

PERFORMANCE MEASURES

2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death

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	■	Antagonist) for Prevention of SCD in Patients With Heart Failure and Reduced Ejection Fraction	■
1. INTRODUCTION	■	4.3.3. PM-4: Use of Guideline-Directed Medical Therapy (Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin-Receptor/Nepriylsin Inhibitor, Beta-Blocker, Aldosterone Receptor Antagonist) for the Prevention of SCD in Patients With Myocardial Infarction and Reduced Ejection Fraction	■
1.1. Scope of the Problem	■		
1.2. Structure and Membership of the Writing Committee	■		
1.3. Disclosure of Relationships With Industry and Other Entities	■		
2. METHODOLOGY	■	4.4. Electrophysiology	■
2.1. Identifying Clinically Important Outcomes	■	4.4.1. PM-5: Documenting the Absence of Reversible Causes of VT/VF Cardiac Arrest and/or Sustained VT Before a Secondary-Prevention ICD is Placed	■
2.2. Dimensions of Care	■	4.4.2. PM-6: Counseling Eligible Patients About an ICD	■
2.3. Definition and Selection of Measures	■	4.4.3. QM-4: Counseling of First-Degree Relatives of Survivors of SCA Associated With an Inheritable Condition	■
3. 2016 AHA/ACC CLINICAL PERFORMANCE AND QUALITY MEASURES FOR PREVENTION OF SCD ..	■	5. POTENTIAL MEASURES CONSIDERED BUT NOT INCLUDED IN THIS SET	■
3.1. Target Population and Care Period	■	5.1. Genetics	■
3.2. Avoiding Overlap and Ensuring Alignment With Existing Measure Sets and Guidelines	■	5.2. Screening of Athletes	■
4. MEASURES INCLUDED IN THE SET	■	6. FUTURE DIRECTIONS	■
4.1. Preventive Cardiology	■	6.1. Adoption and Evaluation of the Measures	■
4.1.1. PM-1: Smoking Cessation Intervention in Patients Who Suffered SCA, Have Ventricular Arrhythmias, or Are at Risk for SCD	■	6.2. Measures Based on Adherence and Optimal Dosing of Medications	■
4.1.2. QM-1: Screening for Family History of SCD	■	6.3. Shared Decision-Making and Shared Accountability	■
4.1.3. QM-2: Screening for Asymptomatic Left Ventricular Dysfunction Among Individuals Who Have a Strong Family History of Cardiomyopathy and SCD	■	6.4. Developing Outcome Measures	■
4.2. Emergency Cardiovascular Care/Resuscitation ..	■	6.5. Data Sources for Performance Measures	■
4.2.1. Rationale for Including Population Health-Based Measures for Prevention of SCA or SCD	■	6.6. Assessment of Potential Advocacy Initiatives to Further SCD Prevention	■
4.2.2. QM-3: Referring for CPR and AED Education Those Family Members of Patients Who Are Hospitalized With Known Cardiovascular Conditions That Increase the Risk of SCA (any AMI, known heart failure, or cardiomyopathy)	■	6.6.1. Tracking of Legislation for the Presence or Absence of a Mandate for High School Student Training in CPR and AED (State and Municipal Level)	■
4.3. Heart Failure/General Cardiology	■	6.6.2. Tracking of Good Samaritan Legislation	■
4.3.1. PM-2: Use of ICD for Prevention of SCD in Patients With Heart Failure and Reduced Ejection Fraction	■	6.6.3. Tracking of Application of an AED by a Layperson to Patients With OHCA in Public Locations Before Arrival of EMS Providers on Scene	■
4.3.2. PM-3: Use of Guideline-Directed Medical Therapy (Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin-Receptor/Nepriylsin Inhibitor, Beta-Blocker, Aldosterone Receptor	■	7. CONCLUSIONS	■
		STAFF	■
		KEY WORDS	■

APPENDIX A

2016 AHA/ACC Prevention of SCD Clinical Performance and Quality Measures	■
1. Preventive Cardiology Measures	■
PM-1: Smoking cessation intervention in patients who suffered SCA, have ventricular arrhythmias, or are at risk for SCD	■
QM-1: Screening for family history of SCD	■
QM-2: Screening for asymptomatic left ventricular dysfunction among individuals who have a strong family history of cardiomyopathy and SCD	■
2. Resuscitation/Emergency Cardiovascular Care Measures	■
QM-3: Referring for CPR and AED education those family members of patients who are hospitalized with known cardiovascular conditions that increase risk of SCA (any AMI, known heart failure, or cardiomyopathy)	■
3. Heart Failure/General Cardiology Measures	■
PM-2: Use of ICD for prevention of SCD in patients with HF and reduced ejection fraction with an anticipated survival of >1 year	■
PM-3: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for prevention of SCD in patients with HF and reduced ejection fraction	■
PM-4: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, beta-blocker, aldosterone receptor antagonist) for the prevention of SCD in patients with MI and reduced ejection fraction	■
4. Electrophysiology Measures	■
PM-5: Documenting the absence of reversible causes for VT/VF cardiac arrest and/or sustained VT before a secondary-prevention ICD is placed	■
PM-6: Counseling eligible patients about an ICD	■
QM-4: Counseling of first-degree relatives of survivors of SCA associated with an inheritable condition	■

APPENDIX B

Author Relationships With Industry and Other Entities—2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death	■
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APPENDIX C

Peer Reviewer Relationships With Industry and Other Entities—2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death	■
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PREAMBLE

The American Heart Association (AHA)/American College of Cardiology (ACC) performance measure sets serve as

vehicles to accelerate translation of scientific evidence into clinical practice. Measure sets developed by the AHA/ACC 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 performance measure development (1) and to ensure that the measures developed are aligned with AHA/ACC clinical practice 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 depends 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 (the task force) distinguishes *quality measures* from *performance measures*. Quality measures are those measures that *may* be useful for local quality improvement but are not yet appropriate for public reporting or pay-for-performance programs (uses of performance measures). 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 feel 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.

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1. INTRODUCTION

The “2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of Sudden Cardiac Death” Writing Committee (the writing committee) was charged with creating the first comprehensive measure set in this area. In this measure set, the writing committee presents 10 measures that are intended for ambulatory and hospital (inpatient) settings or state/municipal use. In developing this measure set, the writing committee established 2 classes of measures: 1) performance, and 2) quality. The Preamble delineated the difference between performance and quality measures. For the purposes of this report, performance measures and quality measures

are designated respectively as “PM,” and “QM,” followed by the appropriate measure number.

The writing committee considered the development of pediatric measures but decided not to do so for this manuscript as this falls outside of the current task force scope. In a future update, the writing committee may reassess whether separate measures should be created for the pediatric population or whether the existing measures should be expanded to include pediatric patients.

The measure set is summarized in [Table 1](#). The detailed measure specifications are available in [Appendix A](#).

1.1. Scope of the Problem

Sudden cardiac arrest (SCA) and sudden cardiac death (SCD) are often used interchangeably; however, the definitions of these 2 terms are distinctly different. SCA is the

“sudden cessation of cardiac activity so that the victim becomes unresponsive, with no normal breathing and no signs of circulation.” If corrective measures are not taken rapidly, this condition progresses to sudden cardiac death (SCD). SCD is defined “as a natural death due to cardiac causes, heralded by abrupt loss of consciousness.” Therefore, SCD should not be used to describe events that are not fatal (2).

Out-of-hospital cardiac arrest (OHCA) occurs outside of the hospital and is usually attended by emergency medical services (EMS) personnel. In the United States, there are approximately 356,500 OHCA per year (3). A significant proportion of individuals in the United States die suddenly, and many of these deaths may be preventable by implementing evidence-based and guideline-endorsed recommendations for primary or secondary prevention of SCD.

TABLE 1 2016 AHA/ACC Clinical Performance and Quality Measures for Prevention of SCD

Measure Type	Description
Preventive Cardiology	
PM-1: Smoking cessation intervention in patients who suffered SCA, have ventricular arrhythmias, or are at risk for SCD	Percentage of patients ≥ 18 years of age for whom a smoking cessation intervention occurred.
QM-1: Screening for family history of SCD	Percentage of patients ≥ 18 years of age who were screened for a family history of SCD.
QM-2: Screening for asymptomatic left ventricular dysfunction among individuals who have a strong family history of cardiomyopathy and SCD Note: strong family history of SCD: affecting an immediate family member and/or >1 immediate or second degree family members	Percentage of patients with a strong family history of cardiomyopathy and SCD who had a noninvasive assessment of the ejection fraction.
Resuscitation/Emergency Cardiovascular Care	
QM-3: Referring for CPR and AED education those family members of patients who are hospitalized with known cardiovascular conditions that increase the risk of SCA (any AMI, known heart failure, or cardiomyopathy)	Percentage of patients ≥ 18 years of age hospitalized with known at-risk cardiovascular condition (any AMI, heart failure, or cardiomyopathy) in whom there is documentation that at least 1 family member has been referred for CPR and AED education.
Heart Failure/General Cardiology	
PM-2: Use of ICD for prevention of SCD in patients with HF and reduced ejection fraction who have an anticipated survival of >1 year	Percentage of patients ≥ 18 years of age with diagnosis of heart failure and NYHA Class II or III and a quantitative ejection fraction $\leq 35\%$ on most recent measurement despite guideline-directed medical therapy, with an anticipated survival of >1 year, who received an ICD for prevention of SCD.
PM-3: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for prevention of SCD in patients with HF and reduced ejection fraction	Percentage of patients ≥ 18 years of age with diagnosis of heart failure and a current quantitative ejection fraction $<40\%$ who received guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for the prevention of SCD.
PM-4: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for the prevention of SCD in patients with myocardial infarction and reduced ejection fraction	Percentage of patients ≥ 18 years of age with diagnosis of myocardial infarction and a current quantitative ejection fraction $<40\%$ who received guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) before hospital discharge.
Electrophysiology	
PM-5: Documenting the absence of reversible causes for VT/VF cardiac arrest and/or sustained VT before a secondary-prevention ICD is placed	Percentage of patients ≥ 18 years of age who received an ICD after presenting with VT/VF cardiac arrest and/or sustained VT with a documented absence of reversible cause of VT/VF cardiac arrest or sustained VT.
PM-6: Counseling eligible patients about an ICD	Percentage of patients ≥ 18 years of age who have an indication for and are eligible for an ICD for whom counseling for an ICD is documented to have occurred.
QM-4: Counseling of first-degree relatives of survivors of SCA associated with an inheritable condition	Percentage of patients ≥ 18 years of age who survived a SCA with a confirmed diagnosis of an inheritable condition associated with increased risk of SCD in whom clinical documentation confirms that their first degree relatives have been notified of the need for screening.

ACC indicates American College of Cardiology; ACE-I, angiotensin-converting enzyme inhibitor; AED, automated external defibrillator; AHA, American Heart Association; AMI, acute myocardial infarction; ARB, angiotensin receptor blocker; ARNI, angiotensin-receptor/neprilysin inhibitor; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; PM, performance measure; QM, quality measure; SCA, sudden cardiac arrest; SCD, sudden cardiac death; VF, ventricular fibrillation; and VT, ventricular tachycardia.

Certain patient groups are known to be at an increased risk for SCD. For example, individuals with heart failure and a low ejection fraction enrolled in clinical trials had an annualized death rate ranging from 5% to 10%, with 30% to 60% of these deaths classified as sudden (4-6). This variability in the percentage of patients who die suddenly as opposed to from other cardiovascular causes is difficult to predict even in these at-risk patients, despite the development of many risk prediction models. Other patient groups, such as those with inherited channelopathies, are at high risk for SCD; however, in the absence of symptoms, these patients remain undiagnosed, and SCD may be the first manifestation of their disease (7,8). Indeed, the largest number of SCD events occur in patients who do not appear to be at an increased risk for this outcome, making effective prevention challenging.

Different strategies should be implemented to have a measurable effect on the risk of SCD at the population level. Because SCD can occur in individuals who do not appear to be at an increased risk for this outcome and accurate risk stratification for SCD is not achievable in many people, prevention of SCD requires a concerted effort at multiple stakeholder levels. Health systems, legislative bodies, and nongovernmental organizations, as well as healthcare practitioners, patients, families, and communities, all have a role to play.

Effective therapies for the prevention of SCD should be used in at-risk patients. Patients with heart failure with reduced ejection fraction should be treated with guideline-directed medical therapy, such as beta-blockers, and if eligible, with an implantable cardioverter defibrillator (ICD). Several studies have shown underutilization of and disparities in the use of primary-prevention ICDs (i.e., those used in patients who are at risk for SCD but have not had SCA or sustained ventricular tachycardia [VT]) (9-11). Efforts should also focus on improving the prompt response to in-hospital cardiac arrest and OHCA, effective cardiopulmonary resuscitation (CPR), and rapid use of automated external defibrillators (AEDs) and therapeutic hypothermia. Studies have shown poor survival rates in victims of SCA and a very low use of AEDs (12-14).

Therefore, initiatives that could improve the quality of care of patients at risk for SCD and of victims of SCA are needed. One such initiative is the development and implementation of well-constructed performance measures (15-17). SCD performance measures are directed at strategies to improve screening for patients at risk for SCD, prevention of SCD at the individual and population levels, and treatments directed at the prevention of SCD.

1.2. Structure and Membership of the Writing Committee

The members of the writing committee included clinicians with expertise in cardiac electrophysiology, interventional cardiology, general cardiology, and emergency medicine, as well as individuals with expertise in guideline development and performance measure development, implementation, and testing.

1.3. Disclosure of Relationships With Industry and Other Entities

The task force makes every effort to avoid actual, potential, or perceived conflicts of interest that could arise as a result of relationships with industry (RWI) or other entities. 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 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 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 committee members and staff from the ACC and AHA.

2. METHODOLOGY

The development of performance measurement systems involves identification of a set of measures targeting a specific patient population observed over a particular time period. To achieve this goal, the task force has outlined a set of mandatory sequential steps (1). The following sections outline how these steps were applied by the present writing committee.

2.1. Identifying Clinically Important Outcomes

SCA is one of the leading causes of death in the United States (3). Even if the patient survives this clinical condition, which is caused mostly by a ventricular arrhythmia, the condition may have an overwhelming effect on the patient's quality and length of life. Subsequently, this clinical outcome imposes a heavy economic burden through healthcare expenditure.

The ACC, AHA, and the Heart Rhythm Society (HRS) have developed and disseminated evidence-based documents for the prevention of SCD (18-20). Although strong guidelines exist (18-20) there has been an underutilization of public health initiatives, treatments, and device therapy for patients at risk for sudden cardiac death (10,11,15,17,19-21). In an attempt to measure this gap, the writing committee sought to identify performance measures that can assess the quality of care for the prevention of SCD. The writing committee considered processes and strategies that quantify the adherence to existing guidelines for the prevention of SCD (9,22). As such, these processes and strategies provide a measurable quality value of health care. The writing committee looked for performance measures (23) that had a precise language, an ascertainable outcome, validity, reliability, and accountability. These performance measures allowed the writing committee to grade and compare the effectiveness of care in the prevention of SCD among practitioners.

2.2. Dimensions of Care

The writing committee studied 5 different domains from which the performance measures for SCD were constructed (1):

- Diagnosis of ST-segment-elevation myocardial infarction and non-ST-segment-elevation myocardial infarction in patients with low ejection fraction and in patients with heart failure with low ejection fraction
- Risk stratification (i.e., of patients with known risk factors for heart disease and their family members) and identification of high-risk individuals (including athletes, patients with hypertrophic cardiomyopathy, and those with inherited channelopathies)
- Treatment with medications and devices
- Public health prevention (legislation; education of patient and family members)
- Emergency cardiovascular care and resuscitation

The measures were studied in the context of what the core needs for health care should be (safe, effective, patient-centered, timely, efficient, and equitable), as outlined by the directive of the Institute of Medicine (24). We considered the full spectrum of preventive,

acute, and chronic interventions to prevent SCD. We divided the measures into 4 sections: preventive cardiology, resuscitation/emergency cardiovascular care, heart failure/general cardiology, and electrophysiology (Table 2).

2.3. Definition and Selection of Measures

In assessing which performance and quality measures should be included in this report, the writing committee reviewed both recent guidelines and other clinical guidance documents. Table 3 briefly presents the guidelines that were reviewed during the creation of this measure set.

All measures were designed to assess quality of care needed for patients at risk for SCD and, when possible, support achievement of the desirable outcomes identified. The measures also were designed to allow for the exclusion of patients with contraindications or other valid reasons for exclusion from the measure. In defining the measure exceptions, the writing committee was guided by the American Medical Association Physician Consortium for Performance Improvement Recommendations for Specification and Categorization of Measure Exclusions (31). The writing committee also considered existing measures that could inform the measures that appear in this set (32).

3. 2016 AHA/ACC CLINICAL PERFORMANCE AND QUALITY MEASURES FOR PREVENTION OF SCD

3.1. Target Population and Care Period

Given that SCA and SCD can affect people of all ages and people with a variety of other demographic characteristics, the writing committee decided to focus on adults (age ≥ 18 years) as the target population for the development of performance measures for the prevention of SCD. Although the pediatric population is an appropriate one for SCD measure development, the consensus of the writing committee was that there was insufficient evidence for or against performance measures related to SCD in children. At a future date, the writing committee may reassess whether pediatric performance or quality measures should be developed. Additionally, no limitations or restrictions with regard to other demographic characteristics, such as sex, race/ethnicity, or socioeconomic status, were applied. Given the complex issues related to SCD, the writing committee took the approach of targeting different domains from which performance measures for SCD were constructed. The writing committee also developed exclusion criteria specific to each measure. With this approach, a wide range of performance measures with their independent relevance and significance could be

TABLE 2 2016 AHA/ACC Prevention of SCD Clinical Performance and Quality Measurement Set—Dimensions of Care Measures Matrix

Measure Name	Diagnosis	Patient Education	Treatment	Self-Management
Preventive Cardiology				
PM-1: Smoking cessation intervention in patients who suffered SCA, have ventricular arrhythmias, or are at risk for SCD		✓		✓
QM-1: Screening for family history of SCD		✓		
QM-2: Screening for asymptomatic left ventricular dysfunction among individuals who have a strong family history of cardiomyopathy and SCD Note: strong family history of SCD: affecting an immediate family member and/or >1 immediate or second degree family members	✓			
Resuscitation/Emergency Cardiovascular Care				
QM-3: Referring for CPR and AED education those family members of patients who are hospitalized with known cardiovascular conditions that increase the risk of SCA (any AMI, known heart failure, or cardiomyopathy)			✓	
Heart Failure/General Cardiology				
PM-2: Use of ICD for prevention of SCD in patients with heart failure and reduced ejection fraction who have an anticipated survival of >1 year			✓	
PM-3: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, beta-blocker, aldosterone receptor antagonist) for prevention of SCD in patients with heart failure and reduced ejection fraction			✓	
PM-4: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, beta-blocker, aldosterone receptor antagonist) for the prevention of SCD in patients with myocardial infarction and reduced ejection fraction			✓	
Electrophysiology				
PM-5: Documenting the absence of reversible causes of VT/VF cardiac arrest and/or sustained VT before a secondary-prevention ICD is placed	✓		✓	
PM-6: Counseling eligible patients about an ICD		✓		
QM-4: Counseling of first-degree relatives of survivors of SCA associated with an inheritable condition		✓		

ACC indicates American College of Cardiology; ACE-I, angiotensin-converting enzyme inhibitor; AED, automated external defibrillator; AHA, American Heart Association; AMI, acute myocardial infarction; ARB, angiotensin receptor blocker; ARNI, angiotensin-receptor/neprilysin inhibitor; CPR, cardiopulmonary resuscitation; EMS, emergency medical services; ICD, implantable cardioverter defibrillator; PM, performance measure; QM, quality measure; SCA, sudden cardiac arrest; SCD, sudden cardiac death; VF, ventricular fibrillation; and VT, ventricular tachycardia.

selected to cover a population at large considered at high risk for SCD, regardless of the presence of specific disease states or symptoms. For example, as an independent intervention, cessation of smoking could be considered as important as screening for asymptomatic

left ventricular dysfunction or adhering to guideline-directed medical therapy in patients with coronary artery disease and heart failure (26,33-37). The writing committee also stressed that the care periods be defined individually for different measures. For example, a care

TABLE 3 Associated Guidelines and Other Clinical Guidance Documents

Guideline
2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure (25)
2015 AHA Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (19)
2013 ACCF/AHA Guideline for the Management of Heart Failure (26)
2012 ACCF/AHA/HRS Focused Update Incorporated into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)
2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease Update (28)
2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (29)
2006 ACC/AHA/ESC Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)
Clinical Guidance Document
2006 AHA Community Lay Rescuer Automated External Defibrillation Programs (30)

ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ESC, European Society of Cardiology; HFSA, Heart Failure Society of America; HRS, Heart Rhythm Society.

period for assessing relevance of a measure that involves appropriate identification and optimal treatment of treatable causes of SCA in a given population of patients eligible for ICD implantation is different from the care period for a measure that would test legislation or regulations requiring training in CPR and AED use in the general community (20,27,38-40).

3.2. Avoiding Overlap and Ensuring Alignment With Existing Measure Sets and Guidelines

Since the formation of the task force in 2000 (41), measures have been developed to improve the quality of care for cardiovascular disease in several clinical areas. Furthermore, other organizations, including The Joint Commission and the Institute of Medicine, have been active in this arena. In the past decade, the National Quality Forum has endorsed >600 performance measures intended to improve quality of health care and outcomes (42). With regard to promoting quality improvement in the prevention of SCD and treatment of SCA, very few performance measures exist; the use of beta-blockers in patients with heart failure and acute myocardial infarction is one of them (16,17). Several performance measures related to SCD are in development, but they are mostly parts of measures designed for other conditions (e.g., heart failure) (32).

To develop measures related to SCD per se, the writing committee made a concerted effort to avoid overlap and ensure harmonization and alignment with existing guidelines related to the management of patients with ventricular arrhythmias and high-risk disease substrates of SCD (e.g., hypertrophic cardiomyopathy) and device-based therapy of cardiac arrhythmias (20,27,29).

The writing committee took the following directives: a) review of the available evidence base to determine whether sufficient evidence existed to elevate strategies known to be effective means to modify the natural history of SCD to the tier of performance measures; b) scrutiny of any existing initiatives related to SCD and whether performance measures were needed in this area; c) determination of whether significant gaps in care existed that were not already addressed by existing performance measures; d) consideration of whether any new and potential areas of interest for performance measurement, including advanced cardiovascular life support, AEDs, bystander CPR, and activation of 911 services, would fall within the purview of the task force; and e) formulation of recommendations to identify the target population(s) for potential measures and possible measureable processes and outcomes to be considered for performance measure development.

4. MEASURES INCLUDED IN THE SET

4.1. Preventive Cardiology

4.1.1. PM-1: Smoking Cessation Intervention in Patients Who Suffered SCA, Have Ventricular Arrhythmias, or Are at Risk for SCD

Smoking is associated with a 2- to 4-fold increased risk of SCD (33,43-45). In individuals with an ICD, continued smoking is associated with a 7-fold increased risk of appropriate shock (35). Multiple studies have shown that smoking cessation is associated with a marked decline in the risk of SCD in population-based cohorts (44), post-myocardial infarction patients (46), and SCA survivors (34). In the Nurse's Health Study, smoking cessation was associated over time with a linear decreased risk of SCD. Compared with current smokers, in women without coronary heart disease the risk of SCD was significantly lower within 5 years of quitting smoking (multivariable hazard ratio: 0.47; 95% confidence interval: 0.24-0.92), and the risk of SCD resembled that of never smokers after 20 years of abstinence (33).

Multiple agencies and guidelines have endorsed the importance of clinicians' asking patients about tobacco use and counseling users to quit. The U.S. Preventive Services Task Force recommends that all adults be queried about tobacco use and individuals who use tobacco products be provided tobacco cessation interventions (Grade A Recommendation) (47). Similarly, the ACC/AHA/European Society of Cardiology (ESC) 2006 ventricular arrhythmia and SCD guidelines recommend discouraging smoking in all patients with suspected or documented ventricular arrhythmias and/or aborted SCD (*Class I, Level of Evidence: B*) (20).

For the PM-1, all patients identified as ever tobacco users should be queried about tobacco use at a minimum of every 2 years. Clinicians should provide explicit documentation that all adults who use tobacco have received a smoking cessation intervention, which may include counseling (such as verbal recommendation to quit or referral to a smoking cessation program or counselor) and pharmacological therapy.

The writing committee discussed challenges to implement this smoking cessation performance measure. We acknowledge that small sample sizes may interfere with reporting of reliable performance measures at the clinician level. With the implementation of electronic health records (EHRs), aggregate data should be accessible at the practice level. One potential caution is that the EHR may contain inaccurate or out-of-date information because of the well-described phenomenon of copy forward ("cloning"). Hence, in the EHR setting, documentation of whether patients have been queried about smoking status every 2 years may have inaccuracies (48). Nevertheless,

the EHR has counterbalancing advantages. EHR prompts have been demonstrated to increase tobacco counseling and referral for treatment (49-51).

Multiple studies have reported that bans on public smoking are associated with a decreased risk of SCD (36,45,52,53). Although the preponderance of evidence supports the role of secondhand smoke in increasing the risk of SCD, the evidence is insufficient to establish a causal relation (45). Hence, the writing committee recommends a quality improvement measure for clinicians to ask patients with documented ventricular arrhythmias who are at risk for SCD or have had SCA about exposure to secondhand smoke every 2 years. Individuals in these high-risk categories should be counseled to avoid secondhand smoke exposure.

4.1.2. QM-1: Screening for Family History of SCD

Multiple studies with varying designs have documented that individuals with a family history of SCD are at a higher risk for SCD (54-58). For instance, compared with 10.6% of referents, 18.6% of individuals in the Paris Prospective Study who experienced SCD in follow-up reported a parental history of SCD at baseline. The adjusted relative risk of a parental history of SCD was 1.80 (95% confidence interval: 1.11-2.88; $p=0.01$). Furthermore, the Paris Study reported a “dose-response” relationship; compared with no parental history of SCD, those with 1 parent with a history of SCD had a relative risk of 1.89, and those with 2 parents with a history of SCD had a relative risk of 9.44 (54). Similarly, in a retrospective case-control study from Finland, individuals who had experienced SCD had a 2.2-fold higher odds of have a first-degree relative with SCD than did control individuals (58).

Elsewhere in the present document, the writing committee proposes a performance measure targeting survivors of SCA who have a confirmed diagnosis of an inheritable condition associated with an increased risk of SCD and requiring clinical documentation that their first-degree relatives have been notified of the need for screening for the condition. However, the writing committee notes that as opposed to screening the families of patients who have survived SCA, the rationale for screening for a family history of SCD is less clear if applied to the general population or even to individuals with many of the conditions associated with increased risk for SCD. Guidelines have recommended family history screening for SCD with a *Level of Evidence: B-C* (20,29,59,60). The 2006 arrhythmia guideline gave a *Class I, Level of Evidence: C* to screening athletes for a family history of premature death or SCD before sports participation, seeking specific evidence of cardiomyopathies and ion channel diseases (20). The 2011 hypertrophic cardiomyopathy guideline gave a *Class I, Level of Evidence: B* to screening for a family history of SCD (including ICD therapy) (29,59,60).

Because of the aforementioned complexities, the writing committee proposed the inclusion of this measure as a quality measure that involves querying all adult patients at a minimum of every 2 years about whether they have a family history of SCD. The 2-year cycle was chosen by the writing committee to ensure that clinicians are not overburdened and to allow for some events in the family to accrue (over 2 years versus 1 year). Exclusions include individuals for whom a family history may be inaccurate (e.g., in cases of adoption or where family history is unknown). Exceptions include individuals who decline to report family history or individuals with an estimated survival of ≤ 1 year.

The recommendation to implement family history of SCD as a quality measure also stems from the lack of guideline *Level of Evidence: A* and the multiple challenges to implementation. The 2006 ventricular arrhythmia guideline acknowledged that in individuals with an inherited arrhythmic condition, such as long-QT syndrome (61), brugada syndrome (62,63), and arrhythmogenic right ventricular cardiomyopathy (ARVC), a family history of SCD was not a powerful predictor of risk of SCD (20). One setting in which a family history of SCD in a first-degree relative may be useful for risk stratifying is when an individual has hypertrophic cardiomyopathy (64); the 2011 hypertrophic cardiomyopathy guideline gave it a *Class IIa, Level of Evidence: C* (29). Furthermore, the accuracy of the classification of the cause of SCD, when compared against autopsy, was limited (64). Also, age thresholds for defining a family history of SCD are inconsistent (54,56,59,60,66-68).

There are advantages to including screening for family history of SCD as a quality measure. The assessment of family history is simple, relatively inexpensive, and noninvasive. The 2013 guideline on the assessment of cardiovascular risk noted that family history of cardiovascular disease may have some clinical utility as a screening tool and that family history may be used to inform treatment decisions if the risk of cardiovascular disease is uncertain after quantitative assessments (National Heart, Lung, and Blood Institute Grade: E [Expert Opinion]; ACC/AHA *Class IIb, Level of Evidence: B*) (68). Others have argued that collecting family history of SCD in general practice is feasible (69) and provides opportunities to personalize risk factor counseling and modification (70).

4.1.3. QM-2: Screening for Asymptomatic Left Ventricular Dysfunction Among Individuals Who Have a Strong Family History of Cardiomyopathy and SCD

The writing committee considered a quality measure in which cardiac imaging (generally echocardiogram) is used to screen for asymptomatic left ventricular dysfunction in individuals with a strong family history of an inherited

disorder associated with SCD. Individuals would not be counted for the quality measure if they or their healthcare proxy declined or if they had a limited life expectancy (typically <1-year survival).

We considered noninvasive assessment of left ventricular ejection fraction as a quality measure in patients with a strong family history of cardiomyopathy or inherited heart muscle disorder associated with SCD. A strong family history is defined as multiple affected individuals or a first-degree relative with the cardiomyopathy. The rationale is that detecting an asymptomatic heart muscle disorder may have diagnostic, prognostic, and therapeutic implications (29). The “2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy” recommended echocardiographic screening for family members unless a family member was genotype negative in a family with known definitive mutations (*Class I, Level of Evidence: B*) (29). The 2009 heart failure guideline recommended that left ventricular ejection fraction be assessed in individuals with a strong family history of cardiomyopathy (*Class I, Level of Evidence: C*), but the authors noted that the cost-effectiveness of this approach has not been determined (71). The 2012 device guideline gave a *Class IIa, Level of Evidence: C* to the implantation of an ICD in individuals with hypertrophic cardiomyopathy who have at least 1 major risk factor for SCD, including a family history of SCD (27). Although the device guidelines did not directly address echocardiography screening in first-degree relatives with hypertrophic cardiomyopathy or ARVC, given the therapeutic implications, it is reasonable to screen with echocardiography family members of individuals who had those conditions and had SCD. The 2006 arrhythmia guideline recommended echocardiography as a *Class I, Level of Evidence: B* guideline in individuals who are the relatives of patients with inherited conditions associated with SCD (20).

This is a quality measure (as opposed to performance measure) because the Level of Evidence is heterogeneous (B-C) in the guidelines and the guideline is potentially complex for primary care practitioners to follow. It seems unlikely, given the modest cost and noninvasive nature of echocardiography, that there would be the equipoise necessary to pursue a randomized controlled trial, particularly because familial cardiomyopathies are uncommon and coordinating a trial would be costly and logistically challenging.

4.2. Emergency Cardiovascular Care/Resuscitation

4.2.1. Rationale for Including Population Health-Based Measures for Prevention of SCA or SCD

OHCA is unique among conditions evaluated by performance measures in that >50% of cases occur without

any prior clinical manifestation of risk for SCA (72). In addition, race/ethnic disparities and regional variation in the process of care (73) and incidence and outcome (3) of OHCA appear to be much greater than those observed with other common cardiovascular conditions. Thus, it seems unlikely that an important improvement in the quality of care related to OHCA or SCD can be achieved without including population health as a denominator in ≥ 1 performance measures.

4.2.2. QM-3: Referring for CPR and AED Education Those Family Members of Patients Who Are Hospitalized With Known Cardiovascular Conditions That Increase the Risk of SCA (any AMI, Known Heart Failure, or Cardiomyopathy)

Improvements in acute cardiovascular care, including primary percutaneous coronary intervention, revascularization, and medical therapy, over the past 2 or 3 decades have markedly decreased the risk of death during hospitalization for ST-elevation or non-ST-elevation myocardial infarction. Implantation of an ICD is a Class I therapy in patients who have an ejection fraction of $\leq 35\%$ due to ischemic or nonischemic cardiomyopathy along with New York Heart Association (NYHA) Class II to III heart failure, but are not recovering from acute myocardial infarction or revascularization. After hospitalization for myocardial infarction, the risk of SCD or SCA is greatest immediately after discharge and then declines over time (74). Given that bystander CPR is lifesaving in many patients and that the majority of SCD or SCA does not occur in public locations (14), people who are likely to witness such an event in a family member who is at an increased risk of SCA should be trained in how to recognize and respond to it. Importantly, a performance measure that involves referring at least 1 family member of those hospitalized with a primary diagnosis of a cardiovascular condition (e.g., ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, heart failure, cardiomyopathy) to CPR and AED use training should be stratified and reported by patient sex and race/ethnicity. This measure does not require that the physician train the family member in CPR or AED use. Some may argue that this measure is unsupported by the results of the Home Automated External Defibrillator Trial (HAT) (75). Although HAT demonstrated that placing an AED in the home, compared with response training for SCA, did not reduce the mortality rate in patients with a previous anterior-wall myocardial infarction who did not have an indication for an ICD, several factors may account for this finding. One is the relatively small number of events in the trial, because patients in trials are relatively “healthier” than patients in real-world practice. Also, all participants in the control group received resuscitation training, including frequent reminders, which is not reflective of real-world practice after myocardial

infarction. Nevertheless, the observed successful delivery of a defibrillating shock in 14 patients and in 4 neighbors, resulting in long-term survival for 6 (33%), confirms that the use of an AED in the home by laypeople with minimal training is feasible and terminates ventricular fibrillation (VF) (75).

The writing committee recognizes that it may not be necessary or appropriate to train family members in CPR and AED use among all patients hospitalized with a primary diagnosis of ST-segment-elevation myocardial infarction. Some patients live alone or in a skilled nursing facility, some have a preexisting do not attempt resuscitation (DNAR) order, and some die before discharge from the hospital.

4.3. Heart Failure/General Cardiology

4.3.1. PM-2: Use of ICD for Prevention of SCD in Patients With Heart Failure and Reduced Ejection Fraction

ICDs have been proved to significantly reduce the risk of SCD attributable to ventricular tachyarrhythmias in patients with NYHA Classes I, II, or III caused by a prior myocardial infarction, and in patients with NYHA Classes II or III caused by nonischemic cardiomyopathy despite optimal guideline-directed medical therapy, in whom survival with good functional capacity is otherwise anticipated to extend beyond 1 year (4,6,26,76).

Given the significant survival benefit of ICD implantation, the writing committee agreed that eligible patients should receive this treatment in the absence of contraindications, such as a myocardial infarction within the past 40 days, revascularization with coronary artery bypass graft or percutaneous coronary intervention within the past 90 days, newly diagnosed cardiomyopathy within the past 90 days, contraindications to implantation of a device (such as infection), limited life expectancy (<1 year), or patient preference.

4.3.2. PM-3: Use of Guideline-Directed Medical Therapy (Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin-Receptor/Neprilysin Inhibitor, Beta-Blocker, Aldosterone Receptor Antagonist) for Prevention of SCD in Patients With Heart Failure and Reduced Ejection Fraction

The writing committee developed this measure because the use of guideline-directed medical therapy has been shown to reduce the risk of SCD and/or all-cause death in patients with left ventricular dysfunction and symptomatic heart failure (77-84). The use of all the medications included in this measure (i.e., angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, angiotensin-receptor/neprilysin inhibitor; beta-blocker and aldosterone antagonist) in patients with heart failure with reduced ejection fraction is supported by *Class I*

recommendations (*Level of Evidence: A*). However, the writing committee acknowledges that some patients may have contraindications to ≥ 1 of these medications. Several exceptions were considered, including patient preference for no treatment, comfort care through palliative or hospice care, or when the patient has NYHA Class I symptoms and as such would not qualify for an aldosterone antagonist.

4.3.3. PM-4: Use of Guideline-Directed Medical Therapy (Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker or Angiotensin-Receptor/Neprilysin Inhibitor, Beta-Blocker, Aldosterone Receptor Antagonist) for the Prevention of SCD in Patients With Myocardial Infarction and Reduced Ejection Fraction

Guideline-directed medical therapy has been shown to reduce the risk of SCD and/or all-cause death in patients with left ventricular dysfunction caused by a prior myocardial infarction (82-86). Unlike the prior 2 measures proposed in the heart failure population (PM-2 and PM-3), this measure was constructed to address the inpatient setting only (i.e., the therapies prescribed before discharge). As such, the exceptions and exclusions for this measure are different from those pertaining to PM-2 and PM-3. The writing committee acknowledges that patients should be excluded if they leave against medical advice or are expected to live for <1 year. Exceptions were considered for patients who had a medical reason for not receiving guideline-directed medical therapy or a patient reason, such as refusal.

4.4. Electrophysiology

4.4.1. PM-5: Documenting the Absence of Reversible Causes of VT/VF Cardiac Arrest and/or Sustained VT Before a Secondary-Prevention ICD Is Placed

The ICD has been shown to prolong the lives of survivors of VT/VF cardiac arrest and/or sustained VT with hemodynamic compromise (27,87-89). This evidence is reflected in the 2012 focused update of the 2008 practice guidelines on ICD implantation, which designated the ICD as a Class I indication in such patients (18,27). However, these guidelines stipulate that reversible causes be ruled out before ICD implantation is considered, because VT/VF cardiac arrest or sustained VT due to reversible causes is best treated by addressing the underlying cause (27). Although an analysis of the Antiarrhythmics versus Implantable Defibrillator (AVID) registry, which included patients who were deemed not eligible for enrollment in the randomized clinical trial, suggested that patients identified with a transient or correctable cause of VT/VF are at high risk for death, there are no data to show that their survival could be improved with an ICD (90). In addition, patients with

VT/VF in the setting of a reversible cause were excluded from the pivotal randomized clinical trials of secondary-prevention ICDs (87-89).

The present measure involves documenting that reversible causes were considered and excluded during the index event before a secondary-prevention ICD was implanted, because this allows for an evaluation of the appropriateness of the ICD. The writing committee acknowledges that it can be difficult to assess what is a “reversible cause” of SCD, as well as to agree on what “ruling out reversible causes” means and how much testing is adequate. For this reason, in the measure specifications, the writing committee provided some concrete recommendations on how one may rule out “reversible causes” that would support nonplacement of an ICD. The consensus among the writing committee was on the following reversible causes: acute myocardial infarction, as evidenced by convincing data on serial cardiac biomarkers and supported by additional data from cardiac catheterization and/or other imaging modalities; electrolyte abnormalities; decompensated heart failure requiring a change in treatment; medications; revascularization; and drug abuse (91-97). Embedding such data elements in registries or EHRs will make it easier to implement this performance measure in clinical practice.

4.4.2. PM-6: Counseling Eligible Patients About an ICD

Of the therapies available to prevent SCD, the ICD is the most effective. This is true not only in patients who survive a VT/VF cardiac arrest or sustained VT with hemodynamic compromise, but also in patients who are deemed at risk for SCD on the basis of systolic left ventricular dysfunction with an ejection fraction of $\leq 35\%$ with NYHA Class I, II, or III symptoms caused by ischemic cardiomyopathy or NYHA Class II or II symptoms caused by nonischemic cardiomyopathy and associated heart failure symptoms (4,6,21,76,98). For this reason, the 2012 practice guidelines designate the ICD as a Class I therapy in patients who meet these criteria (27). However, several studies have shown substantial underutilization of ICDs in potentially eligible patients (9-11,16,99). Furthermore, significant sex and racial/ethnic disparities have been demonstrated in the use of ICDs among Medicare beneficiaries and patients enrolled in the AHA Get With The Guidelines Registry (9-11,16). Given that this therapy is lifesaving in many patients, a performance measure that involves counseling about the potential benefits of primary-prevention ICDs in appropriately selected patients is important. For this measure to achieve its full potential, and in particular because of the clear disparities in utilization of ICD therapy, data on it will have to be stratified and reported by sex and race/ethnicity. Although this measure could not capture the quality of the counseling, healthcare providers should

communicate all relevant information to patients in an easily understandable and culturally competent manner (100).

The writing committee discussed at length whether to focus this measure on counseling alone versus implanting a primary-prevention ICD. In the “ACCF/AHA/AMA-PCPI 2011 Performance Measures for Adults With Heart Failure,” a measure on implanting an ICD in patients with severe left ventricular dysfunction was considered; however, such a measure was not developed because of concerns related to the large number of potential exceptions for patient factors (e.g., comorbidities and patient preferences, including the potential preference to not undergo ICD implantation) and physician factors that may not be readily available in EHRs or administrative data (23). The writing committee agrees with this reasoning; however, unlike the 2011 ACCF/AHA/AMA-PCPI writing committee, which recommended the measure as a quality measure intended for internal use only, our writing committee recommends this measure for public reporting because of the robust data on the efficacy of the ICD and the demonstrated gap in utilizing this lifesaving therapy.

Finally, the writing committee emphasized the need for a measure that involves documenting a plan to reassess a patient’s candidacy for a primary-prevention ICD during follow-up if the patient is not currently a candidate for a primary-prevention ICD because of myocardial infarction, acute heart failure, new-onset heart failure, or recent revascularization.

4.4.3. QM-4: Counseling of First-Degree Relatives of Survivors of SCA Associated With an Inheritable Condition

When providing care to survivors of SCA, healthcare professionals should determine the reasons for the SCA and should carefully consider inheritable conditions associated with an increased risk of SCD. If a condition is found and can be identified by electrocardiography or echocardiography, it is the responsibility of healthcare providers to counsel patients about the importance of having their first-degree relatives screened for the condition of concern. To what extent this counseling occurs in clinical practice is unclear. Given the lifesaving potential of this counseling, a performance measure such as the one proposed here is needed to increase the frequency at which it occurs in clinical practice.

After a lengthy discussion of what conditions to include in this measure, the writing committee agreed to include the following: hypertrophic cardiomyopathy, long-QT syndrome, short-QT syndrome, ARVC, catecholaminergic polymorphic VT, and sudden unexpected death syndrome (20,29,60,65-67,101). These conditions were deemed worthy of inclusion on the basis of recommendations made in the “ACC/AHA/ESC 2006 Guidelines

for the Management of Patients With Ventricular Arrhythmias and the Prevention of SCD” and the “2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy” (20,29). Indeed, the 2006 guidelines designate echocardiography as a Class I test in the subset of patients at high risk for the development of serious ventricular arrhythmias or SCD, including the relatives of patients with inherited disorders associated with SCD (20). Furthermore, in those guidelines, genetic analysis was deemed to be very important in families with long-QT syndrome, useful in families with hypertrophic cardiomyopathy or ARVC, and potentially useful in families of patients with brugada syndrome or short-QT syndrome, because whenever a mutation is identified, one could establish a presymptomatic diagnosis of the disease among family members and then counsel them on their risk of developing the disease and transmitting it to their children (20).

5. POTENTIAL MEASURES CONSIDERED BUT NOT INCLUDED IN THIS SET

The writing committee identified 2 areas of interest for further investigation. Although the areas are relevant to performance measures in general, the writing committee felt they would have particularly important implications for measurement with regard to SCD.

5.1. Genetics

Although there are several strong linkages of SCD to certain diseases or syndromes, very few of these genetic polymorphisms can be supported for general screening, but they have use in clinical practice in limited circumstances. Examples are diseases such as ARVC (*PKP2* gene) and brugada syndrome (*SCN5a*), as well as different mutations that have been associated with long-QT syndrome. The AHA policy statement on genetics and cardiovascular disease outlined the issues and promise of genetics for clinical use (102). However, there are no Class I indications that would apply to the population under assessment that are evidence-based, feasible, and actionable and would support the development of performance measures in this arena.

5.2. Screening of Athletes

SCD in athletes is a high-profile event, and a position statement highlighted the issues and challenges around screening young individuals with a 12-lead electrocardiogram (ECG) (103). Preparticipation checklists for athletes already exist and are focused on many causes of SCD, but limited data support their utility, cost, and applicability. See Table 4, which is derived from the AHA recommendations for preparticipation cardiovascular screening of competitive athletes (104). A recent

TABLE 4 Twelve-Element AHA Recommendations for Preparticipation Cardiovascular Screening of Competitive Athletes

Medical History

Personal history

1. Chest pain/discomfort on exertion
2. Unexplained fainting or near-fainting
3. Excessive and unexplained fatigue associated with exercise
4. Heart murmur
5. High blood pressure

Family history

6. ≥ 1 relatives who died of heart disease (sudden/unexpected or otherwise) before age 50 years
7. Close relative <50 years of age with disability from heart disease
8. Specific knowledge of certain cardiac conditions in family members: hypertrophic or dilated cardiomyopathy, in which the heart cavity or wall becomes enlarged; long-QT syndrome, which affects the heart's electrical rhythm; Marfan syndrome, in which the walls of the heart's major arteries are weakened; or clinically important arrhythmias or heart rhythms

Physical examination

9. Heart murmur
10. Femoral pulses to exclude narrowing of the aorta
11. Physical appearance of Marfan syndrome
12. Brachial artery blood pressure (taken in a sitting position)

Table generated based on Interassociation consensus statement on cardiovascular care of college student-athletes (105).

AHA indicates American Heart Association.

interassociation consensus statement highlighted the importance of preparticipation cardiovascular screening, including a comprehensive personal and family history and physical examination. Although that consensus statement mentioned that electrocardiographic screening can increase the sensitivity to detect potentially lethal cardiac conditions if physician training is improved and cardiology expertise is available, it did not make a firm recommendation about whether a screening ECG should be performed in all athletes (105).

6. FUTURE DIRECTIONS

Although the measure set presented in this report is in many ways a robust measure set, the writing committee identified several areas that will impact both the success of its implementation and the future of SCD measure development efforts.

To further improve quality of care for patients at risk for SCD, the writing committee identified areas that require additional research, including:

- **Adoption and evaluation of the measures:** Successful improvement in quality of care and outcomes will require testing, evaluation, and implementation of the measures in this set across various settings.

- **Measures based on adherence and optimal dosing of medications:** Effort should be devoted to developing measures focused on adherence to the prescribed medications, as well as optimal dosing of medications; however, this will likely be difficult given the current limitations of data capture.
- **Shared decision-making and shared accountability:** Further study is needed to ensure shared decision making is used effectively and to validate alternative measure constructs and determine if they are sufficiently linked to the desired outcomes.
- **Developing outcome measures:** Further research will be necessary to derive and validate risk adjustment models for SCD, with a particular focus on ensuring adequate adjustment for case mix and SCD risk factors, model discrimination and calibration, reliable ascertainment of the outcome of interest, and sufficient size of patient population and duration of follow-up.
- **Data sources for performance measures efforts:** Efforts should shift from administrative claims data, which cannot fully capture important clinical information, to other models, such as registries and EHRs.
- **Assessment of potential advocacy initiatives to further SCD prevention:** Efforts should be taken to explore what advocacy initiatives should be launched at a municipal and state level to further the prevention of SCD (e.g., increased training of high school students in CPR and AED use; Good Samaritan legislation; and AED use by a layperson for patients with SCA in public locations before arrival of EMS providers on scene).

6.1. Adoption and Evaluation of the Measures

To successfully improve quality of care and outcomes, the measures included in the SCD prevention performance measure set should be implemented and integrated across various care settings as eligible patients are encountered (17). Clinical teams and health systems should collect data, review adherence to these measures on a routine basis, provide timely feedback, and adjust clinical decision support tools and practice patterns as needed to improve performance (106,107). Prior studies have demonstrated that use of performance measures for evidence-based medications and devices that prevent SCD as a component of a performance improvement system is associated with substantial improvements in quality of care in both the hospital and outpatient settings (11,106-108). Before they are used for accountability and in seeking endorsement from the National Quality Forum, the specific measures proposed in the present report should undergo extensive evaluation and testing. In addition, studies should be conducted to determine the extent to which these measures are linked to desired

outcomes and are free from unintended consequences. Similar process measures have been shown to be independently associated with outcomes and appear to have a valid process-outcome link (109-111). The upcoming health reform requirements for physician-level and hospital-level public reporting based on performance measures, including those proposed here, further underscore the need for thorough testing before endorsement and widespread adoption.

6.2. Measures Based on Adherence and Optimal Dosing of Medications

Although the prescription medication-based measures included in this performance measure set are based on documentation that guideline-directed medications are prescribed, it will be important to explore whether measures based on adherence to the prescribed medications, as well as optimal dosing of medications, could be developed (112). Using existing data collection systems to efficiently and reliably measure adherence and persistence to prescription medications remains challenging. It also is currently difficult to determine whether the achievement of optimal dosing has not been attempted or instead has been limited by side effects or intolerance.

6.3. Shared Decision-Making and Shared Accountability

Shared decision-making is a collaborative process that allows patients and clinicians to make healthcare decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences (113). The decision to proceed with implantation of devices such as the ICD often requires multiple complex decisions, with patients taking into account their preferences, values, and advanced care planning. The approach used by most AHA/ACC performance measure writing committees and that used in this SCD performance measure set to account for shared decision making is to exclude patients who made informed decisions to decline medications or devices, as documented by the clinician, from the denominator of the measure, with an exception for patient reasons (114). Other measurement designs have been advocated, such as including patients who decline to receive a therapy in the numerator equivalent to receiving the therapy, as well as accounting for patients who remain undecided and want to continue deliberations (115). Determining whether shared decision-making has been adequately provided depends on documenting the extent to which a patient has been provided information on the risks and benefits of a therapy, there has been collaborative engagement in the decision-making process, and the patient's preferences and values were fully considered (115). Further study is needed to validate alternative measure constructs and

determine if they are sufficiently linked to desired outcomes.

The measures in this performance measure set are clinician focused in terms of accountability. However, patient participation and engagement are integral to the success of any treatment plan, including plans for preventing SCD. There has been growing support for the concept of integrating clinician-patient shared accountability into performance measure sets (116,117). The general framework of shared accountability is based on the premise that there should be a partnership between patients and clinicians, in which the patient plays an active role in setting goals, making treatment decisions, defining what outcomes are important, and assessing those outcomes, and this in turn can be integrated into the design of performance measures (117). Ideally, all stakeholders within the healthcare system and all members of the healthcare team, including the patient, are responsible for and contribute to the success of care measures (117). As this methodology evolves and is further tested, future revisions of this performance measure set should aim to integrate principles of shared accountability. In developing the measure set, the writing committee considered including clinician-patient shared accountability in performance measures, but they realized that this accountability is difficult to quantify or implement. Incorporating clinician-patient shared accountability into the development of measures may be feasible in the future but will likely require thorough planning and extensive testing.

6.4. Developing Outcome Measures

The ultimate goal of performance measurement is to improve patient outcomes, including health status (quality of life, symptom burden, and functional status), morbidity, and mortality (114). Although measures focusing on processes of care have substantial utility in measuring and improving care quality and outcomes, direct outcome measures are increasingly being used for quantifying quality (118). Process measures, such as those included in the SCD prevention measure set, determine whether certain components of guideline-directed care were provided to eligible patients, but these measures do not necessarily capture information on the effectiveness of the processes being applied. The attributes of outcome measures suitable for public reporting have been described in an AHA scientific statement endorsed by the ACC (118).

These attributes include: 1) a clear and explicit definition of an appropriate patient sample; 2) clinical coherence of model adjustment variables; 3) sufficiently high-quality and timely data; 4) designation of an appropriate reference time before which covariates are derived and after which outcomes are measured; 5) use of

an appropriate outcome and a standardized period of outcome assessment; 6) application of an analytical approach that takes into account the multilevel organization of data; and 7) disclosure of the methods used to compare outcomes, including disclosure of performance of risk-adjustment methodology in derivation and validation samples (15).

The writing committee recognizes the importance of developing scientifically valid, adequately risk-adjusted, effective, and useful measures of clinical outcomes for prevention of SCD. However, further research will be necessary to derive and validate risk adjustment models for SCD. Particular attention will need to be paid to ensuring adequate adjustment for case mix and SCD risk factors, model discrimination and calibration, reliable ascertainment of the outcome of interest, and sufficient patient population and duration of follow-up in the measure period. Despite these challenges, the writing committee recommends that outcome measurements be developed and strongly considered in future revisions of the performance measures for prevention of SCD.

6.5. Data Sources for Performance Measures

In the coming years, the writing committee anticipates a shift away from administrative claims data to structured clinical data, including clinical registry data, as the basis for performance measurement. Historically, many performance measures have been constructed with administrative claims data, precisely because these are systematically collected structured data that are standardized and readily available. Although readily available, Current Procedural Terminology and *International Classification of Diseases, Ninth and Tenth Revisions*, codes cannot fully capture the subtlety of clinical care as robustly as other data models. Registry-based approaches to data collection, however, include standardized definitions developed by expert clinician teams for specific purposes, including research, workload tracking, and performance measurement (106,114,119). In addition, EHRs will likely evolve as a very viable data source for developing performance measures, and, in fact, the National Quality Forum is encouraging the submission of e-measures.

6.6. Assessment of Potential Advocacy Initiatives to Further SCD Prevention

The writing committee had considered development of a tracking mechanism for advocacy initiatives that: 1) track the presence or absence of legislation that enables or requires high school student training in CPR and AED use; 2) track the progress in ensuring Good Samaritan legislation; and AED by a layperson to patients with SCA in public locations before arrival of EMS providers on scene. All 3

topics could serve as potential advocacy initiatives and are discussed in more detail in subsection 6.6.1-6.6.3.

6.6.1. Tracking of Legislation for the Presence or Absence of a Mandate for High School Student Training in CPR and AED (State and Municipal Level)

Provision of bystander CPR doubles survival after the onset of SCA. Bystander CPR, as well as the application and use of an AED before arrival of EMS providers, doubles survival after the onset of SCA (120,121). This evidence is reflected in many practice guidelines and science advisories related to CPR and emergency cardiovascular care (38-40). Persons trained in CPR can recognize SCA and initiate compressions before the arrival of EMS providers. In most communities, a minority of laypersons are trained in CPR and AED use each year (40). Requiring training in these skills during high school will markedly increase the proportion of laypersons trained over time (122).

Given this, the writing committee thinks that a future activity could focus on advocacy initiatives that would encourage the documentation at the municipal and statewide levels the presence or absence of legislation that enables or requires high school student training in CPR and AED use. The presence or absence of CPR legislation could be assessed annually by verification of state law. The writing committee acknowledges that provision of bystander CPR can be increased by training before the event (i.e., prevention) or by telecommunicator instruction at the time of the event (i.e., treatment). Training students in higher education (e.g., trade schools, community colleges, universities) may be associated with incremental benefits compared with training high school students alone. However, the vast majority of students complete high school. A smaller proportion complete postsecondary education (123). We believe the emphasis on training students in high school rather than in higher education is warranted in future advocacy initiatives.

6.6.2. Tracking of Good Samaritan Legislation

Persons trained in CPR can recognize SCA and initiate compressions before the arrival of EMS providers. Perceived liability is a barrier to layperson provision of CPR or use of AEDs. Therefore, a future advocacy initiative could include tracking Good Samaritan legislation that indemnifies a layperson from liability and increases layperson provision of CPR or use of AEDs (124). This is reflected in science advisories related to CPR and emergency cardiovascular care (30,38-40). The writing committee acknowledged that the implementation of these measures may be difficult to track. However, over time, the writing committee anticipated that the public would

be better informed if Good Samaritan legislation was tracked at the state level and included in an online site.

6.6.3. Tracking of Application of an AED by a Layperson to Patients With OHCA in Public Locations Before Arrival of EMS Providers on Scene

A large, community-based, randomized trial showed that training and equipping laypersons to recognize and respond to OHCA by providing CPR and applying an AED before arrival of EMS providers on scene increased survival as compared with providing CPR alone (120). This is why the 2015 CPR and Emergency Cardiovascular Care Guidelines strongly supported establishment and maintenance of lay AED programs in public locations where there is a reasonable likelihood of witnessed OHCA (e.g., airports, casinos, large sports facilities) (125).

The writing committee believes that there may be value in launching advocacy initiatives that focused on the proportion of individuals treated for OHCA by an EMS provider who have already had an AED applied by a layperson before the arrival of EMS providers on the scene. The writing committee defines a layperson as anyone who is not part of the organized EMS response (i.e., not dispatched to the scene by a telecommunicator based at a public safety answering point or 911 call center). The writing committee recognizes that a layperson might use an AED on a person who is not in SCA and that such patients are not the focus of interest for future advocacy initiatives. They also recognize that a patient with a preexisting DNAR order should not be treated with an AED by a layperson and as such should be excluded from consideration. The writing committee felt that this advocacy initiative might be worth exploring.

7. CONCLUSIONS

The writing committee believes this new performance measure set will greatly assist clinicians in providing better care to their patients at risk of SCA, and robust application of these measures will ultimately improve quality of patient care and outcomes. The writing committee also recognizes that much remains to be done to develop additional measures to prevent SCD and treat SCA, develop outcome measures, and further integrate shared decision making and shared accountability principles into future versions of this measure set.

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KEY WORDS ACC/AHA Performance Measures, health policy and outcome research, out of hospital cardiac arrest, performance measure, quality measure, sudden cardiac arrest, sudden cardiac death

APPENDIX A. 2016 AHA/ACC PREVENTION OF SCD CLINICAL PERFORMANCE AND QUALITY MEASURES**1. Preventive Cardiology Measures****PM-1: Smoking cessation intervention in patients who suffered SCA, have ventricular arrhythmias, or are at risk for SCD****Measure Description:** Percentage of patients ≥ 18 years of age for whom a smoking cessation intervention occurred.

Numerator	Patients who are identified as tobacco users for whom smoking cessation* occurs during the measurement period. *Smoking cessation intervention may include smoking-cessation counseling (e.g., verbal advice to quit, referral to smoking-cessation program or counselor) and/or pharmacological therapy (47,126). Note: The type of intervention should be explicitly captured.
Denominator	All patients ≥ 18 years of age at the start of the measurement period who were identified as tobacco users who have: <ul style="list-style-type: none"> • Documented aborted SCD • Documented ventricular arrhythmias • Documented risk for SCD based on the presence of cardiomyopathy and heart failure
Denominator Exclusions	Patients who have never smoked
Denominator Exceptions	None
Measurement Period	Two-year measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record, registries
Attribution	Facility, individual provider, specialist, practice, ACO, health plan, registry

Rationale

Smoking is an established cardiovascular disease risk factor and is associated with a 2- to 4-fold increased risk of SCD (43,44,34,46). Smoking cessation is associated with decreased risk of initial and recurrent SCD (34), whereas smoking persistence is associated with an increased risk of recurrent SCD (34) and appropriate ICD shocks (35).

There is convincing evidence that legislation banning public smoking is associated with decreased risk of SCD (36,53,46).

Clinical Recommendation(s)**2006 ACC/AHA/ESC Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)**

Smoking should be strongly discouraged in all patients with suspected or documented ventricular arrhythmias and/or aborted SCD. (*Class I, Level of Evidence: B*)
USPSTF (47)

Recommendations: Ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. (*Grade A recommendation*)

Smoking cessation is associated with a reduction in risk of SCD in individuals with and without established SCD (34). The risk of SCD decreases linearly over time after quitting. Among individuals without established CHD, the risk of SCD declines significantly in less than 5 years (versus current smokers: multivariable HR 0.47; 95% CI: 0.24-0.92).

Method of Reporting

Proportion or percentage of patients meeting the measure during the measurement period.

Secondary Measures to Consider for Quality Improvement

Patients queried about tobacco use AND exposure to secondhand smoke ≥ 1 times in the past 2 years (127).

Challenges to Implementation

Sample sizes may preclude reporting of reliable performance estimates, particularly at the clinician level. Whereas this measure may prove to be easy to track on a one-time basis, it may be more complex to measure over time. For example, most EHRs have tobacco use as single variable with only 1 entry (e.g., 3/1/16), which may make it difficult to assess over time (3/1/18).

Clinicians have many time pressures. However, EHR prompts and ancillary staff members have proven effective in increasing smoking cessation counseling and referrals (49-51). Another potential challenge that may exist is the accuracy of data capture in current EHRs.

ACC indicates American College of Cardiology; ACO, accountable care organization; AHA, American Heart Association; CHD, coronary heart disease; CI, confidence interval; EHR, electronic health record; ESC, European Society of Cardiology; HR, hazard ratio; ICD, implantable cardioverter defibrillator; PM, performance measure; SCA, sudden cardiac arrest; and SCD, sudden cardiac death.

APPENDIX A. CONTINUED**QM-1: Screening for family history of SCD****Measure Description:** Percentage of patients ≥ 18 years of age who were screened for a family history of SCD.

Numerator	All patients who were screened for a family history of SCD
Denominator	All patients ≥ 18 years of age
Denominator Exclusions	<ul style="list-style-type: none"> Individuals who are adopted or have no knowledge of their family history of medical conditions Comfort care only, hospice, or any condition documented as limiting 1-year survival
Denominator Exceptions	Counseling or screening decline for patient-centric reason (social, religious, economic, or other patient reason)
Measurement Period	Two-year measurement period
Sources of Data	Prospective flow sheet, retrospective medical record review, electronic medical record
Attribution	Facility, individual provider, specialist, practice, ACO, health plan

Rationale

In the longitudinal Paris Prospective Study I, 18.6% of individuals with SCD in follow-up at baseline had reported a parental history of SCD versus 10.6% of controls, adjusted RR=1.80 (95% CI: 1.11-2.88; $p=0.01$). When restricting the parental history of SCD to age < 65 years, the RR and CIs did not change appreciably (RR=2.00; 95% CI: 1.02-3.90; $p=0.04$). The investigators noted a "dose-response" relationship, such that having 2 parents with a history of SCD was associated with a RR of 9.44, versus an RR of 1.89 for having 1 parent with a history of SCD (54).

Clinical Recommendation(s)**2006 ACC/AHA/ESC Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)**

Preparticipation history and physical examination, including family history of premature or SCD and specific evidence of cardiovascular diseases, such as cardiomyopathies and ion channel abnormalities, is recommended in athletes. (Class I, Level of Evidence: C)

2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (29)**6.3.1. SCD Risk Stratification—Recommendations Class I**

1. All patients with HCM should undergo comprehensive SCD risk stratification at initial evaluation to determine the presence of the following:

- A personal history for ventricular fibrillation, sustained VT, or SCD events, including appropriate ICD therapy for ventricular tachyarrhythmias.†
- A family history for SCD events, including appropriate ICD therapy for ventricular tachyarrhythmias.†
- Unexplained syncope.
- Documented NSVT defined as 3 or more beats at greater than or equal to 120 bpm on ambulatory (Holter) ECG.
- Maximal LV wall thickness greater than or equal to 30 mm.

6.3.1.1.2. A family history for SCD events, including appropriate ICD therapy for ventricular tachyarrhythmias.† (Class I, Level of Evidence: B) (59,60)

†Appropriate ICD discharge is defined as ICD therapy triggered by VT or VF, documented by stored intracardiac electrogram or cycle length data, in conjunction with the patient's symptoms immediately before and after device discharge.

2013 ACCF/AHA Guideline for the Management of Heart Failure (26)

Recommendations for Initial Clinical Assessment of Patients Presenting With Heart Failure

A thorough history and physical examination should be obtained/performed in patients presenting with HF to identify cardiac and noncardiac disorders or behaviors that might cause or accelerate the development or progression of HF. (Class I, Level of Evidence: C)

Method of Reporting

Proportion or percentage of patients meeting the measure during the measurement period

Secondary Measures to Consider for Quality Improvement (if any)

None

Challenges to Implementation

The measure will require manual chart abstraction for facilities without an EHR. Additionally, there is a need to ensure that the provider is documenting in the negative that a patient does not have a family history of SCD.

The sensitivity, specificity, positive predictive value, and negative predictive value of family history of SCD is uncertain (128,129).

The accuracy of the attribution for the cause of SCD on death certificates is limited when studied by autopsy (65).

There is heterogeneity in investigators' age thresholds for defining family history of SCD

- < 35 years (28); 1 or more SCD in relatives;
- < 40 years of age or SCD at any age in a relative with confirmed HCM (59);
- ≥ 2 first-degree relatives* < 40 years (67,128); < 50 years (60); ≤ 50 years (129,130); (128) < 65 years (54,56);
- premature cardiovascular disease = male < 55 years of age; female < 65 years of age, first-degree relative (68).

*First-degree relatives: family members who share about 50% of their genes with a particular individual in a family. First-degree relatives include parents, offspring, and siblings. These relatives are 1 meiosis away from the particular individual in a family

2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk (68)

Recent cardiovascular risk assessment guideline considered FH of premature cardiovascular disease optional.

If, after quantitative risk assessment, a risk-based treatment decision is uncertain, assessment of 1 or more of the following—family history, hs-CRP, CAC score, or ABI—may be considered to inform treatment decision making. (Class IIb, Level of Evidence: B)

ABI indicates ankle brachial index; ACC, American College of Cardiology; ACO, accountable care organization; AHA, American Heart Association; CAC, coronary artery calcium; CI, confidence interval; ECG, electrocardiogram; EHR, electronic health record; ESC, European Society of Cardiology; FH, family history; HF, heart failure; HCM, hypertrophic cardiomyopathy; hs-CRP, C-reactive protein; ICD, implantable cardioverter defibrillator; LV, left ventricular; NSVT, nonsustained ventricular tachycardia; QM, quality measure; RR, relative risk; SCD, sudden cardiac death; VF, ventricular fibrillation; and VT, ventricular tachycardia.

APPENDIX A. CONTINUED

QM-2: Screening for asymptomatic left ventricular dysfunction among individuals who have a strong family history of cardiomyopathy and SCD

Measure Description: Percentage of patients with a strong family history* of cardiomyopathy and SCD who had noninvasive assessment of the ejection fraction.

*Strong family history of SCD: affecting an immediate family member and/or >1 immediate or second-degree family members

Numerator	Patients who have received a noninvasive assessment of the ejection fraction who had a strong family history of cardiomyopathy or inherited disorder associated with SCD
Denominator	Patients with a strong family history [multigenerational or first-degree relative†] of cardiomyopathy or inherited heart muscle disorders associated with SCD
Denominator Exclusions	<ul style="list-style-type: none"> • Family members of patients with HCM who are genotype negative in a family with known definitive mutations • Comfort care only, hospice, or any condition documented as limiting 1-year survival
Denominator Exceptions	Counseling or screening decline for patient-centric reason (social, religious, economic, or other patient reason)
Measurement Period	One-year measurement period
Sources of Data	Paper medical record, EHR data, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, specialist, practice, facility, ACO, health plan, registry

Rationale

On the basis of the absence of any clear or consistent survival benefit of pharmacological therapy for those individuals with these genetic arrhythmia syndromes, the ICD is the preferred therapy for those with prior episodes of sustained VT or VF and may also be considered for primary prevention for some patients with a very strong family history of early mortality (27,29,71).

Clinical Recommendation(s)**2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (29)**

A TTE is recommended as a component of the screening algorithm for family members of patients with HCM unless the family member is genotype negative in a family with known definitive mutations. (Class I, Level of Evidence: B)

Periodic (12 to 18 months) TTE screening is recommended for children of patients with HCM, starting by age 12 years or earlier if a growth spurt or signs of puberty are evident and/or when there are plans for engaging in intense competitive sports or there is a family history of SCD. (Class I, Level of Evidence: C)

2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults (71)

Healthcare providers should perform a noninvasive evaluation of LV function (i.e., LVEF) in patients with a strong family history of cardiomyopathy or in those receiving cardiotoxic interventions. (Class I, Level of Evidence: C)

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)

ICD implantation is reasonable for patients with HCM who have 1 or more major† risk factors for SCD. (Class IIa, Level of Evidence: C)

4. ICD implantation is reasonable for the prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD. (Class IIa, Level of Evidence: C)

2006 ACC/AHA/ESC Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)

Echocardiography is recommended for the subset of patients at high risk for the development of serious ventricular arrhythmias or SCD, such as those with dilated, hypertrophic, or RV cardiomyopathies; AMI survivors; or relatives of patients with inherited disorders associated with SCD. (Class I, Level of Evidence: B)

2003 ACC/AHA/ASE Guideline Update for the Clinical Application of Echocardiography (131)**Section XIII. Screening**

First-degree relatives (parents, siblings, children) of patients with unexplained dilated cardiomyopathy in whom no etiology has been identified. (Class I, Level of Evidence not indicated).

Section XV-F. Congenital Cardiovascular Disease in the Infant, Child, and Adolescent Recommendations for Echocardiography in the Infant, Child, and Adolescent

Presence of a syndrome associated with cardiovascular disease and dominant inheritance or multiple affected family members (e.g., Marfan syndrome or Ehlers-Danlos syndrome). (Class I, Level of Evidence not indicated)

Method of Reporting

Percentage of patients meeting the measure during the measurement period

Secondary Measures to Consider for Quality Improvement

None

Challenges to Implementation

The Level of Evidence for most of the guideline is B or C.

However, the familial cardiomyopathies associated with SCD are uncommon, and there is not equipoise to support a RCT of echocardiogram versus no echocardiogram because of the low risk and modest cost of echocardiography and the lethality of SCD.

The complexity of the guideline may challenge primary care practitioners. There may be challenges in ensuring that the patients with a history of cardiomyopathy are readily identified. Nonetheless, efforts should be taken to appropriately identify the denominator population for this measure. It may also be determined that eliciting family history of cardiomyopathy may require additional effort on the part of the practitioner/practice. To make this a meaningful measure will require that the provider/practice obtain accurate family history for each patient to ensure that only those patients who do not have a family history of cardiomyopathy are excluded from this measure.

ACC indicates American College of Cardiology; ACO, accountable care organization; AHA, American Heart Association; AMI, acute myocardial infarction; ASE, American Society of Echocardiography; ARVD/C, arrhythmogenic right ventricular dysplasia/cardiomyopathy; EHR, electronic health record; ESC, European Society of Cardiology; HCM, hypertrophic cardiomyopathy; HRS, Heart Rhythm Society; LV, left ventricular; LVEF, left ventricular ejection fraction; QM, quality measure; RCT, randomized control trial; RV, right ventricular; SCD, sudden cardiac death; TTE, comprehensive transthoracic echocardiogram; and VT, ventricular tachycardia.

APPENDIX A. CONTINUED

2. Resuscitation/Emergency Cardiovascular Care

QM-3: Referring for CPR and AED education those family members of patients who are hospitalized with known cardiovascular conditions that increase the risk of SCA (any AMI, known heart failure, or cardiomyopathy)

Measure Description: Percentage of patients ≥ 18 years of age hospitalized with known at risk cardiovascular conditions (any AMI, HF, cardiomyopathy) in whom there is documentation that at least 1 family member has been referred for CPR and AED education.

Numerator	Patients hospitalized with a cardiovascular condition that increases the risk of SCA (any AMI, HF, cardiomyopathy) for whom there is documentation that at least 1 family member was referred for CPR and AED education
Denominator	All patients hospitalized with primary diagnosis of a cardiovascular condition that increases the risk of SCA (any AMI, HF, and cardiomyopathy)
Denominator Exclusions	<ul style="list-style-type: none"> • Patients <18 years of age • Patients expire before discharge • Patients on comfort care measures only • Patients live alone • Patients live in SNF or a nursing home
Denominator Exceptions	<ul style="list-style-type: none"> • Patients have preexisting DNAR order • Patients leave against medical advice • Referral declined for patient-centric reason (social, religious, economic, or other patient reason) • Referral declined by family members or caregivers (including because already trained)
Measurement Period	In-hospital encounter resulting in primary diagnosis of a cardiovascular condition
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, individual practice, ACO, health plan

Rationale

Provision of bystander CPR doubles survival after the onset of SCA. Application and use of an AED before arrival of EMS providers further doubles survival after the onset of cardiac arrest. Persons trained in CPR can recognize cardiac arrest and initiate compressions before the arrival of EMS providers. In most communities, the majority of laypersons have not been trained in CPR and AED use. The risk of SCA is highest during the immediate postdischarge period after hospitalization for STEMI. Family members of patients with STEMI are likely to be present on scene in the event of cardiac arrest. Therefore, by educating the family on the importance of CPR and AED training, this may increase a family member's ability to increase the survival of after onset of a cardiac event.

Clinical Recommendation(s)**2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (40)**

Untrained lay rescuers should provide compression-only CPR, with or without dispatcher assistance (*Class I, Level of Evidence: C-LD*). The rescuer should continue compression-only CPR until the arrival of an AED or rescuers with additional training (*Class I, Level of Evidence: C-LD*).

Dispatchers should instruct untrained lay rescuers to provide compression-only CPR for adults with sudden cardiac arrest (*Class I, Level of Evidence: B-R*).

All lay rescuers should, at a minimum, provide chest compressions for victims of cardiac arrest (*Class I, LOE C-LD*). In addition, if the trained lay rescuer is able to perform rescue breaths, he or she should add rescue breaths in a ratio of 30 compressions to 2 breaths. The rescuer should continue CPR until an AED arrives and is ready for use or EMS providers take over care of the victim (*Class I, Level of Evidence: C-LD*).

For lay rescuers, compression-only CPR is a reasonable alternative to conventional CPR in the adult cardiac arrest patient (*Class IIa, Level of Evidence: C-LD*). For trained lay rescuers, it is reasonable to provide ventilation in addition to chest compressions for the adult in cardiac arrest (*Class IIa, Level of Evidence: C-LD*).

For victims with suspected spinal injury, rescuers should initially use manual spinal motion restriction (e.g., placing 1 hand on either side of the patient's head to hold it still) rather than immobilization devices, because use of immobilization devices by lay rescuers may be harmful (*Class III, Harm, Level of Evidence: C-LD*).

Method of Reporting

Proportion or percentage of patients meeting the measure during the measurement period.

Secondary Measures to Consider for Quality Improvement (if any)

None

Challenges to Implementation

Challenges may exist to implementation of this measure in situations where the patient is estranged from his or her family, where the family members work and are unable to meet with the provider, where the family members are non-English speakers, or where the patient or his or her family members have low health literacy. This can in turn impact the ability of the providers to adequately communicate to family members the condition and its prevention. Other challenges that may exist include tracking this information in an EHR, because such a data element is not routinely captured. Resources will need to be allocated at the hospital level to provide the education and training, which is currently not standard practice.

ACO indicates accountable care organization; AED, automated external defibrillator; AHA, American Heart Association; AMI, acute myocardial infarction; CPR, cardiopulmonary resuscitation; DNAR, do not attempt resuscitation; EHR, electronic health record; EMS, emergency medical services; HF, heart failure; QM, quality measure; SCA, sudden cardiac arrest; SNF, skilled nursing facility; and STEMI, ST-segment-elevation myocardial infarction.

APPENDIX A. CONTINUED

3. Heart Failure/General Cardiology Measures

PM-2: Use of ICD for prevention of SCD in patients with HF and reduced ejection fraction with an anticipated survival of >1 year

Measure Description: Percentage of patients ≥ 18 years of age with diagnosis of HF and NYHA Class II or III and a quantitative ejection fraction $\leq 35\%$ on most recent measurement despite guideline-directed medical therapy, with an anticipated survival of >1 year, who received an ICD for prevention of SCD.

Numerator	Patients who have received an ICD or who already have an ICD in place
Denominator	All patients ≥ 18 years of age with: <ol style="list-style-type: none"> History of an MI ≥ 40 days and ischemic cardiomyopathy with an ejection fraction $\leq 35\%$ and Class II or III HF symptoms History of an MI ≥ 40 days and ischemic cardiomyopathy with an ejection fraction $\leq 30\%$ and Class I HF symptoms Class II or III HF symptoms and nonischemic cardiomyopathy of ≥ 3-month duration (27)
Denominator Exclusions (if any)	Documentation of reasons for not providing ICD implantation as a treatment option for the prophylaxis of sudden cardiac death, including: <ul style="list-style-type: none"> NYHA Class I or IV functional status on most recent visit Patients with acute MI within the prior 40 days Revascularization with CABG or PCI within the prior 90 days Patients with newly diagnosed HF (<3 months) Patients not receiving guideline-directed medical therapy (<3 months) Contraindications to implantation of a device, such as infection, comfort care only, hospice, or any condition documented as limiting 1-year survival
Denominator Exceptions (if any)	<ul style="list-style-type: none"> Not receiving guideline-directed medical therapy because of contraindications Counseling or screening decline for patient-centric reason (e.g., social, religious, economic, or other patient reason) Patients with an active infection that in the opinion of the treating physician precludes ICD implantation Patients documented to have been counseled about an ICD in the past 1 year
Measurement Period	One-year measurement period (ICD in place at any visit in most recent year)
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, individual practice, ACO, health plan

Rationale

ICDs have proved effective at preventing sudden cardiac death due to ventricular tachyarrhythmias in a clearly defined subset of patients with HF and those after MI. As a result, ICD implantation is recommended in patients with a sustained reduction of EF ($\leq 35\%$) despite guideline-directed medical therapy and mild to moderate symptoms of HF and in whom survival with good functional capacity is otherwise anticipated to extend beyond 1 year. Given the significant benefits of ICD implantation, eligible patients should receive this treatment in the absence of contraindications.

Clinical Recommendation(s)**2013 ACCF/AHA Guideline for the Management of Heart Failure (26)**

ICD therapy is recommended for primary prevention of SCD to reduce total mortality in selected patients with nonischemic Dilated cardiomyopathy (DCM) or ischemic heart disease at least 40 days post-MI with LVEF of 35% or less and NYHA Class II or III symptoms on chronic (GDMT), who have reasonable expectation of meaningful survival for more than 1 year. (Class I, Level of Evidence: A) (26)

Method of Reporting

Percentage of patients meeting the measure during the measurement period.

Secondary Measures to Consider for Quality Improvement

Percentage of patients ≥ 18 years of age with diagnosis of prior MI, NYHA Class I, and a current quantitative ejection fraction $\leq 30\%$ despite guideline-directed medical therapy who received an ICD for prevention of sudden cardiac death.

2013 ACC/AHA Guideline for the Management of Heart Failure (26)

To prevent sudden death, placement of an ICD is reasonable in patients with asymptomatic ischemic cardiomyopathy who are at least 40 days MI, have an LVEF of 30% or less, are on appropriate medical therapy, and have reasonable expectation of survival with a good functional status for more than 1 year (26). (Class IIa, Level of Evidence: B)

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)

ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. (Class I, Level of Evidence: A)

Challenges to Implementation

Challenges in obtaining documentation of quantified ejection fraction or exceptions to ICD use. Other potential challenges exist with regard to potential patients who are undocumented or are uninsured.

ACC indicates American College of Cardiology; ACO, accountable care organization; AHA, American Heart Association; CABG, coronary artery bypass graft; DCM, dilated cardiomyopathy; EF, ejection fraction; EHR, electronic health record; HF, heart failure; HRS, Heart Rhythm Society; ICD, implantable cardioverter defibrillator; LV, left ventricular; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PM, performance measure; and SCD, sudden cardiac death.

APPENDIX A. CONTINUED

PM-3: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for prevention of SCD in patients with HF and reduced ejection fraction

Measure Description: Percentage of patients ≥ 18 years of age with diagnosis of HF and a current quantitative ejection fraction $< 40\%$ who received guideline-directed medical therapy (ACE-I or ARB or ARNI, and beta-blocker, and aldosterone receptor antagonist) for the prevention of SCD.

Numerator	Patients who have been prescribed guideline-directed medical therapy (ACE-I or ARB or ARNI, and a beta-blocker, and an aldosterone receptor antagonist*)
	*If documented to be NYHA Class I or ejection fraction 36%–40%, aldosterone receptor antagonist use can be omitted.
Denominator	All patients ≥ 18 years of age with a diagnosis of HF and a quantitative ejection fraction $< 40\%$
Denominator Exclusions (if any)	<ul style="list-style-type: none"> • Patients are in palliative care or hospice • Patients' life expectancy is < 1 year
Denominator Exceptions (if any)	<ul style="list-style-type: none"> • No adherence to medical therapy for reasons that are appropriately documented (e.g., contraindication, intolerance to medication, or side effect) • Counseling or screening decline for patient-centric reason (e.g., social, religious, economic, or other patient reason) • Patients have NYHA Class I or ejection fraction 36%–40%, and aldosterone antagonist was omitted • Patients with hyperkalemia within the past 3 years and not in the setting if acutely ill
Measurement Period	Most recent ambulatory care setting visit
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, individual practice, ACO, health plan

Rationale

Guideline-directed medical therapy has been shown to reduce the incidence of SCD in patients with left ventricular dysfunction and symptomatic HF.

Clinical Recommendation(s)**2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure (25)**

The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (*Class I, Level of Evidence: A*), or ARBs (*Class I, Level of Evidence: A*), or ARNI (*Class I, Level of Evidence: B-R*), in conjunction with evidence-based beta-blockers, and aldosterone antagonists in selected patients, is recommended for patients with chronic HFrEF to reduce morbidity and mortality (25).

2013 ACCF/AHA Guideline for the Management of Heart Failure (26)

7.3.2.2. ACE Inhibitors: Recommendation: ACE inhibitors are recommended in patients with HFrEF and current or prior symptoms, unless contraindicated, to reduce morbidity and mortality (26). (*Class I, Level of Evidence: A*)

7.3.2.3. ARBs: Recommendation: ARBs are recommended in patients with HFrEF with current or prior symptoms who are ACE inhibitor intolerant, unless contraindicated, to reduce morbidity and mortality (26). (*Class I, Level of Evidence: A*)

7.3.2.4. Beta-Blockers: Recommendation: Use of 1 of the 3 beta-blockers proven to reduce mortality (i.e., bisoprolol, carvedilol, and sustained-release metoprolol succinate) is recommended for all patients with current or prior symptoms of HFrEF, unless contraindicated, to reduce morbidity and mortality (26). (*Class I, Level of Evidence: A*)

7.3.2.5. Aldosterone Receptor Antagonists: Recommendation: Aldosterone receptor antagonists (or mineralocorticoid receptor antagonists) are recommended in patients with NYHA Class II-IV and who have LVEF of 35% or less, unless contraindicated, to reduce morbidity and mortality (26).

Method of Reporting

Composite performance measure: percentage of patients meeting the composite measure during the measurement period. Defect-free care (all or none) is primary reporting method, with opportunity-based reporting as a secondary reporting method.

Secondary Measures to Consider for Quality Improvement

None

Challenges to Implementation

Challenges in obtaining documentation of NYHA functional class, potassium, creatinine, and heart rate.

ACC indicates American College of Cardiology; ACE, angiotensin-converting enzyme inhibitor; ACO, accountable care organization; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin-receptor/neprilysin inhibitor; EHR, electronic health record; HF, heart failure; HFrEF heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PM, performance measure; and SCD, sudden cardiac death.

APPENDIX A. CONTINUED

PM-4: Use of guideline-directed medical therapy (ACE-I or ARB or ARNI, beta-blocker, aldosterone receptor antagonist) for the prevention of SCD in patients with MI and reduced ejection fraction

Measure Description: Percentage of patients ≥ 18 years of age with diagnosis of MI, and a current quantitative ejection fraction $< 40\%$ who received guideline-directed medical therapy (ACE-I or ARB or ARNI (valsartan/sacubitril), beta-blocker, aldosterone receptor antagonist) before hospital discharge.

Numerator	Patients who were prescribed guideline-directed medical therapy (ACE-I or ARB or ARNI, and a beta-blocker, and an aldosterone receptor antagonist*) at hospital discharge
	*If documented to have diabetes or NYHA II-IV HF.
Denominator	All patients ≥ 18 years of age with a MI during hospital stay and a quantitative ejection fraction $< 40\%$
Denominator Exclusions (if any)	<ul style="list-style-type: none"> • Patients who die before discharge • Patients who leave against medical advice • Patients with a limited life expectancy of < 1 year • Patients are in palliative care or hospice
Denominator Exceptions (if any)	<ul style="list-style-type: none"> • No adherence to medical therapy for reasons that are appropriately documented (e.g., contraindication, intolerance to medication, or side effect) • Counseling or screening decline for patient-centric reason (social, religious, economic, or other patient reason) • Patients who are participant in a clinical trial • Patients with hyperkalemia within the past 3 years and not in the setting of acutely ill
Measurement Period	Assessed at hospital discharge
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, individual practice, ACO, health plan, and facility

Rationale

Guideline-directed medical therapy has been shown to reduce the incidence of SCD in patients with a MI with left ventricular dysfunction.

Clinical Recommendation(s)**2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure (25)**

The clinical strategy of inhibition of the renin-angiotensin system with ACE inhibitors (*Class I, Level of Evidence: A*), or ARBs (*Class I, Level of Evidence: A*), or ARNI (*COR Class I, Level of Evidence: B-R*), in conjunction with evidence-based beta-blockers, and aldosterone antagonists in selected patients, is recommended for patients with chronic HFrEF to reduce morbidity and mortality (25).

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction (132)

An angiotensin-converting enzyme (ACE) inhibitor should be administered within the first 24 hours to all patients with STEMI with anterior location, HF, or ejection fraction (EF) less than or equal to 0.40, unless contraindicated (132). (*Class I, Level of Evidence: A*)

An angiotensin receptor blocker (ARB) should be given to patients with STEMI who have indications for but are intolerant of ACE inhibitors (132). (*Class I, Level of Evidence: B*)

An aldosterone antagonist should be given to patients with STEMI and no contraindications who are already receiving an ACE inhibitor and beta-blocker and who have an EF less than or equal to 0.40 and either symptomatic HF or diabetes mellitus (132). (*Class I, Level of Evidence: B*)

Method of Reporting

Composite performance measure: percentage of patients meeting the composite measure during the measurement period. Defect-free care (all or none) is primary reporting method, with opportunity-based reporting as a secondary reporting method.

Secondary Measures to Consider for Quality Improvement

None

Challenges to Implementation

Challenges in obtaining documentation of EF, hyperkalemia, renal dysfunction or bradycardia, potassium, creatinine, and heart rate.

ACC indicates American College of Cardiology; ACE-I, angiotensin-converting enzyme inhibitor; ACO, accountable care organization; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin-receptor/neprilysin inhibitor; EF, ejection fraction; EHR, electronic health record; HF, heart failure; HFrEF heart failure with reduced ejection fraction; HFSA, Heart Failure Society of America; ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PM, performance measure; and STEMI, ST-segment-elevation myocardial infarction.

APPENDIX A. CONTINUED

4. Electrophysiology Measures

PM-5: Documenting the absence of reversible causes for VT/VF cardiac arrest and/or sustained VT before a secondary-prevention ICD is placed

Measure Description: Percentage of patients ≥ 18 years of age who received an ICD after presenting with VT/VF cardiac arrest or sustained VT with a documented absence of reversible cause of VT/VF cardiac arrest or sustained VT.

Numerator	<p>Patients presenting with VT/VF cardiac arrest and/or sustained VT for whom there is documentation of the absence of reversible causes for the index cardiac arrest event before a secondary-prevention ICD is implanted</p> <p>Note: Reversible causes can include:</p> <ol style="list-style-type: none"> 1. Acute MI as evidenced by serial cardiac biomarkers 2. Electrolyte abnormalities (hypokalemia and hypomagnesemia) 3. Decompensated HF requiring a change in HF treatment 4. Medication (proarrhythmic) 5. During PCI 6. Within 24 hours after CABG or valvular surgery 7. Drug abuse 8. Myocarditis, autoimmune, toxic, inflammatory, infectious, or infiltrative cardiomyopathies
Denominator	All patients ≥ 18 years of age presenting with VT/VF cardiac arrest and/or sustained VT who receive an ICD
Denominator Exclusions (if any)	<ul style="list-style-type: none"> • Patients who die in the hospital • Patients who leave against medical advice • Patients already with an ICD in place • Patients with a limited life expectancy of < 1 year • Patients being treated with a wearable defibrillator • Patients who meet criteria for a primary-prevention ICD • Patients with end-stage renal disease • Patients with an active infection that in the opinion of the treating physician precludes implantation of an ICD
Denominator Exceptions (if any)	<ul style="list-style-type: none"> • Patients who refuse testing needed to rule out reversible causes • Counseling or screening decline for patient-centric reason (social, religious, economic, or other patient reason)
Measurement Period	The in-hospital encounter resulting from the VT/VF cardiac arrest or sustained VT
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data (NCDR ICD Registry after modification of the data elements)
Attribution	Individual provider, individual practice, health plan

Rationale

VT/VF cardiac arrest and sustained VT due to reversible causes are best treated by addressing the cause, and per the guidelines, in these settings, an ICD should not be implanted.

Clinical Recommendation(s)**2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)**

ICD therapy is indicated in patients who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. (Class IIa, Level of Evidence: A)

2006 ACC/AHA/ESC Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)

Myocardial revascularization should be performed, when appropriate, to reduce the risk of SCD in patients experiencing cardiac arrest due to VF or polymorphic VT in the setting of acute ischemia or MI. (Class I, Level of Evidence: C)

Unless electrolyte abnormalities are proved to be the cause, survivors of cardiac arrest due to VF or polymorphic VT in whom electrolyte abnormalities are discovered in general should be evaluated and treated in a similar manner to that of cardiac arrest without electrolyte abnormalities. (Class I, Level of Evidence: C)

Patients who experience sustained monomorphic VT in the presence of antiarrhythmic drugs or electrolyte abnormalities should be evaluated and treated in a manner similar to that of patients with VT without electrolyte abnormalities or antiarrhythmic drugs present. Antiarrhythmic drugs or electrolyte abnormalities should not be assumed to be the sole cause of sustained monomorphic VT. (Class I, Level of Evidence: B)

Patients who experience polymorphic VT in association with prolonged QT interval due to antiarrhythmic medications or other drugs should be advised to avoid exposure to all agents associated with QT prolongation. A list of such drugs can be found on the Web sites www.qtdrugs.org and www.torsades.org. (Class I, Level of Evidence: B)

Method of Reporting

Proportion or percentage of patients meeting the measure during the measurement period

Secondary Measures to Consider for Quality Improvement (if any)

If reversible causes are addressed and patient is not currently a candidate for a primary-prevention device because of MI, acute HF, new-onset HF, or recent CABG, is there a plan in place to reassess the patient's candidacy for a primary-prevention ICD during follow-up?

Challenges to Implementation

Getting consensus on what "ruling out reversible causes" means and how much testing is adequate. To that end, we propose the following list of reversible causes*:

1. Acute MI and acute coronary syndrome, as evidenced by serial cardiac biomarkers
2. Electrolyte abnormalities (hypokalemia and hypomagnesemia)
3. Decompensated HF requiring a change in HF treatment
4. Medication (proarrhythmic)
5. During PCI; within 24 hours after CABG or valvular surgery
6. Drug abuse
7. Myocarditis, autoimmune, toxic, inflammatory, infectious, or infiltrative cardiomyopathies

APPENDIX A. CONTINUED

Challenges to Implementation

Evidence base for reversible causes:*2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)**

1. ICD therapy is indicated in patients who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. (*Class I, Level of Evidence: A*) (27)
2. ICD therapy is not indicated for patients with ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma). (*Class III, Level of Evidence: B*) (27)

*Some individuals are resuscitated from cardiac arrest due to possible transient reversible causes. In such patients, myocardial revascularization may be performed when appropriate to reduce the risk of recurrent sudden cardiac death, with individualized decisions made with regard to the need for ICD therapy (20). Sustained monomorphic VT with prior MI is unlikely to be affected by revascularization (20). Myocardial revascularization may be sufficient therapy in patients surviving VF in association with myocardial ischemia when ventricular function is normal and there is no history of an MI (27).

Unless electrolyte abnormalities are proven to be the sole cause of cardiac arrest, survivors of cardiac arrest in whom electrolyte abnormalities are discovered in general should be treated in a manner similar to that of cardiac arrest survivors without electrolyte abnormalities (27).

2006 ACC/AHA/ESC Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)**Management of cardiac arrest**

1. Reversible causes and factors contributing to cardiac arrest should be managed during advanced life support, including management of hypoxia, electrolyte disturbances, mechanical factors, and volume depletion. (*Class I, Level of Evidence: C*) (20)

Transient Arrhythmias of Reversible Cause Recommendations (91-97,133-135)

1. Myocardial revascularization should be performed, when appropriate, to reduce the risk of SCD in patients experiencing cardiac arrest due to VF or polymorphic VT in the setting of acute ischemia or MI. (*Class I, Level of Evidence: C*) (20)
2. Unless electrolyte abnormalities are proven to be the cause, survivors of cardiac arrest due to VF or polymorphic VT in whom electrolyte abnormalities are discovered in general should be evaluated and treated in a manner similar to that of cardiac arrest without electrolyte abnormalities. (*Level of Evidence: C*) (20)
3. Patients who experience sustained monomorphic VT in the presence of antiarrhythmic drugs or electrolyte abnormalities should be evaluated and treated in a manner similar to that of patients with VT without electrolyte abnormalities or antiarrhythmic drugs present. Antiarrhythmic drugs or electrolyte abnormalities should not be assumed to be the sole cause of sustained monomorphic VT. (*Level of Evidence: B*) (20)
4. Patients who experience polymorphic VT in association with prolonged QT interval due to antiarrhythmic medications or other drugs should be advised to avoid exposure to all agents associated with QT prolongation. A list of such drugs can be found on the Web sites www.qtdrugs.org and www.torsades.org. (*Level of Evidence: B*) (20)

ACC indicates American College of Cardiology; AHA, American Heart Association; CABG, coronary artery bypass graft; EHR, electronic health record; ESC, European Society of Cardiology; HF, heart failure; HRS, Heart Rhythm Society; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; PCI, percutaneous coronary intervention; PM, performance measure; SCD, sudden cardiac death; VF, ventricular fibrillation; and VT, ventricular tachycardia.

APPENDIX A. CONTINUED

PM-6: Counseling eligible patients about an ICD

Measure Description: Percentage of patients ≥ 18 years of age who have an indication for and are eligible for an ICD in whom counseling for an ICD is documented to have occurred.

Numerator	Patients who are eligible for an ICD who are counseled about the potential benefits of ICD implantation
Denominator	All patients ≥ 18 years of age who are on optimal medical therapy and are eligible for a primary-prevention ICD on the basis of the following criteria: 1. History of an MI ≥ 40 days and ischemic cardiomyopathy with an ejection fraction $\leq 35\%$ and Class II or III HF symptoms 2. History of an MI ≥ 40 days and ischemic cardiomyopathy with an ejection fraction $\leq 30\%$ and Class I HF symptoms 3. Class II or III HF symptoms and nonischemic cardiomyopathy of ≥ 3 -month duration (27)
Denominator Exclusions (if any)	<ul style="list-style-type: none"> • Patients with a limited life expectancy of < 1 year. Patients with NYHA Class IV HF symptoms who are not candidates for advanced HF therapies • Patients with an ICD • Patients with an acute MI within the prior 40 days • Patients with newly diagnosed HF (< 3 months) • Patients not receiving guideline-directed medical therapy (< 3 months) • Revascularization with CABG or PCI within the prior 90 days • Contraindication to implantation of a device, such as infection, comfort care only, hospice, or any condition documented as limiting 1-year survival
Denominator Exceptions (if any)	<ul style="list-style-type: none"> • Patients with an active infection that in the opinion of the treating physician precludes ICD implantation • Patients documented to have been counseled about an ICD in the past 1 year • Not receiving guideline-directed medical therapy because of contraindications • Counseling or screening decline for patient-centric reason (social, religious, economic, or other patient reason)
Measurement Period	Most recent ambulatory care setting visit
Sources of Data	EHR data, paper medical record, administrative data/claims (inpatient or outpatient claims), administrative data/claims expanded (multiple-source), registry data
Attribution	Individual provider, individual practice, ACO, health plan.

Rationale

Primary-prevention ICDs have been shown to save lives.

Clinical Recommendation(s)**2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (27)**

ICD therapy is indicated in patients with LVEF less than or equal to 35% due to prior MI who are at least 40 days after MI and are in NYHA functional class II or III (27). (Class I, Level of Evidence: A)

ICD therapy is indicated in patients with nonischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional class II or III (27). (Class I, Level of Evidence: B) ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30%, and are in NYHA functional Class I. (Class I, Level of Evidence: A)

2006 ACC/AHA/ESC Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)

See Table 3 in the document.

Method of Reporting

Proportion or percentage of patients meeting the measure during the measurement period

Secondary Measures to Consider for Quality Improvement (if any)

If patient is not currently a candidate for a primary-prevention device because of MI, acute HF, new-onset HF, or recent CABG, is there a plan in place to reassess the patient's candidacy for a primary-prevention ICD during follow-up

Challenges to Implementation

One potential challenge for implementation and evaluation of this measure is that it will be difficult to assess the quality of the counseling interaction unless formal counseling tools are used for shared decision making with the patient and family/caregiver.

ACC indicates American College of Cardiology; ACO, accountable care organization; AHA, American Heart Association; CABG, coronary artery bypass graft; DCM, dilated cardiomyopathy; EHR, electronic health record; ESC, European Society of Cardiology; HF, heart failure; HRS, Heart Rhythm Society; ICD, implantable cardioverter defibrillator; LV, left ventricular; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; and PM, performance measure.

APPENDIX A. CONTINUED

QM-4: Counseling of first-degree relatives of survivors of SCA associated with an inheritable condition

Measure Description: Percentage of patients ≥ 18 years of age who survived a SCA with a confirmed diagnosis of an inheritable condition associated with increased risk of SCD for whom clinical documentation confirms that their first-degree relatives have been notified of the need for screening.

Numerator	Survivors of SCA attributable to a confirmed diagnosis of an inheritable condition (including hypertrophic cardiomyopathy, long-QT syndrome, short-QT syndrome, ARVC, catecholaminergic polymorphic VT, and sudden unexpected death syndrome) associated with increased risk of sudden cardiac death for whom clinical documentation confirms that their first-degree relatives have been notified of the need for screening.
Denominator	<ul style="list-style-type: none"> All survivors of SCA attributable to a confirmed diagnosis of an inheritable condition associated with increased risk of sudden cardiac death Patients ≥ 18 years of age
Denominator Exclusions (if any)	Those SCA survivors who are adopted or who have no known surviving first-degree relatives.
Denominator Exceptions (if any)	Those SCA survivors for whom cardiac arrest is <i>not</i> believed to be due to an inheritable condition
Measurement Period	One year after the SCA event
Sources of Data	Prospective flowsheet, retrospective medical record review, electronic medical record, claims data, registry data, etc. (modify as appropriate), chart review (documentation in the medical record)
Attribution	Facility, individual provider, specialist, practice, ACO

Rationale

Some conditions associated with SCD (such as LQTS, HCM, ARVC, catecholaminergic polymorphic VT, etc.) can be associated with identifiable risk of sudden cardiac death based on abnormalities on ECG (e.g., LQTS) or by echocardiography (such as ARVC, DCM, and HCM).

2006 ACC/AHA/ESC Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)

- The clinical applicability of genetic analysis to DCM is still limited, as knowledge in this area does not allow genotyping most individuals clinically affected by the disease. Patients with DCM and AV block and patients with DCM and skeletal muscle diseases have higher probability of being successfully genotyped. When a pathogenetic mutation is identified, it becomes possible to establish a presymptomatic diagnosis of the disease among family members and provide them with genetic counseling to monitor progression of the disease and to assess the risk of transmitting the disease to offspring. According to current knowledge, genetic analysis does not contribute to risk stratification in DCM.
- Genetic analysis is useful in families with HCM because whenever a pathogenetic mutation is identified, it becomes possible to establish a presymptomatic diagnosis of the disease among family members and to provide them with genetic counseling to assess the risk of disease development and transmission of the disease to offspring. Genetic analysis may contribute to risk stratification in selected circumstances.
- Genetic analysis is useful in families with RV cardiomyopathy because whenever a pathogenetic mutation is identified, it becomes possible to establish a presymptomatic diagnosis of the disease among family members and to provide them with genetic counseling to monitor the development of the disease and to assess the risk of transmitting the disease to offspring. According to current knowledge, genetic analysis does not contribute to risk stratification of arrhythmogenic RV cardiomyopathy.
- Genetic analysis is very important for identifying all mutation carriers within an LQTS family: Once identified, silent carriers of LQTS genetic defects may be treated with beta-blockers for prophylaxis of life-threatening arrhythmias. Furthermore, silent mutation carriers should receive genetic counseling to learn about the risk of transmitting LQTS to offspring.
- Genetic analysis may help identify silent carriers of short-QT syndrome-related mutations; however, the risk of cardiac events in genetically affected individuals with a normal ECG is currently not known. The risk is also unknown because of the limited number of patients with short-QT syndrome identified to date. At present, genetic analysis does not contribute to risk stratification.
- Genetic analysis may help identify silent carriers of catecholaminergic VT-related mutations; once identified, silent carriers may be treated with beta-blockers to reduce the risk of cardiac events and may receive appropriate genetic counseling to assess the risk of transmitting the disease to offspring. According to current knowledge, genetic analysis does not contribute to further risk stratification.

Clinical Recommendation(s)**2006 ACC/AHA/ESC Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (20)**

Echocardiography is recommended for the subset of patients at high risk for the development of serious ventricular arrhythmias or SCD, such as those with dilated, hypertrophic, or RV cardiomyopathies, AMI survivors, or relatives of patients with inherited disorders associated with SCD. (Class I, Level of Evidence: B)

Method of Reporting

The proportion of first-degree relatives* meeting the measure criteria within the year after the sentinel event in the index patient with the inheritable condition.

*First-degree relatives: family members who share about 50% of their genes with a particular individual in a family. First-degree relatives include parents, offspring, and siblings. These relatives are 1 meiosis away from the particular individual in a family.

Secondary Measures to Consider for Quality Improvement (if any)

N/A

Challenges to Implementation

This measure will require manual chart abstraction from medical records. Another potential limitation of this measure is that it may be difficult to ascertain the quality of the counseling that was provided to the patient with regard to the benefits and risk of ICD placement.

ACC indicates American College of Cardiology; AMI, acute myocardial infarction; ACO, accountable care organization; AHA, American Heart Association; ARVC, arrhythmogenic right ventricular cardiomyopathy, AV, atrioventricular; DCM, dilated cardiomyopathy; ECG, electrocardiogram; ESC, European Society of Cardiology; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator; LQTS, long-QT syndrome; PCI, percutaneous coronary intervention; QM, quality measure; RV, right ventricular; SCD, sudden cardiac death; and VT, ventricular tachycardia.

APPENDIX B. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES—2016 AHA/ACC CLINICAL PERFORMANCE AND QUALITY MEASURES FOR PREVENTION OF SUDDEN CARDIAC DEATH

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Sana Al-Khatib, Co-Chair	Duke University Medical Center	None	None	None	None	None	None
Clyde Yancy, Co-Chair	Northwestern University, Feinberg School of Medicine	None	None	None	None	None	None
Lance B. Becker	North Shore University	• Philips Medical†	None	None	• Medtronic Foundation* • Benechill* • Zoll Medical* • Philips Medical*	None	None
Emelia J. Benjamin	Boston University	None	None	None	None	None	None
Roger G. Carrillo	University of Miami Hospital	• Sensomatic/TYCO • Spectranetics	• Biotronik • Sorin Group	None	None	None	None
Justin A. Ezekowitz	Mazankowski Alberta Heart Institute	• Servier • Astra-Zeneca • Pfizer • Abbott Labs • Bristol-Meyers-Squibb	None	None	Amgen	None	None
Gregg C. Fonarow	Ahmanson-UCLA Cardiomyopathy Center Division of Cardiology	• Medtronic • Novartis* • Boston Scientific	None	None	Novartis*	• Medtronic (Steering Committee IMPROVE-HF)	None
Bharat K. Kantharia	University of Texas Medical School at Houston	None	None	None	None	None	None
Monica Kleinman	Boston Children's Hospital	None	None	Arcadia Solutions†	None	None	None
Graham Nichol	University of Washington	None	None	None	• Phillips Healthcare Inc.† • ZOLL Inc.†	None	None
Penelope Solis	American College of Cardiology	None	None	None	None	None	None
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This table represents all relationships of committee members with industry and other entities. 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% or more of the voting stock or share of the business entity, or ownership of \$10,000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. 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*.

*No financial relationship.

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

ACC indicates American College of Cardiology; AHA, American Heart Association; and IMPROVE-HF, Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting Study; UCLA, University of California Los Angeles; and VA, Veterans Affairs.

APPENDIX C. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES— 2016 AHA/ACC CLINICAL PERFORMANCE AND QUALITY MEASURES FOR PREVENTION OF SUDDEN CARDIAC DEATH

Peer Reviewer	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Fred M. Kusumoto	Official HRS	None	None	None	None	None	None
Frederick A. Masoudi	Official ACC (BOT)	None	None	None	None	<ul style="list-style-type: none"> Health Services Advisory Group† Health Services Advisory Group† 	None
Juan C. Sotomonte	Official ACC (BOG)	<ul style="list-style-type: none"> Boston Scientific* 	None	None	<ul style="list-style-type: none"> Medtronic-Adaptive CRT† 	None	None
William G. Stevenson	Official AHA	<ul style="list-style-type: none"> St Jude Medical 	None	None	None	<ul style="list-style-type: none"> Patent for needle ablation* 	None
Biykem Bozkurt	Content: 2009 Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults	None	None	None	<ul style="list-style-type: none"> Novartis RELAX-AHF-2 Clinical Trial Enroller 	None	None
Mark S. Kremers	Content: ACC ICD Steering Committee	None	<ul style="list-style-type: none"> Boston Scientific† 	<ul style="list-style-type: none"> Boston Scientific† 	<ul style="list-style-type: none"> Boston Scientific-S-ICD Post Approval Study* Medtronic-Wrap it* St Jude Medical* 	<ul style="list-style-type: none"> Boston Scientific Medtronic–Data Safety Monitoring Board 	None
Peter J. Kudenchuk	Content: AHA ECC Committee	None	None	None	None	<ul style="list-style-type: none"> Abbott Laboratories GlaxoSmithKline Merck Novartis Pfizer Sanofi-Aventis 	<ul style="list-style-type: none"> 2015, Defendant, Wrongful death
James McCarthy	Content: AHA Mission Lifeline	None	None	None	None	None	None
Gregg Miller	Content: American College of Emergency Physicians	None	None	None	None	None	None
Cynthia M. Tracy	Content: ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities	None	None	None	None	None	None

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ACC indicates American College of Cardiology; ACCF, American College of Cardiology Foundation; AHA, American Heart Association; BOG, Board of Governors; BOT, Board of Trustees; CRT, cardiac resynchronization therapy; ECC, emergency cardiovascular care; HRS, Heart Rhythm Society; ICD, implantable cardioverter defibrillator; RELAX-AHF-2, Efficacy, Safety and Tolerability of Serelaxin When Added to Standard Therapy in AHF; and S-ICD, subcutaneous-implantable cardioverter defibrillator.