## HEART OF THE MATTER

# Guidelines and ICDs

A recent analysis of the ICD Registry from the National Cardiovascular Data Registry raises significant concerns about the effectiveness of the treatment guidelines for implantable cardioverter defibrillators for the primary prevention of sudden cardiac arrhythmic death.

That study indicates that, although the guidelines as proposed by the sponsoring societies were adhered to in most implantations, a disappointing one-quarter of the implantations were outside of the guidelines. Of the over 111,707 ICDs implanted between 2006 and 2009, 25,145 (22.5%) were implanted in patients who were outside of the recommended guidelines. Certainly one can make a case for the fact that these are *only* guidelines, and doctor should have the prerogative to make clinical decisions, but there have been few guidelines that have been as carefully explored as those for ICD implantation. They emphasize not only the benefit of the devices implanted within the guidelines, but the hazards of the implantation outside of the guidelines (JAMA 2011;305:43-9).

SIDNEY GOLDSTEIN, M.D.

Four guideline deviations were identified and included implantation carried out within 40 days of an acute MI, in 37%; within 3 months of coronary artery bypass surgery, in 3%; in patients with New York Heart Association class IV symptoms, in 12%; and in newly diagnosed heart failure, in 62%. There are adequate randomized clinical trials that clearly show the lack of benefit or increased risks of implantation in these four classes of patients.

Both the cardiology community and the device manufacturers have emphasized the importance of ICD therapy in as many individuals who fit the criteria for implantation as possible. Despite this effort, the implantation of ICDs on the potential candidates with systolic heart failure has significantly lagged. These results may have a further cooling effect on the rate of future implantation.

There are adequate randomized clinical trials that clearly demonstrate the lack of benefit or increased risks of implantation in these four classes of heart failure patients. The delay in implantation in new heart failure patients has been dictated by the observations that many individuals improve cardiac function after an acute event. In addition, a number of studies have shown that implantation at time of surgery is without merit and with some risk, and we have learned that the mode of death in NYHA class IV patients is dominated by progressive heart failure and not primary arrhythmias.

The use of ICDs within 40 days of an acute MI is of particular importance. Several studies have raised concern about the increase in heart failure mortality in patients who have experienced both appropriate and inappropriate ICD discharge for arrhythmias. It is unclear whether the increased heart failure precedes or is a result of ICD discharge. Similar observations were made in patients in whom an ICD was implanted early after an acute MI for the primary prevention of arrhythmic deaths. A recent study of the Defibrillation in Acute Myocardial Infarction Trial (DINAMIT) re-examines the observation that that heart failure mortality increased in patients who received an ICD shock (Circulation 2010;122:2645-52). DINAMIT enrolled patients 6-40 days after an acute MI in patients with left ventricular ejection fraction of less than 35%. Although ICD therapy decreased arrhythmic deaths, there was an increase in heart failure mortality in those patients who had an ICD shock, which resulted in a net increased mortality.

Both the American College of Cardiology and the Heart Rhythm Society have expressed concern about the recent report and plan to further emphasize ICD guidelines. The HRS is cooperating with the Department of Justice in an investigation of the inappropriate Medicare payments of ICDs "to lend expertise concerning the proper guidelines for clinical decision making," according to a statement. Should the Justice Department become involved in the appropriate use of medical guidelines, an entirely new disturbing dimension would be introduced in regard to guideline application. In the meantime, both cardiologists and noncardiologists should rethink their decisions in regard to the use of ICDs. They clearly represent an important medical advance that has saved the lives of many of our patients, but their use does have significant risks which must be balanced against their benefit. ■

DR. GOLDSTEIN, *medical editor of* CARDIOLOGY NEWS, *is professor of medicine at Wayne State University and division head emeritus of cardiovascular medicine at Henry Ford Hospital, both in Detroit. He is on data safety monitoring committees for the National Institutes of Health and several pharmaceutical companies.*



Cardiology News

**President, IMNG** Alan J. Imhoff

**Editor in Chief** Mary Jo M. Dales

**Executive Editors** Denise Fulton, Kathy Scarbeck

**Managing Editor** Catherine Hackett

**Senior Editors** Christina Chase, Kathryn DeMott, Jeff Evans, Lori Buckner Farmer, Keith Haglund, Gina L. Henderson, Sally Koch Kubetin, Teresa Lassman, Mark S. Lesney, Jane Salodof MacNeil, Renée Matthews, Catherine Cooper Nellist, Amy Pfeiffer, Terry Rudd, Leanne Sullivan, Elizabeth Wood

**Editorial Production Manager** Carol Nicotera-Ward

**Associate Editors** Felicia Rosenblatt Black, Therese Borden, Lorinda Bullock, Jay C. Cherniak, Richard Franki, Virginia Ingram-Wells, Jane Locastro, January Payne,

**Reporters** *Chicago:* Patrice Wendling; *Denver:* Bruce Jancin; *Germany*: Jennie Smith; *Miami:* Damian McNamara; *Mid-Atlantic:* Michele G. Sullivan; *New England:* Diana Mahoney; *New York:* Mary Ellen Schneider; *Philadelphia:* Mitchel L. Zoler; *San Diego:* Doug Brunk; *San Francisco:* Sherry Boschert, Robert Finn; *Washington:* Alicia Ault, Elizabeth Mechcatie, Naseem S. Miller, Heidi Splete, Miriam E. Tucker, Kerri Wachter

**Multimedia Producer** Nick Piegari

**Contributing Writers** Christine Kilgore, Mary Ann Moon

**Multimedia Intern** Esther French

**Project Manager** Susan D. Hite

**Assignments Manager** Megan Evans

**Executive Director, Operations** Jim Chicca

**Director, Production/Manufacturing** Yvonne Evans Struss

**Production Manager** Judi Sheffer

**Production Specialists** Maria Aquino, Anthony Draper, Rebecca Slebodnik

**Creative Director** Louise A. Koenig

**Design Supervisor** Elizabeth Byrne Lobdell

**Senior Designers** Sarah L.G. Breeden, Yenling Liu

**Designer** Lisa M. Marfori

**Photo Editor** Catherine Harrell

**Web Production Engineer** Jon Li

**Web Production Specialist** Derrick Boone

**Sales Director, IMNG**
Mark E. Altier, 973-290-8220, m.altier@elsevier.com

**National Account Manager**
Courtney Leonard, 973-290-8223, c.leonard@elsevier.com

**Advertising Offices** 60 Columbia Rd., Bldg. B, 2nd flr., Morristown, NJ 07960, 973-290-8200, fax 973-290-8250

**Classified Sales Manager, IMNG**
Robert Zwick 973-290-8226, fax 973-290-8250, r.zwick@elsevier.com

**Classified Sales Representative**
Andrea LaMonica 800-381-0569, fax 914-381-0573, a.lamonica@elsevier.com

**Reprints/Eprints**
Contact Wright's Media 877-652-5295

**Editorial Offices** 5635 Fishers Lane, Suite 6000, Rockville, MD 20852, 877-524-9335, cardiologynews@elsevier.com

**Address Changes** Fax change of address (with old mailing label) to 973-290-8245 or e-mail change to subs@elsevier.com

**Director of Information Technology** Doug Sullivan

**Senior Systems Administrators** Lee J. Unger, Kreg M. Williams

**Systems Administrator/Application Support** Peter Ayinde

**Sr. Program Manager, Customized Programs** Malika Wicks

**Circulation Analyst** Barbara Cavallaro, 973-290-8253, b.cavallaro@elsevier.com

**Program/Marketing Manager** Jennifer Eckert

**Business Controller** Dennis Quirk

**Adv. Services Manager** Joan Friedman

**Credit Supervisor** Patricia H. Ramsey

**Manager, Administration/Conventions** Lynne Kalish

**Receptionist** Linda Wilson

**Accounts Payable Coordinator** Daniela Silva

CARDIOLOGY NEWS is an independent newspaper that provides the practicing specialist with timely and relevant news and commentary about clinical developments in the field and about the impact of health care policy on the specialty and the physician's practice.

The ideas and opinions expressed in CARDIOLOGY NEWS do not necessarily reflect those of the Publisher. Elsevier Inc. will not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to the products, drugs, or services mentioned herein.

POSTMASTER Send changes of address (with old mailing label) to CARDIOLOGY NEWS Circulation, 60 Columbia Rd., Bldg. B, 2nd flr., Morristown, NJ 07960.

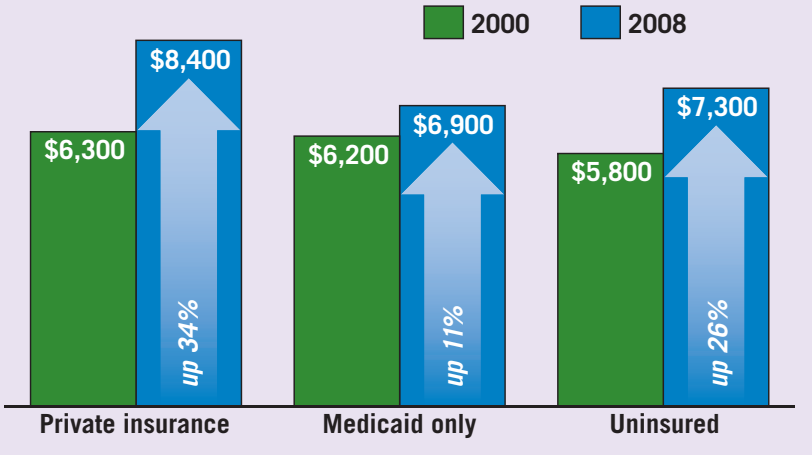
CARDIOLOGY NEWS (ISSN 1544-8800) *is published monthly by Elsevier Inc., 60 Columbia Rd., Bldg. B, 2nd flr., Morristown, NJ 07960, 973-290-8200, fax 973-290-8250. Subscription price is $114.00 per year.*



ELSEVIER INTERNATIONAL MEDICAL NEWS GROUP BPA WORLDWIDE

## VITAL SIGNS

**Cost Increases for Average Hospitalization, 2000-2008**




Note: Based on inflation-adjusted data from the Nationwide Inpatient Sample.
Source: Agency for Healthcare Research and Quality