Anticipating Unintended Consequences of Health Information Technology and Health Information Exchange

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

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Learning Objectives

• 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 Heath 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.
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’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

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
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
Case Studies: Computer-Related

✓ 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

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
• 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
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
How To Collect Health IT Event Data

Standardized tools:

• AHRQ Common Formats for Health IT Event Data
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 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

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

• **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
• 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.
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 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
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).
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_addressUnsafe_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
    https://www.psoppc.org/web/patientsafety/version-1.2_documents.

• Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature

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  ECRI Institute PSO; 2012 Dec:1-41.


• Institute of Medicine (IOM). *Health IT and Patient Safety: Building Safer Systems For Better Care*.

• Kaushal R, Shojania KG, Bates DW. Effects of computerized physician order entry and clinical decision support
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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
• 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/device function
• Equipment/device maintenance
• Hardware failure 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
- Hardware failure or problem
  - Image measurement/corruption issue
  - Image orientation incorrect
- Failure of, or problem with, wired or wireless network
- Ergonomics, including human/device interface issue
  - Incorrect test results
- Security, virus or other malware issue
  - Incorrect software programming calculation
- Unexpected software design issue
  - Incorrect or inappropriate alert
- 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

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- 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
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AHRQ Common Formats – Contributing Factors

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**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, virus or other malware issue
- Unexpected software design issue
- 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

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 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

**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
- 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

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