

*Anticipating Unintended Consequences
of Health Information Technology
and Health Information Exchange*

ONC Webinar: How To Identify and Address Unsafe Conditions Associated with Health IT

By ECRI Institute

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- Describe the role of health information technology (IT) in patient care.
- Identify events that can occur when health IT operates in unanticipated ways.
- Review the socio-technical model for evaluating health IT-related events.
- Describe high reliability and culture of safety principles to support event reporting of errors, near misses, and unsafe conditions with health IT systems.
- Identify tools and methodologies to assist healthcare organizations in developing reporting systems to capture health IT events.
- List the advantages for healthcare organizations to partner with EHR developers and PSOs in learning about and analyzing health IT events.

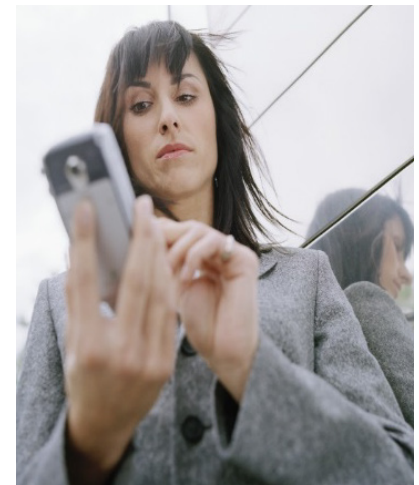
What is Health IT?

- Health IT systems comprise the hardware and software that are used to electronically create, maintain, analyze, store, or receive information to help in the diagnosis, cure, mitigation, treatment, or prevention of disease.



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



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.

- 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

Unintended Consequences



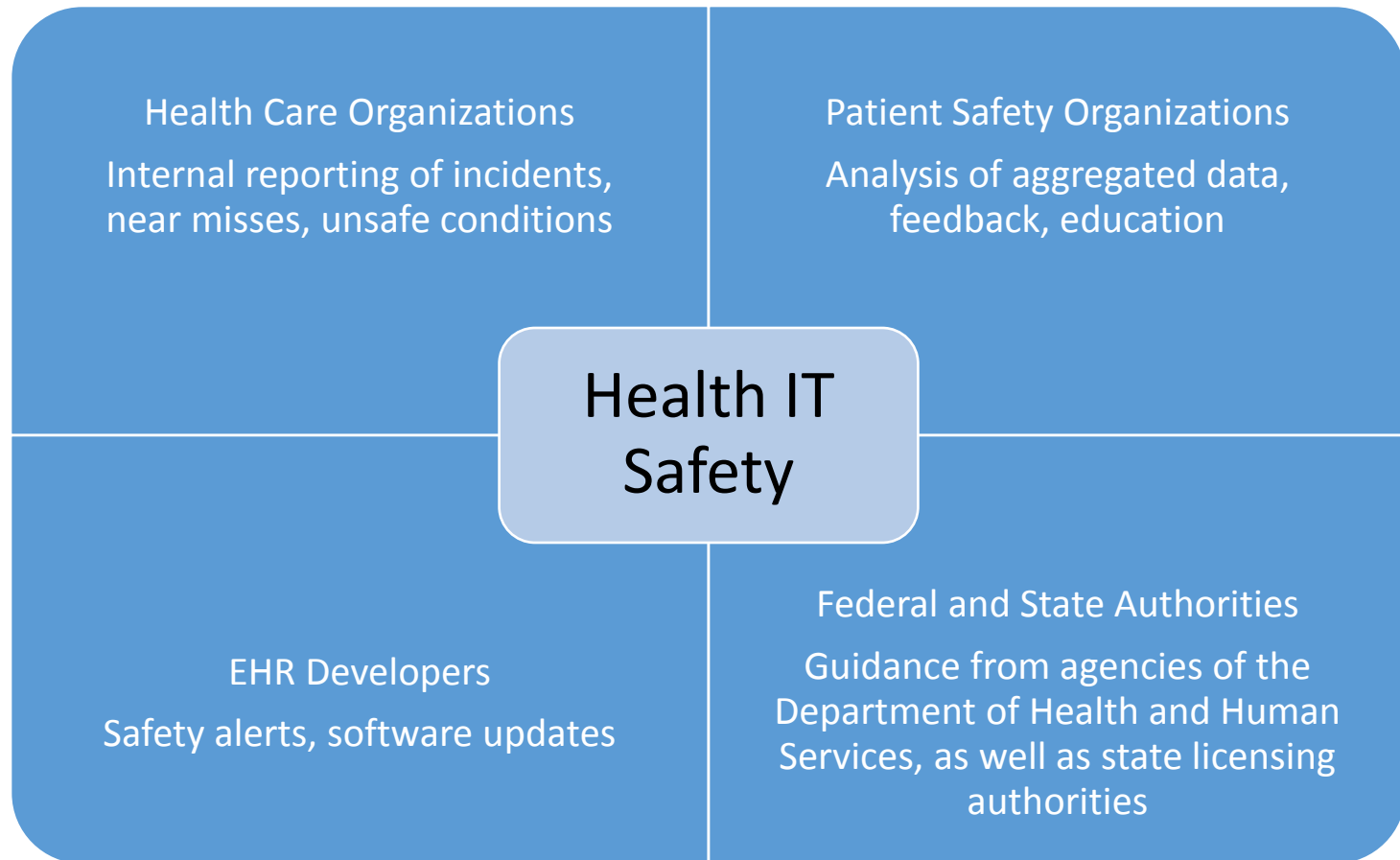
Health IT's potential can be undermined by the hazards that arise when a health IT system operates in unintended and unanticipated ways.

Examples of Unintended Consequences

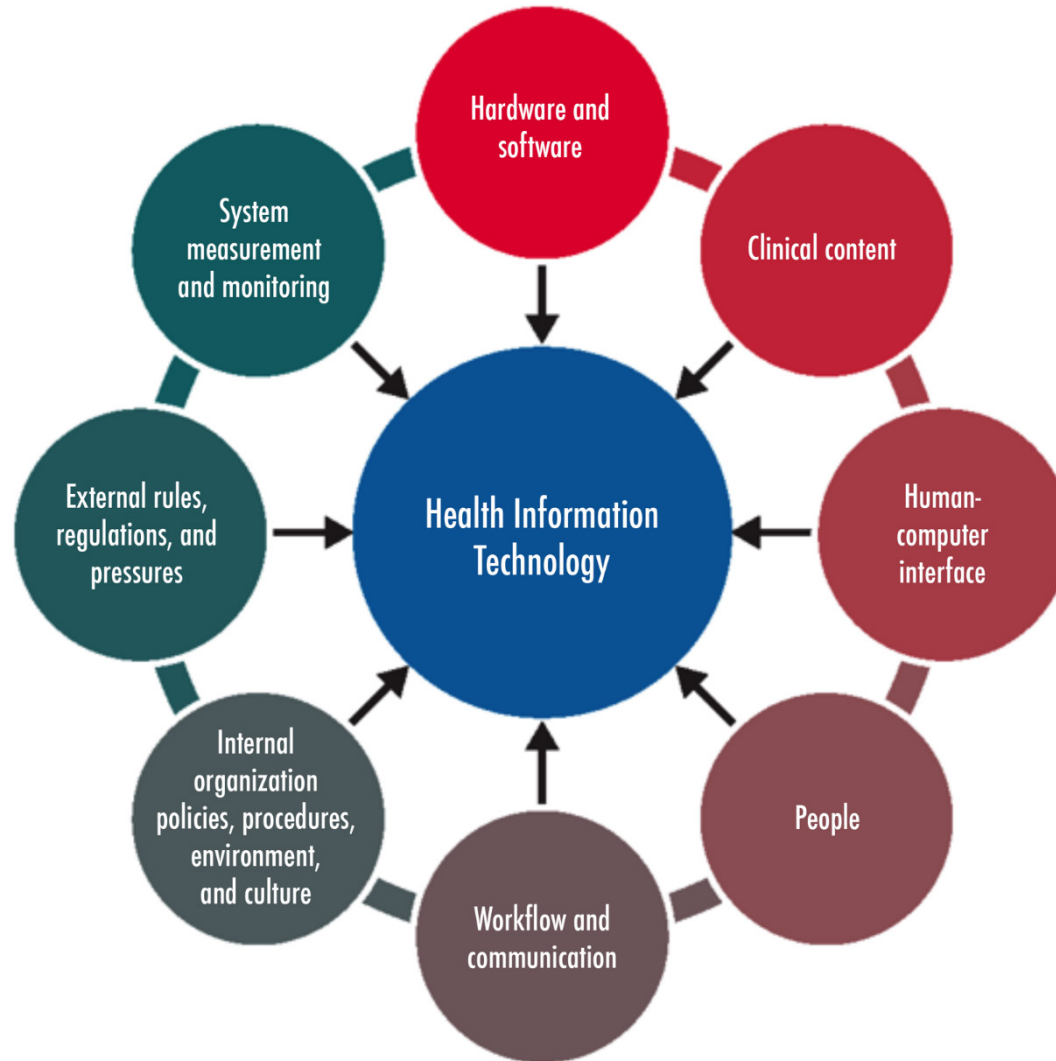
- An EHR system developer notified its customers that a software glitch in its emergency department module prevented ED physicians' notes about medications from transferring into patients' medical records.
- A patient's blood transfusion was ordered and administered under her deceased spouse's medical record. A nurse later noticed the patient's DOB was incorrect on her account. Fortunately, the patient received the necessary correct blood type, but this error could have caused serious patient harm.

Health IT Safety: A Shared Responsibility

Putting the I in HealthIT
www.HealthIT.gov

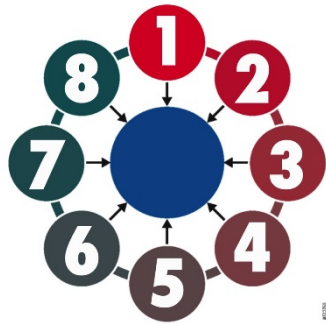


Socio-Technical Model for Health IT



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The Eight Dimensions of the Socio-Technical Model



- 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

Human-computer

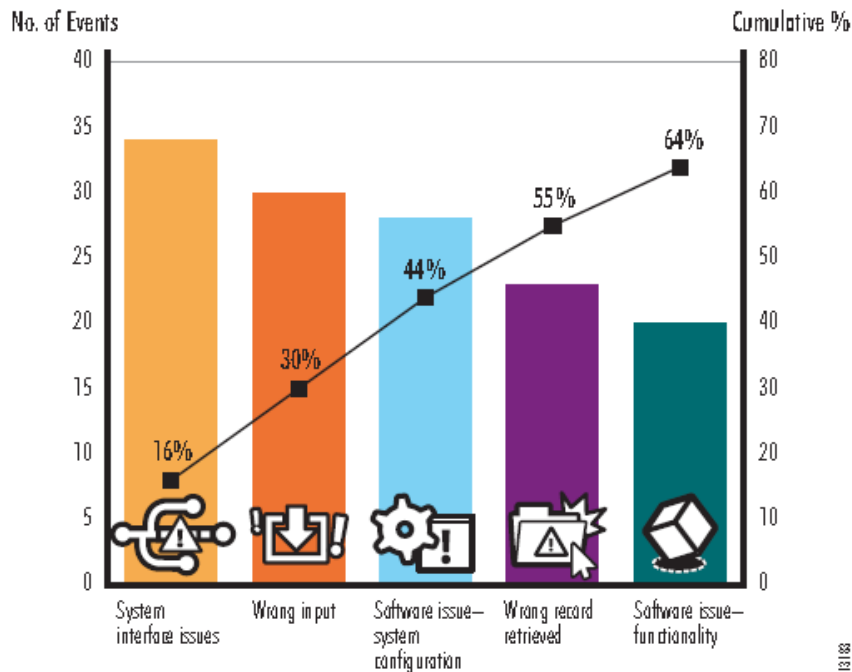
- A patient was not identified properly, and all clinical information was entered into the wrong record.
- Data were entered incorrectly into the electronic record due to multiple records being open.
- The system failed to alert the user of an identified concern with a flag or pop up.
- The user ignored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

Top Five Health IT-related Events

Figure. ECRI Institute PSO Deep Dive Identifies Top Five Safety Issues from Health IT Events



The percentage identified with each event type represents the cumulative total of that event type and any preceding event types as a portion of the 211 safety events.

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

✓ System Interface

- A physician ordered a patient's anticoagulation medication to be discontinued. The order did not cross over to the pharmacy system. The patient received 8 extra doses before the medicine was discontinued.

✓ Software Configuration and Function

- The system prevents the nurse from typing more than five letters in the comment field.
- An influenza vaccine order does not drop off the active work list after it is given.
- An error message displays each time a particular medication is ordered.
- The system does not alert when a pregnancy test is ordered for a male patient.

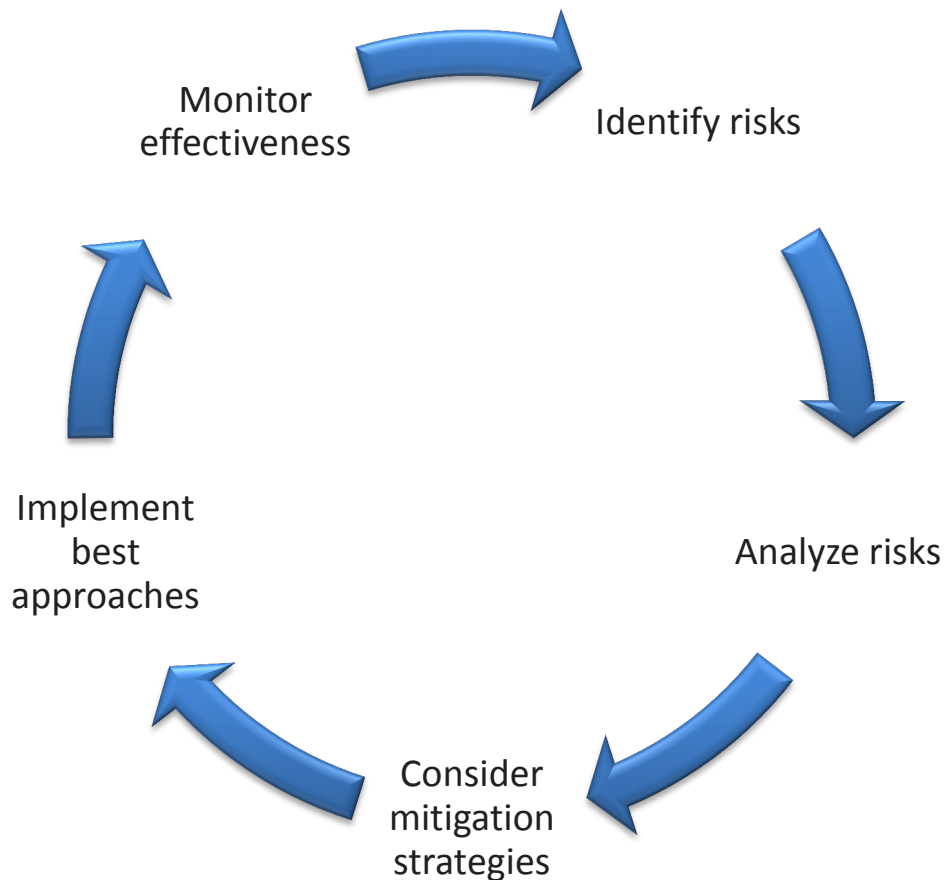
✓ Wrong Data Input

- The nurse entered an incorrect patient identification number and recorded the blood glucose results from the bedside glucose meter for the wrong patient. The correct patient was still treated appropriately because the blood glucose results were immediately available at the bedside.

✓ Wrong Record Retrieved

- The medication management system allows the pharmacist to navigate off one patient profile and pull up another patient profile. An incorrect medication order was placed in the wrong patient's profile. The patient receive incorrect medications as a result.

Continuous Feedback Approach to Health IT System 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
- 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

Event Reporting Within a Culture of Safety

- Encourage reporting of errors, near misses, and unsafe conditions with a clearly defined response
- Educate staff by providing examples of health IT-related incidents
- Provide constructive feedback and fair-minded treatment to facilitate organizational learning

- 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

How To Collect Health IT Event Data

Standardized tools:

- AHRQ Common Formats for Health IT Event Data



The screenshot displays the 'Patient Safety Event Report - Hospital' form, titled 'DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)'. The form includes a header with 'Event ID' and 'Initial Report Date (HERF Q1)'. It contains detailed instructions for reporting events, including definitions of devices and HIT. The form is divided into several sections with numbered questions and checkboxes for responses. Section 1 asks for the best description of the event. Section 2 asks for the type of device involved. Section 3 asks if the device was placed within the patient's tissue. Section 4 asks if the event resulted in the device being removed. Section 5 asks for the name of the device, product, software, or medical/surgical supply. Section 6 asks for the name of the manufacturer. The form is labeled 'Page 1 of 4' at the bottom.

Event ID: _____
Initial Report Date (HERF Q1): _____

Patient Safety Event Report - Hospital:
DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of (1) an implantable device or (2) an item of medical equipment.

For defects or events discovered prior to market approval or clinical deployment, do not use this form. If the event also involves a medication or other substance, please complete the Medication or Other Substance form in addition to this form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Which of the following best describes the event or unsafe condition? CHECK ONE:

- a. ☐ Device defect or failure, including HIT
- b. ☐ Use error
- c. ☐ Combination or interaction of device defect or failure and use error
- d. ☐ Unknown

2. What type of device was involved in the event or unsafe condition? CHECK ONE:

- a. ☐ Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)
- b. ☐ Medical equipment (e.g., walker, hearing aid)
- c. ☐ Medical/surgical supply, including disposable product (e.g., incontinence supply)
- d. ☐ HIT device

3. At the time of the event, was the device placed within the patient's tissue? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

4. Did the event result in the device being removed? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

5. What is the name (brand or generic) of the device, product, software, or medical/surgical supply?

6. What is the name of the manufacturer?

AHRQ Common Formats - Hospital Version 1.2 - April 2012
Page 1 of 4
Device or Medical/Surgical Supply, Including Health Information Technology (HIT)

How To Collect Health IT Event Data

Standardized tools:

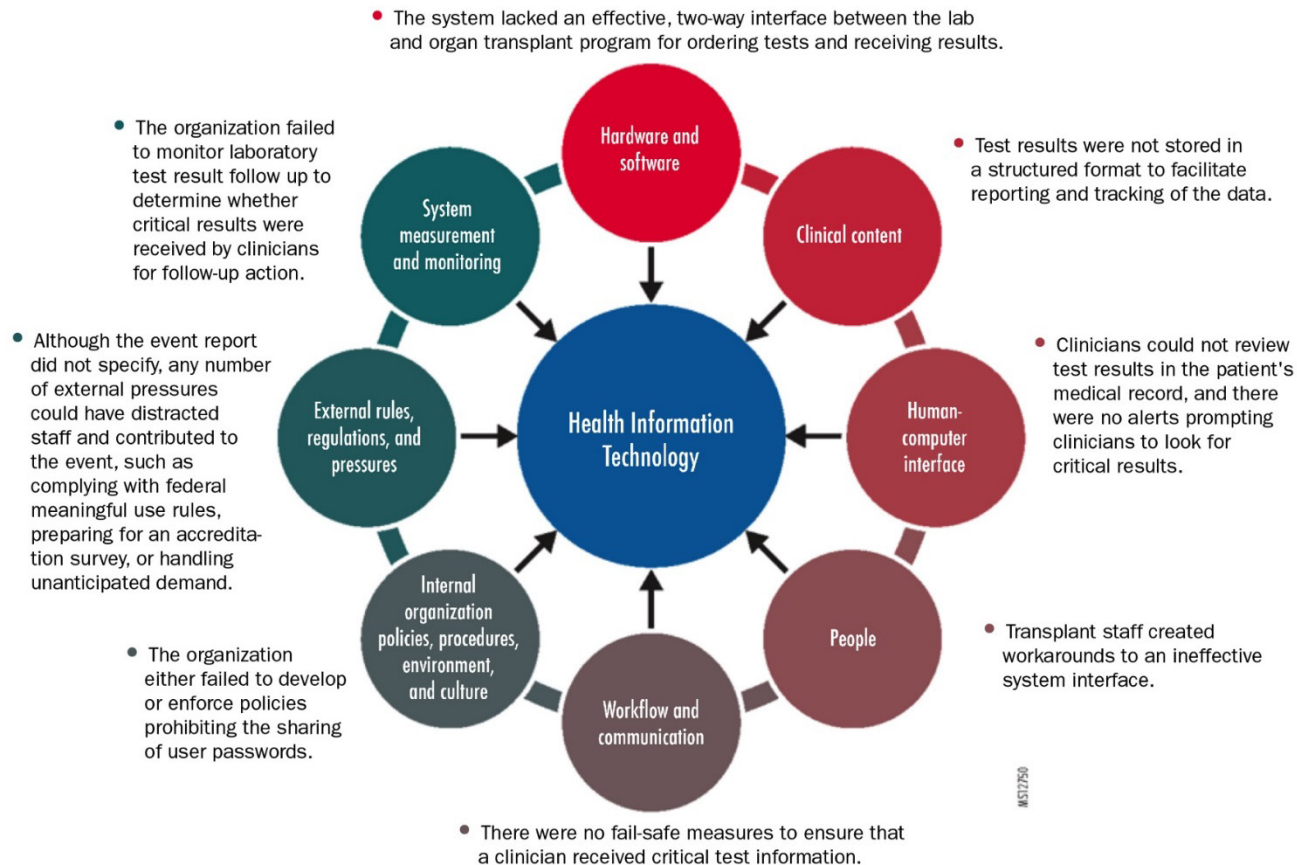
- AHRQ Health IT Hazard Manager

The screenshot displays the HIT Hazard Manager web application. At the top, there is a navigation bar with a '2012' logo and a 'Version 2' indicator. Below this is a menu bar with links for 'Home', 'Admin', 'Hazards', 'Reports', and 'My Account'. The main content area is titled 'HIT Hazard Manager' and contains a series of tabs: '1. Description', '2. Systems Involved', '3. Discovery', '4. Causation', '5. Impact', '6. Hazard Control Plan', '7. Plan Approval', and '8. Notes & References'. The '1. Description' tab is currently selected. It contains three sections of checkboxes for reporting hazards: 'Usability: (Check all that apply.)', 'Data Quality: (Check all that apply.)', and 'Decision Support: (Check all that apply.)'. Each section lists various potential hazards, such as 'Information hard to find', 'Excessive demand on human memory', 'Sub-optimal support of teamwork (situation awareness)', 'Confusing information display', 'Inadequate feedback to the user', 'Mismatch between real workflows and HIT', 'Mismatch between user expectations (mental models) and HIT', 'Other (specify)', 'IT design contributed to entry of data in the wrong patient's record', 'Organizational policy contributed to entry of data in the wrong patient's record', 'Patient information/results routed to the wrong recipient', 'Discrepancy between database and displayed, printed, or exported data', 'Faulty reference information', 'Unpredictable elements of the patient's record available only on paper/scanned documents', 'Lost data', 'Inaccurate natural language processing', 'Virus or other malware', 'Other (specify)', 'Excessive non-specific recommendations/alerts', 'Faulty recommendation', 'Missing recommendation or safeguard', 'Inadequate clinical content', 'Inappropriate level of automation', 'Other (specify)', 'Sub-optimal interfaces between applications (and devices)', 'Non-configurable software', 'Faulty vendor configuration recommendation', 'Unusable software implementation tools', 'Inadequate vendor testing', 'Inadequate vendor software change control', 'Inadequate control of user access', 'Faulty software design (specification)', 'Other (specify)', 'Local Implementation: (Check all that apply.)', and 'Other Factors: (Check all that apply.)'. A 'Save Hazard and Exit' button is located at the bottom right of the form.

Case Study: Health IT Laboratory Event

- Critical lab results were overlooked without a full interface between 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



- Staff Feedback
 - Analysis of event(s)
 - Error-prevention strategies
- 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

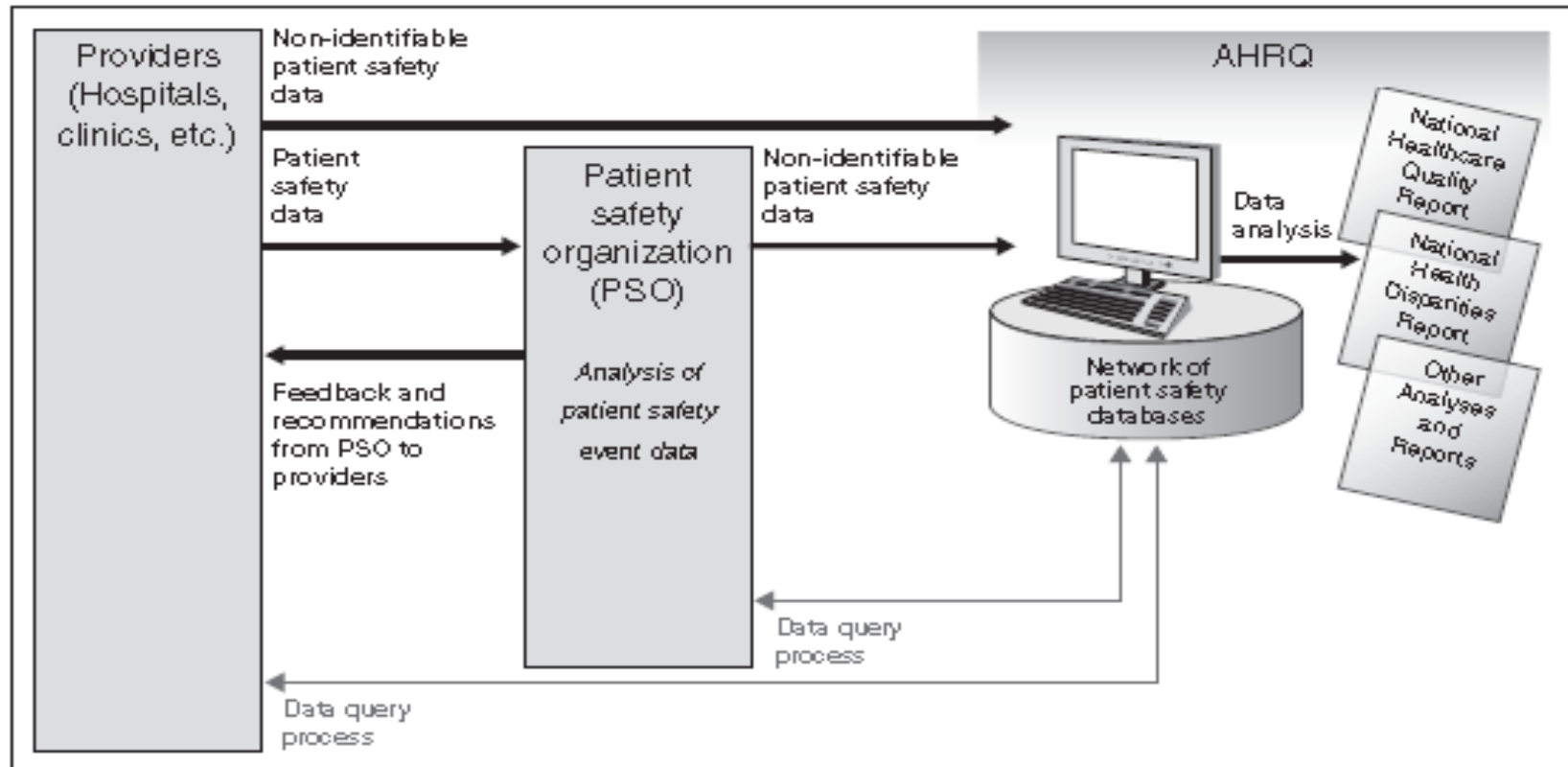
- Other sources of information:
 - Discussion with users
 - Helpdesk logs maintained by the IT Department
 - Medical chart reviews
 - Claims data
 - Executive staff walk-arounds

Reporting Health IT Events to Patient Safety Organizations

- PSOs can receive, review, and analyze information about health IT-related patient safety events.
- 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

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 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.

Purpose of the Partnership

- To make healthcare safer by understanding and mitigating health IT hazards and safety events

Objectives

- Establish a collaborative model for collecting and analyzing health IT hazards and safety events, and sharing best practices and lessons learned
- Evaluate the use of two health IT reporting taxonomies
- Understand the challenges of a safety reporting system for health IT and prepare for a center for health IT safety



- 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).

Links to these resources are in ONC's guide, *How to Identify and Address Unsafe Conditions Associated with Health IT**

- 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
- Institute of Medicine's report, *Health IT and Patient Safety: Building Safer Systems for Better Care*
- ONC's *Health Information Technology: Patient Safety Action & Surveillance Plan*

*http://www.healthit.gov/sites/default/files/how_to_identify_and_address_unsafe_conditions_associated_with_health_it_2013.pdf

- 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. https://www.psoppc.org/web/patientsafety/version-1.2_documents.
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<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=119832>.
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<http://healthit.ahrq.gov/sites/default/files/docs/citation/HealthITHazardManagerFinalReport.pdf>.

Appendix:

Examples of Health IT Events for Reporting into Device/Health IT AHRQ Common Format

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

- Incompatibility between devices
- Equipment
- Equipment
- Hardware
- 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

- Incompatibility between devices
- **Equipment/device function**
 - 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
- Unexpected software design issue

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function

Example:

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

- Failure of wireless network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue

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

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem

Example:

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

- Failure of network
- Ergonomics
- Security, virus or other malware issue
- Unexpected software design issue

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

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

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

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
- Unexplained

Example:

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

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure

Example:

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

- Failure of network
- Ergonomics issue
- Security, virus or other malware issue
- Unexpected software design issue

AHRQ Common Formats – Contributing Factors

- Incompatibility between devices
- Equipment/device function
- Equipment/device maintenance
- Hardware failure or problem

Example:

Medication order placed via CPOE.

When medication appeared on e-MAR,
information related to the drug was omitted.

- Unexpected software design issue