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APPROPRIATE USE CRITERIA

ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

Endorsed by the American Geriatrics Society

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Abstract

The American College of Cardiology Foundation in collaboration with the Heart Rhythm Society and key specialty and subspecialty societies conducted a review of common clinical scenarios where implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) are frequently considered. The clinical scenarios covered in this document address secondary prevention, primary prevention, comorbidities, generator replacement at elective replacement indicator, dual-chamber ICD, and CRT.

The indications (clinical scenarios) were derived from common applications or anticipated uses, as well as from current clinical practice guidelines and results of studies examining device implantation. The 369 indications in this document were developed by a multidisciplinary writing group and scored by a separate independent technical panel on a scale of 1 to 9 to designate care that is Appropriate (median 7 to 9), May Be Appropriate (median 4 to 6), and

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Rarely Appropriate (median 1 to 3). The final ratings reflect the median score of the 17 technical panel members: 45% of the indications were rated as Appropriate, 33% were rated May Be Appropriate and 22% were rated Rarely Appropriate.

In general, Appropriate designations were assigned to scenarios for which clinical trial evidence and/or clinical experience was available that supported device implantation. By contrast, scenarios for which clinical trial evidence was limited or device implantation seemed reasonable for extenuating reasons were categorized as May Be Appropriate. Scenarios for which there were data showing harm, or no data were available, and medical judgment deemed device therapy ill-advised were categorized as Rarely Appropriate. For example, comorbidities including life expectancy and cognitive function impacted appropriateness ratings.

The Appropriate Use Criteria for ICD/CRT have the potential to enhance physician decision making, healthcare delivery, and reimbursement policy. Furthermore, recognition of clinical scenarios rated as May Be Appropriate facilitates the identification of areas that would benefit from future research.

Preface

In an effort to respond to the need for the rational use of cardiovascular services including imaging and invasive procedures in the delivery of high-quality care, the American College of Cardiology Foundation (ACCF) in collaboration with the Heart Rhythm Society (HRS) has undertaken a process to describe the appropriate use of implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) for selected patient populations.

Appropriate use criteria (AUC) publications reflect an ongoing effort by the ACCF to critically and systematically create, review, and categorize clinical situations where physicians utilize diagnostic tests and procedures to care for patients with cardiovascular disease. The process is based on current understanding of the benefits and risks of the procedures examined. Although impossible to be entirely comprehensive given the wide diversity of clinical disease, the indications are meant to identify common clinical scenarios encompassing the majority of situations encountered in contemporary practice. Given the breadth of information they convey, the indications do not directly correspond to the *Ninth Revision of the International Classification of Diseases* system, as these codes do not include clinical information such as disease severity or symptom status.

The ACCF and HRS believe that careful blending of a broad range of clinical experiences and available evidence-based information will help guide a more efficient and equitable allocation of healthcare resources in cardiovascular care and device implantation. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner, but it is not intended to ignore uncertainty and nuance intrinsic to clinical decision making. Therefore, AUC should not be considered substitutes for sound clinical judgment and practice experience.

The AUC process itself is also evolving. The initial AUC documents were directed primarily towards noninvasive cardiovascular imaging tests. Revisions to several of these imaging documents have already been published (1–3). The goal for the AUC process is to provide contemporary reference documents that incorporate new research in a timely manner, including the results of AUC implementation studies. AUC for ICD and CRT is the third in a more recent series of AUC documents that examine the use of invasive procedures (4,5). Because ICDs and CRT play a central role in the care of patients with cardiovascular disease, guidance around the rationale and evidence-based use of the procedure is the goal of the current document.

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1. Introduction

The American College of Cardiology Foundation (ACCF), in collaboration with the Heart Rhythm Society (HRS), developed common clinical scenarios where implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT), also known as biventricular pacing, are frequently considered. These implanted devices are also collectively referred to as cardiovascular implantable electronic devices (CIEDs). The indications, as presented in these clinical scenarios, were derived from common presentations or anticipated uses, as well as from current clinical practice guidelines. The 369 indications in this document were developed by a writing group with diverse clinical expertise and rated by a separate independent technical panel on a scale of 1 to 9, to designate care that is Appropriate (median 7 to 9), May Be Appropriate (median 4 to 6), and Rarely Appropriate (median 1 to 3). Members of the writing group and the technical and review panels were selected in large part because of their active involvement in the clinical practice of electrophysiology, heart failure, and other related areas of cardiovascular medicine.

Describing the appropriate use criteria (AUC) for ICD and CRT has the potential to enhance physician decision making, healthcare delivery, and reimbursement policy. Furthermore, recognition of clinical scenarios categorized as May Be Appropriate facilitates identification of areas that would benefit from future research.

This report addresses the appropriate use of ICD and CRT. Determination of the criteria for the implantation of ICDs and/or CRT is based on the results of evidence

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derived from clinical trials. The same evidence has been incorporated into clinical practice guidelines. However, there is also recognition that in "real world" scenarios, expert opinion is of value in addressing patient populations that are either not represented in currently available randomized clinical trials or for treatment recommendations that are supported by lower levels of evidence. In addition, it is important to recognize that when patients are excluded from a clinical trial, the results of the trial should not be interpreted to mean that the treatment was proven to be ineffective for patients who were excluded. Physicians must use their best judgment in deciding whether a treatment might be beneficial to patients who would have been excluded from a clinical trial. Accordingly, the AUC were designed to include a broad spectrum of clinical scenarios representative of those encountered by physicians in their daily practice. The AUC are also intended to highlight areas of potential misapplication of technology (overutilization) in addition to areas of possible underutilization. For practical implementation, the document was not designed to be all encompassing, and therefore, the writing group focused on the more commonly encountered scenarios. As with other AUC documents, there is an implicit acknowledgment that important deficiencies may be revealed by subsequent clinical trials and AUC implementation studies, which will not only guide further research but also inform expedient updates in the AUC for ICD/CRT. As the field advances, the healthcare community needs to understand how to best incorporate this technology into daily clinical care. The ACCF and the HRS are dedicated to this effort.

2. Methods

A detailed description of the methods that were used for rating the selected clinical indications can be found in a previous publication, "ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging" (6). Briefly, this process combines evidence-based medicine and practice experience by engaging a technical panel in a prospective, modified Delphi exercise. The technical panel was created through nominations given by multiple relevant professional societies and provider-led organizations as well as from health policy and payer communities. To preserve objectivity, technical panels are created so as to not include a majority of individuals whose livelihood is tied to the technology under evaluation. During the development of this document, the AUC Task Force finalized a revision of the terminology and definitions to better clarify the appropriateness categories (7). As a result, the technical panel used the terminology described in the original methodology paper for all but the last round of rating. Further explanation of this change is provided in the following text.

In making its appropriateness determinations, the technical panel was provided with relevant evidence from the medical literature and practice guidelines. Technical panelists were asked to individually assess the benefits and risks of device implantation. Then, following a group discussion of the indications and related considerations, a second individual rating process was performed to determine the final ratings. After the rating process, the final appropriate use ratings were summarized using an established rigorous methodology (8).

Indication Development

The indications were constructed by a writing group with expertise in both the science and clinical practice of electrophysiology, heart failure, general cardiology, invasive cardiology, and noninvasive cardiac imaging. The writing group was tasked with developing a list of clinical scenarios covering the majority of patients that clinicians might consider referring for device implantation. The term "indication" is used interchangeably with "clinical scenario" in the document for brevity and does not imply that a procedure should necessarily be performed. Indication modifications were made through discussions with the ACCF AUC Task Force and feedback from reviewers that included additional experts in the areas noted in the preceding text, along with experts in the fields of geriatric medicine, internal medicine, and clinical outcomes research.

The indications included in this publication incorporate a wide range of cardiovascular signs, symptoms, disease states, and physiological assessments, including, but not limited to, measurement of the left ventricular ejection fraction (LVEF), duration of the QRS complex, monitoring data, and results of electrophysiological studies. Within each main disease category, a standardized approach was used to capture the majority of clinical scenarios with an attempt to avoid making the list of indications excessive. This document does not cover indications for implantation of devices in the pediatric population.

Wherever possible, indications were mapped to relevant clinical guidelines and key publications/references (see Guideline Mapping and References Online Appendix).

Rating Process and Scoring

The technical panel first rated the indications independently. Then, the technical panel convened for a face-to-face meeting to discuss each indication. At this meeting, panelists were provided with their scores and a blinded summary of their peers' scores. After the meeting, panelists once again independently rated each indication to indicate their final scores. The technical panel completed an additional rating process to address a few areas that required further clarification and readdressed ratings following the introduction of revised terminology as outlined in the recently updated methods document (7).

The members of the technical panel completed the rating process using the old terminology and definitions (appropriate, uncertain, and inappropriate, as described in the original methods [6]), and were subsequently asked to participate in an additional round of rating to re-examine

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the indications using the new terminology and expanded definitions. The new terminology was finalized after the technical panel had completed the rating process. As a consequence, the additional round of rating was deemed necessary to minimize potential confusion related to differences in terminology between the old and updated methodology and to assess whether the change could impact the appropriateness classification of the different clinical scenarios. The final rating of the indications using the revised terminology and expanded definitions resulted in a change in ratings for only 1% of the total indications.

When rating each clinical scenario, the technical panel was asked to assess whether device implantation is Appropriate, May Be Appropriate, or Rarely Appropriate, according to the following definition of appropriate use:

> **ICD and/or CRT implantation is appropriate *in general* when the expected value in terms of survival and/or other health benefits (symptoms, functional status, and/or quality of life) exceed the potential adverse health consequences relating to the acute procedural risk and the long-term consequences of living with an implanted device.**

The technical panel scored each indication as follows:

Median Score 7 to 9: Appropriate care

An appropriate option for management of patients in this population due to **benefits generally outweighing risks**; effective option for individual care plans, although not always necessary, depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

Median Score 4 to 6: May Be Appropriate care

At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).

Median Score 1 to 3: Rarely Appropriate care

Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

The division of these scores into 3 levels of appropriateness should be viewed as a continuum. When there is diversity in opinion regarding the management of a particular clinical scenario such that scores fall in the intermediate level of appropriateness, they are labeled May Be Appropriate, as critical patient information or research data may be lacking or discordant. *This must not be treated as either* Appropriate *or* Rarely Appropriate, *but rather as a distinct category of* May Be Appropriate. It is anticipated that the AUC standards will continue to be revised as further data are generated and information from the implementation of the criteria is accumulated.

The level of agreement among panelists as defined by RAND (8) is analyzed based on the BIOMED rule. For each clinical scenario, the voting process produces a result in which there is either mathematical agreement or disagreement among panelists. Agreement exists when 4 or fewer panelists' ratings fell outside the 3-point region containing the median score.

Disagreement exists when 5 or more panelists' ratings fall in both the Appropriate and the Rarely Appropriate categories. Any indication having disagreement will be placed in the May Be Appropriate category regardless of the final median score. The final scores were obtained after the panel had the opportunity to discuss the clinical scenarios at a face-to-face meeting that was followed by a second-round rating to eliminate the possibility of misinterpretation of either the indication wording or the published clinical data.

3. Assumptions

To limit inconsistencies in interpretation, specific assumptions were considered by the writing group in development and were used by the technical panel in rating the clinical indications for the appropriate use of device implantation. Other assumptions also reviewed in the *Discussion* relate to the interpretation of AUC results and implementation.

General Clinical Assumptions

1. For each indication, the rating should reflect whether device implantation is reasonable for the patient according to the appropriate use definition. It should not be assumed that for each indication the decision to treat has already been made.
2. A qualified clinician has completed a thorough clinical history and physical examination such that the clinical status of the patient can be assumed to be valid as stated in the indication. For example, a patient said to be asymptomatic is truly asymptomatic for the condition in question, and sufficient questioning of the patient has been undertaken.
3. End-of-life discussion, advanced directive, and patient consent have been adequately addressed. Patients are assumed to be candidates for ICD/CRT only after a decision-making discussion has been undertaken between the patient, appropriate family and/or legal decision makers, and the physician. It is assumed that the patient and/or decision makers are educated suffi-

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ciently to understand whether or not ICD/CRT implantation is consistent with current care intentions or with prior advance directives.

4. The clinical scenarios should be preferentially rated based on evidence from published literature and clinical practice guidelines regarding the risks and benefits of ICD/CRT. Selected specific patient groups not well represented in the literature or in clinical practice guidelines are presented in many of the current clinical scenarios because the writing group recognizes that decisions about device implantation in such patients are frequently required. Examples of such patients include those with end-stage renal disease or advanced age.
5. All patients are receiving optimal care, also called "guideline-directed medical therapy" (GDMT) in ACC/AHA Clinical Practice Guidelines, including guideline-based risk factor modification for primary or secondary prevention for coronary artery disease (CAD) and heart failure in cardiovascular patients unless specifically noted (9).
6. There are no unusual extenuating logistical or process-of-care circumstances such as inability to comply with follow-up due to any number of reasons (e.g., mental instability, lack of transportation) unless specifically noted.
7. There are no technical limitations for device implantation or other comorbidities that are likely to substantially increase procedural risk, unless specifically noted.
8. Coronary artery disease: for sections that reference revascularization, additional assumptions may apply, including but not limited to the following:
   a. For scenarios in which no revascularization is planned, it should be assumed that revascularization is not indicated unless otherwise specified, for example, there are no major epicardial coronary lesions measuring ≥70% (non-left main) or ≥50% (left main) or no evidence of ischemia by fractional flow reserve or perfusion imaging.
   b. Other scenarios may include cases where patients are not candidates for revascularization for whatever reason, including but not limited to severe, diffuse CAD that is not amenable to revascularization.
   c. When revascularization is considered or performed, it is assumed that patients are also acceptable candidates for revascularization based on the absence of other noncardiac comorbidities that would be a contraindication for revascularization.
   d. If patients are candidates for revascularization, and revascularization is planned, electrophysiology (EP) testing should not be performed until after the intended revascularization is performed.
   e. An ICD should not be implanted before revascularization to circumvent the current Centers for Medicare & Medicaid Services 3-month waiting-period rule (10,11).
9. An assessment of the LVEF during hospitalization following acute infarction or revascularization generally prompts consideration of ICD/CRT implantation. When a subsequent waiting period is required (e.g., after guideline-directed medical therapy, myocardial infarction, or revascularization), it is assumed that the final decision to treat will be based on a follow-up LVEF assessment after expiration of the waiting period, and that the imaging facility understands that quantitative measurement of the LVEF is an important goal of the exam.

Practice Parameters/Standard of Care

10. Operators performing device implantation have appropriate clinical training (12) and experience consistent with established standards of care and have satisfactory outcomes as assessed by quality assurance monitoring, including national benchmark data from the National Cardiovascular Data Registry (NCDR) ICD registry (13). ICDs are implanted with transvenous electrodes. Although different means of delivering electrical therapy have only recently become available, specifically, a totally subcutaneous ICD system, a standard transvenous approach was assumed for the purpose of this document.
11. Geographic/regional variability: issues of local availability of skill in performing the procedure should not be considered during the rating process, as it is assumed that skilled operators and appropriate implantation resources are locally available.
12. Adjunctive cardiac imaging modalities are often required for appropriate patient selection. These may include coronary angiography or cardiac computed tomography for the determination of coronary anatomy in addition to other noninvasive cardiac imaging modalities, including echocardiography, cardiac magnetic resonance imaging, and radionuclide imaging for initial assessment of cardiac structure and function (LVEF) and when needed, a follow-up determination of the LVEF. It assumed that laboratories performing these services have appropriate clinical training and experience, perform these studies and interpret them according to national standards, and have satisfactory outcomes as assessed by quality improvement monitoring.
13. It is recognized that there may be variability in the measurement of the LVEF at different points in time and utilizing different imaging modalities. The labs performing the LVEF assessments will have quality assurance measures in place to ensure accuracy of each individual method for determining and reporting left ventricular (LV) function.
14. For all indications, it is assumed that the LVEF stated in the indications was measured within a timeframe relevant to making the decision about eligibility for ICD implantation. It is assumed that repeat evaluation of the LVEF will be performed after an appropriate

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duration of time following recovery from myocardial infarction or revascularization, or following GDMT in the setting of a new diagnosis of heart failure or cardiomyopathy, before determining ICD eligibility.

15. All procedures presented are to be considered for clinical indications and not as part of a research protocol.
16. With respect to CRT, atrial arrhythmias (including atrial fibrillation, atrial flutter, and atrial tachycardia) are not included in the indication tables. There are fewer data available for CRT in patients with persistent atrial arrhythmias, and the writing group elected to avoid additional scenarios for practical reasons, as the document already includes a large number of scenarios. However, it is assumed that the presence of intermittent or persistent atrial arrhythmias would not preclude CRT implantation, and the benefits of CRT would also apply to patients with persistent atrial arrhythmias, as long as CRT is maintained nearly 100% of the time.
17. The potential adverse effects of right ventricular (RV) pacing in the setting of pre-existing LV systolic dysfunction are well described (14–16). Therefore, attempts should be made to reduce unnecessary RV pacing by appropriate programming of single- and dual-chamber ICDs, whenever possible.
18. Single- versus dual-chamber ICD selection: It is assumed that most patients undergoing ICD implantation who have standard dual-chamber pacing indications will undergo attempted insertion of an atrial lead as described in the 2008 ACC/AHA/HRS device-based therapy guidelines document, and a separate consensus document pertaining to selection of dual- versus single-chamber devices for pacemaker patients, which was recently published (17). However, there is currently controversy regarding single- versus dual-chamber device selection in patients who do not meet strict pacing indications but are undergoing ICD implantation without CRT, and this is an area of ongoing investigation. For example, it has been hypothesized that the availability of dual-chamber discriminators might improve discrimination of ventricular arrhythmias from supraventricular arrhythmias and thus potentially reduce unnecessary ICD shocks. However, a recent meta-analysis demonstrated that the proportion of patients receiving inappropriate therapy was not different between single- and dual-chamber devices using technology available at the time (18). It is currently unknown whether recent advancements in technology utilizing the most current ICD systems will show any benefit of dual-chamber devices in the absence of standard pacing indications, and studies evaluating this controversial topic are currently ongoing. Because there is a difference in cost and a potential difference in longevity of single- versus dual-chamber devices, and dual-chamber systems may potentially improve discrimination between ventricular and supraventricular arrhythmias, but have a higher risk of dislodgment due to the addition of the atrial lead, these scenarios were felt to be important to address in this document.
19. Decisions for ICD implantation should be based on a reasonable expectation of survival with a good functional status for at least 1 year. The clinical trial populations used to derive published predictive survival models may differ from the general heart failure population with regard to age and comorbidities. Therefore, consideration should be given to advanced age or other comorbidities that might reduce the likelihood of benefit or increase the risk of ICD therapy for individuals.

Cost/Value

20. From the standpoint of the practicing physician caring for an individual patient, potential clinical benefits of device implantation should be the highest priority, and this is weighed against potential risks of the procedure. As related to societal benefits, costs should also be considered in relationship to potential benefits in order to better understand comparative value. However, very little has been done to assess cost effectiveness of ICD or CRT treatment across a spectrum of conditions and comorbidities. Although cost and value are clearly important variables, which are also relevant to payers and policymakers, it is recognized that healthcare providers typically do not primarily base individual patient decisions about device implantation on these considerations. Therefore, it is anticipated that technical panel members rate the scenarios primarily based on risks/benefits, although cost/value considerations may also be taken into consideration if deemed Appropriate by panel members for particular scenarios.

Guidance Specifically for AUC Users

21. Reducing care that is Rarely Appropriate remains a valuable means to reduce costs and population risks of ICD and/or CRT implantation.
22. The category of May Be Appropriate should be used when insufficient clinical data are available for a definitive categorization, or there are substantial differences in opinion regarding the appropriateness of that indication. **The absence of definitive data supporting implantation in a particular subset of patients does not imply lack of benefit, and in such cases, careful investigation of the particulars of the clinical scenario is warranted. The designation of May Be Appropriate should not be used as the sole grounds for denial of reimbursement in an individual patient.**

4. Definitions

Definitions of terms used throughout the indication set are listed here.

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Duration of Heart Failure:

The duration of heart failure symptoms is defined as the duration of symptoms since the initial diagnosis of heart failure to the date of the device implantation. Clinical trials and the NCDR ICD registry have utilized time frames of <3 months, 3 to 9 months, and >9 months. The writing group recognizes that 3 months may equate to more or less than 90 days, depending on the calendar months. The 3-month term was chosen because it was used in some randomized clinical trials related to timing for device implantation and is the basis of coverage in the 2005 National Coverage Determination of the Centers for Medicare & Medicaid Services for nonischemic dilated cardiomyopathy.

Dyssynchrony:

Dyssynchrony refers to "ventricular electromechanical delay," which may be identified by multiple imaging techniques, including echocardiography. Prolongation of the QRS complex is seen in approximately one-third of patients with advanced heart failure, and this prolongation may be associated with varying degrees of ventricular electromechanical delay or "dyssynchrony." Modifications in this delay are often seen with CRT pacing or "resynchronization therapy." Studies utilizing CRT have also been performed in patients with narrow QRS complexes in the presence of dyssynchrony. However, no proven benefit has been demonstrated in this cohort with a QRS duration <120 ms (19). Additionally, recent meta-analyses question the utility of CRT in patients with QRS durations of 120 to 149 ms (20,21). Enrollment criteria for CRT trials have typically been based on a QRS duration ≥120 ms, regardless of imaging techniques to evaluate the presence or absence of dyssynchrony. There is current controversy on the role of dyssynchrony in assessing the likelihood of response to CRT, and this argues that dyssynchrony assessments should not be included in consideration for CRT implantation. Therefore, due to the enrollment criteria used in clinical trials and the absence of consensus at this time regarding its assessment, measurement of dyssynchrony prior to implantation is *not* included in the AUC scenarios listed in this document.

Guideline-Directed Medical Therapy for Stable Ischemic Heart Disease:

When tolerated, GDMT (sometimes referred to as "optimal medical therapy") should include aspirin (or a thienoypyridine if aspirin is not tolerated), statin therapy, angiotensin-converting enzyme inhibition (or an angiotensin receptor blocker) and the use of beta-blockers after myocardial infarction. Therapy for angina/ischemia should include at least 1 of the following medications: beta-blockers, calcium channel antagonists, or nitrates. Therapy should also be directed at optimizing the treatment of associated conditions such as diabetes and uncontrolled hypertension.

Guideline-Directed Medical Therapy for Heart Failure:

GDMT for heart failure in the setting of LV systolic dysfunction requires individualization but typically should include the combination of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker and beta-blocker therapy adjusted to target doses as tolerated, with diuretics adjusted if/as needed to control fluid retention. In selected patients, the addition of aldosterone antagonists and hydralazine plus nitrate combinations should be considered. Patients who are going to receive substantial benefit from medical treatment alone usually show some clinical improvement during the first 3 to 6 months. Medical therapy is also assumed to include adequate rate control for tachyarrhythmias, including atrial fibrillation. Therefore, it is recommended that GDMT be provided for at least 3 months before planned reassessment of LV function to consider device implantation. If LV function improves to the point where primary prevention indications no longer apply, then device implantation is not indicated.

Heart Failure:

Heart failure is defined as a clinical syndrome characterized by specific symptoms described in the medical history and signs on the physical examination. The clinical symptoms of heart failure may include dyspnea on exertion, orthopnea, fatigue, or fluid retention. The clinical signs may include jugular venous pressure elevation, râles, an S3 gallop, or lower extremity edema. A low LVEF or diagnosis of cardiomyopathy alone, or peripheral edema without other clinical signs of heart failure, does not qualify as heart failure (22).

Hemodynamic Instability:

Patients may experience periods of clinical instability with hypotension, heart failure symptoms, pre-syncope or syncope, angina, or dyspnea. These symptoms are presumed to result from hypo-perfusion, with a cardiac output and/or rhythm that is inadequate to support normal organ function.

Inducibility at Electrophysiological (EP) Testing:

Inducibility is defined as the induction of sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) at EP testing with an arrhythmia duration ≥30 s and/or resulting in hemodynamic compromise using standardized stimulation protocols.

Myocardial Infarction (MI):

The "Universal Definition of Myocardial Infarction" was developed by Thygesen and colleagues in 2007 and updated in 2012. The multifaceted clinical criteria include timing, mechanism (infarct type), biomarker status, and size. An elevated troponin is not necessarily indicative of an acute MI (23–25).

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Myocardial Infarction Versus Nonspecific, Low-Level Troponin Elevation:

Not infrequently, a low-level troponin elevation is detected when blood is drawn routinely or as a consequence of protocol laboratory testing. If upon further evaluation the troponin levels do not exhibit a typical rise and fall pattern, or there is an alternative explanation for the troponin leak (e.g., cardiac arrest or external defibrillation) that can be explained by a diagnosis other than myocardial ischemia, this should not be misconstrued as a myocardial infarction (as defined by Thygesen et al. [23,25]) based on the laboratory test alone (23,25,26). In addition, a nonspecific transient biomarker elevation may also occur in some situations of cardiac arrest in which there is a low-level rise in troponin with subsequent fall, in the absence of coronary artery disease or thrombosis. This also should not be considered a myocardial infarction without underlying coronary obstruction, as this leak of troponin is likely related to the arrest itself. These low-level rises in biomarkers should not preclude ICD implantation, if criteria for implantation are otherwise met.

New York Heart Association (NYHA) Functional Classification:

The definitions are included in the table in the following text. The patient's NYHA functional classification at the time of the decision to implant the device should be used for this classification. If the patient has left ventricular dysfunction, but no symptoms of heart failure, this should be coded as "class I." If the patient is hospitalized for heart failure at the time the decision is made to implant the device, the NYHA functional class on optimized GDMT should be utilized.

NYHA Functional Classification	
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Adapted with permission from the Heart Failure Society of America (27).

Ambulatory NYHA Functional Class IV:

Ambulatory class IV is defined as class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT.

Normal Left Ventricular Ejection Fraction:

A normal LVEF is defined as ≥50%.

Primary Versus Secondary Prevention for ICD (28)

Secondary Prevention (Section 1 Indications):

Secondary prevention refers to an indication for an ICD exclusively for patients who have survived 1 or more cardiac arrests or sustained ventricular tachycardia. Patients with cardiac conditions associated with a high risk of sudden death who have unexplained syncope that is likely to be due to self-terminating ventricular arrhythmias are also considered to have a secondary prevention indication.

Primary Prevention (Section 2 Indications):

Primary prevention is an indication for an ICD to prevent sudden cardiac death. It refers to use of ICDs in individuals who are at risk for, but have not yet had, an episode of sustained VT, VF, or cardiac arrest.

QRS Duration:

A "narrow" QRS duration is <120 ms. A wide QRS is ≥120 ms and may have a left bundle branch block (LBBB), right bundle branch block (RBBB), or nonspecific intraventricular conduction delay morphology. For the purpose of this AUC document and for consistency with the focused update of the device-based therapy guidelines (29), "non-LBBB" morphology is used to refer to both RBBB and intraventricular conduction delay morphologies. For the purpose of CRT implantation, it is assumed that the wide QRS is present consistently, and does not represent an intermittent bundle branch block or intermittent QRS widening, thereby excluding QRS widening that is transient or rate-related. If there is discrepancy in the measurement of QRS duration on various electrocardiograms (ECGs), the most representative ECG obtained proximate to the final clinical decision-making process will be utilized to determine candidacy for CRT implantation.

Sudden Cardiac Arrest:

Sudden cardiac arrest is defined as the sudden cessation of effective cardiac mechanical activity resulting in unresponsiveness, without normal breathing or signs of circulation. If corrective measures are not rapidly taken, this progresses to sudden death. Cardiac arrest should be used to signify an event that is reversed, usually by cardiopulmonary resuscitation and/or defibrillation, cardioversion, or cardiac pacing. The mechanism for a tachyarrhythmic arrest may be due to VT or VF, or VT degenerating into VF.

Syncope:

Syncope is defined as a sudden loss of consciousness with the inability to maintain postural tone, not related to anesthesia or a seizure disorder, with spontaneous recovery reported by the patient or an observer. This excludes cardiac arrest, which requires resuscitation.

Timing Post-MI:

For the purpose of this AUC document:

- "**Acute MI**" is defined as ≤48 h after the onset of symptoms;
- "**Recent post-infarction**" is defined as ≤40 days after the onset of acute MI symptoms (30,31).

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Ventricular Arrhythmias Prior to Generator Replacement:

As part of ICD follow-up care, decisions must be made regarding the need for generator replacement at the time of battery depletion. In the absence of contraindications or the development of new comorbidities that may significantly limit life expectancy, generator replacement is now typically recommended for patients who had initial devices implanted for primary prevention indications when elective replacement is reached. However, it is recognized that there are few long-term data to support this standard of care. Nonetheless, in addition to assessing for pacemaker dependency, the presence or absence of ICD therapy for ventricular arrhythmias might be taken into account when considering the need for replacement, particularly if new comorbidities have developed that may otherwise have an impact on life expectancy.

Clinically relevant ventricular arrhythmias in an ICD recipient refer to:

a. VT leading to antitachycardia pacing, or VT/VF leading to shock therapy, or
b. VT duration ≥30 s in a monitor-only zone (or <30 s associated with hemodynamically significant symptoms), or
c. VT lasting ≥30 s at a rate near the tachycardia-detection threshold but not receiving therapy due to only intermittent detection.

In the case of antitachycardia pacing therapy for VT, it is recognized that many of these episodes might terminate spontaneously if detection is delayed. "Nonsustained VT" is VT of <30 s that terminates spontaneously before delivery of device therapy (including either antitachycardia pacing or shock therapy). It is recognized that implanting physicians will have a variety of different programming preferences, and some of these may include a monitor zone or prolonged detection duration in an attempt to minimize appropriate or inappropriate therapy for arrhythmias that may terminate spontaneously (32).

Ventricular Fibrillation:

Ventricular fibrillation is a cardiac arrhythmia arising from the ventricles that occurs when the heart's electrical activity becomes disordered and rapid. VF is not synonymous with device-defined VF, as the device defines VT and VF solely based on the programmed heart rate and does not take into account the morphology of the arrhythmia.

Ventricular Tachycardia:

VT is a cardiac tachyarrhythmia of 3 or more consecutive complexes in duration emanating from 1 of the ventricles with a rate of ≥100 beats/min. It can be "sustained" or "nonsustained."

Ventricular Tachycardia, Sustained:

Sustained VT is defined as VT lasting ≥30 s or terminated by cardioversion or pacing before that time.

Ventricular Tachycardia, Hemodynamically Significant:

Hemodynamically significant VT is defined as VT that results in hypotension or hemodynamically significant symptoms such as angina, dyspnea, lightheadedness, pre-syncope, or syncope.

Ventricular Tachycardia, Nonsustained:

Nonsustained VT is defined as 3 or more consecutive premature ventricular complexes but lasting <30 s and terminating spontaneously, without associated hemodynamically significant symptoms, and rate ≥100 beats/min.

5. Abbreviations

CAD = coronary artery disease
CIED = cardiovascular implantable electronic device
CRT = cardiac resynchronization therapy
ECG = electrocardiogram
GDMT = guideline-directed medical therapy
HF = heart failure
ICD = implantable cardioverter-defibrillator
LBBB = left bundle branch block
LV = left ventricular
LVEF = left ventricular ejection fraction
MI = myocardial infarction
NYHA = New York Heart Association
VAD = ventricular assist device
VF = ventricular fibrillation
VT = ventricular tachycardia

6. Results of Ratings

The final ratings for ICDs and CRT therapy are listed by indication in Tables 1.1 to 6.5 (indications listed by ratings are provided as an online appendix). The final score reflects the median score of the 17 technical panel members and has been labeled according to the categories of Appropriate (median 7 to 9), May Be Appropriate (median 4 to 6), and Rarely Appropriate (median 1 to 3). Of the ratings, 45% were rated as Appropriate, 33% were rated May Be Appropriate, and 22% were rated Rarely Appropriate (see Online Ratings Spreadsheet for more details).

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7. Appropriate Use Criteria for ICD/CRT Indications

Section 1: Secondary Prevention ICD

Table 1.1. CAD: VF or Hemodynamically Unstable VT Associated With Acute (<48 h) MI (Newly Diagnosed, No Prior Assessment of LVEF) (Fig. 1)

Indication		Appropriate Use Score (1–9)		
Total Revascularization Completed After Cardiac Arrest				
		LVEF		
		≥50%	36% to 49%	≤35%
1.	• Single episode VF or polymorphic VT during acute (<48 h) MI	R (2)	R (3)	M (4)
2.	• Recurrent VF or polymorphic VT during acute (<48 h) MI	R (3)	R (3)	M (5)
3.	• VF or polymorphic VT during acute (<48 h) MI • NSVT 4 days post-MI • Inducible VT/VF at EPS ≥4 days after revascularization	M (5)	A (7)	A (8)
No Revascularization Indicated (i.e., No Significant CAD)				
		LVEF		
		≥50%	36% to 49%	≤35%
4.	• Single episode VF or polymorphic VT during acute (<48 h) MI	R (2)	R (3)	M (4)
5.	• Recurrent VF or polymorphic VT during acute (<48 h) MI	R (2)	R (3)	M (5)
Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization				
		LVEF		
		≥50%	36% to 49%	≤35%
6.	• VF or polymorphic VT during acute (<48 h) MI • No EPS done	M (5)	M (5)	A (7)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 1.2. CAD: VF or Hemodynamically Unstable VT <48 h (Acute) Post-Elective Revascularization

Indication		Appropriate Use Score (1–9)		
		LVEF		
		≥50%	36% to 49%	≤35%
7.	• No evidence for acute coronary occlusion, restenosis, preceding infarct, or other clearly reversible cause	M (6)	M (6)	A (7)

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 1.3. CAD: VF or Hemodynamically Unstable VT (No Recent MI [≤40 Days] Prior to VF/VT and/or No Recent Revascularization [3 Months] Prior to VF/VT) (Fig. 2)

Indication		Appropriate Use Score (1–9)		
		LVEF		
		≥50%	36% to 49%	≤35%
8.	• No identifiable transient and completely reversible causes • No need for revascularization identified by cath performed following VF/VT	A (9)	A (9)	A (9)
9.	• No revascularization performed (significant CAD present at cath performed following VF/VT, but coronary anatomy not amenable to revascularization)	A (9)	A (9)	A (9)
10.	• Significant CAD identified at cath performed following VF/VT • Complete revascularization performed after cardiac arrest	M (5)	A (7)	A (7)
11.	• Significant CAD identified at cath performed following VF/VT • Incomplete revascularization performed after cardiac arrest	A (7)	A (8)	A (9)

A = Appropriate; CAD = coronary artery disease; cath = catheterization; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia.

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Table 1.4. CAD: VF or Hemodynamically Unstable VT During Exercise Testing Associated With Significant CAD

Indication		Appropriate Use Score (1–9)		
		LVEF		
		≥50%	36% to 49%	≤35%
12.	• No revascularization performed (significant CAD present at cath performed following VF/VT, but coronary anatomy not amenable to revascularization)	A (9)	A (9)	A (9)
13.	• Significant CAD identified at cath performed following VF/VT • Complete revascularization performed after cardiac arrest	M (5)	M (6)	A (7)
14.	• Significant CAD identified at cath performed following VF/VT • Incomplete revascularization performed after cardiac arrest	A (7)	A (7)	A (8)

A = Appropriate; CAD = coronary artery disease; cath = catheterization; LVEF = left ventricular ejection fraction; M = May Be Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 1.5. No CAD: VF or Hemodynamically Unstable VT (Fig. 3)

Indication		Appropriate Use Score (1–9)		
		LVEF		
		≥50%	36% to 49%	≤35%
15.	• Dilated nonischemic cardiomyopathy	A (9)	A (9)	A (9)
16.	• VT/VF associated with cocaine abuse	R (3)	M (4)	M (5)
Severe Valvular Disease VT/VF <48 h After Surgical Repair or Replacement of Aortic or Mitral Valve				
17.	• No evidence of post-operative valvular dysfunction	M (5)	M (6)	M (6)
VF/Hemodynamically Unstable VT Associated With Other Structural Heart Disease				
18.	• Myocardial sarcoidosis		A (9)	
19.	• Myocarditis; not giant cell myocarditis		M (5)	
20.	• Giant cell myocarditis		A (8)	
21.	• Takotsubo cardiomyopathy (stress-induced cardiomyopathy, apical ballooning syndrome) • ≥48 h of onset of symptoms		M (5)	

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 1.6. Genetic Diseases with Sustained VT/VF* (Fig. 3)

Indication		Appropriate Use Score (1–9)
22.	• Congenital long QT	A (9)
23.	• Short QT	A (9)
24.	• Catecholaminergic polymorphic VT	A (9)
25.	• Brugada syndrome	A (9)
26.	• ARVC with successful ablation of all inducible monomorphic VTs	A (9)
27.	• ARVC with unsuccessful attempt to ablate an inducible VT	A (9)
28.	• ARVC without attempted ablation	A (9)
29.	• Hypertrophic cardiomyopathy	A (9)

*Patients with genetic diseases are assumed to have normal LV and RV function, unless otherwise specified.
A = Appropriate; ARVC = arrhythmogenic right ventricular cardiomyopathy; VF = ventricular fibrillation; VT = ventricular tachycardia.

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Table 1.7. No Structural Heart Disease (LVEF ≥50%) or Known Genetic Causes of Sustained VT/VF (Fig. 4)

	Indication	Appropriate Use Score (1–9)
	Pharmacologically Induced Sustained VT/VF	
30.	• Non-torsades de pointes VT/VF in the setting of antiarrhythmic drug use	R (3)
31.	• Drug-induced torsades de pointes	R (2)
	Idiopathic VF With Normal Ventricular Function	
32.	• No family history of sudden cardiac death	A (9)
33.	• First degree relative with sudden cardiac death	A (9)
	Other Causes	
34.	• Bradycardia dependent VT/VF	M (5)
35.	• WPW syndrome with VT/VF • Pathway successfully ablated • Structurally normal heart	R (2)

A = Appropriate; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia; WPW = Wolff-Parkinson-White.

Table 1.8.1. Syncope in Patients Without Structural Heart Disease* (Fig. 5)

	Indication	Appropriate Use Score (1–9)
	Unexplained Syncope With No Structural Heart Disease or Genetically Transmitted Ventricular Arrhythmias	
36.	• Normal ECG and structurally normal heart • Family history of sudden death	R (3)
37.	• Normal ECG and structurally normal heart • No known family history of sudden death	R (1)
	Unexplained Syncope in a Patient With RV or LV Outflow Tract Tachycardia (Idiopathic VT) With Normal LV and RV Function and Anatomy	
38.	• Documented sustained monomorphic VT (LBBB/inferior axis) at the time of syncope • Ablation not yet attempted	R (2)
39.	• Documented history of sustained monomorphic VT (LBBB/inferior axis) but not recorded at the time of syncope • Ablation not yet attempted	R (2)
40.	• Documented sustained monomorphic VT (LBBB/inferior axis) at the time of syncope • Ablation successful	R (2)
	Unexplained Syncope in a Patient With Long QT Syndrome	
41.	• While on treatment with beta blockers	A (9)
42.	• Not being treated with beta blockers	A (7)
	Unexplained Syncope in a Patient With Brugada ECG Pattern	
43.	• No EPS performed	A (8)
44.	• EPS performed • No ventricular arrhythmias induced	A (8)
45.	• EPS performed • Sustained VT/VF induced	A (9)
	Unexplained Syncope in a Patient With Catecholaminergic Polymorphic VT	
46.	• While on treatment with beta blockers	A (8)
47.	• Not being treated with beta blockers	A (8)

*It is assumed that an EPS was not performed unless otherwise specified.

A = Appropriate; ECG = electrocardiogram; EPS = electrophysiological study; LBBB = left bundle branch block; LV = left ventricular; R = Rarely Appropriate; RV = right ventricular; VF = ventricular fibrillation; VT = ventricular tachycardia.

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Table 1.8.2. Syncope in Patients With Coronary Artery Disease (Fig. 6)

	Indication	Appropriate Use Score (1–9)
	Unexplained Syncope With Coronary Heart Disease and No Acute MI LVEF ≥50%	
48.	• Electrophysiology study and noninvasive investigations failed to define a cause of syncope • No prior MI • Nonobstructive CAD; revascularization not indicated	R (2)
49.	• Electrophysiology study and noninvasive investigations failed to define a cause of syncope • No prior MI • Obstructive CAD; not amenable to revascularization	R (3)
	Unexplained Syncope With Prior MI and No Acute MI LVEF 36% to 49%	
50.	• Electrophysiology study failed to define a cause of syncope • Nonobstructive CAD; revascularization not indicated	M (5)
51.	• Electrophysiology study failed to define a cause of syncope • Obstructive CAD; not amenable to revascularization	M (6)
52.	• Electrophysiology study revealed inducible sustained VT/VF	A (9)
	Unexplained Syncope With Prior MI and No Acute MI LVEF ≤35%	
53.	• EPS not performed	A (9)
54.	• Inducible VT/VF at EPS	A (9)
55.	• Not inducible at EPS	A (8)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 1.8.3. Syncope in Patients With Nonischemic Structural Heart Disease (Fig. 7)

	Indication	Appropriate Use Score (1–9)		
	Unexplained Syncope in a Patient With Left Ventricular Hypertrophy Without Criteria for Hypertrophic Cardiomyopathy			
		LVEF		
		≥50%*	**36% to 49%**	**≤35%**
56.	• Left ventricular hypertrophy/hypertensive heart disease	R (3)	M (5)	A (8)
	Unexplained Syncope in a Patient With Nonischemic Cardiomyopathy			
		LVEF		
		≥50%*	**36% to 49%**	**≤35%**
57.	• Nonischemic dilated cardiomyopathy	M (4)	M (6)	A (8)
58.	• Left ventricular non-compaction	M (6)	A (7)	A (8)
59.	• Hypertrophic cardiomyopathy		A (8)	
60.	• Cardiac amyloidosis		M (6)	
61.	• Tetralogy of Fallot with prior corrective surgery		A (7)	
	Unexplained Syncope in a Patient With Arrhythmogenic Right Ventricular Cardiomyopathy			
62.	• No EPS performed		A (7)	
63.	• No inducible VT/VF at EPS		A (7)	
64.	• Inducible VT/VF at EPS • All inducible VTs successfully ablated		A (7)	
65.	• Inducible VT/VF at EPS • Ablation unsuccessful		A (8)	

*LVEF preserved on medical therapy
A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

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Table 1.9. Sustained Hemodynamically Stable Monomorphic VT Associated With Structural Heart Disease (Fig. 8)

Indication		Appropriate Use Score (1–9)		
		LVEF		
		≥50%*	36% to 49%	≤35%
66.	• CAD and prior MI	A (7)	A (7)	A (9)
67.	• CAD and prior MI • All inducible VTs successfully ablated	M (6)	M (6)	A (9)
68.	• CAD and prior MI • Troponin elevation thought to be secondary to VT • All inducible VTs successfully ablated	M (5)	A (7)	A (8)
69.	• Nonischemic dilated cardiomyopathy	A (7)	A (7)	A (9)
70.	• Nonischemic dilated cardiomyopathy • All inducible VTs successfully ablated	M (5)	A (7)	A (8)
71.	• Bundle branch re-entry successfully ablated in a patient with nonischemic cardiomyopathy	M (4)	A (7)	A (8)

*LVEF preserved on medical therapy

A = Appropriate; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia.

Section 2: Primary Prevention ICD

Table 2.1.1. Post-Acute Myocardial Infarction (≤40 Days) LVEF ≤30% (Fig. 9)

Indication		Appropriate Use Score (1–9)
	Plan for Revascularization (Not Yet Performed)	
72.	• No NSVT	R (2)
	Revascularized After Acute MI	
73.	• No NSVT	R (2)
74.	• Asymptomatic NSVT (>4 days post MI) • No EPS performed	R (3)
75.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI)	A (7)
76.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI)	A (8)
77.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed after revascularization, within 30 days after MI)	R (3)
78.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed after revascularization, between 30 and 40 days after MI)	M (4)
	Not Revascularized **Obstructive CAD With Coronary Anatomy Not Amenable to Revascularization**	
79.	• No NSVT	R (2)
80.	• Asymptomatic NSVT (>4 days post MI) • No EPS performed	M (4)
81.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed within 30 days of MI)	A (7)
82.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed between 30 and 40 days after MI)	A (8)
83.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed within 30 days of MI)	M (4)
84.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed between 30 and 40 days after MI)	M (4)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VT = ventricular tachycardia.

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Table 2.1.2. Post-Acute Myocardial Infarction (≤40 Days) LVEF 31% to 40% (Fig. 9)

	Indication	Appropriate Use Score (1–9)
	Revascularized for Acute MI	
85.	• No NSVT	R (2)
86.	• Asymptomatic NSVT (>4 days post MI) • No EPS performed	R (3)
87.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed after revascularization, within 30 days of MI)	A (7)
88.	• Asymptomatic NSVT (>4 days post MI) • EPS with inducible sustained VT (EPS performed after revascularization, between 30 and 40 days after MI)	A (7)
89.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed after revascularization, within 30 days of MI)	R (3)
90.	• Asymptomatic NSVT (>4 days post MI) • EPS without inducible VT (EPS performed after revascularization, between 30 and 40 days after MI)	R (3)

A = Appropriate; CAD = coronary artery disease; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VT = ventricular tachycardia.

Table 2.1.3. Post-Acute MI (≤40 Days) and Pre-Existing Chronic Cardiomyopathy (≥3 Months)

	Indication	Appropriate Use Score (1–9)
91.	• LVEF ≤30% due to old infarction • NYHA class I	A (8)
92.	• LVEF ≤35% due to old infarction • NYHA class II–III	A (9)
93.	• LVEF ≤35% due to nonischemic causes • NYHA class II–III	A (8)

A = Appropriate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association.

Table 2.1.4. Post-MI (≤40 Days) and Need for Guideline-Directed Pacemaker Therapy Post-MI (e.g., SSS, CHB, or Other Indications for Permanent Pacemaker)

	Indication	Appropriate Use Score (1–9)
94.	• LVEF ≤35%	A (7)
95.	• LVEF 36% to 40%	M (6)

A = Appropriate; CHB = complete heart block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; SSS = sick sinus syndrome.

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Table 2.2. Post-Myocardial Infarction (>40 Days) With Ischemic Cardiomyopathy (Fig. 10)

Indication		Appropriate Use Score (1–9)			
No Recent PCI or CABG (≤3 Months)					
		NYHA Class			
		I	II	III	IV
96.	• LVEF ≤30%	A (8)	A (9)	A (9)	
97.	• LVEF 31% to 35%	A (7)	A (9)	A (9)	
98.	• LVEF 36% to 40% • Asymptomatic NSVT • No EPS			M (5)	
99.	• LVEF 36% to 40% • Asymptomatic NSVT • EPS without inducible VT/VF			M (5)	
100.	• LVEF 36% to 40% • Asymptomatic NSVT • EPS with inducible sustained VT/VF			A (8)	
Recent PCI or CABG (≤3 Months)					
101.	• No known pre-existing cardiomyopathy • LVEF ≤35%			M (6)	
102.	• Pre-existing documented cardiomyopathy • LVEF ≤35% on guideline-directed medical therapy >3 months before PCI/CABG			A (8)	
103.	• LVEF ≤35% • Need for ppm post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker)			A (8)	
104.	• LVEF 36%–40% • Need for ppm post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker)			M (6)	

NOTE: grey shaded boxes indicate "not rated."

A = Appropriate; CABG = coronary artery bypass graft surgery; CHB = complete heart block; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; SSS = sick sinus syndrome; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 2.3. Duration of Guideline-Directed Medical Therapy for Ischemic Cardiomyopathy Without Recent MI (Revascularization Not Indicated)

Indication		Appropriate Use Score (1–9)
105.	• LVEF ≤35% • On guideline-directed medical therapy for <3 months	M (5)
106.	• LVEF ≤35% • On guideline-directed medical therapy <3 months • NSVT • EPS with inducible sustained VT	A (8)
107.	• LVEF ≤35% • On guideline-directed medical therapy ≥3 months	A (9)

A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; VT = ventricular tachycardia.

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Table 2.4. Nonischemic Cardiomyopathy (Figs. 11 and 12)

Indication		Appropriate Use Score (1–9)		
Treatment Since Diagnosis <3 Months Newly Diagnosed Cardiomyopathy With Narrow QRS				
		NYHA Class		
		I	**II–III**	**IV**
108.	• LVEF ≤30%	**R (3)**	**M (4)**	
109.	• LVEF 31% to 35%	**R (3)**	**R (3)**	
At Least 3 Months on Guideline-Directed Medical Therapy				
		NYHA Class		
		I	**II–III**	**IV**
110.	• LVEF ≤30%	**A (7)**	**A (9)**	
111.	• LVEF 31% to 35%	**A (7)**	**A (9)**	
112.	• LVEF 36% to 40%		**M (4)**	
Recent Valve Surgery (i.e., Same Hospitalization or <3 Months) Which Included Incidental Bypass Graft				
113.	• LVEF ≤35% • Need for pacemaker and LV function not felt likely to improve		**A (7)**	
Specific Etiologies				
			LVEF	
			≤35%	**>35%**
114.	• Sarcoid heart disease		**A (8)**	**M (6)**
115.	• Myotonic dystrophy		**A (8)**	**M (5)**
116.	• Chagas disease		**A (8)**	**M (6)**
117.	• Amyloidosis with heart failure		**M (6)**	**M (5)**
118.	• Acute lymphocytic myocarditis • Newly diagnosed (<3 months ago)		**R (3)**	**R (3)**
119.	• Giant cell myocarditis		**A (8)**	**A (7)**
120.	• Peripartum cardiomyopathy • Persists >3 months postpartum		**A (8)**	**M (4)**

NOTE: grey shaded boxes indicate "not rated."
A = Appropriate; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NYHA = New York Heart Association; R = Rarely Appropriate.

Table 2.5. Genetic Conditions (Excludes Syncope and Sustained VT, Covered in Section 1) (Fig. 13)

Indication		Appropriate Use Score (1–9)
121.	• Hypertrophic cardiomyopathy with 1 or more risk factors	**A (7)**
122.	• Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia	**A (7)**
Congenital Long QT Syndrome With 1 or More Risk Factors		
123.	• Not receiving guideline-directed medical therapy	**M (6)**
124.	• Receiving guideline-directed medical therapy	**A (7)**
Catecholaminergic Polymorphic VT With Nonsustained VT (Without Syncope)		
125.	• Not receiving beta-blockers, flecainide, or propafenone	**A (7)**
126.	• Receiving beta-blockers	**A (7)**
127.	• Not tolerating or breakthrough nonsustained ventricular arrhythmias on beta-blockers	**A (8)**
Incidentally Discovered Brugada by ECG (Type I ECG Pattern) In the Absence of Symptoms or Family History of Sudden Cardiac Death		
128.	• No EPS	**R (3)**
129.	• Inducible VT or VF at EPS	**A (7)**
130.	• No inducible VT or VF at EPS	**R (3)**
Familial Dilated/Nonischemic Cardiomyopathy (RV/LV) Associated With Sudden Cardiac Death		
131.	• Evidence of structural cardiac disease but LVEF >35%	**A (7)**
132.	• Normal ECG and echo but carrying the implicated gene	**M (6)**
133.	• LV non-compaction with LVEF >35%	**A (7)**

A = Appropriate; ECG = electrocardiogram; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; RV = right ventricular; VF = ventricular fibrillation; VT = ventricular tachycardia.

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Section 3: Comorbidities

It should be noted that the scenarios in this section refer to ICDs implanted for **primary prevention**.

Table 3.1. Special Conditions/Comorbidities in Patients for Primary Prevention (Meeting Indications of ICD Implant Related to HF Diagnosis With LVEF ≤30% on Guideline-Directed Medical Therapy >3 Months) (Fig. 14)

	Indication	Appropriate Use Score (1–9)			
Life Expectancy					
134.	• Life expectancy <1 year from cardiac or noncardiac conditions	R (1)			
135.	• Noncardiac disease with life expectancy 1 to 2 years	M (4)			
Elderly					
		NYHA Class			
		I	II	III	IV
136.	• 80 to 89 years old	M (4)	M (5)	M (5)	
137.	• ≥90 years old	R (3)	M (4)	M (4)	
Cognitive Impairment					
138.	• Not able to understand or provide informed consent • Health care proxy consents to ICD	M (4)			
139.	• Not able to understand or provide informed consent • No health care proxy can be identified	R (3)			
Advanced Psychiatric Impairment					
140.	• Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude regular follow-up	R (1)			
Renal Disease					
		NYHA Class			
		I	II	III	IV
141.	• Severe symptomatic peripheral vascular disease (e.g., peripheral interventions or clinical claudication)	M (6)	A (7)	A (7)	
142.	• Chronic kidney disease on dialysis • Not a candidate for renal transplant	M (5)	M (6)	M (6)	
143.	• Chronic kidney disease with CrCl <30 ml, not yet on dialysis but candidate for dialysis	M (6)	M (6)	M (6)	
Other Comorbidities					
144.	• IV drug abuse (ongoing)	R (2)			
145.	• Unresolved infection associated with risk for hematogenous seeding	R (2)			
146.	• Noncompliance with medical therapy and follow-up	R (3)			
Class IV Heart Failure					
147.	• On waiting list for heart transplant	A (8)			
148.	• Not candidate for cardiac transplantation, CRT, or VAD • Refractory symptoms on oral therapy	R (2)			
149.	• Patient with a VAD	M (6)			
150.	• Not a candidate for transplant or VAD • Does not meet CRT criteria • Planned outpatient continuous intravenous inotropic therapy for palliation	R (2)			

NOTE: grey shaded boxes indicate "not rated."

A = Appropriate; CrCl = creatinine clearance; CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter-defibrillator; IV = intravenous; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular; VAD = ventricular assist device; VT = ventricular tachycardia.

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Section 4: ICD Generator Replacement at Elective Replacement Indicator (ERI)

Table 4.1. Primary Prevention ICD at Initial Implant

	Indication	Appropriate Use Score (1–9)	
	No Clinically Relevant Ventricular Arrhythmias on ICD Since Implant		
151.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now unchanged	A (8)	
152.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now 36% to 49%	M (6)	
153.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now ≥50% (normalized)	M (5)	
	No Clinically Relevant Ventricular Arrhythmias on ICD Since Implant (Now Has Prognosis <1 Year)	**Replace With ICD**	**Replace With Pacemaker**
154.	• Patient received primary prevention ICD • Pacemaker dependent	M (4)	A (8)
155.	• Patient received primary prevention ICD • Not pacemaker dependent	R (2)	
	Clinically Relevant Ventricular Arrhythmias on ICD Since Implant		
156.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now unchanged	A (9)	
157.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now 36% to 49%	A (8)	
158.	• Patient received primary prevention ICD when LVEF was ≤35% • LVEF now ≥50% (normalized)	A (8)	
159.	• Patient received primary prevention ICD • Now has prognosis <1 year	M (5)	

A = Appropriate; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

Table 4.2. Secondary Prevention ICD at Initial Implant

	Indication	Appropriate Use Score (1–9)
160.	• Patient received secondary prevention ICD • No ventricular arrhythmia since initial implant	A (8)
161.	• Patient received secondary prevention ICD • Had ventricular tachyarrhythmias in the monitor zone lasting >30 s, but no treated ventricular arrhythmias since initial implant	A (9)
162.	• Patient received secondary prevention ICD • Had ventricular arrhythmias receiving ICD therapy since implant	A (9)

A = Appropriate; ICD = implantable cardioverter-defibrillator.

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Table 4.3. Primary Prevention at Initial Implant: Replacement of CRT-ICD for ERI

Indication		Appropriate Use Score (1–9)	
Primary Prevention at Initial Implant: Replacement of CRT-ICD for ERI		Replace With CRT-ICD	Replace With CRT-Pacemaker
163.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now unchanged (despite clinical improvement)	A (9)	R (3)
164.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now 36% to 49%	A (8)	M (5)
165.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now ≥50% (normalized)	A (7)	M (6)

A = Appropriate; CRT = cardiac resynchronization therapy; ERI = elective replacement indicator; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

Table 4.4. Secondary Prevention at Initial Implant: Replacement of CRT-ICD for ERI

Indication		Appropriate Use Score (1–9)	
Secondary Prevention at Initial Implant: Replacement of CRT-ICD for ERI		Replace With CRT-ICD	Replace With CRT-Pacemaker
166.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now unchanged (despite clinical improvement)	A (9)	
167.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now 36% to 49%	A (9)	R (3)
168.	• Patient received a CRT-ICD when LVEF was ≤35% • LVEF now ≥50% (normalized)	A (8)	R (3)

NOTE: grey shaded box indicates "not rated."

A = Appropriate; CRT = cardiac resynchronization therapy; ERI = elective replacement indicator; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; R = Rarely Appropriate.

Section 5: Dual-Chamber ICD (As Opposed to Single-Chamber ICD for Patients Who Meet Criteria for ICD Implantation)

In this section, symptoms refer to those potentially related to bradycardia such as lightheadedness, pre-syncope, loss of consciousness, fatigue, or reduced exercise tolerance. All listed scenarios are asymptomatic unless otherwise specified. For scenarios where the QRS is wide, it is assumed that the patient does not otherwise meet criteria for CRT implantation.

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Table 5.1. Conduction System Abnormalities

	Indication	Appropriate Use Score (1–9)	
	Conduction System Abnormalities Sinus Node Dysfunction Who Meets Criteria for ICD		
169.	• Sinus node dysfunction (includes sinus pauses, chronotropic incompetence, or marked sinus bradycardia that results from drug therapy required to treat other conditions) • Symptomatic	**A (9)**	
170.	• Resting sinus bradycardia (resting heart rate <50 beats/min) • Asymptomatic	**A (7)**	
	Conduction System Abnormalities AV Conduction Disease Who Meets Criteria for ICD (Narrow QRS <120 ms)		
171.	• Third-degree AV block or advanced second-degree AV block (Mobitz II AV block or high-degree AV block) • Symptomatic • CRT not indicted	**A (9)**	
172.	• Third-degree AV block or advanced second-degree AV block (Mobitz II AV block or high-degree AV block) • Asymptomatic • CRT not indicated	**A (8)**	
173.	• Mobitz Type I AV block • Asymptomatic • CRT not indicated	**M (6)**	
174.	• First-degree AV block (PR <300 ms) • Asymptomatic	**M (5)**	
175.	• First-degree AV block (PR ≥300 ms) • Asymptomatic	**M (6)**	
	Conduction System Abnormalities Bundle Branch Block		
176.	• Sinus rhythm with normal PR interval • LBBB • CRT not indicated	**M (5)**	
177.	• Sinus rhythm with first-degree AV block • LBBB • CRT not indicated	**M (6)**	
178.	• Sinus rhythm with normal PR interval • Bifascicular block (RBBB/LAFB or RBBB/LPFB) • CRT not indicated	**M (5)**	
179.	• Sinus rhythm with first-degree AV block • Bifascicular block (RBBB/LAFB or RBBB/LPFB) • CRT not indicated	**M (6)**	
180.	• Alternating RBBB and LBBB • CRT not indicated	**A (8)**	
	Conduction System Abnormalities Acute MI or Ischemic Event	**Narrow QRS (<120 ms)**	**Chronic Wide QRS (≥120 ms)**
181.	• Transient AV block thought to be secondary to ischemia • Status post successful revascularization	**M (5)**	**A (7)**
182.	• Transient AV block thought to be secondary to ischemia • Not amenable to revascularization	**M (6)**	**A (7)**
	Conduction System Abnormalities Cardiac Valve Surgery		
183.	• Transient AV block • Narrow QRS (<120 ms)	**M (5)**	
184.	• New LBBB and first-degree AV block	**A (7)**	

A = Appropriate; AV = atrioventricular; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LAFB = left anterior fascicular block; LBBB = left bundle branch block; LPFB = left posterior fascicular block; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; RBBB = right bundle branch block.

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Table 5.2. No Conduction Abnormalities

	Indication	Appropriate Use Score (1–9)
	Meets Criteria for ICD (Narrow QRS <120 ms)	
185.	• Sinus rhythm with normal PR interval • Asymptomatic	M (4)

ICD = implantable cardioverter-defibrillator; M = May Be Appropriate.

Table 5.3. Tachyarrhythmias

	Indication	Appropriate Use Score (1–9)
	Atrial Arrhythmias or "Supraventricular Tachycardia (SVT)" and "No Standard Pacing Indications"*	
186.	• Paroxysmal atrial arrhythmias	A (7)
187.	• Underlying structural heart disease (e.g., ischemic or nonischemic CM) • No known paroxysmal atrial arrhythmias or SVT	M (5)
188.	• Structurally normal heart • No known paroxysmal atrial arrhythmias or SVT	M (4)
189.	• Long-standing persistent or permanent atrial fibrillation or atrial flutter • No plans for cardioversion or rhythm control	R (1)
	Known Slow Ventricular Arrhythmias	
190.	• Active patient • Known "slow VT" that overlaps with sinus tachycardia rate	A (8)

*Use of dual-chamber device for theoretical benefit related to arrhythmia discrimination (SVT vs. VT detection enhancements).
A = Appropriate; CM = cardiomyopathy; M = May Be Appropriate; R = Rarely Appropriate; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

Table 5.4. Other Disorders

	Indication	Appropriate Use Score (1–9)
	Genetic Disorders*	
191.	• Congenital long QT syndrome • ICD for secondary prevention	A (7)
192.	• Congenital long QT syndrome • ICD for primary prevention	A (7)
193.	• Hypertrophic cardiomyopathy • Narrow QRS (<120 ms) • No standard bradycardia pacing indications	M (6)
194.	• Hypertrophic cardiomyopathy • Wide QRS (≥120 ms) • No standard bradycardia pacing indications	M (6)

*Use of dual-chamber device for theoretical benefit related to arrhythmia discrimination (SVT vs. VT detection enhancements) and pacing to reduce the development of ventricular arrhythmias.
A = Appropriate; ICD = implantable cardioverter-defibrillator; M = May Be Appropriate; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

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Section 6: CRT—No Prior Implant

Non-LBBB is defined as RBBB or nonspecific intraventricular conduction block (not transient or rate-related).

Table 6.1. Ischemic Cardiomyopathy (Fig. 15)

Indication		Appropriate Use Score (1–9)		
LVEF ≤30%, Ischemic Cardiomyopathy				
		NYHA Class		
		I	II	III-amb IV
195.	• QRS <120 ms • Sinus rhythm	R (1)	R (1)	R (1)
196.	• QRS 120–149 ms • LBBB • Sinus rhythm	M (5)	A (7)	A (8)
197.	• QRS ≥150 ms • LBBB • Sinus rhythm	A (7)	A (8)	A (9)
198.	• QRS 120–149 ms • Non-LBBB • Sinus rhythm	R (3)	R (3)	M (6)
199.	• QRS ≥150 ms • Non-LBBB • Sinus rhythm	M (4)	M (6)	A (7)
LVEF 31% to 35%, Ischemic Cardiomyopathy				
		NYHA Class		
		I	II	III-amb IV
200.	• QRS <120 ms • Sinus rhythm	R (1)	R (1)	R (1)
201.	• QRS 120–149 ms • LBBB • Sinus rhythm	M (5)	A (7)	A (8)
202.	• QRS ≥150 ms • LBBB • Sinus rhythm	M (6)	A (8)	A (9)
203.	• QRS 120–149 ms • Non-LBBB • Sinus rhythm	R (3)	R (3)	M (6)
204.	• QRS ≥150 ms • Non-LBBB • Sinus rhythm	M (4)	M (6)	A (7)

A = Appropriate; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

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Table 6.2. Nonischemic Cardiomyopathy (Fig. 16)

Indication		Appropriate Use Score (1–9)		
LVEF ≤30%, Nonischemic Cardiomyopathy				
		NYHA Class		
		I	II	III-amb IV
205.	• QRS <120 ms • Sinus rhythm	R (1)	R (1)	R (1)
206.	• QRS 120-149 ms • LBBB • Sinus rhythm	M (4)	A (7)	A (8)
207.	• QRS ≥150 ms • LBBB • Sinus rhythm	M (6)	A (9)	A (9)
208.	• QRS 120-149 ms • Non-LBBB • Sinus rhythm	R (3)	R (3)	M (6)
209.	• QRS ≥150 ms • Non-LBBB • Sinus rhythm	M (5)	M (6)	A (8)
LVEF 31% to 35%, Nonischemic Cardiomyopathy				
		NYHA Class		
		I	II	III-amb IV
210.	• QRS <120 ms • Sinus rhythm	R (1)	R (1)	R (1)
211.	• QRS 120–149 ms • LBBB • Sinus rhythm	M (5)	A (7)	A (8)
212.	• QRS ≥150 ms • LBBB • Sinus rhythm	M (6)	A (8)	A (9)
213.	• QRS 120–149 ms • Non-LBBB • Sinus rhythm	R (3)	R (3)	M (6)
214.	• QRS ≥150 ms • Non-LBBB • Sinus rhythm	M (5)	M (6)	A (7)

A = Appropriate; amb = ambulatory; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

Table 6.3.1. LVEF >35% of Any Etiology (ICD Indicated) (Fig. 17)

Indication		Appropriate Use Score (1–9)	
		NYHA Class	
		I-II	III-amb IV
215.	• QRS <120 ms • Sinus rhythm	R (1)	R (1)
216.	• QRS 120–149 ms • LBBB • Sinus rhythm	R (3)	M (4)
217.	• QRS ≥150 ms • LBBB • Sinus rhythm	M (4)	M (5)
218.	• QRS 120–149 ms • Non-LBBB • Sinus rhythm	R (2)	R (3)
219.	• QRS ≥150 ms • Non-LBBB • Sinus rhythm	R (3)	M (4)

Amb = ambulatory; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

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Table 6.3.2. LVEF ≤35% of Any Etiology (Fig. 18)

Indication		Appropriate Use Score (1–9)
NYHA Class IV on Intravenous Inotropic Support		
220.	• QRS 120–149 ms • LBBB	M (6)
221.	• QRS ≥150 ms • LBBB	M (6)
222.	• QRS 120–149 ms • Non-LBBB	M (4)
223.	• QRS ≥150 ms • Non-LBBB	M (5)

LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association.

Table 6.4. Pre-Existing or Anticipated RV Pacing With a Clinical Indication for ICD or Pacemaker Implantation (Fig. 19)

Indication		Appropriate Use Score (1–9)	
Intrinsic Narrow QRS, LVEF ≤35%			
		NYHA Class	
		I-II	**III-amb IV**
224.	• RV pacing anticipated ≤40%	M (4)	M (5)
225.	• RV pacing anticipated >40%	A (7)	A (8)
Intrinsic Narrow QRS, LVEF >35%			
		NYHA Class	
		I-II	**III-amb IV**
226.	• RV pacing anticipated ≤40%	R (2)	M (4)
227.	• RV pacing anticipated >40%	M (5)	M (6)

A = Appropriate; amb = ambulatory; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular.

Table 6.5. Refractory Class III/IV HF <3 Months Post-Revascularization and/or ≤40 Days Post-MI (Fig. 20)

Indication		Appropriate Use Score (1–9)
No Other Indication for Ventricular Pacing, LVEF ≤35%		
228.	• QRS 120–149 ms • LBBB	A (7)
229.	• QRS ≥150 ms • LBBB	A (8)
230.	• QRS 120–149 ms • Non-LBBB	M (5)
231.	• QRS ≥150 ms • Non-LBBB	A (7)
No Other Indication for Ventricular Pacing, LVEF 36% to 50%		
232.	• QRS 120–149 ms • LBBB	R (3)
233.	• QRS ≥150 ms • LBBB	M (4)
234.	• QRS 120–149 ms • Non-LBBB	R (3)
235.	• QRS ≥150 ms • Non-LBBB	R (3)

A = Appropriate; HF = heart failure; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; RV= right ventricular.

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8. Figures

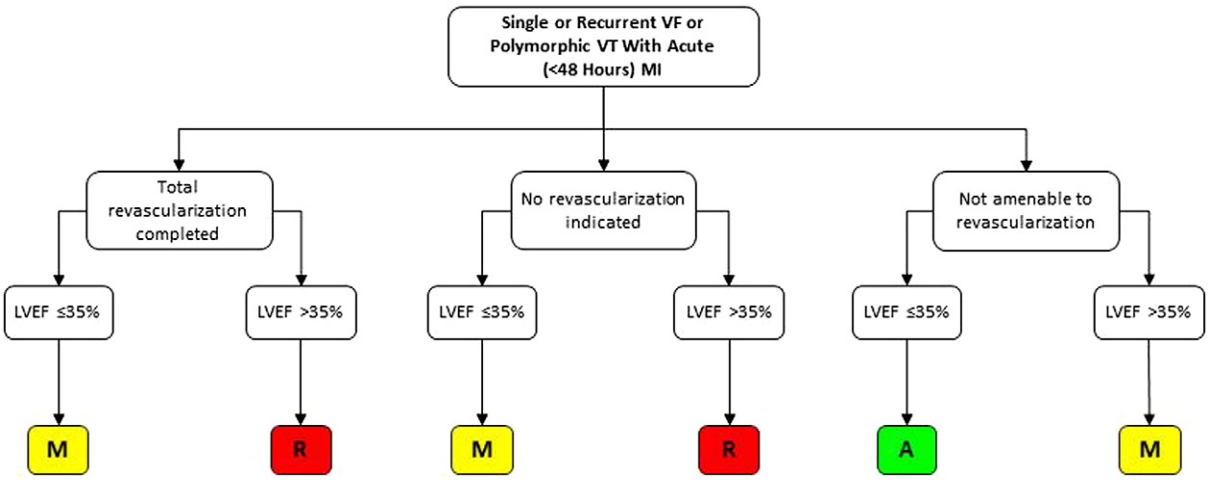

Figure 1. Secondary Prevention: CAD—VF or Hemodynamically Unstable VT Associated With Acute (<48 h) MI

Indication 3 for nonsustained VT 4 days post-MI and inducible VT/VF at EPS ≥4 days after revascularization is not represented in this figure and was rated as Appropriate for LVEF <50% and May Be Appropriate for LVEF ≥50%.

A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

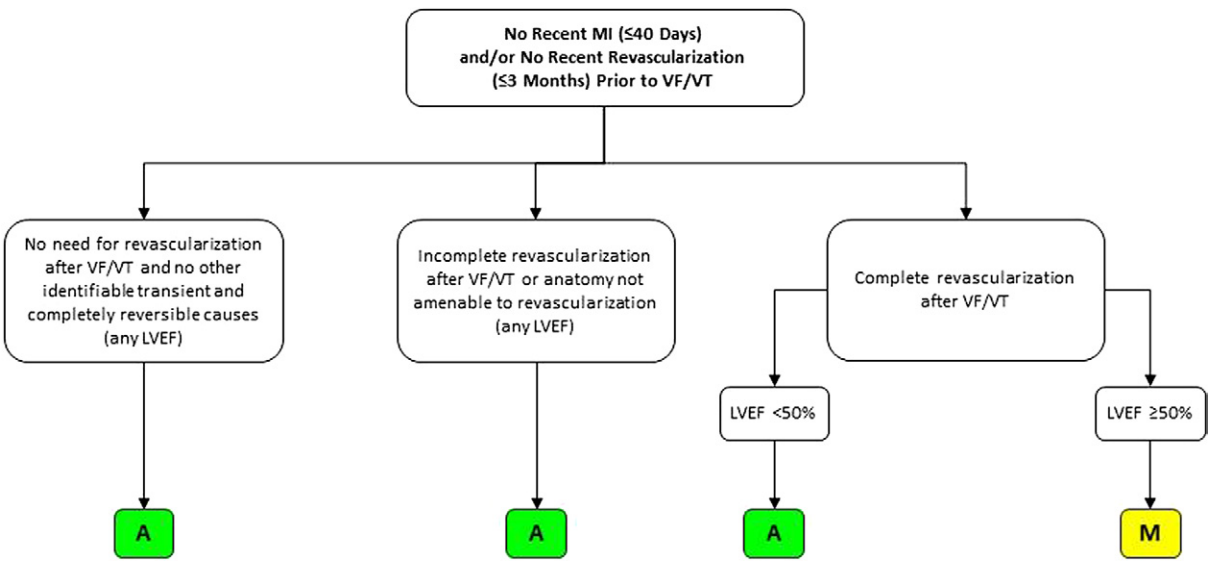

Figure 2. Secondary Prevention: VF or Hemodynamically Unstable VT With No Recent MI and/or No Recent Revascularization

A = Appropriate; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia.

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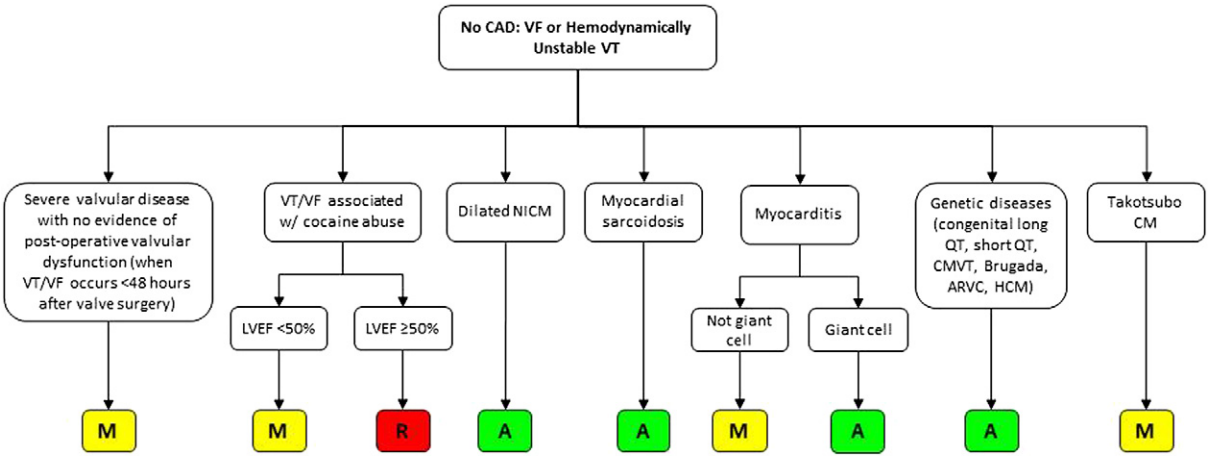

Figure 3. Secondary Prevention: VF or Hemodynamically Unstable VT—No CAD With Structural Heart Disease or Genetic Disorders

A = Appropriate; ARVC = arrhythmogenic right ventricular cardiomyopathy; CM = cardiomyopathy; CMVT = catecholaminergic polymorphic ventricular tachycardia; EPS = electrophysiological study; HCM = hypertrophic cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NICM = non-ischemic cardiomyopathy; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

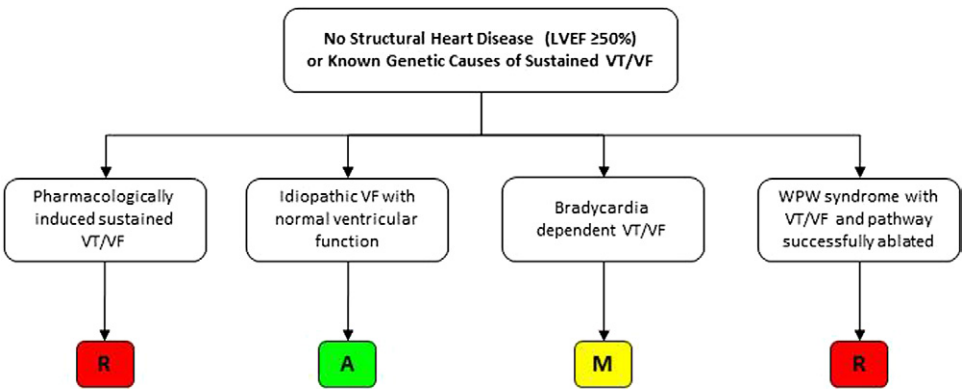

Figure 4. Secondary Prevention: No Structural Heart Disease (LVEF ≥50%) or Known Genetic Causes of Sustained VT/VF

A = Appropriate; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia; WPW = Wolff-Parkinson-White.

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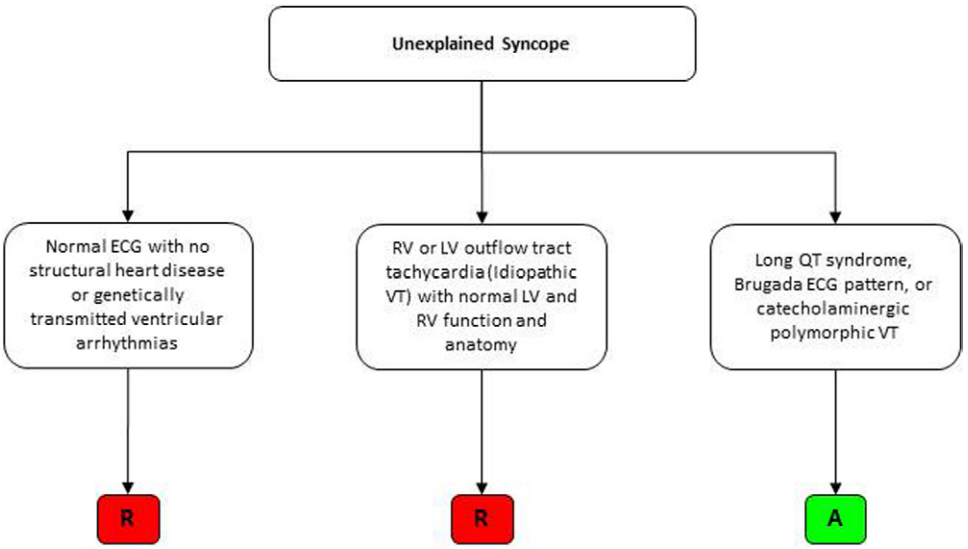

Figure 5. Secondary Prevention: Syncope in Patients Without Structural Heart Disease

A = Appropriate; ECG = electrocardiogram; LV = left ventricular; LVEF = left ventricular ejection fraction; R = Rarely Appropriate; RV = right ventricular; VF = ventricular fibrillation; VT = ventricular tachycardia.

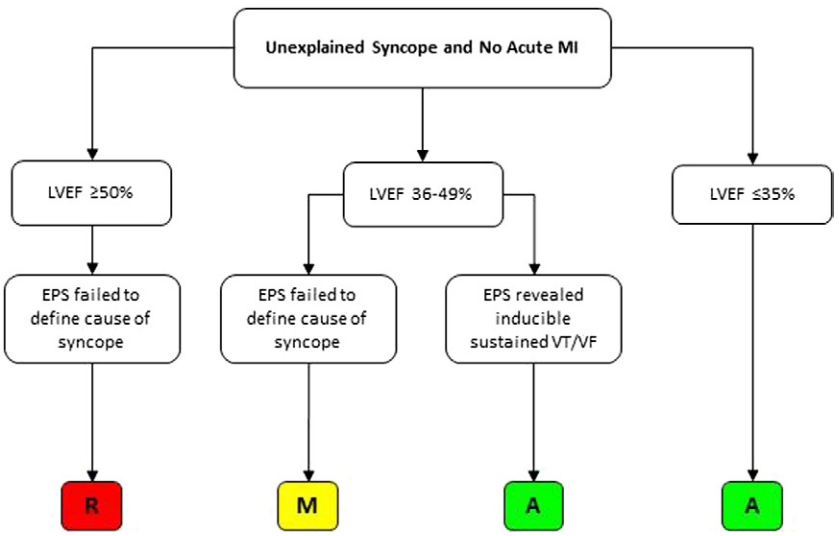

Figure 6. Secondary Prevention: Syncope in Patients With Coronary Artery Disease

A = Appropriate; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

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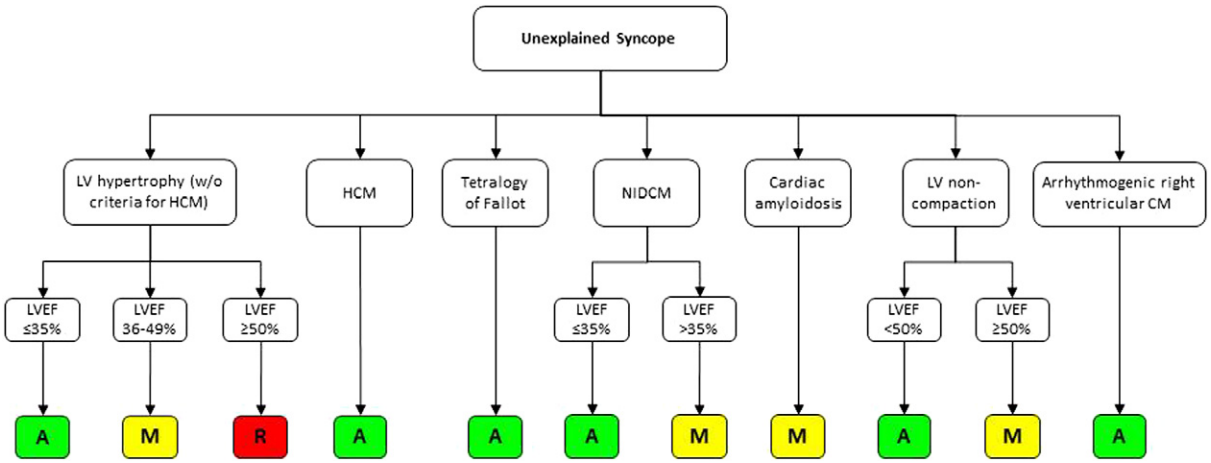

Figure 7. Secondary Prevention: Syncope in Patients with Nonischemic Structural Heart Disease

A = Appropriate; CM = cardiomyopathy; HCM = hypertrophic cardiomyopathy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NIDCM = nonischemic dilated cardiomyopathy; R = Rarely Appropriate.

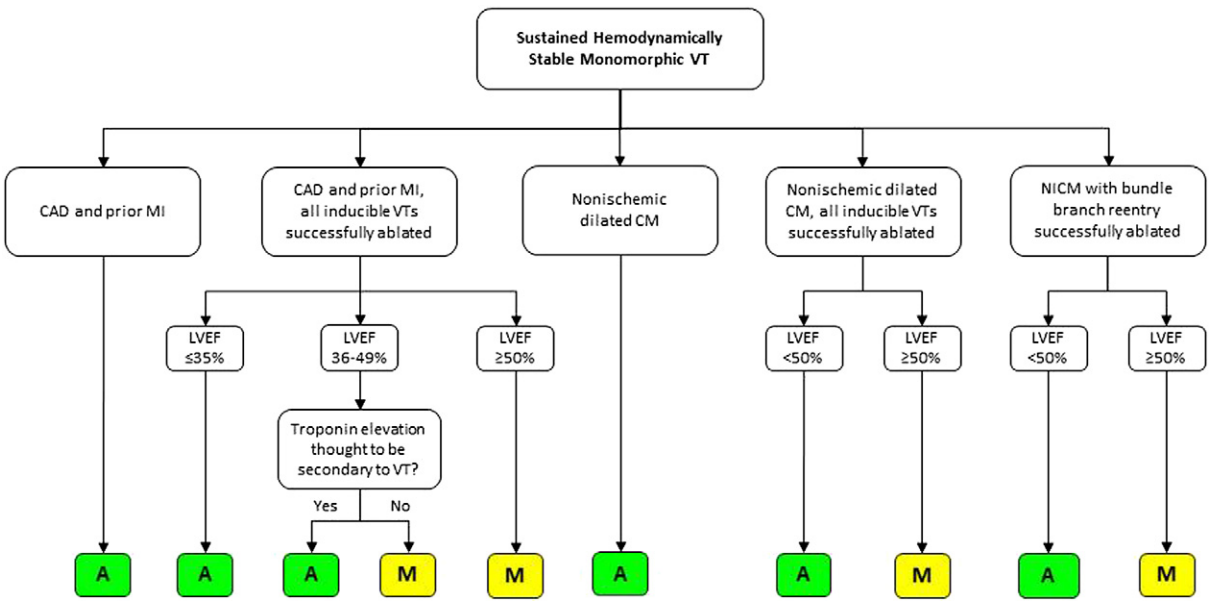

Figure 8. Secondary Prevention: Sustained Hemodynamically Stable Monomorphic VT Associated With Structural Heart Disease

A = Appropriate; CAD = coronary artery disease; CM = cardiomyopathy; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; VT = ventricular tachycardia.

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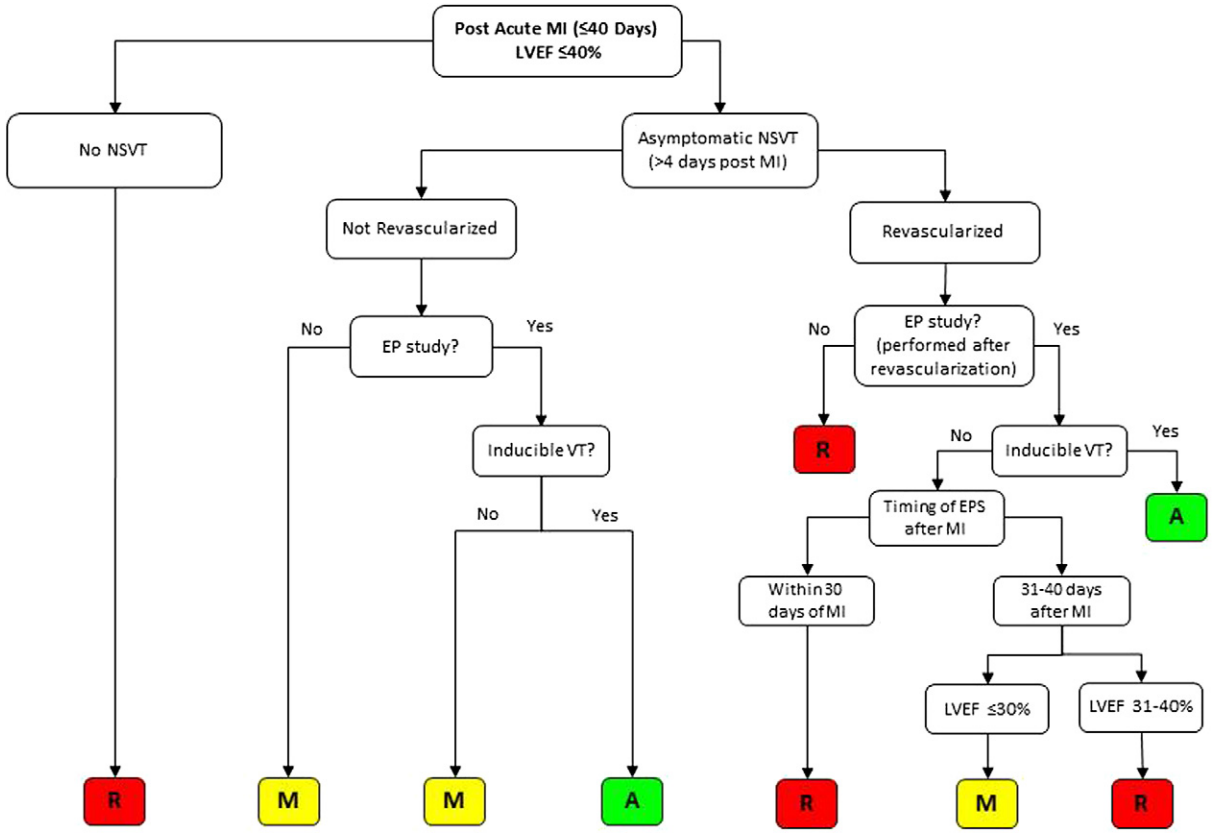

Figure 9. Primary Prevention: Coronary Artery Disease, Post-Acute MI (≤40 Days), LVEF ≤40%

A = Appropriate; EP = electrophysiological; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

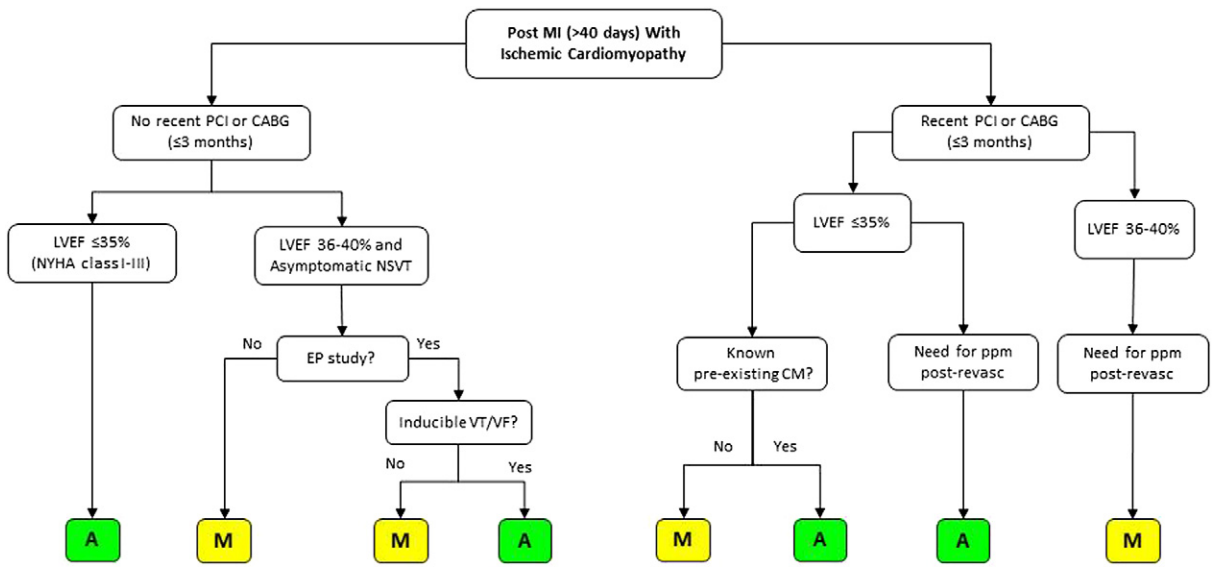

Figure 10. Primary Prevention: Coronary Artery Disease, Prior MI (>40 Days) With Ischemic Cardiomyopathy

A = Appropriate; CABG = coronary artery bypass graft; CM = cardiomyopathy; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; ppm = permanent pacemaker; VF = ventricular fibrillation; VT = ventricular tachycardia.

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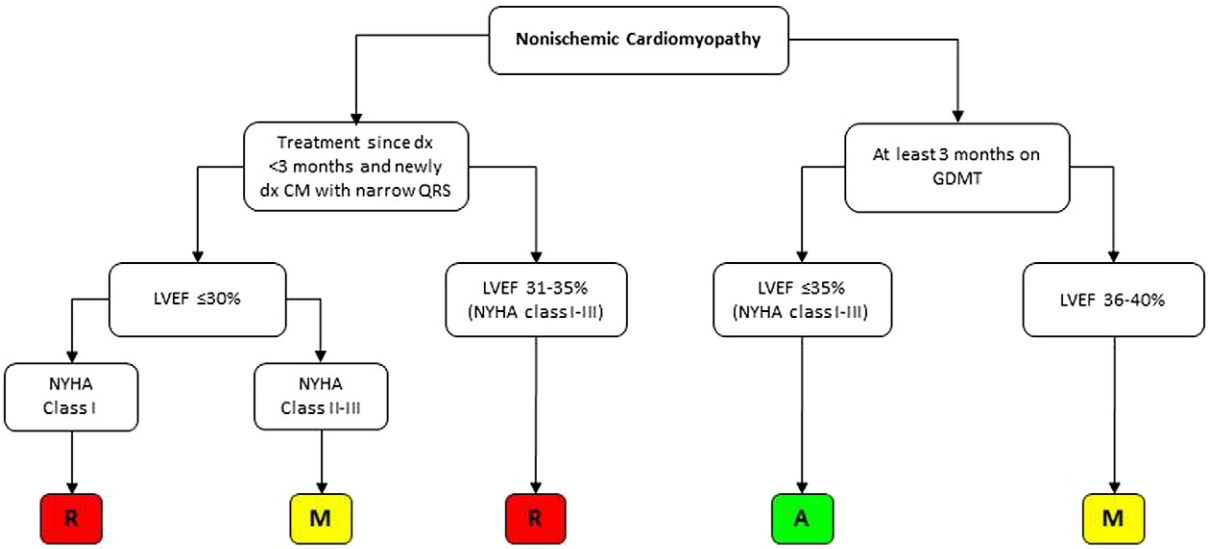

Figure 11. Primary Prevention: Nonischemic Cardiomyopathy

A = Appropriate; CM = cardiomyopathy; dx = diagnosis; GDMT = guideline-directed medical therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

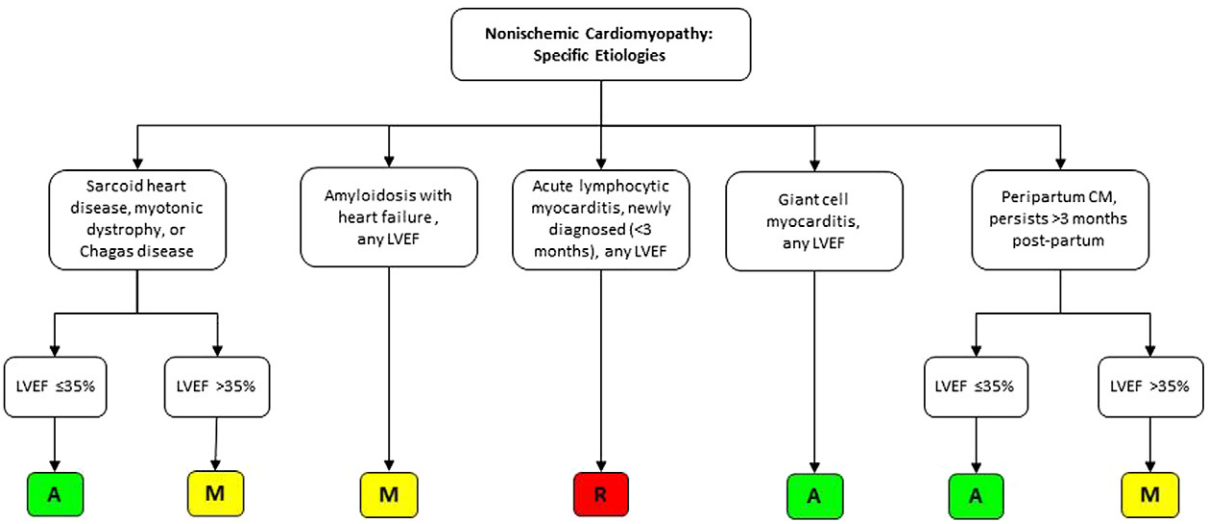

Figure 12. Primary Prevention: Nonischemic Cardiomyopathy, Specific Etiologies

A = Appropriate; CM = cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

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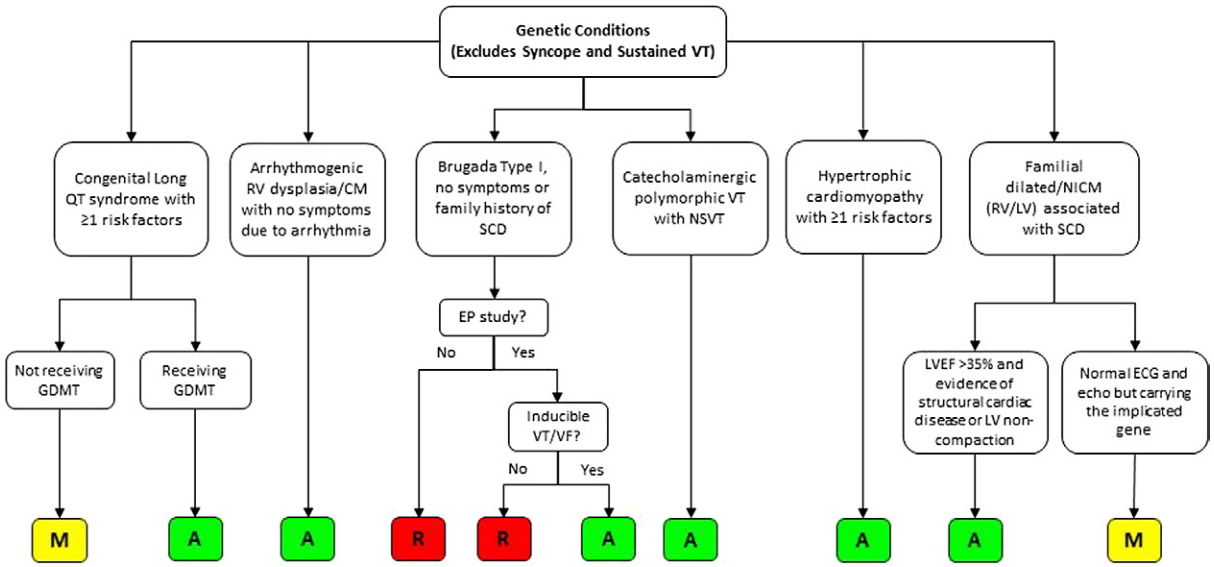

Figure 13. Primary Prevention: Genetic Conditions (Excludes Syncope and Sustained VT)

A = Appropriate; CM = cardiomyopathy; ECG = electrocardiogram; EPS = electrophysiological study; GDMT = guideline-directed medical therapy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; RV = right ventricular; SCD = sudden cardiac death; VF = ventricular fibrillation; VT = ventricular tachycardia.

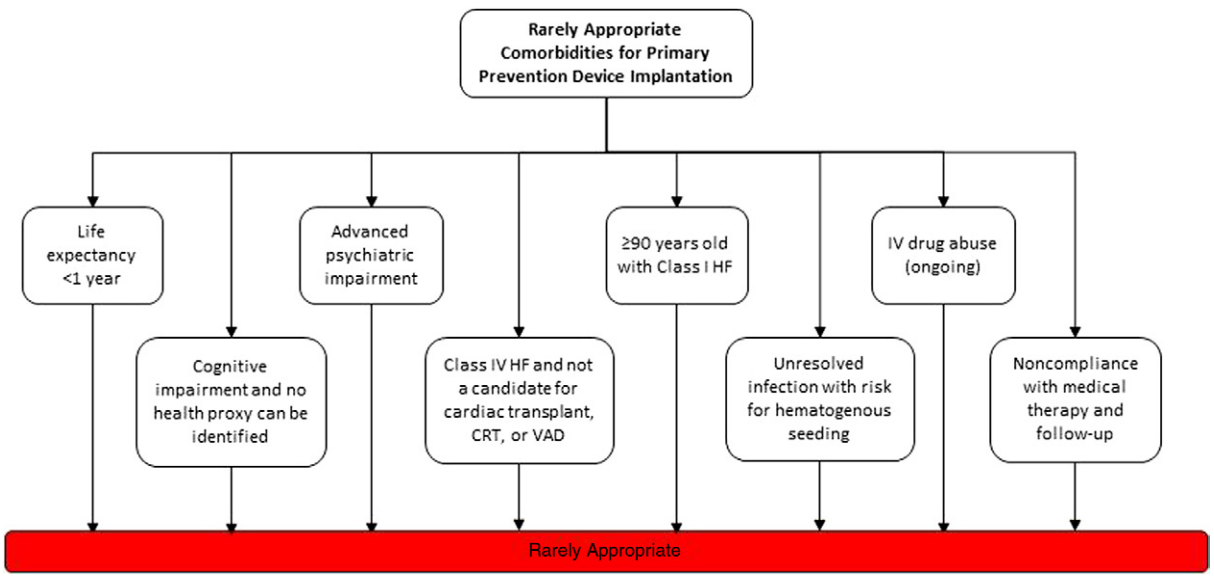

Figure 14. Primary Prevention: Comorbidities (Rarely Appropriate Indications)

CRT = cardiac resynchronization therapy; HF = heart failure; IV = intravenous; VAD = ventricular assist device.

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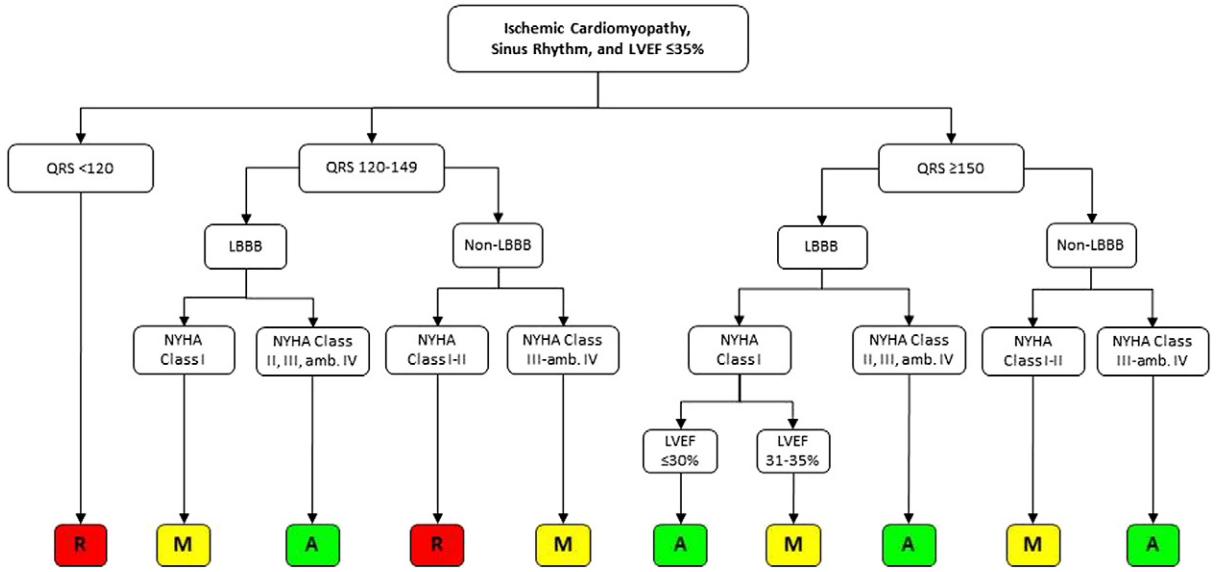

Figure 15. CRT: No Prior Implant—Ischemic Cardiomyopathy

A = Appropriate; amb = ambulatory; CRT = cardiac resynchronization therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

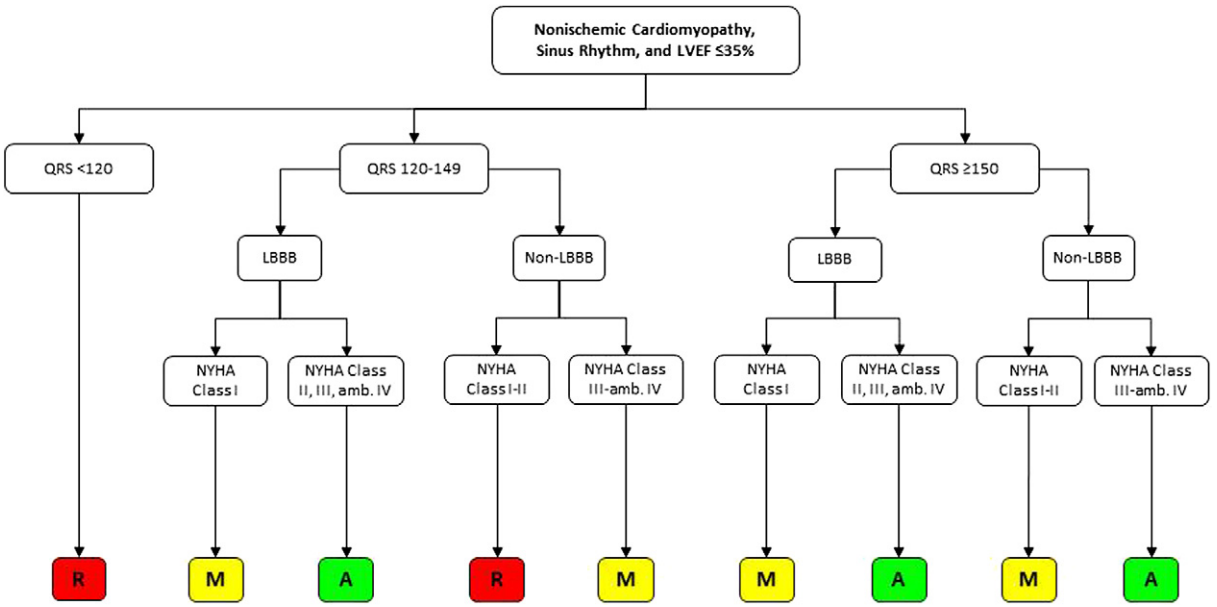

Figure 16. CRT: No Prior Implant—Nonischemic Cardiomyopathy

A = Appropriate; amb = ambulatory; CRT = cardiac resynchronization therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

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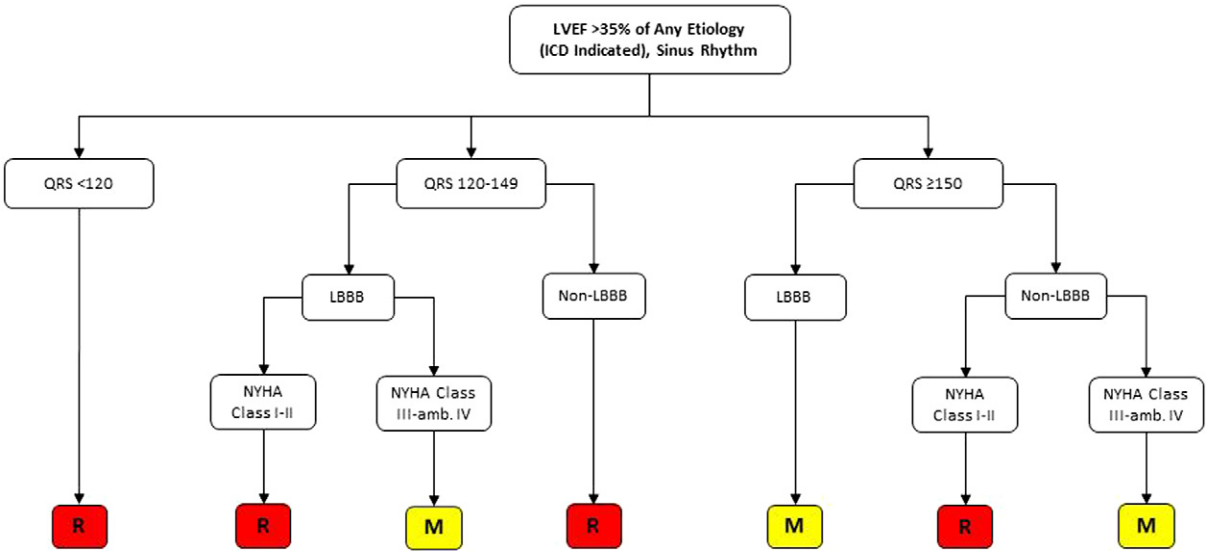

Figure 17. CRT: No Prior Implant—LVEF >35% of Any Etiology (ICD Indicated)

amb = ambulatory; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

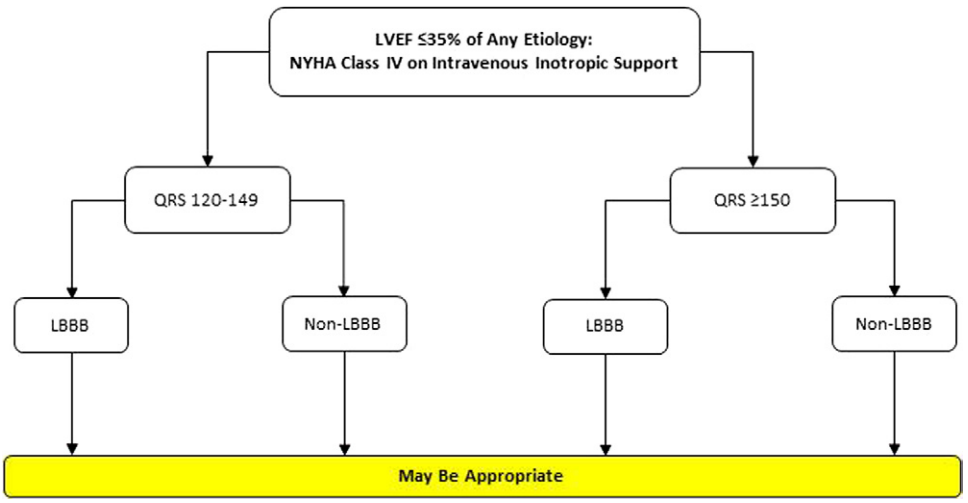

Figure 18. CRT: No Prior Implant—LVEF ≤35% of Any Etiology (NYHA Class IV on IV Inotropic Support)

CRT = cardiac resynchronization therapy; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

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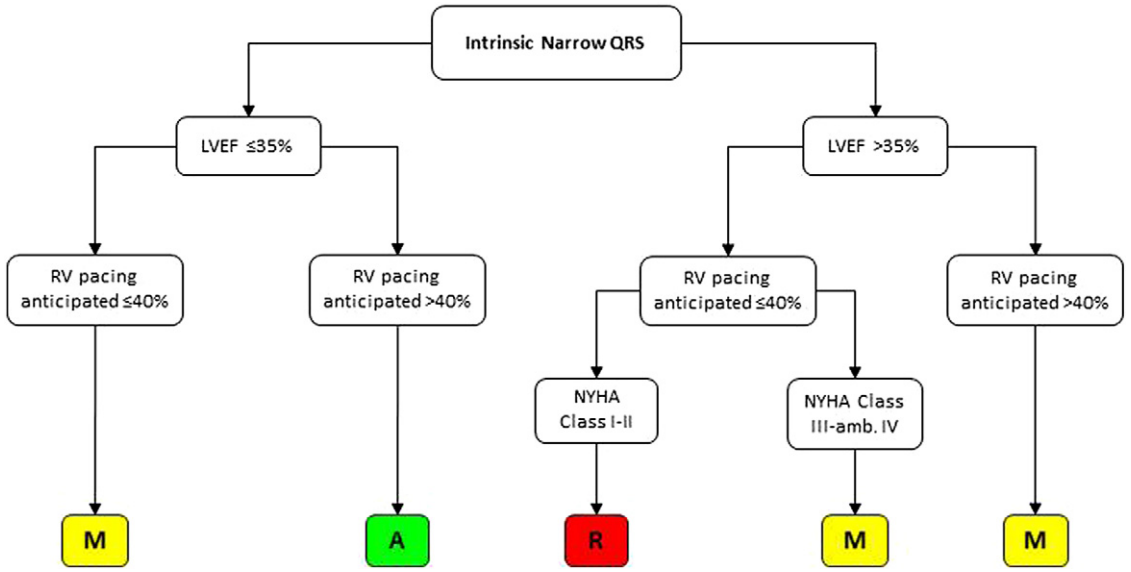

Figure 19. CRT: No Prior Implant—Pre-Existing or Anticipating RV Pacing With a Clinical Indication for ICD or Pacemaker Implantation

A = Appropriate; amb = ambulatory; CRT = cardiac resynchronization therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular.

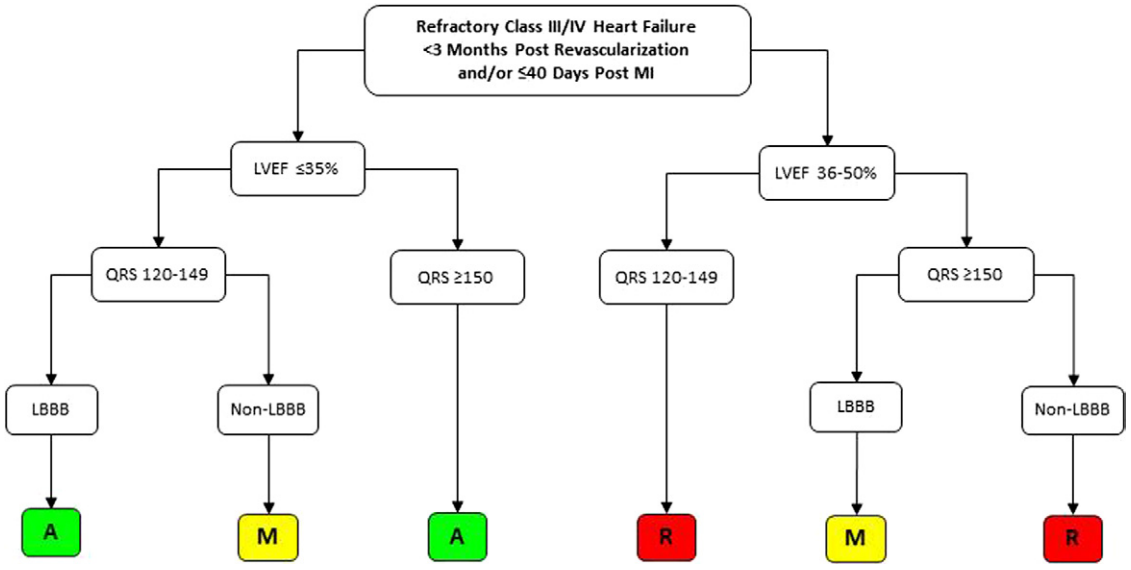

Figure 20. Refractory Class III/IV Heart Failure <3 Months Post Revascularization and/or ≤40 Days Post-MI

A = Appropriate; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; R = Rarely Appropriate.

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9. Discussion

This document summarizes the assessed levels of appropriateness for a variety of clinical scenarios involving the implantation of ICD or CRT devices, including: 1) initial implantation of ICDs (for primary or secondary prevention indications) or CRT devices; 2) generator replacements with pre-existing CIEDs; and 3) choice of dual-chamber, as opposed to single-chamber, ICDs in specific clinical situations. These appropriate use criteria are meant to act as a guide in clinical decision making regarding appropriate patient selection and the timing of device implantation for ICDs or CRT devices. However, the writing group feels it is important to acknowledge that patients may not always fit neatly within a given clinical scenario and that clinical judgment is necessary for assessing individual patients.

The appropriate use criteria should be used in conjunction with the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities and the 2012 focused update (9,29), and are meant to provide additional guidance concerning the decision to implant ICDs and CRT devices in a variety of clinical scenarios that may or may not be represented in the guidelines, often providing additional guidance in areas where there are gaps in the guidelines. This AUC document also highlights scenarios where these conditions and recommendations may be modified by patient comorbidities or limitation of life expectancy because of coexisting diseases.

9.1. ICDs: Initial Implantation

Clinical scenarios involving the implantation of ICDs were separated into primary and secondary prevention indications, as these represent unique patient populations. Modifying considerations, such as LVEF or NYHA class, were included for specific clinical scenarios when deemed appropriate by the writing group based on the evidence and enrollment criteria in previous clinical trials combined with clinical judgment based on practice experience with real-world populations.

A. Secondary Prevention ICD Implantation

Secondary prevention ICD indications included patients presenting with sustained VT, VF, or syncope with high-risk characteristics. Clinical scenarios included a variety of accompanying acute and chronic conditions that could modify consideration of the risk of subsequent recurrence of sustained ventricular arrhythmias or sudden cardiac death.

Scenarios modified by LVEF, presence or absence of CAD or other structural heart disease, revascularization procedure, timing of sustained VT/VF from MI or revascularization procedure, and single or recurrent nature of arrhythmias are described in Tables 1.1 to 1.7. Syncope without clinically documented sustained ventricular arrhythmias modified by presence or absence of CAD or structural heart disease, LVEF, or EP testing results are described in Tables 1.8.1 to 1.8.3, whereas hemodynamically stable VT associated with structural heart disease modified by type of underlying heart disease, LVEF, and outcome of ablation are described in Table 1.9.

VF or Sustained Polymorphic VT

Scenarios in which patients presented with VF or sustained polymorphic VT in the setting of coronary artery disease, modified by timing post-MI and timing post-revascularization, or occurring in the setting of exercise testing are described in Tables 1.1 to 1.4 (Figs 1 and 2). Monomorphic VT was excluded from these early post-infarct scenarios as it was felt that a more uniform tachycardia typically represents a stable substrate that is often related to re-entry, and therefore, the risk of arrhythmia recurrence may be higher than that seen for patients with polymorphic VT/VF. Sustained monomorphic VT occurring within the first 48 to 72 h of myocardial infarction is associated with more extensive myocardial damage, is an independent predictor of in-hospital mortality, and is associated with a poor 1-year outcome (33,34).

ICD implantation was considered Rarely Appropriate for most of these scenarios where VF or polymorphic VT occurred in the setting of acute (<48 h) MI, particularly in the setting of preserved or only mild to moderately reduced LV systolic function, except for the case where nonsustained VT occurred 4 days post-MI and sustained VT/VF was then induced at EP testing (Table 1.1, Fig. 1). This is consistent with clinical evidence where ICD implantation should not be recommended for arrhythmias considered "completely reversible." However, indications were rated May Be Appropriate if LVEF was ≤35%. These indications cover patients with LV dysfunction that could have been pre-existing, as these scenarios did not include any prior assessment of LVEF, or little chance for recovery of LV function (in the absence of revascularization in some scenarios). ICD implantation was rated as Appropriate for obstructive CAD with coronary anatomy not amenable to revascularization if LVEF ≤35%. The presence of obstructive coronary disease that is not amenable to revascularization could place the patient at continued risk for recurrent arrhythmias and, therefore, may not qualify as a "completely reversible" cause.

Sustained VT/VF occurring in the setting of nonischemic heart disease, including genetic diseases, infiltrative cardiomyopathy, or myocarditis, as well as no detectable structural heart disease are described in Tables 1.5 to 1.7 (Figs. 3 and 4). Many of these scenarios are not specifically addressed in the guidelines or clinical trials, and represent a relatively small percentage of the population undergoing ICD implantation. Therefore, clinical judgment based on review of limited evidence is required when making these decisions.

Syncope

Scenarios involving syncope included those with and without underlying structural heart disease or concomitant coronary artery disease. In patients without structural heart

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disease, ICD implantation was rated Appropriate when occurring in the setting of long QT syndrome regardless of treatment with beta-blockers, a Brugada ECG pattern regardless of findings at invasive electrophysiological testing, and catecholaminergic polymorphic VT (Table 1.8.1, Fig. 5). In contrast, ICD implantation was rated as Rarely Appropriate in patients with unexplained syncope who have a normal heart and normal ECG and do not have a genetic condition associated with sudden death, or when syncope occurs in patients with normal LV function and idiopathic VT (e.g., RV outflow tract VT or idiopathic LV VT) whether or not ablation had been attempted. The latter is consistent with the good prognosis of patients with idiopathic VT.

In the setting of coronary artery disease, scenarios were modified by LVEF (Table 1.8.2, Fig. 6). In patients with unexplained syncope, prior MI, and an LVEF ≤35%, ICD implantation was considered Appropriate regardless of the findings of EP study. In the setting of a mildly reduced LVEF (36% to 49%) and prior MI, ICD implantation was considered Appropriate only if EP study revealed inducible sustained VT or VF, but was rated as May Be Appropriate if the EP study failed to define a cause, regardless of revascularization status.

In patients with nonischemic structural heart disease and syncope, scenarios were modified by type of heart disease and LVEF (Table 1.8.3, Fig. 7).

Sustained Hemodynamically Tolerated Monomorphic VT

Hemodynamically tolerated sustained monomorphic VT was considered separately from hemodynamically unstable VT or VF, given the potential differences in arrhythmia substrate as well as the response of VT to catheter ablation. When occurring in the setting of LVEF ≤35%, regardless of the underlying disease process or history of VT ablation, ICD implantation was considered Appropriate (Table 1.9, Fig. 8) (35). With a normal LVEF (≥50%) and hemodynamically tolerated monomorphic VT, ICD implantation was rated Appropriate in the setting of prior MI or nonischemic dilated cardiomyopathy in the absence of VT ablation, but it was rated as May Be Appropriate if successful VT ablation was performed.

B. Primary Prevention ICD Implantation

In the absence of sustained VT/VF or syncope, primary prevention ICD implantation may be considered in a variety of scenarios to reduce mortality related to potentially life-threatening sustained ventricular arrhythmias. Specific time periods for implantation of primary prevention ICDs (i.e., 40 days after an acute MI, 3 months after revascularization, and 3 months after initial diagnosis of a cardiomyopathy) are described. These time periods were selected for this appropriate use document based on prior clinical trials, guideline documents, or contemporary practice. A "waiting period" following MI is supported by the IRIS (Immediate Risk-Stratification Improves Survival) trial and DINAMIT (Defibrillator IN Acute Myocardial Infarction Trial), which demonstrated no overall survival benefit of ICD therapy when devices were implanted very early (within 30 or 40 days) following MI (30,31). Scenarios in this section are also modified by type of heart disease, LVEF, NYHA functional class, and/or duration of medical therapy (Tables 2.1 to 2.5, Figs. 9 to 13).

Timing Post-MI or Revascularization and Electrophysiological Testing

Initial primary prevention ICD trials utilized EP testing in risk stratification. Many of the scenarios in Tables 2.1.1 and 2.1.2 take into account some of the shorter time periods post-MI where limited trial data are available. The definition for MI has evolved in recent years (23,25). For contemporary practice, the diagnosis of MI should be made according to the most recent statement and future trials should precisely define MI and other diagnoses critical to major entry criteria. The MUSTT study enrolled patients with CAD, LVEF ≤40%, and asymptomatic, nonsustained VT (36). The qualifying arrhythmia had to have occurred 6 months or less before enrollment, and 4 or more days after the most recent MI or revascularization procedure. The study showed that EP-guided therapy with ICDs, but not with antiarrhythmic drugs, reduced the risk of sudden death in these patients. However, >80% of randomized patients had suffered their most recent MI more than 1 month before enrollment. Thus, because few patients were enrolled in the first month post-infarction, the utility of EP study in that time period is uncertain.

These scenarios are also modified by the presence or absence of revascularization. To qualify for enrollment, MADIT II required a waiting period of at least 3 months following coronary revascularization. In contrast, patients were eligible for enrollment in MUSTT ≥4 days following revascularization, and 56% of patients enrolled in this trial underwent prior CABG at some point in time (36). However, post-hoc analysis of MUSTT revealed that the occurrence of postoperative NSVT, especially within 10 days after CABG, portends a far better outcome than when it occurs in non-postoperative settings (37). As there are limited data related to EP testing very early following revascularization procedures, and available data suggest that NSVT in this early period may represent a less specific risk factor for future events, decisions related to timing of EP testing should be individualized. As in other areas of this AUC document, panel members were asked to evaluate scenarios where gaps in the guidelines exist, and further investigation may be warranted.

Pre-Existing Cardiomyopathy or Permanent Pacemaker Needed

When a pre-existing cardiomyopathy with LVEF ≤35% had been present for at least 3 months, regardless of the cause, ICD implantation was rated Appropriate even ≤40 days after the acute MI (Table 2.1.3). The rationale is that

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the cardiomyopathy was a pre-existing condition not attributable to acute MI and would not be likely to recover. Furthermore, when the LVEF is severely reduced (≤35%) and the patient requires permanent pacemaker implantation early (≤40 days) following MI, ICD therapy was rated Appropriate (Table 2.1.4). Although these scenarios are not specifically addressed in clinical trials, this is a logical decision from the standpoint of cost and patient safety. If little or no improvement in LV function is expected, the need for a second procedure in 3 months would expose the patient to unnecessary risk. When a patient requires pacing early (≤40 days) post-MI, implantation is also justified to avoid the expense and risk of implanting a pacemaker followed by replacement with an ICD after the 40-day interval. In the REPLACE registry (REPLACE: Implantable Cardiac Pulse Generator Replacement Registry), a high complication rate of 15.3% was observed in patients undergoing planned transvenous lead addition for replacement or upgrade to a device capable of additional therapies (38).

When recent percutaneous coronary intervention or coronary artery bypass grafting had been performed, the technical panel determined that an ICD implantation was Appropriate when there was a known pre-existing cardiomyopathy present for >3 months or when there was an indication for pacing and the LVEF was ≤35% (Table 2.2, Fig. 10).

Duration of Guideline-Directed Medical Therapy

Once a patient with a nonischemic cardiomyopathy is on guideline-directed therapy for at least 3 months, ICD implantation was rated Appropriate for LVEF ≤35% and NYHA class I to III symptoms (Table 2.4). It is generally recommended that patients receive a period of guideline-directed medical therapy following a new diagnosis of nonischemic cardiomyopathy with the hope that LV function will improve. ICD implantation within 3 months of a newly diagnosed cardiomyopathy (LVEF ≤35%) was considered Rarely Appropriate in most instances (Table 2.4, Fig. 11). Similarly, in the setting of an ischemic cardiomyopathy without recent MI, ICD implantation was deemed Appropriate only after the patient had received guideline-directed medical therapy for at least 3 months, unless nonsustained VT had been present and EP study revealed inducible sustained VT/VF (Table 2.3). In patients with ischemic cardiomyopathy status post-MI (>40 days) with an LVEF ≤30% and without revascularization within 3 months (MADIT II [Multicenter Automatic Defibrillator Implantation Trial II] criteria), ICD implantation was rated Appropriate regardless of duration of heart failure therapy (Table 2.2).

The other potential exception to the 3-month waiting period is when pacing is needed after recent valve surgery with an incidental bypass graft, and severe LV function (LVEF ≤35%) is not likely to improve (Table 2.4).

C. Comorbidities

Based on existing data, the risks and benefits of ICD therapy may be modified by specific coexisting comorbidities, even when other primary prevention indications exist for ICD implantation (39–43). Much of these data are based on post hoc analyses from clinical trials, registries, or small studies. Comorbidities may limit life expectancy or enhance risk. The potential risks and benefits should be assessed on an individual basis, and options should be discussed between the healthcare provider and the particular patient. The writing group created scenarios with specific comorbidities that may modify decision making regarding primary prevention ICD implantation when the ICD would otherwise be deemed Appropriate.

The only comorbidities that were felt to make ICD implantation Rarely Appropriate were a life expectancy <1 year, age ≥90 years with NYHA class I symptoms, inability to understand or provide informed consent in the absence of a healthcare proxy, ongoing drug abuse, documented noncompliance with medical therapy and follow-up, unresolved infection associated with the risk of hematogenous seeding, advanced psychiatric impairment, or certain NYHA class IV patients (Table 3.1, Fig. 14). There are many degrees and reasons for non-adherence to medical therapy and follow-up, some of which can be improved through better education and enhanced access to care. Therefore, the individual patient situation and timing of the procedure should clearly be considered prior to determining eligibility for ICD therapy. Amongst the considered comorbidities, ICD implantation was deemed to be Appropriate in the setting of severe symptomatic peripheral vascular disease and NYHA class II to III symptoms and NYHA class IV patients on waiting list for heart transplant. ICD implantation was rated as May Be Appropriate in the setting of other intermediate comorbidities such as a life expectancy of 1 to 2 years, age ≥80 years with NYHA class II to III symptoms, or severe cognitive impairment (with health proxy who consents to an ICD).

Although sudden cardiac death increases with age, elderly patients have been underrepresented in clinical trials, and comorbidities in the elderly might attenuate the benefit of ICD therapy. There is evidence that older patients with ICDs have worse survival than younger patients because death related to comorbidities in elderly patients outweighs the proportion of deaths related to ventricular arrhythmias (44). In addition, characteristics of patients receiving ICDs in clinical practice may differ from those enrolled in randomized clinical trials. For example, in primary prevention ICD trials, the median age was only 60 to 67 years (11,36,45). In the ACT (Advancements in ICD Therapy) registry, which included 4,566 patients who underwent their first ICD or CRT plus defibrillator implantation, 12% were ≥80 years old (75% of whom received devices for primary prevention), which was similar to the NCDR registry at that time where 12.4% of patients receiving ICDs were ≥80

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years old (46). More recent NCDR data reveal that approximately 17% of patients in the NCDR registry are now ≥80 years old, and 0.9% are >90 years old, suggesting an aging population receiving ICDs (47).

The role of ICD therapy for primary prevention of sudden death in patients with chronic kidney disease (with or without dialysis) was rated as May Be Appropriate. Multiple studies have questioned the benefit of ICD implantation in patients with chronic kidney disease, especially when on dialysis (48,49). Chronic kidney disease and associated comorbidities reduce long-term survival of patients and limit the beneficial impact of ICD therapy. In addition, patients with chronic kidney disease who are on dialysis appear to be at higher risk of complications related to ICD implantation, including increased risks related to bleeding and infection (41).

In the setting of Class IV heart failure, if the patient was not deemed a candidate for transplantation, CRT, or ventricular assist device, ICD therapy was rated Rarely Appropriate when outpatient continuous intravenous inotropic therapy was planned (Table 3.1). This is consistent with a low survival rate at least 1 year for NYHA class IV patients with drug-refractory heart failure who are not candidates for cardiac transplantation or CRT.

The survival benefit or complications related to primary prevention ICD implantation appears to be modified by age, LVEF, or pre-existing conditions such as chronic renal disease and peripheral arterial disease (39–43). A simple risk score incorporating peripheral arterial disease, age ≥70 years, creatinine ≥2.0 mg/dl, and ejection fraction ≤20% accurately predicted 1-year mortality in one recent study (42). Therefore, possible adverse effects of comorbidities should be openly discussed with potential ICD recipients before implantation to enhance the informed decision-making process.

The subcutaneous ICD system is not addressed in this document as further study is necessary to determine whether benefits might outweigh risks in patients who currently appear to derive little benefit from ICD therapy due to comorbidities and competing mortality risks.

9.2. CRT Devices

Stratification of ejection fraction (separating LVEF ≤30% from LVEF 31% to 35%), NYHA class (class I through ambulatory class IV), and QRS morphologies (considering LBBB QRS morphologies separate from non-LBBB QRS morphologies) were selected based on data from recent clinical trials.

Recent meta-analyses of CRT trials have suggested that the benefit of CRT is dependent on QRS duration, with a significant benefit associated with CRT in patients with QRS ≥150 ms, but not in patients with QRS <150 ms (20,21). Clinical response to CRT is also dependent on QRS morphology, with the greatest response for patients with LBBB and QRS ≥150 ms (50). There is also evidence that patients with RBBB morphology may not demonstrate benefit from CRT (51).

Recent data demonstrate the benefit of CRT combined with ICD therapy in patients with less severe heart failure (NYHA class I to II), LVEF ≤30%, and QRS duration of ≥130 ms (52). In MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial–Cardiac Resynchronization Therapy), the superiority of CRT was driven by a 41% reduction in the risk of heart-failure events, that was evident primarily in a pre-specified subgroup of patients with a QRS duration of ≥150 ms. MADIT-CRT was limited to patients with ischemic cardiomyopathy (NYHA class I or II) and nonischemic cardiomyopathy (NYHA class II only), so no conclusions can be made for nonischemic patients with class I heart failure based on the results of this study.

Scenarios modified by QRS duration, QRS morphology, NYHA class, type of heart disease, LVEF, need for inotropic support, other clinical indications for CIED therapy with anticipated frequent need for RV pacing, and timing post-MI or revascularization are described in Tables 6.1 to 6.5 (Figs. 15 to 20).

In the setting of an LVEF ≤35% with a narrow QRS and plan to implant an ICD or pacemaker in a patient with anticipated need for frequent RV pacing (>40% of the time), CRT implantation was rated Appropriate regardless of NYHA class, even if the intrinsic QRS was narrow (Table 6.4). However, if anticipated pacing was ≤40% of the time, CRT appropriateness was rated as May Be Appropriate. This is consistent with prior studies implicating the deleterious consequences of RV pacing, specifically suggesting that 41% to 50% RV pacing may result in a higher risk of heart failure, particularly in the setting of pre-existing LV dysfunction (16,53–55).

9.3. Generator Replacement

There are limited data about the management of patients presenting for elective generator replacements in the setting of previously implanted ICD or CRT devices that are nearing end-of-life. Over a patient's life span, clinical situations evolve and previously present conditions that merited ICD or CRT implantation may change. The individual patient's clinical status and concomitant illnesses may evolve so that considerations may include not only replacement of the pulse generator, but also potentially changing the type of device (e.g., from an ICD to a pacemaker). Furthermore, the clinical evidence for CIED placement may evolve over time, with ongoing research and availability of new trial data. Once patients have received appropriate ICD therapy for ventricular arrhythmias, they are subsequently considered "secondary prevention" at the time of generator replacement in the NCDR. There is currently a paucity of data related to generator replacement in patients who received primary prevention ICDs but have not experienced clinically relevant arrhythmias since initial implantation, and generator replacement is often still performed regardless of LVEF at follow-up. However, the

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decision to perform a generator replacement or consider "upgrade" of a device is not without risk. Therefore, the indications seek to assess appropriateness for a variety of clinical scenarios related to either "replace the pre-existing CIED" or "downgrade" ICDs or CRT-ICDs to pacemakers. A recent editorial discussed the potential risks and financial implications related to ICD generator replacements and the need for additional clinical trials to better understand which patients should undergo generator replacements (56).

Scenarios that consider original indication for the device, life expectancy, or LVEF recovery are described in Tables 4.1 to 4.4. Replacement of a CRT-ICD with a CRT-pacemaker when the LVEF had improved since initial device implantation for primary prevention indications was rated as May Be Appropriate (Table 4.3). These ratings of May Be Appropriate are consistent with the gaps of knowledge in this area, as there is a lack of data examining sudden death or ventricular arrhythmia risk following some recovery of LV function.

9.4. Dual-Chamber Versus Single-Chamber ICDs

Clinical trials evaluating the mortality benefit of ICD therapy for primary or secondary prevention have mostly involved implantation of single-chamber devices. While dual-chamber devices are associated with higher complication rates related to implantation (57,58), proponents of dual-chamber devices suggest potential clinical benefits of the atrial lead. Theoretical benefits could include ventricular versus supraventricular arrhythmia discrimination and unnecessary shock reduction, although this remains a subject of debate and is discussed in the following text. A recent report from the NCDR ICD registry demonstrates marked variation in single- versus dual-chamber ICD usage in the United States (59).

The potential benefit of single- versus dual-chamber pacemaker implantation has been recently addressed in a consensus document, but additional considerations may apply to ICD therapy (17). The decision to implant a dual-chamber ICD, rather than a single-chamber ICD, may employ a variety of clinical considerations including the potential need for pacing due to underlying conduction system disease, potential impact of drugs on sinus or atrioventricular conduction, potential suppression of ventricular arrhythmias with atrial pacing in specific disorders, or relative value of device algorithms in arrhythmia discrimination. For scenarios where the QRS was wide, the panel was instructed to assume that the patient does not otherwise meet criteria for CRT implantation.

Scenarios evaluating the need for dual-chamber ICDs are described in Tables 5.1 to 5.4. These scenarios are modified based on concomitant conduction system disease or pacing indications, coexisting atrial arrhythmias with plans for rhythm versus rate control, known slow ventricular arrhythmias, or other disorders (congenital long QT or hypertrophic cardiomyopathy).

Dual-chamber ICD implantation was considered Appropriate for congenital long QT syndrome (Table 5.4). However, the latter rating of Appropriate should not be considered "required," as single-chamber devices may be preferable in some situations of long QT syndrome.

Implantation of a dual-chamber device was also considered Appropriate by the panel in certain scenarios that would not meet standard guidelines for pacemaker implantation (i.e., in the setting of asymptomatic sinus bradycardia, history of paroxysmal atrial arrhythmias, or slow ventricular arrhythmias where "slow VT" overlaps with the sinus tachycardia rate) (Tables 5.1 and 5.3). Although not a clinical indication for dual-chamber pacing per se, the Appropriate rating of dual-chamber device selection for patients with paroxysmal atrial arrhythmias may reflect perceived benefits related to arrhythmia discrimination or detection of "silent" atrial arrhythmias with insertion of an atrial lead.

The only clinical situation in which implantation of a dual-chamber device was rated as Rarely Appropriate was in the setting of long-standing persistent or permanent atrial fibrillation or flutter in patients in whom cardioversion or rhythm control strategies are not planned. All other clinical scenarios, including hypertrophic cardiomyopathy with a wide or narrow baseline QRS and conduction system disease that would not meet guideline criteria for pacemaker implantation and not previously mentioned, were rated as May Be Appropriate. Even a narrow QRS complex with a normal PR interval was rated as May Be Appropriate by the technical panel (Table 5.2), further highlighting differences between the thresholds for inserting an atrial lead in a patient undergoing pacemaker implantation compared with ICD implantation.

9.5. Application of Pre-Specified Cutoffs

The requirements for specific waiting periods after revascularization, diagnosis of a new cardiomyopathy, or recent MI, as well as stratification of QRS duration, LVEF, and other criteria such as percentage of RV pacing were made based on enrollment criteria for clinical trials. However, these criteria varied between various clinical trials. For example, the criterion of 40 days after MI is well established by prospective randomized clinical trials including DINAMIT (6 to 40 days) and IRIS (5 to 31 days) (30,31). In contrast, the waiting period of 3 months after diagnosis of a new cardiomyopathy or revascularization procedure is arbitrary. Although guideline documents identify specific criteria for QRS duration or LVEF, they do not require a mandatory time lapse following heart failure diagnosis or revascularization. The absence of evidence regarding a benefit of ICD implantation during unstudied time frames is not the same as evidence of "no benefit." This is probably why many of these scenarios were rated as May Be Appropriate.

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9.6. Clinical Judgment and the Understanding of AUC Ratings

In creating and rating clinical scenarios, the goal was to focus on the most common clinical situations encountered in practice where an ICD or CRT may be considered. The goal of rating appropriateness is to help inform clinical decision making in areas, particularly in areas where there may be "gaps" in the guidelines, rather than to establish rules by which decisions should be made in clinical practice. Although the appropriate use ratings reflect a general assessment of when ICD or CRT devices may or may not be useful for specific patient populations, physicians and other stakeholders should continue to acknowledge the pivotal role of clinical judgment in determining whether CIED implantation is indicated for an individual patient.

Clinical indications rated as May Be Appropriate also require individual physician judgment and understanding of the individual patient to best determine the usefulness of CIED implantation for a particular clinical scenario. The rating of May Be Appropriate (4 to 6) should not exclude the use of ICD or CRT devices for such patients. It is important to recognize when reviewing the aforementioned criteria that ratings in this middle category may represent either the lack of sufficient data to inform the decision or the fact that, depending on other clinical factors not considered in the brief scenario, device implantation may or may not be considered beneficial. The wide breadth of scenarios rated as May Be Appropriate raises the importance of recognizing the role of applying clinical judgment to decision making when encountering patients who broadly meet these criteria, as well as for the importance of advocating for future clinical trials to better inform decision making in these scenarios.

In addition, physicians recognize that an attribution of Appropriate to a clinical scenario does not necessarily indicate that implantation is mandatory but only that it is reasonable given existing data. There may be some clinical scenarios in which the use of ICD or CRT devices for an indication considered Appropriate does not always represent reasonable practice. Accordingly, the AUC for ICD/CRT devices are intended to evaluate overall patterns of care for device implantation rather than adjudicating specific cases. For situations where there is substantial variation between the appropriate use rating and what the clinician believes is best for the particular patient, further options such as a second opinion may be considered. It is anticipated that physicians practicing good evidence-based care will implant a mix of cases meeting both Appropriate and May Be Appropriate categories. However, if there are marked variations in patterns when compared with national benchmarks, further examination of the patterns of care might be helpful in identifying explanations for these variations.

Thus, appropriate use criteria may be applied in many ways, for example, decision support algorithms and educational tools may be developed. Appropriate use criteria should be considered in concert with the guidelines. The indications in AUC documents are more granular and cover more specific patient scenarios that are not specifically addressed in guidelines. Where there is overlap with the device-based therapy guidelines, the ratings are consistent with the guideline recommendations. Generally, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often meet Class I, IIa, or IIb criteria in guideline documents, are supported by a critical mass of existing data, or were deemed by the technical panel to meet sufficient clinical judgment to be reasonable and appropriate. For further details, see the Guideline Mapping and References.

The manner in which other pertinent information may modify clinical decisions is made most clear by the comorbidities section. This section demonstrates how coexistence of other medical issues may modify the decision to implant an otherwise indicated or appropriate ICD. Thus, it is clear that clinical decision making is complex, and the described scenarios should be used as a guide to work in accompaniment with other clinical information.

Finally, there are differences related to ICD or CRT implantation and previous AUC documents related to other subjects such as imaging or catheterization. The decision to implant a device results in long-term, specialized follow-up and carries anticipated hospitalization costs that accumulate over time. There is a wide array of patient characteristics that could potentially affect clinical decision making that cannot be described in a limited number of brief case scenarios. This raises the importance of understanding these criteria as a "guide," rather than as a list of "do" or "do not do" specifications. The included scenarios do not encompass all possible clinical situations that may be encountered in practice. Therefore, specific clinical situations not addressed in these scenarios should be considered in their unique contexts.

9.7. Reimbursement and Disclaimer

It is the intent of this document to address good medical practice, independent of reimbursement. Some of the scenarios that are deemed Appropriate by the appropriate use criteria may not currently qualify for insurance coverage. For patients, physicians, and insurers, these distinctions are of critical importance because commitment to patient-centered care may warrant implantation of a device appropriate for the individual patient's situation, but it may not fit precisely into a covered indication as defined by coverage policy and requires use of best clinical judgment. Additional evidence-based documents addressing clinical scenarios not specifically covered in currently available guideline documents may help address reimbursement decisions in the future.

9.8. Application of Criteria

Facilities and payers may use these criteria to review procedural indications. Payers may use the criteria in their deliberations about coverage decisions. Furthermore, ser-

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vices rendered for Rarely Appropriate indications should be considered in the context of the clinical situation. Namely, supporting documentation that informed the clinical decision should be sought, as other factors beyond those described in the brief clinical scenarios included in this document may have entered into clinical decision making.

Given recent concerns regarding the potential frequency of "overuse" or inappropriate device implantation, concerns related to reimbursement for device implantation, and Department of Justice investigations, it is important to weigh how these appropriateness criteria fit with existing guidelines and statements regarding national coverage determinations. Many of the clinical scenarios were rated as May Be Appropriate (33%), which demonstrates the need for collaborative approaches to establishing coverage decisions in order to address the "disconnect" between reimbursement criteria and guidelines, promoting evidence-based care.

Although not specifically addressed in this document or in the Department of Justice investigation, "underuse" of ICD therapy has been demonstrated (60,61). These appropriateness criteria may be used to create algorithms or tools that help guide decision making or help understand resource utilization. This may be useful at the point of care where decisions are being made in the hospital or office setting. If these data are used to evaluate performance of physicians or facilities, they should only be used with other measures of quality. For example, establishing prospective preauthorization for procedures may work best once a retrospective review has identified a pattern of inappropriate use. The AUC criteria outlined in this document are based on the most current data. Retrospective application of the ratings to coverage decisions on previously performed procedures may not be valid, as those decisions could not have been made on evidence that was not available at the time the decision was made.

The primary objective of this report was to describe real-life factors that play a role in decisions for ICD and CRT implantation, while providing guidance regarding device implantation for scenarios that are not specifically addressed in the guidelines. The relationship of these criteria to existing guidelines was provided to the technical panel. In addition, extensive links to clinical trials and other literature regarding the role of ICD and CRT in each clinical scenario were provided to technical panel members. Further research is needed to analyze patient outcomes for scenarios where there was disagreement among panel members, that is, rated as both Appropriate and Rarely Appropriate by different panel members. When new clinical trials and other data are published, it will be necessary to incorporate this new information in future iterations of the AUC for ICD and CRT implantation.

In conclusion, this document represents the current understanding of the clinical utility of ICD and CRT implantation in clinical practice as measured by physicians with a variety of backgrounds and areas of expertise. It is the goal that these criteria will help provide a guide to inform medical decisions and help clinicians and stakeholders understand areas of consensus as well as uncertainty, while identifying areas where there are gaps in knowledge that warrant additional investigation.

Appendix A: Additional Methods

Relationships With Industry and Other Entities

The American College of Cardiology Foundation, Heart Rhythm Society, and partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the Appropriate Use Criteria Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by all participants, listed in Appendix B, in the Appropriate Use Criteria for ICD/CRT can be found in Appendix C. In addition, to ensure complete transparency, complete disclosure information—including relationships not pertinent to this document—is available online as a document supplement.

Literature Review

The technical panel members were asked to refer to the relevant guidelines for a summary of the relevant literature, guideline recommendation tables, and reference lists provided for each indication table when completing their ratings (see Guideline Mapping and References Online Appendix).

Appendix B: ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for ICD/CRT Participants

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APPENDIX C: ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 APPROPRIATE USE CRITERIA FOR ICD/CRT PARTICIPANTS—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

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Bruce D. Lindsay	• Boston Scientific • Medtronic	None	None	None	• Boston Scientific* • Medtronic* • St. Jude Medical*	None
Lynne Warner Stevenson	None	None	None	None	None	None

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Participant	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Suraj Kapa	None	None	None	None	None	None
Michael B. Alexander	None	None	None	None	• Cigna	None
Ulrika Birgersdotter-Green	• Biotronik	• Medtronic • St. Jude Medical	None	• Medtronic • St. Jude Medical	None	None
Alan S. Brown	None	None	None	None	None	None
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This table represents the relevant relationships with industry and other entities that were disclosed by participants at the time of participation. It 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 in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Participation does not imply endorsement of this document.

A standard exemption to the ACCF RWI policy is extended to Appropriate Use Criteria writing committees that do not make recommendations but rather prepare background materials and typical clinical scenarios/indications that are rated independently by a separate technical panel. See Section 2.2.3 of the RWI policy for details.

*Significant relationship.

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Key Words: ACCF appropriate use criteria ■ CRT ■ electrophysiology ■ heart failure ■ ICD ■ implantable defibrillator ■ sudden death.

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