Health IT and Patient Safety:

Building Safer Systems for Better Care

November 10, 2011

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the nation / Improving health

Committee membership

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Charge to the committee

- Summarize existing knowledge of the effects of health IT on patient safety
- Make recommendations to HHS regarding specific actions federal agencies should take to maximize the safety of health IT–assisted care
- Make recommendations concerning how private actors can promote the safety of health IT–assisted care, and how the federal government can assist private actors in this regard

Committee process

- 12 month study
- 3 in-person meetings
- 2 public workshops
- Data gathering from the public and vendors
- Extensive literature review
- 9 external reviewers

Key findings

- Health IT can improve patient safety in some areas such as medication safety; however, there are significant gaps in the literature regarding how health IT impacts patient safety overall
- Safer implementation and use begins with viewing health IT as part of a larger sociotechnical system
- All stakeholders need to work together to improve patient safety

Current state of health IT

- Literature has shown that health IT may lead to safer care and/or introduce new safety risks
- Magnitude of harm and impact of health IT on patient safety is not well known because:
  - Heterogeneous nature of health IT products
  - Diverse impact on different clinical environments and workflow
  - Legal barriers and vendor contracts
  - Inadequate and limited evidence in the literature

Safety as a system property

- Safety is a characteristic of a sociotechnical system
- System-level failures occur almost always because of unforeseen combinations of component failures

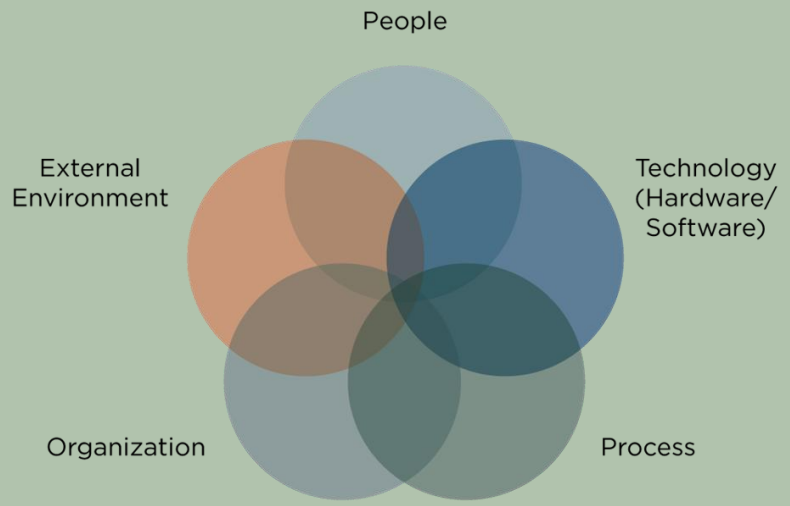

FIGURE 3-1
Sociotechnical system underlying health IT–related adverse events.

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

Features of safer health IT

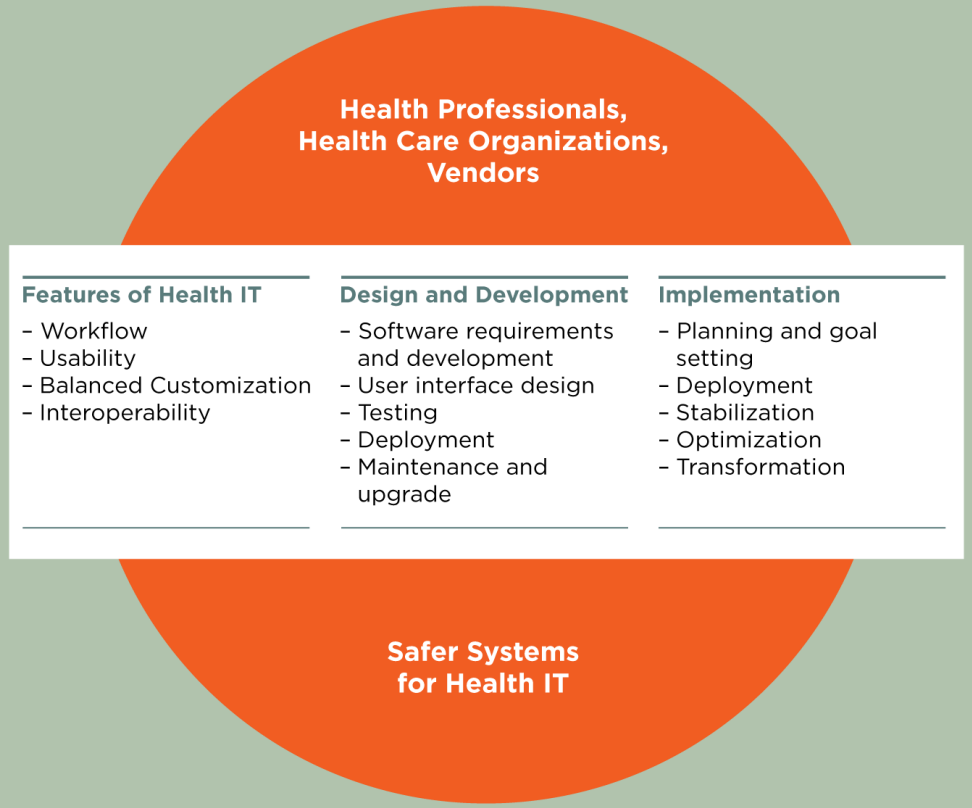

FIGURE 4-1
Interdependent activities for building a safer system for health IT.

Patient engagement tools

- Health IT can lead to safer care by
  - Enabling patients and families to participate in their care
  - Helping patients and families become more knowledgeable about conditions and treatments
  - Improving communication among health care providers, patients, and families
  - Facilitating shared decision making
- However, patient use of health IT adds a layer of complexity to the sociotechnical system

Recommendations: Summary

Current market forces are not adequately addressing the potential risks associated with use of health IT.

All stakeholders must coordinate efforts to identify and understand patient safety risks associated with health IT by:

- Facilitating the free flow of information
- Creating a reporting and investigating system for health IT–related deaths, serious injuries, or unsafe conditions
- Researching and developing standards and criteria for safe design, implementation, and use of health IT

Recommendation 1

The Secretary of Health and Human Services (HHS) should publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use. The plan should specify:

a. The Agency for Healthcare Research and Quality (AHRQ) and the National Library of Medicine (NLM) should expand their funding of research, training, and education of safe practices as appropriate, including measures specifically related to the design, implementation, usability, and safe use of health IT by all users, including patients.

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Recommendation 1 (continued)

b. The Office of the National Coordinator for Health IT (ONC) should expand its funding of processes that promote safety that should be followed in the development of health IT products, including standardized testing procedures to be used by manufacturers and health care organizations to assess the safety of health IT products.

c. ONC and AHRQ should work with health IT vendors and health care organizations to promote post-deployment safety testing of EHRs for high prevalence, high impact EHR-related patient safety risks.

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Recommendation 1 (continued)

d. Health care accrediting organizations should adopt criteria relating to EHR safety.

e. AHRQ should fund the development of new methods for measuring the impact of health IT on safety using data from EHRs.

Recommendation 2

The Secretary of HHS should ensure insofar as possible that health IT vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety.

Recommendation 3

ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.

Recommendation 4

The Secretary of HHS should fund a new Health IT Safety Council to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety. This council should operate within an existing voluntary consensus standards organization.

Recommendation 5

All health IT vendors should be required to publicly register and list their products with ONC, initially beginning with EHRs certified for the meaningful use program.

Recommendation 6

The Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.

Recommendation 7

The Secretary of HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions.

a. Reporting of health IT–related adverse events should be mandatory for vendors.

b. Reporting of health IT–related adverse events by users should be voluntary, confidential, and nonpunitive.

c. Efforts to encourage reporting should be developed, such as removing the perceptual, cultural, contractual, legal, and logistical barriers to reporting.

Recommendation 8

The Secretary of HHS should recommend that Congress establish an independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT. This entity should also monitor and analyze data and publicly report results of these activities.

Recommendation 7-8

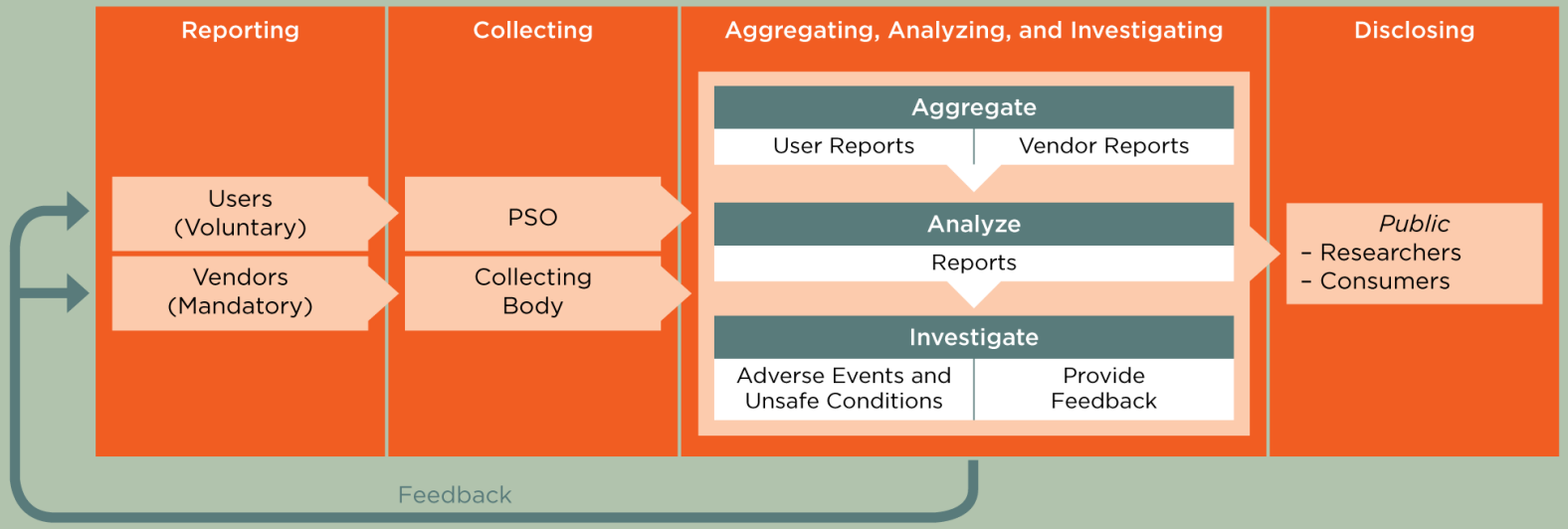

FIGURE 6-3
Reporting system for learning and improving patient safety.

Recommendation 9

a. The Secretary of HHS should monitor and publicly report on the progress of health IT safety annually beginning in 2012. If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs.

b. The Secretary should immediately direct the FDA to begin developing the necessary framework for regulation. Such a framework should be in place if and when the Secretary decides the state of health IT safety requires FDA regulation as stipulated in Recommendation 9a above.

Recommendation 10

HHS, in collaboration with other research groups, should support cross-disciplinary research toward the use of health IT as part of a learning health care system. Products of this research should be used to inform the design, testing, and use of health IT. Specific areas of research include:

a. User-centered design and human factors applied to health IT,

b. Safe implementation and use of health IT by all users,

c. Sociotechnical systems associated with health IT, and

d. Impact of policy decisions on health IT use in clinical practice.

Summary

- Health IT has clear and demonstrated potential to improve patient safety; it also can cause harm. Current literature is inconclusive regarding the overall impact of health IT on patient safety
- All stakeholders, including the private and public sectors, must coordinate efforts to increase our understanding of risks associated with health IT and improve its safe design, implementation, and use

For more information and to download the report:

http://www.iom.edu/hitsafety