When EHRs Cause Patient Harm: Lessons from Malpractice
Thursday, March 3, 2016
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Conflict of Interest

• Trish Lugtu, CPHIMS
• Has no real or apparent conflicts of interest to report.
Agenda

• Defining EHR-related patient harm

• Prevalence of EHR- and HIT-related factors in medical professional liability malpractice claims and suits

• Lead the way toward managing EHR risk through a simplified approach
Learning Objectives

• Classify the EHR-related contributing factors that cause patient harm identified through an analysis of medical malpractice claims and case studies
• List the top factors leading to EHR-related patient harm
• Develop an approach to managing prioritized EHR risks
A Focus on HIT Safety Realizes Benefits for the Value of Health IT

http://www.himss.org/ValueSuite
Constellation’s Footprint

- 21,000+ providers
- 2,700+ clinics
- 600+ hospitals/facilities
Session Roadmap

PART ONE
• Patient harm

PART TWO
• Prevalence of EHR/HIT factors

PART THREE
• Reducing EHR-related risk
Defining Patient Harm
A broken interface isn’t just an I.T. issue to the patient whose life depends on it.
In Mary’s case
Advanced Uterine Carcinosarcoma
Advanced Uterine Carcinosarcoma

Source: American Cancer Society, Inc. “Survival by stage of endometrial cancer.”
What was in the radiologist’s note on day 19?

• New orders/results process implemented
• Physicians not trained on new workflow
• Notifications/sign-offs not configured for all providers
• This was a follow-up systems failure

The uterus demonstrates central decreased attenuation raising the possibility of underlying neoplastic changes. **Ultrasound is recommended for further evaluation.**
EHR is *never* the only factor

- Initial misinterpretation of scan
- Lack of communication amongst providers
- Failure to respond to repeated symptoms
- Cognitive bias by urologist

Common underlying themes
Allegations and harm

Diagnosis-related allegations
• **Patient died** following failure to diagnose and treat small bowel obstruction when abd x-ray not routed correctly in EHR.

Medication-related allegations
• **Patient died** following anaphylactic reaction to amoxicillin. Known drug allergy with no alert.

Medical treatment allegations
• **Delayed treatment** for DVT when orthopedist was allowed to mark result as “done” without reviewing.

Surgical treatment allegations
• **Vision loss** resulted when LASIK converted to PRK during procedure. No place for pt risk factors to be documented (not good PRK candidate). Additionally, X-ray had been deleted to save storage space.
Prevalence of EHR and HIT Factors
The risk manager should be involved in all stages of the health IT project... not only at the end when there’s a problem.

Karen P. Zimmer, M.D., MPH, FAAP
Medical Director
ECRI Institute PSO
Malpractice claims data as indicators
All allegations

2,300+ claims & suits

$329+ million total incurred costs

How often are EHR-related factors involved?

1.1% claims & suits, N=26

MMIC N=2,339 PL cases asserted 2010-2014
Delay from clinical event to case

Clinical event

Cases asserted
Potential for events to increase

All allegations

2,300+ claims & suits

$329+ million total incurred costs

How often are EHR-related factors involved?

1.1% claims & suits, N=26

2.4% total incurred costs, $7.8 million

MMIC N=2,339 PL cases asserted 2010-2014
Allegations with EHR-factors

MMIC N=26 PL cases with at least one EHR-related factor, asserted 2010-2014
Injury severity

High severity outcomes account for 98.5% total incurred costs for allegations with EHR factors

MMIC n=26 PL cases with at least one EHR-related factor, asserted 2010-2014
Digging Deeper

- In 2013, MMIC partnered with Harvard-based CRICO Strategies
- Proprietary clinical coding taxonomy for medical malpractice claims

Comparative Benchmarking System (CBS)

300,000+ open/closed cases
165,000+ physicians
500+ hospitals
30+ academic and teaching hospitals

Top EHR-related factors

- User errors - miscellaneous: 17%
- System and software design: 15%
- Hybrid records/conversion issues: 14%
- Incorrect information: 13%
- Routing of electronic data: 9%
- Pre-populating/copy & paste: 8%
- System dysfunction or malfunction: 8%

*A case will often have multiple factors identified.

CBS N=248 PL cases with 1 or more EHR-related contributing factor

Unsafe use vs. unsafe technology

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Vision loss
Improper performance of eye surgery

- Insufficient area for documentation
- IT staff had deleted image files of patient scans to free up room in computer
Top EHR-related factors

- User errors - miscellaneous: 17%
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Death
Failure to treat bowel obstruction

• Emergency physician contacts primary care for consult of Crohn’s patient
• Two physicians in clinic were tag teaming consult
• Relying on documentation that wasn’t converted
• EHR was just implemented
Top EHR-related factors

- User errors - miscellaneous: 17%
- System and software design: 15%
- Hybrid records/conversion issues: 14%
- Incorrect information: 13%
- Routing of electronic data: 9% (Most frequent in MMIC cases)
- Pre-populating/copy & paste: 8%
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Electronic_Health_Record_Related_Events_in_Medical.99624.aspx
Delayed diagnosis

• New EHR lab module
• Lab results didn’t trigger a notification
• MD failed to view results
• Missed diagnosis of lung cancer
Reducing EHR Risks
EHR is a huge change in the way health care is delivered.

Dean F. Sittig, Ph.D.
Lead the way in three steps

1. build a common language
2. establish rights and responsibilities
3. simplify your approach
Build a common language

EHR

Monitoring & Management

Workflow & Communication

External Rules & Regulations

Organizational Culture

People

Hardware & Software

Clinical Content

User Experience
2 Establish rights and responsibilities

“To improve healthcare quality, a balance must be achieved between rights and responsibilities of EHR users”

Rights and Responsibilities

- Uninterrupted access to records
- Follow security practices

- Access to see all necessary data
- Maintain accurate and up-to-date records

- Succinct patient summaries
- Spend time with the patient

- Ability to override computer-generated interventions
- Justify overrides and be accountable for decisions

- Rationale for clinical decision support
- Continue to use sound medical judgment

2 Rights and Responsibilities

- Reliable performance measurement
  - Review performance feedback and act upon it

- Safe electronic health records
  - Report safety hazards appropriately

- Training and assistance
  - Maintain proficiency and ask for help

- Compatibility with real world clinical workflows
  - Engage in the process to design workflow

- Facilitation of communication coordination and teamwork
  - Use EHR in ways that fosters teamwork

Simplified Approach

1. Incorrect patient identification
2. Extended EHR unavailability
3. Failure to heed warnings and alerts
4. Data exchange breakdowns
5. Failure to identify, find, or use the most recent data
6. Misunderstandings about time
7. Wrong item selected in drop down
8. Open or incomplete orders

Source:
Simplified Approach

- Don’t miss issues
- At the help desk
- Raising the patient safety flag

Simplify EHR Risk Management
Simplified Approach

Unsafe Technology

- System design/configuration
- Electronic routing of data
- System failure, unable to access data
System design

Improper performance of eye surgery led to patient’s vision loss because of inadequate area for documentation on important details. X-ray was deleted to free up storage.

Don’t miss issues
- Patient identifiers on each screen
- Understand your medical record retention policies
- Does information overlap/already exist elsewhere?

At the help desk
- Look for trends-physician complaints re: templates, etc.
- Review with risk management and patient safety

Raising the patient safety flag
- Periodically ask physicians where they wish they had more space to document
- Provide a simple way for clinicians to let you know about issues
Electronic routing of data

Critical test result incorrectly routed in the EHR.

Physician never saw the result and treated patient for over a year.

Patient diagnosed with cancer by another physician.

Don’t miss issues

- Orders whose results are reported missing, for whatever reason.
- Any report of patient receiving incorrect or unnecessary medications.
- Clinicians report inconsistencies on information transferred between systems.
- Whether an interface error log is checked for routing failures and description of process to remedy.

At the help desk

- Look for trends in help desk tickets involving issues with orders and results, as well as notifications and alerts. Review regularly with clinical.

Raising the patient safety flag

- Do you know how to tell if orders/results are failing? Is this a manual process or can someone be alerted?
- How often is it failing? Why is it failing?
- What can you do to make sure critical results are seen?
System failure

Ultrasound ordered on paper during downtime.

Paper result scanned to EHR when system came back up without physician notification set for critical result.

Result not seen resulting in delayed diagnosis of breast cancer.

Don’t miss issues

- No notification procedures for planned downtime
- No robust HIPAA Security policies & procedures
- No preprinted paper forms for emergency mode operations
- No written policies and procedures for post-downtime activities, ie scanning or delayed-entry of paper forms
- For highest known clinical risks, has information that is paramount to have available identified?

At the help desk

- The plan for disaster recovery, business continuity, emergency mode operations, and the backup paper forms used during downtime

Raising the patient safety flag

- Ask clinicians, “From a patient safety perspective, what information is crucial to have access to, if systems were to become unavailable?”
3 Simplified Approach

Unsafe Use

- Hybrid/Conversion issues
- Pre-populating Copy & Paste
- Defaulted data
Hybrid or Conversion Issues

Over several visits, patient’s foot pain escalated and other symptoms appeared. Physician didn’t have access to patient history because of a recent system conversion. Delayed diagnosis of vascular issue resulted in leg amputation.

Don’t miss issues
- No prior visits or history for established, high risk patients (w/co-morbidities, disease registries)
- Dates and tests results not converted, especially abnormal results
- A method to alert in EHR charts when a paper record exists/is available

At the help desk
- Physicians who are concerned that they don’t have access to patient history – ask what and why

Raising the patient safety flag
- Thinking back on past conversions, are these issues still current in your system? How can you (collectively) rectify, moving forward?
Pre-populating & Copy/Paste

After abdominal surgery, patient was prematurely discharged because normal vital signs were copied forward post surgery.

Patient suffered complications and was readmitted for further surgery.

Don’t miss issues
- Extensive use of copy/paste functionality
- Which pre-populating fields are high risk for error – eg) not normally assessed/should be assessed and shouldn’t default to “normal”
- See ECRI’s Copy/Paste Toolkit in resources

At the help desk
- Look for trends in copy/paste issues
- Can volume of copy/paste be audited or limited in any way? Per physician?

Raising the patient safety flag
- Understanding for which fields could be pre-populated
- Review screens for information with clinical pre-populated fields - especially on medications, orders, HPIs, review of systems, other assessments, notes

Which fields can be pre-populated?
Defaulted data

Multiple overdoses in one hospital from opioid narcotics.

Discovered vast majority of patients who received naloxone received higher doses than recommended.

Default dose was set to appropriate amount for someone with opioid tolerance.

Don’t miss issues

- Review screens for information with defaults - especially on medications, orders, HPIs, review of systems, other assessments, notes
- Ask providers if they wish they could change default values, which ones, to what, and why?
- Defaults that are inappropriately set

At the help desk

- Look for trends of complaints about defaults
- Can you monitor percent of expected defaults as a trend?

Raising the patient safety flag

- How are defaults set, and how often are they reviewed?
- Can defaults be set per provider? Do you have a policy for periodic review for the provider?
Closing thoughts
Failing to plan is planning to fail.
- Alan Lakein
What would have happened?

Had Mary’s urologist had processes in place...

• to check open orders
• to audit how test results were routinely routed
• for risk managers and IT to collaborate on risk management

Would Mary have been diagnosed sooner?
Next steps

• Collaborate with risk managers and clinical staff
  – Review known risks
  – Go through the checklists
  – Build your own checklists together

• Help non-IT team members to understand
  – How information flows through the EHR from beginning to end for identified risks
  – They understand the clinical flow, but may be intimidated by the technology.

Remember…

A broken interface, isn’t just an IT issue to the patient whose life depends on it.
Guidance on managing EHR risk

- **ONC Health IT and Safety**
  http://www.healthit.gov/policy-researchers-implementers/health-it-and-safety

- **ONC Health IT Safety Webinar Series**
  http://www.healthit.gov/safer/health-it-safety-webinar-series

- **ECRI Center for Health IT Safety and Innovation**
  https://www.ecri.org/resource-center/Pages/HIT.aspx

  *Health IT Safe Practices: Toolkit for the Safe Use of Copy and Paste (Newly Launched!)*
Guidance on managing EHR risk

- Safety Assurance Factors for EHR Resilience (SAFER) Guides
  http://www.healthit.gov/policy-researchers-implementers/safer

- Guide to Reducing Unintended Consequences of Electronic Health Records
  http://www.healthit.gov/unintended-consequences/

- AHRQ Workflow Assessment for Health IT Toolkit
  http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit
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26 Patients 2010-2014
HIT safety is crucial to quality care.

$7.8 Million 2010-2014
HIT safety is crucial to loss prevention.

REALIZING THE VALUE OF HEALTH IT
Health IT creates five kinds of value of benefit to patients, healthcare providers and communities.

S SATISFACTION
T TREATMENT/CLINICAL
E ELECTRONIC SECURE DATA
P PATIENT ENGAGEMENT AND POPULATION MANAGEMENT
S SAVINGS

Questions

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