US has no good system to track medical implants

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In this undated photo released by ShellyAnn King, King poses with her late husband Michael King. Michael King died in Oct. 2008 when a defective surgical clip failed hours after he donated a kidney to his ailing wife. Doctors didn't know that the manufacturer had issued an urgent recall on the device two years before the surgery. (AP Photo) NO SALES

(AP) -- Three years ago, the maker of a surgical clip called the Hem-o-lok issued an urgent recall notice warning doctors to stop using the fasteners on living kidney donors. It said the clips could dislodge in their bodies, with "serious, even life-threatening consequences."

Not everyone got the message.

Last October, a surgeon in Brooklyn used one of the clips to tie off Michael King's renal artery when he donated a kidney to his ailing wife. Twelve hours later, the clip popped off. King bled to death internally in the hospital as his wife lay helplessly nearby. He was 29.

Experts say such deaths are the result of a major weakness in the nation's system for recalling thousands of medical devices routinely implanted in people's bodies, ranging from screws and plates to artificial knees and hips.

"There is no system for being informed of what the problems are with the products you have in your body. Even your physician may not know," said Terry Fadem, president of the Biomedical Research and Education Foundation in Philadelphia.

Unlike the auto industry, medical equipment makers have no centralized system for tracking products throughout their life span. That means in some instances, manufacturers do not have an easy way of knowing where problematic devices are or which patients got them.

Meanwhile, the number of items implanted in people's bodies is soaring, as is the number of recalls. Nearly 2,500 medical devices were recalled for potential safety problems in fiscal 2008, according to the Food and Drug Administration. That was nearly double the number reported the previous year and a 164 percent increase since 2000.

In 2006 alone, surgeons implanted a million hip and knee replacements, according to the American Academy of Orthopaedic Surgeons. That number is expected to quadruple by 2030.

Fadem's foundation and other groups have been pushing for years for

better tracking of devices, hoping to create something like the patient registries used in Sweden, England and Australia to keep tabs on artificial joints.

Health care reform legislation being considered in Congress includes a proposal to set up the nation's first comprehensive medical device registry. Doctors say its primary use would be to uncover safety problems, but it could also be used to locate patients quickly during a recall.

The FDA currently requires comprehensive tracking of only 14 types of devices, including pacemakers, mechanical heart valves and breast implants. The agency says it is working toward better registration and tracking of other devices.

Manufacturers trace many other medical products only as far as the distributor. Finding them again is not always easy, particularly after they have been implanted into someone's body. Hospitals record the model and lot numbers of implants, but that information is often buried deep in billing records or operating-room log books.

Manufacturers send out thousands of letters announcing recalls, and the FDA puts the information on the Web, but the warnings sometimes go unnoticed.

More than 1,000 such recall notices were sent out in the first seven months of 2009 involving devices such as tracheal tubes, catheters, pacemakers, prosthetic hips, screws, pain pumps and pieces of artificial spine. More than 100 were ranked as "Class 1" recalls by the FDA, which involve a defect serious enough to create a "reasonable probability of adverse health consequences or death."

"Trying to get all that product out of the market is a real effort," said

Tim Ulatowski, director of compliance for the FDA's Center for Devices and Radiological Health.

Dr. Bruce Moskowitz, chairman of the research foundation and an internist in Palm Beach, Fla., said he got a recall notice in February warning about external defibrillators, the paddles doctors use to shock a heart that has stopped beating. The defibrillators had a remote chance of blowing a fuse, delivering a low shock or shutting down in the cold.

The letter included a list of thousands of serial numbers, each representing a flawed device, but no information on who might have bought them or where.

"I couldn't do anything with it," he said. "So they are still out there."

Another patient, Richard Stone, 49, of Palm Beach, Fla., languished for months with undiagnosed pain in his artificial hip before doctors discovered that a piece of metal on the prosthetic had snapped and was scraping out the inside of his femur.

"I couldn't move at all," he said. "Even when I would move an inch, it would send a shock through my entire body."

Doctors later realized that that several batches of the same hip system - though not the one in Stone's body - had been recalled eight months earlier because of similar reports of breakage.

Stone said that if a registry had been in place, the problem might have been diagnosed sooner, saving him nine months of excruciating pain. He is now suing the manufacturer of the hip and a Florida pain clinic that treated him.

A lawyer for the King family, Jeff Korek, said that in Michael King's

case, the hospital had received a registered letter about the Hem-o-lok recall from the manufacturer, Teleflex Inc. He said it was unclear why the alert was not acted upon. The family is suing the hospital, SUNY Downstate Medical Center and the surgeon.

Teleflex Medical said in a statement that it complied with all FDA regulations by notifying medical centers in writing that the clip, while fine for other types of surgery, should not be used to tie off the renal artery on living kidney donors.

Some potential solutions are in the works.

The FDA has been laying the groundwork for a registry of patients with artificial joints, which are more prone to breakage than other types of implants and are also experiencing a huge surge in use. The agency is also working on a system that would make tracking easier by associating each medical device with a unique ID number.

Thomas Gross, director of post-market surveillance for the FDA's Center for Devices, said the agency has been in talks with the industry on both projects for more than a year and is making progress.

He said the issue has gained "momentum" both in the agency and the industry, and that the FDA's new commissioner, Margaret Hamburg, is "putting a priority on post-market safety."

Jeff Secunda, a vice president of regulatory affairs at AdvaMed, an association that represents medical device companies, said the new ID system being developed by the FDA could be "the answer to everyone's problem" if combined with better electronic health records.

AdvaMed has been more critical of the proposal for a national medical device registry, saying it would be too costly and require doctors to

gather information on products unlikely to pose a safety hazard.

Secunda said incidents in which patients have been hurt because of difficulty with a recall are extremely rare.

Yet mistakes do happen.

Premier Inc., an alliance of 2,200 U.S. hospitals, said it examined one recent recall and found that even after a device with a potentially dangerous flaw was pulled from the market, doctors at more than 40 hospitals implanted it in at least 50 patients.

"This is not just an issue in the United States. This is an issue across the globe," said the group's chief information officer, Joe Pleasant.

Not content to wait for government action, some medical organizations have been trying to develop tracking programs on their own.

The Kaiser Permanente health system in California has a registry keeping tabs on 75,000 artificial joints. It also gives doctors valuable information on how often they break down.

"Within 24 hours, we get a printout, by patient and by doctor, of who has those implants," said Dr. Thomas Barber, an orthopedic surgeon, associate physician in chief of the Oakland Medical Center and a board member at the American Academy of Orthopaedic Surgeons.

Without that system, he said, hospitals can have a much tougher time. Many, he said, still keep track of implants using a system involving stickers, provided by the manufacturers, pasted into the pages of operating room log books.

"When there is a recall, hospitals have to manually go through the

implant log by hand," he said.

The American Academy of Orthopaedic Surgeons established a nonprofit organization in June with the goal of building a national joint implant registry similar to the Kaiser Permanente system.

The research foundation in Philadelphia launched a device registry last spring geared toward patients. Any person can sign up for free to automatically get e-mails about potential safety issues with their implant.

For King's still-distraught widow, ShellyAnn King, any reforms will come too late.

The 31-year-old New Yorker had wanted a new kidney so she could get off dialysis and eventually have a baby with her husband.

Thanks to her husband's sacrifice, she is healthy now, but she said every day is "torment and torture."

"I don't want any family to go through what we're going through," she said. "I don't want another husband or wife to feel this unnecessary grief. It should have been prevented."