

Complications Associated With Implantable Cardioverter-Defibrillator Replacement in Response to Device Advisories

Paul A. Gould, MBBS, PhD

Andrew D. Krahn, MD

for the Canadian Heart Rhythm Society Working Group on Device Advisories

IMPLANTABLE CARDIOVERTER-defibrillators (ICDs) have been shown to reduce mortality in patients at risk of sudden cardiac death in large randomized trials for primary¹⁻³ and secondary prevention of sudden death.^{4,5} Accordingly, these data have led to changes in ICD guidelines, increasing indications for implantation^{6,7} and implantation rates.^{8,9} Potential and actual ICD malfunctions caused by failure of generator components, once made public, are known as ICD advisories. ICD advisories potentially affect a large number of patients. The risk of failure (comparing the number of failures with the number of devices implanted) associated with current ICD advisories ranges from 0.009% to 2.6% of devices during a variable follow-up period that is typically less than 24 months (TABLE 1). This risk may vary, depending on variables such as battery reserve and device programming.

These advisories or recalls stem from unanticipated failures of ICD generator components that potentially place the patient at risk and are recognized after commercial release and clinical use. The

See also pp 1901, 1929, 1944, and Patient Page.

Context Recent implantable cardioverter-defibrillator (ICD) advisories and recalls have caused management dilemmas for physicians, particularly because there are no specific guidelines or data on outcomes from current management strategies. The risk of ICD generator replacement has not been assessed in this population.

Objective To determine the complication rate associated with ICD generator replacement for the current ICD advisories.

Design and Setting Seventeen ICD implanting centers in Canada were surveyed to assess complication rates as a result of generator replacements because of ICD advisories from October 2004 to October 2005.

Main Outcome Measure Complications associated with elective ICD generator replacement for current device advisories.

Results At the 17 surveyed centers, 2915 patients had recall devices, including 533 (18.3%) who had advisory ICDs replaced a mean (SD) of 26.5 (11.5) months after their initial implant. Of these patients, 66% had a secondary prevention ICD, and 45% had received a previous appropriate shock. During a mean (SD) of 2.7 (2.8) months' follow-up after ICD generator replacement, complications occurred in 43 patients (8.1%). Major complications attributable to advisory device replacement requiring reoperation occurred in 31 patients (5.8%), with death in 2 patients after extraction for pocket infection. Minor complications occurred in 12 patients (2.3%). There were 3 (0.1%) advisory-related device malfunctions reported, without clinical consequences.

Conclusions ICD generator replacement in patients with advisory devices is associated with a substantial rate of complications, including death. These complications need to be considered in the development of guidelines determining the appropriate treatment of patients with advisory devices.

JAMA. 2006;295:1907-1911

www.jama.com

term *advisory* or *recall* specifically describes the communication issued about these failures by industry and the federal regulatory bodies (Health Canada and the US Food and Drug Administration).^{10,11} The causes for recall range from relatively inconsequential problems such as labeling errors to important problems that compromise device function; the loss of function can often occur in unpredictable ways. Under these circumstances, patients and physicians may focus on immediate potential solutions

such as device replacement, which is generally technically less challenging than a new implant, but the procedure is associated with complications that may place the patient at substantial risk.

Author Affiliations: Division of Cardiology, Department of Medicine, University of Western Ontario, London.

A List of the Investigators in the Canadian Heart Rhythm Society Working Group on Device Advisories appears at the end of this article.

Corresponding Author: Andrew D. Krahn, MD, Arrhythmia Service, London Health Sciences Centre, 339 Windermere Rd, London, Ontario N6A 5A5, Canada (akrahn@uwo.ca).

COMPLICATIONS ASSOCIATED WITH ICD REPLACEMENT

The management of ICD advisories with generator replacement is therefore complex, and as such, the risk of device failure needs to be carefully assessed for each patient.

Few data are available to guide physicians in the appropriateness of their response to risk imposed by these advisories^{12,13} or to quantify the complication rate associated with ICD generator replacement. There are, to our knowledge, no data on replacement rates or associated complications as a result of an ICD generator advisory. Previous studies on ICD implantation complication rates have focused on infection rates, predominantly with de novo implantation.¹⁴⁻¹⁶ A recent physician survey demonstrated that the response to the advisories was not uniform¹⁷ and identified several factors that would lead a physician to electively replace an advisory device, including a secondary prevention indication compared with a primary prevention indication, pacemaker dependence, previous appropriate ICD therapy, higher likelihood of malfunction, and duration of physician practice less than 10 years.

ICD generator advisories are increasing at a greater rate than pacemaker advisories. ICDs accounted for more than three quarters of the US \$870 million spent in medical care in response to device-related advisories in the United

States between 1990 and 2000.⁸ Despite the economic implications, the decision to replace a device must include balancing the risk and potential consequences of device failure against the risks associated with device replacement. We sought to quantify complications arising from ICD device replacement resulting directly from the current device advisories to provide data to help guide clinical decision making and policy making about these risks.

METHODS

At the annual meeting of the Canadian Heart Rhythm Society, a survey of all ICD implant sites about advisory replacement outcome was proposed to all 16 teaching institutions in Canada. There are 3 nonteaching centers that perform ICD implants in Canada, 2 of which participated in the survey. Physician discussion and survey of all ICD manufacturers identified contact information for all institutions, and a request to participate was distributed in October 2005.

In October 2005, ICD implant and follow-up centers (n= 21) in Canada's 13 largest cities were contacted to complete a survey based on device failure and number of complications associated with generator replacement from October 2004 to October 2005 in response to ICD-related advisories that

were issued by ICD manufacturers (Table 1). Four centers did not participate (2 pediatric centers with fewer than 10 annual ICD implants; 2 adult centers), representing a catchment area of approximately 7% of Canada's population. At each follow-up/implanting center, an investigator was nominated and ethics review board permission for data collection was obtained. A list of the participating centers and investigators is included at the end of this article.

The study involved a 4-part questionnaire, with numeric and standardized responses obtaining data on the number of patients with advisory devices at each center and the number of devices replaced directly resulting from the advisory. Factors influencing ICD replacement indication in the context of the advisory were prospectively categorized as patient preference, secondary prevention, previous appropriate shock, pacing dependence, and device failure.

For purposes of this article, complications arising from device replacement were defined as either major or minor and then subcategorized. Major complications after ICD replacement were defined as postoperative death, nonfatal myocardial infarction, cardiogenic shock, pocket infection requiring surgical lead extraction, wound hematoma re-

Table 1. Current ICD Advisories Included in the Survey and Associated Risk

Company/Device*	Date of Advisory	Advisory Issue†	Current Risk of Failure, %†
Medtronic Marquis ICD	February 2005	Accelerated battery depletion caused by internal battery short	0.01
Guidant Ventak Prizm 2 DR ICD	June 2005	Short circuit caused by wire insulation problem within lead connector block	0.1
Guidant Ventak Prizm AVT, Vitality AVT, and Contak Renewal AVT ICDs	June 2005	Random memory error, limiting delivery of therapies	0.0095
Guidant Contak Renewal 3, 4, Renewal 3, 4 AVT, and Renewal RF ICDs	June 2005	Magnetic switch faulty, impairing delivery of therapies	0.009
St Jude Photon DR, Photon Micro VR/DR, and Atlas VR/DR ICDs	October 2005	Memory chip affected by atmospheric radiation, which can impair pacing and delivery of therapies	0.167
ELA Alto ICD	August 2001	Migration of metal, which can impair pacing and delivery of therapies	2.6‡ 0.1§

Abbreviation: ICD, implantable cardioverter-defibrillator.

*Predominantly subpopulation of listed devices affected by advisory.

†Data obtained from physician communications and public statement releases such as those from Medtronic¹⁰ and Guidant.¹¹ The current risk of failure represents the number of failures divided by the number of devices implanted at the time of advisory disclosure.

‡Manufactured between April and July 2003.

§Manufactured between August 2003 and August 2004.

quiring reoperation, and system malfunction requiring reoperation. Minor complications were defined as events distinct from the usual postoperative course that necessitated a significant change in treatment but not reoperation; this included incisional infection, significant site pain (both medically managed), and postoperative exacerbation of current medical conditions requiring hospitalization or medical management. Minor complications, such as minor site pain or wound contusion not requiring specific treatment, were therefore excluded. A standardized datasheet was used to obtain detailed information on patients who underwent elective generator replacement directly as a result of the advisories.

Pacemaker dependency was defined as absence of intrinsic rhythm when the pacemaker was gradually programmed to VVI pacing mode at a rate of 40/min.¹⁸ Previous appropriate shock was defined as an appropriate cardioversion or defibrillation, which successfully terminated a ventricular arrhythmia according to the predetermined ICD detection algorithm. The survey also collected data during the same period on the number of reports of advisory device failures/malfunctions, complications, and deaths attributable to these failures. During the survey (October 2004 to October 2005), there were 6 device advisories (Table 1). This period was chosen because it represented a dramatic increase in ICD device advisories.

The study was a retrospective medical record review of patients affected by ICD advisories. After an advisory was issued, patients were contacted by telephone to inform them of the advisory and discuss further treatment. The decision to replace the device was made at the discretion of the patient's physician according to the nature of the advisory and patient characteristics. Center physicians reviewed patients affected by the advisories and completed detailed data collection on patients who underwent ICD replacement.

After ICD replacement, patients underwent follow-up at 1 to 7 days, 1 to 3 months, and every 6 months there-

after. The duration of follow-up was defined as the time from replacement to last follow-up. All 17 centers provided complete survey data, and 15 of 17 provided complete data for the patients who underwent replacement (476 of the 533; 89.3%). Thus, 57 of the 533 patients (10.7%) had outcome data reported but did not report additional patient characteristics. Devices replaced for indications other than the advisory, such as end of battery life, elective battery replacement indicators, or nonadvisory issues (n=4) during the survey period, were not included in the complication or replacement data.

Data were collected, stored, and analyzed by the Arrhythmia Service at University Hospital in London, Ontario. Data are expressed as mean (SD) or percentage unless otherwise specified.

RESULTS

During the period of the survey, there were 2915 patients with advisory devices (Medtronic, 1825; Guidant, 712; St Jude, 370; ELA, 8) evaluated at 17 participating ICD implanting/follow-up centers. Of these, 533 (18.3%) patients underwent elective replacement of an advisory device at a mean (SD) of 26.5(11.5) months (median,

24.9; range, 4.7-65.8) after initial ICD implant. The patient characteristics of the replacement cohort are presented in TABLE 2. Indications for device replacement in the context of the advisories included pacing dependence and previous appropriate shocks (at all centers), patient preference (9 of 17 centers), and secondary prevention indication for ICD (7 of 17 centers). The proportion of devices replaced ranged from zero of 63 patients in one center to 24 of 53 (45.3%) in another (TABLE 3).

Complications directly attributable to elective advisory device replacement occurred in 43 patients (8.1%) during a mean (SD) of 2.7 (2.8) (median, 1.5; range, 0-10.7) months' follow-up (TABLE 4). Twelve of these were

Table 2. Advisory Device Replacement Population Characteristics (n = 533)

	Data
Total replacements, No.	533
Device manufacturer, %	
Medtronic	72
Guidant	27
St Jude	0.9
ELA	0.1
Patient age, mean (SD), y	64 (13)
Male, %	77
Secondary prevention indication for ICD, %	66
Previous appropriate shock, %	45
Pacing dependency, %	21

Table 3. Summary of Number of Advisory Devices and Number Replaced at Participating Implanting/Follow-up Centers

Site	No. of Advisory Devices	No. (%) Replaced	Devices Implanted/2 y*
1	229	14 (6)	317
2	138	62 (45)	407
3	378	61 (16)	439
4	131	30 (23)	428
5	248	21 (8)	359
6	153	24 (16)	312
7	90	33 (37)	297
8	130	47 (36)	693
9	59	23 (39)	170
10	94	22 (23)	213
11	15	2 (13)	22
12	410	90 (22)	699
13	196	32 (16)	380
14	63	0	149
15	53	24 (45)	0
16	177	21 (12)	449
17	351	27 (8)	405
Total	2915	533 (18.3)	5289

*Either calendar year January 1, 2004, to December 31, 2005, or fiscal year April 1, 2003, to March 31, 2005.

COMPLICATIONS ASSOCIATED WITH ICD REPLACEMENT

Table 4. Complications From 533 Elective Advisory Device Replacements

Severity and Complications	No. (%) [*]
Minor	
Incisional infection, medically managed	9 (1.7)
Significant site pain, medically managed	1 (0.2)
Heart failure requiring admission	1 (0.2)
Major psychological morbidity, medically managed	1 (0.2)
Major	
Pocket infection requiring extraction	10 (1.9)
Postextraction deaths	2 (0.4)
Hematoma requiring reoperation	12 (2.3)
System malfunction requiring reoperation	8 (1.5)
Significant site pain requiring reoperation	1 (0.2)

*Number of patients with the complication.

minor complications (2.3%) according to prespecified criteria, with a 1.7% risk of incisional infection (medically managed) and a 0.2% risk each of exacerbation of heart failure, significant site pain (medically managed), and major psychological morbidity.

Major complications occurred in 31 patients (5.8%); 10 patients developed pocket infections requiring system extraction. Two patients died after extraction (0.38% of all replacements), one death occurred 24 hours after extraction, complicated by perforation of the right ventricle with appropriate resuscitation, and the second death occurred a week postoperatively from multiorgan failure caused by uncontrolled sepsis despite system extraction. The nonextraction reoperation rate was 3.9% (21 patients).

From October 2004 until October 2005, 3 advisory device malfunctions were detected (0.1% of all advisory devices surveyed). All malfunctions were caused by premature battery depletion, 2 of which were detected as a result of the advisory; the other was the index Canadian Medtronic Marquis advisory case that was identified incidentally at routine follow-up. Each patient underwent generator replacement without adverse clinical sequelae.

COMMENT

In this study, ICD replacement in the context of the current advisories was associated with a complication rate of

8.1%. The rate of major complications was 5.8% and included 2 deaths, a mortality risk as a result of pocket infection of 20% (2 of 10). One death was a direct consequence of the lead extraction, and the second death reflected irreversible sepsis despite extraction. The rate of fatal outcome directly attributable to extraction (1 of 10 cases, 10%) is clearly higher than the published incidence of 0.5% in pacemakers, with a recognized higher risk of extraction in ICD patients because of the size of the lead.¹⁹ With a lead extraction procedure-related mortality of 1%, the current data suggest that 6000 replacements would lead to 100 infections requiring extraction, with 1 extraction-related death. The additional sepsis-related death rate is unknown but likely to be at least as high as the lead extraction procedure risk.

In our survey, the number of patients who died as a result of ICD replacement is similar to the number of reported device malfunctions that were not associated with major morbidity or mortality. Worldwide, 1 death associated with device failure has been reported in the medical literature, and 7 deaths were reported in the North American media during the survey.²⁰ Underreporting of deaths and malfunctions attributable to the current device advisories is possible and is a potential source of bias in the study, especially because there is no consensus on how device advisories should be reported or managed. Additionally, follow-up in our study was relatively short, at a mean (SD) of 2.7 (2.8) months. Complications such as infection may have occurred after this period.

Despite these limitations, these data raise important concerns for advisory committees. Future guidelines about management of advisory ICDs should give careful consideration to the formation of guidelines that favor ICD generator replacement in advisory situations, especially if the potential risk of device failure is likely to be less than the complication risks associated with replacement. This potential can be difficult to assess because the risk of replace-

ment is immediate and the risk of device failure from the advisory is generally for the life of the device. It is unlikely, however, that such a high initial complication rate would be anticipated with a management strategy favoring ICD generator replacement.

Complications caused by ICD replacement have not previously been assessed in a large multicenter study or in the context of device advisories. ICD generator replacement is not a benign procedure and carries a substantial risk of complications, which include death. Our data were collected via a national survey of ICD implanting/follow-up sites, thereby incorporating a wide range of surgical practices and management strategies for the current device advisories. All centers performed their ICD replacements in a dedicated replacement room, either a procedure room or operating theater, by using sterile technique and administering prophylactic antibiotics. The operators were all experienced surgeons or cardiologists with large implanting volumes.

The ICD replacement complication rate we observed is similar to that of large randomized ICD trials,^{1,3-5,21} which ranged from 2.5% to 15.2%. The complication rates in these trials, however, are associated with new ICD implantation. It is likely the trial data were not as inclusive as the current survey because complication rate was not the focus of these trials; however, the follow-up in our study was shorter than in the other studies.

Despite these methodological differences, the rate of pocket infections in our current survey (3.4%) is comparable to the rate of pocket infections in new implants in the Canadian Implantable Defibrillator Study (4.6%).⁴ The mortality rate of 0.4% associated with ICD replacement in the current study was similar to the new ICD implantation mortality rate of 0.5% in the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) study² and comparable to the Canadian Implantable Defibrillator Study (0.36%, nonthoracotomy ICD implantation)⁴ and the postoperative

complication mortality rate in the Multicenter Unsustained Tachycardia Trial Investigators (0.5%)²² but higher than Multicenter Automatic Defibrillator Implantation Trial (MADIT II) new implantation mortality rate (0%).¹

Device advisories involving ICDs are likely to increase.¹² There are no national or international guidelines for the appropriate management of these situations.²³ Because each advisory presents a unique risk, mandating universal guidelines is difficult. Nevertheless, our data suggest that strategies focusing on ICD generator replacement involve meaningful risk. These issues are amplified in primary prevention patients in whom the risk:benefit ratio may be more difficult to assess. In Canada, the responsibility for device recall rests with the federal government; however, the provincial Ministries of Health are also concerned with public health and safety.¹³ Device advisories in Canada are classified by Health Canada with a 3-class risk classification (low, intermediate, and high risk) that serves as a general guide for developing an appropriate clinical response. There are no more specific guidelines by which regulatory bodies advise physicians and patients about management for the current advisories, which is highlighted by the differences in indication for and rates of elective ICD replacement at different sites in our survey. The survey results emphasize the need for the physician to balance the risk of device malfunction/failure with the risk of device replacement.

Our study was retrospective and therefore has inherent limitations. The detection and reporting of device malfunctions and failures as a result of advisory issues are not standardized, so problems specifically related to these issues may have been missed in our survey. Longer follow-up may have detected further complications, in particular latent infection, which would only increase the unexpectedly high complication rate. In addition, patients who did not undergo generator replacement continue to be at risk for

the life of the device. Our study was not designed to assess these risks.

In conclusion, ICD generator replacement in patients with advisory devices is associated with a substantial risk of complications, including death. These risks need to be considered in the development of guidelines to determine the appropriate treatment of patients with advisory devices.

Author Contributions: Drs Gould and Krahn had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Gould, Krahn.

Acquisition of data: Gould, Krahn.

Analysis and interpretation of data: Gould, Krahn.

Drafting of the manuscript: Gould, Krahn.

Critical revision of the manuscript for important intellectual content: Gould, Krahn.

Statistical analysis: Gould, Krahn.

Study supervision: Krahn.

Financial Disclosures: Dr Krahn reported receiving consulting fees and research funding from Medtronic and Guidant.

Funding/Support: This study was unfunded and independently performed.

Investigators by Number of Patients Enrolled: Jean Champagne, Quebec Heart Institute, Laval Hospital, Quebec City, Quebec; Doug Cameron, University Health Network, Toronto, Ontario; Stanley Tung, St Paul's Hospital, Vancouver, British Columbia; David Birnie, Ottawa Heart Institute, Ontario; Raymond Yee, George J. Klein, Allan C. Skanes, Lorne J. Gula, London Health Sciences Center, London, Ontario; Derek V. Exner, Libin Cardiovascular Institute of Alberta, Calgary; Ratika Parkash, QEII Health Sciences Centre, Halifax, Nova Scotia; Chris Simpson, Queen's University, Kingston, Ontario; Jeff Healy, Hamilton Health Sciences Center, Hamilton, Ontario; Basilio Petrellis, St Michael's Hospital, Toronto, Ontario; Bernard Thibault, Montreal Heart Institute, Montreal, Quebec; Laurence Sterns, Vancouver Island Health Authority, Victoria, British Columbia; Eugene Crystal, Sunnybrook, Toronto, Ontario; Atul Verma, Southlake Regional Hospital, Newmarket, Ontario; Soori Sivakumaran, Royal Alexander Hospital, Edmonton, Alberta; William Hughes, Peterborough, Ontario; Elizabeth A. Stephenson, The Hospital for Sick Children, Toronto, Ontario.

REFERENCES

- Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med.* 2002;346:877-883.
- Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med.* 2004;350:2140-2150.
- Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med.* 2005;352:225-237.
- Connolly SJ, Gent M, Roberts RS, et al. Canadian Implantable Defibrillator Study (CIDS): a randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation.* 2000;101:1297-1302.
- The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. *N Engl J Med.* 1997;337:1576-1583.
- Gregoratos G, Abrams J, Epstein AE, et al. ACC/

AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). *Circulation.* 2002;106:2145-2161.

7. Sanders GD, Hlatky MA, Owens DK. Cost-effectiveness of implantable cardioverter-defibrillators. *N Engl J Med.* 2005;353:1471-1480.

8. Maisel WH, Sweeney MO, Stevenson WG, Ellison KE, Epstein LM. Recalls and safety alerts involving pacemakers and implantable cardioverter-defibrillator generators. *JAMA.* 2001;286:793-799.

9. Higgins SL. Impact of the Multicenter Automatic Defibrillator Implantation Trial on implantable cardioverter defibrillator indication trends. *Am J Cardiol.* 1999;83:79D-82D.

10. *Medtronic, Marquis Patient Management Information.* Minneapolis, Minn: Medtronic; 2005.

11. *Guidant Advisory Update, CONTAK RENEWAL & CONTAK RENEWAL 2, Models H135 and H155.* Indianapolis, Ind: Guidant; 2005.

12. Newman D, Crystal E, Goldman B. The recall genie: time to go back in the bottle. *Pacing Clin Electrophysiol.* 2004;27:435-436.

13. Goldman BS, Newman D, Fraser J, Irwin M. Management of intracardiac device recalls: a consensus conference: North American Society of Cardiac Pacing and Electrophysiology (NASPE). *Pacing Clin Electrophysiol.* 1996;19:7-17.

14. Smith PN, Vidaillet HJ, Hayes JJ, et al; Endotak Lead Clinical Investigators. Infections with nonthoracotomy implantable cardioverter defibrillators. *Pacing Clin Electrophysiol.* 1998;21:42-55.

15. Lai KK, Fontecchio SA. Infections associated with implantable cardioverter defibrillators placed transvenously and via thoracotomies: epidemiology, infection control, and management. *Clin Infect Dis.* 1998;27:265-269.

16. Trappe HJ, Pfizner P, Klein H, Wenzlaff P. Infections after cardioverter-defibrillator implantation: observations in 335 patients over 10 years. *Br Heart J.* 1995;73:20-24.

17. Maisel WH. Physician management of pacemaker and implantable cardioverter defibrillator advisories. *Pacing Clin Electrophysiol.* 2004;27:437-442.

18. Tang AS, Roberts RS, Kerr C, et al. Relationship between pacemaker dependency and the effect of pacing mode on cardiovascular outcomes. *Circulation.* 2001;103:3081-3085.

19. Byrd CL, Wilkoff BL, Love CJ, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. *Pacing Clin Electrophysiol.* 1999;22:1348-1357.

20. Gornick CC, Hauser RG, Almqvist AK, Maron BJ. Unpredictable implantable cardioverter-defibrillator pulse generator failure due to electrical overstress causing sudden death in a young high-risk patient with hypertrophic cardiomyopathy. *Heart Rhythm.* 2005;2:681-683.

21. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med.* 2004;351:2481-2488.

22. Buxton AE, Lee KL, Fisher JD, et al; Multicenter Unsustained Tachycardia Trial Investigators. A randomized study of the prevention of sudden death in patients with coronary artery disease. *N Engl J Med.* 1999;341:1882-1890.

23. Proceedings document from the Policy Conference on Pacemaker and ICD Performance presented by the Heart Rhythm Society and the Food and Drug Administration, September 16, 2005. Available at: <http://www.hrsonline.org/swPositionStatementFiles/ps119280494.asp>. Accessed March 29, 2006.