Proposed ICD Guidelines Emphasize Transparency

Physicians of patients with implanted heart devices are asked to beef up their surveillance procedures.

BY KATE JOHNSON
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BOSTON — Although industry officials appeared to embrace proposed guidelines from the Heart Rhythm Society aimed at improving postmarket surveillance and the performance of implantable heart devices, the reaction of the Food and Drug Administration was more guarded during a Town Hall Meeting hosted by the society at its annual meeting.

"I was not particularly encouraged by the FDA's comments," remarked Dr. Robert G. Hauser, a member of the Heart Rhythm Society (HRS) task force that drafted the proposed guidelines, and a senior consultant cardiologist at the Minneapolis Heart Institute.

The guideline's intent is to improve both the detection of device malfunctions and the communication of their clinical significance to physicians and patients. The guidelines were released in April; the society plans to publish the final recommendations in October.

Broadly speaking, the guidelines advocate improved transparency in the industry's postmarket monitoring and reporting of device malfunctions in pacemakers and implantable cardioverter defibrillators (ICDs) and their components; the establishment of new systems to identify malfunctioning devices more quickly; and a standard process of notification and communication from manufacturers to patients and physicians in the event of device malfunction.

More specifically, HRS recommends that the industry and the FDA abandon the term "recall"—replacing it with "advisory"—because it is misleading and can cause undue alarm in patients. "It frightens patients, and it is inaccurate," said Dr. Hauser in an interview. "Until they get in to see the physician, they are under the impression that they have to have their device removed and returned to the manufacturer."

But the suggestion met with FDA resistance. "Recall nomenclature is deeply embedded in FDA regulations and operations and cannot be changed quickly," said the FDA's Dr. Bram D. Zuckerman, director of the division of cardiovascular devices in the Center for Devices and Radiological Health.

HRS recommends abandoning the term 'recall,' which is misleading and can cause undue alarm in patients, and using 'advisory' instead.

"They're reluctant because this terminology applies to all the medical devices they oversee," Dr. Leslie A. Saxon, professor of medicine at University of Southern California, Los Angeles, said in an interview. But with roughly 200,000 ICDs falling under the "recall" terminology in the past 12-18 months, and driving an arguably inflated 20% explantation rate, the terminology deserves reconsideration.

For physicians, the guidelines suggest informing patients not only of device therapy's benefits and risks, but also about device and component performance and expected malfunction rates both at initial implantation and replacement.

Furthermore, physicians should consider, when appropriate, alternatives to device explantation, such as reprogramming or enhanced monitoring.

Physicians are also encouraged to enhance surveillance by obtaining patient or family consent for the return of all devices to the manufacturer after explantation—even when malfunction is not suspected—or, when this is not possible, to attempt postmortem device interrogation. The society also noted that physicians should be adequately compensated for their time and effort in the postmortem evaluation and reporting process, and that CPT codes should be set for these activities.

For manufacturers, the society recommended they set standards for device and component performance, and provide regular, unbiased reports on malfunction rates for each device in a user-friendly format that is easily accessible by physicians, health care givers, and patients.

The HRS recommendations also call for an independent advisory committee for industry, made up of medical experts in the field. Such a committee would meet regularly but also in response to specific malfunction reports, and would advise the industry on how to inform physicians and the public.

Manufacturers should communicate the committee findings on malfunctions and performance first to physicians and then directly to patients by using standard communication forms, said the HRS recommendation.

Direct communication to patients is a controversial idea, acknowledged Dr. Saxon, but it fits with the times. "It's an information age. People want to know and I don't blame them."

Timothy S. Samsel, vice president of regulatory affairs for Medtronic Inc., said companies support the notion of an independent advisory panel but acknowledged that the panel's independence could be questioned because panelists would be compensated, would be asked to sign a contract of confidentiality, and could potentially have their advice ignored by the company.

"I think that would be a rare event," commented Dr. Hauser. "If a group of experts makes a recommendation and the company decides to ignore it, they would be going down a separate path—and I don't think you would see that kind of thing happening."

The FDA's Dr. Zuckerman says his agency has already begun to establish a postmarket advisory panel and has appointed Dr. William H. Maisel of Beth Israel Deaconess Medical Center, Boston, as chairman.

HRS also recommended that the FDA enhance its Manufacturer and User Facility Device Experience (MAUDE) database by devising a form that would allow for specific reporting on ICD/pacemaker events. ■

The proposed guidelines are available at www.hrsonline.org. Renée Matthews, associate editor, contributed to this report.

Malfunction Rates Rising in ICDs, Falling in Pacemakers

BY ROBERT FINN
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In recent years, the rate of pacemaker malfunctions has decreased while the rate of implantable cardioverter defibrillator malfunctions has increased dramatically, according to an analysis by Dr. William H. Maisel and a group of investigators from the Food and Drug Administration.

Using data that device manufacturers are required to report to the FDA, the investigators were able to determine that from 1990 to 2002, 2.25 million pacemakers and 416,000 implantable cardioverter-defibrillators (ICDs) were implanted in the United States. During that same period, 8,834 pacemakers and 8,489 ICDs were explanted because of confirmed malfunctions (JAMA 2006;295:1901-6).

The annual rate of malfunctioning devices ranged from 1.4 to 9/1,000 implants for pacemakers and from 7.9 to 38.6/1,000 implants for ICDs. Overall, the ICD malfunction replacement rate was significantly higher than the pacemaker malfunction replacement rate.

The annual pacemaker malfunction replacement rate waned significantly during the years covered by the study. During the final year of the study the pacemaker malfunction replacement rate was 1.4/1,000 devices, the lowest rate of any year in the study.

In contrast, the ICD malfunction replacement rate trended down during the first half of the study, reaching its nadir between 1994 and 1998, but then the rate increased markedly from 1999 through 2001 before falling somewhat in 2002. The ICD malfunction replacement rate for the final 3 years of the study was 26.8/1,000 implants, a statistically significant increase of more than 3 times the ICD malfunction replacement rate for the mid-1990s and more than 10 times the rate of pacemaker malfunctions during that same period.

Device malfunction was directly responsible for deaths in 30 pacemaker patients and 31 ICD patients. Malfunctions of pacemakers and ICDs were equally likely to result in death, but patients with ICDs were 5.6 times more likely to die of device malfunction because of the smaller number of ICD patients.

Hardware malfunctions were by far the most common type of malfunction in both pacemakers and ICDs, comprising 80% of the total. Integral device software or "firmware" was the cause of malfunction 4% of the time; miscellaneous malfunctions including physical damage, foreign material contamination, manufacturing errors, and so on caused 12% of malfunctions; and the manufacturers were unable to determine the cause of the malfunction in 5% of the cases.

Battery/capacitor abnormalities together with electrical issues accounted for more than half the hardware problems in both pacemakers and ICDs. Battery/capacitor abnormalities and charge-circuit abnormalities each accounted for a significantly higher percentage of malfunctions in ICDs than pacemakers. On the other hand, hermetic-seal abnormalities affected a much greater proportion of pacemakers than of ICDs. In absolute numbers, hermetic-seal abnormalities were responsible for 1,082 pacemaker malfunctions and only a single ICD malfunction. This was due primarily to a single manufacturer's repeated problems in multiple pacemaker models in the early 1990s.

The estimates of malfunction numbers and rates included in the study are likely to be underestimates of the true rates. Any devices that were not explanted, not returned to the manufacturer, or found by the manufacturer to be working normally were not counted as malfunctioning. Furthermore, the investigators excluded biventricular pacemakers and ICDs from the analysis because relatively few of those devices were implanted during the study period.

But the biggest source of uncounted malfunctions probably came about because of the investigators' exclusion of malfunctions that involved pacemaker or ICD leads.

In an accompanying editorial, Dr. Bruce L. Wilkoff of Case Western Reserve University, Cleveland, noted that the device, its leads, the chosen programmed parameters, and the patient's response are all interdependent (JAMA 2006;295:1944-6). The malfunction rate of this entire system is probably the most important measure of reliability, he wrote, "but it is also the most elusive because no single measure captures all elements in a verifiable fashion."

He acknowledged that lead dysfunction can be related to design issues, implantation technique, the patient's activities, and the patient's anatomy and physiology, and that lead malfunctions were appropriately excluded from the analysis. ■

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