

## PROFESSION

### IOM calls for monitoring and probe of health IT hazards

EMRs and other computerized medical systems can harm patients, a report says. If a voluntary approach fails, the FDA should regulate.

By **KEVIN B. O'REILLY**, *amednews* staff. *Posted Nov. 21, 2011.*

An independent federal body should be formed to investigate patient deaths and other adverse events related to health information technology, according to an Institute of Medicine report released in November.

Also, the federal government should work with health information technology vendors to reduce patient safety problems associated with electronic systems and mandate reporting of health IT-related adverse events, the panel said.

Poorly designed or poorly implemented health IT systems can endanger patients or worsen care quality, yet it is unclear from the medical literature how big the problem is, the IOM report said.

The panel said the Dept. of Health and Human Services should develop a plan to work with the health IT industry and monitor for safety problems. HHS Secretary Kathleen Sebelius should report annually on progress, the IOM said, but if the rate of adverse events persists or worsens, the Food and Drug Administration should "exercise all available authority to regulate" electronic medical records, health information exchanges and personal health records.

The proposals come as the federal government has committed \$30 billion to help hospitals and physicians computerize medical practices. About 40% of physician practices use electronic medical records systems, according to an Oct. 24 survey released by the physician profiling firm SK&A. The Joint Commission issued a sentinel-event alert in December 2008 that noted reports of serious adverse events related to health IT and cited research showing that 10% of harmful medication errors are related to technology failures.

The IOM committee faced a challenge in trying to strike a balance between allowing technological innovation and taking swifter action to protect patients, said panel member John R. Lumpkin, MD, MPH.

"At one point it seemed pretty safe to say that 640 [kilobytes] was a good upper limit for a computer's memory," said Dr. Lumpkin, senior vice president and director of the health care group at the nonprofit Robert Wood Johnson Foundation. "As things grew, we realized we needed better standards. You want to begin to make the changes and implement the kinds of things to enhance the systems after you have had enough time for experience and innovation. There is a balance between encouraging safety and setting standards that could stifle innovation."

Not everyone on the panel agreed with delaying FDA regulation. Committee member Richard I. Cook, MD, filed a dissent in the report in which he recommended that health IT systems be regulated as class III medical devices.

"It is quite remarkable that we're in this situation," said Dr. Cook, associate professor of anesthesia and critical care at the University of Chicago Pritzker School of Medicine. "It's not surprising that such adverse events are being found related to health IT, and it's not surprising that those promoting these systems have neither looked for them nor anticipated them. To make large-scale investments in these systems and only now be looking at the impact on patient safety borders on recklessness."

Scot M. Silverstein, MD, agreed.

"The bone I have to pick with the IOM report is that the action agenda is weak," said Dr. Silverstein, a consultant in medical informatics at the Drexel University College of Information Science and Technology in Pennsylvania.

It is unethical to expand health IT so dramatically without understanding the precise nature of the risks it poses to patients, Dr. Silverstein said.

### Users faulted

Leaders in the health IT industry also had their share of objections to some of the IOM panel's conclusions.

"We don't think there's a great deal of data to substantiate that there are major safety problems with the majority of electronic health records systems in use today," said Charlie Jarvis, executive committee vice chair of the EHR Assn., a trade group that represents 46 organizations that supply most of the EMR systems implemented in medical practices. "These products are safe, dependable, time-tested and display a lot of the safety features we think are necessary to prevent problems going forward."

Jarvis, also a vice president at the health IT firm NextGen, said vendors and the government should work to help

physicians and other health professional users understand systems, take advantage of their safety features and avoid errors.

The IOM report calls for greater study on how to prevent user errors, calling for "user-centered design." Also, the panel said, HHS should ensure that vendors do not prohibit hospitals and clinics from sharing information with each other -- such as screen shots -- to learn how the systems they are using may lead to patient harm.

In response to the report, HHS National Coordinator for Health IT Farzad Mostishari, MD, noted that a government expert technical panel already is examining how to address adverse events linked to electronic systems. The agency is funding curriculum to help workers who install and maintain health IT systems recognize and act on safety problems. He pledged that his office will work with the FDA and other federal agencies to devise an IT safety monitoring plan within the IOM's one-year time frame.

"More can and should be done to capture safety issues unique to EHRs when and if they arise," Dr. Mostishari said.

---

**ADDITIONAL INFORMATION:****How health IT can go wrong**

When poorly implemented, health information technology can worsen the quality of care. A pediatric intensive care unit in Pittsburgh saw "a significant increase in mortality" after adopting a new computerized physician order entry system, an Institute of Medicine report said. The CPOE adoption in Pittsburgh went badly because:

- Specific order sets designed for critical care were not created.
- Changes in workflow were not sufficiently predicted, resulting in a breakdown of communication between nurses and physicians.
- Orders for patients arriving by critical care transportation could not be written before the patients arrived at the hospital, delaying lifesaving treatments.
- Changes unrelated to the CPOE system were made in the administration and dispensing of medication that further frustrated the clinical staff. For example, the satellite pharmacy serving the neonatal ICU was closed, and medications had to be obtained from the central pharmacy, delaying treatment.
- Emergency prescriptions were required to be preapproved, and all drugs were moved to the central pharmacy.

Source: "Health IT and Patient Safety: Building Safer Systems for Better Care," Institute of Medicine Committee on Patient Safety and Health Information Technology, Nov. 8 ([www.iom.edu/reports/2011/health-it-and-patient-safety-building-safer-systems-for-better-care.aspx](http://www.iom.edu/reports/2011/health-it-and-patient-safety-building-safer-systems-for-better-care.aspx))

**WEBLINK**

"Health IT and Patient Safety: Building Safer Systems for Better Care," Institute of Medicine Committee on Patient Safety and Health Information Technology, Nov. 8 ([www.iom.edu/reports/2011/health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx](http://www.iom.edu/reports/2011/health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx))

"Sentinel Event Alert, Issue 42: Safely implementing health information and converging technologies," Joint Commission, Dec. 11, 2008 ([www.jointcommission.org/sentinel\\_event\\_alert\\_issue\\_42\\_safely\\_implementing\\_health\\_information\\_and\\_converging\\_technologies](http://www.jointcommission.org/sentinel_event_alert_issue_42_safely_implementing_health_information_and_converging_technologies))

Copyright 2011 American Medical Association. All rights reserved.

**RELATED CONTENT**

- » **Why small medical practices lag in EMR adoption** Nov. 7
- » **EMR alerts can signal abnormal tests, but some doctors don't use them** Oct. 19, 2009
- » **Doctors override most e-Rx safety alerts** March 9, 2009
- » **EMRs don't guarantee quality care, a review of 50,000 patient records shows** Aug. 13, 2007