More Postmarketing Data To Be Gathered by FDA

BY ALICIA AULT
Associate Editor, Practice Trends

WASHINGTON — Food and Drug Administration officials said they have started several new initiatives in response to the Institute of Medicine's call to upgrade and overhaul its drug safety efforts. The projects, including a pilot project to more closely monitor the postmarketing safety of four new molecular entities and a plan to put more postmarketing data on the agency's Web site, were revealed at a meeting sponsored by the IOM.

In a September 2006 report that lambasted FDA's safety oversight, the IOM called on the agency to issue an interim report on selected drugs' postmarketing safety at least 18 months, and no longer than 5 years, after launch. "I think 5 years is too late to find out what a drug is doing," said Dr. Robert Temple, associate director for medical policy at the FDA.

The FDA's Center for Drug Evaluation and Research (CDER) has begun a pilot project with four new molecular entities to pull together all available data at 1, 2, and 3 years after launch. Officials will look at the Adverse Events Reporting System database, ongoing postmarketing studies, and other data to see how much can be learned about each particular drug at each time point, said Dr. Temple. He would not disclose which drugs are part of the pilot.

The FDA also plans to publish a newsletter on its Web site that will provide up-to-date information on a drug's postmarketing experience, said Dr. Ellis Unger, acting deputy director for science at CDER's Office of Surveillance and Epidemiology.

He promised a full accounting but noted that the agency will not disclose any proprietary information.

The IOM report also urged Congress to give the FDA greater and more precise enforcement powers, partly to compel pharmaceutical manufacturers to fulfill their commitments to gather postmarketing data.

Peter Barton Hutt, a former FDA general counsel, said that most companies comply with FDA requests because "industry is terrified of FDA." Mr. Hutt said FDA had all the enforcement power it needed already. He argued that the agency did, however, need more funding outside of the user fees it collects.

FDA critics have said the agency is unduly beholden to industry because of user fees. Former FDA Deputy Commissioner Mary Pendergast noted that those fees were likely to make up 80% of the agency's drug review and safety budget if Congress did not provide additional money for fiscal 2007.

She also noted that as of fiscal 2006, companies had 1,632 pending postmarketing commitments. The number of studies being requested is on the rise, said Ms. Pendergast, noting that the average was 1.5 per approved drug before 2003 and 5 per approved drug in 2003-2004. In the most recent report to Congress (fiscal 2006), 63% of those studies had not been started, she said. ■

Facial Capture Emerging as Patient Safety Technology

BY TODD ZWILLICH
Contributing Writer

WASHINGTON — Electronic bar codes and radiofrequency microchips are all the rage in medical error prevention, but one research team thinks avoiding mistakes may be as easy as snapping a photo.

Researchers with the MedStar Health network here are experimenting with facial-capture software that they say could quickly and inexpensively help busy nurses and physicians avoid mistakes.

The software can pick human faces out of any photo image in less than a second. It's tied into a $120 Web camera mounted behind the nurse's triage desk, and anyone who approaches the desk automatically has his or her face captured. Nurses can permanently tie a patient's face to the corresponding electronic health record with one click.

Nurses "don't have to pick up a camera, they don't have to make them say cheese, they don't have to put them in a special location. All they have to do is click on the patient's face," Dr. Michael Gillam, director of the Medical Media Lab at MedStar, said at the annual symposium of the American Medical Informatics Association.

MedStar researchers already developed a state-of-the art electronic health record system allowing doctors and nurses to view patients' full charts at a glance. The system, known as Axyzzi, was snapped up by Microsoft Corp. last July.

Now Dr. Gillam's team is hoping that the facial photo capture system can help avoid errors by capitalizing on humans' natural penchant for recognizing faces. "The problem with a bar code is that it's not human readable," Dr. Gillam said in an interview.

MedStar developers say their software could be used to tack the right face to any medication order, blood product, or device before it goes into a patient.

"Anyone can look and see that that blood doesn't match, because that's not the right person," Dr. Gillam said.

The Medical Media Lab tested the software prototype and found that it captured the faces of all 22 racially diverse adults who approached a MedStar triage desk. But the system has yet to be put it into practice to see if it really enhances patient safety.

Dr. Gillam said the automatic system could be especially useful in overwhelmed emergency departments. "Suddenly 30 patients show up ... at one time from a bus accident. You can imagine trying to take each picture," he said.

But as with most identity technology, privacy is a concern. After all, no one wants to have his or her face on permanent file simply for asking directions to the restroom. Dr. Gillam said that although the system would photograph all comers, images are quickly erased if nurses don't attach them to a medical record. ■

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