

ACCF/AHA Clinical Data Standards

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

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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, assessment of outcomes, and conduct of 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 (EHRs) and to assess the applicability of research to clinical practice. The increasing national focus on adoption of certified EHRs along with financial incentives for providers to demonstrate “meaningful use” of those EHRs 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 mission of fostering optimal cardiovascular care and disease prevention and building healthier lives, free of cardiovascular diseases and stroke.

The specific goals of clinical data standards are

1. To establish a consistent, interoperable, and universal clinical vocabulary as a foundation for both clinical care and clinical research.
2. To promote the ubiquitous use of EHRs 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 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 creation of 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 would likely be required regarding study procedures and drug therapies.

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 privacy regulations, which went into effect in April 2003, have heightened all practitioners’ awareness of our professional commitment to safeguard our patients’ privacy. The Health Insurance Portability and Accountability Act privacy regulations¹ 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. Conversely, 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 committee were required to submit a disclosure form showing all such relationships that might be perceived as real or potential conflicts of interest. These statements were 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 are listed in Appendix 1. Official reviewers’ relationships with industry 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, comparison, 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 the 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, FAHA
Chair, ACCF/AHA Task Force on Clinical Data Standards

1. Introduction

The vision of a seamless care environment, namely the ability to deliver continuity of care in all patient contexts across the spectrum of caregivers and their respective environments through the efficient use of health information technology and interoperable data,² is slowly becoming a reality. To accomplish this vision, the coordination of multiple complex workflows, processes, and technologies is required. First is the universal use of patient-centric EHR solutions that contain all health-related information, including a subset of that information managed as discrete data.³ In close coordination, the ability to use the discrete data for multiple purposes to meet the needs of all stakeholders is also required. Key to accomplishing this is an authoritative master set of data elements that are globally accessible and broadly implemented.

On July 28, 2010, the Centers for Medicare and Medicaid Services published in the *Federal Register* a Notice of the Final Rule titled “Medicare and Medicaid Programs: Electronic Health Record Incentive Program.”⁴ On the same day, the Office of the National Coordinator for Health Information Technology published a companion Final Rule, “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology.”⁵ These 2 publications establish the requirements that hospitals and eligible professionals must meet to achieve “meaningful use” of EHR solutions and thus qualify for financial incentives as stipulated in the health information technology provisions of the American Recovery and Reinvestment Act of 2009.⁶

The tenets of meaningful use include the implementation and utilization of certified EHR solutions in a manner that promotes interoperable health information, improves the quality of health care and care coordination, and reports on quality measures. The functionality measures that define meaningful use (24 for hospitals and 25 for eligible professionals)^{4,5} are built on the premise of interoperable, clinically meaningful, and relevant discrete data. Anticipating the need for clinical data interchange, use of a standardized cardiovascular vocabulary was explicitly included in 2009 as a proposed roadmap requirement for cardiovascular specialty EHR certification by the Certification Commission for

Health Information Technology (CCHIT), with the actual data elements required for certification published as a specification in the “CCHIT Certified 2011 Cardiovascular Criteria” document.⁷

Compared with more mature or naturally discrete types of data concepts such as laboratory results,⁸ interoperability of data representing information acquired historically or during a patient encounter (eg, history, symptoms and signs of heart failure) remains rudimentary. Interoperability is defined at 2 levels: *functional* or *syntactical interoperability*, the ability of ≥ 2 systems to exchange information (involving hardware, software, operating systems, communications protocols, and all components that serve to move data from one system to another); and *semantic interoperability*, the ability to use the information that has been exchanged.⁹ The building block of semantic interoperability is the common data element.¹⁰ Fully formed data elements include metadata that define, delimit, and represent the concept of the data element, including associated permissible values. Standard definitions of distinct clinical concepts ensure semantic interoperability. In turn, semantic interoperability permits the seamless interaction of clinical (and administrative) processes across the continuum of care, including the ability to merge, compare, and leverage observations acquired across clinical encounters. Interoperable information at the data element level may be anticipated to stimulate the adoption and enhance performance of EHR solutions; the 2004 report of the President’s Information Technology Advisory Committee specifically cited the lack of standards at the data element level as a primary reason for the slow rate of adoption of EHRs.¹¹

The facilitation of learning an accountable healthcare system, with the translation of knowledge acquired during research into clinical practice, is likewise a national priority.¹² One of the greatest inefficiencies of current approaches to clinical and translational research is the absence of a unifying infrastructure with streamlined, 1-time data collection; common data terms; and cooperative use of data shared among researchers.¹³ Instead, clinical and research processes typically occur as independent parallel endeavors. For example, clinical evaluation findings and management decisions, with accompanying test results, can be documented in a clinic note; dictated into a letter and communicated to others; coded for reimbursement; keyed into multiple Web-based systems for quality reporting, Joint Commission activities, and clinical trials; and sometime later be extracted from patient records to support additional clinical or research needs. If uniform data standards and terms supported by all these disparate systems were in place, the data could be captured once in the clinical workflow and then be made available to all stakeholders.

Of note, this document is a slight departure from previous work of the ACCF/AHA Task Force on Clinical Data Standards¹⁴ in that quite intentionally none of the clinical definitions are original to this effort. Instead, this document is an aggregation of terms and a recapitulation of definitions from libraries of published data terms and other data sources. In addition to natural language definitions, the description of data elements in this standard couples the text definitions with complete machine-interpretable definitions, extending the investment in the creation of authoritative clinical definitions by rendering those definitions directly computer usable by EHR and other information technology solutions.

2. Methodology

2.1. Writing Committee Composition

The ACCF/AHA Task Force on Clinical Data Standards selected members for the writing committee. The writing committee consisted of 13 people with expertise in cardiovascular medicine, EHR technologies, and medical informatics, and included representation from adult and pediatric cardiovascular medicine and surgery.

2.2. Relationships With Industry and Other Entities

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 committee were required to complete and 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 and updated when changes occur. Authors' and peer reviewers' relationships with industry and other entities pertinent to this data standards document are disclosed in Appendixes 1 and 2, respectively. In addition, to ensure complete transparency, writing committee members' *comprehensive disclosure information*—including relationships not pertinent to this document—is available online as a supplement to this document.

2.3. Data Element Identification, Definitions and Attributes, and Consensus Development

ACCF/AHA data standards are team developed and vetted. Experts in cardiovascular medicine, EHR technologies, and medical informatics participated in the authoring of this set of data elements. Initiated as a reference project, a preliminary set of candidate terms was identified by the American College of Cardiology (ACC) Informatics Committee through face-to-face and conference call meetings, polls, and e-mail correspondence. From the outset, it was envisioned that the list would be the base cardiovascular terms that are universally applicable from primary care through subspecialty cardiovascular care, inclusive of the outpatient and inpatient environments, to facilitate the exchange of clinical information across the continuum of care. The ACC Informatics Committee requested that the ACCF/AHA Task Force on Clinical Data Standards formalize the effort according to the published process methodology.¹⁴ The task force established the writing committee for refinement and final vetting of the list of candidate terms and management of the informatics work product to complete the attributes sets associated with the terms. This was accomplished through a series of additional meetings, polls, and correspondence over 6 months in 2010, resulting in the vocabulary described in Section 3.

The intent of this initiative was to identify a base set of terms with maximal value according to at least one of the criteria described below. Specifically, the target was to identify terms that are to be available in every general purpose EHR, that are interoperable and reusable with every cardiovascular subspecialty EHR, and that are extendable and reusable in the clinical research and institutional, local, state, regional, and national registry and data interchange environments. Terms relevant to adult cardiovascular disorders with

a high prevalence and high burden (morbidity and mortality) were selected preferentially, notably coronary artery disease, valvular heart disease, heart failure, atrial fibrillation/atrial flutter, and serious arrhythmias. Stated in more colloquial terms, the focus of this effort was to identify the “low-hanging fruit.” As such, out of the thousands of potential cardiovascular terms, <100 data elements are included in this document.

For a data element to be included in the cardiovascular vocabulary for EHRs, it had to meet ≥ 1 of the following criteria:

- Represents a waypoint in clinical care, typically as a summary representation or critical element of a more extensive concept (eg, procedure type and date, key procedure finding or result).
- Facilitates the assessment of delivery of quality care (eg, data elements required for meaningful use quality reporting or appropriate use criteria assessment).
- Has proven value in outcomes modeling or prediction (eg, Thrombolysis in Myocardial Infarction [TIMI] risk score in acute coronary syndromes, Society of Thoracic Surgeons (STS) morbidity and mortality risk prediction for cardiothoracic surgery).
- Identifies implanted devices, particularly those that might be subject to recall by the US Food and Drug Administration (eg, pacemaker generator unit and pacemaker leads, prosthetic replacement valves).

Clinical definitions of the selected data elements are repeated verbatim where possible as previously reported in ACCF/AHA data standards documents and/or as fields within existing registries, particularly the ACC National Cardiovascular Data Registry (NCDR), the ACC PINNACLE Registry, the AHA Get With The Guidelines Registry, and the STS National Database.^{15–22} Source documents (noted in the Source column of each data standard table) included the “ACC/AHA/HRS 2006 Key Data Elements and Definitions for Electrophysiological Studies and Procedures,”¹⁶ the “American College of Cardiology Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes,”¹⁷ the “ACC/AHA/ACR/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SIR 2008 Key Data Elements and Definitions for Cardiac Imaging,”¹⁸ the “ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Atrial Fibrillation,”¹⁹ and the “ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Chronic Heart Failure.”²⁰ Allowed values for each data element, such as grades of mitral regurgitation or abbreviations of the names of imaging studies, were culled from the same literature sources and are noted in the Value Domain column of each table.

A key focus is to perform the informatics work to build the portfolio of attributes for each of the data elements according to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 11179 standard,^{23,24} principally to facilitate adoption of these elements by the EHR vendor community. The ISO 11179 metadata repository standard provides a standard grammar and syntax for describing data elements and associated metadata that results in unambiguous representation and interpretation of data. For example, Appendix 3 illustrates the description of the data element New York Heart

Association (NYHA) class. The writing committee, in collaboration with informaticists at the ACC and Duke Clinical Research Institute, Durham, NC, will author the attributes for each of the data elements. This attribute set includes (as appropriate to the individual element) the preferred (longhand) name of the data element, a persistent (and universal) set of metadata tags, the unique identifiers, definition, constituent source of vocabulary, permissible values, data type, units, classification, links or relationships, purpose, and citation and an indication of how the data element is measured. Additionally, administrative attributes, such as steward, authority, status, and version date, are included. For the metadata tags and identifiers, we recommend the use of the construct of the National Institutes of Health/National Cancer Institute Data Standards Registry and Repository,²⁵ informed by the existing data dictionaries of the Duke Information System for Cardiovascular Care, ACC NCDR, ACC PINNACLE Registry, and AHA Get With The Guidelines Registry. Also note that in this publication, the data element “definition” frequently cross-references other (external) resource materials rather than attempting to provide a complete, self-standing definition; the complete definition can be found in the National Cancer Institute Data Standards Registry and Repository.

2.4. Relation to Other Standards

As described previously, the writing committee reviewed available published data standards, including those developed for heart failure, atrial fibrillation, electrophysiology, acute coronary syndromes, and imaging, along with data definitions used in several national registries.^{15–22} The writing committee felt that it was the responsibility of this multidisciplinary group to identify (but not author) a single best definition for the selected data elements to facilitate the uniform adoption of these terms by the clinical, clinical and translational research, regulatory, quality and outcomes, and EHR communities. Some adjustments to existing published definitions were made to eliminate verbiage not relevant to the definition itself (eg, instructions such as the phrase “indicate whether the patient has ...” have been eliminated). In these cases, the writing committee retained only the definition proper.

The writing committee believes that the ACCF/AHA should be the steward, that is, the organizations taking responsibility for a data element, for terms that are explicitly cardiovascular (eg, angina class, mitral valve stenosis). Terms specific to other disciplines (eg, chronic kidney disease) should be the responsibility of the respective society; generic terms (eg, systolic blood pressure) that are implicit and sufficiently commoditized could be the responsibility of either the ACCF/AHA or other society or organization that assumes stewardship. However, to advance this initiative, the ACCF/AHA Task Force on Clinical Data Standards has assumed the responsibility for the terms without another identified steward in the National Cancer Institute Data Standards Registry and Repository, pending assumption of that responsibility by another society or organization.

2.5. Peer Review, Public Review, and Board Approval

The cardiovascular data elements and definitions were independently reviewed by official appointees of the ACC, AHA, and ACCF/AHA Task Force on Clinical Data Standards. To increase its applicability, this document was posted on the ACC Web site

for a 30-day public comment period from November 5, 2010, through December 5, 2010. The document was then approved by the ACCF Board of Trustees on March 11, 2011, and by the AHA Science Advisory and Coordinating Committee on March 14, 2011. The writing committee anticipates that these data standards will require review and updating, just as with other published guidelines, performance measures, and appropriateness criteria. The writing committee will review the set of data elements on a periodic basis, starting with the anniversary of publication of the standards, to ascertain whether modifications should be considered.

2.6. Intended Use

The writing committee anticipates that the cardiovascular vocabulary for EHRs will be the universal and base set of cardiovascular terms to be implemented in all EHR solutions. There is not an attempt to provide a comprehensive or complete list of terms; instead, the goal is to identify terms that have maximal clinical and research utility across the widest spectrum of clinical settings. An emphasis on harmonization should be evident, typically favoring the most recent consensus publication. As such, these data standards will prove useful in several settings:

1. *Clinical care*, particularly transitions of care between and among providers and between outpatient and hospital settings. Data standards will improve communication and care coordination, reduce redundant data collection, and enable clinical decision support and disease management tools.
2. *Clinical workflow*, specifically facilitating a “floor” standard regarding the collection of discrete data elements in the context of caring for the patient with cardiovascular disease. Discreet data collection is critical to the success of implementation of any EHR and is required to meet the goals of data collection and exchange. In this regard, the number of defined data elements has been limited to minimize the documentation burden on the clinical community.
3. *Clinical query*, such as device recalls or changes in therapy predicated by the findings of well-controlled trials or provider notification by regulatory authorities.
4. *Quality assessment/performance measurement*, inclusive of the data elements for quality reporting for meaningful use, along with reporting to other parties such as care organizations, payers, regulators, consumers, and national registries, such as the ACC NCDR and AHA’s Get With The Guidelines Registry.
5. *Clinical research*, including registries, prospective observational and longitudinal studies, and randomized controlled trials. Meta-analyses will be particularly strengthened by consistently implemented data elements across EHR systems.

A modular approach to the use of these terms is implicit. The intent is not to require the EHR vendor community to create a “cardiovascular module” that incorporates these EHR data elements but instead to have the terms tightly integrated within the body of the EHR solution, with the terms used where appropriate on an as-needed basis. Certain data definitions are applicable only to specific situations, such as the coded mitral regurgitation grading result of a ventriculogram, echocardiogram, or magnetic resonance study; outside of this context, inclusion of this field in an EHR would be nonsensical.

Furthermore, although pediatric cardiology representation was involved in the creation of these data standards, these standards are not intended to be the primary source of data standards for pediatric cardiology EHRs. Data standards specific to pediatric and congenital cardiology are in development. The data standards in this document, however, can stand alongside pediatric standards, with the intent of eventual interoperability.

3. Cardiovascular Data Elements and Definitions for Electronic Health Records

3.1. Demographic, Administrative, and Diagnostic Data

The writing committee explicitly elected not to include patient identification, demographic, and administrative information such as patient sex or site of service, diagnosis, and other fundamental concept terms, including data by specific medication, as defined data elements. Comprehensive EHR solutions are anticipated to collect this information as discrete data. Furthermore, a robust solution for patient identification (eg, the

unique patient identifier) is a universal requirement, whether within the context of the EHR of an individual practice or the registry aggregation of information across multiple disparate inpatient and ambulatory encounters. Although patient age, sex, race, and ethnicity are key elements in various risk prediction models, these data elements are expected to be generically available in all EHR solutions and therefore have not been listed. Similarly, because much of meaningful use is constructed around the problem list, diagnosis is not included as a defined data element, as the presence of a codified problem list is assumed.

3.2. History and Physical Examination

From the myriad of candidate terms, the data elements chosen for inclusion in Table 1 are those with predictive value in risk models of acute and chronic cardiovascular disease, particularly acute coronary syndromes, ST-segment elevation acute myocardial infarction, heart failure, and sudden death. Information about the medical history and risk factors is key in appropriate use assessment, quality-performance measurement, clinical research, and

Table 1. History and Physical Examination Elements

Data Field	Definition	Value Domain	Notes	Source
<i>Current Status</i>				
Chest pain (angina) or anginal equivalent	Chest pain, other discomfort, dyspnea, or other sign or symptom possibly, probably, or definitely consistent with myocardial ischemia or infarction: <ul style="list-style-type: none"> ● Noncardiac: signs/symptoms inconsistent with myocardial ischemia ● Atypical: signs/symptoms possibly consistent with myocardial ischemia but not typical of classical angina pectoris (or anginal equivalent) ● Stable angina: angina pectoris (or anginal equivalent) without a recent change in frequency or pattern. Angina is relieved by rest and/or sublingual/transdermal medications. ● Variant (synonym: Prinzmetal angina, coronary vasospasm): angina pectoris (or anginal equivalent) that usually occurs spontaneously and, unlike typical angina, nearly always occurs at rest and does not require physical exertion. It is frequently associated with transient ST-segment elevation. ● Unstable angina/NSTEMI: angina pectoris (or anginal equivalent) with any of the following features: <ul style="list-style-type: none"> –Symptoms at rest and prolonged, usually >20 min –New-onset symptoms of CCS grade III or grade IV severity –Recent acceleration of symptoms with an increase in severity of at least 1 CCS grade to CCS grade III or grade IV severity –Symptoms associated with positive biomarkers for myocardial necrosis but without ST elevation on ECG ● Acute STEMI 	Noncardiac Atypical Stable angina Variant Unstable angina/NSTEMI Acute STEMI [null]		ACCF/AHA Cardiac Imaging Data Standard ¹⁸
Angina grade [CCS]	To grade symptoms or signs in patients with suspected or presumed stable angina (or anginal equivalent) according to the CCS grading scale: <ul style="list-style-type: none"> ● Class I: ordinary physical activity, such as walking or climbing stairs, does not cause angina. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation. ● Class II: slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or climbing stairs after meals, or in cold, in wind, or under emotional stress, or only during the few hours after awakening. Angina occurs on walking >2 blocks on the level and climbing >1 flight of ordinary stairs at a normal pace and in normal conditions. ● Class III: marked limitation of ordinary physical activity. Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs in normal conditions and at a normal pace. ● Class IV: inability to perform any physical activity without discomfort—anginal symptoms may be present at rest. 	1 2 3 4 [null]		ACCF/AHA Acute Coronary Syndrome Data Standards ¹⁷ , Campeau L. Letter: grading of angina pectoris. <i>Circulation</i> . 1976;54:522–3. ²⁶
Heart failure class [NYHA]	To classify symptoms or signs in patients with suspected or presumed heart failure according to the NYHA classification scale: <ul style="list-style-type: none"> ● 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. 	1 2 3 4 [null]		The Criteria Committee of the New York Heart Association. In <i>Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels</i> . 9th ed. Boston, MA: Little, Brown & Co; 1994:253–6. ²⁷

(Continued)

Table 1. Continued

Data Field	Definition	Value Domain	Notes	Source
Syncope	Sudden loss of consciousness with loss of postural tone, not related to anesthesia, with spontaneous recovery as reported by patient or observer. Patients may experience syncope when supine.	Yes [No] [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶
Date of syncope	Indicate date of the most recent event if there is a history of >1 event.	Date [null]	Minimum data: year	ACCF/AHA Electrophysiology Data Standards ¹⁶
<i>Past History</i> (“History of ...”)				
Hypertension*	Current or previous diagnosis of hypertension, defined as any of the following: <ul style="list-style-type: none"> History of hypertension diagnosed and treated with medication, diet, and/or exercise On at least 2 separate occasions, documented blood pressure >140 mm Hg systolic and/or 90 mm Hg diastolic in patients without diabetes or chronic kidney disease, or blood pressure >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 	Yes [No] [null]		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Dyslipidemia	Current or previous diagnosis of dyslipidemia according to National Cholesterol Education Program criteria, defined as any 1 of the following: <ul style="list-style-type: none"> 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 	Yes [No] [null]		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Diabetes	History of diabetes diagnosed and/or treated by a physician. American Diabetes Association criteria include documentation of the following: <ul style="list-style-type: none"> Hemoglobin A1c ≥6.5%; or Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L); or 2-Hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during oral glucose tolerance test; or In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose level ≥200 mg/dL (11.1 mmol/L) This does not include gestational diabetes.	Yes—type 1 Yes—type 2 [No] [null]		ADA Position Statement: Standards of Medical Care in Diabetes—2011 ²⁸
Tobacco use*	Current or previous use of any tobacco product, including cigarettes, cigars, pipes, and chewing tobacco, captured as smoking status: <ul style="list-style-type: none"> Current everyday smoker Current some day smoker Former smoker Never smoker Smoker, current status unknown 	Current everyday smoker Current some day smoker Former smoker Never smoker Smoker, current status Unknown [null]		CMS Meaningful Use ²⁹
Chronic lung disease	Documented history of chronic lung disease (eg, chronic obstructive pulmonary disease, chronic bronchitis) or currently receiving long-term treatment with inhaled or oral pharmacological therapy (eg, beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid) for the indication of lung disease. Date of onset (first diagnosis) may be helpful.	Yes No [null]		ACCF/AHA Atrial Fibrillation Data Standards ¹⁹
Chronic kidney disease	Current or previous history of chronic kidney disease, captured as current status. Chronic kidney disease is defined as either kidney damage or GFR <60 mL/min/1.73 m ² for ≥3 months. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies: <ul style="list-style-type: none"> Stage 0—No known kidney disease Stage 1—Kidney damage with normal or high—GFR ≥90 mL/min/1.73 m² Stage 2—Kidney damage with mildly decreased—GFR 60–89 mL/min/1.73 m² Stage 3—Moderately decreased—GFR 30–59 mL/min/1.73 m² Stage 4—Severely decreased—GFR 15–29 mL/min/1.73 m² Stage 5—Kidney failure—GFR <15 mL/min/1.73 m² or on dialysis 	0 1 2 3 4 5 [null]		ACCF/AHA, NKF KDOQI Advisory Board. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis. 2002;39(suppl 2):S65. ³⁰
Dialysis	Requirement for dialysis treatment, including hemodialysis and peritoneal dialysis	Yes [No] [null]		
Illicit drug use	Documented history of current, recent, or remote abuse of any illicit drug (eg, cocaine, methamphetamine, marijuana) or controlled substance	Yes [No] [null]		ACCF/AHA Atrial Fibrillation Data Standards ¹⁹
HIV infection	HIV infection diagnosed by a physician or qualified medical-care provider documented in a medical record and based on the following laboratory criteria: <ul style="list-style-type: none"> Positive result from an HIV antibody screening test (eg, reactive EIA*) confirmed by a positive result from a supplemental HIV antibody test (eg, Western blot or indirect immunofluorescence assay test); or Positive result or report of a detectable quantity (ie, within the established limits of the laboratory test) from any of the following HIV virologic (ie, non-antibody) tests: <ul style="list-style-type: none"> HIV nucleic acid (DNA or RNA) detection test (eg, PCR) HIV p24 antigen test, including neutralization assay HIV isolation (viral culture) Oral reports of prior laboratory test results are not acceptable.	Yes [No] [null]		CDC—Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years—United States, 2008 ³¹

(Continued)

Table 1. Continued

Data Field	Definition	Value Domain	Notes	Source
Atrial arrhythmias	Current or previous history of any of the following atrial arrhythmias, captured as type of arrhythmia: <ul style="list-style-type: none"> • First detected AF • Paroxysmal AF: AF is self-terminating within 7 days of recognized onset • Persistent AF: AF is not self-terminating within 7 days or is terminated electrically or pharmacologically • Permanent AF: cardioversion failed or not attempted • Atrial flutter • Atrial tachycardia • Sick sinus syndrome 	AF, first detected AF, paroxysmal AF, persistent AF, permanent Atrial flutter Atrial tachycardia Sick sinus syndrome [No] [null]	Can select any of the above choices; "No" is exclusive	ACCF/AHA Electrophysiology Data Standards ¹⁶
Paroxysmal supraventricular tachycardia	Current or previous history of paroxysmal supraventricular tachycardia	Yes [No] [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶
Ventricular arrhythmias	Current or previous history of any of the following ventricular arrhythmias, captured as type of arrhythmia: <ul style="list-style-type: none"> • VT, sustained • VT, nonsustained • VF 	VT, sustained VT, nonsustained VF [No] [null]	Can select any of the VT/VF choices; "No" is exclusive	ACCF/AHA Chronic Heart Failure Data Standards ²⁰
Venous thromboembolism	Current or previous history of DVT or pulmonary embolism	Yes—DVT Yes—Pulmonary embolism [No] [null]		
Depression	Current or previous diagnosis of depression or documentation of a depressed mood or affect	Yes [No] [null]		ACCF/AHA Chronic Heart Failure Data Standards ²⁰
Coronary artery disease*	Current or previous history of any of the following: <ul style="list-style-type: none"> • Coronary artery stenosis $\geq 50\%$ (by cardiac catheterization or other modality of direct imaging of the coronary arteries) • Previous CABG surgery • Previous PCI • Previous MI 	Yes [No] [null]		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Cerebral artery disease	Current or previous history of any of the following: <ul style="list-style-type: none"> • Ischemic stroke: infarction of central nervous system tissue whether symptomatic or silent (asymptomatic) • TIA: transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia without acute infarction • Noninvasive or invasive arterial imaging test demonstrating $\geq 50\%$ stenosis of any of the major extracranial or intracranial vessels to the brain • Previous cervical or cerebral artery revascularization surgery or percutaneous intervention. <p>This does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy.</p>	Yes [No] [null]		ACCF/AHA Cardiac Imaging Data Standards ¹⁸ ; Nomenclature for Vascular Diseases ³² ; 2009 AHA/ASA Definition and Evaluation of Transient Ischemic Attack ³³
Peripheral artery disease	Current or previous history of peripheral artery disease (lower extremity from iliac to tibials and upper extremity from subclavian to brachials. Excludes renal, coronary, cerebral, and mesenteric vessels and aneurysms). Major symptoms can include <ul style="list-style-type: none"> • Claudication relieved by rest • Amputation for severe arterial vascular insufficiency • Vascular reconstruction, bypass surgery, or percutaneous revascularization in the arteries of the lower or upper extremities • Positive noninvasive test (eg, ankle brachial index ≤ 0.90, ultrasound, MR or CT imaging of $>50\%$ diameter stenosis in any peripheral artery (ie, subclavian, femoral, iliac) or angiographic imaging 	Yes [No] [null]		Nomenclature for Vascular Diseases ³²
Aorta disease	Current or previous history of disease of the thoracic, thoracoabdominal, or abdominal aorta (typically aneurysm)	Yes [No] [null]		Nomenclature for Vascular Diseases ³²
Renal artery disease	Current or previous history of disease of the main renal arteries or extrarenal branches	Yes [No] [null]		Nomenclature for Vascular Diseases ³²
Myocardial infarction	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: <ul style="list-style-type: none"> • Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least 1 value above the 99th percentile of the URL together with evidence of myocardial ischemia with at least 1 of the following: <ul style="list-style-type: none"> –Symptoms of ischemia –ECG 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 	Yes [No] [null]		Universal Definition of MI ³⁴

(Continued)

Table 1. Continued

Data Field	Definition	Value Domain	Notes	Source
	<ul style="list-style-type: none"> • Sudden unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST-segment 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 >3×99th 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 >5×99th 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 			
Date of myocardial infarction	Date of documented MI. Indicate the date of most recent MI if there is a history of more than one.	Date [null]	Minimum data is year	ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Sudden cardiac arrest	[Sudden] cardiac arrest is the sudden cessation of cardiac activity. The victim becomes unresponsive with no normal breathing and no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to sudden death. Cardiac arrest should be used to signify an event as described above that is reversed, usually by CPR and/or defibrillation or cardioversion or cardiac pacing. Sudden cardiac death should not be used to describe events that are not fatal.	Yes No [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶
Date of cardiac arrest	Date of documented resuscitated cardiac arrest	Date [null]	Minimum data is year	ACCF/AHA Electrophysiology Data Standards ¹⁶
Heart failure*	Indicate if there is physician documentation or a report that the patient has been in a state of heart failure. Heart failure is defined as physician documentation or a report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention, or the description of rales, jugular venous distention, pulmonary edema on physical examination, or pulmonary edema on chest x-ray presumed to be cardiac dysfunction. A low ejection fraction alone, without clinical evidence of heart failure, does not qualify as heart failure.	Yes [No] [null]		ACCF/AHA Acute Coronary Syndrome Data Standards ¹⁷ ; AR-G ²² ; STS Registry v2.70 ¹⁵
<i>Family History</i>				
Coronary artery disease	Indicate if the patient has/had any direct blood relatives (ie, parents, siblings, children) who have had any of the following diagnosed at age <55 y for male relatives or <65 y for female relatives: <ul style="list-style-type: none"> • Coronary artery disease (ie, angina, previous CABG or PCI) • MI • Sudden cardiac death without obvious cause If the patient is adopted or the family history is unavailable, code "No."	Yes [No] [null]		STS Registry v2.70 ¹⁵
Sudden cardiac death	A first-degree relative (ie, parent, sibling, child) documented to have died suddenly of presumed cardiac etiology without other obvious cause	Yes [No] [null]		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
<i>Patient Assessment</i>				
Systolic blood pressure	Systolic blood pressure in millimeters mercury		Numeric (mm Hg)	
Diastolic blood pressure	Diastolic blood pressure in millimeters mercury		Numeric (mm Hg)	
Weight	Measured actual weight in kilograms. To be converted from conventional units if needed.		Numeric (kg)	
Waist circumference	Average of 2 measurements in centimeters while subject is standing, one taken after inspiration and one after expiration. Measurement to be taken at the midpoint between the lowest rib and the iliac crest.	Numeric (cm)		ACCF/AHA Acute Coronary Syndrome Data Standards ¹⁷
Height	Measured in centimeters. To be converted from conventional units if needed.	Numeric (cm)		
Heart rate	Number of heartbeats over 1 min.	Numeric (bpm)		

*The data element/definition is a 2010 PQRI Measures data point.^{25a}

ACCF indicates American College of Cardiology Foundation; ADA, American Diabetes Association; AF, atrial fibrillation; AHA, American Heart Association; AIDS, acquired immune deficiency syndrome; AR-G, ACTION Registry-Get With the Guidelines; ASA, American Stroke Association; bpm, beats per minute; CABG, coronary artery bypass graft; CCS, Canadian Cardiovascular Society; CDC, Centers for Disease Control and Prevention; CPR, cardiopulmonary resuscitation; CT, computed tomography; DNA, deoxyribonucleic acid; DVT, deep venous thrombosis; ECG, electrocardiogram; EIA, enzyme immunoassay; GFR, glomerular filtration rate; HDL, high-density lipoprotein; HIV, human immunodeficiency virus; KDOQI, Kidney Diseases Outcomes Quality Initiative; LBBB, left bundle-branch block; LDL, low-density lipoprotein; MI, myocardial infarction; MR, magnetic resonance; NKf, National Kidney Fund; NSTEMI, non-ST-segment elevation myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PCR, polymerase chain reaction; PQRI, Physician Quality Reporting Initiative; RNA, ribonucleic acid; STEMI, ST-segment elevation myocardial infarction; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack; URL, upper reference limit; VF, ventricular fibrillation; and VT, ventricular tachycardia.

clinical care. The elements chosen are purposely intended to replicate commonly collected data elements and reflect current consensus guidelines on the classification of disease states. The value domain of these data elements purposely includes as optional the choices of “null” (and where appropriate, “no”) to reflect the typical workflow of documenting only pertinent positives (ie, charting by exception). Data elements in the vocabulary include physician-classified symptom scales (eg, NYHA classification of functional class and Canadian Cardiovascular Society classification of anginal severity). These may be supplemented by patient-reported outcome tools (eg, Kansas City Cardiomyopathy Questionnaire for heart failure and Seattle Angina Questionnaire for angina). The writing committee acknowledges that all potential elements are not included and that additional detail may be needed, depending on the use case.

3.3. Laboratory Results

Only 11 laboratory testing elements are listed in Table 2, reflecting the laboratory tests most likely to be followed

Table 2. Laboratory Results Elements

Data Field	Definition	Value Domain	Notes	Source
<i>Laboratory Testing</i>				
Total cholesterol*	1) Value, 2) units, and 3) date	Number Units Date		
Triglycerides*	1) Value, 2) units, and 3) date	Number Units Date		
LDL cholesterol*	1) Value, 2) units, and 3) date	Number Units Date		
HDL cholesterol*	1) Value, 2) units, and 3) date	Number Units Date		
Fasting blood sugar	1) Value, 2) units, and 3) date	Number Units Date		
Creatinine	1) Value, 2) units, and 3) date	Number Units Date		
BUN	1) Value, 2) units, and 3) date	Number Units Date		
Sodium	1) Value, 2) units, and 3) date	Number Units Date		
Hemoglobin	1) Value, 2) units, and 3) date	Number Units Date		
Hemoglobin A1c	1) Value, 2) units, and 3) date	Number Units Date		
Hematocrit	1) Value, 2) units, and 3) date	Number Units Date		

*The data element/definition is a 2010 PQRI Measures data point.^{25a}

BUN indicates blood urea nitrogen; HDL, high-density lipoprotein; LDL, low-density lipoprotein; and PQRI, Physician Quality Reporting Initiative.

longitudinally by cardiologists for the purpose of cardiovascular risk mitigation via direct interventional management of the laboratory abnormalities. These laboratory result data elements are useful for assessing the appropriate use of cardiovascular procedures, for quality-performance measurement, and for meaningful use reporting. As with elements of the history and physical, the writing committee acknowledges that the list is a limited subset of the universe of laboratory values with potential cardiovascular relevance. Laboratory measurements can be in Système International d’Unites (SI units; eg, mmol/L) or conventional units (eg, mg/dL).

3.4. Diagnostic and Therapeutic Procedures

Diagnostic and therapeutic cardiovascular procedures are central to the evaluation and management of patients with cardiovascular disease. Consistent with the other sections, chosen data elements include those with specific value in representing a waypoint of care (eg, procedure and date), in assessing process in delivery of quality care (eg, appropriate use criteria assessment), that are predictive of outcome (eg, key findings), or that identify implanted devices. The list is purposely limited (Table 3); the “ACC/AHA/ACR/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SIR 2008 Key Data Elements and Definitions for Cardiac Imaging” document provides a much more extensive list of data elements, specifically crafted from the perspective of authoring modality (procedure) reports.¹⁸ For example, the cardiac imaging standards and definitions document notes that when an exercise stress test is performed, the number of metabolic equivalent tasks achieved, the nature of induced chest pain, the maximum amount of ST-segment depression, changes in heart rate and blood pressure, and other parameters should be recorded as structured data. However, from an EHR perspective (the subject of this document), the data elements we have specified include the cardiac diagnostic procedure itself (eg, stress ECG), date of the procedure, pretest probability, and stress test result (positive, negative, indeterminate, and adequate or inadequate). The clinician is referred to the procedure report for additional detail if needed.

Similarly, for therapeutic procedures, only key data elements facilitating clinical care are stressed. For example, for a percutaneous coronary intervention (PCI), in addition to the notation of PCI, the data to be handled as discrete data would include the date of the procedure, lesion treated, and stent-specific information. The original procedure report again would need to be reviewed should more information be required.

Two specific concepts deserve specific mention. Although the data elements “cardiac diagnostic procedure” and “cardiac therapeutic procedure” are listed separately in Table 3, they can be blended as a single concept at an operational level (eg, left-heart catheterization, PCI). Furthermore, the data element set to associate with the concept of a procedure should only be that appropriate to the test. The reader is referred to the applicable reference document (eg, for PCI, the cardiac imaging standards and definitions document¹⁸) to determine which data elements belong together.

Table 3. Diagnostic and Therapeutic Procedures Elements

Data Field	Definition	Value Domain	Notes	Source
<i>Diagnostic Procedures</i>				
Cardiac diagnostic procedure	<p>Procedure to evaluate the structure and/or function of the heart. This lexicon emphasizes common names for procedure concepts even when various subprocedures make up the concept (eg, transthoracic echocardiogram, left-heart catheterization), rather than an unbundled listing of the subprocedures that make up the procedure (eg, CPT code listing). The procedure of greater complexity should be chosen when the concept of greater complexity is inclusive of the one of lesser complexity (eg, stress echocardiography is inclusive of TTE). Selected results data (listed in the next section below) are to be linked to the study.</p> <ul style="list-style-type: none"> ● ECG* ● Holter monitor ● Event monitor ● Electrophysiology study ● Transthoracic echocardiography ● Transesophageal echocardiography ● Stress ECG ● Stress echocardiography ● Nuclear stress test ● MRI ● Stress MRI ● Cardiac MR angiography ● Cardiac CT angiography ● CT (noncontrast) ● PET ● Right-heart catheterization ● Biopsy of the right ventricle ● Left-heart catheterization 	ECG Holter monitor Event monitor EPS TTE TEE Stress ECG Stress echo Nuclear stress test MRI Stress MRI Cardiac MR angiography Cardiac CT angiography Computerized tomography (noncontrast) CTA PET RHC RVBx LHC	Values are mutually exclusive from one diagnostic area to the next but not within one diagnostic modality.	ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Date of cardiac diagnostic procedure	Date of cardiac diagnostic procedure	Date	Requires month/year; day if available	ACCF/AHA Cardiac Imaging Data Standards ¹⁸
<i>Diagnostic Procedure Results</i>	<i>Notes: This is purposely only a partial listing of all possible results, focusing on the key results with critical diagnostic, therapeutic, or prognostic significance. When reported, the result is linked to the diagnostic test.</i>			
Ejection fraction (quantitative)*	The calculated resting LVEF as either a percentage value or the midpoint value when a range is reported	Number		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Ejection fraction (qualitative)*	The estimated resting LVEF as a qualitative score: <ul style="list-style-type: none"> ● Hyperdynamic: >70% ● Normal: 50%–70% (midpoint 60%) ● Mild dysfunction: 40%–49% (midpoint 45%) ● Moderate dysfunction: 30%–39% (midpoint 35%) ● Severe dysfunction: <30% (midpoint 20%) 	Hyperdynamic Normal Mild dysfunction Moderate dysfunction Severe dysfunction		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Left ventricle size, end diastole (quantitative)	Short-axis measurement of the left ventricular chamber size at end diastole, in centimeters	Number (cm)		
Left ventricle size, end systole (quantitative)	Short-axis measurement of the left ventricular chamber size at end systole, in centimeters	Number (cm)		
Left atrium size (quantitative)	Size of the left atrium, in centimeters	Number (cm)		

(Continued)



Table 3. Continued

Data Field	Definition	Value Domain	Notes	Source
Aortic valve area	Severity of stenosis of the aortic valve, in square centimeters	Number (cm ²)		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Aortic valve regurgitation	Severity of regurgitation through the aortic valve: <ul style="list-style-type: none"> ● None ● Mild ● Moderate ● Severe 	None Mild Moderate Severe		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Mitral valve area	Severity of stenosis of the mitral valve, in square centimeters	Number (cm ²)		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Mitral valve regurgitation	Severity of regurgitation through the mitral valve: <ul style="list-style-type: none"> ● None ● Mild ● Moderate ● Severe 	None Mild Moderate Severe		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Stress test result	Result of functional cardiac testing evaluating for evidence of myocardial ischemia	Normal Abnormal Indeterminate		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Myocardium ischemic amount (qualitative)	Qualitative amount of myocardium estimated to be ischemic per functional study (eg, echocardiogram, MRI, SPECT)	None Small Medium Large		
Coronary calcium score	Agatston score of estimate of extent of coronary calcification by coronary CT	Number		ACCF/AHA Cardiac Imaging Data Standards ¹⁸
Coronary artery number of diseased vessels (excludes left main disease)	Number of major epicardial vessels and major branches of epicardial vessels with $\geq 70\%$ luminal obstruction: <ul style="list-style-type: none"> ● None ● 1 ● 2 ● 3 	0 1 2 3		
Left main coronary artery stenosis	Left main coronary disease is present when there is $\geq 50\%$ compromise of vessel diameter.	Yes No [null]		STS Registry v2.70 ¹⁵
Proximal LAD coronary artery stenosis	Luminal narrowing of the proximal LAD at the point of maximal stenosis is $\geq 70\%$.	Yes No [null]		
Third-degree AV block (complete heart block)	Heart rhythm characterized by independent atrial and ventricular complexes with atrial rate usually exceeding ventricular rate	Yes No [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶
Left bundle-branch block	ECG pattern of LBBB characterized by QRS duration of ≥ 120 ms, delayed onset of intrinsicoid deflection in leads 1, V ₅ , and V ₆ ≥ 60 ms; broad and notched or slurred R waves in I, aVL, V ₅ , and V ₆ ; RS or QS complexes in right precordial leads; ST segment and T waves in opposite polarity to the major QRS deflection	Yes No [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶
Intraventricular conduction delay (nonspecific)	ECG pattern of intraventricular conduction delay characterized by QRS duration ≥ 110 ms that does not meet morphology criteria of LBBB or RBBB	Yes No [null]		ACCF/AHA Electrophysiology Data Standards ¹⁶

(Continued)

Table 3. Continued

Data Field	Definition	Value Domain	Notes	Source
<i>Therapeutic Procedures</i>				
Cardiac therapeutic procedure	<p>Procedure to treat pathologic structural/pathophysiological functional disorder of the heart. This lexicon emphasizes common names for procedure concepts even when various subprocedures make up the concept (eg, CRT, PCI) rather than an unbundled listing of the subprocedures that make up the procedure (eg, CPT code listing). The procedure of greatest complexity should be chosen when the concept of greater complexity is inclusive of the one of lesser complexity (eg, ICD is inclusive of pacemaker). Selected results data (listed in the next section below) are to be linked to the study:</p> <ul style="list-style-type: none"> ● Ablation, atrial (eg, for AF) ● Ablation, ventricular (eg, for VT) ● Ablation, other (eg, reciprocating tachycardia ablation) ● Pacemaker ● ICD ● CRT ● Lead extraction ● Electrical cardioversion ● Chemical cardioversion ● PCI ● Septal ablation ● Transcatheter aortic valve implant ● Closure device, atrial ● Closure device, ventricular ● CABG ● Aortic balloon valvotomy ● Aortic valve replacement ● Mitral valve repair ● Mitral valve replacement ● Mitral balloon valvotomy ● Mitral commissurotomy ● Percutaneous mitral repair ● Tricuspid valve repair ● Tricuspid valve replacement ● Pulmonic valvuloplasty ● Pulmonary valve replacement ● Surgical maze ● Pericardiocentesis ● Pericardial window ● Pericardial stripping ● Left atrial appendage occlusion ● Ventricular aneurysm resection ● Left VAD ● Right VAD ● Heart transplant 	<p>Ablation, atrial Ablation, ventricular Ablation, other Pacemaker ICD CRT Lead extraction Electrical cardioversion Chemical cardioversion PCI Septal ablation Transcatheter aortic valve implant Closure device, atrial Closure device, ventricular CABG Aortic balloon valvotomy Aortic valve replacement Mitral valve repair Mitral valve replacement Mitral balloon valvotomy Mitral commissurotomy Percutaneous mitral repair Tricuspid valve repair Tricuspid valvuloplasty Pulmonary valvuloplasty Pulmonary valve replacement Surgical maze Pericardiocentesis Pericardial window Pericardial stripping Left atrial appendage occlusion Aneurysmectomy VAD, left VAD, right Heart transplant</p>	<p>Values are mutually exclusive from one therapeutic area to the next but not within one therapeutic modality.</p>	
Date of therapeutic procedure	Date of cardiac therapeutic procedure	Date (requires month/year; day if available)		

(Continued)



Table 3. Continued

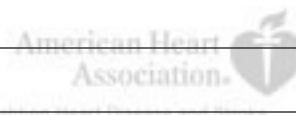
Data Field	Definition	Value Domain	Notes	Source
<i>Therapeutic Procedure Device Implants</i>				
Implanted device	Type of device implanted <ul style="list-style-type: none"> ● Single-chamber pacemaker ● Dual-chamber pacemaker ● Biventricular pacemaker ● Cardioverter-defibrillator ● Cardioverter-defibrillator with resynchronization ● Atrial lead, right ● Atrial lead, left ● Ventricular lead, right ● Ventricular lead, left ● Bare-metal stent ● Drug-eluting stent ● Closure device, atrial ● Closure device, ventricular ● Aortic valve, mechanical ● Aortic valve, tissue ● Aortic valve, transcatheter ● Mitral valve, mechanical ● Mitral valve, tissue ● Left VAD ● Right VAD ● Total artificial heart 	Single-chamber pacemaker Dual-chamber pacemaker Biventricular pacemaker Cardioverter-defibrillator Cardioverter-defibrillator–resynchronization Atrial lead, right Atrial lead, left Ventricular lead, right Ventricular lead, left Bare-metal stent Drug-eluting stent Closure device, atrial Closure device, ventricular Aortic valve, mechanical Aortic valve, tissue Aortic valve, transcatheter Mitral valve, mechanical Mitral valve, tissue VAD, left VAD, right Total artificial heart	Each implanted device is to be associated with a manufacturer, model, serial number, and device parameters as appropriate for the device.	
Manufacturer	Manufacturer of the implanted device	Text		
Model	Model of the implanted device	Text		
Serial number	Serial number of the implanted device, if applicable	Text		
Device parameters	Key manufacturer's specification of the implanted device (eg, size of stent)	Text		
Coronary lesions treated	Per the CASS coronary artery segment map, lesion(s) treated during a PCI procedure.	Text		
Coronary graft anastomoses	Per the CASS coronary artery segment map, anastomoses placed during a CABG procedure.	Text		

*The data element/definition is a 2010 PQRI Measures data point.^{25a}

ACCF indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; AV block, atrioventricular block; CABG, coronary artery bypass graft; CASS, Coronary Artery Surgery Study; CPT, Code of Procedural Terminologies; CRT, cardiac resynchronization therapy; CT, computed tomography; CTA, computed tomography angiography; ECG, electrocardiogram; EPS, electrophysiological study; ICD, implantable cardioverter-defibrillator; LAD, left anterior descending; LBBB, left bundle-branch block; LHC, left-heart catheterization; LVEF, left ventricular ejection fraction; MR, magnetic resonance; MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention; PET, positron emission tomography; PQRI, Physician Quality Reporting Initiative; RBBB, right bundle-branch block; RHC, right-heart catheterization; RVBx, right ventricular endomyocardial biopsy; SPECT, single-photon emission computed tomography; STS, Society of Thoracic Surgeons; TEE, transesophageal echocardiogram; TTE, transthoracic echocardiogram; VAD, ventricular assist device; and VT, ventricular tachycardia.

The writing committee also notes that the ejection fraction, even with a multitude of limitations, is pivotal to patient care, risk modeling, decision support, disease management, and quality reporting. We wish to reiterate several of the comments and conventions of the cardiac imaging writing group¹⁸ as being highly relevant to the cardiovascular EHR vocabulary. The quantitative determination of systolic function occurs with substantial variability between modalities and with different reference ranges by modality. Nonetheless, this quantitative number is purposely included as a single (derived) data element irrespective of modality. Although the original source data and any representation should maintain a linkage between the calculated ejection fraction and the originating modality, the derived ejection fraction is intended

to be a single data element regardless of source so that it can be displayed and computed upon in a longitudinal manner, independent of modality. In addition, qualitative systolic function is to be graded in only 4 categories: normal, mildly reduced, moderately reduced, and severely reduced, with the ranges of quantitative values authored by the cardiac imaging writing group representing differing degrees of qualitative left ventricular dysfunction. For example, for purposes of reporting a quantitative value, the midpoint of the range may be used, for example, moderate left ventricular dysfunction is reported as 35%. Furthermore, quantitative ejection fraction can be reported as a specific value (eg, 58%) or a 5% range (eg, 30% to 35%), with the midpoint of a range to be used for EHR data collection and storage purposes.



3.5. Pharmacological Therapy

Pharmacological therapy data elements (Table 4) are central to many quality reporting initiatives and meaningful use and are intended to capture whether or not the patient is currently receiving or is otherwise prescribed any member of the medication class in question in the context of the patient encounter. The value domain for pharmacological therapy data elements is derived from the National Quality Forum's Quality Data Set. A response of "yes" is intended to be automatically generated if any member of the medication class is prescribed. A response of "no" is the default in the absence of a prescription for the medication class. The generic value "no" could be replaced by a clinician with "no exclusion" or "no exception" where appro-

priate (this would require active intervention on the part of the clinician). Typical exclusions include medication allergy or other medication intolerance. Typical exceptions include contraindications to therapy, such as the patient in heart failure who otherwise qualifies for beta-blocker therapy except for a resting heart rate of 45 bpm. EHR vendors are strongly encouraged to design systems to autoreport this particular set of variables rather than require clinician input, particularly when a medication is prescribed.

3.6. Outcomes

The writing committee elected to focus on all-cause mortality and high-morbidity hospitalization outcomes likely to be

Table 4. Pharmacological Therapy Data Elements

Data Field	Definition	Value Domain	Notes	Source
<i>Pharmacological Therapy</i>	<i>Note: The data elements in this section are derived from the patient medication list (rather than explicitly entered by the provider) to capture whether or not the patient is currently receiving the pharmacological therapy or if the pharmacological therapy was prescribed during the present encounter.</i>			
Aspirin*		Yes No No—exclusion No—exception		
P2Y12 blocker		Yes No No—exclusion No—exception		
Nonsteroidal anti-inflammatory	This does not include aspirin or cyclooxygenase 2 inhibitors.	Yes No No—exclusion No—exception		
Steroid, systemic	This does not include topical or inhaled steroid therapy.	Yes No No—exclusion No—exception		
Cyclo-oxygenase 2 inhibitor		Yes No No—exclusion No—exception		
Anticoagulant*		Yes No No—exclusion No—exception		
Beta blocker*		Yes No No—exclusion No—exception		
Alpha blocker		Yes No No—exclusion No—exception		

(Continued)

Table 4. Continued

Data Field	Definition	Value Domain	Notes	Source
ACE inhibitor*		Yes		
		No		
		No—exclusion		
		No—exception		
ARB		Yes		
		No		
		No—exclusion		
		No—exception		
Calcium channel blocker		Yes		
		No		
		No—exclusion		
		No—exception		
Antiarrhythmics		Yes		
		No		
		No—exclusion		
		No—exception		
Direct renin inhibitors		Yes		
		No		
		No—exclusion		
		No—exception		
Nitrate		Yes		
		No		
		No—exclusion		
		No—exception		
Statin*		Yes		
		No		
		No—exclusion		
		No—exception		
Nonstatin antilipidemic*		Yes		
		No		
		No—exclusion		
		No—exception		
Insulin		Yes		
		No		
		No—exclusion		
		No—exception		
Noninsulin hypoglycemic		Yes		
		No		
		No—exclusion		
		No—exception		
Diuretic		Yes		
		No		
		No—exclusion		
		No—exception		
		Yes		
		No		
Aldosterone receptor antagonist		No—exclusion		
		No—exception		

*The data element/definition is a 2010 PQRI Measures data point.^{25a}

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; and PQRI, Physician Quality Reporting Initiative.



Table 5. Outcomes Data Elements

Data Field	Definition	Value Domain	Notes	Source
Outcomes				
Death	Death includes all deaths regardless of etiology.	Yes		ACCF/AHA Atrial Fibrillation Data Standards ¹⁹
		No		
Date of death		Date		

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

captured and coded for administrative and billing purposes (Table 5). Ongoing efforts through the National Cardiovascular Research Infrastructure project and by the US Food and Drug Administration as noted below are delineating and detailing extended concepts of outcomes assessment in both the inpatient and outpatient arenas and should become available in 2011.

4. Formalization of Terms and Extension of Vocabulary

The foundational work to create a base cardiovascular data element set for EHRs is a component of a broader program to address the cardiovascular data standard needs of the clinical community, secondary stakeholders, ACCF, and AHA. The overarching program is being coordinated under 2 organizations chartered to lead the development of clinical data standards for health care and research: Health Level Seven International (HL7) and the Clinical Data Interchange Standards Consortium. This project will organize multiple complementary initiatives to generate a single set of materials authoritatively defining the data requirements of the cardiovascular domain. Specifically, the initiatives include the ACCF/AHA cardiovascular data elements described herein, the US Food and Drug Administration effort to define cardiovascular endpoint definitions and associated data used in regulated clinical trials, and the joint ACC/Duke Clinical Research Institute collaboration to build a national cardiovascular research infrastructure. These initiatives, working in concert, will collectively result in a common set of data elements, with associated controlled terminology, relationships, and workflow context that are vetted and balloted via the Clinical Data Interchange Standards Consortium, Clinical Data Acquisition Standards Harmonization, and HL7 Clinical Interoperability Council standards development processes and managed in a standards-based, publicly accessible data element repository.

The ultimate destination, the interchange of clinical data acquired as an integrated process in the delivery of care, has multiple potential benefits: reuse of data for decision support and disease management, dissemination of consistent and well-formed data to stakeholders, and efficiencies in integration of clinical processes into the clinical research context. Underpinning these goals is the requirement of semantic interoperability, a goal we believe will be furthered by the adoption of common cardiovascular data elements for EHRs.

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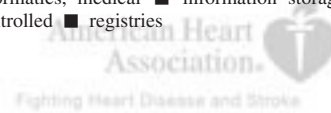
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KEY WORDS: AHA Scientific Statements ■ cardiology ■ electronic health records ■ informatics, medical ■ information storage and retrieval ■ vocabulary, controlled ■ registries



Appendix 1. Author Relationships With Industry and Other Entities—ACCF/AHA 2011 Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for Electronic Health Records

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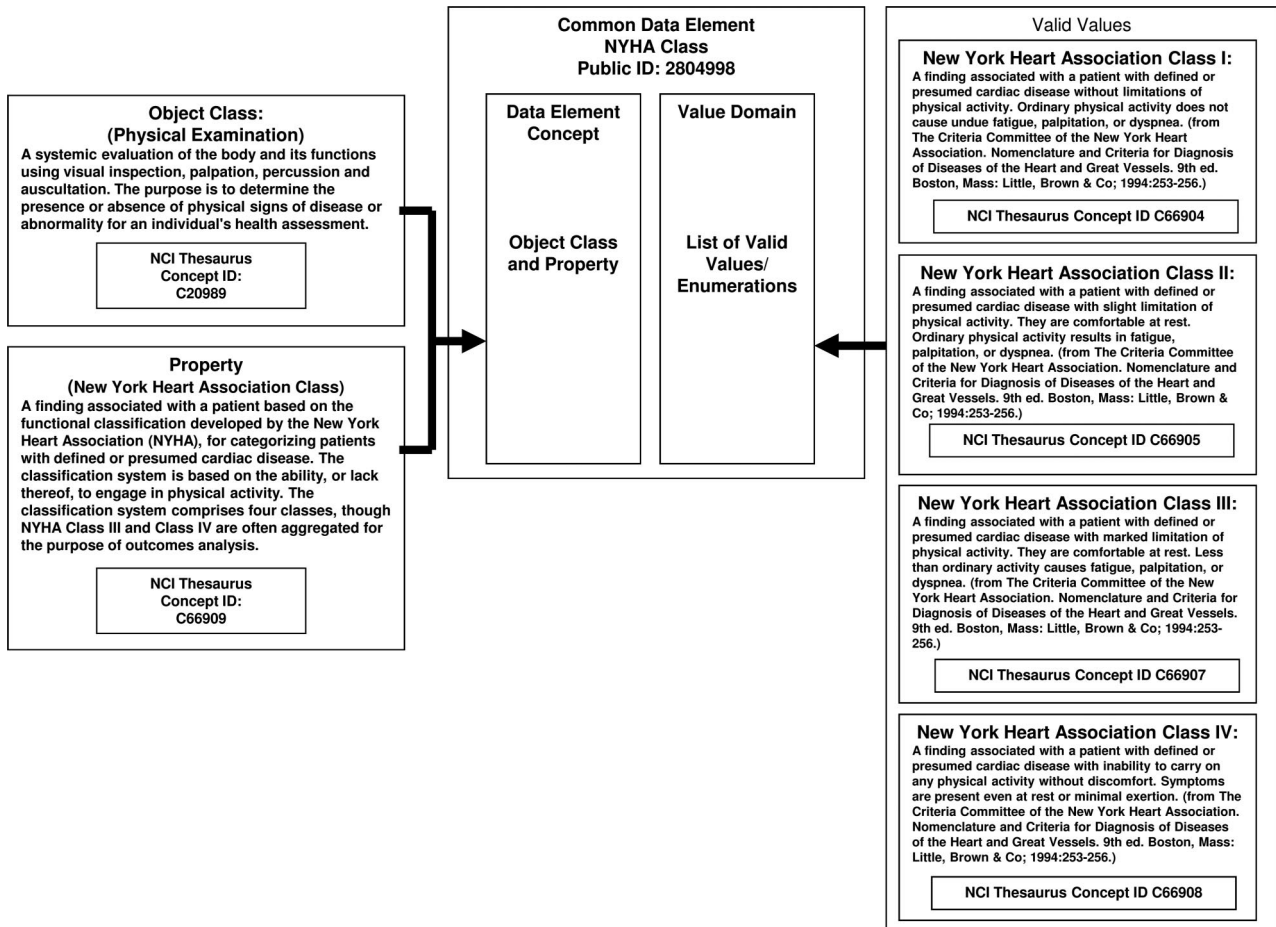
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Appendix 2. Reviewer Relationships With Industry and Other Entities—ACCF/AHA 2011 Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for Electronic Health Records

Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Ann F. Bolger	AHA Official Reviewer—AHA	None	None	None	None	None	None
Neal Lippman	Official Reviewer—ACCF Board of Governors	None	● Medtronic	None	● Boston Scientific ● Medtronic	None	None
Lee H. Schwamm	Official Reviewer—AHA	None	None	None	None	None	None
Matthew Budoff	Content Reviewer—ACC Imaging Council	● General Electric	None	None	None	None	● 2008—Represented defendant: radiology group and internist were sued for not warning a patient with enough emphasis that they were at high risk due to an increased calcium level. Case dismissed before trial.
Martha Radford	Content Reviewer—NCDR Management Board	None	None	None	None	None	None
Véronique L. Roger	Lead Reviewer—ACCF/AHA Task Force on Clinical Data Standards	None	None	None	None	None	None
Richard E. Shaw	Content Reviewer—NCDR Management Board	None	None	None	None	None	None

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ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association and NCDR, National Cardiovascular Data Registry.



Appendix 3. Description of the Common Data Element (CDE) 'NYHA Class.' Simplified view of a CDE in the caDSR Implementation of the ISO 11179 metamodel. This example is for a CDE that describes the physical examination assessment of NYHA class constrained to an enumerated list of values as presented by the HL7 Acute Coronary Syndrome Domain Analysis Model, Release 1. Modified from Komatsoulis et al.²⁴

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

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