

*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**

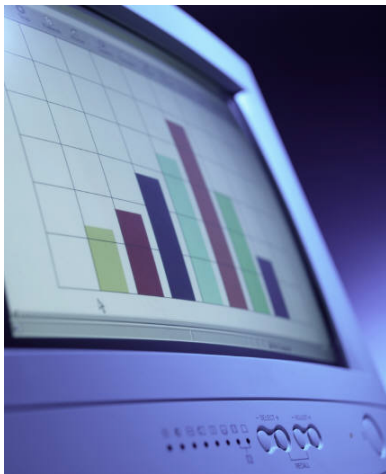
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- Identify how the implementation and use of health information technology (health IT) impacts patient safety
- Identify high reliability and culture of safety principles to assist with health IT implementation and improved patient safety
- Identify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

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.

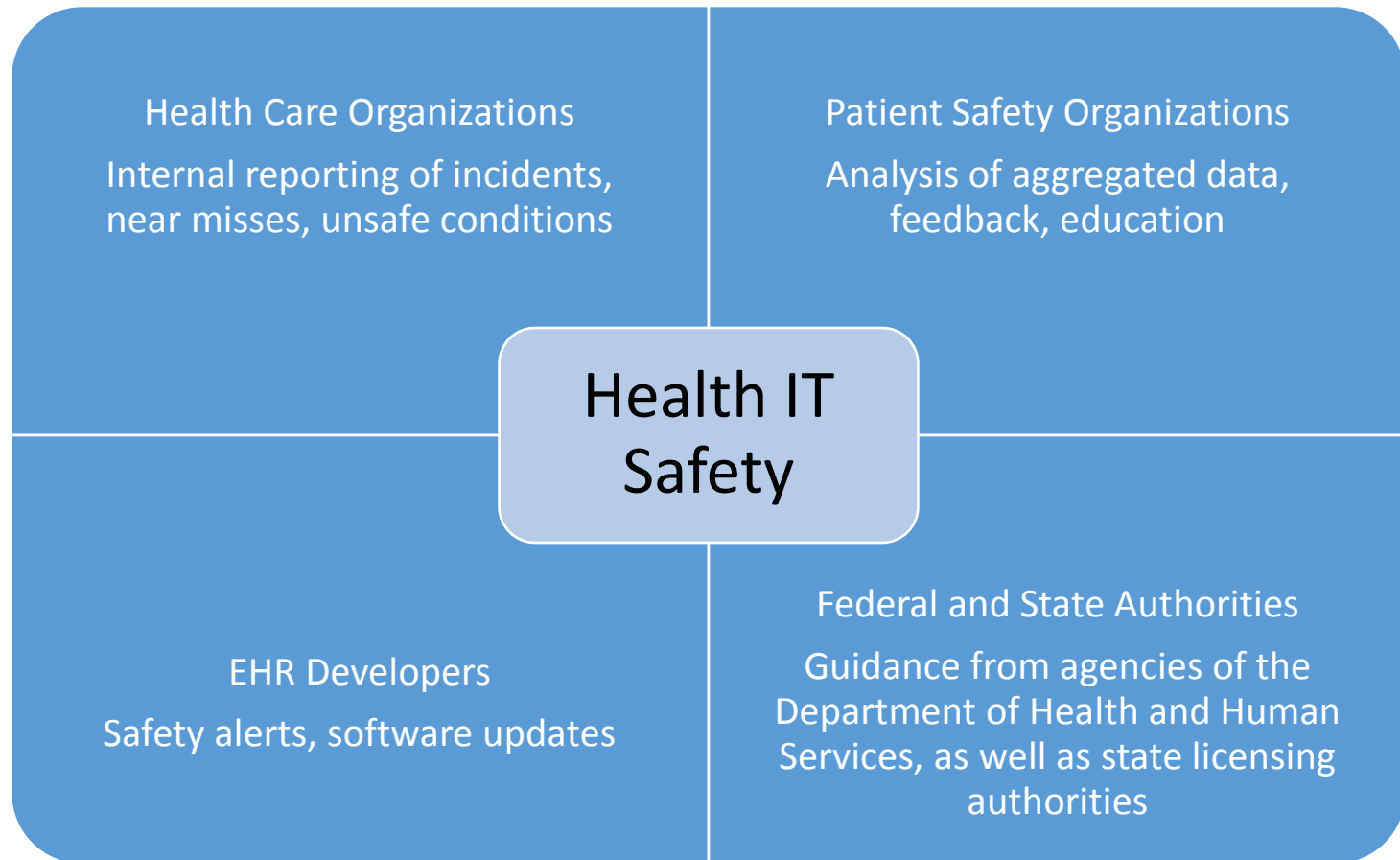


Health IT's potential can be undermined by the hazards that arise when a health IT system operates in unintended and unanticipated ways.

- 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 Safety: A Shared Responsibility

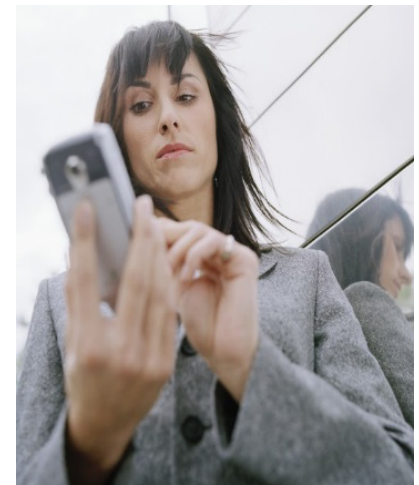
Putting the I in HealthIT  
[www.HealthIT.gov](http://www.HealthIT.gov)





# 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



MS12750



# 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

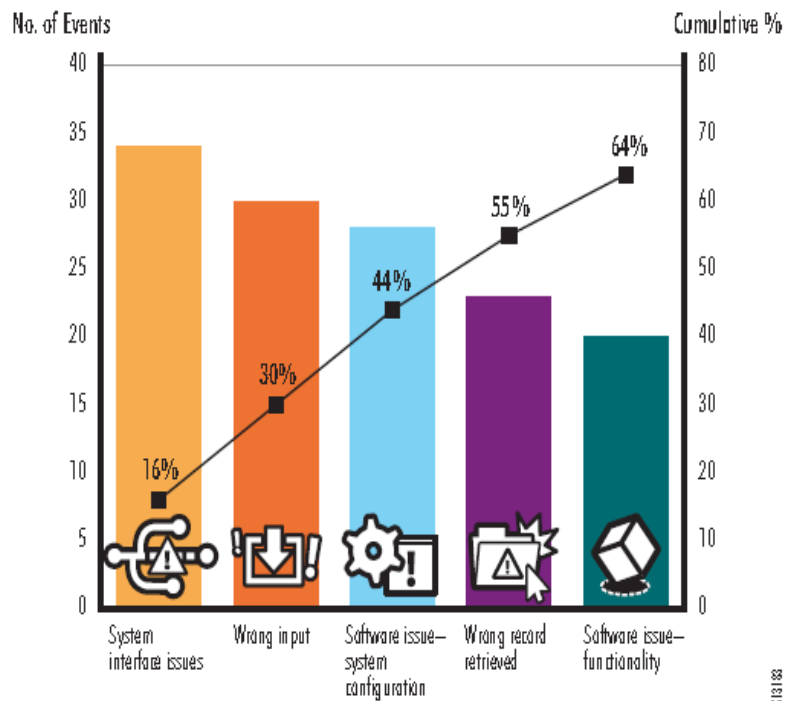
## Human-computer

- 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.

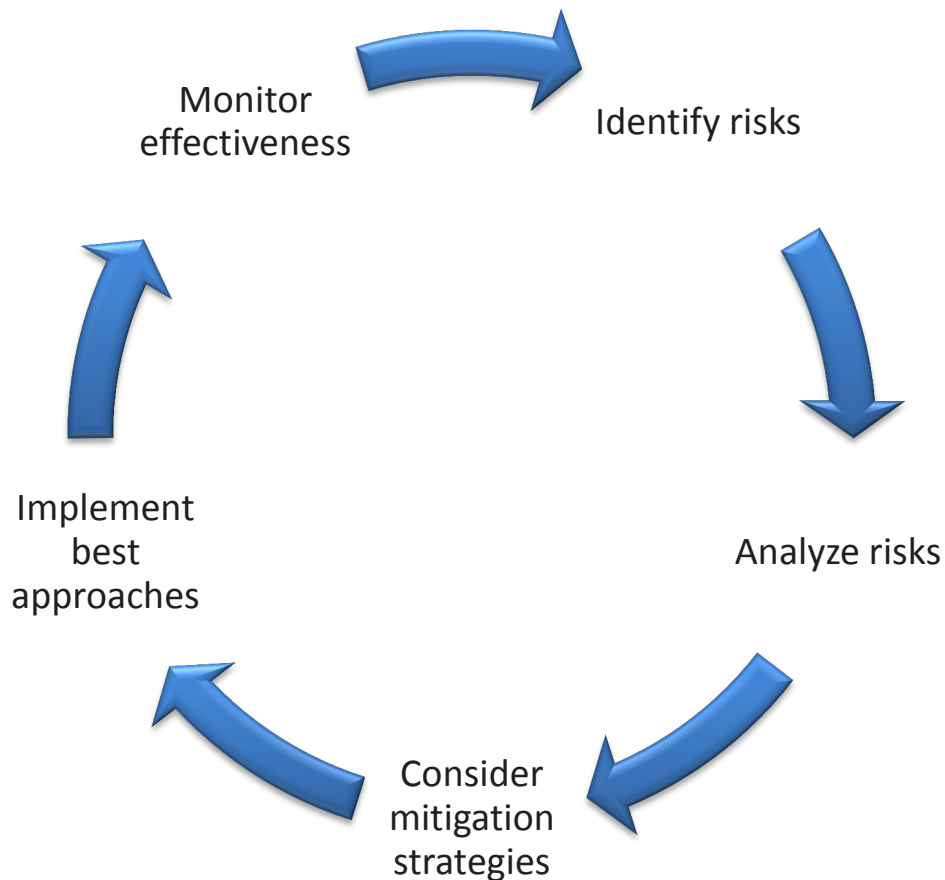
Figure. ECRI Institute PSO Deep Dive Identifies Top Five Safety Issues from Health IT Events



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

## 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
- 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



- 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

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

The screenshot shows the AHRQ (Agency for Healthcare Research and Quality) website. The header includes the AHRQ logo and navigation links for various audiences. The main content area features a news item titled "New Health IT Common Format for adverse event reporting" from the December 2010 issue of Research Activities. The text explains that the format is designed to help health care providers collect information about adverse events related to health information technology and devices. It mentions that the format is currently available as a beta version for public review and comment, and will be revised based on feedback. The format is titled "Device or Medical/Surgical Supply including HIT Device" and is currently available as a beta version for public review and comment. The format will be revised based on feedback and released with AHRQ's Common Formats, Version 1.2 in August 2011. A sidebar on the left lists various newsletters, and a right sidebar provides contact information for Gail Makulowich, Managing Editor.

The screenshot shows the "Patient Safety Event Report - Hospital" form, specifically for "DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)". The form includes a header with the AHRQ logo and a section for "Event ID" and "Initial Report Date (HERF Q1)". The main body of the form contains instructions for use and a series of questions to be answered. The questions are as follows:

- 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
- 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
- At the time of the event, was the device placed within the patient's tissue? CHECK ONE:
  - a. ☐ Yes
  - b. ☐ No
  - c. ☐ Unknown
- Did the event result in the device being removed? CHECK ONE:
  - a. ☐ Yes
  - b. ☐ No
  - c. ☐ Unknown
- What is the name (brand or generic) of the device, product, software, or medical/surgical supply?
- What is the name of the manufacturer?

The form footer includes the text "AHRQ Common Formats - Hospital Version 1.2 - April 2012" and "Page 1 of 4".

# How To Collect Health IT Event Data

## Standardized tools:

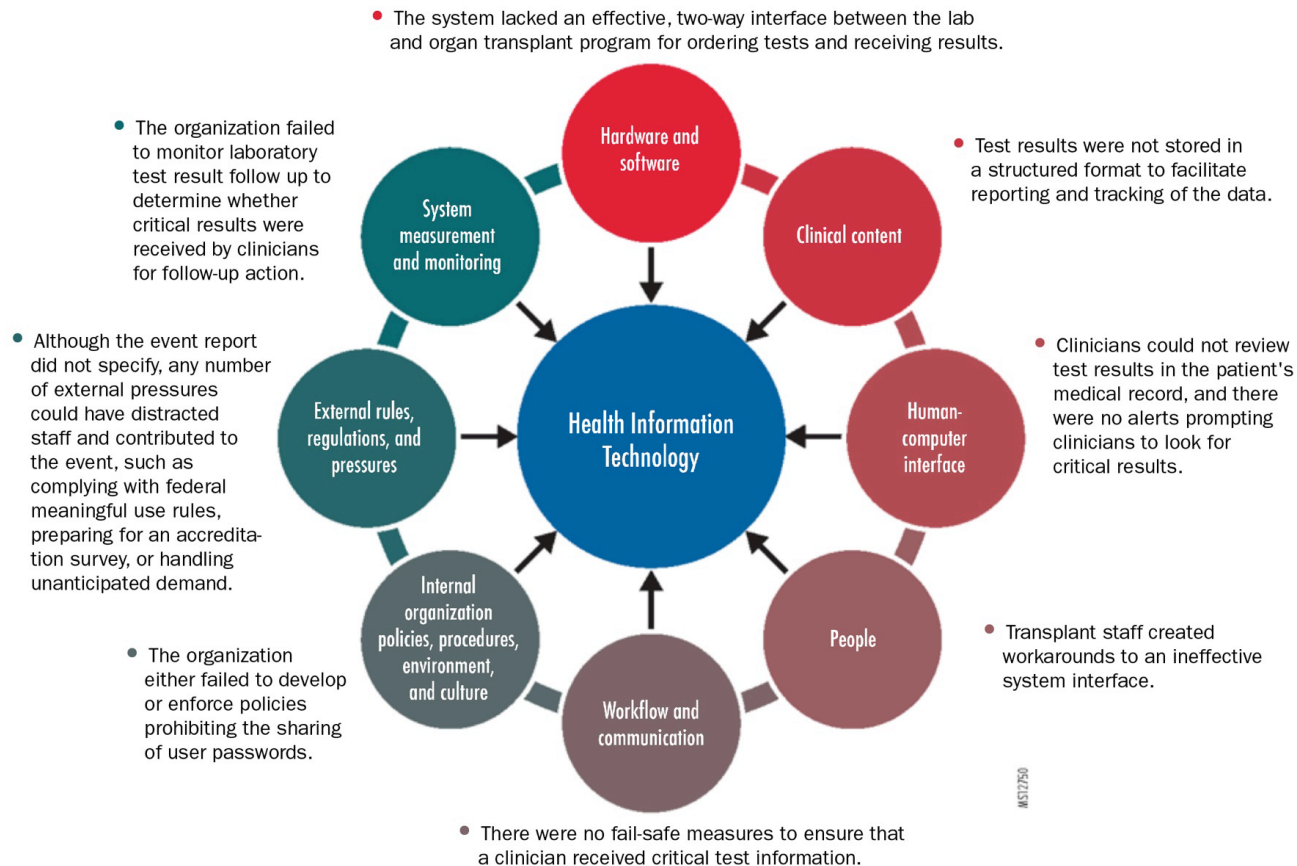
- AHRQ Health IT Hazard Manager

The screenshot shows the HIT Hazard Manager web application. At the top, there's a navigation bar with 'Home', 'Admin', 'Hazards', 'Reports', and 'My Account'. Below this is a tabbed interface with tabs for '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 active. The main content area is divided into three columns of checkboxes under the heading 'Usability: (Check all that apply.)'. The first column lists items like 'Information hard to find', 'Difficult data entry', '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', and 'Other (specify)'. The second column lists items like 'Excessive non-specific recommendations/alerts', 'Faulty recommendation', 'Missing recommendation or safeguard', 'Inadequate clinical content', 'Inappropriate level of automation', and 'Other (specify)'. The third column lists items like 'Faulty local configuration or programming', 'Inadequate local testing', 'Inadequate project management', 'Inadequate software change control', 'Inadequate control of user access', 'Sub-optimal interface management', and 'Other (specify)'. Below these columns are sections for 'Data Quality: (Check all that apply.)' and 'Other Factors: (Check all that apply.)'. The 'Data Quality' section lists items like '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', and 'Other (specify)'. The 'Other Factors' section lists items like 'Inadequate training', 'Excessive workload (including cognitive)', 'Inadequate organizational change management', 'Inadequate management of system downtime or slowdown', 'Unclear policies', 'Compromised communication among clinicians (i.e., during hand-offs)', 'Interactions with other (non-HIT) care systems', 'Physical environment (e.g., hardware location, lighting, engineering)', 'Hardware failure', 'Inadequately secured data', 'Use error in the absence of other factors', and 'Other (specify)'. At the bottom right, there is a 'Save Hazard and Exit' button.

## ***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





- 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

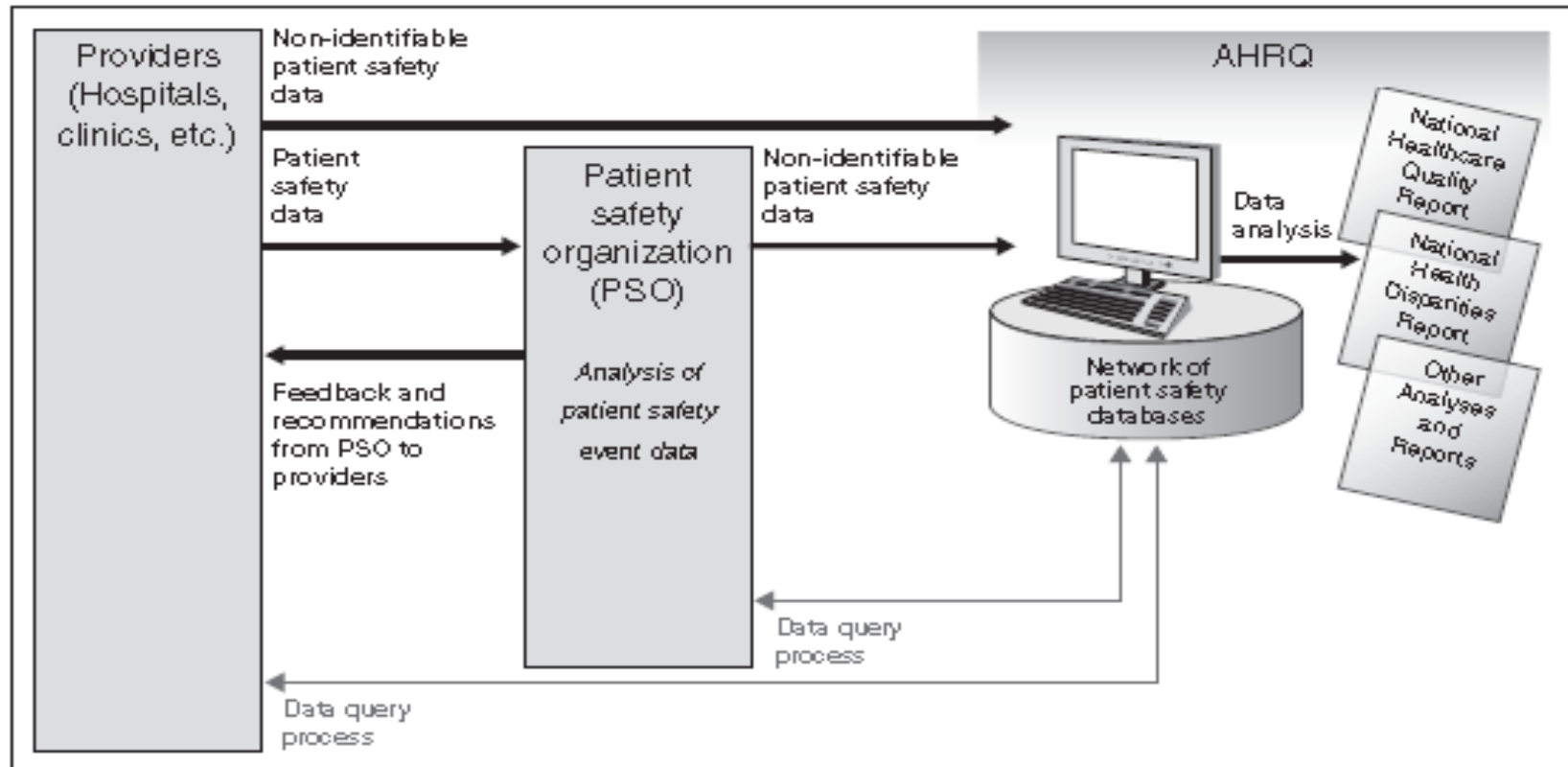
- Other sources of information:
  - Discussion with users
  - Helpdesk logs maintained by the IT Department
  - Medical chart reviews
  - Claims data
  - Executive staff walk-arounds

# 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

## 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](#)



- 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).

- [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](#)

- Agency for Healthcare Research and Quality (AHRQ):
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- 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

## 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
  - Example:**  
Results from the Laboratory Information System did not interface to the results section of the electronic health record
- 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

# 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

- 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
- Failure of network or wireless interface
- Ergonomics or user 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

## **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