The Office of the National Coordinator for Health Information Technology

Anticipating Unintended Consequences of Health Information Technology and Health Information Exchange

How To Identify and Address Unsafe Conditions Associated with Health IT

By ECRI Institute PSO

Cynthia Wallace, CPHRM, Karen P. Zimmer, MD, MPH, FAAP, Robert Giannini, NHA, CHTS–IM/CP, Lorraine Possanza, DPM, JD, MBE, Ronni Solomon, JD

Putting the I in HealthIT
www.HealthIT.gov

Learning Objectives

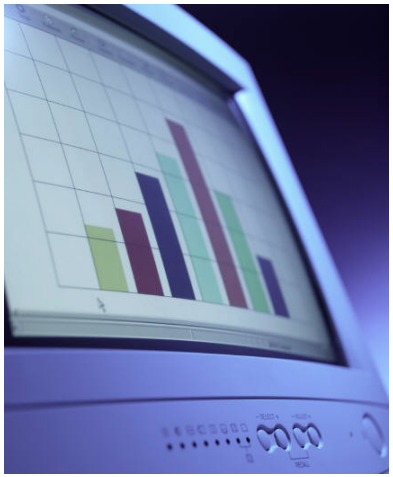
- Identify how the implementation and use of health information technology (health IT) impacts patient safety
- Identify high reliability and culture of safety principles to assist with health IT implementation and improved patient safety
- Identify and address health IT issues with the assistance of EHR developers, healthcare organizations, policymakers, oversight authorities, and PSOs

Introduction

Health IT can provide multiple benefits to enhance patient care if:

- the technology is optimally designed by the system developer;
- thoughtfully implemented by the health care organization; and
- appropriately used by the organization's staff.

Introduction



Health IT's potential can be undermined by the hazards that arise when a health IT system operates in unintended and unanticipated ways.

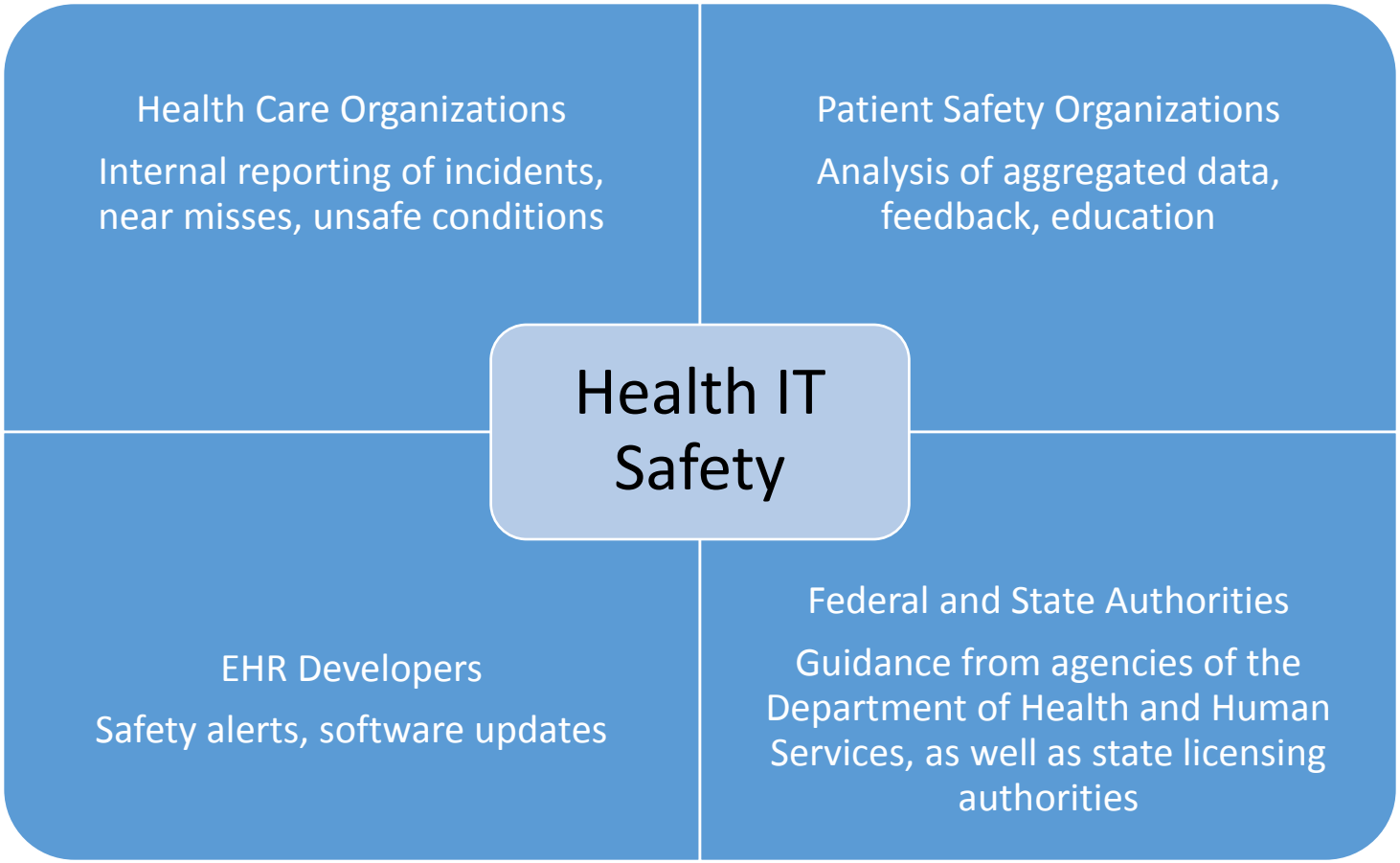
Benefits of Health IT

- Reduce medication errors
- Eliminate illegible writing
- Enable computerized provider order entry
- Achieve best practices using clinical decision support tools (CDS)
- Preventive care recommendations
- Track immunizations, testing, and referrals
- Centralize patient records (availability, timeliness)
- Allow access across a variety of settings for care coordination

Health IT Patient Safety Action Plan and Surveillance Plan (July 2, 2013)

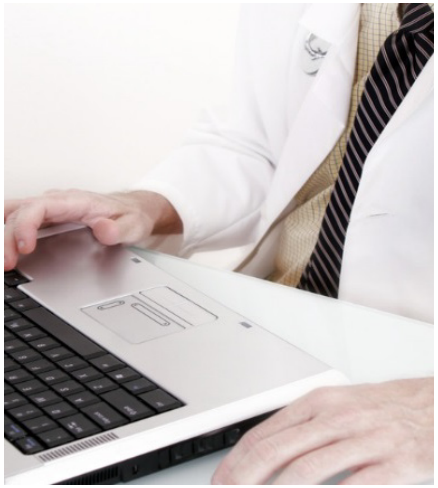
Health IT Safety: A Shared Responsibility

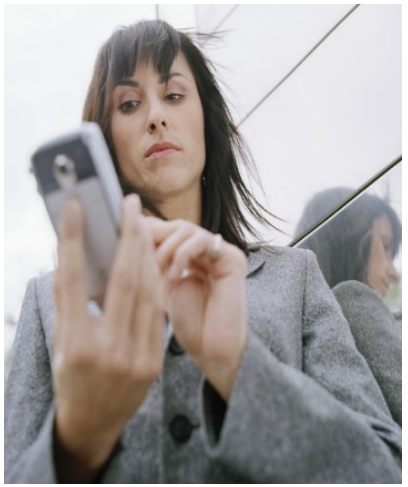
Putting the I in HealthIT
www.HealthIT.gov



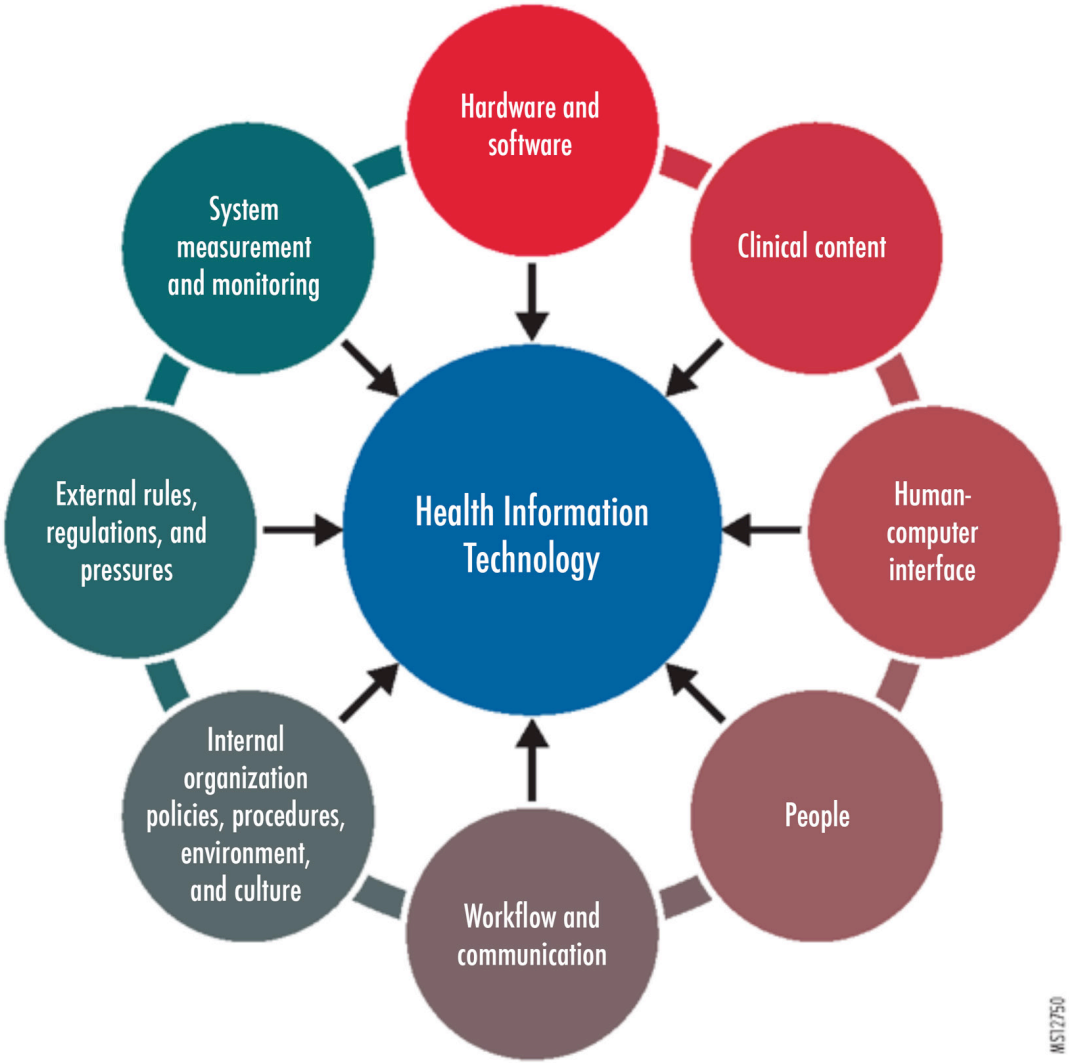
Examples of Health IT Systems

- Administrative – medical billing and scheduling management system
- Automated dispensing system
- Computerized medical devices
- Electronic health records (EHR) or EHR component
- Human interface device
- Laboratory information system
- Radiology/diagnostic imaging system





Socio-Technical Model for Health IT



Adapted by permission from BMJ Publishing Group Limited. Sitting DF and Singh H. A new socio-technical model for studying health information technology in complex adaptive healthcare systems. *Quality and Safety in Health Care.* 19(Supplement 3): i68-74, October 2010; doi: 10.1136/qshc.2010.042085

The Eight Dimensions of the Socio-Technical Model

Putting the I in HealthIT
www.HealthIT.gov

1. Hardware and software
2. Clinical content
3. Human-computer interface
4. People
5. Workflow and communication
6. Internal organizational policies, procedures, environment, and culture
7. External rules, regulations, and pressures
8. System measurement and monitoring

Adapted by permission from BMJ Publishing Group Limited. Sitting DF and Singh H. A new socio-technical model for studying health information technology in complex adaptive healthcare systems. *Quality and Safety in Health Care.* 19(Supplement 3): i68-74, October 2010; doi: 10.1136/qshc.2010.042085

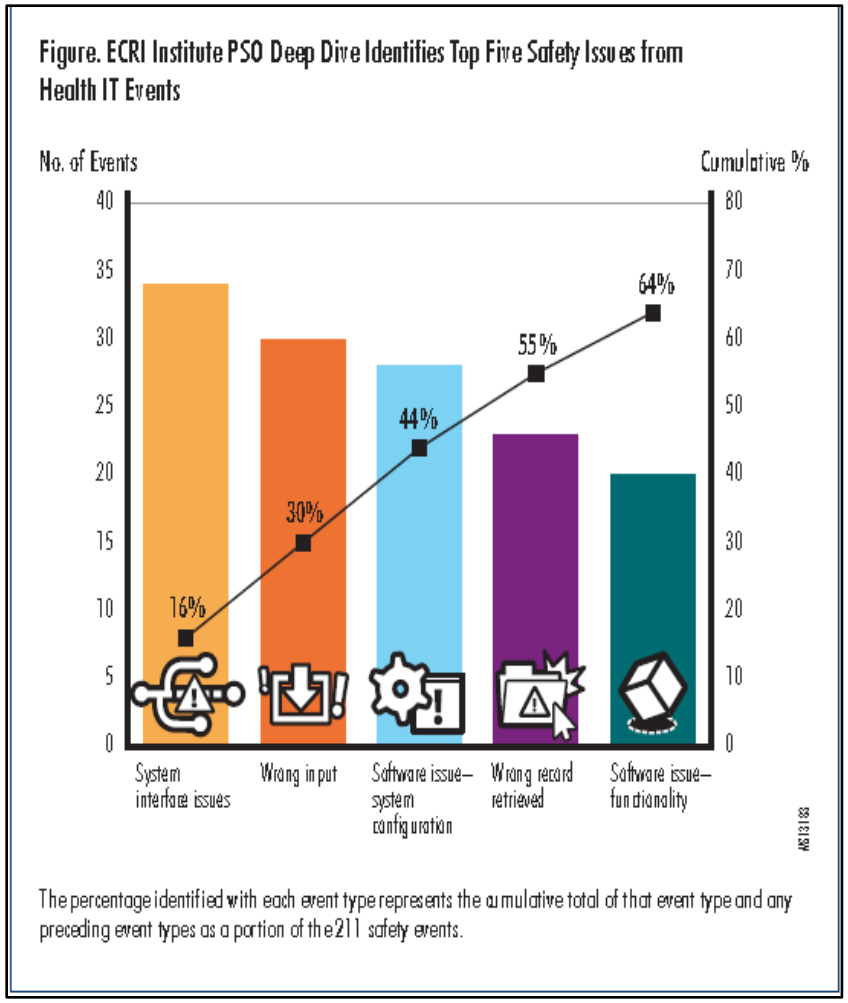
Common Health IT Issues

Human-computer

- A patient was not identified properly, and all clinical information was entered into the wrong record.
- Data were entered incorrectly into the electronic record due to multiple records being open.
- The system failed to alert the user of an identified concern with a flag or po- up.
- The user ignored or overrode an alert.
- Data were not entered into the system.
- Data were incomplete and missing from the entry.

Computer-related

- Data were not displaying properly in the system.
- The network was down or slow.
- Interface issues with the laboratory system caused delays in the ability to retrieve data.
- The software was not up to date.
- Software did not meet the needs of the specialty provider.
- The software was not functioning properly.
- Data were lost.



1. System interface issues
2. Wrong input
3. Software issue – system configuration
4. Wrong record retrieved
5. Software issue – functionality

Identifying Health IT's Unintended Consequences

Continuous Feedback Approach to Health IT System Safety

High-Reliability Organizations' Commitment to Health IT Safety

Leadership commitment to:

- Educating staff about health IT safety
- Advocating health IT safety as everyone's responsibility
- Promoting open communication about health IT safety concerns
- Empowering staff to identify, report, and reduce hazards and risks from health IT systems
- Allocating adequate resources to ensure health IT safety

Event Reporting Within a Culture of Safety

- Establishing a blame-free environment for robust reporting of any health IT-related problems (including errors and near misses) without fear of punishment or reprisal
- Encourage reporting of errors, near misses, and unsafe conditions with a clearly defined response
- Expectation of accountability with constructive feedback and fair-minded treatment to facilitate organizational learning

How To Collect Health IT Event Data

- Reporting system should enable reporters to provide sufficient information, in a standardized format, to identify the health IT problems they encountered
- Standardized tools for event reporting
  - AHRQ Common Formats for Health IT events
  - AHRQ Health IT Hazard Manager
- Staff training and education about Health IT event reporting

How To Collect Health IT Event Data

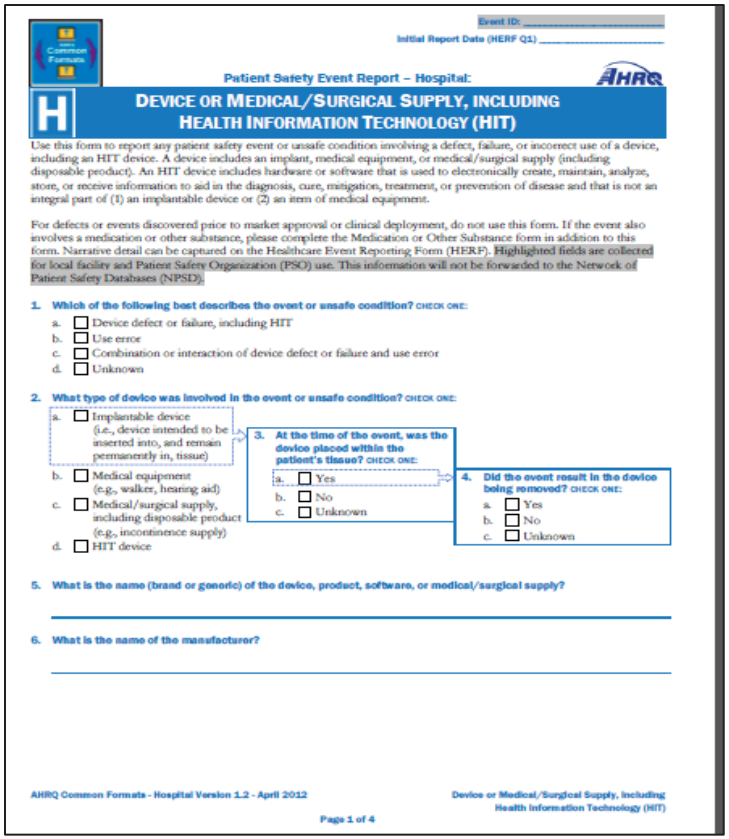
What to include in a health IT-related event report:

- The event reporting system should capture enough information so that those analyzing the event can pinpoint specific health IT-related issues

How To Collect Health IT Event Data

Standardized tools:

- AHRQ Common Format for Health IT Event

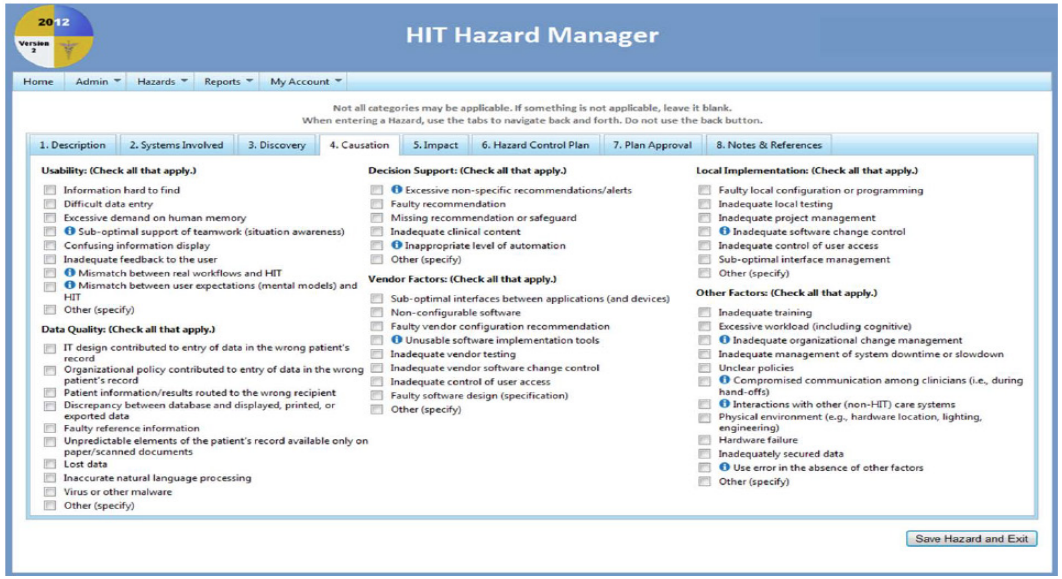


How To Collect Health IT Event Data

Putting the I in HealthIT
www.HealthIT.gov

Standardized tools:

- AHRQ Health IT Hazard Manager

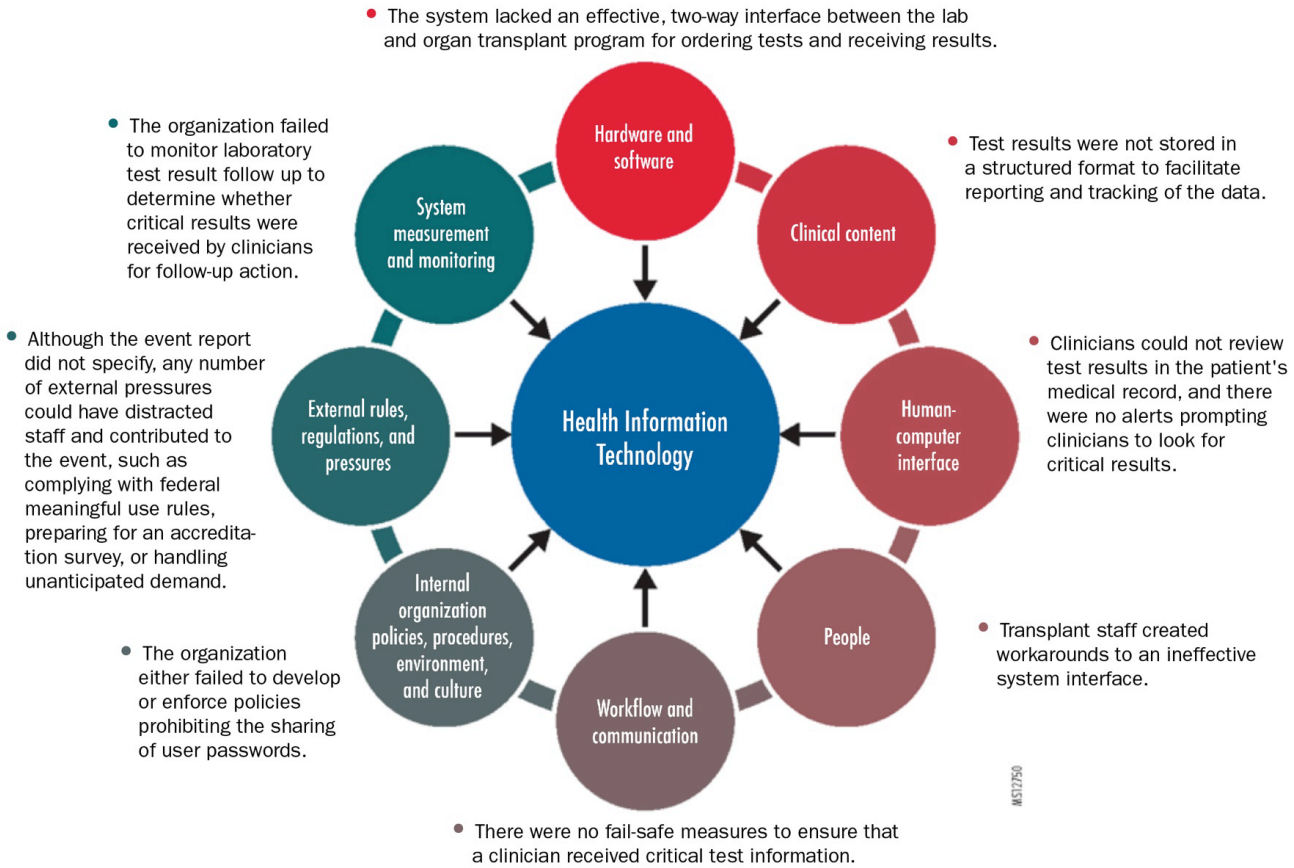


Source: Walker JM, Hassol A, Bradshaw B, et al. *Health IT Hazard Manager Beta-Test: Final Report* [online]. AHRQ Publication No. 12-0058-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2012 May. http://healthit.ahrq.gov/sites/default/files/docs/citation/HealthITHazardManagerFinalReport.pdf.

Case Study: Health IT Laboratory Event

- Critical lab results were overlooked without full interface for different health IT systems.
  - Consider the following poorly designed health IT system interface that hindered the reporting of critical laboratory results to patients' physicians and eventually led to a fatal event:

Case Study: Health IT Laboratory Event



Adapted by permission from BMJ Publishing Group Limited. Sitting DF and Singh H. A new socio-technical model for studying health information technology in complex adaptive healthcare systems. *Quality and Safety in Health Care.* 19(Supplement 3): i68-74, October 2010; doi: 10.1136/qshc.2010.042085

Monitoring and Staff Feedback

- Monitoring
  - Organizations must monitor the effectiveness of their event reporting programs to ensure staff know:
    - How to use the program
    - That the program is capturing the data needed for continuous improvement
- Staff Feedback
  - Analysis of event(s)
  - Error-prevention strategies

Monitoring and Staff Feedback

- Other sources of information:
  - Discussion with users
  - Helpdesk logs maintained by the IT Department
  - Medical chart reviews
  - Claims data
  - Executive staff walk-arounds

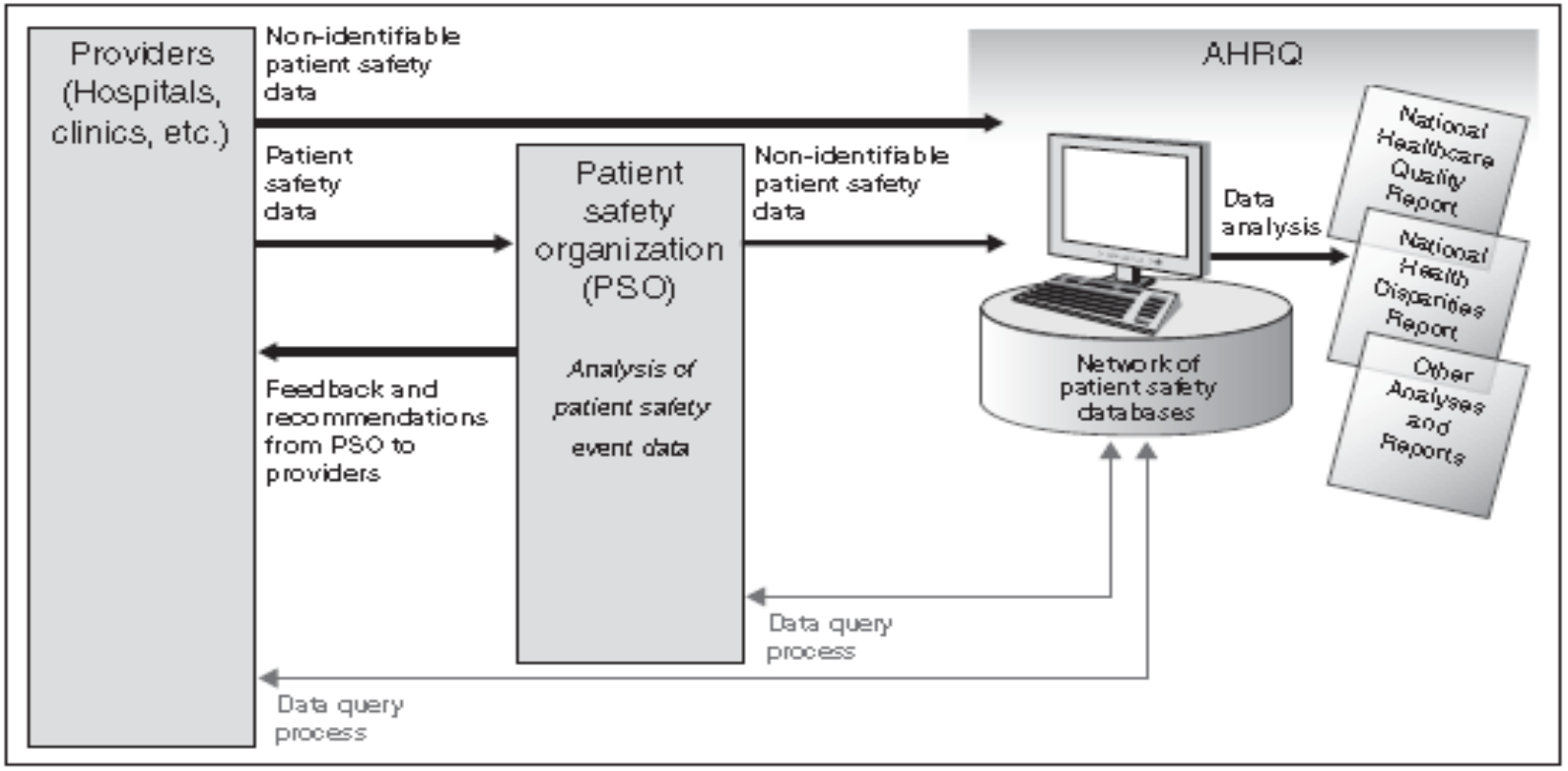
Reporting Health IT Events to Patient Safety Organizations

- PSOs can receive, review, and analyze information about health IT-related patient safety events.
- EHR developers can report health IT patient safety events to PSOs.
- PSOs enable confidential and protected expert review and analysis.
- PSOs aggregate and analyze large volumes of data for facilitated learning.

Reporting Health IT Events to Patient Safety Organizations

Putting the I in HealthIT
www.HealthIT.gov

Intended Flow of Patient Safety Event Data and Feedback



Source: U.S. Government Accountability Office (GAO). *Patient Safety Act: HHS is in the process of implementing the Act, so its effectiveness cannot yet be evaluated.* GAO-10-281. Washington (DC): GAO; 2010 Jan. http://www.gao.gov/assets/310/300382.pdf.

EHR Developers' Role In Ensuring Patient Safety

- Support patient safety in their product design, development, and deployment.
- Share best practices with customers for safe deployment, implementation, maintenance, and use of their products.
- Participate with one or more PSOs for reporting, reviewing, and analyzing health IT-related patient safety events.
- Notify customers when they identify or become aware of software issues that could materially affect patient safety and to offer solutions.
- Recognize the value of their customers' participation in discussions about patient safety and not contractually limit their customers from discussing patient safety issues in appropriate venues.

Teaming Up with PSOs

There are three ways in which EHR developers might work with providers and PSOs under the framework of the Patient Safety Act:

- Serving as a contractor to a PSO
- Serving as a contractor to a provider
- Creating a component organization to seek listing and serve as a PSO.

See also: *AHRQ's FAQs about PSOs*

Conclusion

- Health IT is changing the landscape of health care.
- It is important to recognize the benefits and the potential pitfalls of health IT.
- Reporting health IT events and near-misses will facilitate learning.
- Improvements will occur when involving multiple stakeholders (providers, EHR developers, policymakers, human factor analysts).

Resources

- *AHRQ Common Format: Device or Medical/Surgical Supply, Including Health Information Technology (Health IT) Form*
- *AHRQ's FAQs about PSOs*
- *EHR Contracts: Key Contract Terms for Users to Understand*
- *Electronic Health Record Association's EHR Developer Code of Conduct Principles*
- *Health IT Hazard Manager Beta-Test: Final Report*
- *How to Identify and Address Unsafe Conditions Associated with Health IT*
- *ONC's Health Information Technology: Patient Safety Action & Surveillance Plan*
- Institute of Medicine's report, *Health IT and Patient Safety: Building Safer Systems for Better Care*

References

- Agency for Healthcare Research and Quality (AHRQ):
  - Device or medical/surgical supply, including health information technology (HIT) [online]. In: *Hospital Common Formats—version 1.2: Event Descriptions, Sample Reports, and Forms*. 2013 Apr 24 [cited 2013 Aug 20]. https://www.psoppc.org/web/patientsafety/version-1.2_documents.
  - PSO FAQs [online]. [cited 2013 Aug 27]. http://www.pso.ahrq.gov/psos/fastfacts.htm.
- Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J Am Med Inform Assoc* 2004 Mar-Apr;11(2):104-12.
- ECRI Institute PSO. *ECRI Institute PSO Deep Dive: Health Information Technology*. Plymouth Meeting (PA): ECRI Institute PSO; 2012 Dec:1-41.
- Electronic Health Record Association (EHRA). *EHR Developer Code of Conduct Principles* [online]. 2013 Jun 11 [cited 2013 Aug 27]. http://www.himssehra.org/docs/EHR%20Developer%20Code%20of%20Conduct%20Final.pdf.
- Institute of Medicine (IOM). *Health IT and Patient Safety: Building Safer Systems For Better Care.* Washington (DC): National Academies Press; 2011 Nov 8.
- Kaushal R, Shojania KG, Bates DW. Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. *Arch Intern Med* 2003 Jun 23;163(12):1409-16.

References

- Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. *JAMA* 2005 Mar 9;293(10):1197-203.
- Magrabi F, Ong MS, Runciman W, et al. Using FDA reports to inform a classification for health information technology safety problems. *J Am Med Inform Assoc.* 2012;19(1):45-53.
- Office of the National Coordinator for Health Information Technology (ONC). *Health Information Technology: Patient Safety Action & Surveillance Plan* [online]. 2013 Jul 2 [cited 2013 Aug 26]. http://www.healthit.gov/sites/default/files/safety_plan_master.pdf.
- Sittig DF, Singh H:
  - A new socio-technical model for studying health information technology in complex adaptive healthcare systems. *Qual Saf Health Care* 2010 Oct;19(Suppl 3):i68-74.
  - Defining health information technology-related errors. *Arch Intern Med* 2011 Jul 25;171(14):1281-4.
- Sparnon E, Marella WM. The role of the electronic health record in patient safety events. *Pa Patient Saf Advis.* 2012;9(4):113-21.
- U.S. Food and Drug Administration (FDA). *Class 2 Recall: ED Pulsecheck* [online]. 2013 Jul 29 [cited 2013 Sep 15]. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=119832.
- Walker JM, Hassol A, Bradshaw B, et al. *Health IT Hazard Manager Beta-Test: Final Report* [online]. AHRQ Publication No. 12-0058-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2012 May. http://healthit.ahrq.gov/sites/default/files/docs/citation/HealthITHazardManagerFinalReport.pdf.

Extra Slides
Details on the Device/Health IT AHRQ Common Format Form

AHRQ Common Formats – Event Categories

Putting the I in HealthIT
www.HealthIT.gov

Event-specific categories include:

- Blood or blood product
- ***Device or Medical/Surgical Supply, including Health Information Technology (Health IT)***
- Fall
- Healthcare-associated infection
- Medication or other substance
- Perinatal
- Pressure ulcer
- Surgery or anesthesia
- Other

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equi
- Equi
- Hard
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue

Example:

Results from the Laboratory Information System did not interface to the results section of the electronic health record

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equi
- Hard
- Failu
  netw
- Ergo
- Secu
- Unexpected software design issue

  - Loss or delay of data
  - System returns or stores data that does not match patient
  - Image measurement/corruption issue
  - Image orientation incorrect
  - Incorrect test results
  - Incorrect software programming calculation
  - Incorrect or inappropriate alert

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function
- Equi
- Hard
- Failu ireless network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue

Example:

When entering a dose in mg/kg/hr, the system inappropriately calculated an incorrect IV rate of infusion

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failu… …eless netw…
- Ergo… …erface issue
- Security, virus or other hardware issue
- Unexpected software design issue

Example:
When entering a dose in mg/kg/hr, the system inappropriately calculated an incorrect IV rate of infusion

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failure of, or problem with, wired or wireless network
- Ergo erface issue
- Secu
- Unex

Example:

I was working on a mobile workstation trying to complete my documentation, and I was unable to save it.

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
- Secu
- Unex

  - Hardware location
  - Data entry or selection
  - Information display or interpretation
  - Alert fatigue/alarm fatigue

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
- Secu
- Unex

Example:

I was attempting to select my patient and inadvertently selected the next patient on my list.

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hard
- Failu s
  netw
- Ergo ce issue
- Security, virus or other malware issue
- Unexpected software design issue

Example:
My log-in was not working and I was unable to access the computer system to obtain information on my patient.

AHRQ Common Formats – Contributing Factors

Putting the I in HealthIT
www.HealthIT.gov

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem
- Failu… netw…
- Ergo… issue
- Secu…
- Unexpected software design issue

Example:
Medication order placed via CPOE.
When medication appeared on e-MAR, information related to the drug was omitted.