LETTERS

Guidance for ICD Replacement

Dr. Sidney Goldstein points out that recalls of implantable cardioverter defibrillators can have a chilling effect on prophylactic ICD implantations, and have heightened the need for better risk stratification to select patients likely to benefit from ICD prophylaxis ("When Is a Recall Not a Recall?" Heart of the Matter, November 2006, p. 2).

In the pivotal Sudden Cardiac Death in Heart Failure Trial (SCDHeft), fewer than 10% of patients receiving prophylactic ICDs had a mortality benefit during a 5-year follow-up.

We proposed a four-step algorithm for determining which patients with a recalled ICD should have their prophylactic ICD system revised or replaced (Am. J. Cardiol. 2006;98:1291-93), using the following questions:

1. Is the patient too sick to have his ICD system revised?
2. Has a sustained ventricular tachyarrhythmia occurred since implant?
3. Is the left ventricular ejection fraction still less than 0.36?
4. Is the microvolt T-wave alternans test abnormal?

This same four-step method should help to select patients for ICD prophylaxis as well. Recently, the ABCD trial proposed a combination of MTWA and electrophysiologic studies to select patients for ICD prophylaxis (Circulation 2006;114:2426 [abstr]). These approaches promise to improve selection of patients for ICD prophylaxis and management of patients facing ICD recalls.

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No Standardization Without Investment

The current situation with electronic health records reminds us of the state of affairs at the beginning of the automobile industry when several dozen brands competed for market share. Only a few were left standing by the 1940s ("Panel Certifies First 22 Ambulatory EHR Products," September 2006, p. 21).

I will not invest in an EHR product that has not been standardized. But standardization would require a large up-front investment for which no third-party payer is willing to pick up the tab. I already capture all of my revenues with custom-made paper progress notes and by keeping up to date with billing issues.

Ely Robert Tandeter, M.D.
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President's Veto Will Cost Lives

President Bush's recent veto of federal funding for embryonic stem cell research is dismaying but not surprising, considering the continual pandering among Republicans to the Religious Right ("Disappointment Follows Bush's Veto of Stem Cell Research Bill," September 2006, p. 22).

For Bush to use the first veto of his presidency to prevent federal research on a technology that may hold the best promise in fighting disease is the sacrifice of actual human lives to discarded clumps of cells. The only opposition to this funding is religiously based and therefore should have no place in our governmental decision-making process. Physicians must not sit in silence, and they must not allow "snowflake" children and other techniques reminiscent of anti-abortion activists to rattle their determination.

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LETTERS

Letters in response to articles in CARDIOLOGY NEWS and its supplements should include your name and address, affiliation, and conflicts of interest in regard to the topic discussed. Letters may be edited for space and clarity.

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POLICY & PRACTICE

Surprise! DES Suits Filed

It didn't take long—the nation's plaintiffs' attorneys have begun recruiting clients who allegedly were harmed by a drug-eluting stent. One suit, filed in Palm Beach, Fla., County Circuit Court, claims that Johnson & Johnson's Cordis unit failed to warn that its Cypher stent might be associated with a higher risk of clotting, heart attack, and death. The plaintiff, 46-year-old Sean O'Shea, said that he began having chest pains after he stopped taking clopidogrel (Plavix), which he'd taken after two procedures in 2005 in which he received five stents. Mr. O'Shea's attorneys, Babbitt, Johnson, Osborne, and LeClainche of West Palm Beach, allege that he suffers permanent disability, mostly from bleeding related to his now-resumed Plavix regimen. Plaintiffs' attorney firms have set up Web sites to recruit patients, including Pulaski & Middleman's www.drugcoatedstentattorney.com and O'Steen & Harrison's http://taxus.vanosteen.com. In a statement, Boston Scientific's senior vice president for corporate communications, Paul Donovan, said of the suit against his company, "We don't believe there is any basis for the claims that are being made in this litigation, and we think the case is without merit."

Generic Plavix Blocked Again

The reintroduction of a generic version of Plavix just got pushed further off into the future. The U.S. Court of Appeals for the Federal Circuit in Washington ruled last month that generic sales should be halted until the Plavix patent can be validated. The ruling was the latest in an ongoing battle among generic maker Apotex Inc. and the two companies that make and sell Plavix, Sanofi-Aventis and Bristol-Myers Squibb, which allege patent infringement by Apotex. In late August, the U.S. District Court for the Southern District of New York ruled in favor of the brand name companies and granted a preliminary injunction against sales of the generic, which had been on the market a few weeks. Apotex did not have to recall product already in distribution. The generic had made a significant dent in Plavix sales, pegged at $6.3 billion worldwide in 2005.

New Code for Plaque Test

The American Medical Association has issued a unique category I CPT code for a diagnostic that measures lipoprotein-associated phospholipase A2. That inflammatory enzyme is found in unstable, rupture-prone plaque. The only Food and Drug Administration–approved test is made and sold by diaDexus of South San Francisco. The company said the code—83698—was issued under the pathology and laboratory section of the CPT I schedule. The Centers for Medicare and Medicaid Services is recommending a payment of $47.43 for the blood test, effective January 1, 2007.

ACC-MedAxiom Alliance

The American College of Cardiology is joining forces with the quality improvement consulting company MedAxiom. ACC will promote MedAxiom's programs to its members, and MedAxiom will do likewise to its client base. Through March 2007, MedAxiom is offering ACC members a 10% discount on subscriptions to its services, which include statistical analyses and benchmark reporting systems, workflow and process redesign, and strategic planning. The two organizations also are developing a leadership institute, which they expect to launch in 2007, according to the ACC.

Von Eschenbach Confirmed for FDA

Almost 9 months after he was first nominated to be commissioner of the FDA, Dr. Andrew von Eschenbach was finally confirmed by the Senate by an 80-11 vote in the wee hours of the 109th Congress. Confirmation came after an 89-6 vote to limit debate on his nomination. The naysayers included Sen. Chuck Grassley (R-Iowa), who voted against invoking cloture and against confirmation. Sen. Grassley has been one of Dr. von Eschenbach's most vocal critics. As chairman of the Finance Committee, he and his staff have been investigating what they call an inappropriate approval of the antibiotic Ketek (telithromycin). Sen. Grassley maintains that Dr. von Eschenbach has stonewalled committee investigators, and in an agitated floor statement during the nomination vote, he accused the nominee of hiding documents and intimidating FDA employees who dissented. With Democrats taking control of Congress, Sen. Grassley will lose his Finance Committee chairmanship. But he warned his colleagues across the aisle that Dr. von Eschenbach was a prime illustration of concerns about the lack of Senate oversight of the Bush administration. "I believe we need to send a message to the executive branch that it's not okay to impede congressional investigations. It's not okay to limit the Senate's access to documents, information, and employees of the executive branch," the senator said.

Poll: No Off-Label Use

About half of Americans said physicians should not be allowed to prescribe pharmaceuticals for unapproved uses, according to a recent WSJ.com/Harris Interactive poll. About half of those polled—approximately 3,000 adults in November—were not even aware that the FDA allowed off-label prescribing. But, 48% said it should not be allowed; 27% said it was fine, and 24% were not sure. A majority (69%) said drug companies should not be allowed to promote off-label uses, while only 12% said this was permissible. Sixty-two percent said they strongly agreed with the statement that prescription drug use for unapproved indications should be prohibited except in a clinical study.

—Alicia Ault

Facial Capture Technology Could Prevent Mistakes

WASHINGTON — Avoiding medical errors may be as easy as snapping a photo.

Researchers with the MedStar Health network here are experimenting with facial-capture software that they say could quickly and inexpensively help busy nurses and physicians avoid mistakes.

The software can pick human faces out of any photo image in less than a second. It's tied into a $120 Web camera mounted behind the nurse's triage desk, and anyone who approaches the desk automatically has his or her face captured. Nurses can permanently tie a patient's face to the corresponding electronic health record with one click.

Nurses "don't have to pick up a camera, they don't have to make them say cheese, they don't have to put them in a special location. All they have to do is click on the patient's face," Dr. Michael Gillam, director of the Medical Media Lab at MedStar, said at the annual symposium of the American Medical Informatics Association.

MedStar researchers already developed a state-of-the art electronic health record system allowing doctors and nurses to view patients' full charts at a glance. The system, known as Axyzzi, was snapped up by Microsoft Corp., in July. Now Dr. Gillam's team is hoping that the facial photo capture system can help avoid errors by capitalizing on humans' natural penchant for recognizing faces. "The problem with a bar code is that it's not human readable," Dr. Gillam said in an interview.

MedStar developers say their software could be used to tack the right face to any medication order, blood product, or device before it goes into a patient.

The Medical Media Lab tested the software prototype and found that it captured the smiling faces of all 22 racially diverse adults who approached a MedStar triage desk. But the system has yet to be put it into practice to see if it really enhances patient safety.

—Todd Zwillich