http://www.heart.org/HEARTORG/HealthcareProfessional/GetWithTheGuidelinesHFStroke/GetWithTheGuidelinesStrokeHomePage/Get-With-The-Guidelines-Stroke-Home-Page_UCM_306098_SubHomePage.jsp. Accessed June 14, 2011.
21. Centers for Medicare and Medicaid Services. Place of Service Codes for Professional Services Database. Available at: http://www.cms.gov/manuals/downloads/clm104c26.pdf. Accessed August 11, 2011.
22. Executive summary: standards of medical care in diabetes—2011. Diabetes Care. 2011;34 Suppl 1:S4–10.
23. National Heart, Lung and Blood Institute–National Cholesterol Education Program. Available at: http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm. Accessed August 11, 2011.
24. Centers for Medicare & Medicaid Services. Health Information Technology for Economic and Clinical Health Act–Electronic Health Record Incentive Program; Final Rule. 2010. Available at: http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf Accessed August 11, 2011.
25. Easton JD, Saver JL, Albers GW, et al. Definition and evaluation of transient ischemic attack: a scientific statement for healthcare professionals from the American Heart Association/American Stroke Association Stroke Council; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Nursing; and the Interdisciplinary Council on Peripheral Vascular Disease. Stroke. 2009;40:2276–93.
26. Adams HP Jr, Bendixen BH, Kappelle LJ, et al. Classification of subtype of acute ischemic stroke: definitions for use in a multicenter clinical trial. Stroke. 1993;24:35–41.
27. Kolominsky-Rabas PL, Weber M, Gefeller O, et al. Epidemiology of ischemic stroke subtypes according to TOAST criteria: incidence, recurrence, and long-term survival in ischemic stroke subtypes: a population-based study. Stroke. 2001;32:2735–40.
28. Dolgin M. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, MA: Little, Brown & Co; 1994.
29. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis. 2002;39:S1–266.
30. Collins R, Burch J, Cranny G, et al. Duplex ultrasonography, magnetic resonance angiography, and computed tomography angiography for diagnosis and assessment of symptomatic, lower limb peripheral arterial disease: systematic review. BMJ. 2007;334:1257. Abstract.
31. Olin JW, Piedmonte MR, Young JR, et al. The utility of duplex ultrasound scanning of the renal arteries for diagnosing significant renal artery stenosis. Ann Intern Med. 1995;122:833–8.
32. Ferguson GG, Eliasziw M, Barr HW, et al. The North American Symptomatic Carotid Endarterectomy Trial: surgical results in 1415 patients. Stroke. 1999;30:1751–8.
33. Maniglia AJ, Han DP. Cranial nerve injuries following carotid endarterectomy: an analysis of 336 procedures. Head Neck. 1991;13:121–4.

KEY WORDS: ACCF/AHA Data Standards ■ clinical outcomes ■ peripheral atherosclerotic vascular disease ■ registries.

Appendix 1. Author Relationships With Industry and Other Entities—2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS Key Data Elements and Definitions for Peripheral Atherosclerotic Vascular Disease

Name	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Mark A. Creager, Chair	Brigham & Women's Hospital—Director, Vascular Center	• AstraZeneca • Biomarin • Genzyme • Roche • Merck • Vascutek	None	None	• Merck • Sanofi-aventis	• American Board of Vascular Medicine • Vascular Disease Foundation	None
Michael Belkin	Brigham & Women's Hospital—Chief of Vascular and Endovascular Surgery	None	None	None	None	None	None
Edward I. Bluth	Ochsner Clinic Foundation	None	None	None	None	None	None
Donald E. Casey, Jr	Atlantic Health—VP, Quality and Chief Medical Officer	None	None	None	None	None	None
Seemant Chaturvedi	Wayne State University—Director, Stroke Program	• Merck	• Boehringer-Ingelheim • BMS/Sanofi Pharmaceuticals	None	None	None	None
Michael D. Dake	Stanford University School of Medicine—Professor, Department of Cardiothoracic Surgery	None	• Abbott Vascular • Angiodynamics • Boehringer-Ingelheim • Cook • Cordis Endovascular • ev3 • Medtronic • WL Gore	None	None	None	None
Jerome L. Fleg	NHLBI, Division of Epidemiology and Clinical Applications—Medical Officer	None	None	• Bristol-Myers Squibb • General Electric	None	None	None
Alan T. Hirsch	University of Minnesota Medical School—Director, Vascular Medicine Program	• ev3 • Cytokinetics • Talecris	None	None	• Abbott Vascular* • BMS/Sanofi Pharmaceuticals* • Sanofi-aventis* • Summit Doppler	• AHA Scientific Council and Educational Committee (leadership role) • Vascular Disease Foundation	None
Michael R. Jaff	Massachusetts General Hospital—Director, Vascular Center	• Abbott Vascular • Access Closure • Arsenal Medical • Atheromed • Baxter Cell Therapies • Becker Venture Services Group* • Boston Scientific • Harvard Clinical Research Institute • IC Sciences • Medtronic Vascular • Micell • Nexeon Medical Systems • Sadra Medical • Vascular Therapies	None	• Hotspur • Icon Interventional • Primacea	None	• VIVA Physicians' Group	• 2009—Represented defendant—stroke and carotid artery disease
John A. Kern	University of Virginia Health Systems—Cardiothoracic Surgeon	None	None	None	None	None	None
David J. Malenka	Dartmouth Hitchcock Medical Center, Section of Cardiology—Professor of Medicine	None	None	None	• Abbott Vascular* • St. Jude Medical Foundation*	None	None
Edward T. Martin	Oklahoma Heart Institute—Director, Cardiovascular MRI	• Astellas Pharma • Siemens	None	None	• Siemens	None	None

(*Continued*)

Appendix 1. Continued

Name	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Emile R. Mohler III	University of Pennsylvania Health System—Professor of Medicine	• AMAG Pharmaceuticals • GlaxoSmithKline	• BMS/Sanofi Pharmaceuticals • Merck	None	• BMS/Sanofi Pharmaceuticals* • GlaxoSmithKline*	NIH*	None
Timothy Murphy	Rhode Island Hospital, Department of Diagnostic Imaging—Medical Director, Vascular Disease Research Center	• Bristol-Myers Squibb • GlaxoSmithKline	None	None	• Abbott Vascular* • Boston Scientific* • Cordis/Johnson & Johnson* • Otsuka Pharmaceuticals*	None	None
Jeffrey W. Olin	Mt. Sinai School of Medicine—Director, Vascular Medicine	• Fibromuscular Dysplasia Society of America • Genzyme	None	None	• Merck • BMS/Sanofi Pharmaceuticals	• Colorado Prevention Center	• 2009—Represented defendant—pulmonary embolism
Judith G. Regensteiner	University of Colorado School of Medicine—Director, Center for Women's Health Research	None	• BMS/Sanofi Pharmaceuticals	None	None	None	None
Robert H. Rossenwasser	Thomas Jefferson University Hospital for Neuroscience—Chair, Department of Neurological Surgery	None	None	None	None	None	None
Peter Sheehan	Mt. Sinai School of Medicine—Senior Faculty	None	• BMS/Sanofi Pharmaceuticals • Edwards Lifesciences • FoxHollow	None	None	None	None
Kerry J. Stewart	Johns Hopkins Bayview Medical Center—Director, Clinical/Research Exercise Physiology	• Boston Scientific • Medifast • Milner-Fenwick	None	None	• NIH*	None	None
Diane Treat-Jacobson	University of Minnesota School of Nursing—Associate Professor	None	• BMS/Sanofi Pharmaceuticals	None	• NHLBI*	None	None
Gilbert R. Upchurch, Jr	University of Virginia—Chief of Vascular and Endovascular Surgery	None	None	None	None	None	None
Christopher J. White	Ochsner Heart and Vascular Institute—Director	• Baxter	None	None	• Boston Scientific • Neovasc • St. Jude	• NCDR-Care Registry • SCAI	None
Jack A. Ziffer	Baptist Hospital South Florida—Corporate Vice President, Physician Enterprises. Radiology Associates of South Florida—President and CEO	• Lantheus	None	• Spectrum Dynamics	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% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted.

*Significant relationship.

AHA indicates American Heart Association; NCDR, National Cardiovascular Data Registry; NIH, National Institutes of Health; NHLBI, National Heart, Lung, and Blood Institute; and SCAI, Society for Cardiovascular Angiography and Interventions.

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Appendix 2. Peer Reviewer Relationships With Industry and Other Entities—2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS Key Data Elements and Definitions for Peripheral Atherosclerotic Vascular Disease

Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
David R. Holmes, Jr	ACCF—BOT	None	None	None	None	• Technology licensed from Mayo Clinic to Atritech	None
Richard Kovacs	ACCF—BOG	• Biomedical Systems • Cook • ECG Scanning Services • Eli Lilly • Essentialis • Intercept • Xenoport	None	None	None	None	None
William Hiatt	AHA Lead Reviewer	None	None	None	• Aastrom • Aldagen • BMS/Sanofi Pharmaceuticals • Cytokinetics • GlaxoSmithKline • Theravasc • Vermillion	None	None
Eric E. Smith	Task Force Lead Reviewer	None	None	None	• Canadian Institutes for Health Research Grants • Canadian Stroke Network • Hotchkiss Brain Institute • NIH	• AHA	None
Ricardo Cury	Official Reviewer—SCCT	• Astellas Pharma • GE Healthcare	None	None	• Astellas Pharma • GE Healthcare • Pfizer	• SCCT	None
Yung-Wei Chi	Official Reviewer—SVM	None	None	None	None	None	None
James Galloway	Official Reviewer—ADA	None	None	None	None	None	None
Jerry Goldstone	Official Reviewer—VDF	None	None	None	None	None	None
John A. Kaufman	Official Reviewer—ACR	None	None	None	None	None	None
Marjorie King	Official Reviewer—AACVPR	• Healthways	None	None	None	None	None
Debrah Kohlman-Trigoboff	Official Reviewer—SVN	None	None	None	None	None	None
Sanjoy Kundu	Official Reviewer—SIR	None	None	None	None	None	None
Giuseppe Lanzino	Official Reviewer—AANS	None	None	None	None	None	None
Scott Mitchell	Official Reviewer—STS	None	None	None	None	None	None
Martin Prince	Official Reviewer—SCMR	None	None	None	None	None	None
Diane M. Reid	Official Reviewer—NHLBI	None	None	None	None	None	None
Robert Schainfeld	Official Reviewer—SCAI	None	None	None	None	None	None
Joseph R. Schneider	Official Reviewer—SVS	None	None	None	None	None	None
Allen Taylor	Official Reviewer—SAIP	• Abbott	None	None	• Resverlogix	• CBCCT • SCCT • SAIP	None
Randal J. Thomas	Official Reviewer—ACP	None	None	None	None	None	None
Jeffrey L. Anderson	Content Reviewer	None	None	None	• Toshiba	• Academic Research Group • Astra-Zeneca • Deseret Foundation • Harvard University • NIH	• 2010—Represented defendant; stroke after ablation for atrial fibrillation
Diane Branks	Content Reviewer	None	None	None	None	None	None
Heather Gornik	Content Reviewer	None	None	• Zin Medical	• Zin Medical	• AHA • Fibromuscular Dysplasia Society of America • Summit Doppler Systems • SVM • VDF	None
Lee Green	Content Reviewer	None	None	None	None	None	None
Andrew J. Ringer	Content Reviewer	None	None	None	None	None	None

(*Continued*)

Appendix 2. Continued

Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Kim Smolderen	Content Reviewer	None	None	None	None	None	None
Sarah A. Spinler	Content Reviewer	None	None	None	None	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% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships 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.

AACVPR indicates American Association of Cardiovascular and Pulmonary Rehabilitation; ACCF—BOG, American College of Cardiology Foundation—Board of Governors; ACCF—BOT, American College of Cardiology Foundation—Board of Trustees; ACP, American College of Physicians; ACR, American College of Radiology; ADA, American Diabetes Association; AHA, American Heart Association; AANS, American Association of Neurological Surgeons; CBCCT, Certification Board of Cardiovascular Computed Tomography; NIH, National Institutes of Health; NHLBI, National Heart, Lung, and Blood Institute; SAIP, Society of Atherosclerosis Imaging and Prevention; SCAI, Society for Cardiovascular Angiography and Interventions; SCCT, Society for Cardiovascular Computed Tomography; SCMR, Society for Cardiovascular Magnetic Resonance; SIR, Society of Interventional Radiology; STS, Society of Thoracic Surgeons; SVM, Society of Vascular Medicine; SVN, Society of Vascular Nursing; SVS, Society of Vascular Surgery; and VDF, Vascular Disease Foundation.