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18 May 2011 07:35 EDT **DJ IN THE PIPELINE: US Aims To Plumb Stores Of Health-Care Data**

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Rather than waiting for patients or doctors to report safety problems with drugs or medical devices, the government recently started to mine vast stores of electronic health data on millions of patients for signs of possible trouble.

The Food and Drug Administration's Sentinel Initiative, which went into an active pilot phase within the past year, is one of several nascent efforts by government agencies to use health-insurer and hospital data to spot adverse drug reactions, compare the effectiveness of treatments or improve clinical research methods.

The FDA's Sentinel effort focuses on drug and device safety, in keeping with the agency's mission.

"No one has ever done secondary use on this scale before," said Rachel Behrman, director of FDA's Office of Critical Path Programs and the agency executive leading the Sentinel Initiative, an effort required by a 2007 law. By secondary use, she meant the use of data from other sources, such as records related to patient care that are now being used in research on drug safety.

"The methodology is new," she said. "We're inventing it as we go."

Until now, the FDA relied primarily on spontaneous reports in the post-market setting; someone had to let the agency or the manufacturer know if something went wrong with a medication or device, said Behrman.

In a New England Journal of Medicine article early this year, Behrman and colleagues cited examples of the type of data that the FDA would seek through its mini-Sentinel pilot: the frequency of myocardial infarction among those using oral diabetes drugs, and the occurrence of adverse events associated with select, routinely administered vaccines.

Two years ago, the FDA awarded Harvard Pilgrim Health Care Institute a contract to lead development of the Sentinel system. After spending a year working on privacy and security issues, the agency launched mini-Sentinel, which has started monitoring data.

"It's actually an up-and-running, active surveillance program in which we are starting to query the entities we call data partners," Behrman said in an interview. FDA's mini-Sentinel already has access to data covering nearly 70 million individuals, and should surpass the 100 million that it's required to reach by 2012, she said.

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Those developing Sentinel, a "distributed" data network, say patient information stays with the insurers or other organizations, behind firewalls. Government researchers make specific queries and generally don't have direct access to information that would identify individuals. The health plan or other partner maintains control of the information and will conduct an analysis based on its aggregated data, then transmit the result to an FDA Sentinel data coordinating center.

"Sentinel is one more tool in the toolbox," along with spontaneous reports and post-market clinical trials, said Behrman, explaining that mini-Sentinel itself won't provide a definitive yes or no answer on the safety of a product. Researchers might launch a full epidemiological study to confirm what they think they see on Sentinel, according to Behrman, who wouldn't say if they had spotted any red flags yet via the project.

Organizations working on mini-Sentinel include HealthCore Inc., the health outcomes research subsidiary of giant insurer WellPoint Inc. (WLP); health insurer Cigna Corp. (CI); the University of Miami-Humana Health Services Research Center, affiliated with insurer Humana Inc. (HUM); managed-care industry trade group America's Health Insurance Plans; and several members of the HMO Research Network, a coalition of 16 research-oriented health-care organizations.

Meanwhile, the Department of Health and Human Services recently started work on a newer, complementary pilot project--the Multi Payor Claims Database--aimed at using data from private health insurers and the U.S. Centers for Medicare & Medicaid Services to compare the effectiveness of medical treatments. So-called comparative effectiveness research is a key element of President Obama's health-care agenda, and the claims database project was established as part of the 2009 economic stimulus legislation.

HHS' Multi Payor Claims Database expects to work in a similar fashion to the Sentinel Initiative, and leaders of the projects have been exploring ways the two networks could work together.

"The MPCD builds on the work of the Sentinel Initiative and other distributed network approaches," said Richard Kronick, an HHS deputy assistant secretary, and would allow researchers to better understand the effects of alternative treatment choices on a variety of populations.

UnitedHealth Group Inc.'s (UNH) Ingenix health data business was selected in a competitive bidding process to develop and operate the MCPD. Vendors also include Microsoft Corp.'s (MSFT) Vexcel subsidiary and Thomson Reuters Corp. (TRI), which received contracts to construct pilot versions of the MPCD.

Also, the National Institutes of Health, working with the HMO Research Network, is developing a similar infrastructure, the HMO Collaboratory, which aims to make disease research faster and more efficient through mega-epidemiological studies and clinical trials. The Collaboratory would integrate data from HMOs and possibly other health-care organizations "to enable a range of transformative, transdisciplinary research studies," according to a recent contract bid announcement.
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