Agenda

• Dana Siegal RN, CPHRM
  – Lessons learned through the analysis of medical malpractice claims involving EHR events

• Mary Beth Blake J.D.
  – Lessons learned through collaborations between providers and HIT Developers
Lessons Learned through the analysis of Medical Malpractice Claims

- Understanding the impact of EHR as a contributor to medical errors and claims
- Developing solutions that focus on realized events impacted by the EHR
Conflict of Interest
Dana Siegal RN, CPHRM

Has no real or apparent conflicts of interest to report.
HITECH Act Summary

- **2009 - American Recovery and Reinvestment Act** signed into law by the federal government. *(ARRA = investment in measures to modernize our nation's infrastructure)*

- Included in this law is **$19.2 Billion** intended to be used to **increase the use of Electronic Health Records (EHR)** by physicians and hospitals;

  - This portion of the bill is called, the **Health Information Technology for Economic and Clinical Health Act**, or the **HITECH Act**.

- Through the **HITECH Act**, the ONC* was charged with developing an initial set of **HIT standards**, and creating an incentive program for meaningful users of EHR certified technology.

  *Located within the Department of HHS, ONC is the Office of the **National Coordinator for Health Information Technology (ONC HIT)**.*
So how are we doing?

SOURCE: ONC/AHA, AHA Annual Survey Information Technology Supplement

• In 2014, 3 out of 4 (76%) hospitals had adopted at least a Basic EHR system. This represents an increase of 27% from 2013 and an eight-fold increase since 2008.

• Nearly all reported hospitals (97%) possessed a certified EHR technology in 2014, increasing by 35% since 2011.

• Since 2008, office-based physician adoption of any EHRs has nearly doubled, from 42% to 83%, while adoption of Basic EHRs has nearly tripled from 17% to 51%. Between 2013 and 2014, adoption of any EHR grew by 6% and Basic EHR adoption grew by 5%.

• By the end of 2014, about 8 in 10 (83%) of office-based physicians had adopted any EHR[2] and about half (51%) adopted a "Basic EHR"[1].
Three out of Four Hospitals have a Basic EHR System.

Figure 1: Percent of non-Federal acute care hospitals with adoption of at least a Basic EHR with notes system and possession of a certified EHR: 2008-2014

NOTES: Basic EHR adoption requires the EHR system to have a set of EHR functions defined in Table A1. A certified EHR is EHR technology that meets the technological capability, functionality, and security requirements adopted by the Department of Health and Human Services. Possession means that the hospital has a legal agreement with the EHR vendor, but is not equivalent to adoption.

*Significantly different from previous year (p < 0.05).

SOURCE: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement
Percentage of Office-based Physicians with Electronic Health Record System
2004 - 2014

- Any EHR
- Basic EHR

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The Data Source
CRICO’S Comparative Benchmark System
Using medical malpractice data to drive risk mitigation for <30 years
Comparative Benchmark System (CBS):
Over 300,000 Medical Malpractice cases for analysis, trending and case study

- Captive and Commercial Insurers
- Open and closed claims and suites
- 23 Academic organization and their affiliates (MD clinics / practices... Community Hospitals... )
- Represents ~30% of the National Practitioner Data Bank (reported claims w/ $$ - 2007-2011)

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Volume</th>
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</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>&gt; 400</td>
</tr>
<tr>
<td>Physicians</td>
<td>180,000+</td>
</tr>
<tr>
<td>New cases/year</td>
<td>8,000+</td>
</tr>
</tbody>
</table>
Learning from the past to plan a better future

Import Client Claims

Apply Clinical Coding

Produce Data Analysis

Prioritize Interventions

Clinical Coding

- Experienced clinicians
- Documented process and guidelines
- Training & ongoing education
- Structured governance & oversight
- Ongoing audits / updates / revisions

Analyzed Data

- Individual Reports
- Comparative Data
- Collaboration
- Solutions

• Claim Files
• Medical Records
To me, error analysis is the sweet spot for improvement

- A Fentanyl order is altered by a decimal point;
- The EHR automatically “signed” a test result when in fact it had not been read; MD;
- Pt complained of “sudden onset of chest pains with burning epigastric pain, some relief with antacid”; Complaint field was too small;
- OB patient requested tubal ligation at the time of her 4th planned Caesarian section. Noted on paper record in office but not transferred to new EMR.
- Critical blood gas value misrouted to the wrong unit;
- Critical ultrasound result routed to the wrong tab in the EHR;
- MD not able to access nursing ED triage note, which would have changed management;
- History copied from a previous note which did not document patient’s new amiodarone medication;

To me, error analysis is the sweet spot for improvement

Donald Norman Scientist

#HIMSS16
Learning from errors of the past is the wisdom and success of the future.

Dale Turner
Musician

- Fentanyl order is altered by a decimal point; **patient died**
- The EHR automatically “signed” a test result when in fact it had not been read; MD, and thus patient **did not receive results** of co-existing (to lung) **liver cancer and was not treated**
- Pt complained of “sudden onset of chest pains with burning epigastric pain, some relief with antacid”; Complaint field was too small; entry noted only as “epigastric pain”; no EKG done; patient **experienced a serious cardiac event later that day**
- OB patient requested tubal ligation at the time of her 4th planned Caesarian section. Noted on paper record in office but not transferred to new EMR. Covering MD delivered the baby but did not know of request for tubal ligation; Patient **became pregnant 6 months later**
- Critical blood gas value misrouted to the wrong unit; patient **expired from respiratory failure**
- Critical ultrasound result routed to the wrong tab in the EHR; MD never saw the result until a year later; **patient experienced delayed diagnosis of cancer**
- MD not able to access nursing ED triage note, which **would have changed management; patient died of subarachnoid hemorrhage**
- History copied from a previous note which did not document patient’s new amiodarone medication; **delayed recognition of amiodarone toxicity**

Learning from errors of the past is the wisdom and success of the future.

Dale Turner
Musician
The Data Analysis

Analysis of 248 Medical Malpractice Cases with a contributing factor of EHR
Medicine is the most noted service in cases with an EHR-related issue

- **Medicine** is the most prevalent service with 91 cases noting an EHR-related issue - Top Services
  - General Medicine
  - Cardiology
- **Surgery** is the 2nd largest service with 40 cases having a documented EHR-related issue - Top Services;
  - General Surgery
  - Orthopedics
- **Nursing** is the 3rd largest service with 32 cases noting an EHR-related issue
  - more prevalent in the **inpatient setting**, in part due to medication cases
Summary of findings - continued

<table>
<thead>
<tr>
<th></th>
<th>Ambulatory</th>
<th>Inpatient</th>
<th>Emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>146 cases</td>
<td>77 cases</td>
<td>25 cases</td>
</tr>
</tbody>
</table>

Top Allegations:
The majority of cases (90%) were represented by these 3 categories.

- medication errors (76 cases)
- diagnostic failures (69 cases)
- treatment events: (medical, surgical, or OB\GYN treatment (76 cases, 31%).

- **Contributing Factors identified the top issues were related to:**
  - system design
  - organizational conversion (hybrid record)
  - data routing
Medication (76 cases) and DX-related (69 cases) are most common allegations in cases with EHR-related contributing factor(s)

- **NUMBER OF CASES**
  - **Medication-related**: 76 cases
  - **Diagnosis-related**: 69 cases
  - **Medical Tx**: 57 cases
  - **Surgical Tx**: 31 cases
  - **OB-related Tx**: 27 cases
  - **Communication**: 16 cases
  - **Violation of Rights**: 15 cases
  - **Pt Monitoring**: 13 cases
  - **Breach of Confidentiality**: 12 cases
  - **Safety and Security**: 11 cases

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DISTRIBUTION BY ALLEGATION: N=248 PL cases with an EHR-related contributing factor.
Ambulatory cases are more prevalent - Inpatient cases have a greater % of high severity outcomes

<table>
<thead>
<tr>
<th>CASE TYPE</th>
<th># OF CASES</th>
<th>% OF CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory</td>
<td>146</td>
<td>59%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>77</td>
<td>31%</td>
</tr>
<tr>
<td>ED</td>
<td>25</td>
<td>10%</td>
</tr>
</tbody>
</table>

**TOP AMBULATORY LOCATIONS**

<table>
<thead>
<tr>
<th>LOCATION</th>
<th># CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hosp clinic/MD office</td>
<td>106</td>
</tr>
<tr>
<td>Ambulatory/day surgery</td>
<td>17</td>
</tr>
<tr>
<td>Radiology / Imaging</td>
<td>10</td>
</tr>
<tr>
<td>Ancillary Service</td>
<td>7</td>
</tr>
</tbody>
</table>

**TOP INPATIENT LOCATIONS**

<table>
<thead>
<tr>
<th>LOCATION</th>
<th># CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s room</td>
<td>28</td>
</tr>
<tr>
<td>OR/ Recovery</td>
<td>13</td>
</tr>
<tr>
<td>ICU, SICU, MICU, CCU</td>
<td>10</td>
</tr>
<tr>
<td>Inpatient Unit / other</td>
<td>7</td>
</tr>
<tr>
<td>Ancillary Service</td>
<td>4</td>
</tr>
</tbody>
</table>

Severity Scale: NAIC - High Severity = Death, Permanent Grave, Permanent Major, or Permanent Significant

DISTRIBUTION BY ALLEGATION: N=248 PL cases with an EHR-related contributing factor.
Design, conversion and data routing failures are key EHR contributors to malpractice cases

• In **Ambulatory** cases with an EHR issue:
  – 18% are **conversion** issues (paper to electronic or upgrades)
  – 14% are **design** issues

• In **Inpatient** cases with an EHR issue:
  – 16% are **design** issues
  – 13% are issues related to the electronic **routing of data**

• In **Emergency Medicine** cases
  – 20% are **design** issues
  – 12% are issues related to the electronic **routing issues**
Design, conversion and data routing failures are key EHR contributors to malpractice cases

<table>
<thead>
<tr>
<th>TOP EHR RELATED FACTORS IN 248 MED MAL CASES</th>
<th># CASES*</th>
<th>% OF ALL 248 CASES*</th>
</tr>
</thead>
<tbody>
<tr>
<td>System/software design issues</td>
<td>38</td>
<td>15%</td>
</tr>
<tr>
<td>Conversion issues (hybrid paper and electronics)</td>
<td>34</td>
<td>14%</td>
</tr>
<tr>
<td>Routing of electronic data</td>
<td>23</td>
<td>9%</td>
</tr>
<tr>
<td>Pre-populating / copy &amp; paste</td>
<td>20</td>
<td>8%</td>
</tr>
<tr>
<td>System failure (freeze / crash)</td>
<td>19</td>
<td>7%</td>
</tr>
</tbody>
</table>

These top 5 factors* account for half (51%) of the EHR issues contributing to med mal claims

* A case will often have multiple factors identified.

N=248 PL cases with 1 or more EHR-related contributing factor
The events...

• A Fentanyl order is altered by a decimal point;
• The EHR automatically “signed” a test result when in fact it had not been read; MD,
• Pt complained of “sudden onset of chest pains with burning epigastric pain, some relief with antacid”; Complaint field was too small;
• OB patient requested tubal ligation at the time of her 4th planned Caesarian section. Noted on paper record in office but not transferred to new EMR.
• Critical blood gas value misrouted to the wrong unit;
• Critical ultrasound result routed to the wrong tab in the EHR;
• MD not able to access nursing ED triage note, which would have changed management;
• History copied from a previous note which did not document patient’s new amiodarone medication;
### Distribution of Technology and User-related EHR issues in 248 malpractice cases*

<table>
<thead>
<tr>
<th>Technology Related Factors</th>
<th># Cases*</th>
<th>% of Technology Cases*</th>
</tr>
</thead>
<tbody>
<tr>
<td>System/Software design</td>
<td>38</td>
<td>24%</td>
</tr>
<tr>
<td>Routing of electronic data</td>
<td>23</td>
<td>15%</td>
</tr>
<tr>
<td>System failure (froze / crash)</td>
<td>19</td>
<td>12%</td>
</tr>
<tr>
<td>Integration of systems</td>
<td>16</td>
<td>10%</td>
</tr>
<tr>
<td>Failure of alert / alarm (to function as expected)</td>
<td>14</td>
<td>8%</td>
</tr>
<tr>
<td>Fragmented electronic health record</td>
<td>10</td>
<td>6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>User Related Factors</th>
<th># Cases*</th>
<th>% of User Related Cases*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion issues (hybrid paper and electronics)</td>
<td>34</td>
<td>14%</td>
</tr>
<tr>
<td>Incorrect information in EHR (not classified elsewhere)</td>
<td>32</td>
<td>13%</td>
</tr>
<tr>
<td>Pre-populating / copy &amp; paste</td>
<td>20</td>
<td>8%</td>
</tr>
<tr>
<td>EHR training and education</td>
<td>15</td>
<td>6%</td>
</tr>
<tr>
<td>Alert fatigue / workarounds</td>
<td>13</td>
<td>5%</td>
</tr>
</tbody>
</table>

*A case may have multiple factors identified. A small number of cases were categorized as “other” and are not represented here.

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

EHR serves a critical role in delivering safer care

• Ready access to (system-wide) coordinated medical records
• Decision support, clinical alerts, follow-up/screening reminders
• Tracking/trending of clinical data over time (e.g. Rx levels, VS, etc.)
• Quality reporting, billing, research, legal support

Claims data provides a unique lens into vulnerabilities of EHR

• Events w/ an EHR issue vs. an EHR event
• “Tip of the iceberg” insight into extent of issues and errors
• Severity of outcome is a result of the clinical setting – not the error
• EHR events rarely “stand alone” and must be understood in the context of broader system breakdowns and care failures
  o Clinical judgment factors
  o Communication factors
  o Policy and procedure factors
Next Steps: What can we do now...

1) **Organizational-wide response** that embraces the EHR as an integral part of your risk and patient safety programs
   - Model after other “safety” teams e.g. Biomed, Infectious Disease
   - Standard element in Adverse Event / RCA investigations
     - *not if* but *how* EHR was involved in the care process or event
     - track, trend and report e.g. falls and med errors / dashboards etc..

2) **System-wide awareness / education** re: what we *do* know
   - Share (develop) data outcomes & case studies that demonstrate the most frequent / know vulnerabilities in EHR use
   - Include EHR elements in M&Ms, Grand Rounds, safety meetings, team meetings, risk / leadership reports, dashboards
   - Review “awareness / action steps” for common vulnerabilities
     - Conversion / hybrid vulnerabilities (communication plan for org progress)
     - Routing issues / delay in obtaining results (follow up on delayed results)
     - Copy/paste and pre-populating issues (awareness of “old data”)
Next Steps (con’t):

3) **IT / Clinician collaboration (internal)** to understand provider needs, improve system design and function (where possible)
   - Help desk service must be robust enough to be responsive to “in the moment” needs in order to protect clinicians and patients from real time error
     - Minimize clinician frustration and resulting workarounds
   - Prioritize resolution of known issues (where this lies w/in Org IT)
     - Design and routing issues > 30 % of the cases
   - Maximize functionality / positive support elements of EHR
     - e.g. management of test result reporting and sign-off

4) **Vender / IT / Clinician collaboration** to understand / improve system design and usability functions:
   - For issues beyond the scope of internal IT management, we must engage Venders in efforts to define a common focus, language, and response to EHR issues
HIT Safety Lessons Learned
February 29, 2016
Mary Beth Blake, Senior Partner
Conflict of Interest
Mary Beth Blake, J.D.

Has no real or apparent conflicts of interest to report.
Learning Objectives

• Explain improvements made through collaborations between providers and HIT Developers
• Recognize tools created by providers to implement best practices
• Identify clinical decision support enhancements developed by providers to improve the functionality of the electronic health records
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
Cooperation Trumps Confrontation - Case Study in Successful Cooperation

• Home Health Agency ("HHA") was preparing the document submission for a ZPIC Audit of 40 patient records when it discovered an issue with the intake documentation
  
  – The time frame for submission of information to the ZPIC was short
  
  – Nurses’ signature that certified a compliant and complete intake process did not show up on the printed documents
Cooperation Trumps Confrontation (continued)

– The lack of signatures presented a situation where the intake documents were technically incomplete

– The “signature issue” dated back to implementation of the EMS and affected approximately 40% of the EMS charts
HHA’s Initial Investigation and Next Step

- HHA verified that the nurses had signed the records
- Signatures had been visualized on the screen by the supervisors who checked every initial assessment
- HHA reached out to its EMS Vendor for diagnosis and a request that: “The Problem be Fixed Immediately!!!”
DX Discovered

• The wrong “button” had been used by the supervisors to ‘verify” that the record was complete
• Some signatures could be recovered and printed and some could not
• The issue was traced to a combination of:
  – A “glitch” in the system, and
  – Training misunderstandings
Reactions

- HHA: Sue the Vendor!
- VENDOR: It wasn’t our fault
Next: All Involved Stepped Back And Took Deep Breaths and a Reality Check

- The response to the ZPIC was due in 30 days
- The system issues and training issues needed to be corrected
- Some of the signatures could be printed
- The supervising nurses always checked for the signature
- The nurse who evaluated the patient was documented as working on the day in question and could attest to the fact the record had been signed
Surprise Solution

• The attorneys looked for a solution that could be implemented quickly and that would lead to resolution of the signature issues

• The solution came from a fundamental tenant of their Attorney/Client relationships:

  1. Attorney Client Privilege (ACP)
  2. The Patient Safety Organization (“PSO”) protections were used
  3. The parties memorialized the fact that the parties had agreed that communication about this issue would only be used to resolve the issues created by the signature glitch
Elements of HHA’s Response to the ZPIC Auditors

• Description of how the ‘signature issue” was discovered
• Timely report to the ZPIC Auditor about the discovery of the signature issue
• Use of PSO protections and attorney client privilege to work toward solution
• A detailed explanation of the Signature Issue
  – When it was discovered
  – How and when the cause of Signature Issue was diagnosed
  – How the issue was corrected
Outcome --- Extraordinary!!

• All Glitches were diagnosed and corrected
• Training was modified to more effectively address the issue
• All signatures for time frame at issue that could be recovered were recovered by the EMS vendor
• HHA’s policies were improved
• Efforts of both parties were described in detail in the submission to the ZPIC ….AND…
The Final Results were Fantastic!!

• No adverse ZPIC finding based on the missing signatures AND

• The relationship between the Vendor and Provider was preserved and enhanced
Objectives Met

- Improvements thru collaboration
  - Better communication between the providers and the HIT staff from the vendor
  - Roles of PSO, the attorneys, and the EMS provider, and the health provider are now more clearly understood
  - Attorney Client Privilege and Confidentiality Agreement helped facilitate communication
  - Improved client satisfaction with the vendor
  - Solid relationship built between the EMS vendor and the health care provider
Questions?

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