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)

Endorsed by the Mediterranean Society of Pacing and Electrophysiology

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This document was approved by the American College of Cardiology Board of Trustees in February 2004 and the American Heart Association Science Advisory and Coordinating Committee in January 2004.

When citing this document, the American College of Cardiology Foundation and the American Heart Association would appreciate the following citation format: McNamara RL, Brass LM, Drozda JP Jr, Go AS, Halperin JL, Kerr CR, Lévy S, Malenka DJ, Mittal S, Pelosi F Jr, Rosenberg Y, Stryer D, Wyse DG. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the ACC/AHA Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). *J Am Coll Cardiol* 2004;44:475–95.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (www.acc.org) and the American Heart Association (www.americanheart.org). Single copies of this document as published in the July 21, 2004, issue of the *Journal of the American College of Cardiology* and the June 29, 2004, issue of *Circulation* or its companion online Reference Guide are available for $10.00 each by calling 1-800-253-4636 or writing the American College of Cardiology Foundation, Resource Center, at 9111 Old Georgetown Road, Bethesda, MD 20814-1699. To purchase bulk reprints (specify version and reprint number—71-0290 for the published document; 71-0297 for the Reference Guide): Up to 999 copies, call 1-800-611-6083 (US only) or fax 413-665-2671; 1000 or more copies, call 214-706-1789, fax 214-691-6342, or e-mail pubauth@heart.org.

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(J Am Coll Cardiol 2004;44:475–95.)

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doi:10.1016/j.jacc.2004.06.041

JACC Vol. 44, No. 2, 2004
July 21, 2004:475–95

Preamble

The American College of Cardiology (ACC) and the American Heart Association (AHA) recognize the importance of refining the lexicon used to describe the process and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality-improvement initiatives. Broad professional agreement on a common vocabulary with common definitions will facilitate cross-study comparisons or, when advantageous, combining of data across studies and will improve the assessment of any project's generalizability to clinical practice. To further efforts aimed at standardizing such a lexicon, the ACC and AHA have undertaken to develop and publish clinical data standards, sets of standardized data elements and corresponding definitions that can be used in a variety of data collection efforts for a range of cardiovascular conditions.

It is hoped that these clinical data standards will:

1. Improve cross-comparison of results and clinical outcomes between different trials and registries.
2. Facilitate the development and conduct of future registries, at both hospital and national levels, by providing a list of major variables, outcomes, and definitions.
3. Facilitate measurement for quality-improvement programs.
4. Become the basis for a standardized charting process with the anticipation that medical charting will progress to an electronic format.

The ACC/AHA Task Force on Clinical Data Standards makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or a personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated as changes occur.

The ACC/AHA Task Force on Clinical Data Standards selects cardiovascular conditions and procedures that would benefit from the creation of a data standard set. Experts in the subject are selected to examine/consider existing data standards and develop a comprehensive, yet not exhaustive, data standard set. Users should understand that when they undertake a data collection effort, only a subset may be needed, or conversely, they 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 ACC and AHA aim to standardize the language used to describe cardiovascular diseases and procedures, enhance consistency in cardiology, and increase opportunities for sharing data across various data sources. The ultimate goal of ACC/AHA clinical data standards is to contribute to the infrastructure necessary for accomplishing the ACC/AHA's mission of fostering optimal cardiovascular care and disease prevention.

The ACC and AHA support the goals of its members to improve cardiovascular care and disease prevention through professional education, promotion of research, development of guidelines and standards for cardiovascular care, and the fostering of policy that supports optimal patient outcomes. The ACC and AHA recognize the importance of the use of clinical data for patient management, in the assessment of patient outcomes, and in research efforts focused on improving clinical treatment of patients.

As a component of this objective, the ACC/AHA clinical data standards concentrate on the identification, definition, and standardization of data that correspond to various clinical topics in cardiology. The primary goal of clinical data standards is to assist in the collection of data by providing an initial platform of data elements and corresponding definitions applicable to various disease conditions in cardiology. These key elements and definitions are a compilation of variables applicable in the measurement of patient clinical management and outcomes and for research and epidemiological assessments.

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 our patients' privacy. Our goal is to treat every patient's health information with the same respect and courtesy as their person. The HIPAA privacy regulations (http://www.hhs.gov/ocr/combinedregtext.pdf, page 31) 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, and research studies that use 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 (PHI) in the data standards.

Our understanding of the importance of data element standardization, derives from experience with clinical care, clinical research, and quality-performance measurement. In clinical care, caregivers communicate with each other through a common vocabulary. The integrity of clinical research depends in large part 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 facilitated, thus deepening our understanding of individual clinical trials.

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 among the professional community about the importance of data standards. For the first time, a wide audience, including nonmedical professionals such as payers,

regulators, and consumers, may draw conclusions about care and outcomes. For comparison of care patterns and outcomes to be fair, the data elements that compose the descriptions of these patterns and outcomes of care must be clearly defined, consistently used, and properly interpreted by a broader audience than ever before.

Martha J. Radford, MD, FACC, FAHA
Chair, ACC/AHA Task Force on Clinical Data Standards

I. Introduction

Atrial fibrillation (AF) is the most common arrhythmia encountered in clinical practice. Prevalence of AF increases with age, reaching as high as 9% in octogenarians (1–4). New pharmacological and nonpharmacological treatments, as well as results from some large clinical trials (5–7), have increased interest in the management of AF. To address this increased need and interest, the American College of Cardiology (ACC), the American Heart Association (AHA), and the European Society of Cardiology (ESC) jointly released the ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (8). The ACC and AHA are following this effort with the ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation. AF is one of several conditions identified for development of clinical data standards by the ACC/AHA Task Force on Clinical Data Standards and is preceded by clinical data standards on acute coronary syndrome.

A. Purpose

The ACC/AHA Atrial Fibrillation Data Standards Writing Committee proceeded to develop data elements and definitions with the goal that they may be useful in a variety of circumstances:

- *Clinical programs,* where many providers and health plans work together to achieve specific goals for the care of patients with AF. Data standards will assist in the organization and design of electronic medical information initiatives, such as electronic medical records, pharmacy and other clinical databases, or computerized decision support.
- *Clinical research,* including prospective registries and randomized controlled trials (RCTs). Meta-analyses of RCTs would be particularly strengthened by the use of standardized data for key variables.
- *Quality-performance measurement initiatives.* Data standards will especially facilitate interpretation for nonmedical users, such as payers, regulators, and consumers.

These data standards were designed to facilitate the above initiatives. Because they were developed to support many varied uses, they were not designed to provide an operational format for any one specific use. Thus, the definitions are often stated in a more general fashion than will be appropriate for certain purposes. More specific operational definitions likely will be used for actual data collection, with these data standards providing a uniform guide for their development. In addition, because the data standards were developed for potential application in varied environments, all elements are not expected to pertain to each application.

II. Methodology

A. Writing Committee Composition

The ACC/AHA Writing Committee to Develop Clinical Data Standards for Atrial Fibrillation included a group of 13 physicians who are active in clinical programs, clinical research, and/or quality-performance measurement initiatives in AF. To improve generalization to a broad population, the committee included membership from the United States, France, and Canada. To ensure consistency within the topic of AF, the committee included three members from the ACC/AHA/ESC Committee to Develop Guidelines for the Management of Patients With Atrial Fibrillation. To enhance uniformity among different data standards efforts, the committee included one member from the ACC/AHA Task Force on Clinical Data Standards.

B. Review of Literature and Existing Data Definitions

The AF data standards are intended to provide data elements that parallel and complement other ACC and AHA standards, specifically guidelines. The ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (8) served as the primary evidence-based document that was referenced in the development of data elements and definitions for this statement. The writing committee gathered as many additional candidate data elements and definitions as possible from large clinical trials, national quality-performance measurement initiatives, relevant guidelines, and other national, international, and local cardiovascular data collection efforts. Examples of these data sources include the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) (7,9), the AnTicoagulation and Risk factors In Atrial fibrillation (ATRIA) Study (4), the ALFA Study (Etude en Activité Liberale sur le Fibrillation Auriculaire) (10), the Canadian Trial of Atrial Fibrillation (11,12), and the Canadian Registry of Atrial Fibrillation (CARAF) (13).

C. Prioritizing Data Elements

Once the writing committee reviewed the relevant literature and additional resources, a comprehensive list of potential items was created with the understanding that the final set would be limited to those elements most likely to be needed in data collection efforts. The initial list of data elements was graded according to priority as "high," "medium," or "low." All of the data elements with an average "high" score and a majority of those with an average "medium" score were included in the final set. The remaining elements are not included at this time but may be added and defined in the future.

The subsequent process of writing and revising data element definitions included prioritizing, adding, and removing elements for the purpose of defining the elements in a manner that facilitates consistent data collection.

D. Defining Data Elements

Members of the writing committee were assigned to one of four working groups, each of which was responsible for drafting definitions for a subset of data elements deemed to have priority for the first publication of the AF data standards.

Each writer received a template to assist in drafting the definitions and to provide for a structured format across authors. Writers were encouraged to compose definitions that were broad enough to be applicable in a variety of data collection settings (e.g., inpatient versus outpatient) but specific enough that the data elements could be uniformly interpreted.

To ensure consistency across ACC/AHA clinical data standards and clinical guidelines, previously published definitions were used verbatim whenever appropriate. Furthermore, data element definitions were linked to pre-existing definitions.

E. Writing Considerations for Use

The writing committee determined three major settings in which these data elements may be particularly useful: clinical care, clinical research, and quality-performance measurement.

F. Consensus Development

The ACC/AHA data standards are consensus, team-written documents that are based on judgments of experts in the field of cardiology. This writing committee met several times, both in person and through conference calls, over the course of 18 months to define and refine the data elements and definitions. Consensus was met through meetings, conference calls, and e-mail communications.

G. Peer Review, Public Comment, and Board Approval

The set of AF data elements was reviewed by 6 official reviewers nominated by the ACC, AHA, and the ACC/AHA Task Force on Clinical Data Standards and 10 individual content reviewers (see Appendix A for names and affiliations). To increase its applicability further, the document was posted on the ACC World Wide Web site for a 30-day public comment period between July 30 and August 30, 2003. Response forms were received from 63 individuals, representing 15 countries, including the United States. The document was approved for publication by the governing bodies of the ACC and the AHA. The document has been formally endorsed by the Mediterranean Society of Pacing and Electrophysiology. To determine whether a revision is necessary, these clinical data standards will be reviewed one year after publication and yearly thereafter by the ACC/AHA Task Force on Clinical Data Standards.

H. Document Format

This document is divided into three sections, outlined as follows:

1. *Introduction*: A description of the methodology for developing the AF clinical data standards and intended goals for their use.
2. *Data Elements and Definitions*: A listing of key data elements and definitions.
3. *Reference Guide*: A multipurpose resource that maps common data fields between AF data elements and other national/regional data registries and links AF data elements to relevant ACC/AHA guidelines (available online at www.acc.org/clinical/data_standards/AF/pdf/AF_refguide.pdf).

III. General Considerations of the AF Clinical Data Standards

A. Patient-Oriented Format

Given that AF is a chronic condition, the individual patient is the foundation of this data element set. This focus contrasts with other comparable efforts in which the field of interest may be a procedure (e.g., cardiac catheterization) or an event (e.g., acute coronary syndrome). Thus, the format of these data elements was designed to follow multiple events over time for each individual patient.

B. Balance Between Focus and Comprehensiveness

The writing committee focused on commonly collected data elements that were thought to be most useful for the broadest set of applications. These data standards are not intended to be a comprehensive data element catalog, encompassing every possible data need or use. The writing committee realizes that individual users likely will supplement these elements to suit their individual needs. Conversely, other users will select only a few data elements to collect.

C. Dates

The committee recognizes the critical importance of obtaining dates for most data elements in order to understand the clinical course, therapy, and outcomes of AF for the individual patient and across populations. The exact date (month, day, and year) for all elements and dates of events for prospective data elements should be obtained whenever possible. Because the ability to obtain precise dates of prior events is limited, best estimate of dates should be obtained (e.g., month/year), with emphasis placed on the most current events. The operational format of date collection will vary depending on particular use.

D. Varied Clinical Presentations

These data elements are intended to encompass the full range of patients with AF, including acute and chronic presentations, inpatient and outpatient settings, and scheduled and unscheduled medical care encounters.

E. Balance Between Primary and Summary Data Elements

These data elements consist of both individual data elements (for example, age and left atrial size) and summary elements (for example, New York Heart Association [NYHA] class for heart failure and primary cardiac diagnosis). In general, the committee included summary elements only to supplement primary data elements.

F. Atrial Fibrillation-Specific Elements

When possible, the committee chose data element names and definitions common to other ACC/AHA clinical data standard efforts. However, some elements were designed to specifically meet the needs of patients with AF. The committee wanted to highlight a subset of these AF-specific elements

that were particularly noteworthy. These elements appear in bold print in the "Element" column. They are:

Section II.A. Retrospective Data

Patient Category:

- **Qualifying cardiac rhythm**
- **Predominant cardiac diagnosis**
- **Atrial fibrillation due to transient or reversible cause**

Prior AF:

- **Previously used therapeutic strategies**
- **Frequency of prior symptomatic episodes**
- **Duration of prior symptomatic episodes**

Section II.B. Prospective Data

General:

- **Primary reason for encounter**
- **Patient classification of type of AF episodes**
- **Current management strategy**

Quality of Life:

- **Symptoms with prior episodes of AF**

Cardioversion:

- **Success of cardioversion attempt**
- **Pattern of recurrence**
- **Complications of conversion**

Resource Utilization:

- **Primary reason for admission**
- **Procedures performed**
- **Specialty of principal provider**

G. Quality of Life

Considerations of quality of life are particularly important in the management of AF. The currently available general health status measures, such as EuroQOL (www.euroqol.org), the SF-36 (14), or the SF-12 (15), are valuable in the breadth of domains that they measure and in their use for comparison across disease states. However, valid and reliable measures focused on the specific health burdens of AF are needed to supplement general health status measures. These focused measures may quantify health status effects of the arrhythmia itself, such as the AF Severity Scale and AF Symptom Burden Checklist used by the Canadian Registry of Atrial Fibrillation (16); of complications, such as stroke (National Institutes of Health Stroke Scale (17)); or of therapy, such as inconvenience and lifestyle changes associated with chronic warfarin therapy (18). At this point, no single approach to measurement of health status of patients with AF can be recommended.

H. Atrial Flutter and Other Atrial Tachycardias

Although many elements and definitions within this document will apply to patients with atrial flutter and other atrial tachycardias, the identification and definition of the unique features of these rhythms are not within the scope of this document.

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IV. Atrial Fibrillation Clinical Data Elements and Definitions

Note, **boldfaced type** in Tables 1 and 2 indicates elements of particular relevance to atrial fibrillation (AF).

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TABLE 1. Retrospective and Concurrent Data (Collected at or Near the Time of Study Initiation)*

ELEMENT	DEFINITION
Patient Demographics	
Registry or study identifier	Unique encrypted numeric identifier (unrelated to subject's personal identifying information) to enhance comparisons across studies while protecting patient privacy
Date of study entry	Date of initiation of collection of information for study purposes
Date of birth	Patient date of birth (day, month, and year of patient's birth)
Gender	Indicate the patient's gender at birth. Choose one of the following: • Male • Female
Hispanic ethnicity	Is this patient Spanish, Hispanic, or Latino? Choose one of the following: • Yes • No
Race	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 • Unknown
Insurance payer	Indicate the patient's primary insurance payer for this admission. Choose one of the following: • *Government*: Refers to patients who are covered by government-reimbursed care. In the U.S., this includes Medicare, Medicaid (including all state or federal Medicaid-type programs), Champus, and the Veteran's Administration health plan. • *Commercial*: Refers to all indemnity (fee-for-service) carriers and preferred provider organizations (PPOs). • *HMO*: Refers to a health maintenance organization characterized by coverage that provides healthcare services for members on a prepaid basis. • *None*: Refers to individuals with no or limited health insurance; thus, the individual 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. • *Non-U.S. Insurance*: Refers to individuals who reside in and have health insurance in another country.
Government payer type	If the patient's primary insurance payer for this encounter is "Government," choose the type of government insurance: • Medicare • Medicaid • Other
Education	Indicate the highest degree the patient has received. Categories include (recommend listing years of schooling if degrees do not apply to a specific population): • Less than high school graduate (fewer than 12 years) • High school graduate or equivalent (12 years) • Some college (more than 12 but fewer than 16 years) • Bachelor's degree (16 years) • Master's degree or higher degree (more than 16 years)
Patient Category	
Qualifying cardiac rhythm	Rhythm recorded that qualified the person for the study: • *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
Predominant cardiac diagnosis	Exclusive categories include: • Mitral stenosis, with or without regurgitation • Coronary artery disease, with or without left ventricular dysfunction (prior documented myocardial infarction, angina, coronary revascularization, or stenosis on angiography greater than or equal to 50%) • Other structural heart disease, including nonischemic left ventricular systolic dysfunction (left ventricular ejection fraction less than 40% or fractional shortening less than 25%), moderate or severe valvular heart disease, asymmetrical left ventricular hypertrophy, and congenital heart disease. Exclude concentric left ventricular hypertrophy. • Hypertension, with or without left ventricular hypertrophy • No underlying structural or functional heart disease or hypertension
Atrial fibrillation due to transient or reversible cause	Indicate whether the qualifying AF is due to a transient or reversible cause. Indicate all that apply: • Postoperative from cardiac surgery • Postoperative from noncardiac thoracic surgery • Postoperative from noncardic, nonthoracic surgery

*__Boldfaced type__ indicates elements of particular relevance to atrial fibrillation (AF).

TABLE 1. Continued

ELEMENT	DEFINITION
	• Pericarditis • Lung disease • Hyperthyroidism • Other, specify
Prior Atrial Fibrillation	
Previously used therapeutic strategies	Indicate the types of therapeutic strategies that have been employed previously. Indicate all that apply. (Note: One therapy may apply to more than one category, e.g., amiodarone may be used for rate and rhythm control.) Rate Control: • Pharmacological • Nonpharmacological • Hybrid* • None Rhythm Control: • Pharmacological • Nonpharmacological • Hybrid* • None **Hybrid* is defined as concurrent use of: • Pharmacological and nonpharmacological therapies or • 2 or more nonpharmacological therapies
Frequency of prior symptomatic episodes	Patient estimate of average interval between symptomatic episodes in days
Duration of prior symptomatic episodes	Patient estimate of duration of each of longest, shortest, and usual symptomatic episodes: • Less than 48 hours • 48 hours to 7 days • 7 days to 3 months • Longer than 3 months If more specific short-term intervals are desired, recommend dividing the first category (less than 48 hours) into the following: less than 5 minutes, 5 minutes to less than 6 hours, 6 hours to less than 48 hours.
Successful prior pharmacological cardioversion	List all generic drug names previously used that resulted in the absence of AF or atrial flutter.
Unsuccessful prior pharmacological cardioversion attempted	List all generic drug names previously used that did not result in the absence of AF or atrial flutter.
Successful prior transthoracic electrical cardioversion	Number of previous transthoracic electrical cardioversion sessions attempted that resulted in the absence of AF or atrial flutter. A session may include multiple successive shocks.
Unsuccessful prior transthoracic electrical cardioversion attempted	Number of previous transthoracic electrical cardioversion sessions attempted that did not result in the absence of AF or atrial flutter. A session may include multiple successive shocks.
Successful prior transvenous electrical cardioversion	Number of previous transvenous electrical cardioversion sessions attempted that resulted in the absence of AF or atrial flutter. A session may include multiple successive shocks.
Unsuccessful prior transvenous electrical cardioversion attempted	Number of previous transvenous electrical cardioversion sessions attempted that did not result in the absence of AF or atrial flutter. A session may include multiple successive shocks.
History of ablation for supraventricular arrhythmia	Documented history of ablation for supraventricular arrhythmia. Indications (may have more than one): • Supraventricular tachycardia (e.g., atrioventricular node re-entry tachycardia, atrioventricular re-entry tachycardia) • AF • Atrial flutter • Atrial tachycardia • Other, specify For AF/atrial flutter, indicate approach taken: • Focal (specify site) • Cavotricuspid isthmus • Other linear sites, specify • AV node ablation plus permanent pacemaker Indicate energy source: • Radiofrequency • Cryoablation • Ultrasound • Laser • Other, specify

TABLE 1. Continued

ELEMENT	DEFINITION
Thromboembolic History	
History of ischemic stroke	Documented history of stroke or cerebrovascular accident with acute loss of neurological function caused by an ischemic or hemorrhagic event with residual symptoms at least 24 hours after onset. List most likely etiology: • Larger-artery disease (e.g., carotid) • Small-artery disease (lacunar) • Embolism • Other, specify • Not specified Indicate whether confirmed by CT, MRI scan, or cerebral angiography.
Residual deficit from prior stroke	Assessed via current level of functioning. Categories include: • Complete/near-complete recovery (able to return to prestroke level of function) • Mild to moderate deficit (deficits present, but patient can perform activities of daily living, such as dressing and feeding, with no or little assistance) • Severe deficit (required assistance to complete activities of daily living)
History of transient ischemic attack	Documented history of transient ischemic attack (TIA) consisting of acute loss of neurological function caused by an ischemic event with resolution of symptoms by 24 hours after onset.
History of systemic peripheral embolism	Documented history of abrupt vascular insufficiency associated with clinical and radiological or pathological evidence of arterial occlusion in a vascular bed other than the cerebrovascular system in the absence of other likely mechanisms (e.g., atherosclerosis). Indicate site.
History of carotid artery disease	History of carotid artery disease with 50% or more stenosis. Indicate all modalities of assessment: • Ultrasound • Magnetic resonance angiography • Angiography
Hemorrhagic History	
History of intracranial hemorrhage	History of any prior bleeding into or around the brain. Categories include: • Hemorrhagic conversion of a primary ischemic stroke • Subarachnoid hemorrhage • Intracerebral hemorrhage • Other (including subdural and epidural hematomas) • Unknown Indicate whether documented by CT or MRI
Residual deficit from prior intracranial hemorrhage	Assessed via current level of functioning. Categories include: • Complete/near-complete recovery (able to return to prestroke level of function) • Mild to moderate deficit (deficits present, but patient can perform activities of daily living, such as dressing and feeding, with no or little assistance) • Severe deficit (requires assistance to complete activities of daily living)
History of other hemorrhage	History of bleeding is defined as either major or minor according to the following criteria: • *Major*: Leading to transfusion of at least 2 units of whole blood or erythrocytes, requiring hospitalization or surgery, resulting in permanent disability, or involving a critical anatomic site (retroperitoneal, pericardial, intraspinal, intracranial, atraumatic intra-articular, or intra-ocular bleeding associated with abrupt deterioration of visual acuity). • *Clinically overt* (but not major) • *Occult* (e.g., asymptomatic guaiac-positive stool) Include amount of hemoglobin drop and the time interval if data available.
Other Cardiovascular History	
History of hypertension	Indicate whether the patient has hypertension as documented by: • History of hypertension diagnosed and treated with medication, diet, and/or exercise • Blood pressure greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic on at least 2 occasions • Currently undergoing antihypertensive pharmacological therapy More than one of the above may apply. The year of onset (first diagnosis) may be helpful.
History of heart failure	Physician documentation or report of any of the following symptoms of heart failure before this care encounter, described as dyspnea, fluid retention, or low cardiac output secondary to cardiac dysfunction; or the description of rales, jugular venous distension, or pulmonary edema. A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history.
History of valvular heart disease	Documented history of moderate or severe stenosis or regurgitation. Indicate stenosis or regurgitation for each valve involved. Date of onset (first diagnosis) may be helpful.
History of valve intervention	Indicate each valve repair, valvuloplasty, or valve replacement in patient history. For valve replacement, indicate location and type.
History of myocardial infarction (MI)	Previous MI before this encounter as determined by the following (indicate all that apply): • Hospital admission for acute MI

TABLE 1. Continued

ELEMENT	DEFINITION
	• Electrocardiogram (ECG) report indicating previous (old) or acute MI • Increase in biochemical marker (e.g., creatine kinase or troponin) consistent with MI • Patient reports history of acute MI or heart attack Date of the first and the most recent episodes may be helpful.
History of other coronary artery disease	Indicate whether there is a documented history of any of the following: • Prior coronary artery bypass surgery (CABG) • Prior percutaneous coronary intervention (PCI) • Angiographically documented coronary artery stenosis greater than or equal to 50% • Positive stress test; specify imaging modality if performed • Angina pectoris
History of hypertrophic cardiomyopathy	Echocardiographically established hypertrophic cardiomyopathy. Specify type: • Obstructive • Nonobstructive, nonhypertensive Does not include hypertensive cardiomyopathy (concentric hypertrophy).
History of cardiomyopathy	Left ventricular systolic dysfunction with an estimated ejection fraction less than 0.40.
History of congenital heart disease	Cardiac anomaly present from birth or congenital abnormality on echocardiography. Specify diagnosis and any prior repair.
History of ventricular arrhythmias	Ventricular tachycardia or ventricular fibrillation requiring cardioversion and/or medication (intravenous or oral) with antiarrhythmic drugs.
History of sinus bradycardia/sick sinus syndrome	Symptoms due to sinus node dysfunction and manifested by the following (indicate all that apply): • *Sinus bradycardia*: Sinus rate 40 to 50 bpm with normal P-wave axis and PR interval • *Severe sinus bradycardia*: Sinus rate less than 40 bpm with normal P-wave axis and PR interval • *Sinus arrest*: Sudden absence of sinus activity • *Sinoatrial exit block*: Loss of sinus activity at an interval fixed to that of the basic P-P interval • *Tachycardia-bradycardia syndrome*: Paroxysmal tachycardias followed by bradycardia upon termination
History of atrioventricular (AV) block	Highest degree of block in past history: • *1st Degree:* P-R interval greater than 200 ms • *2nd Degree*: —Mobitz I (Wenckebach): gradual PR prolongation until AV block —Mobitz II: fixed PR interval until AV block —Advanced AV block (e.g., 2:1, 3:1) • *3rd Degree* (complete heart block): independent atrial and ventricular activity with an atrial rate faster than the ventricular rate
History of supraventricular tachycardia	Indicate any documented history of: • Atrial tachycardias • AV nodal re-entrant tachycardias • Orthodromic re-entrant tachycardias utilizing a concealed accessory bypass tract • Other supraventricular tachycardias, including undifferentiated re-entrant tachycardias; specify
History of ablation for other than AF or atrial flutter	Specify indication, which may include: • Wolff-Parkinson-White syndrome (manifest accessory AV connection) • AV nodal re-entrant tachycardias • Concealed accessory bypass tracts • Atrial tachycardias • Ventricular tachycardia
History of pacemaker insertion	Indicate whether the patient has or has had a pacemaker inserted. If yes: Specify type: • Single chamber (atrial) • Single chamber (ventricular) • Dual chamber (both atrial and ventricular, but not biventricular) • Biventricular of any type Specify indication (all that apply): • Sinus node dysfunction • AV block • Congestive heart failure • Atrial fibrillation Specify if capable of: • Burst pacing • Antitachycardia pacing
History of intracardiac defibrillator insertion	Indicate whether the patient has or has had an intracardiac defibrillator inserted. If yes: Specify type: • Single-chamber pacing and shock therapies; specify chamber • Dual-chamber pacing and shock therapies

TABLE 1. Continued

ELEMENT	DEFINITION
	• Atrial pacing with ventricular pacing and shock therapies • Ventricular shock and biventricular pacing therapies Specify indication: • Atrial fibrillation • Secondary prevention of cardiac arrest • Primary prevention of cardiac arrest. High risk for ventricular tachycardia (e.g., ischemic heart disease, hypertrophic cardiomyopathy, Brugada syndrome, long-QT syndrome, arrhythmogenic right ventricular cardiomyopathy) • Syncope with inducible ventricular tachycardia • Unexplained syncope Specify if capability exists: • Burst pacing • Antitachycardia pacing • Cardioversion
Other Medical History	
History of diabetes mellitus	History of diabetes, regardless of duration of disease, need for antidiabetic agents, or a fasting blood sugar greater than or equal to 7 mmol/l or 126 mg/dl. The year of onset (first diagnosis) may be helpful.
Diabetes control history	Method of diabetic control at time of encounter. Choose one of the following: • *None*: No treatment for diabetes • *Diet*: Diet treatment • *Oral*: Oral agent treatment • *Insulin*: Insulin treatment • *Insulin and oral*: Insulin and oral agent treatment
History of chronic lung disease	Documented history of chronic lung disease (e.g., chronic obstructive pulmonary disease, chronic bronchitis) or currently being chronically treated with inhaled or oral pharmacological therapy (e.g., 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.
History of thyroid disease	History of hyperthyroidism or hypothyroidism. Indicate history of prior radioactive iodine treatment or prior medical treatment for hyperthyroidism.
History of chronic kidney disease	Stages are determined by measured or estimated glomerular filtration rate: • *None*: Greater than or equal to 90 mL/min/1.73 m^2 without kidney damage (e.g., proteinuria) • *Stage I*: Greater than or equal to 90 mL/min/1.73 m^2 with kidney damage (e.g., proteinuria) • *Stage II*: 60 to 89 mL/min/1.73 m^2 • *Stage III*: 30 to 59 mL/min/1.73 m^2 • *Stage IV*: 15 to 29 mL/min/1.73 m^2 • *Stage V*: Less than 15 mL/min/1.73 m^2 or on maintenance dialysis
History of chronic liver disease	Documented cirrhosis or chronic liver disease
Habits/Substance Abuse	
History of alcohol consumption/dependency	Alcohol consumption history: • None • One or fewer alcoholic drinks per week • 2 to 7 alcoholic drinks per week • 8 to 14 alcoholic drinks per week • 15 or more alcoholic drinks per week Alcohol dependency history: • Documented alcohol dependence • Medical sequelae of alcohol consumption (alcoholic hepatitis, cirrhosis, alcohol neuropathy, Wernicke-Korsakoff syndrome) • Treatment for alcohol dependency For dependent consumers of alcohol, note treatment for dependency, cessation of use, or continued use.
History of smoking	History confirming cigarette smoking in the past. Choose from the following categories: • *Current*: Smoking cigarettes within 1 month of this encounter • *Recent*: Stopped smoking cigarettes between 1 month and 1 year before this encounter • *Former*: Stopped smoking cigarettes more than 1 year before this encounter • *Never*: Never smoked cigarettes For current or former smokers, total pack-years may be useful.
History of illicit drug use	Documented history of current, recent, or remote abuse of any controlled substance. Indicate substance.

TABLE 1. Continued

ELEMENT	DEFINITION
Past Medications	
Past antiarrhythmic drugs and rate-control agents	List generic names of all prior medications for rate and rhythm control. For each antiarrhythmic and rate-control medication used in the past (above), indicate the primary reason for discontinuation: • Ineffective • Not tolerated, specify • Other, specify
Past antithrombotic medications	List generic names for all anticoagulation and antiplatelet medications (including aspirin and clopidogrel) used in the past. For each antithrombotic medication used in past (above), indicate the primary reason for discontinuation: • Ineffective • Not tolerated, specify • Other, specify
Past contraindication to antithrombotic therapy	Has patient been considered for antithrombotic therapy in the past but not treated due to a contraindication? If yes, list contraindication.

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TABLE 2. Prospective Data (Collected After Enrolling in Study)*†

ELEMENT	DEFINITION
General	
Type of encounter	Type of encounter in healthcare facility: • Emergency admission for AF • Emergency admission for other cardiovascular problem • Emergency admission for noncardiovascular problem (e.g., pneumonia) • Planned admission for AF • Planned admission for cardiovascular disease • Planned admission for noncardiovascular disease • Regularly scheduled outpatient visit • Emergency room visit, not admitted • Other outpatient visit It may be useful to collect more specific information.
Primary reason for encounter	Primary symptom or condition that prompted patient to seek medical attention: • AF related • Other cardiac-related reason • Not cardiac related
Patient classification of type of AF episodes	Classify patient based on the episodes of AF within the past 12 months: • *First Detected*: Patient with a first-detected episode lasting fewer than 6 months • *Paroxysmal*: Patient with history of 2 or more episodes of paroxysmal AF only • *Persistent*: Patient with history of 2 or more episodes of persistent AF only • *Mixed Paroxysmal/Persistent*: Patient with history of 2 or more episodes of AF of either paroxysmal or persistent type • *Permanent*: Patient with history of 2 or more episodes of AF with at least 1 episode of permanent AF, or a first-detected episode lasting more than 6 months for which no attempt or further attempt to restore sinus rhythm is planned (See "Qualifying Rhythm" for definitions of episode classification.)
Current management strategy	Indicate the types of strategies that are currently being employed. Indicate all that apply: *Rate Control*: • Pharmacological • Nonpharmacological • Hybrid* *Rhythm Control*: • Pharmacological • Nonpharmacological • Hybrid* **Hybrid* is defined as concurrent use of: • Pharmacological and nonpharmacological therapies or • Two or more nonpharmacological therapies.
Medications on Encounter	
Antiarrhythmic drugs and rate-control agents	List generic names of all antiarrhythmic and rate-control medications (including beta-blockers, calcium-channel blockers, and digoxin) that are currently prescribed to patient. Indicate daily dose.
Antithrombotic agents	List generic names for all antithrombotic and antiplatelet medications (including aspirin and clopidogrel) that are currently prescribed to patient. Indicate daily dose.
Angiotensin-converting enzyme inhibitors	List generic names for all angiotensin-converting enzyme inhibitors that are currently prescribed to patient.
Angiotensin receptor blockers	List generic names for all angiotensin receptor blockers that are currently prescribed to patient.
Other cardiac medications	List generic names for all other cardiac medications that are currently prescribed to patient.
Thyroid replacement	Indicate whether patient is currently receiving thyroxine and/or T3.
Antidiabetic therapy	Patient has current prescription for antidiabetic medication. Indicate type: • Oral agent • Insulin • Both oral agent and insulin
Nonsteroidal anti-inflammatory drugs (NSAIDs), not including aspirin or cyclooxygenase (Cox)-2 inhibitors	List NSAIDs taken on average more than once per week. (Note: This category does not include aspirin, acetaminophen, or Cox-2 inhibitors.)
Cox-2 inhibitor	List Cox-2 inhibitors taken on average more than once per week.
Beta-agonists	List inhaled and oral beta-2-adrenergic agonists taken on average more than once per week.
Physical Examination	
Heart rate	Heart rate (beats per minute) recorded closest to the time of presentation to the healthcare facility and/or on discharge (for inpatient). Heart rate may be ascertained from ECG tracing or from record of physical examination.

*Note: Each element may be collected multiple times during clinical follow-up.
†**Boldfaced type** indicates elements of particular relevance to atrial fibrillation (AF).

TABLE 2. Continued

ELEMENT	DEFINITION
Systolic and diastolic blood pressure	Systolic and diastolic blood pressure (mm Hg) recorded closest to the time of presentation to the healthcare facility. Patient position (supine, sitting, other) should be noted.
Height	Patient's height in centimeters or inches (list units)
Weight	Patient's weight in kilograms or pounds (list units). Body mass index can be calculated from height and weight.
Physical signs and symptoms of congestive heart failure	Indicate whether patient meets criteria for congestive heart failure as defined by the Framingham Heart Study (19). A diagnosis of heart failure requires that 2 major criteria are present or that 1 major and 2 minor criteria are present concurrently. *Major Criteria* include: • Acute pulmonary edema • Cardiomegaly • Increased venous pressure • Neck vein distension • Positive hepatojugular reflex • Inspiratory rales • S3 gallop *Minor Criteria* include: • Dyspnea on exertion • Extremity edema • Hepatomegaly • Night cough • Pleural effusion • Tachycardia (more than 120 beats per minute)
Pregnancy	Indicate whether the patient is pregnant.
Laboratory Tests (include local reference ranges)	
Thyroid function tests	• Serum thyroid-stimulating hormone level (μU/mL–micro units per milliliter) • Free T4 (local laboratory units) • Total T3 (local laboratory units)
Serum creatinine	Serum creatinine level (mg/dl or mmol/l)
Liver function/ assessment	• Total bilirubin (g/dl) • Alkaline phosphatase (IU/dl) • Aspartate transaminase (AST) (U/dl) • Alanine transaminase (ALT) (U/dl) • Serum albumin (g/dl)
Potassium	Serum potassium (mg/dl or mmol/l)
Magnesium	Serum magnesium (mg/dl or mmol/l)
Hemoglobin	Serum hemoglobin (mg/dl)
International Normalized Ratio (INR)	Measured INR for assessment of anticoagulation status/prothrombin time
Goal INR	Indicate the listed goal INR for the patient • 2.5 to 3.5 • 2.0 to 3.0 • Other (specify goal INR range and reason)
Partial thromboplastin time (PTT)	Indicate whether activators used (aPTT) or not (PTT). Measured in seconds.
Electrocardiography	
Rhythm	The categories of rhythm are: • Sinus rhythm • Atrial fibrillation • Atrial flutter • Paced • Other rhythm (e.g., ventricular tachycardia, supraventricular tachycardia)
Heart rate on ECG	Heart rate as measured on ECG. Recommended measurement is over at least 6 seconds.
Previous MI	Indicate whether pathological Q waves are present on ECG.
Left ventricular hypertrophy	Specify criteria. The following criteria have been validated prospectively in clinical studies: • *Sokolow-Lyon Voltage*: S in V1+R V5 or V6 greater than 38 mm (does not require gender or age adjustment) • *Cornell Voltage*: R avL+S V3 greater than 20 mm in females or 28 mm in males • *Cornell Product*: Cornell voltage times the QRS duration greater than 2440 (in females, 6 mm is added to their Cornell voltage)

TABLE 2. Continued

ELEMENT	DEFINITION
Complete bundle-branch block	Specify whether any of the following are present, defined as QRS more than 120 milliseconds: • Right bundle-branch block • Left bundle-branch block • Nonspecific intraventricular conduction delay
Pre-excitation	Indicate whether characteristic delta wave is present.
Atrial abnormality	Indicate whether left, right, or biatrial abnormality is present.
U-waves	Indicate whether U-waves are present.
Corrected QT (QTc) interval	QTc interval measured from the ECG
Echocardiography	
Echocardiographic modality	Transthoracic or transesophageal
Left atrial size—M-mode on echocardiography	Left atrial size, using the "leading edge to leading edge" method, in centimeters, measured from M-mode in the parasternal long-axis view at end-ventricular systole.
Left atrial volume on echocardiography	On two-dimensional imaging, using the left atrial areas traced in the four- and two-chamber views as calculated by the standardized methods (e.g., Simpson's method of disks) (20).
Left ventricular diastolic diameter	Left ventricular diameter measured at end ventricular diastole (in centimeters). Indicate whether by M-mode or two-dimensional imaging.
Left ventricular systolic function	Subjective assessment as: • Normal • Mildly decreased • Mild to moderately decreased • Moderately decreased • Moderately to severely decreased • Severely decreased
Ejection fraction	Number measured (specify technique) or estimated. Give midpoint if range given. Listed as a percentage.
Left ventricular diastolic function	Categories include: • Normal • Impaired relaxation (Grade I) • Pseudonormal (Grade II) • Restrictive, reversible (Grade III) • Restrictive, irreversible (Grade IV) • Not obtained
Left ventricular wall thickness	Left ventricular end-diastolic thickness of septal and posterior walls as measured in the parasternal long-axis view (in centimeters). Indicate whether by M-mode or two-dimensional imaging.
Thrombus with location	• Left atrial appendage • Left atrium • Right atrium • Left ventricle • Right ventricle Indicate all that apply.
Spontaneous echo contrast with location	• Left atrial appendage • Left atrium • Right atrium • Left ventricle • Right ventricle Indicate all that apply.
Mitral valve morphology	Predominant assessment as: • Normal • Rheumatic • Myxomatous • Prolapsed • Flail • Prosthetic • Other abnormal, specify
Mitral stenosis	Mitral valve area estimated from the pressure half-time of the left ventricular inflow (220/pressure half-time)
Mitral regurgitation	• None • Mild • Mild to moderate • Moderate • Moderate to severe • Severe

TABLE 2. Continued

ELEMENT	DEFINITION
Other valvular disease	List other valvular disease and severity.
Aortic plaque	• Small (less than 1 mm) • Moderate (1 to 4 mm) • Large (greater than 4 mm) • Mobile
Brain Imaging	
Head CT or MRI	Indicate evidence of ischemic or hemorrhagic events on head CT or MRI. Also indicate other major abnormalities.
Quality of Life (See "General Considerations of the AF Clinical Data Standards" for a brief consideration of quality-of-life issues.)	
Self-reported health status	Ask patient: "In general, compared to other people your age, would you say your health is. . .": • Excellent • Very good • Good • Fair • Poor
Symptoms with prior episodes of AF	For each of (a) usual episode and (b) worst episode, symptoms as described by the patient as: • Minimal or no symptoms • Disabling
Summary Assessment	
Heart failure status: New York Heart Association (NYHA) classification	NYHA class as reported by a physician (definitions adopted from NYHA without revision): • *Class I*: Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea. • *Class II*: Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea. • *Class III*: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea. • *Class IV*: Patients with cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms are present even at rest or on minimal exertion. If any physical activity is undertaken, shortness of breath is increased.
Angina status	Category of patient's angina type if present (choose one): • *Atypical chest pain*: Pain, pressure, or discomfort in the chest, neck, or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. • *Stable angina*: Angina without a change in frequency or pattern for the 6 weeks before this procedure. Angina is controlled by rest and/or sublingual/oral/transdermal medications. • *Unstable angina* (one of the following criteria is necessary): –Angina that occurred at rest and was prolonged, usually lasting more than 20 minutes –New-onset angina of at least Canadian Cardiovascular Society (CCS) class III severity –Recent acceleration of angina reflected by an increase in severity of at least 1 CCS class to at least CCS class III • *Myocardial Infarction*: For a complete definition, please refer to "Myocardial Infarction (MI)" in the "Other Events" section.
Angina class: Canadian Cardiovascular Society (CCS) classification	Grading of patient's angina by class (CCS classification system) (21,22): • *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 more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal condition. • *Class III*: Marked limitations 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.
Cardioversion	
Site	Indicate all that apply. • Transthoracic (single defibrillator) • Transthoracic (dual defibrillators) • Intracardiac/intravascular • Epicardial
Waveform	Categories include: • Monophasic, all types

TABLE 2. Continued

ELEMENT	DEFINITION
	• Rectilinear biphasic • Truncated exponential biphasic • Other, specify
Number of shocks delivered	Indicate the number of shocks delivered during current session.
Maximal energy used	Indicate maximal energy used in current session.
Medication for cardioversion attempt	List generic name for medication used to attempt cardioversion for a patient from AF to normal sinus rhythm. Indicate route of administration (intravenous or oral) and total daily dose and units. (Include total dose until cardioversion or accepted failure.)
Success of cardioversion attempt	Absence of AF or atrial flutter for at least 10 seconds after shock delivery or at any time after antiarrhythmic drug administration. For pharmacological cardioversion, time frame for assessment will depend on medication and route of administration (e.g., success for intravenous ibutilide may be within 1 hour from the end of infusion, whereas success for oral amiodarone may be within several days).
Pattern of recurrence	After successful conversion: • Immediate recurrence of AF (returns in less than 2 minutes) • Subacute recurrence of AF (returns between 2 minutes and 14 days) • Late recurrence of AF (returns after 14 days)
Complications of conversion	Include all complications occurring from the initiation of cardioversion attempt to 28 days after cardioversion. Specify complication and categorize into: • Anesthesia related • Thromboembolic • Arrhythmic • Other
Nonpharmacological Therapy	
Supraventricular ablation	Indications (may have more than one): • Supraventricular tachycardia (e.g., AV node re-entry tachycardia, AV re-entry tachycardia, atrial tachycardia) • Atrial fibrillation • Atrial flutter • Other, specify For AF/atrial flutter, indicate approach taken: • Focal (specify site) • Cavotricuspid isthmus • Other linear sites, specify • Atrioventricular node ablation plus permanent pacemaker Indicate energy source: • Radiofrequency • Cryoablation • Ultrasound • Laser • Other, specify
Pacemaker insertion	Specify type: • Single chamber (atrial) • Single chamber (ventricular) • Dual chamber (both atrial and ventricular, but not biventricular) • Biventricular of any type Specify indication: (all that apply) • Sinus node dysfunction • AV block • Intraventricular (IV) block • Congestive heart failure • Atrial fibrillation with bradycardia • Atrial fibrillation without bradycardia Specify whether capable of: • Pacing for prevention of atrial arrhythmias • Burst/antitachycardia pacing for tachycardia termination
Intracardiac defibrillator insertion	Specify type: • Single chamber • Dual chamber • Biventricular Specify indication: • Atrial fibrillation • Secondary prevention of cardiac arrest

TABLE 2. Continued

ELEMENT	DEFINITION
	• Primary prevention of cardiac arrest. High risk for ventricular tachycardia (e.g., hypertrophic cardiomyopathy, Brugada syndrome, long-QT syndrome) • Syncope with inducible ventricular tachycardia Specify whether capability exists: • Burst pacing • Antitachycardia pacing • Cardioversion
Surgery/type	• Maze: −Approach: epicardial/endocardial −Energy: radiofrequency ablation, cryoablation, laser, other • Other, specify
Complications of nonpharmacological therapy	Include all complications occurring from the initiation of nonpharmacological therapy to 28 days after nonpharmacological therapy. Specify complication and categorize into: • Anesthesia related • Thromboembolic • Arrhythmic • Procedural • Other
Thromboembolic Events	
Ischemic stroke	Documented stroke or cerebrovascular accident consisting of acute loss of neurological function caused by an ischemic event with residual symptoms at least 24 hours after onset. The date of the most recent stroke should be noted. List most likely etiology: • Larger-artery disease (e.g., carotid) • Small-artery disease (lacunar) • Embolism • Not specified Indicate whether confirmed by CT, MRI scan, or cerebral angiography.
Severity of stroke	Assessed at approximately 3 months after event. Categories include: • Complete/near-complete recovery (able to return to prestroke level of function) • Mild to moderate deficit (deficits present, but patient can perform activities of daily living, such as dressing and feeding, with no or little assistance). • Severe deficit (required assistance to complete activities of daily living)
Transient ischemic attack	Acute loss of neurological function caused by an ischemic event with resolution of symptoms by 24 hours after onset.
Non-central nervous system arterial embolic event	Abrupt vascular insufficiency associated with clinical and radiological evidence of arterial occlusion in a vascular bed other than the cerebrovascular system in the absence of other likely mechanisms (e.g., atherosclerosis). In the presence of peripheral arterial disease, diagnosis of embolism requires angiographic demonstration of abrupt arterial occlusion.
Hemorrhagic Events	
Intracranial hemorrhage	Bleeding into or around the brain: • Hemorrhagic conversion of a primary ischemic stroke • Subarachnoid hemorrhage • Intracerebral hemorrhage • Other (including subdural and epidural hematomas) • Unknown Indicate whether documented by CT or MRI.
Other hemorrhage	Bleeding is defined as either major or minor according to the following criteria: • *Major*: Leading to transfusion of at least 2 units of whole blood or erythrocytes, requiring hospitalization or surgery, resulting in permanent disability, or involving a critical anatomic site (retroperitoneal, pericardial, intraspinal, intracranial, atraumatic intra-articular, or intra-ocular bleeding associated with abrupt deterioration of visual acuity). • *Clinically overt* (but not major) • *Occult* (e.g., asymptomatic guaiac-positive stool) Include amount of hemoglobin drop and the time interval if data available.
Transfusion	Transfusion of either whole blood or packed red blood cells due to a hemorrhagic event. Note the number of units transfused. Specify type (e.g., whole blood, packed erythrocytes, other blood products) and quantity (units or milliliters).
Procedural intervention to control bleeding	Indicate type of procedural intervention (e.g., surgical or catheter-based) performed to control an episode of bleeding.

TABLE 2. Continued

ELEMENT	DEFINITION
Adverse Drug or Device Event	
Adverse drug or device event	An adverse event is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product or a medical device and which does not have to have a causal relationship with this treatment. Information regarding an adverse event should include: • Generic name of drug or device associated with the event • Dose, if applicable • *Cardiac*: Subcategories of cardiac reactions include: —Congestive heart failure —Classic torsade de pointes —Other sustained ventricular tachycardia or fibrillation —Supraventricular tachycardia —Mobitz type II or third-degree AV node block —Mobitz type I or first-degree AV heart block —Sinus bradycardia —Other cardiac. Briefly specify • *Noncardiac*, specify • *Severity*. A *serious adverse event* is defined as one that satisfies any of the following criteria: —Results in death —Is life-threatening (NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe.) —Requires inpatient hospitalization or prolongation of existing hospitalization —Results in persistent or significant disability or incapacity —Is a congenital abnormality or birth defect • *Nonserious Event* • *Causality*: Relationship of adverse event to the drug as determined by the judgment of the investigator: —Definite —Probable —Possible • *Action Taken*: —Drug or device permanently stopped —Dose reduced or device changed —Drug or device temporarily stopped —Drug dosage or device not changed
Resource Utilization	
Hospital admission	Official admission to a hospital or other acute healthcare facility. Include dates of admission and discharge.
Primary reason for admission	Primary diagnosis of the event that prompted admission, as determined by the judgment of the investigator, given as text description and latest ICD code (e.g., ICD-9 or ICD-10). May be the same as principal discharge diagnosis.
Number of days in intensive care	Number of days in intensive care
Principal discharge diagnosis	Principal discharge diagnosis listed in official record (e.g., used for reimbursement), given as text description and latest ICD code (e.g., ICD-9 or ICD-10)
Emergency department visit	Include visits not resulting in hospitalization.
Procedures performed	In addition to the procedure information obtained elsewhere in the data set (e.g., ECG, ablation, cardioversion, pacemaker/implantable cardioverter-defibrillator implant, echocardiography), other important procedures to document utilization include: • Chest X-ray • Exercise test (list imaging techniques if performed) • Holter monitor • Electrophysiology study • Angiography • Percutaneous intervention • Bypass surgery • Valve repair/replacement
Specialty of principal provider	Indicate specialty of any provider substantially involved with decision making for encounter. Indicate all that apply: • Electrophysiologist • Cardiologist (nonelectrophysiologist) • Internist (noncardiologist) • Family physician • Other, specify

TABLE 2. Continued

ELEMENT	DEFINITION
Other Events	
Myocardial infarction	Either one of the following criteria satisfies the diagnosis for an acute, evolving, or recent MI: • Typical rise and gradual fall (troponin) or more rapid rise and fall (creatine kinase–MB) of biochemical markers of myocardial necrosis with at least 1 of the following: –Ischemic symptoms –Development of pathological Q waves on the ECG –ECG changes indicative of ischemia (ST-segment elevation or depression) –Coronary artery intervention (e.g., coronary angioplasty) preceding enzyme rise Or • Pathological findings of an acute MI In addition, indicate whether the MI is: • ST-elevation MI • Non–ST-elevation MI • Based on presence of complete left bundle-branch block or uncertain
Death	Death includes all deaths regardless of etiology. Specify location • Hospital • Other institution • Community (includes home)
Cause of death	Primary cause of death as determined by investigator: • Cardiovascular death indicates cause of death was sudden cardiac death, MI, unstable angina, or other coronary artery disease; vascular death (e.g., stroke, arterial embolism, pulmonary embolism, ruptured aortic aneurysm, or dissection); congestive heart failure; or cardiac arrhythmia. Consider further specifications, such as: –Myocardial infarction –Ischemic stroke –Primary arrhythmic death (without MI) –Progressive heart failure –Intracranial hemorrhage –Non–intracranial hemorrhage-related death –Unexplained sudden death –Other cardiovascular, specify • Noncardiovascular death, specify • Unknown/unable to categorize

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Appendix A
External Peer Reviewers

TABLE 3. External Peer Reviewers: ACC/AHA Atrial Fibrillation Clinical Data Standards*

Reviewer Name†	Reviewer Category and Affiliation
Official Reviewers	
W. Barton Campbell, MD, FACC	ACC Board of Governors
Valentin Fuster, MD, PhD, FACC	ACC/AHA Task Force on Practice Guidelines
Bruce Lindsay, MD, FACC	ACC Board of Trustees
Martha Radford, MD, FACC, FAHA	ACC/AHA Task Force on Data Standards Lead Reviewer
David Sherman, MD, FAHA	AHA Reviewer, Neurology
Albert Waldo, MD, FACC, FAHA	AHA Reviewer
Content Reviewers	
A. John Camm, MD, FACC	Individual
Jamie Conti, MD, FACC	Individual
James Emery, MD, FACC	ACC Board of Governors Secondary Reviewer
Linda Gillam, MD, FACC	Individual
David Goff, MD	Individual
Robert Hong, MD, FACC	ACC Board of Governors Secondary Reviewer
Ira Nash, MD, FACC	Individual
Richard Page, MD, FACC	Individual
Edward Pritchett, MD, FACC	Individual
Denis Roy, MD, FACC	Individual

*Participation in the peer review process does not imply endorsement of the document.
†Names are listed in alphabetical order within each category of review.

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