ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation)

N. A. Mark Estes, III, Jonathan L. Halperin, Hugh Calkins, Michael D. Ezekowitz, Paul Gitman, Alan S. Go, Robert L. McNamara, Joseph V. Messer, James L. Ritchie, Sam J.W. Romeo, Albert L. Waldo and D. George Wyse

The online version of this article, along with updated information and services, is located on the World Wide Web at:

http://circ.ahajournals.org/cgi/content/full/117/8/1101

ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation)

Developed in Collaboration With the Heart Rhythm Society

WRITING COMMITTEE MEMBERS

N.A. Mark Estes III, MD, FACC, FAHA, FHRS, Co-Chair;
Jonathan L. Halperin, MD, FACC, FAHA, Co-Chair; Hugh Calkins, MD, FACC, FAHA;
Michael D. Ezekowitz, MB, ChB, DPhil, FACC; Paul Gitman, MD, MACP; Alan S. Go, MD;
Robert L. McNamara, MD, MHS, FACC; Joseph V. Messer, MD, MACC, FAHA;
James L. Ritchie, MD, FACC, FAHA; Sam J.W. Romeo, MD, MBA;
Albert L. Waldo, MD, FACC, FAHA, FHRS; D. George Wyse, MD, PhD, FACC, FAHA, FHRS

ACC/AHA TASK FORCE ON PERFORMANCE MEASURES

Robert O. Bonow, MD, FACC, FAHA, Chair; N.A. Mark Estes III, MD, FACC, FAHA, FHRS;
Elizabeth DeLong, PhD; David C. Goff, Jr, MD, PhD, FAHA, FACP; Kathleen Grady, PhD, RN,
FAHA, FAAN; Lee A. Green, MD, MPH; Ann Hiniker, RN, MS, CNS; Jane Ann Linderbaum, NP*;
Frederick A. Masoudi, MD, MSPH, FACC; Ileana L. Piña, MD, FACC; Susan Pressler, DNS, RN,
FAAN, FAHA*; Martha J. Radford, MD, FACC; John S. Rumsfeld, MD, PhD, FACC, FAHA

Circulation is available at http://circ.ahajournals.org   **DOI: 10.1161/CIRCULATIONAHA.107.187192**

Table of Contents

Preamble

Consistent with the national focus on healthcare quality, the American College of Cardiology (ACC) and the American Heart Association (AHA) have developed a multifaceted strategy to facilitate the process of improving clinical care. The first aspect of this effort is the creation of clinical practice guidelines that carefully synthesize available evidence to guide better patient care. Such guidelines are written to suggest diagnostic or therapeutic interventions that apply to patients in most circumstances, but clinical judgment is required to adapt these guidelines to the care of individual patients. The guidelines are based on available evidence, providing varying degrees of recommendation (Table 1). Occasionally, the evidence supporting a particular aspect or process of care is so strong that failure to perform such actions reduces the likelihood of optimum patient outcomes.

Accordingly, the second aspect of the ACC/AHA effort to improve the quality of cardiovascular care is the development of performance measures. The ACC/AHA Task Force on Performance Measures was formed in February 2000, with 3 nominees from each organization charged with identifying the clinical topics for which performance measures are to be developed and then assembling teams of clinical and methodological experts for a given topic (eg, atrial fibrillation), both from within the sponsoring organizations and from other organizations dedicated to the care of the patients covered by the performance measurement set. The writing committee for each performance measure set is carefully guided with respect to the methodology of development of performance measures.[1] Moreover, to avoid duplication of performance measure development efforts, writing committees are also instructed to evaluate existing nationally recognized performance measures using the attributes of good performance measures specified by the ACC/AHA. In addition, the measures are constructed to facilitate both retrospective and prospective data collection with explicit administrative and/or easily documented clinical criteria. Furthermore, the data elements required for the performance measures are linked to existing ACC/AHA clinical data standards to encourage uniform measurements of cardiovascular care.

Although the focus of the performance measures writing committees is on measures intended for quality improvement efforts, other organizations may use these measures for external review or public reporting of provider performance. Therefore, it is within the scope of the writing committee's task to comment, when appropriate, on the strengths and limitations of such external reporting for a particular cardiovascular disease state or patient population.

All the measures in this set have limitations and pose challenges to implementation that could result in unintended consequences when used for accountability. The implementation of these measures for purposes other than quality improvement requires field testing to address issues related but not limited to sample size, frequency of use of an intervention, comparability, and audit requirements. The way in which these issues are addressed is dependent on the type of accountability developed, including the method of data collection, assignment of patients to physicians for measurement purposes, establishment of baseline measures, incentives, and public reporting methods, among other things. The ACC/AHA encourages those interested in implementing these measures for purposes other than quality improvement to work with the ACC/AHA to understand these complex issues in pilot testing projects, to assess limitations and confounding factors, and to guide refinements of the measures to enhance their utility for these additional purposes.

By facilitating measurements of cardiovascular healthcare quality, ACC/AHA performance measurement sets may serve as vehicles to accelerate appropriate translation of scientific evidence into clinical practice. These documents are intended to provide practitioners with tools to measure the quality of care and identify opportunities for improvement. Because the target audience for these measures is the practitioner, they were constructed from the provider's perspective and not to characterize "good" or "bad" practice. Rather, it is our hope

Table 1. Applying classification of recommendations and level of evidence.

"Size of Treatment Effect"

	Class I *Benefit >>> Risk* *Procedure/Treatment SHOULD be performed/administered*	Class IIa *Benefit >> Risk* *Additional studies with focused objectives needed* *IT IS REASONABLE to perform procedure/administer treatment*	Class IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* *Procedure/Treatment MAY BE CONSIDERED*	Class III *Risk ≥ Benefit* *No additional studies needed* *Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL*
Level A *Multiple (3-5) population risk strata evaluated** *General consistency of direction and magnitude of effect*	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation that procedure or treatment not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses
Level B *Limited (2-3) population risk strata evaluated**	• Recommendation that procedure or treatment is useful/effective • Limited evidence from single randomized trial or non-randomized studies	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from single randomized trial or non-randomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or non-randomized studies	• Recommendation that procedure or treatment not useful/effective and may be harmful • Limited evidence from single randomized trial or non-randomized studies
Level C *Very limited (1-2) population risk strata evaluated**	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard-of-care	• Recommendation in favor of treatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation that procedure or treatment not useful/effective and may be harmful • Only expert opinion, case studies, or standard-of-care
Suggested phrases for writing recommendations †	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown /unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

"Estimate of Certainty (Precision) of Treatment Effect"

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

†In 2003, the ACC/AHA Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All recommendations in this guideline have been written in full sentences that express a complete thought, such that a recommendation, even if separated and presented apart from the rest of the document (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level.

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

Robert O. Bonow, MD, FACC, FAHA
Chair, ACC/AHA Task Force on Performance Measures

I. Introduction

The ACC/AHA/Physician Consortium Atrial Fibrillation or Atrial Flutter Performance Measures Writing Committee (the Writing Committee) was charged to develop performance measures concerning the diagnosis and treatment of atrial fibrillation (AF) and atrial flutter. These performance measures refer to adults (18 years of age or older) with nonvalvular AF evaluated in the outpatient setting. They do not apply to patients with acute, reversible causes of AF or flutter, such as postoperative patients, patients with transient or reversible causes of AF (eg, pneumonia or hyperthyroidism), patients with mitral stenosis or prosthetic heart valves, or patients who are pregnant.

A. Scope of the Problem

Atrial fibrillation is the most common arrhythmia encountered in clinical practice, accounting for approximately one third of all hospitalizations for cardiac rhythm disturbances. It has been estimated that 2.2 million Americans have paroxysmal or persistent AF, but the actual number may be higher.[2] The prevalence of AF increases with age, reaching as high as 9% in octogenarians.[3,4] During the past 20 years, there has been a 66% increase in hospital admissions for AF due to a combination of factors, including the aging of the population, a rising prevalence of chronic heart disease, and more frequent diagnosis through use of ambulatory monitoring devices.[3,4] Atrial fibrillation is associated with an increased risk of stroke, heart failure, and all-cause mortality, especially in women. The mortality rate of patients with AF is higher than that of patients in normal sinus rhythm and is linked to severity of underlying heart disease.[3,4] The guidelines for management of patients with AF recommend as a Class I indication that antithrombotic therapy for patients with atrial flutter follow the same approach as for patients with AF, given the evidence of their comparable risk of thromboembolism.[4] Accordingly, these performance measures also apply to patients with atrial flutter who do not have valvular heart disease.

Given the morbidity, mortality, and costs associated with AF and atrial flutter, the ACC, AHA, and Physician Consortium chose this topic for performance measures both to raise the level of awareness of current guidelines and to provide tools physicians can use in practice to improve the quality of care provided to patients with nonvalvular AF and atrial flutter.

B. Structure and Membership of the Writing Committee

The members of the Writing Committee included senior clinicians, specialists in cardiac arrhythmias and electrophysiology, and a representative from the ACC/AHA/European Society of Cardiology (ESC) Atrial Fibrillation Guideline Revision Writing Committee. The Writing Committee also included members of the American Medical Association, the American College of Physicians, and the Heart Rhythm Society.

C. Disclosure of Relationships With Industry

The work of the Writing Committee was supported exclusively by the ACC, AHA, and Physician Consortium for Performance Improvement. Committee members volunteered their time, and there was no direct commercial support for the development of these performance measures. Meetings of the Writing Committee were confidential and attended only by committee members and staff. Writing Committee members were required to disclose in writing all financial relationships with industry relevant to this topic according to standard ACC and AHA reporting policies, and they verbally acknowledged these relationships to the other members (Appendix A).

D. Review and Endorsement

Between January 15 and February 15, 2007, the performance measures document underwent a 30-day public comment period, during which ACC and AHA members and other healthcare professionals had an opportunity to review and comment on the text in advance of its final approval and publication. More than 15 responses were received.

The official peer review/content review of the document was conducted simultaneous with the 30-day public comment period, with 6 peer reviewers nominated by the ACC and 3 by the AHA (Appendix B). Additional comments were sought from clinical content experts and performance measurement experts.

The ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Atrial Fibrillation or Atrial Flutter were adopted by the respective governing bodies of the ACC and the AHA in September 2007 and approved by the American Medical Association–Physician Consortium for Performance Improvement in December 2007. These measures will be reviewed for currency once every year and updated as needed. They should be considered valid until either updated or rescinded by the ACC/AHA Task Force on Performance Measures.

II. Methodology

The development of performance measures involves identification of measures that target a specific patient population observed over a particular time period. To achieve this goal, the ACC/AHA Task Force on Performance Measures delineated 5 mandatory sequential steps. The following sections outline how the Writing Committee addressed these elements.

A. Definition of AF and Atrial Flutter

The Writing Committee used the "ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation" and the "ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation" for definitions of AF and atrial flutter.[4,5] These guidelines define AF as a supraventricular tachyarrhythmia characterized by uncoordinated atrial activity with consequent deterioration of atrial mechanical function.[4,5] On the electrocardiogram (ECG), AF

is characterized by the replacement of consistent P waves with rapid oscillations or fibrillatory waves that vary in amplitude, shape, and timing, associated with an irregular, frequently rapid ventricular response when atrioventricular conduction is intact.[4,5]

Multiple classification schemes for AF have been proposed with a consensus driven by the desire for simplicity and clinical relevance.[4,5] The clinician should distinguish a first-detected episode of 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. With 2 or more episodes, AF is considered recurrent. If AF terminates spontaneously, recurrent AF is designated as paroxysmal; when sustained, AF is designated as persistent. When persistent, AF that terminates with pharmacological therapy or electrical cardioversion does not change the designation. Persistent AF may be either the initial presentation of the arrhythmia or the culmination of recurrent episodes of paroxysmal AF. The category of persistent AF also includes cases of longstanding AF (ie, more than 1 year) when cardioversion is not indicated, not attempted, or unsuccessful. This usually leads to permanent AF. This terminology applies to episodes of AF that last more than 30 seconds and that are unrelated to a reversible cause.[4,5] These performance measures were developed to apply to all classifications of AF lasting longer than 30 seconds, with the exclusion of secondary AF due to acute reversible causes.[4]

Reversible or secondary AF can occur in the setting of acute myocardial infarction, cardiac surgery, pericarditis, myocarditis, hyperthyroidism, pulmonary embolism, pneumonia, acute pulmonary disease, or other acute illness. This form of reversible AF is considered separately because AF is less likely to recur once the precipitating condition has resolved. In these settings, AF is not the primary problem, and treatment of the underlying disorder concurrently with management of the episode of AF usually results in termination of the arrhythmia without recurrence.[4] These performance measures do not apply to such forms of secondary AF that are due to acute reversible causes.

Atrial fibrillation may occur in association with atrial flutter or atrial tachycardia.[4] The typical form of atrial flutter is characterized by a sawtooth pattern of regular atrial activation called flutter (*f*) waves on the ECG, particularly visible in leads II, III, aVF, and V$_1$. If untreated, the atrial rate typically ranges from 240 to 320 beats per minute, with *f* waves inverted in leads II, III, and aVF and upright in lead V$_1$.[4,5] The direction of activation in the right atrium may be reversed, resulting in upright *f* waves in leads II, III, and aVF and inversion in lead V$_1$. Atrial flutter may degenerate into AF, and AF may convert to atrial flutter. Atrial flutter is usually readily distinguished from AF, but misdiagnosis may occur when coarse fibrillatory atrial activity is prominent in more than 1 ECG lead.[4,5]

The guidelines indicate that it is prudent to estimate thromboembolic risk for patients with atrial flutter using the same criteria as for AF.[4] Although there are fewer data regarding risk stratification and anticoagulation for atrial flutter, and treatment strategies for atrial flutter differ from those for AF, the Writing Committee included atrial flutter as

Table 2. Relevant ICD-9-CM Diagnosis Code

ICD-9-CM Code	Description
427.31	Atrial fibrillation
427.32	Atrial flutter

ICD-9-CM indicates *International Classification of Diseases*, 9th Revision, Clinical Modification.

an arrhythmia appropriate for these performance measures on the basis of several considerations. Atrial flutter commonly occurs in patients with AF at risk for thromboembolism. The current guidelines indicate as a Class I recommendation that it is prudent to stratify patients on the basis of thromboembolic risk and to consider anticoagulation for atrial flutter in a fashion similar to that for patients with AF. To align these performance measures with the practice guidelines, the Writing Committee developed the performance measures to apply both to patients with AF and to those with atrial flutter.[4]

Table 2 lists the relevant International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes for these measures. The specific period of interest for each measure is further defined in the full specifications in Appendix C.

B. Dimensions of Care

Given the multiple aspects of treatment that can be measured, the Writing Committee identified the dimensions of care that should be evaluated and categorized each potential performance measure into the relevant dimension of care. The dimensions of care selected as performance measures for AF include evaluation and management. Classification into dimensions of care facilitated the identification of areas in which evidence was lacking and prevented duplication of measures.

The focus of this initial set of performance measures is prevention of thromboembolism. Although the Writing Committee considered a number of additional potential measures that focus on equally important aspects of care, either the evidence base or other challenges to measurement of these components of care across all patients undermined their benefits.

Although the Writing Committee considered outcomes as potential performance measures, none were included at this time. These performance measures focus only on processes, because their specific purpose is to assist physicians in improving clinical care. The dimensions of care measurement matrix relevant to the performance measures for AF is presented in Table 3.

C. Literature Review

The Writing Committee reviewed the 2001 "ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation," the 2003 "Management of Newly Detected Atrial Fibrillation: A Clinical Practice Guideline From the American College of Physicians and the American Academy of Family Physicians," the 2004 "Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation," and the "ACC/AHA/ESC 2006 Guidelines for the Management of

Table 3.   ACC/AHA/Physician Consortium AF and Atrial Flutter Performance Measurement Set: Dimension of Care Measures Matrix

Performance Measure	Diagnostics	Patient Education*	Treatment	Self-Management*	Monitoring of Disease Status*
1. Assessment of thromboembolic risk factors	√				
2. Chronic anticoagulation therapy				√	
3. Monthly INR measurement†				√	

*Although no current measures exist for these dimensions for the outpatient setting, future measure development efforts will examine how to address these gaps.

†INR refers to the international normalized ratio of prothrombin time ($[patient/control]^{ISI}$), where ISI denotes the international sensitivity index of the thromboplastin reagent used to perform the test.

Patients With Atrial Fibrillation" as the primary sources for deriving these measures.[3–6] One of the co-chairs of the Writing Committee also participated on the writing committee to develop the "ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation,"[4] and 4 members participated in the development of the "ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients With Atrial Fibrillation."[5] As a participant in the guideline writing committee, the co-chair was able to offer insights into measurement issues and provide suggestions for clarity and specificity of guideline recommendations.

D. Definition and Selection of Measures

Explicit criteria exist for the development of performance measures that accurately reflect quality of care; these include definition of the numerators and denominators of potential measures and evaluation of their applicability, interpretability, and feasibility. To select measures for inclusion in the performance measurement set, the Writing Committee prioritized the Class I and Class III recommendations from the 2001 ACC/AHA/ESC AF guideline and the grade 1 recommendations from the 2003 American College of Physicians/ American Academy of Family Physicians guidelines for the management of newly detected AF.[3,6] After publication of the "ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation,"[4] the Writing Committee re-evaluated the performance measures to ensure consistency with the 2006 recommendations for risk stratification and anticoagulation.[4]

From analysis of these recommendations, the Writing Committee identified potential measures relevant to the management of patients with AF and then independently evaluated their potential for use as performance measures using exclusion criteria adapted from the ACC/AHA "Attributes of Good Performance Measures" (Table 4) and the quality indicator survey form and definitions (Appendix D). Member ratings of all the potential measures were collated and discussed by the full committee to reach a consensus on which measures should advance for inclusion in the final measure set. Eight potential measures then advanced for full specification to assess their suitability as performance measures. The Writing Committee met again to review and clarify these specifications and to select measures for inclusion in the final set. At this stage, the Writing Committee also decided to include as an additional measure the assessment of thromboembolic risk factors.

III. Atrial Fibrillation and Atrial Flutter Performance Measures

A. Patient Population and Care Period

The target population consists of patients aged 18 years or older with a diagnosis of nonvalvular AF or atrial flutter. Exclusion criteria specific to each measure were developed to further specify the target population (see Appendix D for an outline of the process employed). For the present document, the outpatient care period is defined as the time under evaluation for care provided in an outpatient setting (1 reporting year).

B. Brief Summary of the Measurement Set

Table 5 shows the ACC/AHA/Physician Consortium AF and Atrial Flutter Performance Measurement Set, which consists of those measures with the highest level of evidence and the greatest support among the committee members. The measures include the following: 1) assessment of thromboembolic risk factors, 2) chronic anticoagulation therapy, and 3) monthly international normalized ratio (INR) measurement. These performance measures are intended for patients with nonvalvular AF or atrial flutter that is not due to acute

Table 4.   Summary of ACC/AHA Attributes of Good Performance Measures

Useful to improve patient outcomes
    1. Evidence-based
    2. Interpretable
    3. Actionable

Measure design
    1. Denominator precisely defined
    2. Numerator precisely defined
    3. Validity
      a. Face validity
      b. Content validity
      c. Construct validity
    4. Reliability

Measure implementation
    1. Feasibility for collection
      a. Reasonable effort
      b. Reasonable cost
      c. Reasonable time

Overall assessment
    Assessment of measure for inclusion in measurement set

Table 5.   ACC/AHA/Physician Consortium AF and Atrial Flutter Performance Measurement Set

Performance Measure Name	Measure Description
Assessment of thromboembolic risk factors	Nonvalvular AF patients for whom assessment of thromboembolic risk factors is documented
Chronic anticoagulation therapy	Prescription of warfarin for all patients with any high-risk factor or more than 1 moderate-risk factor
Monthly INR measurement	Frequency of monitoring of INR

INR indicates international normalized ratio.

reversible causes. Appendix C provides the detailed specifications for each performance measure, including the numerator, denominator, period of assessment, method of reporting, sources of data, rationale, clinical recommendations, and challenges to implementation.

C. Data Collection

These performance measures for AF and atrial flutter are intended for prospective use to enhance the quality improvement process but may also be applied retrospectively if prospective data collection is not possible. Use of a data collection instrument is recommended to aid compilation, and a sample instrument is provided in Appendix E. Individual institutions may modify the instrument or develop a different tool based on local practice and standards.

IV. Discussion

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

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

A. Risk Stratification

The Writing Committee recognizes that controversy exists regarding the threshold for use of chronic anticoagulation, especially for patients at intermediate risk of thromboembolism.[4,7] In addition to prior stroke or transient ischemic attack (TIA), heart failure or impaired left ventricular systolic function, hypertension, advanced age, and diabetes mellitus have consistently emerged as independent risk factors for ischemic stroke associated with nonvalvular AF.[3–6,8] The relative risk of ischemic stroke associated with specific clinical features, derived from a collaborative analysis of participants given no antithrombotic therapy in the control groups of 5 randomized trials, is displayed in Table 6.[9]

To balance the benefits and toxicity of chronic antithrombotic prophylaxis, it is important to assess the risk of stroke for individual patients, but interactions among risk factors, concomitant therapy, and differences in statistical methodology limit the precision of these estimates. In patients with nonvalvular AF, prior stroke or TIA is the most powerful independent predictor of stroke, being significantly associated with stroke in all 6 studies in which it was evaluated, with incremental relative risk between 1.9 and 3.7 (averaging approximately 3.0).[4] All patients with prior stroke or TIA require anticoagulation unless contraindications exist in a given patient.[3–6,8–11] Risk stratification based on other clinical features should be based on their independent predictive value and the absolute stroke rates with which they are associated for primary prevention. Patient age is a consistent independent predictor of stroke, but older people are also at increased risk for anticoagulant-related bleeding.[3–6,8–11] Similarly, hypertension is a consistent, powerful predictor of stroke, with a history of hypertension being independently predictive in 5 studies (median relative risk approximately 2.0) and with systolic blood pressure higher than 160 mm Hg being significant in 2 others (mean relative risk approximately 2.0). The effect of blood pressure control on the risk of thromboembolism has not been investigated. Diabetes mellitus was a significant independent predictor in 4 studies, being associated with an average relative risk of 1.8, but was not a significant predictor in 2 others, and this condition is a less powerful independent predictor than prior stroke/TIA, hypertension, or age; however, the type, duration, and control of diabetes mellitus have not been evaluated to refine its predictive value for thromboembolism in patients with AF. Clinical heart failure has not been shown conclusively to have

Table 6.   Risk Factors for Ischemic Stroke or Systemic Embolism in Patients With Nonvalvular AF*

Risk Factors (Control Groups)	Relative Risk
Previous stroke or TIA	2.5
History of hypertension	1.6
Heart failure or impaired left ventricular systolic function	1.4
Advanced age (continuous, per decade)	1.4
Diabetes mellitus	1.7
Coronary artery disease	1.5

*Data derived from collaborative analysis of untreated control groups in 5 primary prevention trials.[9] As a group, patients with nonvalvular AF have approximately a 6-fold increased risk of thromboembolism compared with patients in sinus rhythm. Relative risk refers to comparison of patients with AF to patients without these risk factors.

Adapted from Fuster et al.[4]

Table 7. CHADS$_2$ Stroke Risk Stratification Scheme

CHADS$_2$ Criteria	Risk Score
Prior stroke or TIA	2 points
Age 75 years or older	1 point
Hypertension	1 point
Diabetes mellitus	1 point
Heart failure or impaired left ventricular systolic function	1 point

independent predictive value for stroke in studies of AF patients, but when the definition of the risk factor was expanded to include left ventricular systolic dysfunction (defined as echocardiographic fractional shortening less than 25%) with or without clinical heart failure within 3 months, it became a significant independent predictor.[3–6,8–11] Although coronary artery disease, variously defined, was a relatively weak but statistically significant predictor of stroke in 1 large study, it was not independently predictive of stroke in 3 other patient cohorts.

The CHADS$_2$ (Cardiac failure, Hypertension, Age, Diabetes, Stroke [Doubled]) index integrates elements from several schemes[12] and is based on a point system in which 2 points are assigned for a history of stroke or TIA and 1 point each is assigned for age over 75 years and a history of hypertension, diabetes mellitus, or recent heart failure, as shown in Table 7. The predictive value of this scoring system was evaluated in 1733 Medicare beneficiaries with nonvalvular AF between the ages of 65 and 95 years who were not given warfarin at hospital discharge (Table 8).[12–15] Although high scores were associated with an increased stroke rate in this elderly cohort, few patients had a score of 5 or more or a score of zero. Relatively few patients (8% of the CHADS$_2$ derivation cohort) had a history of stroke or TIA in the absence of other independent predictors. Hence, the index

Table 9. Antithrombotic Therapy for Patients With Nonvalvular AF*

Risk Category	Recommended Therapy
No risk factors	Aspirin 81 to 325 mg daily
One moderate-risk factor	Aspirin 81 to 325 mg daily or warfarin (INR 2.0 to 3.0, target 2.5)
Any high-risk factor or more than 1 moderate-risk factor†	Warfarin (INR 2.0 to 3.0, target 2.5)†

*Adapted from Fuster et al.[4]
†See Table 10 for definition of moderate- and high-risk factors.
INR indicates international normalized ratio.

may underestimate the incremental risk contributed by prior thromboembolism, and anticoagulation is indicated for secondary prevention regardless of the CHADS$_2$ score.

Although schemes for stratification of stroke risk identify patients who benefit most and least from anticoagulation, the threshold for use of anticoagulation remains controversial. Opinion is particularly divided about anticoagulation for those at intermediate risk (stroke rate 3% to 5% per year). Some advocate the routine use of anticoagulation for patients with stroke rates in this range, whereas others favor selective anticoagulation for patients at intermediate risk, with consideration given to individual bleeding risks, availability of organized anticoagulation management programs, and patient preferences.[4,8,10] The threshold of benefit at which AF patients decide with their physicians to initiate anticoagulation varies; some at intermediate risk elect to undergo anticoagulation, whereas others do not.[4,7] Table 9 summarizes the recommendations for antithrombotic therapy in patients with AF and atrial flutter given in the 2006 ACC/AHA/ESC AF guidelines. Table 10 shows risk factors for AF and atrial flutter.

Table 8. Stroke Risk in Patients With Nonvalvular AF Not Treated With Anticoagulation According to the CHADS$_2$ Stroke Risk Stratification Scheme Applied to Several Patient Cohorts*

		Study Cohort (Reference)		
		Hospital Discharge Cohort (15)	HMO Outpatients (14)	Aspirin-Treated Clinical Trial Participants (12)
No. of patients		1733	5089	2580
Mean age, y		81	71	72
% With prior stroke		25	4	22
No. of events		94‡	249	207
Overall stroke rate, %		4.4‡	2.0	4.2
CHADS$_2$ score	% of AF Outpatients†	Stroke + TIA Rate, % per Year‡	Stroke Rate, % per Year	Stroke Rate, % per Year
0	22	1.9	0.5	0.8
1	32	2.8	1.5	2.2
2	26	4.0	2.5	4.5
3	13	5.9	5.3	8.6
4	5	8.5	6.0	10.9
5	2	>12	6.9	>12

*Adapted from Fuster et al.[4]
†Based on 11 526 outpatients in the Kaiser Permanente Northern California Health Maintenance Organization.[14]
‡This inpatient cohort was a decade older than most others, and 56% of patients had heart failure; the 30-day mortality rate was unusually high (27%), 25% of outcome events were TIAs, and stroke rates averaged ≈25% lower.[12]
HMO indicates health maintenance organization.

Table 10.   Risk Factors for Stroke in Patients With AF

Less Validated or Weaker Risk Factors	Moderate-Risk Factors*	High-Risk Factors
Female gender	Age more than or equal to 75 y	Prior stroke, TIA, or systemic embolism
Age 65 to 74 y	Hypertension	
Coronary artery disease	Heart failure	
Thyrotoxicosis	LVEF 35% or less	
	Diabetes mellitus	

*Adapted from Fuster et al (4).
LVEF indicates left ventricular ejection fraction.

B. Potential Measures Addressing Patients Undergoing Cardioversion

A key goal of this initial phase of AF performance measure development is to increase awareness of the AF guidelines and the evidence in support of these guidelines among all practitioners. The Writing Committee therefore designed this set of performance measures to apply to the widest possible patient and physician populations. Because cardioversion is performed only by specialists and for only a selected subset of patients, measures related to this procedure were not included. It is anticipated that measures related to cardioversion of AF or atrial flutter will be considered for addition to an expanded set of AF performance measures in the future.

C. Potential Measures Addressing the Quality of Anticoagulation Therapy

Although clearly an essential part of the care of patients receiving chronic anticoagulation therapy, assessment of the consistency of anticoagulation (eg, the proportion of the treatment period during which the INR is maintained in the target therapeutic range) does not lend itself easily to the development of performance measures. The data collection effort required for measurement of performance would be substantial, because it depends on determining both when the patient was taking warfarin and the dates of all INR measurements. In addition, numerous clinical trials have shown that even in controlled environments, the maintenance of INR within a narrow target range for patients prescribed warfarin for stroke prevention is challenging. The goal for this measure would therefore be less than 100 percent, which would make it necessary to define an acceptable level of performance. For these reasons, the Writing Committee deferred the inclusion of a performance measure related to achievement of target INR intensity for future consideration. [14,15]

Staff

American College of Cardiology
John C. Lewin, MD, Chief Executive Officer
Charlene May, Director, Clinical Policy and Documents
Tilithia McBride, Associate Director, Performance
    Measurement Policy
Melanie Shahriary, RN, BSN, Clinical Performance
    Measurement
Erin A. Barrett, Senior Specialist, Clinical Policy and
    Documents

American Heart Association
M. Cass Wheeler, Chief Executive Officer
Gayle R. Whitman, RN, PhD, FAAN, FAHA, Vice President,
    Office of Science Operations
Kathryn A. Taubert, PhD, FAHA, Senior Science Advisor

Appendix A. Relationships With Industry—Writing Committee for ACC/AHA/Physician Consortium 2008 Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter

Name	Research Grant	Speakers' Bureau/Honoraria/Expert Witness	Stock Ownership/Equity Interests	Consultant/Advisory Board/Steering Committee
N.A. Mark Estes III	None	Boston Scientific; Medtronic; St. Jude Medical	None	None
Jonathan L. Halperin	None	None	None	Astellas Pharma US; Bayer Health Care; Boehringer Ingelheim; Daiichi Sankyo Pharma; GlaxoSmithKline; Johnson & Johnson; Medtronic; Sanofi-Aventis
Hugh Calkins	Guidant; Medtronic; Bard Peripheral	None	None	None
Michael D. Ezekowitz	Boehringer Ingelheim	Pfizer		Boehringer Ingelheim; Aryx Pharmaceuticals; Bristol-Myers Squibb
Paul Gitman	None	None	None	None
Alan S. Go	None	None	None	None
Robert L. McNamara	None	None	None	Scios
Joseph V. Messer	None	None	None	None
James L. Ritchie	None	None	None	None
Sam J.W. Romeo	None	None	None	None
Albert L. Waldo	Boehringer Ingelheim	Reliant; Sanofi-Aventis	None	Cryocor; Reliant; Sanofi-Aventis; Biosense Webster; GlaxoSmithKline; Biosense Webster
D. George Wyse	Cardiome/Astellas; Medtronic	Cardiome/Astellas; Chugai Pharma; Daiichi Pharma; Eisai	None	Cardiome/Astellas; Medtronic; Bristol-Myers Squibb/Sanofi-Aventis; Organon/Sanofi-Aventis

This table represents the actual or potential relationships of committee members with industry that were reported orally at the initial committee meeting and updated in conjunction with all meetings and conference calls of the writing committee. It does not necessarily reflect actual or potential relationships at the time of publication.

Appendix B. Relationships With Industry—Peer Reviewers for ACC/AHA/Physician Consortium 2008 Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter

Name	Representing	Research Grant	Speakers' Bureau/Honoraria/ Expert Witness	Stock Ownership/Equity Interests	Consultant/ Advisory Board/ Steering Committee
Loren D. Berenbom	Official–ACC Board of Governors	None	Medtronic*	None	None
Vincent F. Carr	Official–ACC Board of Governors	None	None	None	None
William H. Carter	Official–ACC Board of Governors	None	None	None	None
Michael Honan	Official–ACC Board of Governors	Bristol-Myers Squibb/Sanofi-Aventis†; Boeringer Ingelheim†	None	None	None
Bruce D. Lindsay	Official–ACC Board of Trustees	None	Guidant Corporation†; Stereotaxis, Inc.*	None	None
Stuart Winston	Official–ACC Board of Governors	Biotronik*; Medtronic*; Boston Scientific*	Boston Scientific*	AstraZeneca*; Cambridge Heart*	None
Jeffrey L. Anderson	Organizational–American Heart Association	King Pharmaceuticals*; Sanofi*; Novartis*; AstraZeneca*	Thrombovision*; DiaDexus; Bristol-Myers Squibb†; Merck†	None	None
Robert G. Hart	Organizational–American Heart Association	None	None	None	None
Gerald V. Naccarelli	Organizational–American Heart Association	Medtronic†; Reliant†; Sanofi-Aventis†	Boehringer Ingelheim†; Cardiofocus*; Pfizer*; Astellas*; GlaxoSmithKline*; Biocritique*; Medifacts*; Xention*; Wyeth-Ayerst*; Novartis*; Guidant*; Reliant*; Sanofi-Aventis†; Medtronic*	Guidant†	None
Robert O. Bonow	Content–ACC/AHA Task Force on Performance Measures–Lead Reviewer	None	Edwards Lifesciences*; Bristol-Myers Squibb Medical Imaging*	None	None
Valentin Fuster	Content–ACC/AHA Task Force on Practice Guidelines	None	None	None	None

This table represents the relationships of peer reviewers with industry that were disclosed at the time of peer review of these performance measures. It does not necessarily reflect relationships with industry at the time of publication. Names are listed in alphabetical order within each category of review.

*Indicates modest level relationship ($10 000 or less).

†Indicates significant level relationship (more than $10 000).

Appendix C. ACC/AHA/Physician Consortium AF Performance Measurement Set Specifications

1. Assessment of Thromboembolic Risk Factors

Patients with nonvalvular AF or atrial flutter in whom assessment of thromboembolic risk factors has been documented

Numerator	Patients with nonvalvular AF or atrial flutter in whom assessment of all of the specified thromboembolic risk factors is documented.
	For patients with nonvalvular AF or atrial flutter, assessment of thromboembolic risk should include the following factors:

Risk Factors	Weighting
Prior stroke or TIA	High risk
Age ≥75 y	Moderate risk
Hypertension	Moderate risk
Diabetes mellitus	Moderate risk
Heart failure or impaired LV systolic function	Moderate risk

Denominator	All patients 18 years of age or older with nonvalvular AF or atrial flutter other than those specifically excluded.

Excluded Populations:

- Patients with mitral stenosis or prosthetic heart valves
- Patients with transient or reversible causes of AF (e.g., pneumonia or hyperthyroidism)
- Postoperative patients
- Patients who are pregnant
- Medical reason(s) documented by a physician, nurse practitioner, or physician assistant for not assessing risk factors. Examples of medical reasons for not assessing risk factors include but are not limited to the following:
    - Allergy to warfarin
    - Risk of bleeding

Period of Assessment	Reporting year
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

Assessment of thromboembolic risk **and discussion of the potential benefits and risks of anticoagulant therapy** are crucial steps in the evaluation and management of patients with nonvalvular AF or atrial flutter. Identification of factors that increase risk warrants consideration of chronic anticoagulant therapy. Individual risk varies over time, so the need for anticoagulation must be re-evaluated at regular intervals in all patients with AF or atrial flutter.

Clinical Recommendation(s)

ACC/AHA/ESC 2006 Guidelines for the Management of Patients With AF:

Preventing Thromboembolism

(Recommendations regarding antithrombotic therapy other than those listed below pertain to patients with AF or atrial flutter undergoing cardioversion) (4)

Class I

1. Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. *(Level of Evidence: A)*

2. The selection of the antithrombotic agent should be based on the absolute risks of stroke and bleeding and the relative risk and benefit for a given patient. *(Level of Evidence: A)*

3. Anticoagulation with a vitamin K antagonist is recommended for patients with more than 1 moderate risk factor. Such factors include age 75 y or greater, hypertension, HF, impaired LV systolic function (ejection fraction 35% or less or fractional shortening less than 25%), and diabetes mellitus. *(Level of Evidence: A)*

4. For patients without mechanical heart valves at high risk of stroke, chronic oral anticoagulant therapy with a vitamin K antagonist is recommended in a dose adjusted to achieve the target intensity INR of 2.0 to 3.0, unless contraindicated. Factors associated with highest risk for stroke in patients with AF are prior thromboembolism (stroke, TIA, or systemic embolism) and rheumatic mitral stenosis. *(Level of Evidence: A)*

5. The INR should be determined at least weekly during initiation of therapy and monthly when anticoagulation is stable. *(Level of Evidence: A)*

6. Aspirin, 81 to 325 mg daily, is recommended as an alternative to vitamin K antagonists in low-risk patients and in those with contraindications to oral anticoagulation. *(Level of Evidence: A)*

7. Antithrombotic therapy is recommended for patients with atrial flutter in a manner similar to that for those with AF. *(Level of Evidence: C)*

Method of Reporting

Per patient:

- Documentation that thromboembolic risk was assessed

Per patient population:

- Percentage of patients assessed for thromboembolic risk factors

---

Challenges to Implementation

- Lack of documentation regarding medical or patient reasons for not prescribing warfarin
- Difficulty locating reasons in the medical record for not prescribing antithrombotic therapy

---

2. Chronic Anticoagulation Therapy

Prescription of warfarin for all patients with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to risk stratification and 2006 guideline recommendations, as follows:

Low risk	No risk factors	Aspirin 81 to 325 mg daily
Intermediate risk	One moderate-risk factor	Aspirin 81 to 325 mg daily or warfarin (INR 2.0 to 3.0, target 2.5)
High risk	Any high-risk factor or more than 1 moderate-risk factor	Warfarin (INR 2.0 to 3.0, target 2.5)

Numerator	All patients with nonvalvular AF or atrial flutter at high risk of thromboembolism (i.e., those with any high-risk factor or more than 1 moderate-risk factor) for whom warfarin was prescribed.

Denominator	**Included population:**
	
	 Patients with nonvalvular AF or atrial flutter for whom assessment of the specified thromboembolic risk factors documented 1 or more high-risk factor or more than 1 moderate-risk factor.
	
	 The assessment of patients with nonvalvular AF for thromboembolic risk factors should include the following criteria:
	
	 Risk Factors / **Weighting**
	 Prior stroke, TIA, or systemic embolism — High risk
	 Age ≥75 y — Moderate risk
	 Hypertension — Moderate risk
	 Diabetes mellitus — Moderate risk
	 Heart failure or impaired left ventricular systolic function — Moderate risk
	
	 Excluded Populations:
	
	 • Patients with valvular AF, specifically those with prosthetic heart valves or mitral stenosis
	
	 • Patients at low risk for thromboembolism (i.e., those with none of the risk factors listed above)
	
	 • Patients with only 1 moderate-risk factor
	
	 • Postoperative patients
	
	 • Patients with transient or reversible causes of AF (e.g., pneumonia or hyperthyroidism)
	
	 • Patients who are pregnant
	
	 • Medical reason(s) documented by a physician, nurse practitioner, or physician assistant for not prescribing warfarin. Examples of medical reasons for not prescribing warfarin include but are not limited to the following:
	
	    • Allergy
	
	    • Risk of bleeding
	
	 • Documentation of patient reason(s) for not prescribing warfarin (e.g., economic, social, and/or religious impediments, noncompliance, or other reason for refusal to take warfarin)

Period of Assessment	Reporting year
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

Adjusted-dose warfarin is highly efficacious in preventing thromboembolism in patients with AF and should be prescribed for all high-risk patients except those with contraindications to anticoagulation. Aspirin is preferred in patients without risk factors and in those with contraindications to anticoagulation and is an alternative to anticoagulation in those with only 1 moderate-risk factor.

<div align="center">

Clinical Recommendation(s)

</div>

ACC/AHA/ESC 2006 Guidelines for the Management of Atrial Fibrillation Patients With AF

Chronic Anticoagulation Therapy

(Recommendations other those listed below pertain to antithrombotic therapy for patients with AF undergoing cardioversion) (4)

Class I

1. Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. *(Level of Evidence: A)*

2. The selection of the antithrombotic agent should be based on the absolute risks of stroke and bleeding and the relative risk and benefit for a given patient. *(Level of Evidence: A)*

3. Anticoagulation with a vitamin K antagonist is recommended for patients with more than 1 moderate risk factor. Such factors include age 75 y or greater, hypertension, HF, impaired LV systolic function (ejection fraction 35% or less or fractional shortening less than 25%), and diabetes mellitus. *(Level of Evidence: A)*

4. For patients without mechanical heart valves at high risk of stroke, chronic oral anticoagulant therapy with a vitamin K antagonist is recommended in a dose adjusted to achieve the target intensity INR of 2.0 to 3.0, unless contraindicated. Factors associated with highest risk for stroke in patients with AF are prior thromboembolism (stroke, TIA, or systemic embolism) and rheumatic mitral stenosis. *(Level of Evidence: A)*

5. The INR should be measured at least weekly during initiation of therapy and monthly when anticoagulation is stable. *(Level of Evidence: A)*

6. Aspirin, 81 to 325 mg daily, is recommended as an alternative to vitamin K antagonists in low-risk patients and in those with contraindications to anticoagulation. *(Level of Evidence: A)*

7. Antithrombotic therapy is recommended for patients with atrial flutter in a manner similar to that for those with AF. *(Level of Evidence: C)*

<div align="center">

Method of Reporting

</div>

Per patient:

- Whether or not warfarin was prescribed for a patient with AF or atrial flutter who has 1 or more high-risk factors or more than 1 moderate-risk factor for thromboembolism

Per patient population:

- Percentage of all patients with AF or atrial flutter who have 1 or more high-risk factors or more than 1 moderate-risk factor for thromboembolism for whom warfarin was prescribed

- Percentage of all patients with AF or atrial flutter who have 1 or more high-risk factors or more than 1 moderate-risk factors for thromboembolism for whom warfarin was prescribed, once all denominator exclusions have been applied

---

<div align="center">

Challenges to Implementation

</div>

- Ambiguity regarding medical or patient reasons for not prescribing warfarin

- Difficulty locating reasons in the medical record for not prescribing warfarin

---

3. Monthly INR Measurement

Assessment of INR at least once monthly for patients with nonvalvular AF or atrial flutter receiving anticoagulation therapy with warfarin

Numerator	The number of calendar months in which at least 1 INR measurement was made
Denominator	The number of calendar months in which the patient was receiving warfarin therapy during the reporting year.
	Exclusions:
	• Documentation of patient reason(s) for no INR measurement: Examples of patient reasons for no INR measurement include but are not limited to the following:
	• Month(s) during a calendar year in which patient noncompliance with INR monitoring is documented, despite 1 or more documented attempts to contact the patient to ensure compliance
	• Documentation of system reason(s) for no INR measurement: Examples of system reasons for no INR measurement include but are not limited to the following:
	• Month(s) during a calendar year in which monitoring of INR is documented as the responsibility of another caregiver
Period of Assessment	Reporting year
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record

Rationale

Frequent monitoring of INR level is essential to guiding warfarin dose adjustment to maintain anticoagulation intensity in the desired target range. More frequent monitoring may be required during initiation of warfarin therapy or when other drugs that interact with warfarin are started or stopped.

Clinical Recommendation(s)

ACC/AHA/ESC 2006 Guidelines for the Management of Atrial Fibrillation Patients With AF

Monitoring of INR

Class I

1. Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. *(Level of Evidence: A)*

2. The selection of the antithrombotic agent should be based on the absolute risks of stroke and bleeding and the relative risk and benefit for a given patient. *(Level of Evidence: A)*

3. Anticoagulation with a vitamin K antagonist is recommended for patients with more than 1 moderate risk factor. Such factors include age 75 y or greater, hypertension, HF, impaired LV systolic function (ejection fraction 35% or less or fractional shortening less than 25%), and diabetes mellitus. *(Level of Evidence: A)*

4. For patients without mechanical heart valves at high risk of stroke, chronic oral anticoagulant therapy with a vitamin K antagonist is recommended in a dose adjusted to achieve the target intensity INR of 2.0 to 3.0, unless contraindicated. Factors associated with highest risk for stroke in patients with AF are prior thromboembolism (stroke, TIA, or systemic embolism) and rheumatic mitral stenosis. *(Level of Evidence: A)*

5. INR should be determined at least weekly during initiation of therapy and monthly when anticoagulation is stable. *(Level of Evidence: A)*

6. Aspirin, 81 to 325 mg daily, is recommended as an alternative to vitamin K antagonists in low-risk patients and in those with contraindications to oral anticoagulation. *(Level of Evidence: A)*

7. Antithrombotic therapy is recommended for patients with atrial flutter in a manner similar to that for those with AF. *(Level of Evidence: C)*

Method of Reporting

Per patient:

• Number of calendar months during which INR measurements were made during the reporting year.

Per patient population:

- Percentage of patient months in which at least 1 INR measurement was made during the reporting year.*

Challenges to Implementation

- Difficulty determining when the patient is receiving warfarin

- Difficulty locating and determining the dates of all INR measurements

- Difficulty collecting data for patients who receive care in multiple locations when responsibility for anticoagulation monitoring is shared among multiple caregivers or when patients self-monitor the INR using a point-of-care device.

*Example: The physician has 9 patients on warfarin for reporting year 2006. Seven patients were on warfarin for the entire calendar year. One patient was on warfarin for 6 months and the other patient was on warfarin for 10 months, which cumulate to 100 patient months. [(712)+(16)+(110)=100]. Two of the patients who were on warfarin for the entire year missed INR monitoring for 1 month each. The patient who was on warfarin for 6 months also missed INR monitoring 1 month. The population report for this measure in this practice would be 97 percent.

AF indicates atrial fibrillation; HF, heart failure; INR, international normalized ratio; and LV, left ventricular.

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

SAMPLE SURVEY FORM

CLASS (ACC/AHA/ ESC) or GRADE (AAFP/ACP)	ATRIAL FIBRILLATION GUIDELINE RECOMMENDA- TIONS	**PERFORMANCE MEASURE SURVEY** Please see the definition for each of the criteria below in the enclosed Performance Measure Survey Guide. Indicate your selection by marking X in the appropriate field										
		A. Insufficient evidence	B. Uninter-pretable	C. Not actionable	D. Unclear patient population	E. Not clinically meaningful	F. Uncertain feasibility due to data collection effort	G. Uncertain feasibility due to cost of data collection	H. Uncertain data collection period	Other, specify	Potential measure? Y/N/Other	Comment
Management Area (e.g., Antithrombotic Therapy in Patients With AF)												
Class (I, II or III) or Grade (1A, 1B, 1C+, 1C, 2A, 2B, 2C)	Recommendation from guideline to be considered as potential measure with *Level of Evidence*											
Example: Class I	*Example:* Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. *(Level of Evidence: A)*											

PERFORMANCE MEASURE SURVEY

EXCLUSION CRITERIA DEFINITIONS

Exclusion Criteria	Considerations
Useful in Improving Patient Outcomes	
1. **Insufficient evidence:** The scientific basis for the recommendation is not well established.	Please note that ACC/AHA guideline recommendations with **Level of Evidence B** are based on limited evidence from a single randomized trial or nonrandomized studies, and recommendations with **Level of Evidence C** are only based on expert opinion, case studies, or standard of care. *Considering level of evidence*, s*elect this criterion if you find it appropriate to exclude a recommendation as a potential quality indicator.*
2. **Uninterpretable:** The degree to which a provider can clearly understand what must be done to successfully implement the recommendation.	
3. **Not actionable:** The recommendation addresses an area that is not under the practitioner's control.	This is your assessment of the degree to which a provider is empowered to influence the activities of the healthcare system toward improvement.
Useful in Measure Design	
4. **Unclear patient population:** The patient group to whom this recommendation applies (denominator) is not clinically meaningful.	
5. **Not clinically meaningful:** The recommendation does not capture clinically meaningful aspects of care.	
6. **Uncertain reliability across settings:** The recommendation is not likely to apply across organizations and delivery settings.	
Useful in Measure Implementation	
7. **Uncertain feasibility due to effort:** The data required to measure successful implementation of the recommendation cannot be obtained with reasonable effort.	From your perspective, the required data can be typically abstracted from patient charts or readily available national registries or databases.
8. **Uncertain feasibility due to cost of data collection:** The data required to measure successful implementation of the recommendation cannot be obtained at reasonable cost.	
9. **Uncertain data collection period:** The data required to measure successful implementation of the recommendation cannot be obtained within the period allowed.	

Appendix E. Sample Prospective Data Collection Flow Sheet

American College of Cardiology, American Heart Association, and Physician Consortium for Performance Improvement
Atrial Fibrillation and Atrial Flutter Core Physician Performance Measurement Set

Prospective Data Collection Flow Sheet

| SAMPLE |

Provider No. _____ Patient Name or Code _____ Birth Date _____ / _____ / _____ Gender M ____ F ____
                                                                                                                        (mm / dd / yyyy)

Allergies: _____

Monitoring						

Medical History
Stroke, TIA, or systemic embolism: ____   Hypertension: ____   Heart failure or impaired LV systolic function: ____

Age ≥75 years: ____   Diabetes mellitus: ____

Other:

Warfarin Therapy Initiated
Date: ____/____/____   Aspirin prescribed instead of warfarin based on low risk of thromboembolism (≤1 risk factor): ☐

Dosage: _____   Warfarin not prescribed due to medical reason: _____

Warfarin not prescribed due to patient reason: _____

Date (mm/dd/yyyy)	____/____/_____	____/____/_____	____/____/_____	____/____/_____	____/____/_____	____/____/_____
INR measurement

Target INR:
___ 2.0 to 3.0
___ Other*

*Provide reason in comments box below | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ | _____
Not measured:
Med. reason*: _____
Pt. reason*: _____ |
Warfarin dose						
Concurrent medications reviewed	Yes _____	Yes _____	Yes _____	Yes _____	Yes _____	Yes _____
Comments (e.g., patient self-monitoring INR using a point-of-care device)						

Date (mm/dd/yyyy)	____/____/_____	____/____/_____	____/____/_____	____/____/_____	____/____/_____	____/____/_____
INR measurement

*Provide reason in comments box below | _____
Not measured:
Med. reason*_____
Pt. reason*_____ | _____
Not measured:
Med. reason*_____
Pt. reason*_____ | _____
Not measured:
Med. reason*_____
Pt. reason*_____ | _____
Not measured:
Med. reason*_____
Pt. reason*_____ | _____
Not measured:
Med. reason*_____
Pt. reason*_____ | _____
Not measured:
Med. reason*_____
Pt. reason*_____ |
Warfarin dose						
Concurrent medications reviewed	Yes _____	Yes _____	Yes _____	Yes _____	Yes _____	Yes _____
Comments						

References

1. Spertus JA, Eagle KA, Krumholz HM, et al; American College of Cardiology/American Heart Association Task Force on Performance Measures. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol. 2005;45:1147–56.

2. Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular trends in incidence of atrial fibrillation in Olmsted County, Minnesota, 1980 to 2000, and implications on the projections for future prevalence [published correction appears in Circulation. 2006;114:e498]. Circulation. 2006;114: 119–25.

3. Fuster V, Rydén LE, Asinger RW, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Committee to Develop Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the North American Society of Pacing and Electrophysiology. J Am Coll Cardiol. 2001;38: 1231–66.

4. Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation) [published correction appears in J Am Coll Cardiol. 2007;50:562]. J Am Coll Cardiol. 2006; 48:854–906.

5. McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). Circulation. 2004;109:3223–43.

6. Snow V, Weiss KB, LeFevre M, et al; for the Joint AAFP/ACP Panel on Atrial Fibrillation. Management of newly detected atrial fibrillation: a clinical practice guideline from the American Academy of Family Physicians and the American College of Physicians. Ann Intern Med. 2003: 139;1009–17.

7. Howitt A, Armstrong D. Implementing evidence based medicine in general practice: audit and qualitative study of antithrombotic treatment for atrial fibrillation. BMJ. 1999;318:1324–7.

8. Hart RG, Pearce LA, McBride R, et al; the Stroke Prevention in Atrial Fibrillation (SPAF) Investigators. Factors associated with ischemic stroke during aspirin therapy in atrial fibrillation: analysis of 2012 participants in the SPAF I–III clinical trials. Stroke. 1999;30:1223–9.

9. Landefeld CS, Goldman L. Major bleeding in outpatients treated with warfarin: incidence and prediction by factors known at the start of outpatient therapy. Am J Med. 1989;87:144–52.

10. Atrial Fibrillation Investigators. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation: analysis of pooled data from five randomized controlled trials [published correction appears in Arch Intern Med. 1994;154:2254]. Arch Intern Med. 1994;154:1449–57.

11. Moulton AW, Singer DE, Haas JS. Risk factors for stroke in patients with nonrheumatic atrial fibrillation: a case-control study. Am J Med. 1991; 91:156–61.

12. Gage BF, Waterman AD, Shannon W, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA. 2001;285:2864–70.

13. Van Walraven C, Hart RG, Wells GA, et al. A clinical prediction rule to identify patients with atrial fibrillation and a low risk for stroke while taking aspirin. Arch Intern Med. 2003;163:936–43.

14. Go AS, Hylek EM, Chang Y, et al. Anticoagulation therapy for stroke prevention in atrial fibrillation: how well do randomized trials translate into clinical practice? JAMA. 2003;290:2685–92.

15. Gage BF, van Walraven C, Pearce L, et al. Selecting patients with atrial fibrillation for anticoagulation. Stroke risk stratification in patients taking aspirin. Circulation. 2004;110:2287–92.