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HEART BEAT

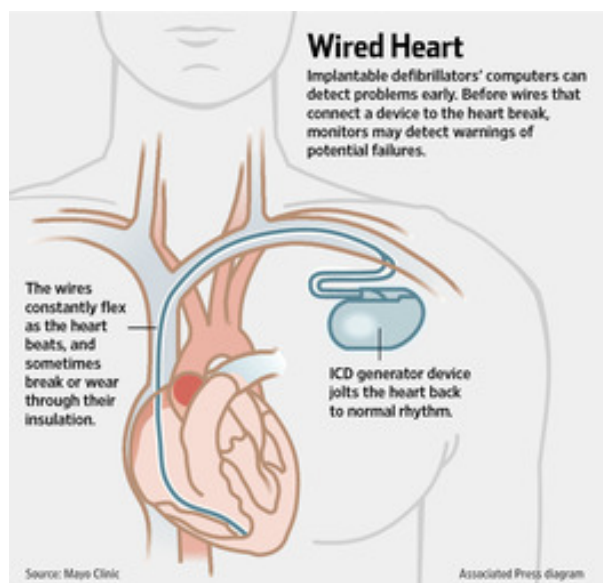
The Dial-Up Heart: Heading Off Device Trouble

By **CHRISTOPHER WEAVER**

June 25, 2012 7:11 p.m. ET

A burst of data relayed wirelessly from a defibrillator to a phone line and on to a website might have saved the life of one of Leslie Saxon's patients this spring.

The Los Angeles heart doctor made sure a tiny radio in the defibrillator was set up to send signals to a Medtronic Inc. website, where she could monitor its electrical performance from the University of Southern California's Keck Hospital, where she is chief of cardiovascular medicine. She took the step because the defibrillator lead—a wire running through the patient's heart—could potentially fail, causing needless shocks or cutting off the device's lifesaving ability to shock the heart back to normal rhythm.



When the system showed electrical "noise" signaling potential problems, Dr. Saxon called in the patient and replaced the wire the next day, before it caused harm. Medtronic says its monitoring system, CareLink, and a related program to detect lead problems, offer early warning of 76% of lead failures before they result in unneeded shocks.

Such systems are available in nearly all of the defibrillators made for the U.S. market by Medtronic, Boston Scientific Corp. and St. Jude Medical Inc.

Nevertheless, device makers and some cardiologists say doctors have been slow to make wireless defibrillator monitoring a cornerstone of their practice. Only half to two-thirds of patients with devices capable of wireless monitoring are enrolled in the systems, company data show.

"It vexes me, because they're techies," said Dr. Saxon of the specialist physicians who have built careers around the latest in medical technology, yet only use the monitors half the time. A USC group she runs, the Center for Body Computing is "trying to convince doctors that it's worth doing."

MORE ON DEFIBRILLATORS

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Medtronic, like other manufacturers, is pushing its sales force to promote wireless monitoring to doctors, said Elizabeth Hoff, general manager of the company's Cardiac Connected Care division. It is also focusing on developing easier-to-use versions for older patients, she says.

The Heart Rhythm Society, which writes heart-device guidelines, suggests doctors use remote monitoring at their own discretion. The group runs educational programs to promote its use and pushed Medicare to pay doctors to use the systems, said Anne Gillis, the society's president and a professor of medicine at the University of Calgary in Canada. The group is waiting to upgrade its recommendations because the technology is advancing so quickly, she said.



Boston Scientific's Incepta implantable defibrillator allows remote monitoring. *BOSTON SCIENTIFIC*

Device failures are rare, but manufacturers have struggled to perfect the complicated implantable defibrillators.

The leads that connect the devices to the heart are widely considered the

systems' weakest link: As the heart pulses, the wires constantly flex, and sometimes break or wear through their insulation. A series of high-profile failures beginning in 2005, with a defibrillator made by Guidant Corp., (now owned by Boston Scientific) have underscored the devices' vulnerabilities. Last year, when St. Jude's Riata defibrillator leads were recalled, the company advised doctors to monitor patients remotely. St. Jude stopped selling the leads, which have been linked to 20 deaths, in 2010.

"We're never going to achieve perfection," said Kenneth Stein, chief medical officer of Boston Scientific's rhythm-management division. But, "whatever we can do to get early warning of device issues, we want to do."

| Wireless Monitoring | | | | |
|---------------------|-----------------------------------|----------------|--------|--|
| COMPANY | DEVICE (RECALL YEAR) | ACTIVE DEVICES | DEATHS | PATIENTS ENROLLED IN REMOTE DEFIBRILLATOR MONITORING |
| St. Jude Medical | Riata lead (2011) | 78,000 | 20 | 55% |
| Medtronic | Sprint Fidelis lead (2007) | 100,000 | 13 | 69% |
| Boston Scientific | Ventak Prizm defibrillator (2005) | 1,500* | 5 | 46% |

Sources: Company reports on select device recalls, WSJ reporting. *World-wide figure, all others U.S.

That makes the slow adoption of monitoring systems a "very frustrating issue for us," Dr. Stein said. "We've got very clear data convincingly showing patients followed on remote monitoring have significantly better outcomes."

About half of Boston Scientific's 260,000 U.S. defibrillators use its system, called Latitude. Medtronic has 306,000 high-voltage heart devices enrolled in its CareLink system, of the 442,000 that are equipped to wirelessly transmit device and medical data to bedside monitors that relay it to doctors. St. Jude's Merlin system monitors 55% of its defibrillator patients.

A 200-patient study published last week in the journal *Circulation* showed heart-failure patients with defibrillators that were monitored remotely made 35% fewer visits to the emergency room than patients not enrolled in monitoring systems. The systems also allow doctors to track indicators, such as heartbeat irregularities, and catch symptoms early.

A large, 2010 study also in *Circulation* showed that remotely monitored defibrillator patients were about 30% more likely to survive over five years than comparable patients who were followed only during office visits. Dr. Saxon contributed to that study, which was funded by Boston Scientific.

Like other companies, Boston Scientific provides the service for no additional charge. Virtually all defibrillators now in use support monitoring, which has been available from Medtronic for a decade and Boston Scientific since 2006. "Aside from actually paying docs to use it, it's hard for us to go any further," Dr. Stein said.

Doctors say the holdup is partly driven by the need to add staff and change workflow to use monitoring effectively. In addition, the devices transmit data over traditional phone lines, which a growing number of people are abandoning. Many patients live in nursing homes or other complexes that only have digital phones and, sometimes, patients fail to plug in the devices. Patients also simply may not be aware that the monitoring option is available.

Westby Fisher, an electrophysiologist at NorthShore University HealthSystem near Chicago, said he provides all his patients with monitoring devices. Only about 60% ever use them, though. "Sometimes, people only have cellphones at home," he says.

The Food and Drug Administration is reviewing a cellular-capable monitoring system from Boston Scientific and approved a preliminary Medtronic cellular device in 2010.

Using the monitoring systems can provide a financial bonus for doctors. Medicare pays doctors an average of \$542.54 a year to use remote monitoring, coupled with a pair of annual, in-person visits, said Jim Collins, the president of billing consultant CardiologyCoder.com. Doctors could expect to earn \$325 on average each year for four traditional, in-office device checks.

Heart clinics are slowly beginning to expand use of the systems. At NYU Langone Medical Center in New York, Larry Chinitz, director of cardiac electrophysiology, said he and his colleagues use monitoring for every new implant, and are adding existing patients.

St. Jude's problems with the Riata device have refocused some doctors on remote monitoring, hastening their uptake, doctors say. All patients with the Riata leads have been enrolled at the University of California-San Francisco Medical Center, said Gregory Marcus, an electrophysiologist there. In at least two cases, the system detected electrical changes alerted doctors to device problems early, he says.

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