AN ANALYSIS OF ELECTRONIC HEALTH RECORD-RELATED PATIENT SAFETY CONCERNS

HARDEEP SINGH, MD, MPH
MICHAEL E. DEBAKEY VA MEDICAL CENTER
BAYLOR COLLEGE OF MEDICINE

DEAN SITTIG, PHD
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER
Design, development, implementation, use, and evaluation of health IT is complex and prone to failure.

Also happens to be well-covered in the media.
Smokers prescribed Viagra to quit

Smokers trying to quit the habit were mistakenly prescribed anti-impotence drug Viagra by doctors.

NHS Greater Glasgow and Clyde said the error was due to a computer glitch at two city GP practices.

When GPs selected anti-smoking pill Zyban, computers selected sildenafil, the generic name for Viagra.

A health board spokeswoman said: "At no time was patient care affected by this as all prescriptions are subject to stringent double checking."

The e-Formulary computer system used by GPs automatically selects a list of the most popular drugs when doctors fill out prescriptions.

Some patients went to the pharmacy with a prescription for the anti-impotence drug instead of tablets to help them stop smoking.
Study Rationale

- EHRs can improve safety and efficiency of patient care, however...

- Increasing evidence that rapid implementation leads to unintended consequences and new patient safety concerns
Major National Reports


- ONC’s Health IT Patient Safety Action and Surveillance Plan (2013)
What Makes This Area Complex?

- Detecting and preventing these safety concerns is challenging because of their complexity.

- Concerns involve not only potentially unsafe EHR technology but also clinical workflow issues, behaviors of EHR users, organizational policies and procedures, and rules and regulations that guide EHR-related activities.
8-dimensional Socio-Technical Model of Safe & Effective Health IT Use

Organizational Policies, Procedures, & Culture
Workflow & Communication

User Interface

Content

Hardware & Software

Personnel

Measurement & Monitoring

External Rules & Regulations

Sittig Singh QSHC 2010
Why Study VA’ EHR Use?

- Successfully used a comprehensive EHR since 1999
- Considered an international leader in both use of health IT and patient safety initiatives
- As an early adopter, the VA has evolved into a “learning system”
- Dedicates resources to investigation, analysis and EHR-related safety improvements
In a bid to describe common EHR-related safety concerns and understand their characteristics, we used a comprehensive, “sociotechnical” approach to analyze completed EHR-related safety investigations from voluntary reports within the VA.
METHODS – Design & Setting

- Retrospective analysis of completed investigation reports about EHR-related safety concerns
- 2005 - VA created Informatics Patient Safety (IPS) system for reporting of EHR-related safety concerns
  - Non-punitive
  - Voluntary
  - Only health IT-related reports
  - Clinical or administrative users can report
  - Most common reporting method is by notification to local IT staff
- Local IT determines need for escalation to national level
- IPS analysts at national level investigate reports
METHODS – Design & Setting

IPS investigation goals
- Understand system states and user actions preceding the safety concern
- Identify the underlying root causes
- Replicate the incident

Scored according to potential severity, frequency, and detectability
- Low score – solution dependent on available resources
- Intermediate score – solution (i.e. training or software modification) mandatory
- High score – immediate action (i.e. software patch or safety notification) required
METHODS – Design & Setting

- IPS makes recommendations to software developers, individual medical facilities, or other relevant stakeholders

- Final closed investigation contains:
  - Narrative of the incident
  - Details of investigation by IPS and IT staff
  - Solutions identified

- Provides additional contextual details compared with traditional event reports
METHODS – Data Collection

- Identified closed investigations with full analyses and narratives with meaningful information
- Excluded incidents related to editing or merging records (not routinely analyzed by IPS)
- Extracted 100 records meeting criteria
Example Investigation Report

**Subject:** Remote Data Interoperability (RDI) is unavailable. Several VA Medical Centers reported RDI is not connecting. VistA Outpatient Pharmacy users are seeing the following message when processing orders: “Remote data not available. Only local order checks are processed.”

<table>
<thead>
<tr>
<th>Case ID: 52</th>
<th>Application(s) involved:</th>
<th>Risk Score total: 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code: HIE, Med</td>
<td>Outpatient Pharmacy</td>
<td>Severity = 4, Frequency = 2, Detectability = 3</td>
</tr>
<tr>
<td></td>
<td>Health Data Repository</td>
<td>CPRS</td>
</tr>
</tbody>
</table>

**Overview:**
A Veterans Administration Medical Center (VAMC) reported that Remote Data Interoperability was unavailable. This resulted in a dialog whereby numerous VA Medical Centers were experiencing the same issue. Veteran’s Health Information Systems and Technology Architecture (VistA) and Computerized Patient Record System (CPRS) users were receiving the following message: “Remote data not available. Only local order checks are processed.” This indicated that connectivity to the Health Data Repository (HDR-2) had been lost, so remote order checks were not done. The issue reported resulted in a patient receiving a prescription for Lortab (acetaminophen/hydrocodone) when the patient was allergic to hydrocodone. The allergy to hydrocodone was documented on the patient's CPRS chart at another VA medical center, but not at the VA medical center prescribing the Lortab. The patient noticed the product name and recognized that they had a previous adverse reaction and returned to the facility to obtain a replacement prescription for an alternate analgesic. At the time of the order, remote order checking was not available for the prescriber or the pharmacist. While the pharmacist was processing the prescription, he/she may not see an alert from Remote Data Interoperability (RDI) during the finishing of the prescription. In this case, during the pharmacist verification step, the RDI order check did not display and pharmacist saw the message: “Remote Order Checking not available – checks done on local data only”. As described here the patient was prescribed and received a prescription for Lortab when they did have an allergy to the medication. In this case the prescription was discontinued until the informatics pharmacist was able to locate the remote allergy information. This resulted in a two hour delay in processing the prescription.

Another report presented as: VAMC B had a patient with a documented adverse reaction to lisinopril in their system. The reaction the patient experiences when ingesting lisinopril is angioedema (localized
METHODS – Data Analysis

- Used framework analysis method - 5 stages
  - **Familiarization** – two authors independently reviewed and summarized the reports
  - **Thematic analysis** – guided by 8-dimension sociotechnical model
  - **Indexing** – concern indexed according to:
    - underlying or contributory sociotechnical dimension(s)
    - ‘phases’ of safety related to EHR implementation
  - **Charting** – rereading and rearranging the reports in to groups that represented a common theme
  - **Mapping and interpretation** – emergent and recurring safety concerns were identified and described according to their sociotechnical origins and EHR safety phase.
RESULTS

- 100 unique investigations (Aug 09 – May 13)
- 344 reported incidents
- 55 VA facilities
- IPS-assessed safety scores
  - Low score – 48
  - Intermediate score – 38
  - High score – 14
# EHR-related safety concerns

## Category of Concern

### Unmet display needs (n=36)

<table>
<thead>
<tr>
<th>Contributory dimensions</th>
<th>Phase 1 unsafe technology or technology failures</th>
<th>Phase 2 unsafe or inappropriate use of technology</th>
<th>Phase 3 lack of monitoring of safety concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>hardware and software</td>
<td>22</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>human–computer interface</td>
<td>22</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>workflow and communication</td>
<td>10</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>clinical content</td>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Definition:** Mismatch between information needs and content display

### Examples

- User required to review multiple screens to determine status of orders or review active medications
- EHR allows simultaneous order entry on two different patients with subsequent medication order for wrong patient
- User interface wording and function inconsistent throughout EHR
- Order entry dialog allows conflicting information to be entered
EHR-related safety concerns

<table>
<thead>
<tr>
<th>Category of Concern</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software modifications (n=24)</td>
<td>Concerns due to upgrades, modifications, or configuration</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contributory dimensions</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>unsafe technology or technology failures</td>
<td>unsafe or inappropriate use of technology</td>
<td>lack of monitoring of safety concerns</td>
</tr>
<tr>
<td>hardware and software</td>
<td>21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>clinical content</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>human–computer interface</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Examples**

- Software designed at remote facility conflicts with local software use
- Despite testing, a new feature allows unauthorized users to sign orders
- Corrupted files or databases prevent entry of diagnoses and orders
- Corrupted files or databases prevent retrieval of complete patient information
# EHR-related safety concerns

<table>
<thead>
<tr>
<th>Category of Concern</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>System-system interface (n=17)</td>
<td>Concerns due to failure of interface between EHR systems or components</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contributory dimensions</th>
<th>Phase 1 unsafe technology or technology failures</th>
<th>Phase 2 unsafe or inappropriate use of technology</th>
<th>Phase 3 lack of monitoring of safety concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>hardware and software</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>workflow and communication</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>clinical content</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Examples

- Failure of patient context manager
- Remote internal server failure prevents patient data from being retrieved
- Radiology studies canceled in EHR remain active in Picture Archiving and Communication System (PACS) workflow
- Interface flaw causing duplicate patient record creation from external source
## EHR-related safety concerns

<table>
<thead>
<tr>
<th>Category of Concern</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hidden dependencies in distributed systems (n=17)</td>
<td>One component of the EHR is unexpectedly or unknowingly affected by the state or condition of another component</td>
</tr>
</tbody>
</table>

### Contributory dimensions

<table>
<thead>
<tr>
<th>Hardware and software</th>
<th>Workflow and communication</th>
<th>Clinical content</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>14</td>
<td>6</td>
<td>9</td>
</tr>
</tbody>
</table>

### Examples

- Transition of patients between wards or units not reflected in EHR, resulting in missed medications or orders
- Bulk ordering of blood products results in prolonged delay due to matching algorithm
- Template completion depends on remote data and user is unaware that network delays have caused incomplete data retrieval
- User assigns surrogate signer for patient alerts, but alerts not forwarded due to logic error not known by user
Key Study Implications

- Even with highly sophisticated technology and close monitoring, electronic health records (EHR)-related safety concerns can persist long after "go-live".

- Given the pace of EHR implementation within the US, we suggest that health care institutions using EHRs should build a robust infrastructure to monitor and learn from safety concerns.
Evolution of Safety (and Risks) – 3 Phases

- **Safe IT:**
  - Events unique/specific to EHRs; more likely early in implementation

- **Using IT safely:**
  - Unsafe or inappropriate use of technology
  - Unsafe changes in the workflows that emerge from technology use

- **Using IT to improve/monitor safety**
  - Monitor health care processes and patient outcomes to identify potential safety concerns before harm

Sittig & Singh NEJM Nov 2012
Phase 1 Concern

Sutter electronic records system crashed Monday

Kathy Robertson
Senior Staff Writer-
Sacramento Business Journal
Email | Twitter | LinkedIn | Google+

At about 8 a.m. Monday, the electronic health record system at seven East Bay hospitals, medical offices and clinics went dark. The meltdown continued through late afternoon or early evening, according to early reports from the California Nurses Association.
Too many electronic health record alerts may be leading doctors to skip them

Your doctor may be more likely to ignore your test results if they come electronically.

A new study published in the JAMA Internal Medicine on Mar. 4 revealed that doctors receive about 63 electronic health record (EHR)-based alerts each day, which are supposed to let them know about abnormal patient results. And, almost one-third of the doctors surveyed — about 30 percent — admitted that they had missed some results because of too many alerts.

"If you're getting 100 emails a day, you are bound to miss a few. I study this area and I still sometimes miss emails. We have good intentions, but sometimes getting too many can be a problem," Dr. Hardeep Singh, chief of health policy, quality, and informatics at the Michael E. DeBakey Veterans Affairs Medical Center, in Houston, told TIME.
Suggested Approach

Phase 1: Make HIT safe

Phase 2: Use HIT safely

Phase 3: Use HIT to improve safety

EHR-enabled Healthcare system

Meeks et al JAMIA 2013

Paper-based healthcare system

Sociotechnical Work System

Measurement & Monitoring

External Rules & Regulations

Internal Organizational Features

Workflow & Communication

Hardware & Software

Clinical Content

Human-Computer Interface

People
Significance for your Institutions?

- Few healthcare systems currently have comprehensive reporting and analytic infrastructure similar to the VA's.

- Thus, our findings may be useful in guiding broader proactive efforts to monitor and improve safety.
Not Just a Technology problem

- Recommend taking a ‘sociotechnical’ approach to understand and fix these issues
  - Study suggests that technology-based solutions alone will only partially mitigate concerns
  - Interventions to improve EHR-related safety should encompass the people, organizations, systems, and policies that influence how EHRs are used (see general mitigating procedures in Table 3)
Strengths

- Use of an information-rich data source
- An independent human factors and informatics investigation
- Detailed narratives
  - Level of detail enabled a more robust analysis in terms of understanding the larger sociotechnical context around event
- Nationwide distribution of our sample
- Sophisticated implementation and use of the EHR across the VA healthcare system
Limitations

- Incidents related to single EHR within a single healthcare system thus might not be generalizable
- Sample size
- Our findings may not represent all types of EHR-related safety concerns
- Did not analyze additional data on patient outcomes as a result of these concerns
- <10% of errors captured through reporting and such data does not allow us to calculate prevalence rates
What Next?

- How do we develop and operationalize sophisticated monitoring systems to unearth the complex mix of human and technological causes behind these problems?
  - Need to detect and address safety concerns long after EHR implementation and "go-live" has occurred
- A national reporting and analysis infrastructure?
- Proactive risk assessments to identify safety concerns
Need More Guidance for the Frontlines

- Clinicians/institutions unaware of best practices for safe EHR implementation & use

- Difficult to identify errors embedded in flawed interfaces between components of the EHR

- Solutions cannot be addressed through improvements in technology alone

The SAFER Guides: Empowering Organizations to Improve the Safety and Effectiveness of Electronic Health Records. *American Journal of Managed Care*, 2014
“SAFER Guides”

- ONC-sponsored “Safety Assurance Factors for EHR Resilience (SAFER) project”
- Proactive risk assessment and guidance
- Self-assessment; not meant to be regulatory
  - Focused on high-risk areas
  - Nine guides including Test Results Reporting and Follow-up

http://www.healthit.gov/safer

Singh et al BMC Med Inf 2013
Each SAFER Guide has between 10-25 “recommended practices”

“What” to do to optimize the safety and safe use of the EHR

Practices assessed as “fully implemented,” “partially implemented,” or “not implemented”
Planning Worksheets

- Help organizations/practices set goals and track progress

- Provide rationale to explain “why” each recommended practice is important

- Provide examples to operationalize each recommended practice
  - Examples illustrate “how” the recommended practices could be implemented
The Checklist is structured as a quick way to enter and print your self-assessment. Your selections on the checklist will automatically update the related section of the corresponding recommended practice worksheet.

### Recommended Practices for Phase 1 — Safe Health IT

<table>
<thead>
<tr>
<th>Recommended Practice</th>
<th>Implementation Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Test names, values, and interpretations for laboratory results are stored in the EHR as structured data using standardized nomenclature.</td>
<td>Worksheet 1</td>
</tr>
<tr>
<td>2. Predominately test-based test reports (e.g., radiology or pathology reports) have a coded (e.g., abnormal/normal at a minimum) interpretation associated with them.</td>
<td>Worksheet 2</td>
</tr>
<tr>
<td>3. Functionality for ordering tests and reporting results is tested pre- and post-go-live.</td>
<td>Worksheet 3</td>
</tr>
<tr>
<td>4. After system changes in components or applications related to CPOE and diagnostic services, the data and data presentation are reviewed to ensure accuracy and completeness.</td>
<td>Worksheet 4</td>
</tr>
</tbody>
</table>

### Recommended Practices for Phase 2 — Using Health IT Safety

<table>
<thead>
<tr>
<th>Recommended Practice</th>
<th>Implementation Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Orders for diagnostic tests are placed using CPOE and electronically transmitted to the diagnostic service provider (e.g., laboratory or radiology).</td>
<td>Worksheet 5</td>
</tr>
<tr>
<td>6. The EHR is able to track the status of all orders and related procedures (e.g., specimen received and collected or test completed, reported, and acknowledged).</td>
<td>Worksheet 6</td>
</tr>
<tr>
<td>7. The ordering clinician is identifiable on all ordered tests and test reports, and, if another clinician is responsible for follow-up, that clinician is also identified in the EHR.</td>
<td>Worksheet 7</td>
</tr>
<tr>
<td>8. When test results are amended, the change is clearly visible in the EHR and printed reports.</td>
<td>Worksheet 8</td>
</tr>
<tr>
<td>9. When test results are changed or amended, the ordering clinician and other clinicians responsible for follow-up are notified electronically. For clinically significant changes, the clinicians are also contacted directly.</td>
<td>Worksheet 9</td>
</tr>
</tbody>
</table>

The Worksheet provides guidance on implementing the Practice. To the right of each Recommended Practice is a link to the Recommended Practice Worksheet in this PDF.

The Phase associated with the Recommended Practice(s) appears at the top of the column. Click on the link to access more information about the Phases and Principles from the website.

The Recommended Practice(s) for the topic appear below the associated Phase.
In Closing…

- Patient safety in a health IT-enabled setting is an evolving concept
- Surveillance to detect and address safety concerns long after EHR implementation
- Proactive risk assessment (such as through SAFER guides) could be a place to start
Acknowledgements of Funding Support

Veterans Affairs Health Services Research & Development
Veterans Affairs National Center for Patient Safety
National Institutes of Health
Agency for Healthcare Research and Quality
Office of the National Coordinator for Health Information Technology

Thank You

No disclosures