# Complete Summary

## GUIDELINE TITLE

ACC/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. 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).

## BIBLIOGRAPHIC SOURCE(S)

Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Faxon DP, Halperin JL, Hiratzka LF, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura RA, Ornato JP, Page RL, Riegel B, Tarkington LG, Yancy CW, American College of Cardiology/American Heart Association Task Force on Practice , American Association for Thoracic Surgery, Society of Thoracic Surgeons. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force [trunc]. J Am Coll Cardiol 2008 May 27;51(21):e1-62. [527 references] PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices. Bethesda (MD): American College of Cardiology Foundation; 2002. 48 p. [447 references]

## COMPLETE SUMMARY CONTENT

## SCOPE

### DISEASE/CONDITION(S)

Cardiac rhythm abnormalities requiring cardiac pacemakers or implantable cardioverter-defibrillator (ICD) devices including:

- Sinus node dysfunction
- Acquired atrioventricular (AV) block
- Chronic bifascicular block
- AV block following acute myocardial infarction
- Hypersensitive carotid sinus syndrome
- Neurocardiogenic syncope
- Bradycardia or syncope following cardiac transplantation
- Arrhythmias associated with neuromuscular diseases, sleep apnea syndrome or cardiac sarcoidosis
- Long QT syndrome
- Tachycardias
- Atrial fibrillation
- Severe systolic heart failure
- Hypertrophic cardiomyopathy
- Congenital heart disease

### GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

### CLINICAL SPECIALTY

Cardiology
Geriatrics
Internal Medicine
Pediatrics
Thoracic Surgery

### INTENDED USERS

Physicians

### GUIDELINE OBJECTIVE(S)

- To provide guidelines on the appropriate use of heart rhythm devices (pacemakers for bradyarrhythmias and heart failure management, e.g., cardiac resynchronization, and implantable cardioverter-defibrillators [ICDs]), not the treatment of cardiac arrhythmias
- To revise and update the 2002 "American College of Cardiology/American Heart Association/North American Society for Pacing and Electrophysiology

Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices"

### TARGET POPULATION

Children, adolescents, and adults in need of permanent cardiac pacemaker and/or implantable cardioverter-defibrillator insertion to restore normal cardiac rhythm or prevent life-threatening cardiac arrhythmias

### INTERVENTIONS AND PRACTICES CONSIDERED

1. Permanent cardiac pacemaker insertion
2. Implantable cardioverter-defibrillator (ICD) therapy

**Note**: The committee considered extending the scope of the guideline to include recommendations for follow-up and device replacement but deferred the decision given other published statements and guidelines on the topic. These are addressed in the original guideline document as a matter of information; however, no endorsement is implied.

### MAJOR OUTCOMES CONSIDERED

- Subjective and objective symptom improvement
- Quality of life
- Functional status
- New York Heart Association functional classification
- Exercise capacity
- Patient adherence
- Heart failure end points
- Atrial fibrillation end points
- Stroke or thromboembolism end points
- Rates of inappropriate implantable cardioverter-defibrillator detections and therapies
- Sudden cardiac death
- All-cause mortality

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An extensive literature survey was conducted that led to the incorporation of 527 references. Searches were limited to studies, reviews, and other evidence conducted in human subjects and published in English. Key search words included but were not limited to antiarrhythmic, antibradycardia, atrial fibrillation, bradyarrhythmia, cardiac, cardiac resynchronization therapy (CRT), defibrillator, device therapy, devices, dual chamber, heart, heart failure, implantable cardioverter-defibrillator (ICD), implantable defibrillator, device implantation,

long-QT syndrome, medical therapy, pacemaker, pacing, quality-of-life, resynchronization, rhythm, sinus node dysfunction, sleep apnea, sudden cardiac death, syncope, tachyarrhythmia, terminal care, and transplantation. Additionally, the committee reviewed documents related to the subject matter previously published by the American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS).

**NUMBER OF SOURCE DOCUMENTS**

Not stated

**METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

**RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

**Applying Classification of Recommendations and Level of Evidence**

| | | **SIZE OF TREATMENT EFFEC** | | |
|---|---|---|---|---|
| | | **CLASS I**<br><br>*Benefit >>> Risk*<br><br>Procedure/Treatment<br><br>**SHOULD** be performed/ administered | **CLASS IIa**<br><br>*Benefit >> Risk*<br>*Additional studies with focused objectives needed*<br><br>**IT IS REASONABLE** to perform procedure/administer treatment | **CLASS IIb**<br><br>*Benefit ≥ Risk*<br>*Additional stud*<br>*objectives nee*<br>*registry data w*<br>*helpful*<br><br>Procedure/Trea<br>**MAY BE CONS** |
| **Estimate of Certainty (Precision) of Treatment Effect** | **LEVEL A**<br><br>Multiple populations evaluated*<br><br>Data derived from multiple randomized clinical trials or meta-analyses | • Recommendation that procedure or treatment is useful/effective<br>• Sufficient evidence from multiple randomized trials or meta-analyses | • Recommendation in favor of treatment or procedure being useful/effective<br>• Some conflicting evidence from multiple randomized trials or meta-analyses | • Recomm usefuln less we<br>• Greater evidenc multiple trials or analyse |
| | **LEVEL B**<br><br>Limited populations evaluated* | • Recommendation that procedure or treatment is useful/effective<br>• Evidence from single | • Recommendation in favor of treatment or procedure being useful/effective<br>• Some conflicting | • Recomm usefuln less we<br>• Greater evidenc |

| | | SIZE OF TREATMENT EFFEC | | |
|---|---|---|---|---|
| | Data derived from a single randomized trial or nonrandomized studies | randomized trial or nonrandomized studies | evidence from single randomized trial or nonrandomized studies | random nonran studies |
| | **LEVEL C**<br><br>Very limited populations evaluated*<br><br>Only consensus opinion of experts, case studies, or standard of care | • Recommendation that procedure or treatment is useful/effective<br>• Only expert opinion, case studies, or standard-of-care | • Recommendation in favor of treatment or procedure being useful/effective<br>• Only diverging expert opinion, case studies, or standard-of-care | • Recomm usefuln less we<br>• Only di opinion or stan |

*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.

**NOTE**: In 2003, the American College of Cardiology/American Heart Association (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. (See Table 1 in the Focused Update document for a list of suggested phrases for writing recommendations.)

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Writing committees were 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. 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. See "Rating Scheme for the Strength of the Evidence" above.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Experts in the subject under consideration are selected from the American College of Cardiology (ACC) and the American Heart Association (AHA) to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner 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, 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.

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 reemphasize 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. In the section on atrioventricular (AV) block associated with acute myocardial infarction (AMI), the recommendations follow closely those in the "ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction". However, because of the rapid evolution of pacemaker/implantable cardioverter-defibrillator (ICD) science, it has not always been possible to maintain consistency with other published guidelines.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

See the "Rating Scheme for the Strength of the Evidence" field above.

## COST ANALYSIS

### Optimizing Pacemaker Technology and Cost

The cost of a pacemaker system increases with its degree of complexity and sophistication. For example, the cost of a dual-chamber pacemaker system exceeds that of a single-chamber system with respect to the cost of the generator and the second lead (increased by approximately $2500), additional implantation time and supplies (approximately $160), and additional follow-up costs (approximately $550 per year). A biventricular pacemaker entails even greater costs, with the hardware alone adding $5000 to $10,000 to the system cost. With respect to battery life, that of a dual-chamber generator is shorter than that of a single-chamber generator and that of a biventricular device is shorter still. There are also quality of life (QOL) concerns associated with the more complex systems, including increased device size and increased frequency of follow-up. Against these additional costs are the potential benefits of the more sophisticated systems with respect to QOL, morbidity, and mortality. Furthermore, when a single-chamber system requires upgrading to a dual-chamber system, the costs are significant; one study estimated the cost of such an upgrade to be $14,451. An analysis of the Mode Selection Trial (MOST) found that the cost-effectiveness of dual-chamber pacemaker implantation compared with ventricular pacemaker implantation was approximately $53,000 per quality-adjusted year of life gained over 4 years of follow-up. Extended over the expected lifetime of a typical patient, the calculated cost-effectiveness of dual-chamber pacing improved to $6800 per quality-adjusted year of life gained.

### Cost-Effectiveness of Implantable Cardioverter-Defibrillator (ICD) Therapy

Long-term follow-up studies have consistently demonstrated that cumulative medical costs are increased substantially among patients receiving an ICD. Several studies have attempted to weigh whether these added costs are worthwhile in light of the potential for improved survival among patients receiving ICD therapy. These studies calculate a cost-effectiveness ratio that is defined as the difference in the total cost of patients receiving an ICD and patients receiving alternative therapy, divided by the additional life-years of survival provided by an ICD compared with alternative therapy. A benchmark for comparison is provided by renal dialysis, which costs approximately $50,000 to add 1 life-year of survival. Cost-effectiveness, like other outcome measures in clinical research studies, must be interpreted in light of the characteristics of the study populations and the length of follow-up available.

The early studies of ICD cost-effectiveness were based on mathematical models and relied on nonrandomized studies to estimate clinical efficacy and cost. These studies found cost-effectiveness ratios of $17,000, $18,100, and $29,200 per year of life saved. Another model incorporated costs of nonthoracotomy ICDs and efficacy estimates based on randomized trials and found ICD cost-effectiveness was between $27,300 and $54,000 per life-year gained, which corresponded to risk reductions of 40% and 20%, respectively.

Several randomized clinical trials have measured both cost and clinical outcomes and thus can directly estimate ICD cost-effectiveness. The Multicenter Automatic

Defibrillator Implantation Trial (MADIT) found a 54% reduction in total mortality and a cost-effectiveness ratio of $27,000 per life-year added. In contrast, CIDS found a 20% reduction in total mortality and a cost-effectiveness ratio of $139,000 per life-year added. The cost-effectiveness ratio from the AVID trial was $66,677 per life-year added. MADIT II found a 32% reduction in total mortality and $39,200 higher costs among ICD-assigned patients than among those treated with conventional therapy. The cost-effectiveness ratio in MADIT II was measured as $235,000 per year of life added at 2 years of follow-up but was projected to be between $78,600,and $114,000 per year of life added by 12 years of follow-up. The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) reported that total mortality was reduced by 23% and costs increased by $19 000 over 5 years of follow-up in patients assigned to ICDs compared with patients assigned to placebo. SCD-HeFT estimated the lifetime cost-effectiveness ratio of the ICD strategy was $38,400 per year of life added. This range of results from randomized studies is primarily due to different estimates of the effectiveness of the ICD in reducing mortality, because all showed similar increases in the cost of care among ICD recipients. When the results of all clinical trials were used in a model that used a consistent framework to project the full gain in life expectancy and lifetime costs in each trial, the cost-effectiveness of the ICD ranged from $25,300 to $50,700 per life-year added in the randomized trials in which the ICD reduced mortality. In the Coronary Artery Bypass Graft-Patch (CABG-Patch) trial and Defibrillator in Acute Myocardial Infarction Trial (DINAMIT), however, patients assigned to an ICD had lower survival and higher costs than patients assigned to conventional therapy, and the ICD strategy was not cost-effective. The evidence suggests that proper patient selection is necessary for ICD implantation to be cost-effective; when ICD implantation is restricted to appropriately selected patients, it has a cost-effectiveness ratio similar to other accepted cardiovascular therapies and compares well to the standard benchmark of renal dialysis ($30,000 to $50,000 per year of life saved). In principle, ICD implantation will be more cost-effective when used for patients at high risk of arrhythmic death and at low risk of other causes of death. Additional risk stratification of patients with a reduced left ventricular ejection fraction (LVEF) may improve patient selection for the ICD and thereby enhance its cost-effectiveness. Cost-effectiveness of the ICD would also be improved by lowering the cost of the device itself and further improving its reliability and longevity.

### Cardiac Resynchronization Therapy (CRT)

The cost-effectiveness of CRT has not been evaluated extensively. A CRT device that provides pacing but not defibrillation capability (CRT-P device) reduces hospitalization for heart failure patients, and these cost savings partially offset the initial cost of device implantation. CRT-P devices are also effective in improving QOL and may improve survival. The cost-effectiveness of CRT-P devices versus medical therapy appears to be favorable. There are few data on the cost-effectiveness of a CRT device that incorporates both pacing and defibrillation capabilities (CRT-D) compared with CRT-P devices.

## METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The document was reviewed by 2 official reviewers nominated by each of the American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (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. The section "Pacing in Children and Adolescents" was reviewed by additional reviewers with special expertise in pediatric electrophysiology.

The guideline document was approved by the ACC Foundation Board of Trustees, the AHA Science Advisory and Coordinating Committee, and the HRS Board of Trustees in February 2008.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

The American College of Cardiology/American Heart Association (ACC/AHA) classification of the recommendations for patient evaluation and treatment (Classes I-III) and the levels of evidence (A-C) are defined at the end of the "Major Recommendations" field.

### Indications for Pacing

### Recommendations for Permanent Pacing in Sinus Node Dysfunction (SND)

*CLASS I*

1. Permanent pacemaker implantation is indicated for SND with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms. *(Level of Evidence: C)* (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981)
2. Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence. *(Level of Evidence: C)* (Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Linde-Edelstam et al., 1992; Gammage et al., 1991)
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)* Kay, Estioko, & Wiener, 1982; Kusumoto & Goldschlager, 1996; Rasmussen, 1981; Shaw, Holman, & Gowers, 1980; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972)
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)* (Fisher, 1981, Reiffel & Kuehnert, 1994)

*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)* (Kay, Estioko, & Wiener, 1982; 1996; Rasmussen, 1981; Linde-Edelstam et al., 1992; Shaw, Holman, & Gowers, 1980; Dreifus, Michelson, & Kaplinsky, 1983; Rubenstein et al., 1972)

*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)*

**Recommendations for Acquired Atrioventricular (AV) 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)* (Dreifus, Michelson, & Kaplinsky, 1983; Friedberg, Donoso, & Stein, 1964; British Pacing and Electrophysiology Group, 1991; Kastor, 1975)
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 therapy that results in symptomatic bradycardia. *(Level of Evidence: C)* (Dreifus, Michelson, & Kaplinsky, 1983; Friedberg, Donoso, & Stein, 1964; British Pacing and Electrophysiology Group, 1991; Kastor, 1975)
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 (Ector, Rolies, & De Geest, 1983) or any escape

rate less than 40 bpm, or with an escape rhythm that is below the AV node. *(Level of Evidence: C)*(Kay, Estioko, & Wiener, 1982; Shaw, Holman, & Gowers, 1980)

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 (AF) 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)* (Gallagher et al., 1982; Langberg et al., 1989)
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)* (Kim et al., 2001; Kastor, 1975; Glikson et al., 1997; Koplan et al., 2003)
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)* (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962)
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)* (Strasberg et al., 1981)
9. Permanent pacemaker implantation is indicated for asymptomatic persistent third-degree AV block at 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)* (British Pacing and Electrophysiology Group, 1981; Shaw et al., 1985)
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)* (Chokshi et al., 1990; Barold & Mugica, 1991)

*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)* (Dreifus, Michelson, & Kaplinsky et al., 1983; Friedberg, Donoso, & Stein, 1964; Gadboys, Wisoff, & Litwak, 1964; British Pacing and Electrophysiology Group, 1991; Barold & Mugica, 1991; Kastor, 1975)
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)* (Strasberg et al., 1981; British Pacing and Electrophysiology Group, 1991; Shaw et al., 1985)
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)* (Barold, 1996; Kim et al., 1993)

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 original guideline document.) *(Level of Evidence: B)* (Barold, 1996; British Pacing and Electrophysiology Group, 1991; Zipes, 1979; Kastor, 1975)

*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)* (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff & Kark, 1979; Charles et al., 1981; James, 1962)
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)* (Zeltser et al., 2004; Shohat-Zabarski et al., 2004)

*CLASS III*

1. Permanent pacemaker implantation is not indicated for asymptomatic first-degree AV block. *(Level of Evidence: B)* (Mymin et al., 1986) (See Section 2.1.3, "Chronic Bifascicular Block" in the original guideline document.)
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)* (Strasberg et al., 1981)
3. Permanent pacemaker implantation is not indicated for AV block that is expected to resolve and is unlikely to recur (McAlister, et al., 1989) (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)* (Shohat-Zabarski et al., 2004; McAlister et al., 1989)

**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)* (Friedberg, Donoso, & Stein, 1964; Gadboys, Wisoff, & Litwak, 1964; Johansson, 1966; Hindman et al., 1978; Donmoyer, DeSanctis, & Austen, 1967; Edhag & Swahn, 1976)
2. Permanent pacemaker implantation is indicated for type II second-degree AV block. *(Level of Evidence: B)* (Dhingra et al., "The significance," 1974; Donoso, Adler, & Friedberg, 1964; Ranganathan et al., 1972; Dhingra et al.,"Syncope," 1974)

3. Permanent pacemaker implantation is indicated for alternating bundle-branch block. *(Level of Evidence: C)* (Josephson, 1993)

*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)* (Fisch, Zipes, & Fisch, 1980; McAnulty et al., 1982; Kulbertus & Collignon, 1969; DePasquale & Bruno, 1973; Denes, 1977; McAnulty et al., 1978; Peters et al., 1979; Scheinman et al., 1982; Morady et al., 1984; Click et al., 1987; Ezri et al., 1983; Twidale et al., 1988; Englund et al., 1995; Scheinman et al., 1977; Probst et al., 1979; Dhingra et al., 1979; Cheng, 1971; Dhingra et al., "Syncope," 1974; Brignole et al., 2001)
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)* (Scheinman et al., 1982)
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)* (Dhingra et al., 1979)

*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)* (Perloff et al., 1984; Hiromasa et al., 1987; Stevenson et al., 1990; James & Fisch, 1963; Roberts, Perloff, & Kark, 1979; Charles et al., 1981; James, 1962)

*CLASS III*

1. Permanent pacemaker implantation is not indicated for fascicular block without AV block or symptoms. *(Level of Evidence: B)* (McAnulty et al., 1982; McAnulty et al.,1978; Scheinman et al., 1982; Scheinman et al., 1977)
2. Permanent pacemaker implantation is not indicated for fascicular block with first-degree AV block without symptoms. *(Level of Evidence: B)* (McAnulty et al., 1982; McAnulty et al.,1978; Scheinman et al., 1982; Scheinman et al., 1977)

**Recommendations for Permanent Pacing After the Acute Phase of Myocardial Infarction (MI)**

*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 MI. *(Level of Evidence: B)* (Ranganathan et al., 1972; Col

& Weinberg, 1972; Ritter et al., 1976; Ginks et al., 1977; Domenighetti & Perret, 1980; Lamas et al., 1986)
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)* (Col & Weinberg, 1972; Ritter et al., 1976)
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)* (Shaw, Holman, & Gowers, 1980)

*CLASS III*

1. Permanent ventricular pacing is not indicated for transient AV block in the absence of intraventricular conduction defects. *(Level of Evidence: B)* (Col & Weinberg, 1972)
2. Permanent ventricular pacing is not indicated for transient AV block in the presence of isolated left anterior fascicular block. *(Level of Evidence: B)* (Ginks et al., 1977)
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)* (Hindman et al., 1978; Col & Weinberg, 1972)
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)* (Col & Weinberg, 1972)

*These recommendations are consistent with the "ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction" (Antman et al., 2004).

**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)* (Brignole et al., 1992; Brignole et al., 1991)

*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)* (Brignole et al., 1992)

*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)* (Sutton et al., 2000; Ammirati, Colivicchi, & Santini, 2001; Connolly et al., 2003; Sheldon et al., 1998)

*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)*

**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)*

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

*CLASS IIa*

1. Permanent pacing is reasonable for symptomatic recurrent supraventricular tachycardia (SVT 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)* (Peters et al., 1985; Fisher et al., 1987; Den et al., 1984; Saksena et al., 1986; Barold et al., 1987)

*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)*

**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)* (Eldar et al., 1987; Eldar et al., 1992)

*CLASS IIa*

1. Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome. *(Level of Evidence: C)* (Eldar et al., 1987; Eldar et al., 1992)

*CLASS IIb*

1. Permanent pacing may be considered for prevention of symptomatic, drug-refractory, recurrent AF in patients with coexisting SND. *(Level of Evidence: B)* (Lamas et al., 2000; Saksena et al., 1996; Saksena et al, 1998)

*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)* (Fisher et al., 1987)
2. Permanent pacing is not indicated for torsade de pointes VT due to reversible causes. *(Level of Evidence: A)* (Moss & Robinson, 1992; Viskin et al., 1996)

**Recommendation for Pacing to Prevent Atrial Fibrillation**

*CLASS III*

1. Permanent pacing is not indicated for the prevention of AF in patients without any other indication for pacemaker implantation. *(Level of Evidence: B)* (Knight et al., 2005)

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

*CLASS I*

1. For patients who have left ventricular ejection fraction (LVEF) less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and sinus rhythm, cardiac resynchronization therapy (CRT) with or without an ICD is indicated for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy. *(Level of Evidence: A)* (Abraham et al., 2002; Bristow et al., 2004; Cleland et al., 2005; Hunt, 2005)

*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 AF, 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)* (Cazeau et al., 2001; Hunt, 2005)

2. For patients with LVEF less than or equal to 35% with New York Heart Association (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)* (Hunt, 2005)

*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 and who are undergoing implantation of a permanent pacemaker and/or ICD with anticipated frequent ventricular pacing, CRT may be considered. *(Level of Evidence: C)* (Hunt, 2005)

*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)* (Abraham et al., 2002; Bristow et al., 2004; Cleland et al., 2005; Hunt, 2005)
2. CRT is not indicated for patients whose functional status and life expectancy are limited predominantly by chronic noncardiac conditions. *(Level of Evidence: C)* (Hunt, 2005)

**Recommendations for Pacing in Patients With Hypertrophic Cardiomyopathy (HCM)**

*CLASS I*

1. Permanent pacing is indicated for SND or AV block in patients with HCM as described previously (see Section 2.1.1, "Sinus Node Dysfunction," and Section 2.1.2, "Acquired Atrioventricular Block in Adults" in the original guideline document). *(Level of Evidence: C)*

*CLASS IIb*

1. Permanent pacing may be considered in medically refractory symptomatic patients with HCM 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 implantable cardioverter defibrillator (ICD) (see Section 3, "Indications for Implantable Cardioverter-Defibrillator Therapy" in the original guideline document). (Fananapazir et al., 1994; Nishimura et al., 1997; Kappenberger et al., 1997; Maron et al., 1999; Nishimura et al., "Effect of," 1996; Nishimura et al., "Dual-chamber," 1996)

*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)*

**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)* (Kay, Estioko, & Wiener, 1982; Ector, Rolies, & De Geest, 1983; Beder et al., 1983; Kelly et al., 2001)
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)* (Strasberg et al., 1981; Lillehei et al., 1963)
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)* (Michaelsson, Jonzon, & Riesenfield , 1995; Moak et al., 2001; Villain et al., 2006)
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)* (Pinsky et al., 1982; Jaeggi et al., 2002)

*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 reentrant tachycardia; SND may be intrinsic or secondary to antiarrhythmic treatment. *(Level of Evidence: C)* (Silka et al., 1990; Stephenson et al., 2003; Pfammatter et al., 1995)
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)* (Dewey, Capeless, & Levy, 1987; Sholler & Walsh, 1989)
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)* (Cohen et al., 2001)
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)* (Villain et al., 2006; Banks, Jenson, & Kugler, 2001; Gross et al., 2006; Villain et al., 2003)

*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)* (Krongrad, 1978)
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)* (Sholler & Walsh, 1989; Michaelsson, Jonzon, & Riesenfield, 1995)
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)* (Weindling et al., 1988; Krongrad, 1978)
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 minimum heart rate more than 40 bpm. *(Level of Evidence: C)*

## Indications for Implantable Cardioverter-Defibrillator Therapy

### Recommendations for Implantable Cardioverter Defibrillators

*CLASS I*

1. ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation (VF) 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)* (European Heart Rhythm Association et al., 2006; The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators, 1997; Wever et al., 1995; Siebels & Kuck, 1994; Connolly et al., "Canadian," 2000; Kuck et al., 2000; Connolly et al., "Meta-analysis," 2000)
2. ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. *(Level of Evidence: B)* (European Heart Rhythm Association et al., 2006; The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators, 1997; Wever et al., 1995; Siebels & Kuck, 1994; Connolly et al., "Canadian," 2000; Kuck et al., 2000; Connolly et al., "Meta-analysis," 2000)
3. ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at

electrophysiological study. *(Level of Evidence: B)* (European Heart Rhythm Association et al., 2006; Connolly et al., "Canadian," 2000)

4. ICD therapy is indicated in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III. *(Level of Evidence: A)* (European Heart Rhythm Association et al., 2006; Bardy et al., 2005)
5. ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy (DCM) who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. *(Level of Evidence: B)* (European Heart Rhythm Association et al., 2006; Bardy et al., 2005; Kadish et al., 2004; Desai et al., 2004)
6. ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA functional Class I. *(Level of Evidence: A)* (European Heart Rhythm Association et al., 2006; Moss et al., 2002)
7. ICD therapy is indicated in patients with nonsustained VT due to prior myocardial infarction (MI), LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study. *(Level of Evidence: B)* (European Heart Rhythm Association et al., 2006; Moss et al., 1996; Buxton et al., 1999)

*CLASS IIa*

1. ICD implantation is reasonable for patients with unexplained syncope, significant LV dysfunction, and nonischemic DCM. *(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 HCM who have 1 or more major risk factors for sudden cardiac death (SCD). (See Section 3.2.4, "Hypertrophic Cardiomyopathy" in the original guideline document for definition of major risk factors.) *(Level of Evidence: C)*
4. ICD implantation is reasonable for the prevention of SCD in patients with ARVD/C who have 1 or more risk factors for SCD. *(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)* (Zareba et al., 2003; Viskin, 2003; Goel et al., 2004; Monnig et al., 2005; Goldenberg et al., 2006; Hobbs et al., 2006)
6. ICD implantation is reasonable for non hospitalized 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)* (European Heart Rhythm Association et al., 2006; Zareba et al., 2003; Viskin, 2003; Goel et al., 2004; Monnig et al., 2005; Goldenberg et al., 2006; Hobbs et al., 2006)
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 VF. *(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 CRT-D. *(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 VF or VT is amenable to surgical or catheter ablation (e.g., atrial arrhythmias associated with the Wolff-Parkinson-White syndrome, RV 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)* (European Heart Rhythm Association et al., 2006)

**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)* (Silka et al., 1993; Hamilton et al., 1996; Alexander et al., 2004; Choi, Porter, & Ackerman, 2004)

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)* (Karamlou, 2006)

*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)* (Mushlin et al., 1998; Khairy et al., 2004)

*CLASS IIb*

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)* (Kammeraad et al., 2004; Dubin et al., 2003)

*CLASS III*

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

**Definitions**:

**Applying Classification of Recommendations and Level of Evidence**

| | | **SIZE OF TREATMENT EFFEC** | | |
|---|---|---|---|---|
| | | **CLASS I**<br><br>*Benefit >>> Risk*<br><br>Procedure/Treatment<br><br>**SHOULD** be performed/ administered | **CLASS IIa**<br><br>*Benefit >> Risk*<br>*Additional studies with focused objectives needed*<br><br>**IT IS REASONABLE** to perform procedure/administer treatment | **CLASS IIb**<br><br>*Benefit ≥ Risk*<br>*Additional stud*<br>*objectives nee*<br>*registry data w*<br>*helpful*<br><br>Procedure/Trea<br>**MAY BE CONS** |
| **Estimate of Certainty (Precision)** | **LEVEL A**<br><br>Multiple populations | • Recommendation that procedure or treatment is useful/effective | • Recommendation in favor of treatment or procedure being useful/effective | • Recomm<br>usefuln<br>less we<br>• Greater |

| | | SIZE OF TREATMENT EFFEC | | |
|---|---|---|---|---|
| **of Treatment Effect** | evaluated*<br><br>Data derived from multiple randomized clinical trials or meta-analyses | • Sufficient evidence from multiple randomized trials or meta-analyses | • Some conflicting evidence from multiple randomized trials or meta-analyses | evidenc<br>multiple<br>trials or<br>analyse |
| | **LEVEL B**<br><br>Limited populations evaluated*<br><br>Data derived from a single randomized trial or nonrandomized studies | • Recommendation that procedure or treatment is useful/effective<br>• Evidence from single randomized trial or nonrandomized studies | • Recommendation in favor of treatment or procedure being useful/effective<br>• Some conflicting evidence from single randomized trial or nonrandomized studies | • Recomm<br>usefuln<br>less we<br>• Greater<br>evidenc<br>random<br>nonran<br>studies |
| | **LEVEL C**<br><br>Very limited populations evaluated*<br><br>Only consensus opinion of experts, case studies, or standard of care | • Recommendation that procedure or treatment is useful/effective<br>• Only expert opinion, case studies, or standard-of-care | • Recommendation in favor of treatment or procedure being useful/effective<br>• Only diverging expert opinion, case studies, or standard-of-care | • Recomm<br>usefuln<br>less we<br>• Only di<br>opinion<br>or stan |

*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.

**NOTE**: In 2003, the American College of Cardiology/American Heart Association (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. (See Table 1 in the Focused Update document for a list of suggested phrases for writing recommendations.)

## CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Selection of Pacemaker Systems for Patients with Atrioventricular (AV) Block
- Selection of Pacemaker Systems for Patients with Sinus Node Dysfunction

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

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. When indications at level C are supported by historical clinical data, appropriate references (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 if there was a consensus regarding specific pacing indications.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Appropriate use of cardiac pacemakers and implantable cardioverter-defibrillators (ICDs)
- Improved effectiveness of care, optimal outcomes, and appropriate use of resources
- Decreased morbidity and mortality in patients requiring implantation of cardiac pacemakers or ICDs

#### Subgroups Most Likely to Benefit

- Patients with hypertrophic obstructive cardiomyopathy who may benefit the most from pacemaker implantation are those with significant gradients (more than 30 mm Hg at rest or more than 50 mm Hg provoked).
- Patients with reduced left ventricular function may experience greater benefit with ICD therapy than with drug therapy.

### POTENTIAL HARMS

- Recent evidence suggests that ventricular desynchronization due to right ventricular apical (RVA) pacing may have adverse effects on left ventricular

(LV) and left atrial structure and function. These adverse effects likely explain the association of RVA pacing, independent of atrioventricular synchrony, with increased risks of atrial fibrillation and heart failure in randomized clinical trials of pacemaker therapy and, additionally, ventricular arrhythmias and death during implantable cardioverter-defibrillator (ICD) therapy.

- Studies have suggested that chronic RVA pacing in young patients, primarily those with congenital complete heart block, can lead to adverse histological changes, LV dilation, and LV dysfunction.
- Conventional ICD therapy in any form may be associated with worsening heart failure, ventricular tachycardia, ventricular fibrillation, and noncardiac death that can be related to the adverse effects of RVA pacing.
- Complications related to replacement of ICD generators under advisory have been well documented, including infection, the need for reoperation, and death. The estimated device failure rate and the likelihood of mortality resulting from device failure must be weighed against the risk of procedural morbidity and mortality associated with device replacement.
- The use of ICD therapy carries a risk for psychological consequences and may lead to a decrement on quality of life, especially among patients who have experienced shocks. Reports of significant behavioral disorders, including anxiety, device dependence, or social withdrawal, have been described with ICD implantation.
- Thoracotomy in fragile patients with heart failure has been associated with bleeding, stroke, hypotension, and arrhythmias.
- Cardiac resynchronization devices and ICDs are not infallible; failure of electronics, batteries, and leads can occur.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

#### Permanent Pacemaker Implantation

A prosthetic mechanical tricuspid valve represents an absolute contraindication to placement of transvenous right ventricular leads, because such leads will cross the valve and may interfere with valve function. This scenario occurs commonly in patients with tricuspid valve endocarditis and a transvenous pacemaker.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- 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.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads
Pocket Guide/Reference Cards
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

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## ADAPTATION

Not applicable: The guideline was not adapted from another source.

## DATE RELEASED

1998 Apr (revised 2008 May 27)

## GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association
Heart Rhythm Society - Professional Association

## SOURCE(S) OF FUNDING

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## GUIDELINE COMMITTEE

Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

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*Recused from voting on guideline recommendations (see Section 1.2, "Document Review and Approval," for more detail)

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### 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 | Re |
|---|---|---|---|---|
| Dr. Andrew E. Epstein* | • Boston Scientific<br>• CryoCath<br>• Medtronic<br>• Sanofi-Aventis<br>• St. Jude** | • Boston Scientific<br>• Medtronic<br>• Reliant Pharmaceuticals<br>• Sanofi-Aventis<br>• St. Jude | None | • |
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| Committee Member | Consulting Fees/Honoraria | Speakers' Bureau | Ownership/ Partnership/ Principal | Re |
|---|---|---|---|---|
| DiMarco* | • CV Therapeutics**<br>• Daiichi Sankyo<br>• Medtronic**<br>• Novartis**<br>• Sanofi-Aventis<br>• Solvay<br>• St. Jude | | | • |
| Dr. Kenneth A. Ellenbogen* | • Ablation Frontiers<br>• Atricure<br>• Biosense Webster<br>• Biotronik<br>• Boston Scientific<br>• Medtronic<br>• Sorin/ELA<br>• St. Jude | • Reliant Pharmaceuticals<br>• Sanofi-Aventis | None | • |
| Dr. N.A. Mark Estes III | • Medtronic | • Boston Scientific<br>• Medtronic<br>• St. Jude | None | None |
| Dr. Roger A. Freedman* | • Boston Scientific<br>• Medtronic<br>• Sorin/ELA<br>• St. Jude | • Boston Scientific<br>• St. Jude | • St. Jude | • |
| Dr. Leonard S. Gettes | None | None | None | None |
| Dr. A. Marc Gillinov* | • AtriCure<br>• Edwards**<br>• Medtronic | • Guidant<br>• St. Jude | • Viacor** | None |
| Dr. Gabriel Gregoratos | None | None | None | None |
| Dr. Stephen C. Hammill | Biosense Webster | Boston Scientific | None | Medtro |

| Committee Member | Consulting Fees/Honoraria | Speakers' Bureau | Ownership/ Partnership/ Principal | Re |
|---|---|---|---|---|
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| Dr. L. Kristin Newby | • AstraZeneca/Atherogenics<br>• Biosite<br>• CV Therapeutics<br>• Johnson & Johnson<br>• Novartis<br>• Procter & Gamble<br>• Roche Diagnostics | None | None | • <br>• <br>• <br>• <br>• <br>• <br>• |
| Dr. Richard L. Page | • Astellas<br>• Berlex<br>• Pfizer<br>• Sanofi-Aventis** | None | None | • |
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| Dr. Lynne Warner Stevenson | • Biosense Webster***<br>• Boston Scientific***<br>• CardioMEMS<br>• Medtronic<br>• Medtronic***<br>• Scios | None | None | • <br>• |
| Dr. Michael O. Sweeney* | • Medtronic** | • Boston Scientific<br>• Medtronic** | 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

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***Indicates spousal relationship.

See Appendix II in the original guideline document for peer reviewer relationships with industry.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices. Bethesda (MD): American College of Cardiology Foundation; 2002. 48 p. [447 references]

## GUIDELINE AVAILABILITY

Electronic copies: Available from the American College of Cardiology (ACC) Web site and the American Heart Association (AHA) Web site.

Print copies: Available from the American College of Cardiology, Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- 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. J Am Coll Cardiol, 2008; 51:2085-2105. Electronic copies: Available from the American College of Cardiology (ACC) Web site.
- ACC/AHA pocket guideline. Device-based therapy of cardiac rhythm abnormalities. 2008 May. 39 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology Web site. Also available for Palm download from the ACC Web site.

- ACC/AHA/HRS 2008 guidelines or device-based therapy of cardiac rhythm abnormalities. Slide set. 2008 May. 74 p. Electronic copies: Available from the American College of Cardiology Web site.

Print copies: Available from the American College of Cardiology, Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699.

### PATIENT RESOURCES

None available

### NGC STATUS

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