PRACTICE GUIDELINE: EXECUTIVE SUMMARY

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices)

Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons

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Preamble

It is important that the medical profession play a significant role in critically evaluating the use of diagnostic procedures and therapies as they are introduced and tested in the detection, management, or prevention of disease states. Rigorous and expert analysis of the available data documenting absolute and relative benefits and risks of those procedures and therapies can produce helpful guidelines that improve the effectiveness of care, optimize patient outcomes, and favorably affect the overall cost of care by focusing resources on the most effective strategies.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly engaged in the production of such guidelines in the area of cardiovascular disease since 1980. The American College of Cardiology (ACC)/AHA Task Force on Practice Guidelines, whose charge is to develop, update, or revise practice guidelines for important cardiovascular diseases and procedures, directs this effort. Writing committees are charged with the task of performing an assessment of the evidence and acting as an independent group of authors to develop, update, or revise written recommendations for clinical practice.

Experts in the subject under consideration have been selected from both organizations to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner and specialty groups when appropriate. Writing committees are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular

treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers and comorbidities and issues of patient preference that may influence the choice of particular tests or therapies are considered, as well as frequency of follow-up and cost-effectiveness. When available, information from studies on cost will be considered; however, review of data on efficacy and clinical outcomes will constitute the primary basis for preparing recommendations in these guidelines.

The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or perceived conflicts of interest that may arise as a result of an industry relationship or personal interest of the writing committee. Specifically, all members of the writing committee, as well as peer reviewers of the document, were asked to provide disclosure statements of all such relationships that may be perceived as real or potential conflicts of interest. Writing committee members are also strongly encouraged to declare a previous relationship with industry that may be perceived as relevant to guideline development. If a writing committee member develops a new relationship with industry during his or her tenure, he or she is required to notify guideline staff in writing. The continued participation of the writing committee member will be reviewed. These statements are reviewed by the parent task force, reported orally to all members of the writing committee at each meeting, and updated and reviewed by the writing committee as changes occur. Please refer to the methodology manual for ACC/AHA guideline writing committees for further description of the relationships with industry policy (1). See Appendix 1 for author relationships with industry and Appendix 2 for peer reviewer relationships with industry that are pertinent to this guideline.

These practice guidelines are intended to assist health care providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, and prevention of specific diseases or conditions. Clinical decision making should consider the quality and availability of expertise in the area where care is provided. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available current scientific evidence and are intended to improve patient care.

Patient adherence to prescribed and agreed upon medical regimens and lifestyles is an important aspect of treatment. Prescribed courses of treatment in accordance with these recommendations will only be effective if they are followed. Because lack of patient understanding and adherence may adversely affect treatment outcomes, physicians and other health care providers should make every effort to engage the patient in active participation with prescribed medical regimens and lifestyles.

If these guidelines are used as the basis for regulatory or payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the health care provider and the patient in light of all of the circumstances presented by that patient. There are circumstances in which deviations from these guidelines are appropriate.

The guidelines will be reviewed annually by the ACC/AHA Task Force on Practice Guidelines and will be considered current unless they are updated, revised, or sunsetted and withdrawn from distribution. The executive summary and recommendations are published in the May 27, 2008, issue of the *Journal of the American College of Cardiology*, May 27, 2008, issue of *Circulation*, and the June 2008 issue of *Heart Rhythm*. The full-text guidelines are e-published in the same issue of the journals noted above, as well as posted on the ACC (www.acc.org), AHA (http://my.americanheart.org), and Heart Rhythm Society (HRS) (www.hrsonline.org) Web sites. Copies of the full-text and the executive summary are available from each organization.

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1 Introduction

1.1 Organization of Committee

This revision of the "ACC/AHA/NASPE Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices" updates the previous versions published in 1984, 1991, 1998, and 2002. Revision of the statement was deemed necessary for multiple reasons: 1) Major studies have been reported that have advanced our knowledge of the natural history of bradyarrhythmias and tachyarrhythmias, which may be treated optimally with device therapy; 2) there have been tremendous changes in the management of heart failure that involve both drug and device therapy; and 3) major advances in the technology of devices to treat, delay, and even prevent morbidity and mortality from bradyarrhythmias, tachyarrhythmias, and heart failure have occurred.

The committee to revise the "ACC/AHA/NASPE Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices" was composed of physicians who are experts in the areas of device therapy and follow-up and senior clinicians skilled in cardiovascular care, internal medicine, cardiovascular surgery, ethics, and socioeconomics. The committee included representatives of the American Association for Thoracic Surgery, Heart Failure Society of America, and Society of Thoracic Surgeons.

1.2 Document Review and Approval

The document was reviewed by 2 official reviewers nominated by each of the ACC, AHA, and HRS and by 11 additional peer reviewers. Of the total 17 peer reviewers, 10 had no significant relevant relationships with industry. In addition, this document has been reviewed and approved by the governing bodies of the ACC, AHA, and HRS, which include 19 ACC Board of Trustees members (none of whom had any significant relevant relationships with industry), 15

AHA Science Advisory Coordinating Committee members (none of whom had any significant relevant relationships with industry), and 14 HRS Board of Trustees members (6 of whom had no significant relevant relationships with industry). All guideline recommendations underwent a formal, blinded writing committee vote. Writing committee members were required to recuse themselves if they had a significant relevant relationship with industry. The guideline recommendations were unanimously approved by all members of the writing committee who were eligible to vote.

1.3 Methodology and Evidence

The recommendations listed in this document are, whenever possible, evidence based. An extensive literature survey was conducted and limited to studies, reviews, and other evidence conducted in human subjects and published in English. Additionally, the committee reviewed documents related to the subject matter previously published by the ACC, AHA, and HRS. References selected and published in this document are representative and not all-inclusive.

The committee reviewed and ranked evidence supporting current recommendations, with the weight of evidence ranked as Level A if the data were derived from multiple randomized clinical trials that involved a large number of individuals. The committee ranked available evidence as Level B when data were derived either from a limited number of trials that involved a comparatively small number of patients or from well-designed data analyses of nonrandomized studies or observational data registries. Evidence was ranked as Level C when the consensus of experts was the primary source of the recommendation. In the narrative portions of these guidelines, evidence is generally presented in chronological order of development. Studies are identified as observational, randomized, prospective, or retrospective. The committee emphasizes that for certain conditions for which no other therapy is available, the indications for device therapy are based on expert consensus and years of clinical experience and are thus well supported, even though the evidence was ranked as Level C. An analogous example is the use of penicillin in pneumococcal pneumonia, for which there are no randomized trials and only clinical experience. When indications at Level C are supported by historical clinical data, appropriate references (e.g., case reports and clinical reviews) are cited if available. When Level C indications are based strictly on committee consensus, no references are cited. In areas where sparse data were available (e.g., pacing in children and adolescents), a survey of current practices of major centers in North America was conducted to determine whether there was a consensus regarding specific pacing indications.

The schema for classification of recommendations and level of evidence is summarized in Table 1, which also illustrates how the grading system provides an estimate of the size of the treatment effect and an estimate of the certainty of the treatment effect.

The focus of these guidelines is the appropriate use of devices (e.g., pacemakers for bradyarrhythmias and heart failure management, cardiac resynchronization, and implantable cardioverter-defibrillators [ICDs]), not the treatment of cardiac arrhythmias. The fact that the use of a device for treatment of a particular condition is listed as a Class I indication (beneficial, useful, and effective) does not preclude the use of other therapeutic modalities that may be equally effective. As with all clinical practice guidelines, the recommendations in this document focus on treatment of an average patient with a specific disorder and may be modified by patient comorbidities, limitation of life expectancy because of coexisting diseases, and other situations that only the primary treating physician may evaluate appropriately.

The term "symptomatic bradycardia" is used in this document. Symptomatic bradycardia is defined as a documented bradyarrhythmia that is directly responsible for development of the clinical manifestations of syncope or near syncope, transient dizziness or lightheadedness, or confusional states resulting from cerebral hypoperfusion attributable to slow heart rate. Fatigue, exercise intolerance, and congestive heart failure may also result from bradycardia. These symptoms may occur at rest or with exertion. Definite correlation of symptoms with a bradyarrhythmia is required to fulfill the criteria that define symptomatic bradycardia. Caution should be exercised not to confuse physiological sinus bradycardia (as occurs in highly trained athletes) with pathological bradyarrhythmias. Occasionally, symptoms may become apparent only in retrospect after antibradycardia pacing. Nevertheless, the universal application of pacing therapy to treat a specific heart rate cannot be recommended except in specific circumstances, as detailed subsequently.

In these guidelines, the terms "persistent," "transient," and "not expected to resolve" are used but not specifically defined because the time element varies in different clinical conditions. The treating physician must use appropriate clinical judgment and available data in deciding when a condition is persistent or when it can be expected to be transient.

Recommendations for ICD implantation have been updated to reflect the numerous new developments in this field and the voluminous literature related to the efficacy of these devices in the treatment and prophylaxis of sudden cardiac death (SCD) and malignant ventricular arrhythmias. Indications for ICDs, cardiac resynchronization therapy (CRT) devices, and combined ICDs and CRT devices are continuously changing and can be expected to change further as new trials are reported. Indeed, it is inevitable that the indications for device therapy will be refined with respect to both expanded use and the identification of patients expected to benefit the most from these therapies. Furthermore, it is emphasized that when a patient has an indication for both a pacemaker (whether it be single-chamber, dual-chamber, or biventricular) and an ICD, a combined device with appropriate programming is indicated.

Table 1 Applying Classification of Recommendations and Level of Evidence

SIZE OF TREATMENT EFFECT →

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *Risk ≥ Benefit* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations†	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

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

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

The 2008 revision reflects what the committee believes are the most relevant and significant advances in pacemaker/ICD therapy since the publication of these guidelines in the *Journal of the American College of Cardiology* and *Circulation* in 2002 (2,3).

All recommendations assume that patients are treated with optimal medical therapy according to published guidelines, as had been required in all the randomized controlled clinical trials on which these guidelines are based. The committee believes that comorbidities, life expectancy, and quality-of-life issues must be addressed forthrightly with patients and their families. We have repeatedly used the phrase "reasonable expectation of survival with a good functional status for more than 1 year" to emphasize this integration of factors in decision making. Even when physicians believe that the anticipated benefits warrant device implantation, patients have the option to decline intervention after having been provided with a full explanation of the potential risks and benefits of device therapy. Finally, the committee is aware that other guidelines/expert groups have interpreted the same data differently (4–7).

In preparing this revision, the committee was guided by the following principles:

1. Changes in recommendations and levels of evidence were made either because of new randomized trials or because of the accumulation of new clinical evidence and the development of clinical consensus.
2. The committee was cognizant of the health care, logistic, and financial implications of recent trials and factored in these considerations to arrive at the classification of certain recommendations.
3. For recommendations taken from other guidelines, wording changes were made to render some of the original recommendations more precise.
4. The committee would like to re-emphasize that the recommendations in this guideline apply to most patients but may require modification because of existing situations that only the primary treating physician can evaluate properly.
5. All of the listed recommendations for implantation of a device presume the absence of inciting causes that may be eliminated without detriment to the patient (e.g., nonessential drug therapy).
6. The committee endeavored to maintain consistency of recommendations in this and other previously published guidelines. The recommendations on atrioventricular (AV) block associated with acute myocardial infarction closely follow those in the "ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction" (8). However, because of the rapid evolution of pacemaker/ICD science, it has not always been possible to maintain consistency with other published guidelines.

The following represents the complete set of recommendations for the implantation of antiarrhythmia devices. Prior executive summaries of ACC/AHA guidelines have included variable amounts of explanatory text ranging from none to large amounts. Because the supporting text in the full-text document was important to the present writing committee, we decided to provide only the recommendations in the Executive Summary and recommend readers access the full-text document for more explanation. Table 2 and Figures 1 and 2 are provided to help practitioners choose which pacing device is appropriate for an individual patient.

2 Recommendations for Permanent Pacing in Sinus Node Dysfunction

Class I

1. **Permanent pacemaker implantation is indicated for sinus node dysfunction (SND) with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms.** ***(Level of Evidence: C)*** (9–11)
2. **Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence.** ***(Level of Evidence: C)*** (9–13)
3. **Permanent pacemaker implantation is indicated for symptomatic sinus bradycardia that results from required drug therapy for medical conditions.** ***(Level of Evidence: C)***

Class IIa

1. **Permanent pacemaker implantation is reasonable for SND with heart rate less than 40 bpm when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented.** ***(Level of Evidence: C)*** (9–11,14–16)
2. **Permanent pacemaker implantation is reasonable for syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered or provoked in electrophysiological studies.** ***(Level of Evidence: C)*** (17,18)

Class IIb

1. **Permanent pacemaker implantation may be considered in minimally symptomatic patients with chronic heart rate less than 40 bpm while awake.** ***(Level of Evidence: C)*** (9,11,12,14–16)

Class III

1. **Permanent pacemaker implantation is not indicated for SND in asymptomatic patients.** ***(Level of Evidence: C)***
2. **Permanent pacemaker implantation is not indicated for SND in patients for whom the symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia.** ***(Level of Evidence: C)***
3. **Permanent pacemaker implantation is not indicated for SND with symptomatic bradycardia due to nonessential drug therapy.** ***(Level of Evidence: C)***

3 Recommendations for Acquired Atrioventricular Block in Adults

Class I

1. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block.** ***(Level of Evidence: C)*** (15,19–21)
2. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with arrhythmias and other medical conditions that require drug ther-**

Table 2 Choice of Pacemaker Generator in Selected Indications for Pacing

Pacemaker Generator	Sinus Node Dysfunction	Atrioventricular Block	Neurally Mediated Syncope or Carotid Sinus Hypersensitivity
Single-chamber atrial pacemaker	No suspected abnormality of atrioventricular conduction and not at increased risk for future atrioventricular block Maintenance of atrioventricular synchrony during pacing desired	Not appropriate	Not appropriate
Single-chamber ventricular pacemaker	Maintenance of atrioventricular synchrony during pacing not necessary Rate response available if desired	Chronic atrial fibrillation or other atrial tachyarrhythmia or maintenance of atrioventricular synchrony during pacing not necessary Rate response available if desired	Chronic atrial fibrillation or other atrial tachyarrhythmia Rate response available if desired
Dual-chamber pacemaker	Atrioventricular synchrony during pacing desired Suspected abnormality of atrioventricular conduction or increased risk for future atrioventricular block Rate response available if desired	Rate response available if desired Rate response available if desired Atrioventricular synchrony during pacing desired Atrial pacing desired Rate response available if desired	Sinus mechanism present Rate response available if desired
Single-lead, atrial-sensing ventricular pacemaker	Not appropriate	Desire to limit the number of pacemaker leads	Not appropriate

apy that results in symptomatic bradycardia. ***(Level of Evidence: C)*** (15,19–21)

3. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients in sinus rhythm, with documented periods of asystole greater than or equal to 3.0 seconds** (22) **or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node.** ***(Level of Evidence: C)*** (9,14)
4. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients with atrial fibrillation and bradycardia with 1 or more pauses of at least 5 seconds or longer.** ***(Level of Evidence: C)***
5. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level after catheter ablation of the AV junction.** ***(Level of Evidence: C)*** (23,24)
6. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with postoperative AV block that is not expected to resolve after cardiac surgery.** ***(Level of Evidence: C)*** (21,25–27)
7. **Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms.** ***(Level of Evidence: B)*** (28–34)
8. **Permanent pacemaker implantation is indicated for second-degree AV block with associated symptomatic bradycardia regardless of type or site of block.** ***(Level of Evidence: B)*** (35)
9. **Permanent pacemaker implantation is indicated for asymptomatic persistent third-degree AV block at**

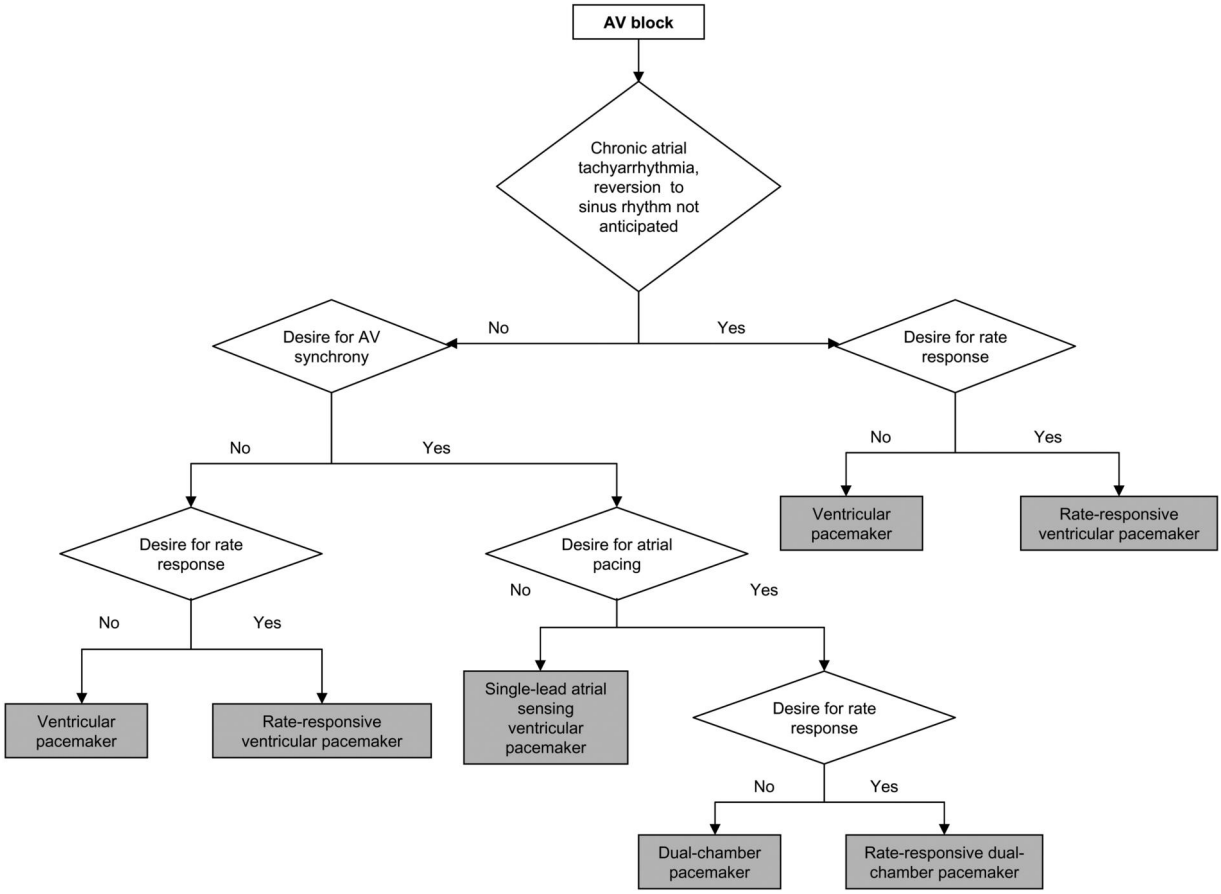

Figure 1 Selection of Pacemaker Systems for Patients With Sinus Node Dysfunction. Decisions are illustrated by diamonds. Shaded boxes indicate type of pacemaker. AV indicates atrioventricular.

any anatomic site with average awake ventricular rates of 40 bpm or faster if cardiomegaly or left ventricular (LV) dysfunction is present or if the site of block is below the AV node. ***(Level of Evidence: B)*** (20,36)

10. **Permanent pacemaker implantation is indicated for second- or third-degree AV block during exercise in the absence of myocardial ischemia.** ***(Level of Evidence: C)*** (37,38)

Class IIa

1. **Permanent pacemaker implantation is reasonable for persistent third-degree AV block with an escape rate greater than 40 bpm in asymptomatic adult patients without cardiomegaly.** ***(Level of Evidence: C)*** (15,19–21,38,39)
2. **Permanent pacemaker implantation is reasonable for asymptomatic second-degree AV block at intra- or infra-His levels found at electrophysiological study.** ***(Level of Evidence: B)*** (20,35,36)
3. **Permanent pacemaker implantation is reasonable for first- or second-degree AV block with symptoms similar to those of pacemaker syndrome or hemodynamic compromise.** ***(Level of Evidence: B)*** (40,41)
4. **Permanent pacemaker implantation is reasonable for asymptomatic type II second-degree AV block with a narrow QRS. When type II second-degree AV block occurs with a wide QRS, including isolated right bundle-branch block, pacing becomes a Class I recommendation. (See Section 2.1.3, "Chronic Bifascicular Block," in the full-text guidelines.)** ***(Level of Evidence: B)*** (20,21,40,42)

Class IIb

1. **Permanent pacemaker implantation may be considered for neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with any degree of AV block (including first-degree AV block), with or without symptoms, because there may be unpredictable progression of AV conduction disease.** ***(Level of Evidence: B)*** (28–34)
2. **Permanent pacemaker implantation may be considered for AV block in the setting of drug use and/or drug toxicity when the block is expected to recur even after the drug is withdrawn.** ***(Level of Evidence: B)*** (43,44)

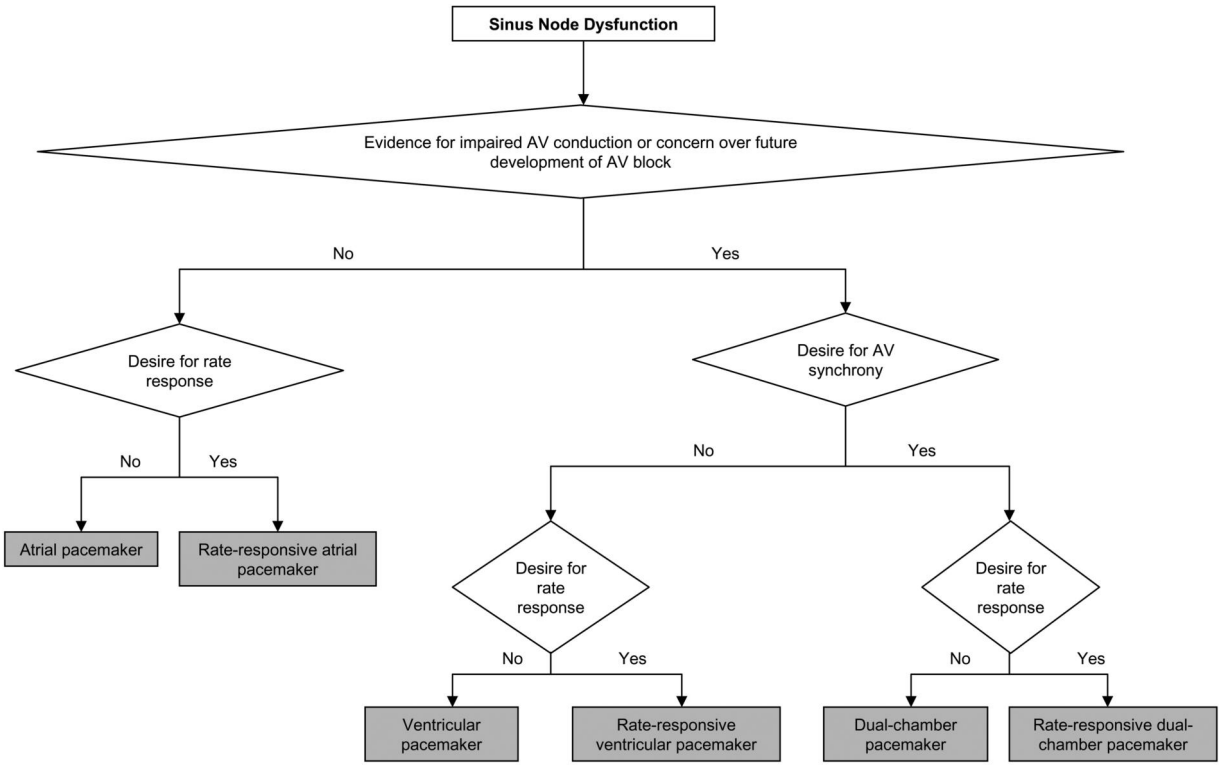

Figure 2 Selection of Pacemaker Systems for Patients With Atrioventricular Block. Decisions are illustrated by diamonds. Shaded boxes indicate type of pacemaker. AV indicates atrioventricular.

Class III

1. **Permanent pacemaker implantation is not indicated for asymptomatic first-degree AV block.** ***(Level of Evidence: B)*** (45) **(See Section 2.1.3, "Chronic Bifascicular Block," in the full-text guidelines.)**
2. **Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian.** ***(Level of Evidence: C)*** (35)
3. **Permanent pacemaker implantation is not indicated for AV block that is expected to resolve and is unlikely to recur** (46) **(e.g., drug toxicity, Lyme disease, or transient increases in vagal tone, or during hypoxia in sleep apnea syndrome in the absence of symptoms).** ***(Level of Evidence: B)*** (44,46)

4 Recommendations for Permanent Pacing in Chronic Bifascicular Block

Class I

1. **Permanent pacemaker implantation is indicated for advanced second-degree AV block or intermittent third-degree AV block.** ***(Level of Evidence: B)*** (19,39,47–51)
2. **Permanent pacemaker implantation is indicated for type II second-degree AV block.** ***(Level of Evidence: B)*** (52–55)
3. **Permanent pacemaker implantation is indicated for alternating bundle-branch block.** ***(Level of Evidence: C)*** (56)

Class IIa

1. **Permanent pacemaker implantation is reasonable for syncope not demonstrated to be due to AV block when other likely causes have been excluded, specifically ventricular tachycardia (VT).** ***(Level of Evidence: B)*** (55,57–74)
2. **Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of a markedly prolonged HV interval (greater than or equal to 100 milliseconds) in asymptomatic patients.** ***(Level of Evidence: B)*** (65)
3. **Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of pacing-induced infra-His block that is not physiological.** ***(Level of Evidence: B)*** (72)

Class IIb

1. **Permanent pacemaker implantation may be considered in the setting of neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular**

atrophy with bifascicular block or any fascicular block, with or without symptoms. ***(Level of Evidence: C)*** (28–34)

Class III

1. **Permanent pacemaker implantation is not indicated for fascicular block without AV block or symptoms.** ***(Level of Evidence: B)*** (59,61,64,65)
2. **Permanent pacemaker implantation is not indicated for fascicular block with first-degree AV block without symptoms.** ***(Level of Evidence: B)*** (59,61,64,65)

5 Recommendations for Permanent Pacing After the Acute Phase of Myocardial Infarction*

Class I

1. **Permanent ventricular pacing is indicated for persistent second-degree AV block in the His-Purkinje system with alternating bundle-branch block or third-degree AV block within or below the His-Purkinje system after ST-segment elevation myocardial infarction.** ***(Level of Evidence: B)*** (54,75–79)
2. **Permanent ventricular pacing is indicated for transient advanced second- or third-degree infranodal AV block and associated bundle-branch block. If the site of block is uncertain, an electrophysiological study may be necessary.** ***(Level of Evidence: B)*** (75,76)
3. **Permanent ventricular pacing is indicated for persistent and symptomatic second- or third-degree AV block.** ***(Level of Evidence: C)***

Class IIb

1. **Permanent ventricular pacing may be considered for persistent second- or third-degree AV block at the AV node level, even in the absence of symptoms.** ***(Level of Evidence: B)*** (14)

Class III

1. **Permanent ventricular pacing is not indicated for transient AV block in the absence of intraventricular conduction defects.** ***(Level of Evidence: B)*** (75)
2. **Permanent ventricular pacing is not indicated for transient AV block in the presence of isolated left anterior fascicular block.** ***(Level of Evidence: B)*** (77)
3. **Permanent ventricular pacing is not indicated for new bundle-branch block or fascicular block in the absence of AV block.** ***(Level of Evidence: B)*** (48,75)
4. **Permanent ventricular pacing is not indicated for persistent asymptomatic first-degree AV block in the presence of bundle-branch or fascicular block.** ***(Level of Evidence: B)*** (75)

*These recommendations are consistent with the "ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction" (8).

6 Recommendations for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Class I

1. **Permanent pacing is indicated for recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds.** ***(Level of Evidence: C)*** (80,81)

Class IIa

1. **Permanent pacing is reasonable for syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer.** ***(Level of Evidence: C)*** (80)

Class IIb

1. **Permanent pacing may be considered for significantly symptomatic neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing.** ***(Level of Evidence: B)*** (82–85)

Class III

1. **Permanent pacing is not indicated for a hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms.** ***(Level of Evidence: C)***
2. **Permanent pacing is not indicated for situational vasovagal syncope in which avoidance behavior is effective and preferred.** ***(Level of Evidence: C)***

7 Recommendations for Pacing After Cardiac Transplantation

Class I

1. **Permanent pacing is indicated for persistent inappropriate or symptomatic bradycardia not expected to resolve and for other Class I indications for permanent pacing.** ***(Level of Evidence: C)***

Class IIb

1. **Permanent pacing may be considered when relative bradycardia is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery from cardiac transplantation.** ***(Level of Evidence: C)***
2. **Permanent pacing may be considered for syncope after cardiac transplantation even when bradyarrhythmia has not been documented.** ***(Level of Evidence: C)***

8 Recommendations for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardias

Class IIa

1. **Permanent pacing is reasonable for symptomatic recurrent supraventricular tachycardia that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects. *(Level of Evidence: C)*** (86–90)

Class III

1. **Permanent pacing is not indicated in the presence of an accessory pathway that has the capacity for rapid anterograde conduction. *(Level of Evidence: C)***

9 Recommendations for Pacing to Prevent Tachycardia

Class I

1. **Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation. *(Level of Evidence: C)*** (91,92)

Class IIa

1. **Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome. *(Level of Evidence: C)*** (91,92)

Class IIb

1. **Permanent pacing may be considered for prevention of symptomatic, drug-refractory, recurrent atrial fibrillation in patients with coexisting SND. *(Level of Evidence: B)*** (93–95)

Class III

1. **Permanent pacing is not indicated for frequent or complex ventricular ectopic activity without sustained VT in the absence of the long-QT syndrome. *(Level of Evidence: C)*** (97)
2. **Permanent pacing is not indicated for torsade de pointes VT due to reversible causes. *(Level of Evidence: A)*** (98,99)

10 Recommendation for Pacing to Prevent Atrial Fibrillation

Class III

1. **Permanent pacing is not indicated for the prevention of atrial fibrillation in patients without any other indication for pacemaker implantation. *(Level of Evidence: B)*** (100)

11 Recommendations for Cardiac Resynchronization Therapy in Patients With Severe Systolic Heart Failure

Class I

1. **For patients who have LV ejection fraction (LVEF) less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and sinus rhythm, CRT with or without an ICD is indicated for the treatment of New York Heart Association (NYHA) functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy. *(Level of Evidence: A)*** (101,101a–101c)

Class IIa

1. **For patients who have LVEF less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and atrial fibrillation, CRT with or without an ICD is reasonable for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms on optimal recommended medical therapy. *(Level of Evidence: B)*** (101,102)
2. **For patients with LVEF less than or equal to 35% with NYHA functional Class III or ambulatory Class IV symptoms who are receiving optimal recommended medical therapy and who have frequent dependence on ventricular pacing, CRT is reasonable. *(Level of Evidence: C)*** (101)

Class IIb

1. **For patients with LVEF less than or equal to 35% with NYHA functional Class I or II symptoms who are receiving optimal recommended medical therapy undergoing implantation of a permanent pacemaker and/or ICD with anticipated frequent ventricular pacing, CRT may be considered. *(Level of Evidence: C)*** (101)

Class III

1. **CRT is not indicated for asymptomatic patients with reduced LVEF in the absence of other indications for pacing. *(Level of Evidence: B)*** (101,101a–101c)
2. **CRT is not indicated for patients whose functional status and life expectancy are limited predominantly by chronic noncardiac conditions. *(Level of Evidence: C)*** (101)

12 Recommendations for Pacing in Patients With Hypertrophic Cardiomyopathy

Class I

1. **Permanent pacing is indicated for SND or AV block in patients with hypertrophic cardiomyopathy as described previously (see Section 2.1.1, "Sinus Node Dysfunction," and Section 2.1.2, "Acquired Atrioven-**

tricular Block in Adults," in the full-text guidelines). ***(Level of Evidence: C)***

Class IIb

1. **Permanent pacing may be considered in medically refractory symptomatic patients with hypertrophic cardiomyopathy and significant resting or provoked LV outflow tract obstruction.** ***(Level of Evidence: A)*** **As for Class I indications, when risk factors for SCD are present, consider a DDD ICD (see Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," in the full-text guidelines).** (103–108)

Class III

1. **Permanent pacemaker implantation is not indicated for patients who are asymptomatic or whose symptoms are medically controlled.** ***(Level of Evidence: C)***
2. **Permanent pacemaker implantation is not indicated for symptomatic patients without evidence of LV outflow tract obstruction.** ***(Level of Evidence: C)***

13 Recommendations for Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Class I

1. **Permanent pacemaker implantation is indicated for advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.** ***(Level of Evidence: C)***
2. **Permanent pacemaker implantation is indicated for SND with correlation of symptoms during age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate.** ***(Level of Evidence: B)*** (9,22,109,110)
3. **Permanent pacemaker implantation is indicated for postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery.** ***(Level of Evidence: B)*** (35,111)
4. **Permanent pacemaker implantation is indicated for congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction.** ***(Level of Evidence: B)*** (113–115)
5. **Permanent pacemaker implantation is indicated for congenital third-degree AV block in the infant with a ventricular rate less than 55 bpm or with congenital heart disease and a ventricular rate less than 70 bpm.** ***(Level of Evidence: C)*** (116,117)

Class IIa

1. **Permanent pacemaker implantation is reasonable for patients with congenital heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial re-entrant tachycardia; SND may be intrinsic or secondary to antiarrhythmic treatment.** ***(Level of Evidence: C)*** (118–120)
2. **Permanent pacemaker implantation is reasonable for congenital third-degree AV block beyond the first year of life with an average heart rate less than 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence.** ***(Level of Evidence: B)*** (121,122)
3. **Permanent pacemaker implantation is reasonable for sinus bradycardia with complex congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds.** ***(Level of Evidence: C)***
4. **Permanent pacemaker implantation is reasonable for patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony.** ***(Level of Evidence: C)*** (123)
5. **Permanent pacemaker implantation is reasonable for unexplained syncope in the patient with prior congenital heart surgery complicated by transient complete heart block with residual fascicular block after a careful evaluation to exclude other causes of syncope.** ***(Level of Evidence: B)*** (115,124–126)

Class IIb

1. **Permanent pacemaker implantation may be considered for transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block.** ***(Level of Evidence: C)*** (127)
2. **Permanent pacemaker implantation may be considered for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex, and normal ventricular function.** ***(Level of Evidence: B)*** (113,122)
3. **Permanent pacemaker implantation may be considered for asymptomatic sinus bradycardia after biventricular repair of congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds.** ***(Level of Evidence: C)***

Class III

1. **Permanent pacemaker implantation is not indicated for transient postoperative AV block with return of normal AV conduction in the otherwise asymptomatic patient.** ***(Level of Evidence: B)*** (127,127a)
2. **Permanent pacemaker implantation is not indicated for asymptomatic bifascicular block with or without first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block.** ***(Level of Evidence: C)***
3. **Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block.** ***(Level of Evidence: C)***
4. **Permanent pacemaker implantation is not indicated for asymptomatic sinus bradycardia with the longest relative risk interval less than 3 seconds and a mini-**

mum heart rate more than 40 bpm. ***(Level of Evidence: C)***

14 Recommendations for Implantable Cardioverter-Defibrillators

Secondary prevention refers to the prevention of SCD in those patients who have survived a prior cardiac arrest or sustained VT. Primary prevention refers to the prevention of SCD in individuals without a history of cardiac arrest or sustained VT. Patients with cardiac conditions associated with a high risk of sudden death who have unexplained syncope that is likely to be due to ventricular arrhythmias are considered to have a secondary indication.

Recommendations for consideration of ICD therapy, particularly those for primary prevention, apply only to patients who are receiving optimal medical therapy and have a reasonable expectation of survival with good functional status for more than 1 year. It is difficult to estimate survival with heart failure in the general population, for whom comorbidities and age differ from those in trial populations from which the predictive models have been derived. Patients with repeated heart failure hospitalizations, particularly in the presence of reduced renal function, are at high risk for early death due to heart failure (128–130). Please see Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy," in the full-text guidelines for discussion regarding the use of LVEFs on the basis of trial inclusion criteria.

We acknowledge that the "ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death" (4) used an LVEF of less than 40% as a critical point to justify ICD implantation for primary prevention of SCD. The LVEF used in clinical trials assessing the ICD for primary prevention of SCD ranged from less than 40% in MUSTT (Multicenter Unsustained Ventricular Tachycardia Trial) to less than 30% in MADIT II (Multicenter Automatic Defibrillator Implantation Trial II) (131,132). Two trials, MADIT I (Multicenter Automatic Defibrillator Implantation Trial I) (6) and SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) (7) used LVEFs of less than 35% as entry criteria. The present writing committee reached the consensus that it would be best to offer ICDs to patients with clinical profiles as similar to those included in the trials as possible. Having given careful consideration to the issues related to LVEF for these updated ICD guidelines, we have written these indications for ICDs on the basis of the specific inclusion criteria for LVEF in the trials. Because of this, there may be some variation from previously published guidelines (4).

We also acknowledge that the determination of LVEF lacks a "gold standard" and that there may be variation among the commonly used clinical techniques of LVEF determination. All clinical methods of LVEF determination lack precision, and the accuracy of techniques varies among laboratories and institutions. On the basis of these considerations, the present writing committee recommends that clinicians use the LVEF determination that they believe is the most clinically accurate and appropriate in their institution.

Class I

1. **ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes.** ***(Level of Evidence: A)*** (4,133–138)
2. **ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable.** ***(Level of Evidence: B)*** (4,133–138)
3. **ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study.** ***(Level of Evidence: B)*** (4,136)
4. **ICD therapy is indicated in patients with LVEF less than 35% due to prior myocardial infarction who are at least 40 days post--myocardial infarction and are in NYHA functional Class II or III.** ***(Level of Evidence: A)*** (4,139)
5. **ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III.** ***(Level of Evidence: B)*** (4,139–141)
6. **ICD therapy is indicated in patients with LV dysfunction due to prior myocardial infarction who are at least 40 days post--myocardial infarction, have an LVEF less than 30%, and are in NYHA functional Class I.** ***(Level of Evidence: A)*** (4,132)
7. **ICD therapy is indicated in patients with nonsustained VT due to prior myocardial infarction, LVEF less than 40%, and inducible ventricular fibrillation or sustained VT at electrophysiological study.** ***(Level of Evidence: B)*** (4,131,142)

Class IIa

1. **ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic dilated cardiomyopathy.** ***(Level of Evidence: C)***
2. **ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function.** ***(Level of Evidence: C)***
3. **ICD implantation is reasonable for patients with hypertrophic cardiomyopathy who have 1 or more major† risk factor for SCD.** ***(Level of Evidence: C)***
4. **ICD implantation is reasonable for the prevention of SCD in patients with arrhythmogenic right ventricu-**

†See Section 3.2.4, "Hypertrophic Cardiomyopathy," in the full-text guidelines for definition of major risk factors.

lar dysplasia/cardiomyopathy who have 1 or more risk factor for SCD. *(Level of Evidence: C)*
5. ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers. *(Level of Evidence: B)* (143–148)
6. ICD implantation is reasonable for nonhospitalized patients awaiting transplantation. *(Level of Evidence: C)*
7. ICD implantation is reasonable for patients with Brugada syndrome who have had syncope. *(Level of Evidence: C)*
8. ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. *(Level of Evidence: C)*
9. ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. *(Level of Evidence: C)*
10. ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. *(Level of Evidence: C)*

Class IIb

1. ICD therapy may be considered in patients with nonischemic heart disease who have an LVEF of less than or equal to 35% and who are in NYHA functional Class I. *(Level of Evidence: C)*
2. ICD therapy may be considered for patients with long-QT syndrome and risk factors for SCD. *(Level of Evidence: B)* (4,143–148)
3. ICD therapy may be considered in patients with syncope and advanced structural heart disease in whom thorough invasive and noninvasive investigations have failed to define a cause. *(Level of Evidence: C)*
4. ICD therapy may be considered in patients with a familial cardiomyopathy associated with sudden death. *(Level of Evidence: C)*
5. ICD therapy may be considered in patients with LV noncompaction. *(Level of Evidence: C)*

Class III

1. ICD therapy is not indicated for patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria specified in the Class I, IIa, and IIb recommendations above. *(Level of Evidence: C)*
2. ICD therapy is not indicated for patients with incessant VT or ventricular fibrillation. *(Level of Evidence: C)*
3. ICD therapy is not indicated in patients with significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up. *(Level of Evidence: C)*
4. ICD therapy is not indicated for NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or implantation of a CRT device that incorporates both pacing and defibrillation capabilities. *(Level of Evidence: C)*
5. ICD therapy is not indicated for syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmias and without structural heart disease. *(Level of Evidence: C)*
6. ICD therapy is not indicated when ventricular fibrillation or VT is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with Wolff-Parkinson-White syndrome, right ventricular or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease). *(Level of Evidence: C)*
7. ICD therapy is not indicated for patients with ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease (e.g., electrolyte imbalance, drugs, or trauma). *(Level of Evidence: B)* (4)

15 Recommendations for Implantable Cardioverter-Defibrillators in Pediatric Patients and Patients With Congenital Heart Disease

Class I

1. ICD implantation is indicated in the survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. *(Level of Evidence: B)* (149–152)
2. ICD implantation is indicated for patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. *(Level of Evidence: C)* (153)

Class IIa

1. ICD implantation is reasonable for patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. *(Level of Evidence: B)* (6,154)

Class Ib

1. ICD implantation may be considered for patients with recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction when thorough invasive and noninvasive investigations have failed to define a cause. *(Level of Evidence: C)* (155,156)

Class III

1. **All Class III recommendations found in Section 3 of the full-text guidelines, "Indications for Implantable Cardioverter-Defibrillator Therapy," apply to pediatric patients or patients with congenital heart disease, and ICD implantation is not indicated in these patient populations.** ***(Level of Evidence: C)***

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Appendix 1. Author Relationships with Industry—ACC/AHA/HRS Guidelines For Device-Based Therapy Of Cardiac Rhythm Abnormalities

Committee Member	Consulting Fees/ Honoraria	Speakers' Bureau	Ownership/ Partnership/ Principal	Research Grants	Institutional or Other Financial Benefit
Dr. Andrew E. Epstein*	• Boston Scientific • CryoCath • Medtronic • Sanofi-Aventis • St. Jude†	• Boston Scientific • Medtronic • Reliant Pharmaceuticals • Sanofi-Aventis • St. Jude	None	• Biotronik† • Boston Scientific† • C. R. Bard/ Electrophysiology Division† • Irving Biomedical† • Medtronic† • St. Jude†	Electrophysiology fellowship support from: • Medtronic† • St. Jude†
Dr. John P. DiMarco*	• Boston Scientific† • CV Therapeutics† • Daiichi Sankyo • Medtronic† • Novartis† • St. Jude • Solvay • Sanofi-Aventis	None	None	• Boston Scientific† • CV Therapeutics† • Medtronic • Sanofi-Aventis • St. Jude	None
Dr. Kenneth A. Ellenbogen*	• Ablation Frontiers • Atricure • Biosense Webster • Biotronik • Boston Scientific • Medtronic • St. Jude • Sorin/ELA	• Reliant Pharmaceuticals • Sanofi-Aventis	None	• Biosense Webster • Boston Scientific† • Cameron Medical • Impulse Dynamics • Medtronic† • St. Jude	None
Dr. N.A. Mark Estes III	• Medtronic	• Boston Scientific • Medtronic • St. Jude	None	None	None

Committee Member	Consulting Fees/ Honoraria	Speakers' Bureau	Ownership/ Partnership/ Principal	Research Grants	Institutional or Other Financial Benefit
Dr. Roger A. Freedman*	• Boston Scientific • Medtronic • Sorin/ELA • St. Jude	• Boston Scientific • St. Jude	• St. Jude	• Boston Scientific† • Medtronic† • St. Jude†	University of Utah Division of Cardiology receives electrophysiology fellowship support grants from: • Boston Scientific† • Medtronic† • St. Jude†
Dr. Leonard S. Gettes	None	None	None	None	None
Dr. A. Marc Gillinov*	• AtriCure • Edwards† • Medtronic	• Guidant • St. Jude	• Viacor†	None	None
Dr. Gabriel Gregoratos	None	None	None	None	None
Dr. Stephen C. Hammill	• Biosense Webster	• Boston Scientific	None	• Medtronic	None
Dr. David L. Hayes*	• AI Semi • Blackwell/Futura† • Boston Scientific† • Medtronic† • Sorin/ELA • St. Jude	None	None	• Boston Scientific† • Medtronic† • St. Jude	• Biotronik • Boston Scientific† • Medtronic† • Sorin/ELA • St. Jude
Dr. Mark A. Hlatky	• Blue Cross/Blue Shield Technology Evaluation Center	None	None	None	None
Dr. L. Kristin Newby	• AstraZeneca/Atherogenics • Biosite • CV Therapeutics • Johnson & Johnson • Novartis • Procter & Gamble • Roche Diagnostics	None	None	• Adolor • American Heart Association† • BG Medicine • Bristol-Myers Squibb/Sanofi† • Inverness Medical† • Medicure† • Schering-Plough†	None
Dr. Richard L. Page	• Astellas • Berlex • Pfizer • Sanofi-Aventis†	None	None	• Procter & Gamble	• Boston Scientific† • Medtronic† • St. Jude†
Dr. Mark H. Schoenfeld	None	None	None	None	None
Dr. Michael J. Silka	None	None	None	None	None
Dr. Lynne Warner Stevenson	• Biosense Webster‡ • Boston Scientific‡ • CardioMEMS • Medtronic • Medtronic‡ • Scios	None	None	• Biosense Webster‡ • Medtronic	None
Dr. Michael O. Sweeney*	• Medtronic†	• Boston Scientific • Medtronic†	None	None	None

This table represents the relationships of committee members with industry that were reported orally at the initial writing committee meeting and updated in conjunction with all meetings and conference calls of the writing committee during the document development process (last revision, January 16, 2008). 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 noted in this table are modest unless otherwise noted.

*Recused from voting on guideline recommendations.

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

‡Indicates spousal relationship.

Appendix 2. Peer Reviewer Relationships with Industry—ACC/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

Peer Reviewer*	Representation	Consulting Fees/ Honoraria	Speakers' Bureau	Ownership/ Partnership/ Principal	Research Grant	Institutional or Other Financial Benefit
Dr. Mina K. Chung	Official—Heart Rhythm Society	• American College of Cardiology Foundation • Boston Medical Center • Boston Scientific (honoraria donated) • Elsevier • Medtronic (honoraria donated) • Nexcura (no honoraria received) • University of Texas Health Science Center • WebMD Health (For CryoCath Technologies, Inc.)	None	None	• Biotronik† (research grants to electrophysiology section, Cleveland Clinic) • Boston Scientific† (research grants to electrophysiology section, Cleveland Clinic) • Medtronic* (research grants to electrophysiology section, Cleveland Clinic) • Reliant Pharmaceuticals† (research grants to electrophysiology section, Cleveland Clinic) • St. Jude Medical† (research grants to electrophysiology section, Cleveland Clinic)	None
Dr. Fred Kusumoto	Official—Heart Rhythm Society	• Boston Scientific • Medtronic	None	None	None	None
Dr. Bruce Lindsay	Official—American College of Cardiology Board of Trustees	None	None	None	None	None
Dr. Samir Saba	Official—American Heart Association	None	None	• Boston Scientific • Medtronic • St Jude Medical	None	None
Dr. Paul Wang	Official—American Heart Association; Content—American Heart Association Electrocardiography and Arrhythmias Committee	• Boston Scientific† • Lifewatch† • Medtronic • St. Jude	• Boston Scientific† • Medtronic • St. Jude	• Hansen Medical†	• Boston Scientific† • Medtronic • St. Jude	None
Dr. Stuart Winston	Official—American College of Cardiology Board of Governors	• Boston Scientific	None	None	None	None
Dr. Patrick McCarthy	Organizational—Society of Thoracic Surgeons	• CV Therapeutics† • Medtronic	None	None	None	None
Dr. Mandeep Mehra	Organizational—Heart Failure Society of America	• Astellas • Boston Scientific • Cordis • Debiopharma • Medtronic • Novartis • Roche Diagnostics • Scios • Solvay • St. Jude	None	None	• National Institutes of Health† • Maryland Industrial Partnerships† • Other Tobacco Related Diseases†	• University of Maryland† (salary); • Legal consultant

Peer Reviewer*	Representation	Consulting Fees/ Honoraria	Speakers' Bureau	Ownership/ Partnership/ Principal	Research Grant	Institutional or Other Financial Benefit
Dr. Jennifer Cummings	Content—American College of Cardiology Foundation Clinical Electrophysiology Committee	• Corazon • Medtronic • Reliant • Signalife • St. Jude • Zin	None	None	None	None
Dr. Christopher Fellows	Content—American College of Cardiology Foundation Clinical Electrophysiology Committee	• Boston Scientific • St. Jude	None	None	None	None
Dr. Nora Goldschlager	Content—Individual	• St. Jude	None	None	None	None
Dr. Peter Kowey	Content—American College of Cardiology Foundation Clinical Electrophysiology Committee	None	• Medtronic†	• CardioNet†	None	None
Dr. Rachel Lampert	Content—Heart Rhythm Society Scientific and Clinical Documents Committee	None	None	None	• Boston Scientific† • Medtronic† • St. Jude†	None
Dr. J. Philip Saul	Content—Pediatric Expert and American College of Cardiology Foundation Clinical Electrophysiology Committee	None	None	None	None	None
Dr. George Van Hare	Content—Individual	• St. Jude	None	None	• Medtronic† (fellowship funding)	None
Dr. Edward P. Walsh	Content—Individual Pediatric Expert	None	None	None	None	None
Dr. Clyde Yancy	Content—American College of Cardiology/ American Heart Association Lead Task Force Reviewer and 2005 Chronic Heart Failure Guideline Writing Committee	• AstraZeneca • GlaxoSmithKline • Medtronic • NitroMed • Otsuka • Scios	• GlaxoSmithKline • Novartis	None	• GlaxoSmithKline • Medtronic • NitroMed • Scios	None

This table represents the relationships of reviewers with industry that were reported at peer review. 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 noted in this table are modest unless otherwise noted.

*Names are listed in alphabetical order within each category of review. Participation in the peer review process does not imply endorsement of this document.

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

Appendix 3. Abbreviations List

ACC = American College of Cardiology
ACCF = American College of Cardiology Foundation
AHA = American Heart Association
AV = Atrioventricular
CRT = Cardiac resynchronization therapy
DDD = Dual-chamber pacemaker that senses/paces in the atrium/ventricle and is inhibited/triggered by intrinsic rhythm
LVEF = Left ventricular ejection fraction
HRS = Heart Rhythm Society
ICD = Implantable cardioverter-defibrillator
LV = Left ventricular/left ventricle
MADIT I = Multicenter Automatic Defibrillator Implantation Trial I
MADIT II = Multicenter Automatic Defibrillator Implantation Trial II
MUSTT = Multicenter UnSustained Ventricular Tachycardia Trial
NYHA = New York Heart Association
SCD = Sudden cardiac death
SCD-HeFT = Sudden Cardiac Death in Heart Failure Trial
SND = Sinus node dysfunction
VT = Ventricular tachycardia