Information Edge: The missing link?  
Using EHRs to extract data on adverse drug events

During the opening reception at the National Patient Safety Foundation’s annual conference in San Francisco last May, patient-safety pioneer Lucian Leape was holding court and talking about how electronic health records could be used to automatically capture data on any adverse reactions or side effects of new drugs on the market.

If such a system were in place, the Harvard University adjunct professor of health policy said, information that now takes years to gather could be collected in a matter of months. Other experts also see the potential of using EHRs for post-market drug safety surveillance. “This has been one of the big missing links in the patient-safety movement, and it could prevent a lot of harm and a lot of costs,” says Michael Cohen, president of the Institute for Safe Medication Practices.

“That was always part of the vision of having a fully integrated electronic health record—you suddenly have access to this information in close to real time,” says Kenneth Kizer, a physician who is chairman of the board and chief executive officer of Medsphere Systems Corp., a clinical information systems developer. Kizer is also former president and CEO of the National Quality Forum, a not-for-profit standards consensus development organization. “Drug reactions are the most common untoward event that happens in healthcare and, while a significant amount are because of errors,” they also can occur via adverse reactions or side effects, he says.

As undersecretary for health in the Veterans Affairs Department from 1994 to 1999, Kizer promoted using health IT to improve quality and safety. Building a national health information network would not be necessary to conduct the needed surveillance, Kizer says. Instead, he says an effective sentinel network could be created by linking the Veterans Health Administration with about six of the largest health systems that use IT extensively. “Just think of the data you could accrue in a short period of time,” Kizer says.

While the VA conducts its own adverse drug event surveillance, the Food and Drug Administration’s MedWatch program, established in 1993, is the federal government’s main post-market drug safety effort. MedWatch, a repository of voluntary reports on adverse drug events, has long been criticized for its ineffectiveness. “It’s better than nothing, but I think most people view it as anemic,” Kizer says. “Certainly, the completeness of reporting leaves a lot to be desired. You’re basically waiting for something to come across the transom.”

Landen Bain, the healthcare liaison for the Austin, Texas-based Clinical Data Interchange Standards Consortium, or CDISC, went further and called it “abysmal,” and says the MedWatch adverse drug event reporting form is so cumbersome that “I wouldn’t fill it out at gunpoint.”

In addition to the troubles of getting information into the system, it’s also tough to get anything out of it, Cohen says. “When physicians participate in a voluntary effort, they want to get something out of it,” he says. “In order to get information (from MedWatch), you need to file a Freedom of Information Act request, and people just don’t want to do that.” Jonathan Nebeker, associate director of the Informatics, Decision Enhancement and Surveillance Center at the VA Medical Center in Salt Lake City, notes that the drug
companies assemble reports for MedWatch, which raises some concern. “A lot of times, it is
easier to report things to industry directly, so industry helps collect information,” he says.
“I’m not saying it’s all bad. It’s just filtered.”
The FDA defends MedWatch, but notes that it has heard the criticism. “We do get 450,000
adverse event reports a year,” says Paul Seligman, FDA associate director for safety policy
and communication. “We’re always cognizant of the fact that it takes pharmacists,
physicians and nurses a moment out of their day to report to us.”
The FDA has scheduled a public meeting for March 7-8 in Rockville, Md., to discuss linking
private and public sector post-market drug surveillance efforts to create an integrated
electronic Sentinel Network. An FDA spokeswoman says the new network would not
replace MedWatch. Instead, she says it would serve as a way to leverage all available
resources toward the goal of improving drug safety.
On Jan. 30, the FDA also announced a series of initiatives to improve its drug and medical-
device safety programs, including working with the VA to improve post-market tracking of
adverse drug events and posting MedWatch findings in an online newsletter (Feb. 5, p. 6).
Others, however, are not waiting. Bain’s organization teamed up with IT vendor Allscripts
Healthcare Solutions and pharmaceutical manufacturer Pfizer on a “retrieve form for data
capture” demonstration project that, if put in place, could make reporting on adverse drug
events much easier.
The demonstration had its “dress rehearsal” last month at the Integrating the Healthcare
Enterprise Connectathon, an event that gets competing IT vendors to work together on
improving the interoperability of their products. The CDISC-Allscripts-Pfizer team will
reassemble in New Orleans for the Interoperability Showcase, which will be part of the
Healthcare Information and Management Systems Society’s annual conference Feb. 25-
March 1.
The concept involves an easily retrievable electronic form that a physician can access, fill
out and send to the FDA or Centers for Disease Control and Prevention. Bain says retrieval
of the form is instantaneous, but the real time savings comes from not having to exit the
EHR a physician might be working on at the time.
“It’s not rocket science—it’s not brilliant or sexy—but I personally feel it could make a great
difference in public safety by making it much easier to report and improve the quality of the
reporting,” says Michael Ibara, Pfizer information resources director. “At HIMSS, it will be
one of the most technologically simple things that will be showed there, but that doesn’t
mean it won’t have a great effect.”

What do you think?
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