PATIENT SAFETY BLOG

PATRICK MALONE & ASSOCIATES, P.C.
From Tragedy To Justice - Attorneys For The Injured

Toll Free: 888.625.6635
(888.MaloneLaw)
Local: 202.742.1500

A Higher Gear for Medical Device Followup

February 29, 2012 by Patrick A. Malone

When Congress authorized creation of the Sentinel Initiative in 2007, it was concrete acknowledgment that the failure to follow up on the performance of medical devices recently approved by the FDA was compromising patient safety.

Five years later, medical device followup is still a work in progress, and there's no reason it can't be moving along at a friskier pace. In a commentary published in the New England Journal of Medicine, Dr. Robert G. Hauser submits that "patients in the United States continue to be exposed to underperforming and potentially hazardous medical devices after they have been approved by the Food and Drug Administration … despite multiple recalls and some tragic adverse events."

He cites one particular case involving an implantable cardioverter-debrillator (ICD) that has been implanted in 79,000 heart patients in the U.S. alone. ICDs are used to treat sudden cardiac arrest with a shock, or electrical impulse, via a small device implanted near the heart. But it's hardly the only "livesaving" device that can put life at risk.

Hauser names two other ICD components used by more than 350,000 patients that might cause problems that, with a bit of foresight, could be consigned to irrelevance. He asks: "Why are we placing patients at risk when the tools and technology are available to monitor vital medical devices such as ICDs, heart valves and coronary stents?

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

The problem is that our current passive postmarketing surveillance system fails to detect significant device defects before large patient populations have been exposed. Consequently, we repeatedly find ourselves reacting ineffectively, even dangerously, to big problems with devices by subjecting patients to care strategies that are not supported by solid clinical evidence."

We need to collect more data, he says, in order to: **1.** identify adverse events even if they're infrequent and; **2.** review information as it pertains to certain patient groups.

That means using existing clinical registries and remote monitoring databases to improve surveillance of medical devices. Data should be collected on an ongoing basis, and compared with established medical products that have been shown to be reliable. The point is to detect problems early and collect information to guide patient care toward best practice. "[M]anufacturers," Hauser writes, "should conduct postmarketing studies of this type for marketed … devices that sustain or support life."

Seems like a no-brainer, as the creation of the Sentinel Initiatives reflects. It's supposed to augment the current after-the-fact process of reporting adverse events by implementing a real-time network that's faster and more efficient, and capable of spreading the word to health-care providers and the public.

The Sentinel Initiative's ambitious reach is to collect electronic health data from 100 million people by the end of this year. The initiative must set priorities, develop tools to analyze the data and design a public-alert procedure when a safety signal is detected. Hauser says we're years away from a fully operational Sentinel network.

More than 150,000 U.S. patients rely on lifesaving medical devices, Hauser says, and he wants professional organizations, the medical device industry and the FDA to muster the resources *now* to improve their surveillance once they're on the market. We'd add that a rising chorus of patient voices could boost this sense of urgency.

If you think tracking the usefulness and safety of medical devices long after their hosts have been released from the hospital isn't happening fast enough, make your feelings known to your congressional representatives and to the FDA by linking here.

If you're interested in the specific projects being reviewed by the Sentinel Initiative at any given time, link here.

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