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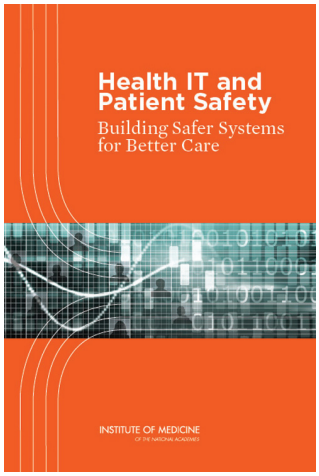
Health IT and Patient Safety

Building Safer Systems for Better Care



In their continuous efforts to improve health care, both the public and private sectors have invested—and continue to invest—heavily in health information technologies, collectively referred to as health IT. When designed and used appropriately, health IT is expected to help improve the performance of health professionals, reduce operational and administrative costs, and enhance patient safety.

However, some products have begun being associated with increased safety risks for patients. The Office of the National Coordinator for Health Information Technology (ONC), the unit within the Department of Health and Human Services (HHS) that is responsible for coordinating the development of a national health IT infrastructure and promoting the use of health IT, asked the Institute of Medicine (IOM) to evaluate safety concerns and to identify actions that both government and the private sector can take to alleviate those actions. The IOM appointed a study committee, which interpreted its charge as recommending ways to make patient care *safer* using health IT so that the nation will be in a better position to realize its potential benefits.

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Critical Knowledge Gaps and Barriers

In its report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, the committee examines the safety of health IT products and their effects on patient safety. Overall, the committee finds the literature about health IT and patient safety to be inconclusive. Some health IT applications are definitively successful at improving medication safety. For example, the number of patients who receive the correct medication in hospitals increases when these

hospitals implement well-planned, robust computerized prescribing mechanisms and use barcoding systems. But even in these instances, the ability to generalize the results across the health care system may be limited. For other products—including electronic health records, which are being employed with greater frequency—some studies find improvements in patient safety, while other studies find no effect.

More worrisome, some case reports suggest that poorly designed health IT can create new hazards in the already complex delivery of care. Although the magnitude of the risk associated with health IT is not known, some examples illustrate the concerns. Dosing errors, failure to detect life-threatening illnesses, and delaying treatment due to poor human–computer interactions or loss of data have led to serious injury and death.

Fostering a Systems Approach

In looking for ways to make health IT–assisted care safer, it is important to recognize that the products are not used in isolation. Rather, they are part of a larger sociotechnical system that also includes people—such as clinicians or patients—organizations, processes, and the external environment (see Figure). Safety emerges from the interactions of these factors. Comprehensive safety analyses, therefore, should not look for a single "root cause" of problems but should consider the system as a whole in looking for ways to reduce the likelihood that any given patient will experience an adverse health event.

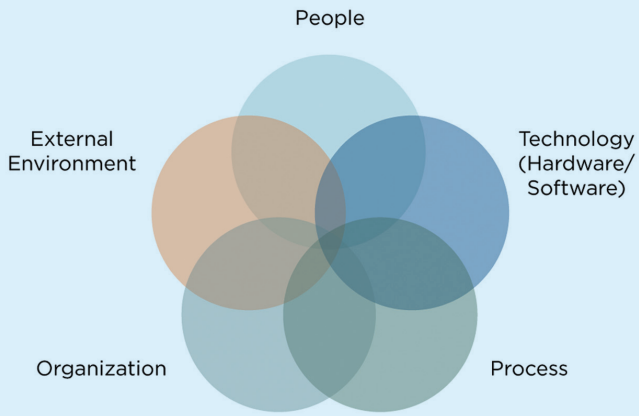
Creating safer systems begins with user-centered design principles and includes adequate testing and quality assurance assessments conducted in actual or simulated clinical environments, or both. Designers and users of health IT should work together to develop, implement, optimize, and maintain health IT products. For most end users, an effective health IT product will provide easy retrieval of accurate, timely, and reliable data; incorporate simple and intuitive data displays; and yield evidence at the point of care to inform decisions. Among other improvements, the product will

- enhance workflow, perhaps by automating mundane tasks or streamlining work, without increasing physical or cognitive workloads;
- allow easy transfer of information to and from other organizations and providers; and
- cause no unanticipated downtime.

Promoting Sharing of Safety Data

While the private sector, including health IT vendors, users, patients, and professional societies,

Figure: Sociotechnical System Underlying Health IT–Related Adverse Events



SOURCE: Adapted from: Harrington et al. (2010), Sittig and Singh (2010), and Walker et al. (2008).

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must play a major role in improving safety, the government can help in various ways. As one step, HHS should ensure that vendors support users in freely exchanging information about health IT experiences and issues, including details relating to patient safety. The ability to generate, develop, and share details of safety risks is essential to a properly functioning market in which health care providers have the ability to choose products that best suit their needs. Currently, many contracts with vendors include clauses that could impede efforts to improve patient safety. For example, nondisclosure clauses can discourage users from sharing information, and limited liability clauses can essentially shift liability from the vendor to the users when an adverse event occurs.

The ONC also should work with the private sector to make comparative user experiences publicly available. In other industries, public product reviews allow users to rate their experiences with products and share lessons learned. A consumer guide for health IT safety could help identify safety concerns, increasing system transparency.

Improving Standards, Measures, and Criteria for Safe Use

HHS also should take steps to help improve information gathering and analysis. This includes promoting the development of new measures for reliably assessing the current state of health IT safety and monitoring for improvements. Currently, no entity is developing such measures. To lead, HHS should fund a new Health IT Safety Council, within an existing voluntary consensus standards organization, that would evaluate criteria for judging the safe use of health IT and the use of health IT to enhance safety.

Promoting Transparency and Accountability

In addition, HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions. This effort would supplement current private-sector efforts and help quantify patient safety risks. Reporting should be mandatory for vendors, while reporting by users should be voluntary, confidential, and nonpunitive. Strategies also should be developed to encourage reporting; such efforts might include removing any perceptual, contractual, legal, and logistical barriers to reporting.

While improving reporting of patient safety incidents is critical, it is only one part of a larger solution to maximize the safety of health IT–assisted care. Another part is ensuring the ability to learn from and act on this information. To this end, HHS should recommend that Congress establish an independent federal entity—similar to the National Transportation Safety Board—that would perform the needed analytic and investigative functions in a transparent, nonpunitive manner. The entity would make nonbinding recommendations to the Secretary of HHS, providing

flexibility and allowing HHS, health care organizations, vendors, and external experts to collectively determine the best course forward.

These and other recommendations would comprise the first stage for action, greatly advancing current understanding of the threats to patient safety. However, because the private sector has not taken substantive action on its own, the committee further recommends that HHS monitor and publicly report on the progress of health IT safety annually, beginning in 2012. If progress is not sufficient, HHS should direct the Food and Drug Administration (FDA) to exercise its authority to regulate health IT. To be effective, the FDA will need to commit sufficient resources and add capacity and expertise to carry this out.

Conclusion

To achieve better health care, a robust infrastructure that supports learning and improving the safety of health IT is essential. Proactive steps must be taken to ensure that health IT is developed and implemented with safety as a primary focus. If appropriately implemented, health IT can help improve health care providers' performance, better communication between patients and providers, and enhance patient safety, which ultimately may lead to better care for Americans.

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500 Fifth Street, NW
Washington, DC 20001
TEL 202.334.2352
FAX 202.334.1412

www.iom.edu