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ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation – Reference Guide

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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I. Introduction

Members of the ACC/AHA Writing Committee for Atrial Fibrillation Clinical Data Standards, in conjunction with staff, developed a multipurpose reference guide to accompany the publication of the ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation. The intent of this document is to provide a resource that maps common data fields between atrial fibrillation (AF) core elements and other national/regional data registries and links AF core elements to elements to relevant ACC/AHA guidelines.

Table 1 is a sample from the Reference Guide that briefly illustrates its layout and column headings. A description of each column heading is listed below:

- **Element**: AF core element name
- **Definition**: AF core element definition
- **National Registries**: Maps to other national databases or registries that have used this data element
- **Reference**: Links to published ACC/AHA practice guidelines and other key sources

Table 1. Sample Page From the Reference Guide

Element	Definition	Registries	Reference
Demographics			
Date of birth	Patient date of birth (day, month, and year of patient's birth)	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) **Pg. 1266viii:** "Figure 5. Estimated prevalence of AF in relation to age in the United States, based on 4 population-based surveys. The median age of AF patients is about 75 years. Approximately 70% are between 65 and 85 years old. The overall number of men and women with AF is about equal, but approximately 60% of AF patients over age 75 years are female prevalence, age, distribution, and gender of patients with atrial fibrillation analysis and implications." **Pg. 1266xiii:** "The effect of advancing age in increasing stroke risk in AF is multifactorial. In patients with AF, aging is associated with LA enlargement, reduced LAA flow velocity, and spontaneous echo contrast, all of which predispose to LA thrombus formation. Additionally, age is a risk factor for atherosclerosis, including complex aortic arch plaque, and is associated with stroke independently of AF." **Pg. 1266xiii:** "In the Stroke Prevention in Atrial Fibrillation (SPAF) studies, age was a more potent risk factor when combined with other risk factors such as hypertension or female gender, placing women over age 75 years with AF at particular risk for cardioembolic strokes." **Pg. 1266xv:** "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."
Gender	Indicate the patient's gender at birth. Choose one of the following: • Male • Female	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) **Pg. 1266xv:** "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."

Element	Definition	Registries	Reference
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	CARAF	U.S. Census (see http://www.census.gov/population/www/socdemo/race/racefactcb.html)

II. Atrial Fibrillation Registries Column

Atrial fibrillation data elements are mapped to the most recently revised data elements from 4 AF data registries. A brief description of these registries and the total number of data fields for each registry that were mapped to the AF Clinical Data Standards are presented in Table 2. With this information, you will be able to quickly assess which common data fields can be mapped to and/or from the AF Clinical Data Standards.

Table 2. AF Data Registries

AF Data Registry	Description	Number of Mapped Fields
Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) (2)	The Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) Study is a randomized evaluation of treatment of AF by 1 of 2 strategies: ventricular rate control and anticoagulation versus rhythm control and anticoagulation. The primary end point is total mortality, analyzed by intention-to-treat. Secondary end points are composite end points (total mortality, disabling intracranial bleed [subdural and/or subarachnoid hemorrhage], stroke [embolus, thrombosis, hemorrhage], disabling anoxic encephalopathy, cardiac arrest, major noncentral nervous system bleed), cost of therapy, and quality of life. AFFIRM randomized 4060 patients and followed them for an average of 3.5 years at 213 sites in the United States and Canada.	36
The Anticoagulation and Risk Factors In Atrial Fibrillation Study (ATRIA) (3)	The Anticoagulation and Risk Factors In Atrial Fibrillation Study (ATRIA) sought to determine the prevalence of AF in the United States. The hypothesis was that the prevalence of AF in the United States could be projected for the years 1995 to 2050 by age- and sex-specific prevalence calculations and US census data. A cross-sectional study of adults aged 20 years or older who were enrolled in a large health maintenance organization in California was performed to identify all cases of AF. The age- and sex-specific prevalence calculations of AF in the study population were applied to 1995 United States census data to estimate the number of US adults with this condition in 1995. Given the anticipated growth of the population in the United States, the number of adults who will have diagnosed AF was projected by directly applying age- and sex-specific prevalence estimates from the study to US census projections for each adult age and sex category through the year 2050. The study confirms that AF is common among older adults and provides a contemporary basis for estimates of prevalence in the United States. The number of patients with AF is likely to increase 2.5-fold during the next 50 years, reflecting the growing proportion of elderly individuals.	58

AF Data Registry	Description	Number of Mapped Fields
Canadian Registry of Atrial Fibrillation (CARAF) (4)	The Canadian Registry of Atrial Fibrillation (CARAF) was a prospective, observational study. Between 1990 and 1996, 1097 patients from 6 cities across Canada (Vancouver, Calgary, London, Hamilton, Ottawa, and Montreal) were enrolled in the study at the time of their first ECG-documented episode of AF. Patients were recruited from physicians' offices and emergency departments and during hospital admission for another diagnosis. Enrollees were obtained through routine, consistent screening of emergency departments and in-hospital patients, as well as consistent referrals from general practitioners. Follow-up visits were conducted at 3 months, 1 year, and then annually. Detailed information regarding AF recurrence, medication usage, therapeutic interventions, and clinical history was collected at each follow-up visit. Treatment was at the discretion of each patient's own caregiver and was not directed by CARAF investigators.	40
Canadian Trial of Atrial Fibrillation (CTAF) (5)	The Canadian Trial of Atrial Fibrillation (CTAF) was a 25-center study sponsored by the Medical Research Council of Canada to determine the best treatment strategy to maintain sinus rhythm in patients with persistent or paroxysmal AF. Recruitment began in November 1996 and continued for 1.5 years. Patients were randomized to receive either low-dose amiodarone or conventional antiarrhythmic drug therapy. Drug selection and loading and electrical cardioversion, if necessary, were performed within 21 days of randomization, with a planned minimum follow-up period of 1 year. The primary end point was the time to first relapse of AF. Data will be analyzed on an intention-to-treat basis. Secondary outcomes are medication toxicity, mortality, major clinical events, costs of each approach, and quality of life.	2

III. Reference Column

The desire to link to current scientific evidence provided the basis for the selection and definition of appropriate data elements required to evaluate, manage, and identify relevant outcomes for patients with AF. By focusing primarily on evidence-based national guidelines, it is our hope that these linked data elements can be used to support monitoring of physician adherence to clinical practice guideline recommendations. It is also our intent that the information collected and analyzed with these elements be used to provide data on the effectiveness of therapies in practice, which could then be considered in the national guideline revision process. With this document, you will be able to quickly review links to relevant ACC/AHA guidelines. For purposes of these clinical data standards, we chose to review and reference the ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1).

We chose to link the data elements to this guideline in 2 ways: as a direct link to a class recommendation or through references within the guideline text and tables. In many instances, these links are merely presented to be illustrative of the many recommendations that speak to the importance of collecting a particular data element and are not illustrative of all links. For example, antithrombotic agents are recommended for AF patients in the most recent ACC/AHA/ESC AF guidelines (1). In Table 3, the guideline, the relevant section, and the class recommendation are referenced. Similarly, there are references about the use of antithrombotic agents throughout the guideline reviewed. We have selected only 1 such reference as an illustration. It is clear that it is necessary to collect information on the use of antithrombotic agents for this population.

Table 3. Example of Guideline Link: "Antithrombotic agents (including aspirin)"

Element	Definition	Reference
Antithrombotic agents (including aspirin)	List generic names for all antithrombotic and antiplatelet medications that patient is currently prescribed. Indicate daily dose.	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xlviii: "*Recommendations for Antithrombotic Therapy in Patients With AF Class I* 1. Administer antithrombotic therapy (oral anticoagulation or aspirin) to all patients with AF, except those with lone AF, to prevent thromboembolism. *(Level of Evidence:* A)"

The guideline may be referenced for data elements and definitions that are derived from guideline text. For example, "history of ischemic stroke" is not linked to any specific recommendation per se within the guideline. However, a description of its importance in describing a potential patient history factor is given on page 1266vii of the ACC/AHA/ESC AF Guidelines (1): "The rate of ischemic stroke among patients with non-rheumatic AF averages 5% per year, which is between 2 and 7 times that of people without AF. One of every 6 strokes occurs in patients with AF."

On a few occasions, data elements and definitions were linked to elements collected in key clinical trials, such as CARAF (4) or AFFIRM (2).

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IV. Atrial Fibrillation Clinical Data Standards Reference Guide

A. Retrospective Data[1]

Element	Definition	Registries	Reference
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	ATRIA CARAF	
Date of study entry	Date of initiation of collection of information for study purposes	ATRIA CARAF	
Date of birth	Patient date of birth (day, month, and year of patient's birth)	ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266viii: "Figure 5. Estimated prevalence of AF in relation to age in the United States, based on 4 population-based surveys. The median age of AF patients is about 75 years. Approximately 70% are between 65 and 85 years old. The overall number of men and women with AF is about equal, but approximately 60% of AF patients over age 75 years are female prevalence, age, distribution, and gender of patients with atrial fibrillation analysis and implications." Pg. 1266xiii: "The effect of advancing age in increasing stroke risk in AF is multifactorial. In patients with AF, aging is associated with LA enlargement, reduced LAA flow velocity, and spontaneous echo contrast, all of which predispose to LA thrombus formation. Additionally, age is a risk factor for atherosclerosis, including complex aortic arch plaque, and is associated with stroke independently of AF." Pg. 1266xiii: "In the Stroke Prevention in Atrial Fibrillation (SPAF) studies, age was a more potent risk factor when combined with other risk factors such as hypertension or female gender, placing women over age 75 years with AF at particular risk for cardioembolic strokes." Pg. 1266xv: "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."

[1] **Boldfaced type** indicates elements of particular relevance to atrial fibrillation (AF).

	Definition	Regist	Reference
Gender	Indicate the patient's gender at birth. Choose one of the following: • Male • Female	ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."
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	ATRIA CARAF	U.S. census (see http://www.census.gov/population/www/socdemo/race/racefactcb.html)
Insurance payor	Indicate the patient's primary insurance payor 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 payor 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.	ATRIA	ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6) (modified)
Government payor type	If the patient's primary insurance payor for this encounter is "Government," choose the type of government insurance: • Medicare • Medicaid • Other		

	Definition	Regis	Reference
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)	CARAF	
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		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg 1266v-1266vii: "An episode of AF may be self-limited or require medical intervention for termination. Over time, the pattern of AF may be defined in terms of the number of episodes, duration, frequency, mode of onset and possible triggers, and response to therapy, but these features may be impossible to discern when AF is first encountered in an individual patient. Although the pattern of the arrhythmia can change over time, it may be of clinical value to characterize the arrhythmia at a given moment. Assorted labels have been used to describe the pattern of AF, including acute, chronic, paroxysmal, intermittent, constant, persistent, and permanent, but the vagaries of definitions make it difficult to compare studies of AF in terms of the effectiveness of therapeutic strategies based on these designations. The classification scheme recommended in this document represents a consensus driven by a desire for simplicity and clinical relevance. "The clinician should distinguish a first detected episode AF, whether or not it is symptomatic or self-limited, recognizing that there may be uncertainty about the duration of the episode and about previous undetected episodes (Fig. 3). When a patient has had 2 or more episodes, AF is considered recurrent. If the arrhythmia terminates spontaneously, recurrent AF is designated paroxysmal; when sustained, AF is designated persistent. In the latter case, termination with pharmacological therapy or electrical cardioversion does not change the designation. Persistent AF may be either the first presentation of the arrhythmia or the culmination of recurrent episodes of paroxysmal AF. The category of persistent AF also includes cases of longstanding AF (e.g., greater than 1 year) in which cardioversion has not been indicated or attempted, usually leading to permanent AF (Fig. 3)."

	Definition	Registries	Reference
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	AFFIRM	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."
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 • Pericarditis • Lung disease • Hyperthyroidism • Other, specify		

	Definition	Registries	Reference
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.	ATRIA	
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.	AFFIRM	

	Definition	Registries	Reference
Unsuccessful prior pharmacological cardioversion attempted	List all generic drug names previously used that did not result in the absence of AF or atrial flutter.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xix: "Pharmacological cardioversion has been the subject of intense research for over a decade. Although pharmacological and electrical cardioversion have not been compared directly, pharmacological approaches appear to be simpler but less efficacious than electrical cardioversion." Pg. 1266xix: "The development of new drugs has increased the popularity of pharmacological cardioversion, although some disadvantages persist, including the risk of drug-induced torsade de pointes ventricular tachycardia or other serious arrhythmias. Pharmacological cardioversion is still less effective than electrical cardioversion, but the latter requires conscious sedation or anesthesia, whereas the former does not."
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.	AFFIRM	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Page 1266xxiv: "Electrical cardioversion is used to normalize all abnormal cardiac rhythms except ventricular fibrillation. "Successful cardioversion of AF depends on the nature of the underlying heart disease and the current density delivered to the atrial myocardium. The latter, in turn, depends on the voltage of the defibrillator capacitor, the output waveform, the size and position of the electrode paddles, and transthoracic impedance. The current density delivered decreases as the impedance increases for a given paddle surface area. The impedance is related to the size and composition of the electrode paddles, the contact medium between the electrodes and the skin, the distance between the paddles, body size, phase of the respiratory cycle, number of shocks delivered, and interval between shocks. Proper attention to each of these variables is important for successful cardioversion."
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.		

	Definition	Registries	Reference
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.	AFFIRM	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxv: "A technique for delivering high-energy (200 to 300 J) direct current internally for cardioversion of AF was introduced by Lévy et al. in 1988, using an RA catheter and a backplate. In a randomized trial, internal cardioversion was superior to external countershock, particularly in obese patients and patients with chronic obstructive lung disease, but the frequency of recurrence of AF over the long term did not differ between the 2 methods. A monophasic shock waveform was used for external cardioversion in the study; use of a biphasic waveform would likely necessitate internal cardioversion considerably less frequently. Other techniques for internal cardioversion apply low-energy (less than 20 J) shocks via a large-surface cathodal electrode in the RA and an anode in the coronary sinus or left pulmonary artery. These techniques have been successful for restoration of sinus rhythm in 70% to 90% of mixed cohorts, including those who did not respond to external cardioversion."
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		

Element	Definition	Registries	Reference
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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266vii: "The rate of ischemic stroke among patients with nonrheumatic AF averages 5% per year, which is between 2 and 7 times that of people without AF. One of every 6 strokes occurs in patients with AF."
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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266vii: "The rate of ischemic stroke among patients with nonrheumatic AF averages 5% per year, which is between 2 and 7 times that of people without AF. One of every 6 strokes occurs in patients with AF."
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.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xii: "Although ischemic stroke and systemic arterial occlusion in AF are generally attributed to embolism of thrombus from the LA, the pathogenesis of thromboembolism is complex. Up to 25% of AF-associated strokes may be due to intrinsic cerebrovascular diseases, other cardiac sources of embolism, or atheromatous pathology in the proximal aorta."

Element	Definition	Registries	Reference
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	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xii: "About half of all elderly AF patients have chronic hypertension (a major risk factor for cerebrovascular disease), and approximately 12% harbor cervical carotid artery stenosis. Carotid atherosclerosis is not substantially more prevalent in AF patients with stroke than in patients without AF, however, and is probably a relatively minor contributing factor."
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	AFFIRM ATRIA	
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.	AFFIRM ATRIA	

Element	Definition	Registries	Reference
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 mmHg systolic or 90 mmHg 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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1255xiii: "The strong association between hypertension and stroke in AF is probably mediated primarily by embolism originating in the LAA, but hypertension also increases the risk of noncardioembolic strokes in AF. Hypertension in AF patients is associated with reduced LAA flow velocity, spontaneous echo contrast, and thrombus formation."
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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxv: "Patients with congestive HF are particularly prone to the ventricular proarrhythmic effects of antiarrhythmic drugs related to underlying myocardial dysfunction and electrolyte disturbances." Pg. 1266xxlii: "Table 17. Risk Factors for Ischemic Stroke and Systemic Embolism in Patients With Nonvalvular Atrial Fibrillation"
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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266vii: "AF is prevalent in patients with congestive HF or valvular heart disease and increases in prevalence with the severity of these conditions."
History of valve intervention	Indicate each valve repair, valvuloplasty, or valve replacement in patient history. For valve replacement, indicate location and type.	ATRIA	
History of myocardial infarction (MI)	Previous MI before this encounter as determined by the following (indicate all that apply): • Hospital admission for acute MI • 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.		

Element	Definition	Registries	Reference
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	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Specific cardiovascular conditions associated with AF include valvular heart disease (most often mitral valve disease), **coronary artery disease (CAD)**, and hypertension, particularly when LV hypertrophy is present. In addition, AF may be associated with HCM or dilated cardiomyopathy or congenital heart disease, especially atrial septal defect in adults. Sinus node disease, ventricular preexcitation, and supraventricular tachycardias may also underlie AF. The list of etiologies also includes restrictive cardiomyopathies (such as amyloidosis, hemochromatosis, and endomyocardial fibrosis), cardiac tumors, and constrictive pericarditis. Other heart diseases, such as mitral valve prolapse even without mitral regurgitation, calcification of the mitral annulus, cor pulmonale, and idiopathic dilation of the RA, have been associated with a high incidence of AF. Atrial fibrillation is commonly encountered in patients with the sleep apnea syndrome, but whether the arrhythmia is provoked by hypoxia or other biochemical abnormality or mediated by changes in pulmonary dynamics or RA factors has not been determined. Table 3 shows a list of associated heart diseases in the contemporary population of the ALFA study."
History of hypertrophic cardiomyopathy	Echocardiographically established hypertrophic cardiomyopathy. Specify type: • Obstructive • Nonobstructive, nonhypertensive Does not include hypertensive cardiomyopathy (concentric hypertrophy).		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Specific cardiovascular conditions associated with AF include valvular heart disease (most often mitral valve disease), coronary artery disease (CAD), and hypertension, particularly when LV hypertrophy is present. In addition, AF may be associated with **HCM** or dilated cardiomyopathy or congenital heart disease, especially atrial septal defect in adults."
History of cardiomyopathy	Left ventricular systolic dysfunction with an estimated ejection fraction less than 0.40.	AFFIRM CARAF CTAF	
History of congenital heart disease	Cardiac anomaly present from birth or congenital abnormality on echocardiography. Specify diagnosis and any prior repair.	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Specific cardiovascular conditions associated with AF include valvular heart disease (most often mitral valve disease), coronary artery disease (CAD), and hypertension, particularly when LV hypertrophy is present. In addition, AF may be associated with HCM or dilated cardiomyopathy or **congenital heart disease**, especially atrial septal defect in adults."
History of ventricular arrhythmias	Ventricular tachycardia or ventricular fibrillation requiring cardioversion and/or medication (intravenous or oral) with antiarrhythmic drugs.	CARAF	ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6)

Element	Definition	Registries	Reference
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 >200 msec • 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	AFFIRM	
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		

Element	Definition	Registries	Reference
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	ATRIA CARAF	
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 • 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		

Element	Definition	Registries	Reference
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.	AFFIRM ATRIA CARAF CTAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xlii: "In addition to prior thromboembolism, HF, hypertension, increasing age, and **diabetes mellitus** have consistently emerged as independent risk factors for ischemic stroke in nonvalvular AF." Pg. 1266xxlii: "Table 17. Risk Factors for Ischemic Stroke and Systemic Embolism in Patients With Nonvalvular Atrial Fibrillation"
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.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Atrial fibrillation may be related to acute, temporary causes, including alcohol intake ("holiday heart syndrome"), surgery, electrocution, MI, pericarditis, myocarditis, **pulmonary embolism or other pulmonary diseases**, and hyperthyroidism or other metabolic disorders." Pg. 1266lv: "Supraventricular arrhythmias, including AF, are common in patients with chronic obstructive lung disease and have adverse prognostic implications in patients with acute exacerbations of chronic obstructive pulmonary disease. Treatment of the underlying lung disease and correction of hypoxia and acid base imbalance are of primary importance."
History of thyroid disease	History of hyperthyroidism or hypothyroidism. Indicate history of prior radioactive iodine treatment or prior medical treatment for hyperthyroidism.	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Atrial fibrillation may be related to acute, temporary causes, including alcohol intake ("holiday heart syndrome"), surgery, electrocution, MI, pericarditis, myocarditis, pulmonary embolism or other pulmonary diseases, and **hyperthyroidism** or other metabolic disorders." Pg. 1266liii: "AF occurs in 10% to 25% of patients with hyperthyroidism, more commonly in men and the elderly than in women or patients less than 75 years old."

Element	Definition	Registries	Reference
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	AFFIRM ATRIA CARAF	National Kidney Foundation. "K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification" (7)
History of chronic liver disease	Documented cirrhosis or chronic liver disease	AFFIRM ATRIA	
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.	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Atrial fibrillation may be related to acute, temporary causes, including **alcohol intake** ("holiday heart syndrome"), surgery, electrocution, MI, pericarditis, myocarditis, pulmonary embolism or other pulmonary diseases, and hyperthyroidism or other metabolic disorders."
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.	AFFIRM CARAF	ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6) (modified)
History of illicit drug use	Documented history of current, recent, or remote abuse of any controlled substance. Indicate substance.	CARAF	

Element	Definition	Registries	Reference
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.		

B. Prospective Data[2,3]

Element	Definition	Registries	Reference
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.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Atrial fibrillation may be symptomatic or asymptomatic, even in the same patient. The dysrhythmia may present for the first time with an embolic complication or exacerbation of HF, but most patients with AF complain of palpitations, chest pain, dyspnea, fatigue, lightheadedness, or syncope."

[2] Each may be collected multiple times during clinical follow-up.
[3] **Boldfaced type** indicates elements of particular relevance to atrial fibrillation (AF).

Element	Definition	Registries	Reference
Primary reason for encounter	Primary symptom or condition that prompted patient to seek medical attention: • AF-related • Other cardiac-related reason • Not cardiac related	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266v-1266vii: "An episode of AF may be self-limited or require medical intervention for termination. Over time, the pattern of AF may be defined in terms of the number of episodes, duration, frequency, mode of onset and possible triggers, and response to therapy, but these features may be impossible to discern when AF is first encountered in an individual patient. Although the pattern of the arrhythmia can change over time, it may be of clinical value to characterize the arrhythmia at a given moment. Assorted labels have been used to describe the pattern of AF, including acute, chronic, paroxysmal, intermittent, constant, persistent, and permanent, but the vagaries of definitions make it difficult to compare studies of AF in terms of the effectiveness of therapeutic strategies based on these designations. The classification scheme recommended in this document represents a consensus driven by a desire for simplicity and clinical relevance. "The clinician should distinguish a first detected episode AF, whether or not it is symptomatic or self-limited, recognizing that there may be uncertainty about the duration of the episode and about previous undetected episodes. When a patient has had 2 or more episodes, AF is considered recurrent. If the arrhythmia terminates spontaneously, recurrent AF is designated paroxysmal; when sustained, AF is designated persistent. In the latter case, termination with pharmacological therapy or electrical cardioversion does not change the designation. Persistent AF may be either the first presentation of the arrhythmia or the culmination of recurrent episodes of paroxysmal AF. The category of persistent AF also includes cases of longstanding AF (e.g., greater than 1 year) in which cardioversion has not been indicated or attempted, usually leading to permanent AF."
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.)		

Element	Definition	Registries	Reference
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.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xviii: "The major issues in management of patients with AF are related to the arrhythmia itself and to prevention of thromboembolism. In patients with persistent AF, there are fundamentally 2 ways to manage the dysrhythmia: to restore and maintain sinus rhythm or to allow AF to continue and ensure that the ventricular rate is controlled. Although this decision must be faced often by clinicians because AF is common, remarkably little research has been conducted in the form of controlled trials of antiarrhythmic drugs that take into account the various mechanisms and patterns of AF. Management strategies and therapeutic algorithms must be based on the scant evidence available. Information on prevention of thromboembolism is more substantial, however, enabling recommendations to be based on a higher level of evidence."
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.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxix: "Fourteen controlled trials of drug prophylaxis involving patients with paroxysmal AF have been published, and there have been 22 published trials of drug prophylaxis for maintenance of sinus rhythm in patients with persistent AF. Comparative data are not sufficient to permit subclassification by drug or etiology."
Antithrombotic agents	List generic names for all antithrombotic and antiplatelet medications (including aspirin and clopidogrel) that are currently prescribed to patient. Indicate daily dose.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xlviii: "*Recommendations for Antithrombotic Therapy in Patients With AF* *Class I* 1. Administer antithrombotic therapy (oral anticoagulation or aspirin) to all patients with AF, except those with lone AF, to prevent thromboembolism. *(Level of Evidence:* A)"
Angiotensin-converting enzyme inhibitors	List generic names for all angiotensin-converting enzyme inhibitors that are currently prescribed to patient.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266lii: "ACE inhibition appears to reduce the incidence of AF in patients with LV dysfunction after acute MI."
Angiotensin receptor blockers	List generic names for all angiotensin receptor blockers that are currently prescribed to patient.	ATRIA	

Element	Definition	Registries	Reference
Other cardiac medications	List generic names for all other cardiac medications that are currently prescribed to patient.	ATRIA	
Thyroid replacement	Indicate whether patient is currently receiving thyroxine and/or T3.	ATRIA	
Antidiabetic therapy	Patient has current prescription for antidiabetic medication. Indicate type: • Oral agent • Insulin • Both oral agent and insulin	ATRIA	
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.)	ATRIA	
Cox-2 inhibitor	List Cox-2 inhibitors taken on average more than once per week.	ATRIA	
Beta-agonists	List inhaled and oral beta-2-adrenergic agonists taken on average more than once per week.	ATRIA	
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.		ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6) (modified)
Systolic and diastolic blood pressure	Systolic and diastolic blood pressure (mmHg) recorded closest to the time of presentation to the healthcare facility. Patient position (supine, sitting, other) should be noted.		ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6) (modified)
Height	Patient's height in centimeters or inches (list units)	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."
Weight	Patient's weight in kilograms or pounds (list units). Body mass index can be calculated from height and weight.	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3. Demographics and Associated Conditions Among Patients With Atrial Fibrillation in the ALFA Study."

Element	Definition	Registries	Reference
Physical signs and symptoms of congestive heart failure	Indicate whether patient meets criteria for congestive heart failure as defined by the Framingham Heart Study (8). 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)		McKee PA, Castelli WP, McNamara PM, Kannel WB. The natural history of congestive heart failure: the Framingham study (8)
Pregnancy	Indicate whether the patient is pregnant.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xl: "Atrial fibrillation is rare during pregnancy and is usually associated with another underlying cause, such as mitral stenosis, congenital heart disease, or hyperthyroidism. A rapid ventricular response to AF can have serious hemodynamic consequences for both the mother and the fetus."
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)	ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xviii: "Blood tests are routine but can be abbreviated. It is important that thyroid function, serum electrolytes, and the hemogram be measured at least once."
Serum creatinine	Serum creatinine level (mg/dl or mmol/l)	ATRIA CARAF	ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6) (modified)

Element	Definition	Registries	Reference
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)	ATRIA	
Potassium	Serum potassium (mg/dl or mmol/l)	ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xviii: "Blood tests are routine but can be abbreviated. It is important that thyroid function, serum electrolytes, and the hemogram be measured at least once."
Magnesium	Serum magnesium (mg/dl or mmol/l)	ATRIA CARAF	
Hemoglobin	Serum hemoglobin (mg/dl)	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xviii: "Blood tests are routine but can be abbreviated. It is important that thyroid function, serum electrolytes, and the hemogram be measured at least once."
International Normalized Ratio (INR)	Measured INR for assessment of anticoagulation status/prothrombin time	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xlvii: "*Recommendations for Antithrombotic Therapy in Patients With AF* *Class I* 3. Chronic oral anticoagulant therapy in a dose adjusted to achieve a target intensity INR of 2 to 3 in patients at high risk of stroke, unless contraindicated. (*Level of Evidence: A*) b. INR should be determined at least weekly during the initiation of oral anticoagulation therapy and monthly when the patient is stable. (*Level of Evidence: A*)"
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.		

Element	Definition	Registries	Reference
Electrocardiography			
Rhythm	The categories of rhythm are: • Sinus rhythm • Atrial fibrillation • Atrial flutter • Paced • Other rhythm (e.g., ventricular tachycardia, supraventricular tachycardia)	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266iv: "On the electrocardiogram (ECG), AF is described by the replacement of consistent P waves by rapid oscillations or fibrillatory waves that vary in size, shape, and timing, associated with an irregular, frequently rapid ventricular response when atrioventricular (AV) conduction is intact." Pg. 1266xv: "Table 3 2. Electrocardiogram, to identify • **Rhythm (verify AF)** • LV hypertrophy • P-wave duration and morphology or fibrillatory waves • Preexcitation • Bundle-branch block • Prior MI • Other atrial arrhythmias • To measure and follow the RR, QRS, and QT intervals in conjunction with antiarrhythmic drug therapy"
Heart rate on ECG	Heart rate as measured on ECG. Recommended measurement is over at least 6 seconds.	AFFIRM	
Previous MI	Indicate whether pathological Q waves are present on ECG.	ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xvii: "Table 4. Minimum and Additional Clinical Evaluation in Patients With Atrial Fibrillation"

Element	Definition	Registries	Reference
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)	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3 2. Electrocardiogram, to identify • Rhythm (verify AF) • **LV hypertrophy** • P-wave duration and morphology or fibrillatory waves • Preexcitation • Bundle-branch block • Prior MI • Other atrial arrhythmias • To measure and follow the RR, QRS, and QT intervals in conjunction with antiarrhythmic drug therapy"
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	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3 2. Electrocardiogram, to identify • Rhythm (verify AF) • LV hypertrophy • P-wave duration and morphology or fibrillatory waves • Preexcitation • **Bundle-branch block** • Prior MI • Other atrial arrhythmias • To measure and follow the RR, QRS, and QT intervals in conjunction with antiarrhythmic drug therapy"
Pre-excitation	Indicate whether characteristic delta wave is present.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xiv: "Atrial fibrillation may be associated with another supraventricular tachycardia, the WPW syndrome, or AV nodal reentrant tachycardias, and treatment of these primary arrhythmias reduces the incidence of recurrent AF."
Atrial abnormality	Indicate whether left, right, or biatrial abnormality is present.		
U-waves	Indicate whether U-waves are present.		

Element	Definition	Registries	Reference
Corrected QT (QTc) interval	QTc interval measured from the ECG		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xv: "Table 3 2. Electrocardiogram, to identify • Rhythm (verify AF) • LV hypertrophy • P-wave duration and morphology or fibrillatory waves • Preexcitation • Bundle-branch block • Prior MI • Other atrial arrhythmias • **To measure and follow the RR, QRS, and QT intervals in conjunction with antiarrhythmic drug therapy**"
Echocardiography			
Echocardiographic modality	Transthoracic or transesophageal		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xviii: "TEE places high frequency ultrasound transducers in close proximity to the heart to provide high-quality images of cardiac structure and function. It is the most sensitive and specific technique to detect sources and potential mechanisms for cardiogenic embolism and has been used in AF to stratify patients in terms of stroke risk and to guide cardioversion." Pg. 1266xliii: "TEE is the most sensitive and specific imaging technique for detection of LA and LAA thrombus, far surpassing transthoracic echocardiography."
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.		D.J. Sahn et al. "Recommendations regarding quantitation in M-mode echocardiography: results of a survey of echocardiographic measurements" (9) ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266 xvii: "Two dimensional transthoracic echocardiography should be acquired during the initial workup of all AF patients to determine LA and LV dimensions and LV wall thickness and function and to exclude occult valvular or pericardial disease or HCM. LV systolic and diastolic performance help guide decisions regarding antiarrhythmic and antithrombotic therapy. Thrombus should be sought in the LA but is seldom detected without TEE."

Element	Definition	Registries	Reference
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) (10)		Gutman J, Wang YS, Wahr D, Schiller NB. Normal left atrial function determined by 2-dimensional echocardiography. (10)
Left ventricular diastolic diameter	Left ventricular diameter measured at end ventricular diastole (in centimeters). Indicate whether by M-mode or two-dimensional imaging.		N.B. Schiller et al. "Recommendations for quantitation of the left ventricle by two-dimensional echocardiography. American Society of Echocardiography Committee on Standards, Subcommittee on Quantitation of Two-Dimensional Echocardiograms" (11)
Left ventricular systolic function	Subjective assessment as: • Normal • Mildly decreased • Mild to moderately decreased • Moderately decreased • Moderately to severely decreased • Severely decreased		J.M. Gardin. Recommendations for a standardized report for adult transthoracic echocardiography. American Society of Echocardiography, 3/02 (modified) (12)
Ejection fraction	Number measured (specify technique) or estimated. Give midpoint if range given. Listed as a percentage.	AFFIRM CARAF	
Left ventricular diastolic function	Categories include: • Normal • Impaired relaxation (Grade I) • Pseudonormal (Grade II) • Restrictive, reversible (Grade III) • Restrictive, irreversible (Grade IV) • Not obtained		J.M. Gardin. Recommendations for a standardized report for adult transthoracic echocardiography. American Society of Echocardiography, 3/02 (modified) (12)
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.	AFFIRM	
Thrombus with location	• Left atrial appendage • Left atrium • Right atrium • Left ventricle • Right ventricle Indicate all that apply.	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266 xviii: "Thrombus should be sought in the LA but is seldom detected without TEE."
Spontaneous echo contrast with location	• Left atrial appendage • Left atrium • Right atrium • Left ventricle • Right ventricle Indicate all that apply.		

Element	Definition	Registries	Reference
Mitral valve morphology	Predominant assessment as: • Normal • Rheumatic • Myxomatous • Prolapsed • Flail • Prosthetic • Other abnormal, specify		J.M. Gardin. Recommendations for a standardized report for adult transthoracic echocardiography. American Society of Echocardiography, 3/02 (modified) (12)
Mitral stenosis	Mitral valve area estimated from the pressure half-time of the left ventricular inflow (220/pressure half-time)	CARAF	
Mitral regurgitation	• None • Mild • Mild to moderate • Moderate • Moderate to severe • Severe	CARAF	J.M. Gardin. Recommendations for a standardized report for adult transthoracic echocardiography. American Society of Echocardiography, 3/02 (modified) (12)
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		J.M. Gardin. Recommendations for a standardized report for adult transthoracic echocardiography. American Society of Echocardiography, 3/02 (modified) (12)
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			
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		A.S. Bierman et al. "How well does a single question about health predict the financial health of Medicare managed care plans?" (13)
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		

Element	Definition	Registries	Reference
Summary Assessment			
Heart failure status (NYHA classification)	New York Heart Association 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.	AFFIRM	The Criteria Committee of the New York Heart Association. *Diseases of the Heart and Blood Vessels: Nomenclature and Criteria for Diagnosis*. 6th ed. Boston, Mass: Little Brown; 1964.
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.		ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6)

Element	Definition	Registries	Reference
Angina class (CCS class)	Grading of patient's angina by class (CCS classification system) (14):(15) • *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.	AFFIRM	Campeau L. Grading of angina pectoris (14) Gibbons RJ, Abrams J, Chatterjee K, et al. ACC/AHA 2002 guideline update for the management of patients with chronic stable angina (15)
Cardioversion			
Site	Indicate all that apply. • Transthoracic (single defibrillator) • Transthoracic (dual defibrillators) • Intracardiac/intravascular • Epicardial		
Waveform	Categories include: • Monophasic, all types • Rectilinear biphasic • Truncated exponential biphasic • Other, specify		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxiv: "The output waveform also influences the amount of energy delivered to the heart during electrical cardioversion. Most equipment used for external cardioversion has monophasic waveform. In a randomized trial that compared cardioversion with a standard damped sine wave monophasic waveform with cardioversion applying a rectilinear biphasic waveform, the 77 patients treated with monophasic shocks had a cumulative success rate of 79%, whereas 94% of 88 subjects cardioverted with biphasic shocks were successfully converted to sinus rhythm." Pg. 1266xxv: "The initial energy delivered with a monophasic waveform may be low (50 J) for cardioversion of atrial flutter. Higher energy is required for AF cardioversion, starting with at least 200 J."

Element	Definition	Registries	Reference
Number of shocks delivered	Indicate the number of shocks delivered during current session.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxv: "Some physicians begin with higher energies to reduce the number of shocks (and thus the total energy) delivered. Lower energies are required with a biphasic waveform. To avoid myocardial damage, the interval between 2 consecutive shocks should not be less than 1 minute."
Maximal energy used	Indicate maximal energy used in current session.		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxv: "The initial energy delivered with a monophasic waveform may be low (50 J) for cardioversion of atrial flutter. Higher energy is required for AF cardioversion, starting with at least 200 J. The energy output is increased successively in increments of 100 J until a maximum of 400 J is reached. Some physicians begin with higher energies to reduce the number of shocks (and thus the total energy) delivered. Lower energies are required with a biphasic waveform. To avoid myocardial damage, the interval between 2 consecutive shocks should not be less than 1 minute."
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.)		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxvi: "*Recommendations for Pharmacological Therapy to Maintain Sinus Rhythm* *Class I* 1. Base selection of pharmacological therapy to maintain sinus rhythm in patients with disabling or otherwise troublesome symptoms during AF predominantly on safety. *(Level of Evidence:* B)"
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).		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxv: "Rates of **electrical cardioversion** of AF vary from 70% to 90%. This variability is explained in part by differences in patient characteristics and in part by the definition of success. The interval at which the result is evaluated ranges in the literature from immediately after cardioversion to several days afterward. Restoration and maintenance of sinus rhythm are less likely to occur through cardioversion when AF has been present for longer than a year than in patients with AF of shorter duration."

Element	Definition	Registries	Reference
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)		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxix: "Although it has long been known that most recurrences of AF occur within the first month after electrical cardioversion, recent research with internal atrial cardioversion, as well as day-to-day postconversion studies, have established several patterns of recurrence. In some cases, there is complete failure of direct-current countershock to elicit even a single isolated sinus or ectopic atrial beat, tantamount to a high atrial defibrillation threshold. In others, AF reappears within 1 to 2 minutes after a period of sinus rhythm. Sometimes recurrence is delayed from 1 day to 2 weeks or more after the shock. Complete shock failure and immediate recurrences occur in approximately 25% of patients undergoing electrical cardioversion, and subacute recurrences occur within 2 weeks in about an equal proportion."
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		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxvi: "The risks of electrical cardioversion are mainly related to embolic events and cardiac arrhythmias."
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	CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxvi: "Given the success of surgical approaches to AF, several catheter ablation strategies have been designed to produce similar effects." Pg. 1266xxxvii: "Catheter ablation is more effective than antiarrhythmic drugs for treatment of atrial flutter, reducing the recurrence rate from 93% to 5% when used as first-line therapy. In addition, the risk of developing AF may also be lower after catheter ablation of atrial flutter than with pharmacological therapy (29% vs. 60% over the first year)." Pg. 1266xli: "The use of catheter ablation to modify AV nodal conduction by eliminating posterior atrial inputs to the AV node has been reported to decrease the ventricular rate during AF and to improve cardiac symptoms without requiring pacemaker implantation."

Element	Definition	Registries	Reference
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 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	AFFIRM CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xl: "**3. Nonpharmacological/AV Nodal Ablation.** AV nodal ablation and permanent pacemaker implantation provide a highly effective means of improving symptoms in selected patients with AF."
Intracardiac defibrillator insertion	Specify type: • Single chamber • Dual chamber • Biventricular Specify indication: • Atrial fibrillation • Secondary prevention of cardiac arrest • 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		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxvii: "D. INTERNAL ATRIAL DEFIBRILLATORS There has been an interest in internal cardioversion of AF for the past 10 years. Early work using a sheep model showed that delivery of a synchronous shock between the high RA and coronary sinus was effective for the termination of AF. A clinical trial of a low-energy transvenous atrial cardioverter/ defibrillator that used a 3/3-ms biphasic waveform shock synchronized to the R wave established that internal cardioversion was safe, although the energy required in patients with persistent AF was relatively high (a mean of 3.5 J). "Another device with dual-chamber sensing, pacing, and cardioversion capabilities and a maximum output of 27 J has both atrial and ventricular cardioversion/defibrillation capabilities. The device, which weighs 93 g, was designed to treat both atrial and ventricular arrhythmias with pacing modalities before delivering low-energy shocks. A number of investigators are pursuing other techniques to terminate AF by pacing, but the efficacy of this technique may be limited to atrial tachycardia and atrial flutter. Because these units record the number of AF episodes, they provide a very accurate representation of AF control."

Element	Definition	Registries	Reference
Surgery/type	• Maze: – Approach: epicardial/endocardial – Energy: radiofrequency ablation, cryoablation, laser, other • Other, specify	AFFIRM	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxvi: "Based on mapping studies of animal and human AF, Cox developed a surgical procedure (maze operation) that controls AF in more than 90% of selected patients."
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		ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xxxvii: "Potential complications of catheter ablation for AF include systemic embolism, pulmonary vein stenosis, pericardial effusion, cardiac tamponade, and phrenic nerve paralysis." Pg. 1266xli: "Complications of AV nodal ablation include those of pacemaker implantation, as well as ventricular arrhythmias, relatively rare instances of worsened LV function, thromboembolism associated with interruption of anticoagulation, and a greater rate of progression from paroxysmal to persistent AF."
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.	ATRIA	
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)	ATRIA	
Transient ischemic attack	Acute loss of neurological function caused by an ischemic event with resolution of symptoms by 24 hours after onset.	ATRIA	ACC Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Acute Coronary Syndromes (6)

Element	Definition	Registries	Reference
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.	ATRIA	
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.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xlvi: "Anticoagulation increases the frequency and severity of major extracranial and intracranial hemorrhage, however, and all of these trials excluded patients considered at high risk of bleeding. Patient age and the intensity of anticoagulation are the most powerful predictors of major bleeding."
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.	ATRIA	
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).	ATRIA	
Procedural intervention to control bleeding	Indicate type of procedural intervention (e.g., surgical or catheter-based) performed to control an episode of bleeding.	ATRIA	

Element	Definition	Registries	Reference
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	CARAF	International Conference on Harmonisation Clinical Safety Data Management Guidelines as adopted by the Food and Drug Administration (http://www.fda.gov/cber/guidelines.htm)

Element	Definition	Registries	Reference
Resource Utilization			
Hospital admission	Official admission to a hospital or other acute healthcare facility. Include dates of admission and discharge.	ATRIA	
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.	ATRIA	
Number of days in intensive care	Number of days in intensive care	ATRIA	
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)	ATRIA	
Emergency department visit	Include visits not resulting in hospitalization.	ATRIA	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266xvi: "The setting in which the physician initially encounters the AF patient may be a clue to its origin. Patients seen in the hospital emergency department tend to have a higher incidence of organic heart disease than those seen in an ambulatory clinic setting, where the incidence of lone AF can be higher than 30%."
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	ATRIA	
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		

Element	Definition	Registries	Reference
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	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266lii: "Atrial fibrillation is an independent risk factor for increased in-hospital mortality in the setting of acute MI (25.3% with AF vs. 16.0% without AF), 30-day mortality (29.3% vs. 19.1%), and 1-year mortality (48.3% vs. 32.7%); patients who developed AF during hospitalization had a worse prognosis than those with AF on admission. Stroke rates are also increased in patients with MI and AF compared with those without AF."
Death	Death includes all deaths regardless of etiology. Specify location • Hospital • Other institution • Community (includes home)	AFFIRM ATRIA CARAF	ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation (1) Pg. 1266lii: Atrial fibrillation is an independent risk factor for increased in-hospital mortality in the setting of acute MI (25.3% with AF vs. 16.0% without AF), 30-day mortality (29.3% vs. 19.1%), and 1-year mortality (48.3% vs. 32.7%); patients who developed AF during hospitalization had a worse prognosis than those with AF on admission. Stroke rates are also increased in patients with MI and AF compared with those without AF."

Element	Definition	Registries	Reference
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	AFFIRM ATRIA	S.J. Connolly et al., "Effects of Physiologic Pacing versus Ventricular Pacing on the Risk of Stroke and Death Due to Cardiovascular Causes" (16)

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