PERFORMANCE MEASURES

2016 ACC/AHA Clinical Performance and Quality Measures for Adults With Atrial Fibrillation or Atrial Flutter



A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures

Developed in Collaboration With the Heart Rhythm Society

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TABLE OF CONTENTS

PREAMBLE	Short Title: QM-2: ACEI or ARB Prescribed Prior to Discharge (When LVEF \leq 40) 550
	Short Title: QM-3: Inappropriate Prescription
1. INTRODUCTION	of Antiarrhythmic Drugs to Patients With
1.1. Scope of the Problem	Permanent Atrial Fibrillation
1.2. Disclosure of Relationships With Industry and	Dofetilide or Sotalol Prior to Discharge 552
Other Entities	Short Title: QM-5: Inappropriate Prescription of
	a Direct Thrombin or Factor Xa Inhibitor Prior to
2. METHODOLOGY	Discharge
	Short Title: QM-7: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy
2.1. Literature Review	Prior to Discharge555
2.2. Definition and Selection of Measures 529	Short Title: QM-8: Inappropriate Prescription of Nondihydropyridine Calcium Channel
3. 2016 ACC/AHA ATRIAL FIBRILLATION/ATRIAL	Antagonist Prior to Discharge556 Short Title: QM-9: Patients Who Underwent
FLUTTER CLINICAL PERFORMANCE AND QUALITY	Atrial Fibrillation Catheter Ablation Who Were
MEASURES	Not Treated With Anticoagulation Therapy Both
	During or After a Procedure 557
3.1. Discussion of 2016 Atrial Fibrillation/Atrial Flutter	Short Title: QM-10: Shared Decision Making
Clinical Performance and Quality Measures 530	Regarding Anticoagulation Prescription Prior to
3.1.1. Retired Measures531	Discharge
3.1.2. Revised Measures 531	Outpatient Measures
3.1.3. New Measures	Short Title: QM-11: Beta Blocker Prescribed (When LVEF ≤40)
	Short Title: QM-12: Inappropriate Prescription
4. AREAS FOR FURTHER RESEARCH 533	of Antiarrhythmic Drugs to Patients With
	Permanent Atrial Fibrillation
REFERENCES	of Dofetilide or Sotalol
KEI EKENOES	Short Title: QM-14: Inappropriate Prescription
	of a Direct Thrombin or Factor Xa Inhibitor 562
APPENDIX A	Short Title: QM-16: Inappropriate Prescription
2016 ACC/AHA Atrial Fibrillation Clinical Performance	of Antiplatelet and Oral Anticoagulation
and Quality Measures 539	Therapy
Performance Measures for Use in Patients With	Short Title: QM-17: Inappropriate Prescription
Inpatient and Outpatient Atrial Fibrillation or	of Nondihydropyridine Calcium Channel Antagonist
Atrial Flutter 539	Short Title: QM-18: Shared Decision Making in
Inpatient Measures539	Anticoagulation Prescription 566
Short Title: PM-1: CHA ₂ DS ₂ -VASc Risk Score	/inteledigate ion Trescription
Documented Prior to Discharge	APPENDIX B
Short Title: PM-2: Anticoagulation Prescribed	
Prior to Discharge	Author Relationships With Industry and Other Entities
Follow-Up Documented Prior to Discharge for	(Relevant)–2016 ACC/AHA Clinical Performance and Quality Measures for Adults With Atrial Fibrillation or
Warfarin Treatment	Atrial Flutter
Outpatient Measures	1111111 1 1411C1
Short Title: PM-4: CHA ₂ DS ₂ -VASc Score Risk	APPENDIX C
Score Documented	
Short Title: PM-5: Anticoagulation Prescribed . 545	Peer Reviewer Relationships With Industry and Other Entities—2016 ACC/AHA Clinical Performance and
Short Title: PM-6: Monthly INR for Warfarin	Quality Measures for Adults With Atrial Fibrillation or
Treatment 547	Atrial Flutter
Quality Improvement Measures for Inpatient or	
Outpatient Atrial Fibrillation or Atrial Flutter	DDEAMBLE
Patients	PREAMBLE
Inpatient Measures	
Short Title: QM-1: Beta Blocker Prescribed Prior	The American College of Cardiology (ACC)/American
to Discharge (When LVEF ≤40) 549	Heart Association (AHA) clinical performance and quality

measure sets serve as vehicles to accelerate translation of scientific evidence into clinical practice. Measure sets developed by the ACC/AHA are intended to provide practitioners and institutions that deliver cardiovascular services with tools to measure the quality of care provided and identify opportunities for improvement.

Writing committees are instructed to consider the methodology of clinical performance measure development (1) and to ensure that the measures developed are aligned with ACC/AHA clinical guidelines. The writing committees also are charged with constructing measures that maximally capture important aspects of care quality, including timeliness, safety, effectiveness, efficiency, equity, and patient-centeredness, while minimizing, when possible, the reporting burden imposed on hospitals, practices, and practitioners.

Potential challenges from measure implementation may lead to unintended consequences. The manner in which challenges are addressed is dependent on several factors, including the measure design, data collection method, performance attribution, baseline performance rates, reporting methods, and incentives linked to these reports.

The ACC/AHA Task Force on Performance Measures distinguishes *quality measures* from *performance measures*. Quality measures are metrics that *may* be useful for local quality improvement but are not yet appropriate for public reporting or pay-for-performance programs (i.e., contexts in which performance measures are used). New measures are initially evaluated for potential inclusion as performance measures. In some cases, a measure is insufficiently supported by the guidelines. In other instances, when the guidelines support a measure, the writing committee may decide it is necessary to have the measure tested to identify the consequences of measure implementation. Quality measures may then be promoted to the status of performance measures as supporting evidence becomes available.

Paul A. Heidenreich, MD, MS, FACC, FAHA Chair, ACC/AHA Task Force on Performance Measures

1. INTRODUCTION

In the summer of 2015, the ACC/AHA convened the writing committee to begin the process of revising the existing atrial fibrillation (AF) and atrial flutter measure set that was released in 2008 (2) and for which implementation notes had been issued in 2011 (3). The writing committee also was charged with the task of developing new measures to benchmark and improve the quality of care for patients with AF or atrial flutter. Throughout the report, the term AF will include atrial flutter, unless specifically stated.

All the measures included in the clinical performance and quality measure set are briefly summarized in **Table 1**, which provides information on the measure number, measure title, and care setting. The detailed measure specifications (available in Appendix A) provide not only the information included in **Table 1** but also more detailed information, including the measure description, numerator, denominator (including denominator exclusions and exceptions), rationale for the measure, guidelines that support the measure, measurement period, source of data, and attribution.

This AF clinical performance and quality measure set is notable for several reasons. First, the writing committee considered whether measures should be developed for the inpatient setting, expanding the scope of the original measure set. Specifically, the writing committee decided to broaden the care setting, from a solely outpatient context to the inpatient setting, to further improve the continuity of care for these patients by addressing the multiple settings in which they receive care.

Second, new measures were developed for care domains that were not previously addressed, including patient safety, effective clinical care, communication, and care coordination. Many measure concepts were considered but were ultimately not included in this set after committee discussion. It is the hope of this writing committee that this clinical performance and quality measure set will be reassessed as new science is developed and as electronic health record data standards are more broadly implemented across settings.

The writing committee has developed a comprehensive AF measure that includes 24 total measures, including 6 performance measures (3 inpatient measures and 3 outpatient measures) and 18 quality measures (10 inpatient measures and 8 outpatient measures), as reflected in Table 1 and the full measure specifications in Appendix A. The writing committee believes that implementation of this clinical performance and quality measure set by providers, physician practices, and hospital systems will help to enhance the quality of care provided to patients with AF in both the inpatient and outpatient settings.

The clinical performance and quality measure set that is represented in this report is intended to serve as an ACC/AHA AF measures library. The writing committee acknowledges that a site may not adopt all of the quality measures, but the writing committee wanted to ensure that the quality measures were developed on the basis of guideline recommendations and were made available to sites that may choose to implement them to look at the quality of care rendered to patients with AF.

No.	Measure Title	Care Setting	Measure Domain
Performar	nce Measures		
PM-1	CHA ₂ DS ₂ -VASc Risk Score Documented Prior to Discharge	Inpatient	Effective Clinical Care
PM-2	Anticoagulation Prescribed Prior to Discharge	Inpatient	Effective Clinical Care
PM-3	PT / INR Planned Follow-Up Documented Prior to Discharge for Warfarin Treatment	Inpatient	Effective Clinical Care
PM-4	CHA ₂ DS ₂ -VASc Risk Score Documented	Outpatient	Effective Clinical Care
PM-5	Anticoagulation Prescribed	Outpatient	Effective Clinical Care
PM-6	Monthly INR for Warfarin Treatment	Outpatient	Effective Clinical Care
Quality M	easures		
QM-1	Beta Blocker Prescribed Prior to Discharge (When LVEF \leq 40)	Inpatient	Effective Clinical Care
QM-2	ACEI or Angiotensin-Receptor Blocker Prescribed Prior to Discharge (When LVEF \leq 40)	Inpatient	Effective Clinical Care
QM-3	Inappropriate Prescription of Antiarrhythmic Drugs Prior to Discharge to Patients With Permanent Atrial Fibrillation for Rhythm Control	Inpatient	Patient Safety
QM-4	Inappropriate Prescription of Dofetilide or Sotalol Prior to Discharge in Patients With Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis Prior to Discharge	Inpatient	Patient Safety
QM-5	Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor Prior to Discharge in Patients With Atrial Fibrillation With a Mechanical Heart Valve	Inpatient	Patient Safety
QM-6	Deleted in response to new data in 2018		
QM-7	Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy Prior to Discharge for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease	Inpatient	Patient Safety
QM-8	Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist Prior to Discharge in Patients With Reduced Ejection Fraction Heart Failure	Inpatient	Patient Safety
QM-9	Patients Who Underwent Atrial Fibrillation Catheter Ablation Who Were Not Treated With Anticoagulation Therapy During or After a Procedure	Inpatient	Patient Safety
QM-10	Shared Decision Making Between Physician and Patient in Anticoagulation Prescription Prior to Discharge	Inpatient	Communication and Care Coordination
QM-11	Beta Blocker Prescribed (When LVEF ≤40)	Outpatient	Effective Clinical Care
QM-12	Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation for Rhythm Control	Outpatient	Patient Safety
QM-13	Inappropriate Prescription of Dofetilide or Sotalol in Patients With Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis	Outpatient	Patient Safety
QM-14	Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor in Patients With Atrial Fibrillation With Mechanical Heart Valve	Outpatient	Patient Safety
QM-15	Deleted in response to new data in 2018		
QM-16	Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease	Outpatient	Patient Safety
QM-17	Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist in Patients With Reduced Ejection Fraction Heart Failure	Outpatient	Patient Safety
QM-18	Shared Decision Making Between Physician and Patient in Anticoagulation Prescription	Outpatient	Communication and Care Coordination

ACC indicates American College of Cardiology; ACE, angiotensin-converting enzyme; ACEI, angiotensin-converting enzyme inhibitor; AHA, American Heart Association; ARB, angiotensin receptor blocker; INR, International Normalized Ratio; LVEF, left ventricular ejection fraction; PM, performance measure; PT, prothrombin time; and QM, quality measure.

1.1. Scope of the Problem

AF is recognized as the most common cardiac arrhythmia in the United States and is associated with increased mortality rate for individuals who have other cardiovascular conditions and procedures, such as heart failure (4-6), myocardial infarction (7,8), coronary artery bypass graft (9,10), stroke (11) and hypertension (12-15). Furthermore, AF is associated with a 4- to 5-fold increased risk for stroke (16).

It is estimated that AF impacts between 2.7 million and 6.1 million American adults, and this number is expected

to double by 2050 (17,18). Among Medicare patients who are ≥65 years of age who were diagnosed from 1993 to 2007, the prevalence of AF increased 5% per year, from approximately 41.1 per 1000 beneficiaries to 85.5 per 1000 beneficiaries (19).

Hospitalizations with AF listed as the primary diagnosis increased by 34% from 1996 to 2001 (20). Just over half of patients admitted for AF were men (50.8%) (21). The costs of care for patients with AF are substantial, with estimates ranging from \$6 billion to \$26 billion a year, of which \$6 billion was attributed directly to AF, \$9.9 billion

to other cardiovascular expenses, and \$10.1 billion to noncardiovascular expenses (22). On the basis of this information, identifying performance and quality measures that can be implemented by providers or healthcare systems may aid not only in improving patient care, but also in reducing costs by reducing adverse outcomes of AF (e.g., fewer strokes).

Accordingly, updating the existing AF performance measure set was a priority for the ACC and AHA. Particular attention was given to assessments, therapies, and interventions that could improve the quality of life for patients with AF. Effective clinical care, patient safety, and care coordination measures were developed. The writing committee believes that these measures have the potential to improve the patient care and thereby improve the quality of life. This document serves to reflect those measures that were developed by the writing committee after comprehensive internal discussion, peer review, and public comment.

1.2. Disclosure of Relationships With Industry and Other Entities

The ACC/AHA Task Force on Performance Measures makes every effort to avoid actual, potential, or perceived conflicts of interest that could arise as a result of relationships with industry or other entities (RWI). Detailed information on the ACC/AHA policy on RWI can be found online. All members of the writing committee, as well as those selected to serve as peer reviewers of this document, were required to disclose all current relationships and those existing within the 12 months before the initiation of this writing effort. ACC/AHA policy also requires that the writing committee co-chairs and at least 50% of the writing committee have no relevant RWI.

Any writing committee member who develops new RWI during his or her tenure on the writing committee is required to notify staff in writing. These statements are reviewed periodically by the Task Force and by members of the writing committee. Author and peer reviewer RWI that are relevant to the document are included in the appendixes: Please see Appendix B for relevant writing committee RWI and Appendix C for relevant peer reviewer RWI. Additionally, to ensure complete transparency, the writing committee members' comprehensive disclosure information, including RWI not relevant to the present document, is available online. Disclosure information for the Task Force is also available online.

The work of the writing committee was supported exclusively by the ACC and the AHA without commercial support. Members of the writing committee volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by writing committee members and staff from the ACC and AHA, as

well as from the Heart Rhythm Society (HRS), which served as a collaborator on this project.

2. METHODOLOGY

2.1. Literature Review

In developing the updated AF clinical performance and quality measure set, the writing committee reviewed evidence-based guidelines and statements that would potentially impact the construct of the measures. The practice guidelines and statements that most directly contributed to the development of these measures can be seen in Table 2.

2.2. Definition and Selection of Measures

The writing committee reviewed both recent guidelines and other clinical guidance documents referenced in **Table 2**. The writing committee also examined available information on gaps in care to address which new measures might be appropriate as performance measures or quality measures for this measure set update.

All measures were designed to assess quality of care experienced by individuals who have AF or atrial flutter in the inpatient and outpatient setting. The measures also were designed to limit clinical performance and quality measurement to patients without a valid reason for exclusion from the measure. Measure *exclusions* are those reasons that automatically remove a patient from the denominator. For example, all measures excluded patients who were <18 years of age or on comfort care. In contrast to exclusions, denominator *exceptions* are conditions that remove a patient from the denominator only if the numerator criteria are not met (29). Denominator exceptions are used in select cases to allow for a fairer measurement of quality for providers who serve higher-

TABLE 2

Associated Guidelines and Other Clinical Guidance Documents

GUIDELINES

2014 AHA/ACC/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23) $\,$

2013 ACCF/AHA Guideline for Management of Heart Failure (24)

STATEMENTS

2013 Treatment of Atrial Fibrillation (25.26)

2012 AHA/ASA Oral Antithrombotic Agents for the Prevention of Stroke in Nonvalvular Atrial Fibrillation: A Science Advisory for Healthcare Professionals (27)

2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation Recommended for Patient Selection, Procedural Techniques, Patient Management and Follow-Up, Definitions, Endpoints, and Research Trial Design (28)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ASA, American Stroke Association; ECAS, the European Cardiac Arrhythmia Society; EHRA, European Heart Rhythm Association; and HRS, Heart Rhythm Society.

risk populations. Exceptions are also used to defer to the clinical judgment of the provider. Several of the measures include exceptions. For example, in the case of the inpatient and outpatient anticoagulation measure, a physician may write a script for anticoagulation therapy even if the patient says that he/she will not take the medication for a number of reasons (e.g., religion). In this case, the physician would receive credit for the measure. If the patient has told the physician that he/she does not wish to have the medication prescribed, the physician can choose not to write the script and to document in the medical record that the patient refused the medication. In this scenario, the provider will not be penalized for not writing a prescription if the patient's reason is documented. The writing committee closely examined which exceptions should be included for each measure and in some cases determined to not include any exceptions, as in the case of the patient safety measures.

During the course of developing the clinical performance and quality measure set, the writing committee evaluated the potential measures against the ACC/AHA attributes of clinical performance and quality measures which were derived on work of experts (30) (Table 3) to reach consensus on which measures should be advanced for inclusion in the final clinical performance and quality measure set. After the peer review and

public comment period, the writing committee reviewed and discussed the comments received and further refined the measure set. The writing committee acknowledges that the new measures created in this set will need to be tested and validated over time. By publishing this clinical performance and quality measure set, the writing committee encourages adoption of these performance and quality measures, which will help to facilitate the collection and analysis of data needed to assess the validity of these measures. In the future, the writing committee anticipates having data that will allow them to reassess whether any of the measures included in this set should be modified or potentially promoted from a quality measure to a performance measure.

3. 2016 ACC/AHA ATRIAL FIBRILLATION/ATRIAL FLUTTER CLINICAL PERFORMANCE AND QUALITY MEASURES

3.1. Discussion of 2016 Atrial Fibrillation/Atrial Flutter Clinical Performance and Quality Measures

After reviewing the existing guidelines, the 2008 measure set (2), and the 2011 implementation notes (3), the writing committee discussed which measures needed to be revised to reflect the updated science and worked to identify which guideline recommendations could serve as

TABLE 3 ACC/AHA Task Force on Per	formance Measures: Attributes for Clinical Performance and Quality Measures (30)
1. Evidence based	
High-impact area that is useful in improving patient outcomes	 a) For structural measures, the structure should be closely linked to a meaningful process of care that in turn is linked to a meaningful patient outcome. b) For process measures, the scientific basis for the measure should be well established, and the process should be closely linked to a meaningful patient outcome. c) For outcome measures, the outcome should be clinically meaningful. If appropriate, performance measures based on outcomes should adjust for relevant clinical characteristics through the use of appropriate methodology and high-quality data sources.
2. Measure selection	
Measure definition	 a) The patient group to whom the measure applies (denominator) and the patient group for whom conformance is achieved (numerator) are clearly defined and clinically meaningful.
Measure exceptions and exclusions	b) Exceptions and exclusions are supported by evidence.
Reliability	c) The measure is reproducible across organizations and delivery settings.
Face validity	d) The measure appears to assess what it is intended to.
Content validity	e) The measure captures most meaningful aspects of care.
Construct validity	f) The measure correlates well with other measures of the same aspect of care.
3. Measure feasibility	
Reasonable effort and cos	a) The data required for the measure can be obtained with reasonable effort and cost.
Reasonable time period	b) The data required for the measure can be obtained within the period allowed for data collection.
4. Accountability	
Actionable	a) Those held accountable can affect the care process or outcome.
Unintended consequences avoided	b) The likelihood of negative unintended consequences with the measure is low.

TABL		trial Fibrillation Measures	
No.	Care Setting	Measure Title	Rationale for Revisions
PM-4	Outpatient	CHA ₂ DS ₂ -VASc Risk Score Documented	This measure was revised to reflect the update in the "2014 AHA/ACC/HRS Guideline for Management of Patients With Atrial Fibrillation" (23) that recommends the use of the CHA ₂ DS ₂ -VASc score instead of the CHA ₂ DS ₂ -Additionally, this measure was revised to allow for a patient reason exception that reflects instances in which a patient chooses to have an atrial appendage device placed or to clearly account for medical instances in which a patient already has such a device in place.
PM-5	Outpatient	Anticoagulation Prescribed	This measure had the same changes made as noted in the CHA_2DS_2 -VASc Risk Score Documented "Rationale for Revisions." This measure was also revised to require that the healthcare provider document if the patient has a CHA_2DS_2 -VASc Risk Score of ≥ 2 as a reason for why anticoagulation was prescribed. This was accomplished by modifying the denominator to include in this measure all patients with nonvalvular atrial fibrillation or atrial flutter who do not have a score of 0 or 1 documented in the medical record.
PM-6	Outpatient	Monthly INR for Warfarin Treatment	This measure was maintained as previously specified in the 2008 measure set. However, the attribution was changed to facility or provider level instead of being limited to physician level. The writing committee acknowledged that this measure has been difficult to implement in registries; however, the sentiment was that this measure does lead to improved patient care and can be implemented in certain instances, such as in the Department of Veterans Affairs or integrated healthcare systems. It is the hope of the writing committee that with increased interoperability and common data standards, this measure may be more readily adopted by more systems in the future.

ACC indicates American College of Cardiology; AHA, American Heart Association; HRS, Heart Rhythm Society; INR, International Normalized Ratio; and PM, performance measure.

the basis for new performance or quality measures. The writing committee also reviewed existing measure sets that were publicly available.

The following subsections serve as a synopsis of the revisions that were made to previous measures and a description of why the new measures were created for both the inpatient and outpatient settings.

3.1.1. Retired Measures

The writing committee decided not to retire the 3 measures that were previously included in the 2008 measure set. Although the writing committee did note that the data needed for the monthly International Normalized Ratio Warfarin Treatment measure have proved difficult to collect for some institutions, it was noted that some healthcare systems, such as the U.S. Department of Veterans Affairs, may be able to collect this information. The writing committee hopes that by maintaining this as a performance measure, health systems will encourage sites to improve data collection. The writing committee also anticipates that increased interoperability of healthcare data in general, and across inpatient and outpatient records in particular, will facilitate reporting of this measure.

3.1.2. Revised Measures

The writing committee did make a number of changes to the 3 measures, which are summarized in **Table 4**. The majority of the changes were made to reflect the updated guideline recommendations, whereas other changes were made to strengthen the measure construct. **Table 4**

provides the measure care setting, title, and a brief rationale for the revisions made to the measure.

3.1.3. New Measures

The writing committee has worked to create a comprehensive list of measures that can be used for patients with AF. This set includes 21 new measures, of which 3 are inpatient performance measures and 18 are quality measures (10 inpatient, 8 outpatient). **Table 5** includes a list of the measures with information on the care setting and a brief rationale.

Six of the quality measures are structured in a typical format, in which the goal is to seek a higher performance score nearing 100%. However, for several of these new measures on patient harm (safety measures; 12 in total), the goal is to approach or be near 0%, and a score of 90% is not a positive score but is effectively viewed as -90%.

The writing committee acknowledges that some sites may choose to adopt some but not all of the quality measures. In creating these quality measures, the writing committee considered the guidelines that supported their development. Although in some instances there may be some redundancy in the measures that were created with existing measures, the intent is to create a set of quality measures that may be used by sites that want to examine a "snapshot" of care for their patient population with AF only.

For more detailed information on the measure construct, please refer to the detailed measure specifications for each measure in Appendix A.

				Rationale for Designating as a Quality Measure
No.	Care Setting	Measure Title	Rationale for Creating New Measure	as Opposed to a Performance Measure (if Applicable)
PM-1	Inpatient	CHA ₂ DS ₂ -VASc Risk Score Documented Prior to Discharge	The writing committee determined that it should create inpatient measures. This measure seeks to implement a Class I, Level of Evidence: A, recommendation that patients have a CHA ₂ DS ₂ -VASc risk score assessment performed prior to discharge, which will aid in the treatment of eligible patients in the outpatient setting with anticoagulation medications.	Not applicable.
PM-2	Inpatient	Anticoagulation Prescribed Prior to Discharge	The writing committee developed this measure because members felt that prior to discharge, the provider should ensure that the patient was prescribed anticoagulation medication in accordance with recommendations in the "2014 AHA/ACC/HRS Guideline for Management of Patients With Atrial Fibrillation." As in the outpatient measure, the CHA ₂ DS ₂ -VASc risk score must be documented to receive credit for this measure.	Not applicable.
PM-3	Inpatient	PT/INR Planned Follow-Up Documented Prior to Discharge for Warfarin Treatment	The writing committee discussed whether to expand this measure from documentation that follow-up was scheduled to documentation that follow-up was performed. However, the writing committee felt that the burden of documenting a referral was sufficiently burdensome for the inpatient setting. Furthermore, because most systems are not integrated and there are limits in terms of electronic data sharing between the inpatient and the outpatient settings, extending this measure to require documentation of actual PT/INR for warfarin treatment completed after discharge would be a significant burden on hospitals and physicians.	Not applicable.
QM-1	Inpatient	Beta Blocker Prescribed Prior to Discharge (When LVEF ≤40)	Patients with AF and atrial flutter can benefit from having beta blockers prescribed in the inpatient	Although the recommendation supporting beta blocker use in controlling AF is a Class I, Level of
QM-11	Outpatient	Beta Blocker Prescribed (When LVEF ≤40)	and outpatient settings. The 2013 ACCF/AHA Guideline for Management of Heart Failure recommends the use of beta blockers to control ventricular rate in patients with paroxysmal, persistent, or permanent AF. Given this recommendation, the writing committee felt that it would be valuable to measure whether beta blockers were prescribed to patients with AF/atrial flutter. The guidelines to support this measure come from sections in the 2013 ACCF/AHA Guideline for Management of Heart Failure that address patient care for individuals who have both HF and AF. It is worth noting that Table 3 of the 2013 ACCF/AHA Guideline for Management of Heart Failure states that HFrEF is an LVEF ≤40.	Evidence: B, recommendation, the writing committee felt that it would be appropriate to designate this as a quality measure only. The writing committee also felt that this concept was more appropriately designated as a quality measure given that it is not inappropriate in patients without HF to consider the use of nondihydropiridine calcium channel blockers.
QM-2	Inpatient	ACEI or ARB Prescribed Prior to Discharge (When LVEF ≤40)	Patients with AF who are also diagnosed with having HF and an LVEF ≤40 can benefit from having ACEIs/ARBs prior to discharge. Given this, the writing committee determined that it would be valuable to develop a measure that would evaluate whether ACEIs/ARBs were prescribed. Although there is a HF measure that looks at ACEI/ARB use, the writing committee felt that this measure may not be used for quality improvement efforts in concert with the other AF measures included in this set.	There is a strong linkage between AF and HF. Given this, the writing committee felt that there would be some benefit in developing an inpatient and outpatient quality measure that examined whether patients were placed on ACEIs/ARBs but did not feel that there was sufficient evidence at this time to validate this becoming a performance measure.
QM-3	Inpatient	Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation Prior to Discharge for Rhythm Control	The 2014 AHA/ACC/HRS Guidelines for Management of Patients With Atrial Fibrillation recommends that antiarrhythmic drugs for rhythm control not be continued when AF becomes permanent. In accordance with this	The writing committee felt that there would be value in developing an inpatient and an outpatient quality measure for inappropriate prescription of antiarrhythmic drugs for rhythm control, in accordance with the 2014 AHA/ACC/
QM-12	Outpatient	Inappropriate Prescription of Antiarrhythmic Drugs to	recommendation, the writing committee sought to develop a measure that would attempt to	HRS Guidelines for Management of Patients With Atrial Fibrillation. The writing committee intends that this quality measure apply only when the

TAB	LE 5 Con	tinued		
No.	Care Setting	Measure Title	Rationale for Creating New Measure	Rationale for Designating as a Quality Measure as Opposed to a Performance Measure (if Applicable)
QM-9	Inpatient	Patients Who Underwent Atrial Fibrillation Catheter Ablation Who Were Not Treated With Anticoagulation Therapy During or After a Procedure	AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure. Given this, the writing committee felt that it would be important to develop a measure for the occurrence of this "never event." This measure includes a medical reason exception because there are some instances in which a patient may not be treated with anticoagulation therapy during or after a procedure. For example, a patient who undergoes repeat ablation with only 1 or 2 radiofrequency lesions placed in the left atrium to re-isolate the pulmonary veins develops a new pericardial effusion that is not hemodynamically significant.	Additional data are required prior to making this measure a performance measure. The ability to elevate these measures to a performance measure will depend on the quality of data obtained once the measures are implemented. If it is found that patients are being provided with medications that can have a negative impact on patient safety, the writing committee may determine that the measure should be elevated to the status of a performance measure. However at this time we do not whether there is evidence to support elevation to a performance measure.
QM-10	Inpatient	Shared Decision Making Between Physician and Patient in Anticoagulation Prescription Prior to Discharge	The writing committee believed that there would be value in developing a measure to capture shared decision making between physicians and the patient on the type of anticoagulation	The writing committee felt that although these measures are important, they are associated with a high level of administrative burden. Therefore, it was decided that at this time, without any
QM-18	Outpatient	Shared Decision Making Between Physician and Patient in Anticoagulation Prescription	medication prescribed. The writing committee acknowledged that this measure may create some administrative burden in documentation for hospitals, practices, or practitioners but believed that this measure is critical for patient engagement and empowerment in the medication regimen that they are prescribed. This measure is based on language included in the 2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation.	data, it would be more appropriate to designate these constructs as quality measures.

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; ACEI, angiotensin-converting enzyme inhibitor; AF, atrial fibrillation; AHA, American Heart Association; ARB, angiotensin receptor blocker; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; HRS, Heart Rhythm Society; INR, International Normalized Ratio; LVEF, left ventricular ejection fraction; PM, performance measure; PT, prothrombin time; and QM, quality measure.

4. AREAS FOR FURTHER RESEARCH

The writing committee felt that documentation of a bleeding score may be beneficial but that more data are needed before calculation of a bleeding score is advanced to the level of a performance or quality measure. Although the "2014 AHA/ACC/HRS Guideline for Management of Patients With Atrial Fibrillation" reference the HAS-BLED score, no specific guideline recommendations are included with regard to bleeding risk assessment. Although other guidelines, like the 2014 National Institute For Health Care and Excellence atrial fibrillation guidelines (32), do include recommendations for use of the HAS-BLED score to assess the risk of bleeding, the writing committee felt that additional evidence was needed before creating a performance or quality measure. Future research is needed to determine whether bleeding scores can lead to actionable risk stratification of patients. The writing committee also discussed whether any outcome measures should be developed specific to AF. The committee felt that there is insufficient evidence to support the use of an outcome measure (e.g., stroke rate per capita) as a measure of quality of AF care. It is not clear that patient outcomes will be improved by having patients select providers on the basis of outcome metrics when measures of process of care are equivalent.

The writing committee also acknowledges that there are patients with adult congenital heart disease some of whom have residual atrial septal defects that may change the indication for anticoagulation used in these patients. While these patients are not featured in the CHA₂DS₂-VASc, the writing committee does acknowledge that they are at greater risk of stroke with atrial fibrillation. At a future date, the writing committee may examine whether the clinical performance and quality measure set should include a measure to address adult congenital heart disease patients that are at risk of having atrial fibrillation.

Although numerous areas can be explored in the future for measure development, there were some additional concepts that the writing committee may want to explore in the future. These concepts include:

- Shared decision making between the physician and patient on whether a rhythm or rate control strategy should be pursued. This may be an important measure concept to address, given the value of symptom management and the relative risks and benefits of different strategies.
- Toxicity from amiodarone screening every 6 to 12 months.

- Inappropriate use of anticoagulation in patients with extreme low risk of stroke (i.e., CHA₂DS₂-VASc = 0)
- Prevention of re-occurrence of atrial fibrillation or flutter by controlling blood pressure in patients with hypertension.
- Exploring the feasibility of integration of pharmacokinetic guides for dose adjustments for new oral anticoagulants (e.g. renal conditions, or other conditions).

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537

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KEY WORDS ACC/AHA Performance Measures, atrial fibrillation, atrial flutter, performance measures, quality measures, quality indicators

APPENDIX A. 2016 ACC/AHA ATRIAL FIBRILLATION CLINICAL PERFORMANCE AND QUALITY MEASURES

Performance Measures for Use in Patients With Inpatient and Outpatient Atrial Fibrillation or Atrial Flutter

Inpatient Measures

SHORT TITLE: PM-1

CHA₂DS₂-VASc Risk Score Documented Prior to Discharge

PM-1: Atrial Fibrillation/Atrial Flutter: CHA2DS2-VASc Risk Score Documented Prior to Discharge

Numerator	\bullet Patients with nonvalvular AF or atrial flutter for whom a CHA $_2\text{D}$	S ₂ -VASc risk score was documented prior to discharge	
	For patients with nonvalvular AF or atrial flutter, assessment of thromboembolic risk should include:		
	CHA ₂ DS ₂ -VASc	Score	
	Congestive HF	1	
	Hypertension	1	
	Age ≥75 y	2	
	Diabetes mellitus	1	
	Stroke, TIA, or thromboembolism	2	
	Vascular disease (prior myocardial infarction,	1	
	peripheral artery disease, or aortic plaque)		
	Age 64-74 y	1	
	Sex category (i.e., female)	1	
Denominator	All patients with nonvalvular AF or atrial flutter		
Denominator exclusions	Patients age <18 y		
	 Patients with transient or reversible causes of AF (e.g., pneumo 	nia, hyperthyroidism, pregnancy, cardiac surgery)	
	Patients who leave against medical advice		
	 Patients who die during hospitalization 		
	Patients who are on comfort care measures only		
	 Patients who are transferred to another acute care hospital 		
	Patients with other indication for anticoagulation		
Denominator exceptions	Medical reason(s) documented for not assessing risk factors and	documenting the CHA ₂ DS ₂ -VASc score, including atria	
zenemiater exceptions	appendage device in place	J 2 2	
	appendage device in place		

	Fatient choice of having attract appendage device placed
Measurement period	Encounter
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care setting	Inpatient

Rationale

AF, whether paroxysmal, persistent, or permanent, and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular AF increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm.

Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and greater risk of death (11). Silent AF is also associated with ischemic stroke (33-36). The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia, substantially reduce stroke risk.

One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHA2DS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack or thromboembolism [doubled]), or CHA₂DS₂-VAŜc (congestive heart failure, hypertension, age ≥75 years [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65 to 74 years, sex category).

When compared with the CHA₂DS₂ score (39), the CHA₂DS₂-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex, 65 to 74 years of age, and vascular disease) (40,41).

The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Continued on the next page

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA2DS2-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, TIA, or a CHA₂DS₂-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42–45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54). (Class I, Level of Evidence: B)
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I, Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HF, heart failure; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; and TIA, transient ischemic attack.

SHORT TITLE: PM-2 **Anticoagulation Prescribed Prior to Discharge**

PM-2: Atrial Fibrillation/Atrial Flutter: Anticoagulation Prescribed Prior to Discharge

Measure description: Percentage of patients, age ≥18 y, with nonvalvular AF or atrial flutter who were discharged on warfarin or another FDA-approved anticoagulant drug for the prevention of thromboembolism.

Numerator	Patients with nonvalvular AF or atrial flutter for whom warfarin or another FDA-approved anticoagulant was prescribed* prior to discharge *Prescribed—also satisfied by documentation in current medication list All patients with nonvalvular AF or atrial flutter who do not have a documented CHA ₂ DS ₂ -VASc risk score of O or 1	
	<u> </u>	
	All patients with nonvalvular AF or atrial flutter who do not have a documented CHA ₂ DS ₂ -VASc risk score of 0 or 1	
Denominator		
Denominator exclusions	 Patients age <18 y Patients with transient or reversible causes of AF (e.g., pneumonia, hyperthyroidism, pregnancy, cardiac surgery) Patients who leave against medical advice Patients who die during hospitalization Patients who are on comfort care measures only Patients who are transferred to another acute care hospital 	
Denominator exceptions	 Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patient with a CHA₂DS₂-VASc score of ≥2, including atrial appendage device in place Documentation of a patient reason for not prescribing warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism, including patient choice of having atrial appendage device placed Patient currently enrolled in a clinical trial related to AF/atrial flutter 	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

Rationale

- AF, whether paroxysmal, persistent, or permanent and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular atrial fibrillation increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm. Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and mortality (11). Silent AF is also associated with ischemic stroke (33-36). The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia,
- One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHA2DS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or TIA or thromboembolism [doubled]), or CHA2DS2-VASc (congestive heart failure, hypertension, age ≥75 years [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65 to 74 years, sex category).
- When compared with the CHA2DS2 score (39), the CHA2DS2-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex, 65 to 74 years of age, and vascular disease) (40,41).
- The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA2DS2-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, TIA, or a CHA2DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54). (Class I, Level of Evidence: B)
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I, Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, US Food and Drug Administration; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; and TIA, transient ischemic attack.

SHORT TITLE: PM-3 PT/International INR Planned Follow-Up Documented Prior to Discharge for Warfarin Treatment

PM-3: Atrial Fibrillation/Atrial Flutter: PT/INR Planned Follow-Up Documented Prior to Discharge for Warfarin Treament

Measure description: Percentage of patients, age ≥18 y, with nonvalvular AF or atrial flutter who have been prescribed warfarin and who have a PT/INR follow-up scheduled prior to hospital discharge.

Numerator	Patients with nonvalvular AF or atrial flutter for whom warfarin was prescribed prior to discharge and for whom a PT/INR follow-up* is scheduled *Follow-up is scheduled within 2 weeks for patients who were newly prescribed warfarin or scheduled within 30 days for patients who were previously on warfarin. A "yes" or "no" should be documented in the medical record to denote whether follow-up PT/INR was scheduled.	
Denominator	Patients with nonvalvular AF or atrial flutter who were prescribed warfarin	
Denominator exclusions	 Patients age <18 y Patients with transient or reversible causes of AF (e.g., pneumonia, hyperthyroidism, pregnancy, cardiac surgery) Patients who leave against medical advice Patients who die during hospitalization Patients who are on comfort care measures only Patients who are transferred to another acute care hospital 	
Denominator exceptions	None	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

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)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA2DS2-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49–51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA₂DS₂-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B.)
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I, Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; PT, prothrombin time; and TIA, transient ischemic attack.

Outpatient Measures

SHORT TITLE: PM-4 CHA₂DS₂-VASc Score Risk Score Documented

PM-4: Atrial Fibrillation/Atrial Flutter: CHA2DS2-VASc Score Risk Score Documented

Measure description: Percentage	of patients, age ≥18 y, with nonvalvular AF or atrial flutter for whom a CHA ₂ DS ₂ -VASc risk score is documented.
Numerator	Patients with nonvalvular AF or atrial flutter for whom a CHA ₂ DS ₂ -VASc risk score is documented
Denominator	All patients with nonvalvular AF or atrial flutter
Denominator exclusions	 Patients age <18 y Patients with transient or reversible causes of AF (e.g., pneumonia, hyperthyroidism, pregnancy, cardiac surgery Patients who are on comfort care measures only Patients with other indication for anticoagulation
Denominator exceptions	 Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patient with a CHA₂DS₂-VASc score of ≥2, including atrial appendage device in place Patient choice of having atrial appendage device placed
Measurement period	Reporting year
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or provider level
Care setting	Outpatient
-	

Rationale

- AF, whether paroxysmal, persistent, or permanent and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular atrial fibrillation increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm. Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and mortality (11). Silent AF is also associated with
- ischemic stroke (33-36). The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia, substantially reduce stroke risk.
- One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHA2DS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or TIA or thromboembolism [doubled]), or CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥75 years [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65 to 74 years, sex category).
- When compared with the CHA₂DS₂ score (39), the CHA₂DS₂-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex, 65 to 74 years of age, and vascular disease) (40.41).
- The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA₂DS₂-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA2DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B).
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I. Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, US Food and Drug Administration; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; and TIA, transient ischemic attack.

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SHORT TITLE: PM-5 Anticoagulation Prescribed

PM-5: Atrial Fibrillation/Atrial Flutter: Anticoagulation Prescribed

Measure description: Percentage of patients, age ≥18 y, who were prescribed warfarin or another FDA-approved anticoagulant drug for the prevention of thromboembolism during the measurement period

Numerator	Patients with nonvalvular AF or atrial flutter for whom warfarin or another FDA-approved anticoagulant was prescribed* *Prescribed—also satisfied by documentation in current medication list	
Denominator	All patients with nonvalvular AF or atrial flutter who do not have a documented CHA ₂ DS ₂ -VASc risk score of 0 or 1	
Denominator exclusions	 Patients age <18 y Patients with transient or reversible causes of AF (e.g., pneumonia, hyperthyroidism, pregnancy, cardiac surgery Patients who are on comfort care measures only 	
Denominator exceptions	 Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patient with a CHA₂DS₂-VASc score of ≥2, including atrial appendage device in place Documentation of a patient reason for not prescribing warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism, including patient choice of having atrial appendage device placed Patient currently enrolled in a clinical trial related to AF/atrial flutter treatment 	
Measurement period	Reporting year	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or provider level	
Care setting	Outpatient	

Rationale

- AF, whether paroxysmal, persistent, or permanent and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular atrial fibrillation increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm. Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and mortality (11). Silent AF is also associated with ischemic stroke (33-36). The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia, substantially reduce stroke risk.
- One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHA₂DS₂ (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or TIA or thromboembolism [doubled]), or CHA2DS2-VASc (congestive heart failure, hypertension, age ≥75 years [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65 to 74 years, sex category).
- When compared with the CHA2DS2 score (39), the CHA2DS2-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex, 65 to 74 years of age, and vascular disease) (40,41).
- The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA₂DS₂-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I. Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA₂DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B).
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I, Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, US Food and Drug Administration; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; and TIA, transient ischemic attack.

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SHORT TITLE: PM-6 Monthly INR for Warfarin Treatment

PM-6: Atrial Fibrillation/Atrial Flutter: Monthly INR for Warfarin Treatment

Measure description: Percentage of patients, age ≥18 y, with nonvalvular AF or atrial flutter for whom there is documentation in the medical record of an assessment of INR at least once per month if 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 with nonvalvular AF or flutter was receiving warfarin therapy during the reporting year
Denominator exclusions	 Patients age <18 y Patients who are on comfort care measures only
Denominator exceptions	 Documentation of a patient reason for no INR measurement Documentation of system reason(s) for no INR measurement
Measurement period	Reporting year
Sources of Data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or provider level
Care setting	Outpatient

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)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I. Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA₂DS₂-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA2DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B).
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I. Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; INR, International Normalized Ratio; PM, performance measure; and TIA, transient ischemic attack.

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Quality Improvement Measures for Inpatient or Outpatient Atrial Fibrillation or Atrial Flutter Patients

Inpatient Measures

SHORT TITLE: QM-1

Beta Blocker Prescribed Prior to Discharge (When LVEF ≤40)

QM-1: Atrial Fibrillation/Atrial Flutter: Beta Blocker Prescribed Prior to Discharge (When LVEF ≤40)

Measure description: Percentage	Measure description: Percentage of patients, age ≥18 y, with a diagnosis of AF or atrial flutter with an LVEF ≤40 who were prescribed a beta blocker prior to discharge.	
Numerator	Patients with a diagnosis of AF or atrial flutter and with an LVEF ≤40 for whom a beta blocker was prescribed* during the measurement period *Prescribed—also satisfied by documentation in current medication list	
Denominator	All patients with AF or atrial flutter with an LVEF ≤40	
Denominator exclusions	 Patients age <18 y Patients with transient or reversible causes of AF (e.g., pneumonia, hyperthyroidism, pregnancy, cardiac surgery) Patients who leave against medical advice Patients who die during hospitalization Patients who are on comfort care measures only Patients who are transferred to another acute care hospital 	
Denominator exceptions	 Documentation of a medical reason for not prescribing a beta blocker Documentation of a patient reason for not prescribing a beta blocker Patient currently enrolled in a clinical trial related to AF/atrial flutter treatment 	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

Rationale

- AF, whether paroxysmal, persistent, or permanent, and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular AF increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm.
- Rate control in AF is an important strategy. It impacts quality of life, reduces morbidity, and decreases the potential for developing tachycardia-induced cardiomyopathy. Multiple agents, including beta blockers and nondihydropyridine calcium channel blockers, and certain antiarrhythmic drugs, including amiodarone and sotalol, have been evaluated with regard to efficacy in attaining rate control. When considering which agent(s) to use, clinicians must consider the patient's degree of symptoms, hemodynamic status, presence or absence of HF, and potential precipitants of AF.
- In general, beta blockers are the most common agents used for rate control, followed by nondihydropyridine calcium channel blockers, digoxin, and amiodarone. Patient comorbidities must be understood to avoid medications that may precipitate adverse events, such as decompensation of HF, exacerbation of chronic obstructive pulmonary disease, or acceleration of conduction in patients with pre-excitation.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. Control of the ventricular rate using a beta blocker or nondihydropyridine calcium channel antagonist is recommended for patients with paroxysmal, persistent, or permanent AF (58-60). (Class I, Level of Evidence: B)
- 2. Intravenous administration of a beta blocker or nondihydropyridine calcium channel blocker is recommended to slow the ventricular heart rate in the acute setting in patients without pre-excitation. In hemodynamically unstable patients, electrical cardioversion is indicated (61-64). (Class I, Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HF, heart failure; HRS, Heart Rhythm Society; LVEF, left ventricular ejection fraction; and QM, quality measure.

SHORT TITLE: QM-2 ACEI or ARB Prescribed Prior to Discharge (When LVEF ≤40)

QM-2: Atrial Fibrillation/Atrial Flutter: ACEI or ARB Prescribed Prior to Discharge (When LVEF ≤40)

Measure description: Percenta	age of patients with a diagnosis of AF or atrial flutter, with HF with an LVEF \leq 40, who were prescribed an ACEI or ARB prior to discharge.	
Numerator	Patients with a diagnosis of AF or atrial flutter, with heart failure with an LVEF ≤40, for whom an ACEI or ARB was prescribed*† during the measurement period *Prescribed—also satisfied by documentation in current medication list †This measure includes fixed-dose combination medications that contain an ARB.	
Denominator	All patients with AF or atrial flutter with heart failure with an LVEF ≤40	
Denominator exclusions	 Patients age <18 y Patients who leave against medical advice Patients who die during hospitalization Patients who are on comfort care measures only Patients who are transferred to another acute care hospital 	
Denominator exceptions	 Documentation of a medical reason for not prescribing an ACEI or ARB Documentation of a patient reason for not prescribing an ACEI or ARB Patient currently enrolled in a clinical trial related to AF/atrial flutter 	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Patients with HF are more likely than the general population to develop AF (5). There is a direct relationship between the NYHA Class and prevalence of AF in patients with HF, progressing from 4% in those who are NYHA Class I to 40% in those who are NYHA Class IV (65). AF is also a strong independent risk factor for subsequent development of HF. In addition to those with heart failure with reduced ejection fraction (HFrEF), patients with heart failure with a preserved EF (HFpEF) are also at greater risk for AF than the general age matched population (66). HF and AF can interact to promote their perpetuation and worsening through mechanisms such as rate-dependent worsening of cardiac function, fibrosis, and activation of neurohumoral vasoconstrictors. AF can worsen symptoms in patients with HF, and, conversely, worsened HF can promote a rapid ventricular response in AF.

ACE inhibitors can reduce the risk of death and reduce hospitalization in HFrEF. The benefits of ACE inhibition were seen in patients with mild, moderate, or severe symptoms of HF and in patients with or without coronary artery disease (CAD). ACE inhibitors should be prescribed to all patients with HFrEF. Unless there is a contraindication, ACE inhibitors are used together with a beta blocker. Patients should not be given an ACE inhibitor if they have experienced life-threatening adverse reactions (i.e., angioedema) during previous medication exposure or if they are pregnant or plan to become pregnant. Clinicians should prescribe an ACE inhibitor with caution if the patient has very low systemic blood pressures (systolic blood pressure < 80 mm Hg), markedly increased serum levels of creatinine (>3 mg/dL), bilateral renal artery stenosis, or elevated levels of serum potassium (>5.0 mEq/L).

ARBs are used in patients with HFrEF who are ACE inhibitor intolerant; an ACE-inhibition intolerance primarily related to cough is the most common indication. In addition, an ARB may be used as an alternative to an ACE inhibitor in patients who are already taking an ARB for another reason, such as hypertension, and who subsequently develop HF. Angioedema occurs in <1% of patients who take an ACE inhibitor, but it occurs more frequently in blacks. Because its occurrence may be life-threatening, clinical suspicion of this reaction justifies the subsequent avoidance of all ACE inhibitors for the lifetime of the patient. ACE inhibitors should not be initiated in any patient with a history of angioedema. Although ARBs may be considered as alternative therapy for patients who have developed angioedema while taking an ACE inhibitor, there are some patients who have also developed angioedema with ARBs, and caution is advised when substituting an ARB in a patient who has had angioedema associated with use of an ACE inhibitor (67-70).

Clinical Recommendation(s)

2013 ACCF/AHA Guideline for Management of Heart Failure (24)

- 1. ACE inhibitors are recommended in patients with HFrEF and current or prior symptoms, unless contraindicated, to reduce morbidity and mortality (71-74). (Class I, Level of Evidence: A)
- 2. In all patients with a recent or remote history of myocardial infarction or acute coronary syndrome (ACS) and reduced EF, ACE inhibitors should be used to prevent symptomatic HF and reduce mortality (71,75,76). In patients intolerant of ACE inhibitors, ARBs are appropriate unless contraindicated (75,77). (Class I, Level of Evidence: A)
- 3. ARBs are recommended in patients with HFrEF with current or prior symptoms who are ACE inhibitor intolerant, unless contraindicated, to reduce morbidity and mortality (75,78-80). (Class I, Level of Evidence: A)
- 4. ARBs are reasonable to reduce morbidity and mortality as alternatives to ACE inhibitors as first-line therapy for patients with HFrEF, especially for patients already taking ARBs for other indications, unless contraindicated (81-86). (Class IIa, Level of Evidence: A)
- 5. Addition of an ARB may be considered in persistently symptomatic patients with HFrEF who are already being treated with an ACE inhibitor and a beta blocker in whom an aldosterone antagonist is not indicated or tolerated (87.88), (Class IIb. Level of Evidence: A)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; ACE, angiotensin-converting enzyme; ACEI, angiotensin-converting enzyme inhibitor; AF, atrial fibrillation: AHA, American Heart Association: ARB, angiotensin receptor blocker: HF, heart failure: HFpEF, heart failure with preserved ejection fraction: HFrEF, heart failure with reduced ejection fraction; HRS, Heart Rhythm Society; LVEF, left ventricular ejection fraction; NHYA, New York Heart Association; and QM, quality measure.

SHORT TITLE: QM-3 Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation

QM-3: Atrial Fibrillation: Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation Prior to Discharge for **Rhythm Control**

Measure description: Percentage of patients, age ≥18 y, with permanent AF who were prescribed an antiarrhythmic medication prior to discharge for rhythm control.

Numerator	Patients with a diagnosis of AF who were inappropriately prescribed an antiarrhythmic medication* for rhythm control
Numerator	*For purposes of this measure, <i>antiarrhythmic drugs</i> includes the medications provided in the below.
	Vaughan Williams Class IA
	Disopyramide
	o Ouinidine
	Vaughan Williams Class IC
	○ Flecainide
	o Propafenone
	Vaughan Williams Class III
	⊙ Dofetilide
	 Dronedarone
	○ Sotalol
Denominator	All patients with permanent AF
Denominator exclusions	Patients age <18 y
	 Patients prescribed amiodarone for rate control
Denominator exceptions	None
Measurement period	Encounter
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care setting	Inpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

In selecting a strategy of rhythm control with an antiarrhythmic drug, providing for adequate rate control in the event of AF recurrence should also be considered. Well-Once antiarrhythmic drug therapy is initiated, patient symptoms may improve without complete AF suppression. The transition from frequent AF to infrequent, tolerated recurrence of AF is a reasonable outcome and does not necessarily indicate that the therapy should be discontinued. However, if attempts at rhythm control are abandoned (e.g., after AF has been declared permanent), the antiarrhythmic drug should be discontinued.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. Antiarrhythmic drugs for rhythm control should not be continued when AF becomes permanent (Class III, Level of Evidence: C), including dronedarone (89). (Class III Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-4 Inappropriate Prescription of Dofetilide or Sotalol Prior to Discharge

QM-4: Atrial Fibrillation: Inappropriate Prescription of Dofetilide or Sotalol Prior to Discharge in Patients With Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis

Measure description: Percentage of patients, age ≥18 y, with AF who also have end-stage kidney disease (CrCl <15 mL/min) or are on dialysis and who were prescribed dofetilide or sotalol prior to discharge.

Patients with a diagnosis of AF who do not have normal kidney function who were prescribed dofetilide or sotalol prior to discharge All patients with AF who also have end-stage kidney disease (CrCl <15 mL/min) or are on dialysis Patients age <18 y None	
Patients age <18 y	
<i>-</i>	
None	
None	
Encounter	
Medical record or other database (e.g., administrative, clinical, registry)	
Measure reportable at the facility or provider level	
Inpatient	
_	

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Sotalol and dofetilide are predominantly renally cleared and should be used with caution or avoided in patients with end-stage kidney disease or on dialysis. Table 11 in the 2014 ACC/AHA/HRS Guidelines for Management for Patients With Atrial Fibrillation provides more guidance with regard to types of patients who should be excluded. Manufacturer/FDA recommendations suggest that both drugs are contraindicated because of increased risk of toxicity (including potentially lifethreatening proarrhythmic effects) in patients with severely reduced renal function.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. The following antiarrhythmic drugs are recommended in patients with AF to maintain sinus rhythm, depending on underlying heart disease and comorbidities (Class I, Level of Evidence: A):
 - a. Amiodarone (90-93)
- b. Dofetilide (94,95)
- c. Dronedarone (96-98)
- d. Flecainide (91,99)
- e. Propafenone (92,100-103)
- f. Sotalol (91,101,104)
- 2. The risks of the antiarrhythmic drug, including proarrhythmia, should be considered before initiating therapy with each drug. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CrCl, creatinine clearance; FDA, US Food and Drug Administration; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-5 Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor Prior to Discharge

QM-5: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor Prior to Discharge in Patients With Atrial Fibrillation With a Mechanical Heart Valve

Measure description: Percentage of patients, age ≥18 y, with a mechanical heart valve and with a diagnosis of AF who were inappropriately prescribed a direct thrombin or factor Xa inhibitor prior to discharge.

Numerator	Patients with a diagnosis of AF and a mechanical heart valve who were prescribed a direct thrombin or factor Xa inhibitor prior to discharge
Denominator	All patients with a diagnosis of AF with a mechanical heart valve
Denominator exclusions	Patients age <18 y
Denominator exceptions	None
Measurement period	Encounter
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care setting	Inpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Patients with AF and a mechanical heart valve should not be prescribed dabigatran.

Patients with mechanical heart valves or hemodynamically significant mitral stenosis were excluded from all 3 major trials (RE-LY [Randomized Evaluation of Long-Term Anticoagulation Therapy], ROCKET AF [Rivaroxaban-once daily, oral, direct factor Xa inhibition compared with vitamin K antagonism for prevention of stroke and Embolism], and ARISTOTLE [Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation]) (105-107). Therefore, these patients should be managed with warfarin. Patients with aortic stenosis or aortic insufficiency who, in the estimation of the local randomized clinical trial principal investigator, would not need a surgical procedure before the conclusion of the trial were included. The RE-ALIGN (Randomized, Phase II Study to Evaluate the Safety and Pharmacokinetics of Oral Dabigatran Etexilate in Patients After Heart Valve Replacement) trial, a phase 2 dose-range study of the use of dabigatran compared with warfarin in patients with mechanical heart valves, was stopped because dabigatran users were more likely to experience strokes, myocardial infarction, and thrombus forming on the mechanical heart valves than were warfarin users (108-110). There was also more bleeding after valve surgery in the dabigatran users than in the warfarin users; thus, dabigatran is contraindicated for use in patients with mechanical heart valves. Similar drug safety and efficacy information is lacking for rivaroxaban and apixaban and mechanical heart valves. Bioprosthetic heart valves have not been studied with any of the new anticoagulants. None of the 3 major trials included pregnant or lactating women, children, patients with reversible causes of AF, or patients with severe hypertension (systolic blood pressure >180 mm Hg or diastolic blood pressure >100 mm Hg). Patients with a recent stroke (within 7-14 days), patients with significant liver disease, and complex patients with multible chronic conditions were excluded from all trials.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. The direct thrombin inhibitor dabigatran should not be used in patients with AF and a mechanical heart valve (108). (Class III, Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; and QM, quality measure.

554

APPENDIX A. CONTINUED

"QM-6: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa inhibitor (Rivaroxaban or Edoxaban) Prior to Discharge in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" has been deleted. For more information on this change, please consult "Addendum: Removal/Modification of Measures" and the associated correction notice.

SHORT TITLE: QM-7 Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy Prior to Discharge

QM-7: Atrial Fibrillation: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy Prior to Discharge for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease

Measure description: Percentage of patients, age ≥18 y, with AF who do not currently have coronary artery disease and/or vascular disease who where inappropriately prescribed both an antiplatelet and an oral anticoagulant prior to discharge.

Numerator	Patients with a diagnosis of AF who do not currently have coronary artery disease and/or vascular disease who were prescribed both an antiplatelet and an anticoagulant prior to discharge	
Denominator	All patients with AF who do not currently have coronary artery disease and/or vascular disease	
Denominator exclusions	Patients less than 18 years of age Patients with mechanical heart valves	
Denominator exceptions	None	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Stroke prevention trials compared warfarin or aspirin with placebo and compared aspirin with warfarin or clopidogrel and aspirin. Warfarin was also compared with dual antiplatelet agents (clopidogrel and aspirin). Trials have also compared direct thrombin inhibitors and factor Xa inhibitors with warfarin and, in 1 case, with aspirin. Both primary and secondary stroke prevention have been evaluated. The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clopidogrel plus aspirin was evaluated for stroke prevention in the ACTIVE (Atrial Fibrillation Clopidogrel Trial With Irbesartan for Prevention of Vascular). ACTIVE-W found a 40% RR reduction (95% CI, 18%-56%; p<0.001) for stroke with warfarin compared with the dual antiplatelet regimen. ACTIVE-A compared clopidogrel Events)-W trial (114). The combination of clopidogrel and aspirin resulted in a 28% RR reduction (95% CI, 17%-38%; p<0.0002) in all strokes compared with aspirin alone. Major bleeding was significantly greater with the combination and increased by 57% (95% CI, 29%-92%; p<0.001).

Clinical Recommendation(s)

No clinical recommendation currently exists for this measure.

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CI, confidence interval; HRS, Heart Rhythm Society; INR, International Normalized Ratio; QM, quality measure; and RR, relative risk.

SHORT TITLE: QM-8 Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist Prior to Discharge

QM-8: Atrial Fibrillation: Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist Prior to Discharge in Patients With Reduced Ejection Fraction

Measure description: Percentage of patients, age ≥18 y, with reduced ejection fraction (≤40) and a diagnosis of AF who were inappropriately prescribed nondihydropyridine calcium channel antagonist prior to discharge.

Numerator	Patients with a diagnosis of AF and reduced ejection fraction (≤40) who were prescribed a nondihydropyridine calcium channel antagonist prior to discharge.
Denominator	All patients with AF and reduced ejection fraction (≤40)
Denominator exclusions	Patients age <18 y
Denominator exceptions	None
Measurement period	Encounter
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care setting	Inpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

In general, beta blockers are the most common agents used for rate control, followed by nondihydropyridine calcium channel blockers, digoxin, and amiodarone. Patient comorbidities must be understood to avoid medications that may precipitate adverse events, such as decompensation of HF, exacerbation of chronic obstructive pulmonary disease, or acceleration of conduction in patients with preexcitation.

Nondihydropyridine calcium channel blockers should not be used in patients with left ventricular systolic dysfunction and decompensated HF because of their negative inotropic effects, but they may be used in patients with HF with preserved left ventricular systolic function. In addition, these agents should not be used in patients with pre-excitation and AF because of the potential for shortening bypass tract refractoriness, which may accelerate the ventricular rate to precipitate hypotension or ventricular fibrillation.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. Nondihydropyridine calcium channel antagonists should not be used in patients with decompensated HF as these may lead to further hemodynamic compromise. (Class III, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HF, heart failure; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-9

Patients Who Underwent Atrial Fibrillation Catheter Ablation Who Were Not Treated With Anticoagulation Therapy Both During or After a Procedure

QM-9: Atrial Fibrillation: Patients Who Underwent Atrial Fibrillation Catheter Ablation Who Were Not Treated With Anticoagulation Therapy During or After a Procedure

Measure description: Percentage of patients, age ≥18 y, who underwent AF ablation who were not treated with anticoagulation therapy both during and after a procedure.

Numerator	Patients who were not treated with anticoagulation both during and after a procedure
Denominator	All patients with AF who underwent catheter ablation
Denominator exclusions	 Patients age <18 y Patients who leave against medical advice Patients who die during hospitalization Patients who are on comfort care measures only Patients who are transferred to another acute care hospital
Denominator exceptions	Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patient with a CHA ₂ DS ₂ -VASc score of ≥2
Measurement period	Encounter
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or physician level
Care setting	Inpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Because of the well-established risk of periprocedure stroke or transient ischemic attack (TIA) associated with AF catheter ablation, there is consensus that anticoagulation is indicated to prevent thromboembolism around the time of radiofrequency catheter ablation regardless of the patient's baseline thromboembolic risk. Detailed consensus recommendations have been published about the approach to anticoagulation before, during, and after catheter ablation (28). Both Intraprocedural heparin and oral anticoagulation are recommended for =2 months post-procedure. AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and after the procedure. (Class III, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, U.S. Food and Drug Administration; HRS, Heart Rhythm Society; QM, quality measure; and TIA, transient ischemic attack.

SHORT TITLE: QM-10 Shared Decision Making Regarding Anticoagulation Prescription Prior to Discharge

QM-10: Atrial Fibrillation/Atrial Flutter: Shared Decision Making Between Physician and Patient in Anticoagulation Prescription Prior to Discharge

Measure description: Percentage of patients, age ≥18 y, with AF or atrial flutter who were educated on the benefits and risks of anticoagulation and the specific type of anticoagulation therapy recommended by the physician, and who were consulted during the decision-making process about whether to prescribe and which anticoagulant to prescribe prior to discharge.

Numerator	Patients with AF or atrial flutter with documentation of engagement in the decision-making process with regard to the	
	benefits and risks of anticoagulation and the specific type of anticoagulation therapy for AF or atrial flutter	
Denominator	All patients with AF or atrial flutter	
Denominator exclusions	Patients age <18 y	
	Patients who leave against medical advice	
	Patients who die during hospitalization	
	Patients who are on comfort care measures only	
	 Patients who are transferred to another acute care hospital 	
Denominator exceptions	 Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patien with a CHA,DS,-VASc score of ≥2 	
	Patient currently enrolled in a clinical trial related to AF/atrial flutter	
Measurement period	Encounter	
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)	
Attribution	Measure reportable at the facility or physician level	
Care setting	Inpatient	

Rationale

- AF, whether paroxysmal, persistent, or permanent and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular atrial fibrillation increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm. Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and mortality. Silent AF is also associated with ischemic stroke. The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia, substantially reduce stroke risk.
- One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHADS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or TIA or thromboembolism [doubled]), or CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥75 years [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65 to 74 years, sex category).
- When compared with the CHADS2 score (39), the CHA2DS2-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex, 65 to 74 years of age, and vascular disease) (40,41).
- The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.
- Selection of agents for antithrombotic therapy depends on a large number of variables, including clinical factors, clinician and patient preference, and, in some circumstances, cost. The new agents are currently considerably more expensive than warfarin. However, dietary limitations and the need for repeated INR testing are eliminated with the new agents. If patients are stable, their condition is easily controlled, and they are satisfied with warfarin therapy, it is not necessary to change to a new agent. However, it is important to discuss this option with patients who are candidates for the new agents.
- All 3 new oral anticoagulants [dabigatran, rivaroxaban, apixaban] represent important advances over warfarin because they have more predictable pharmacological profiles, fewer drug-drug interactions, an absence of major dietary effects, and less risk of intracranial bleeding than warfarin. They have rapid onset and offset of action so that bridging with parenteral anticoagulant therapy is not needed during initiation, and bridging may not be needed in patients on chronic therapy requiring brief interruption of anticoagulation for invasive procedures. However, strict compliance with these new oral anticoagulants is critical. Missing even 1 dose could result in a period without protection from thromboembolism. As a result, the FDA issued black box warnings that discontinuation of these new agents can increase the risk of thromboembolism and that coverage with another anticoagulant may be needed. In addition, reversal agents, while in development, are not available, although the short half-lives lessen the need for an antidote. Although dose adjustments may be warranted for those with chronic kidney disease or body weight extremes, these new agents do not require regular monitoring of INR or activated partial thromboplastin time.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I, Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA2DS2-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA2DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B).
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I. Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, U.S. Food and Drug Administration; HRS, Heart Rhythm Society; INR. International Normalized Ratio: OM. quality measure: and TIA, transient ischemic attack.

Outpatient Measures

SHORT TITLE: QM-11 Beta Blocker Prescribed (When LVEF ≤40)

QM-11: Atrial Fibrillation/Atrial Flutter: Beta Blocker Prescribed (When LVEF ≤40)

Measure description: Percentage of patients, age ≥18 y, with a diagnosis of AF or atrial flutter and with an LVEF ≤40 who were prescribed a beta blocker during the measurement period.

Numerator	Patients with a diagnosis of AF or atrial flutter and with an LVEF ≤40 for whom a beta blocker was prescribed* during the measurement period *Prescribed—Also satisfied by documentation in current medication list
Denominator	All patients with AF or atrial flutter and with an LVEF ≤40
Denominator exclusions	 Patients age <18 y Patients who are on comfort care measures only
Denominator exceptions	 Documentation of a medical reason for not prescribing a beta blocker Documentation of a patient reason for not prescribing a beta blocker Patient currently enrolled in a clinical trial related to AF/atrial flutter treatment
Measurement period	Reporting year
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or provider level
Care setting	Outpatient

Rationale

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. Control of the ventricular rate using a beta blocker or nondihydropyridine calcium channel antagonist is recommended for patients with paroxysmal, persistent, or permanent AF (58-60). (Class I, Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HF, heart failure; HRS, Heart Rhythm Society; LVEF, left ventricular ejection fraction; and QM, quality measure.

AF, whether paroxysmal, persistent, or permanent, and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular AF increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm.

Rate control in AF is an important strategy. It impacts quality of life, reduces morbidity, and decreases the potential for developing tachycardia-induced cardiomyopathy. Multiple agents, including beta blockers and nondihydropyridine calcium channel blockers, and certain antiarrhythmic drugs, including amiodarone and sotalol, have been evaluated with regard to efficacy in attaining rate control. When considering which agent(s) to use, clinicians must consider the patient's degree of symptoms, hemodynamic status, presence or absence of HF, and potential precipitants of AF.

In general, beta blockers are the most common agents used for rate control, followed by nondihydropyridine calcium channel blockers, digoxin, and amiodarone. Patient comorbidities must be understood to avoid medications that may precipitate adverse events, such as decompensation of HF, exacerbation of chronic obstructive pulmonary disease, or acceleration of conduction in patients with preexcitation.

SHORT TITLE: QM-12 Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation

QM-12: Atrial Fibrillation: Inappropriate Prescription of Antiarrhythmic Drugs to Patients With Permanent Atrial Fibrillation for Rhythm Control

Measure description: Percentage of patients, age ≥18 y, with permanent AF who were inappropriately prescribed antiarrhythmic medications for rhythm control.	
Numerator	Patients with a diagnosis of AF who were prescribed antiarrhythmic* medications for rhythm control. *For purposes of this measure, antiarrhythmic drugs includes the medications provided in the list belov • Vaughan Williams Class IA • Disopyramide • Quinidine • Vaughan Williams Class IC • Flecainide • Propafenone • Vaughan Williams Class III • Dofetilide • Dronedarone • Sotalol
Denominator	All patients with permanent AF
Denominator exclusions	 Patients age <18 y Patients prescribed amiodarone for rate control
Denominator exceptions	None
Measurement period	Reporting year
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)
Attribution	Measure reportable at the facility or provider level
Care setting	Outpatient

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

In selecting a strategy of rhythm control with an antiarrhythmic drug, providing for adequate rate control in the event of AF recurrence should also be considered. Once antiarrhythmic drug therapy is initiated, patient symptoms may improve without complete AF suppression. The transition from frequent AF to infrequent, welltolerated recurrence of AF is a reasonable outcome and does not necessarily indicate that the therapy should be discontinued. However, if attempts at rhythm control are abandoned (e.g., after AF has been declared permanent), the antiarrhythmic drug should be discontinued.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Antiarrhythmic drugs for rhythm control should not be continued when AF becomes permanent (Class III, Level of Evidence: C), including dronedarone (89). (Class III Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-13 Inappropriate Prescription of Dofetilide or Sotalol

QM-13: Atrial Fibrillation: Inappropriate Prescription of Dofetilide or Sotalol in Patients With Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis

Measure description: Percentage of patients, age ≥18 y, with AF who also have end-stage kidney disease (CrCl <15 mL/min) or are on dialysis and who were prescribed dofetilide or sotalol.

Numerator	Patients with a diagnosis of AF who do not have normal kidney function and were prescribed dofetilide or sota					
Denominator	All patients with AF who also have end-stage kidney disease (CrCl $<$ 15 mL/min) or are on dialysis					
Denominator exclusions	Patients age <18 y					
Denominator exceptions	None					
Measurement period	Reporting year					
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)					
Attribution	Measure reportable at the facility or provider level					
Care setting	Outpatient					

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Sotalol and dofetilide are predominantly renally cleared and should be used with caution or avoided in patients with end-stage kidney disease or on dialysis. Table 11 in the 2014 ACC/AHA/HRS Guidelines for Management for Patients With Atrial Fibrillation provides more quidance with regard to types of patients who should be excluded. Manufacturer/FDA recommendations suggest that both drugs are contraindicated because of increased risk for toxicity (including potentially life-threatening proarrhythmic effects) in patients with severely reduced renal function.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. The following antiarrhythmic drugs are recommended in patients with AF to maintain sinus rhythm, depending on underlying heart disease and comorbidities (Class I, Level of Evidence: A):
- Amiodarone (90-93)
- b. Dofetilide (94,95)
- c. Dronedarone (96-98)
- d. Flecainide (91,99)
- e. Propafenone (92,100-103)
- f. Sotalol (91,101,104)
- 2. The risks of the antiarrhythmic drug, including proarrhythmia, should be considered before initiating therapy with each drug. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CrCl, creatinine clearance; FDA, U.S. Food and Drug Administration; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-14 Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor

QM-14: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor in Patients With Atrial Fibrillation With Mechanical **Heart Valve**

Measure description: Percentage of patients, age ≥18 y, with a mechanical heart valve and with a diagnosis of AF who were inappropriately prescribed a direct thrombin or factor Xa inhibitor.

Numerator	Patients with a diagnosis of AF who were prescribed a direct thrombin or factor Xa inhibitor despite having a mechanical heart valve					
Denominator	All patients with a diagnosis of AF with a mechanical heart valve					
Denominator exclusions	Patients age <18 y					
Denominator exceptions	None					
Measurement period	Reporting year					
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)					
Attribution	Measure reportable at the facility or provider level					
Care setting	Outpatient					

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

Patients with AF and a mechanical heart valve should not be prescribed dabigatran.

Patients with mechanical heart valves or hemodynamically significant mitral stenosis were excluded from all 3 major trials (RE-LY, ROCKET AF, and ARISTOTLE) (105-107); therefore, these patients should be managed with warfarin. Patients with aortic stenosis or aortic insufficiency who, in the estimation of the local randomized controlled trial principal investigator, would not need a surgical procedure before the conclusion of the trial were included. The RE-ALIGN (Randomized, Phase II Study to Evaluate the Safety and Pharmacokinetics of Oral Dabigatran Etexilate in Patients After Heart Valve Replacement) trial, a phase 2 dose-range study of the use of dabigatran compared with warfarin in patients with mechanical heart valves, was stopped because dabigatran users were more likely to experience strokes, myocardial infarction, and thrombus forming on the mechanical heart valves than were warfarin users (108-110). There was also more bleeding after valve surgery in the dabigatran users than in the warfarin users; thus, dabigatran is contraindicated for use in patients with mechanical heart valves. Similar drug safety and efficacy information is lacking for rivaroxaban and apixaban and mechanical heart valves. Bioprosthetic heart valves have not been studied with any of the new anticoagulants. None of the 3 major trials included pregnant or lactating women, children, patients with reversible causes of AF, or patients with severe hypertension (systolic blood pressure >180 mm Hg or diastolic blood pressure >100 mm Hg). Patients with a recent stroke (within 7-14 days), patients with significant liver disease, and complex patients with multiple chronic conditions were excluded from all trials.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

The direct thrombin inhibitor dabigatran should not be used in patients with AF and a mechanical heart valve (108). (Class III, Level of Evidence: B)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; and QM, quality measure.

"QM-15: Atrial Fibrillation: Inappropriate Prescription of a Direct Thrombin or Factor Xa Inhibitor (Rivaroxaban or Edoxaban) in Patients with Atrial Fibrillation and End-Stage Kidney Disease or on Dialysis" has been deleted. For more information on this change, please consult "Addendum: Removal/Modification of Measures" and the associated correction notice.

Attribution

Care setting

SHORT TITLE: QM-16 Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy

QM-16: Atrial Fibrillation: Inappropriate Prescription of Antiplatelet and Oral Anticoagulation Therapy for Patients Who Do Not Have Coronary Artery Disease and/or Vascular Disease

Measure Description: Percentage of patients, age 18 and older, with atrial fibrillation who do not currently have coronary artery disease and/or vascular disease that were inappropriately prescribed both an antiplatelet and an oral anticoagulant

were mappropriat	tety prescribed both an antiplatetet and an oral anticoagulant.			
Numerator	Patients with a diagnosis of atrial fibrillation who do not have coronary artery disease and/or vascular disease that were inappropriately prescribed both an antiplatelet and an oral anticoagulant.			
Denominator	All patients with atrial fibrillation who do not currently have coronary artery disease and/or vascular disease.			
Denominator exclusions	 Patients less than 18 years of age Patients with mechanical heart valves Patients undergoing procedures using certain devices where they are appropriately prescribed both an antiplatelet and an oral anticoagulant (e.g., WATCHMAN device) 			
Denominator exceptions	None			
Measurement period	d Reporting year			
Sources of data	Medical record or other database (e.g., administrative, clinical, registry).			

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (3)

Measure reportable at the facility or provider level

Stroke prevention trials compared warfarin or aspirin with placebo and compared aspirin with warfarin or clopidogrel and aspirin. Warfarin was also compared with dual antiplatelet agents (clopidogrel and aspirin). Trials have also compared direct thrombin inhibitors and factor Xa inhibitors with warfarin and, in 1 case, with aspirin. Both primary and secondary stroke prevention have been evaluated. The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.

Clopidogrel plus aspirin was evaluated for stroke prevention in the ACTIVE (Atrial Fibrillation Clopidogrel Trial With Irbesartan for Prevention of Vascular ACTIVE-W found a 40% RR reduction (95% CI: 18% to 56%; p < 0.001) for stroke with warfarin compared with the dual antiplatelet regimen. ACTIVE-A compared clopidogrel Events)-W trial (12). The combination of clopidogrel and aspirin resulted in a 28% RR reduction (95% CI: 17% to 38%; p < 0.0002) in all strokes compared with aspirin alone. Major bleeding was significantly greater with the combination and increased by 57% (95% CI: 29% to 92%; p < 0.001).

Clinical Recommendation(s)

No clinical recommendation currently exists for this measure.

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; CI, confidence interval; HRS, Heart Rhythm Society; INR, International Normalized Ratio; QM, quality measure; and RR, relative risk.

SHORT TITLE: QM-17 Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist

QM-17: Atrial Fibrillation: Inappropriate Prescription of Nondihydropyridine Calcium Channel Antagonist in Patients With Reduced Ejection Fraction

Measure description: Percentage of patients, age ≥18 y, with reduced ejection fraction (≤40) and a diagnosis of AF who were inappropriately prescribed a nondihydropyridine calcium channel antagonist.

Numerator	Patients with a diagnosis of AF and reduced ejection fraction (≤40) who were prescribed a nondihydropyridine calc channel antagonist					
Denominator	All patients with AF and reduced ejection fraction (≤40)					
Denominator exclusions	Patients age <18 y					
Denominator exceptions	None					
Measurement period	Reporting year					
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)					
Attribution	Measure reportable at the facility or provider level					
Care setting	Outpatient					

Rationale

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

In general, beta blockers are the most common agents used for rate control, followed by nondihydropyridine calcium channel blockers, digoxin, and amiodarone. Patient comorbidities must be understood to avoid medications that may precipitate adverse events, such as decompensation of HF, exacerbation of chronic obstructive pulmonary disease, or acceleration of conduction in patients with preexcitation.

Nondihydropyridine calcium channel blockers should not be used in patients with left ventricular systolic dysfunction and decompensated HF because of their negative inotropic effects, but they may be used in patients with HF with preserved left ventricular systolic function. In addition, these agents should not be used in patients with pre-excitation and AF because of the potential for shortening bypass tract refractoriness, which may accelerate the ventricular rate to precipitate hypotension or ventricular fibrillation.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

1. Nondihydropyridine calcium channel antagonists should not be used in patients with decompensated HF because these drugs may lead to further hemodynamic compromise. (Class III, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HF, heart failure; HRS, Heart Rhythm Society; and QM, quality measure.

SHORT TITLE: QM-18 Shared Decision Making in Anticoagulation Prescription

QM-18: Atrial Fibrillation/Atrial Flutter: Shared Decision Making Between Physician and Patient in Anticoagulation Prescription

Measure description: Percentage of patients, age ≥18 y, with AF or atrial flutter who were educated on the benefits and risk of anticoagulation and the specific type of anticoagulation therapy recommended by the physician, and who were consulted during the decision-making process about whether to prescribe and which anticoagulant to prescribe during the measurement period.

Numerator	Patients with AF or atrial flutter with documentation of engagement in the decision-making process with regard to the be and risks of anticoagulation and the specific type of anticoagulation therapy for AF or atrial flutter				
Denominator	All patients with AF or atrial flutter				
Denominator exclusions	 Patients age <18 y Patients who are on comfort care measures only 				
Denominator exceptions	 Documentation of a medical reason for not prescribing warfarin or another FDA-approved anticoagulant to a patient with a CHA₂DS₂-VASc score of ≥2 Patient currently enrolled in a clinical trial related to AF/atrial flutter 				
Measurement period	Reporting year				
Sources of data	Medical record or other database (e.g., administrative, clinical, registry)				
Attribution	Measure reportable at the facility or provider level				
Care setting	Outpatient				

Rationale

- AF, whether paroxysmal, persistent, or permanent, and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke. Nonvalvular AF increases the risk of stroke 5 times, and AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm.
- Thromboembolism occurring with AF is associated with a greater risk of recurrent stroke, more severe disability, and greater risk of death. Silent AF is also associated with ischemic stroke. The appropriate use of antithrombotic therapy and the control of other risk factors, including hypertension and hypercholesterolemia, substantially reduce stroke risk.
- One meta-analysis has stratified ischemic stroke risk among patients with nonvalvular AF using the following point scoring systems (37): AF Investigators; CHADS₂ (congestive heart failure, hypertension, age ≥75 y, diabetes mellitus, prior stroke or TIA or thromboembolism [doubled]), or CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥75 y [doubled] (38), diabetes mellitus, prior stroke or TIA or thromboembolism [doubled], vascular disease, age 65-74 y, sex category).
- When compared with the CHADS2 score (39), the CHA2DS2-VASc score for nonvalvular AF has a broader score range (0 to 9) and includes a larger number of risk factors (female sex. age 65-74 v. and vascular disease) (40.41).
- The selection of an antithrombotic agent should be based on shared decision making that takes into account risk factors, cost, tolerability, patient preference, potential for drug interactions, and other clinical characteristics, including time in the INR therapeutic range if the patient has been on warfarin, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.
- Selection of agents for antithrombotic therapy depends on a large number of variables, including clinical factors, clinician and patient preference, and, in some circumstances, cost. The new agents are currently considerably more expensive than warfarin. However, dietary limitations and the need for repeated INR testing are eliminated with the new agents. If patients are stable, their condition is easily controlled, and they are satisfied with warfarin therapy, it is not necessary to change to a new agent. However, it is important to discuss this option with patients who are candidates for the new agents.
- All 3 new oral anticoagulants (dabigatran, rivaroxaban, and apixaban) represent important advances over warfarin because they have more predictable pharmacological profiles, fewer drug-drug interactions, an absence of major dietary effects, and less risk of intracranial bleeding than warfarin. They have rapid onset and offset of action so that bridging with parenteral anticoagulant therapy is not needed during initiation, and bridging may not be needed in patients on chronic therapy requiring brief interruption of anticoagulation for invasive procedures. However, strict compliance with these new oral anticoagulants is critical. Missing even 1 dose could result in a period without protection from thromboembolism. As a result, the FDA issued black box warnings that discontinuation of these new agents can increase the risk of thromboembolism and that coverage with another anticoagulant may be needed. In addition, reversal agents, while in development, are not available, although the short half-lives lessen the need for an antidote. Although dose adjustments may be warranted for those with chronic kidney disease or body weight extremes, these new agents do not require regular monitoring of INR or activated partial thromboplastin time.

Clinical Recommendation(s)

2014 ACC/AHA/HRS Guidelines for the Management of Patients With Atrial Fibrillation (23)

- 1. In patients with AF, antithrombotic therapy should be individualized based on shared decision-making after discussion of the absolute and RRs of stroke and bleeding, and the patient's values and preferences. (Class I. Level of Evidence: C)
- 2. Selection of antithrombotic therapy should be based on the risk of thromboembolism, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent (42-45). (Class I, Level of Evidence: B)
- 3. In patients with nonvalvular AF, the CHA2DS2-VASc score is recommended for assessment of stroke risk (46-48). (Class I, Level of Evidence: B)
- 4. For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis (49-51). (Class I, Level of Evidence: B)
- 5. For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA2DS2-VASc score of 2 or greater, oral anticoagulants are recommended. Options include: warfarin (INR 2.0 to 3.0) (42-45) (Class I, Level of Evidence: A), dabigatran (52) (Class I, Level of Evidence: B), rivaroxaban (53) (Class I, Level of Evidence: B), or apixaban (54) (Class I, Level of Evidence: B).
- 6. Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anticoagulation (INR in range) is stable (55-57). (Class I, Level of Evidence: A)
- 7. For patients with nonvalvular AF unable to maintain a therapeutic INR level with warfarin, use of a direct thrombin or factor Xa inhibitor (dabigatran, rivaroxaban, or apixaban) is recommended. (Class I, Level of Evidence: C)
- 8. Re-evaluation of the need for and choice of antithrombotic therapy at periodic intervals is recommended to reassess stroke and bleeding risks. (Class I, Level of Evidence: C)
- 9. For patients with atrial flutter, antithrombotic therapy is recommended according to the same risk profile used for AF. (Class I, Level of Evidence: C)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; FDA, U.S. Food and Drug Administration; HRS, Heart Rhythm Society; INR, International Normalized Ratio; QM, quality measure; and TIA, transient ischemic attack.

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Paul Heidenreich, <i>Chair</i>	Stanford VA Palo Alto Health Care System — Professor of Medicine	None	None	None	None	None	None
N. A. Mark Estes III	Tufts Medical Center — Professor of Medicine	Boston Scientific†Medtronic†St. Jude Medical†	None	None	Boston Scientific	Medtronic†St. Jude Medical†Boston Scientific†	None
Gregg C. Fonarow	Ahmanson-UCLA Cardiomyopathy Center Division of Cardiology — Director	Boston ScientificMedtronic	None	None	Medtronic	 Medtronic- IMPROVE HF Steering Committee* 	None
Corrine Y. Jurgens	Stony Brook University School of Nursing — Associate Professor	None	None	None	None	None	None
Joseph E. Marine	Johns Hopkins School of Medicine — Associate Professor of Medicine	None	None	None	None	None	None
David D. McManus	University of Massachusetts Memorial Medical Center — Assistant Professor of Medicine	None	None	None	Biotronik—IMPACT study Philip Healthcare— SENTINEL-HF study	None	None
Robert L. McNamara	Yale University School of Medicine Section of Cardiology — Associate Professor of Medicine	None	None	None	None	None	None
Penelope Solis	American College of Cardiology	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥5% of the voting the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC/AHA, a person has a relevant relationship IF: a) the relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or b) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the document; or c) the person or a member of the person's household has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the document. Biotronik IMPACT Study indicates Home Monitoring and Predefined Anticoagulation to Reduce Stroke Risk; and IMPROVE HF, Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting.

*No financial relationship.

†Significant (greater than \$5,000) relationship.

APPENDIX C. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES— 2016 ACC/AHA CLINICAL PERFORMANCE AND QUALITY MEASURES FOR ADULTS WITH ATRIAL FIBRILLATION OR ATRIAL FLUTTER

Peer Reviewer	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Timothy A. Dewhurst	Official ACC BOG	None	None	None	Biotronik- Protoge Phase IV registry clinical trial enroller	None	None
Deepak L. Bhatt	Official ACC BOT	DCRI: Novartis† DCRI: Bristol- Meyers Squibb/ Pfizer DCRI: Eli Lilly	None	None	 Roche† Medtronic† Takeda* Sanofi Aventis† Ethicon† Bristol Myers Squibb† Pfizer† Biotronik (BIOFLOW-V clinical trial enroller) St. Jude (CardioMEMS HF System Post Approval Study clinical trial enroller) 	• Novartis	None
Jonathan P. Piccini	Official AHA	 Johnson & Johnson Medtronic	None	None	ARCA biopharma†Boston Scientific†GE Healthcare†Johnson & Johnson†	None	None
Fred Kusumoto	Official HRS	None	None	None	None	None	None
Paul D. Varosy	Official TFPM Lead & Content ACC Data Development Work Group	None	None	None	None	None	None
Matthew R. Reynolds	Content NCDR SQOC	 Medtronic Edwards Lifesciences Biosense- Webster 	None	None	Medtronic†	None	None
Hani Jneid	Content ACCF/AHA TFDS	None	None	None	None	None	None
Craig T. January	Content ACCF/AHA TFPG	None	None	None	None	None	None

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ACC indicates American College of Cardiology; AHA, American Heart Association; BOT, Board of Trustees; BOG, Board of Governors; DCRI, Duke Clinical Research Institute; DSMB, Data and Safety Monitoring Board; HRS, Heart Rhythm Society; NCDR, National Cardiovascular Data Registry; NCDR SQOC, National Cardiovascular Data Registry Science and Quality Oversight Committee; TFDS, Task Force on Clinical Data Standards; TFPG, Task Force on Practice Guidelines; and TFPM, Task Force on Performance Measures.

^{*}No financial relationship.

[†]Significant (greater than \$5,000) relationship.