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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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
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.
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 Safety: A Shared Responsibility

- Health Care Organizations
  Internal reporting of incidents, near misses, unsafe conditions

- Patient Safety Organizations
  Analysis of aggregated data, feedback, education

- EHR Developers
  Safety alerts, software updates

- Federal and State Authorities
  Guidance from agencies of the Department of Health and Human Services, as well as state licensing authorities
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

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

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 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.
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

- Identify risks
- Analyze risks
- Consider mitigation strategies
- Implement best approaches
- Monitor effectiveness
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
• 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
How To Collect Health IT Event Data

Standardized tools:
- **AHRQ Health IT Hazard Manager**

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

- The system lacked an effective, two-way interface between the lab and organ transplant program for ordering tests and receiving results.

- The organization failed to monitor laboratory test result follow up to determine whether critical results were received by clinicians for follow-up action.

- Although the event report did not specify, any number of external pressures could have distracted staff and contributed to the event, such as complying with federal meaningful use rules, preparing for an accreditation survey, or handling unanticipated demand.

- The organization either failed to develop or enforce policies prohibiting the sharing of user passwords.

- There were no fail-safe measures to ensure that a clinician received critical test information.

- Test results were not stored in a structured format to facilitate reporting and tracking of the data.

- Clinicians could not review test results in the patient’s medical record, and there were no alerts prompting clinicians to look for critical results.

- Transplant staff created workarounds to an ineffective system interface.

• 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
• 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.
Intended Flow of Patient Safety Event Data and Feedback

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):


• Sittig DF, Singh H:
  


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
• 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
• Incompatibility between devices

**Example:**

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

• Equipment/function

• Equipment/maintenance

• Hardware failure or problem

• Failure or, 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
- Equipment/device maintenance
- Hardware failure or problem
- Network
- Ergonomics, including human/device interface issue
- Security, virus or other malware issue
- Unexpected software design issue
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**Example:**
When entering a dose in mg/kg/hr, the system inappropriately calculated an incorrect IV rate of infusion
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• Incompatibility between devices
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• 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
    - Hardware location
  - Uneasy
    - Data entry or selection
    - Information display or interpretation
    - Alert fatigue/alarm fatigue
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- 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

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

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

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