Safety Implications of EHR/HIT

PSA Board Meeting
July 24, 2012

Erin Sparnon, MEng.
William M. Marella, MBA

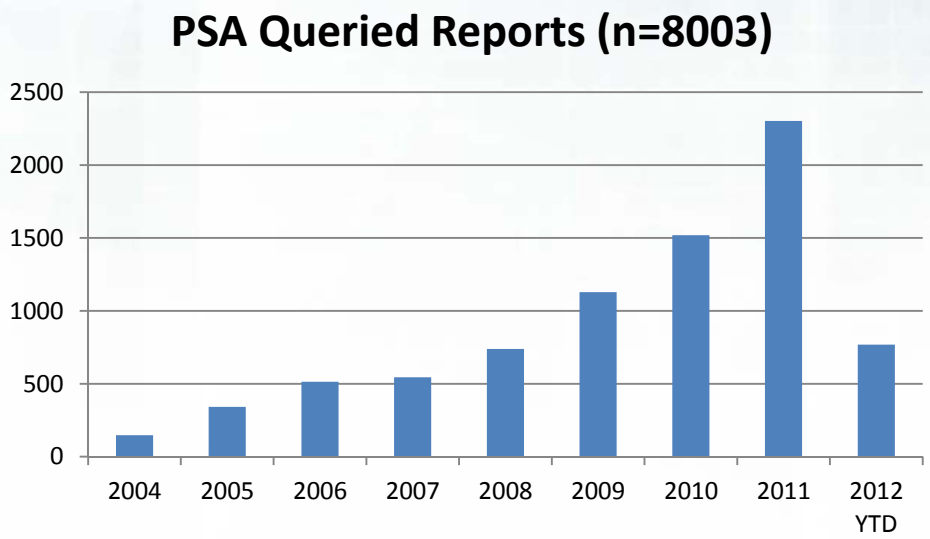
PENNSYLVANIA PATIENT SAFETY ADVISORY

Analyzing, Educating and Collaborating for Patient Safety

What does it take to have “safe” HIT?

- What if your x-ray is saved under the wrong patient?
- What if your test result goes missing?
- What if the media accesses a high-profile patient’s record?

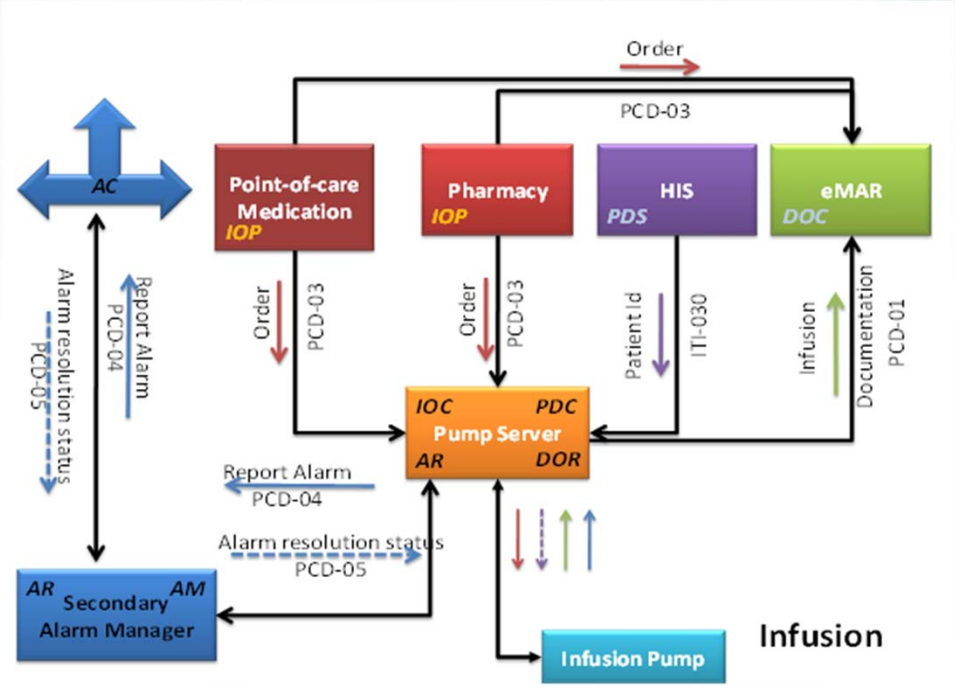
HIT/EHR Reports are Increasing



Reports Manually Classified as EHR/HIT			
Year	Incident Event	Serious Event	Total
2004	8		8
2005	32		32
2006	51	1	52
2007	59	1	60
2008	81	1	82
2009	139	2	141
2010	171		171
2011	298		298
2012 YTD	88	1	89
Total	927	6	933

Analyzing, Educating and Collaborating for Patient Safety

HIT is more than just EHR

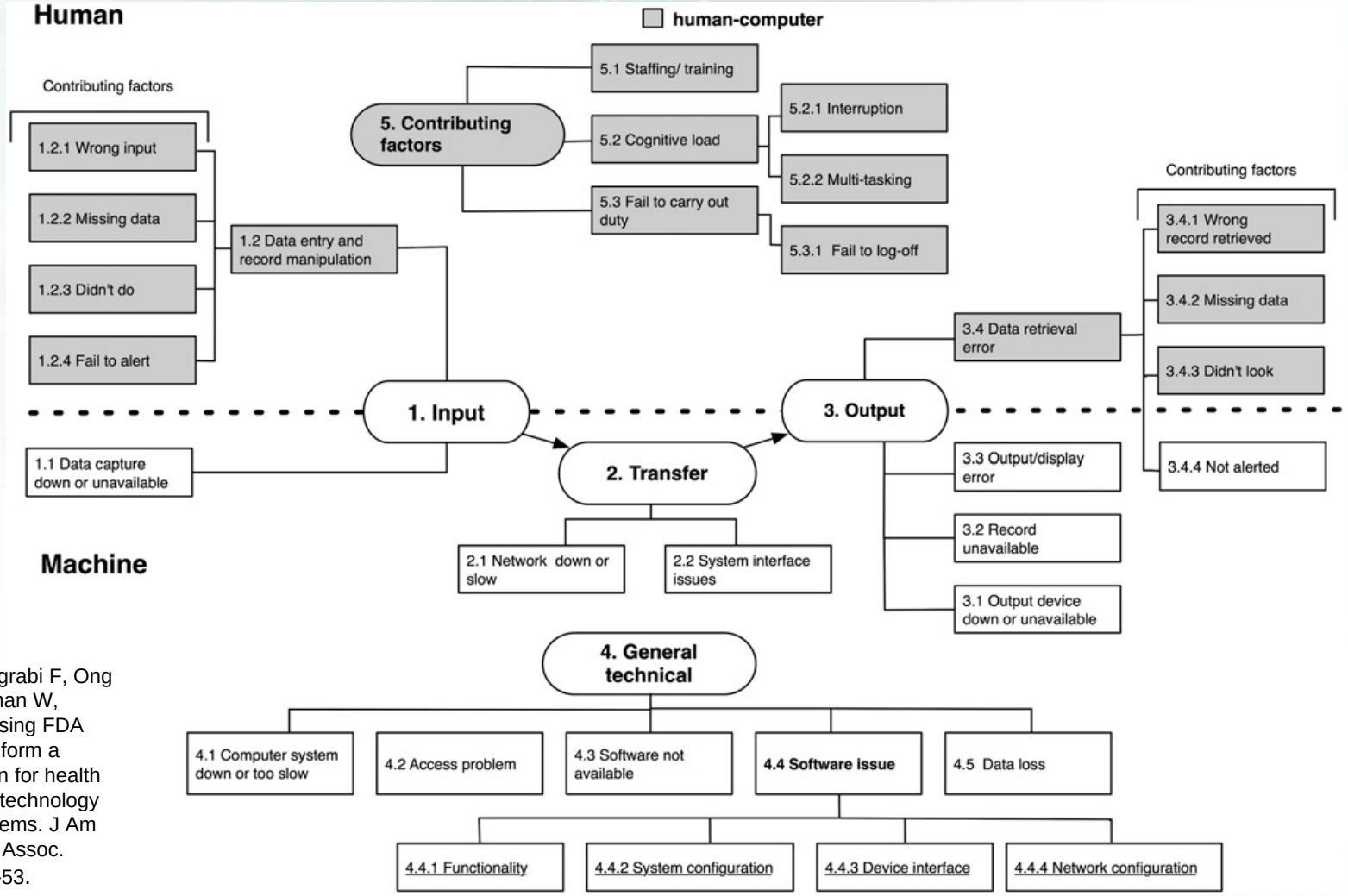


- Medical devices are increasingly being integrated into hospital information systems:
  - Build your own interface based on standards like IHE
  - Buy an interface product from your EHR supplier
  - Buy an interface product from a third-party integrator

Methodology

- Query of PSA database performed on 5/23/12: 8003 potentially EMR-related reports since 6/9/04
- Random sample of 1,568 (20%) reports
- Reports were tagged with a previously published classification system for HIT safety reports developed for use with the FDA MAUDE database
  - Farah Magrabi, Mei-Sing Ong, William Runciman, Enrico Coiera. Using FDA reports to inform a classification for health information technology safety problems. J Am Med Inform Assoc 2012;19:1 45-53 Published Online First: 8 September 2011 doi:10.1136/amiajnl-2011-000369
- Many reports received multiple tags, and we added 4 unique contributing factors

Tagging Methodology



Source: Magrabi F, Ong MS, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. J Am Med Inform Assoc. 2012;19:45-53.

Initial Findings- Reported Events

	Count	Percent of Relevant Reports
TOTAL	933	100%
1.2.1 Wrong input	538	58%
1.2.3 Didn’t do	238	26%
4.4.2 Software issue- system configuration	122	13%
3.4.1 Wrong record received	59	6%
2.2 System Interface Issues	54	6%
3.4.3 Didn't look	42	5%
3.2 Record Unavailable	31	3%
4.5 Data Loss	25	3%
3.4.4 Not Alerted	22	2%
4.1 Computer system down or too slow	21	2%
1.2.4 Failed to Alert	20	2%
1.2.2 Missing Data- Entry	18	2%
4.4.1 SW issue- functionality	15	2%
4.2 Access problem	7	1%
2.1 Network Down or slow	6	1%
4.3 Software not available	5	1%

Initial Findings- Contributing Factors

	Count	Percentage
Default Values caused trouble	85	9%
Paper vs. EHR mismatch	47	5%
Wrong field entered or viewed	22	2%
5.1 Staffing/training	21	2%
Wrong Units entered or selected	6	1%
5.2.1 Cognitive Load- Interruption	4	0%
Couldn't fix an error once identified	4	0%
5.3.1 Failure to log off	3	0%
5.2.2 Cognitive Load- Multi-tasking	2	0%

Entry Error

- 776 reports included either an incorrect entry of data (wrong input) or a failure to enter data (didn't do)

Pt. had TPN and Lipids hanging at 11 p.m. The night nurse did a chart check at 2:20 a.m. and found no order for TPN/lipids. She called the Pharmacy and they had no record of an order for TPN/lipids. However, the medication and the pharmacy label on the bags. Investigation indicates that the Pharmacist gave his computer User ID and password to the Tech and she processed the order on the wrong pt. Then the nurse did not verify an order before she hung these meds.

Entry Error

- EHR with clinical decision support is intended to reduce data input errors
  - EHR without CDS only fixes handwriting problems
- But what if the EHR user is not the caregiver?
  - Translation/omission errors with unit clerk or pharmacy technician entering an order or data
  - NIST guidance on allied health professionals' use of EHR http://www.nist.gov/customcf/get_pdf.cfm?pub_id=907991

System Configuration- Design

- 122 reports indicated problems with system configuration or design

MTHFR mutation C677T placed in Cerner. Purple top tube sent as per instructions in Cerner. When lab received the tube, they cancelled order because in SunQuest, the instructions stated yellow top tube. Investigation showed information in Cerner correct but in Sun Quest it was wrong. There are 2 MTHFR mutations. One requires purple top and the other a yellow top tube. The information in Lab's Sun Quest system lists yellow top for both. Lab QPI Specialist followed up with Lab Director and Sun Quest contact person to resolve issue so correct information is in both systems. MD re-ordered test and pt redrawn.

System Configuration- Design

- Every system in a facility requires extensive configuration to match policy and procedure
  - Initial configuration must support ordering, administration, and stocking practices
  - Coordination between connected systems
  - Change management- the “ripple effect”
- Many reports of system interface issues could be traced to a configuration error in one or more system

System Configuration- Defaults

- 85 reports indicated that default values caused trouble- especially time or dosing defaults

Pt was given tizanidine 8mg and approximately one hour later became unresponsive, apneic, and hypotensive. Condition C called and patient transported to the ICU. It was discussed by the attending on rounds that tizanidine was to be given in a small dose at night. The resident mistakenly ordered the default in the system of 8mg (not 2mg or 4mg as MD had discussed) and ordered it TID, not HS. House staff counseled.

System Configuration- Defaults

- Problems with default time and dosing values were particularly common
  - Scheduled times vs. “Now”, “Stat”
- Two competing drivers
  - Evidence-based, Standards-based Medicine says defaulting to protocol means fewer errors
  - Patient-Centeredness says outlier patients are placed at risk by defaults

Hybrid System Issues

- 47 reports included risks related to using both an electronic and a paper-based system at once

The medication was given to the patient by a RN just prior to that RN leaving her shift. The nurse relieving her gave a second dose of the medication after reviewing the written order for the medication. The relieving nurse did not verify the electronic medical record before administration of the second dose which would have indicated correctly that the medication was already administered.

Dose given 12 hours early. I started this med, signed out on flowsheet not SCM. Next shift thought med was q12h and was able to sign out in SCM since my initial dose was not recorded on computer

Hybrid System Issues

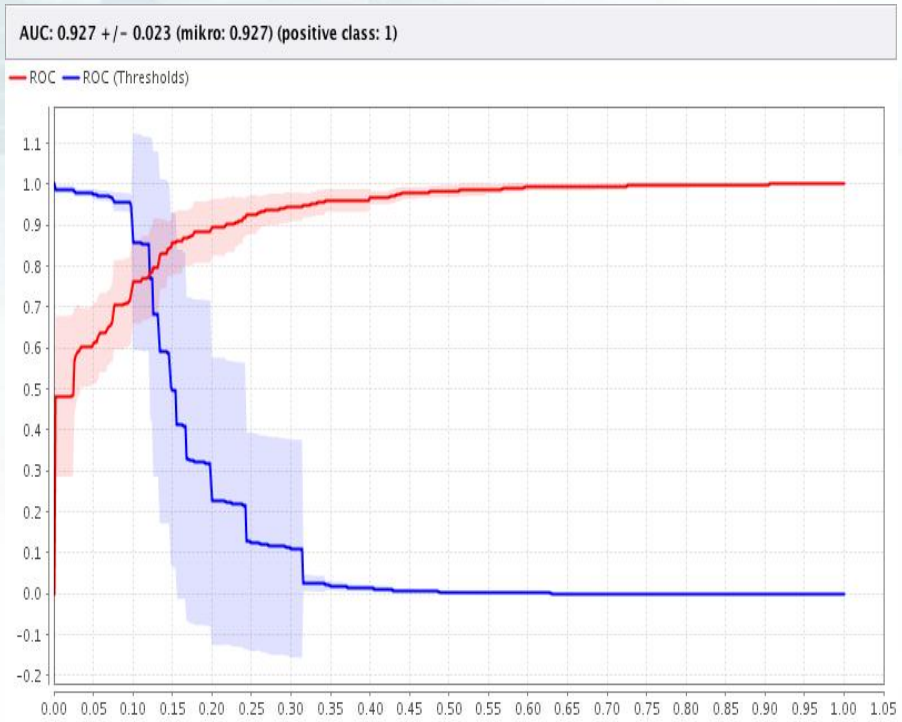
- Reports indicate that frontline caregivers are still using paper records or forms as a supplement to EHR, which is more risky than either a paper-based or fully electronic system
  - No one source of truth
  - No access control or notification of other users' changes

Next Steps with PSA Data

- 80% of initial 8,003 reports not screened for relevance or classified for type of problem
- Used machine learning tools to screen remaining 6,436 unread cases for relevance
- Of those, 2,500 determined relevant, 1,696 irrelevant
- Will allow us to increase the number of cases by 160% in upcoming Advisory article
- Saves us from reviewing up to 4,196 likely irrelevant cases

Model Performance

- After dropping predictions <90% confidence, Naïve Bayes classifier performed with 86% accuracy
- AUC = 0.927 +/-0.023



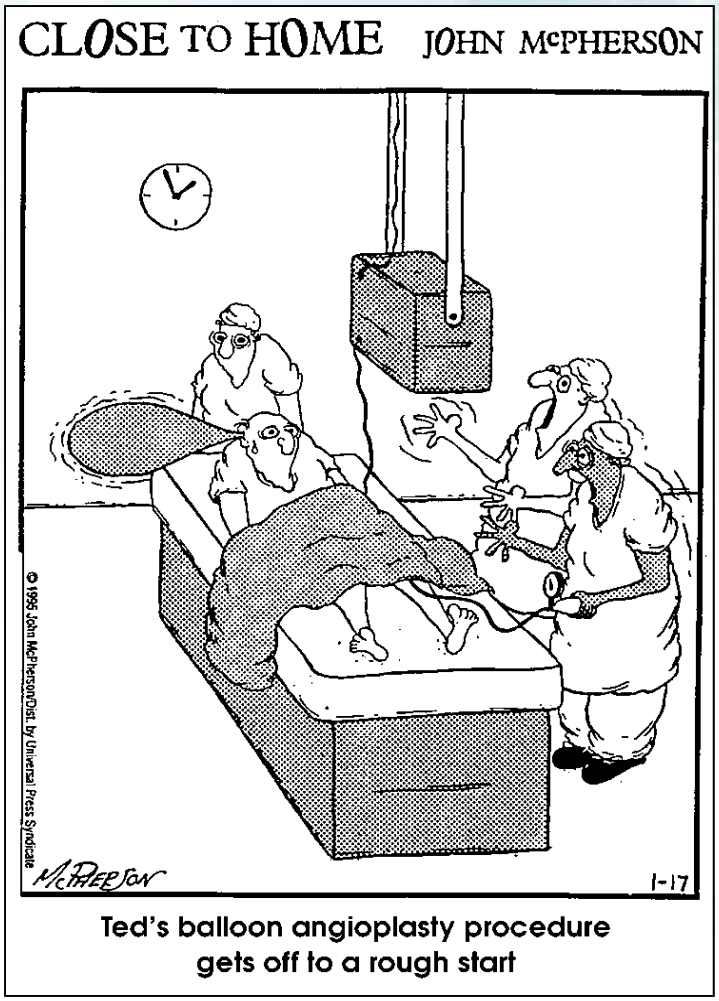
What the machine learning tool adds

Harm Score	Manual Review	Machine Learning
A	116	229
B1	11	46
B2	311	1,148
C	411	903
D	78	163
E	5	9
F	0	2
G	0	0
H	1	0
I	0	0
Total	933	2,500

Top Predictive Variables	Weights*
Event Type	1.000
enter	0.487
specimen	0.428
order	0.417
discontinu	0.392
duplic	0.392
contact	0.307
epic	0.217
record	0.193
call	0.180

*Standardized weights determined by Chi Squared test

ECRI Accident/Forensic Investigations



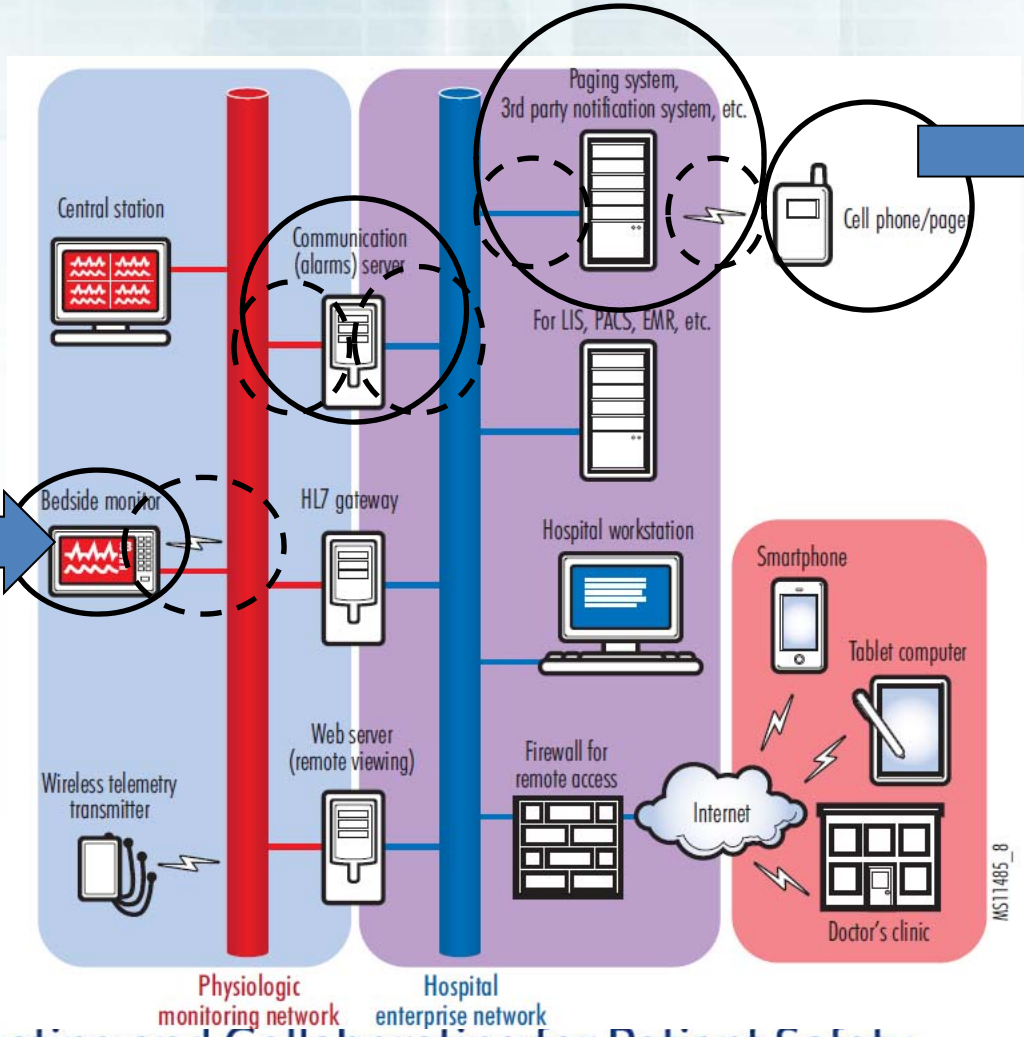
Ted's balloon angioplasty procedure gets off to a rough start

- In-depth investigations of events, especially in anticipation of litigation
  - Root causes
  - Practice or infrastructure recommendations
- Increasingly involving EHR and HIT
  - Integrated devices
  - EHR-associated harm

Analyzing, Educating and Collaborating for Patient Safety

Where are the Risks?

Physiologic Monitoring System on a Hospital Network



Analyzing, Educating and Collaborating for Patient Safety

PATIENT SAFETY AUTHORITY

Investigating Integrated Medical Devices

Characteristic	Isolated Medical Device	Integrated Medical Devices
Investigation Complexity	From simple to complex	Typically complex
Number of devices involved	One to many	Usually many
Value of information resources (e.g., MAUDE, literature)	Typically good – databases can provide rich examples of problems	Currently close to useless
Parties interviewed	Clinicians, biomeds	Same + IT
Location investigated	Often limited to treatment area	Often spans a facility, potentially other facilities
Time to identify root cause	Days to weeks	Sometimes months
Vendor support in investigation	Medical device vendors have obligation based on FDA regulation	IT system vendors currently do not have regulatory obligations

EMR-related reports to ECRI Institute PSO

Event Description	Number	%
Delay/Failure entering physician order	39	16%
* Discrepancy between EMR and paper chart	37	15%
Delay/Failure to act on charted order	28	11%
Wrong order entered/order entered in error	27	11%
* Discrepancy among EMR views or EMR and linked systems	23	9%
Wrong patient/patient identification problem	21	9%
Wrong information charted (test results, vital signs, observations)	20	8%
Delay/Failure entering information (test results, vital signs, observations)	16	6%
Information/data transfer problem	10	4%
Delay/Failure to act on charted information (test results, vital signs, observations)	7	3%
* EMR system down/unavailable	7	3%
Duplicate order	4	2%
* System prevents charting care accurately	4	2%
* Orders incorrectly started/stopped/continued automatically by system	2	1%
* Clinically appropriate selections unavailable	2	1%

Notes: Includes 230 event reports; reports may be counted in more than one category above.
Represents data from 12 hospitals about events occurring from approximately Jan 2009 through Apr 2011.

*Problems unique to HIT

Analyzing, Educating and Collaborating for Patient Safety

Evaluating HIT as a sociotechnical system

Sittig, D. F., and H. Singh. 2010. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Quality & Safety in Health Care* 19(Suppl 3):i68-i74.