

Enabling Reporting of Patient Safety Events to Improve Health IT

Panel: Governmental Perspectives on Advancing Risk Prevention and Mitigation

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Patient Safety: Ensuring Data Integrity in Health Information Exchange

Patient safety relies on data integrity or “trust” in every electronic transaction, starting with the laboratory test order and ending with the test result for every potential end user.

The **LabHIT Team** focuses its efforts on interoperability and harmonization of all interfaces transmitting laboratory data within healthcare settings and to public health agencies.

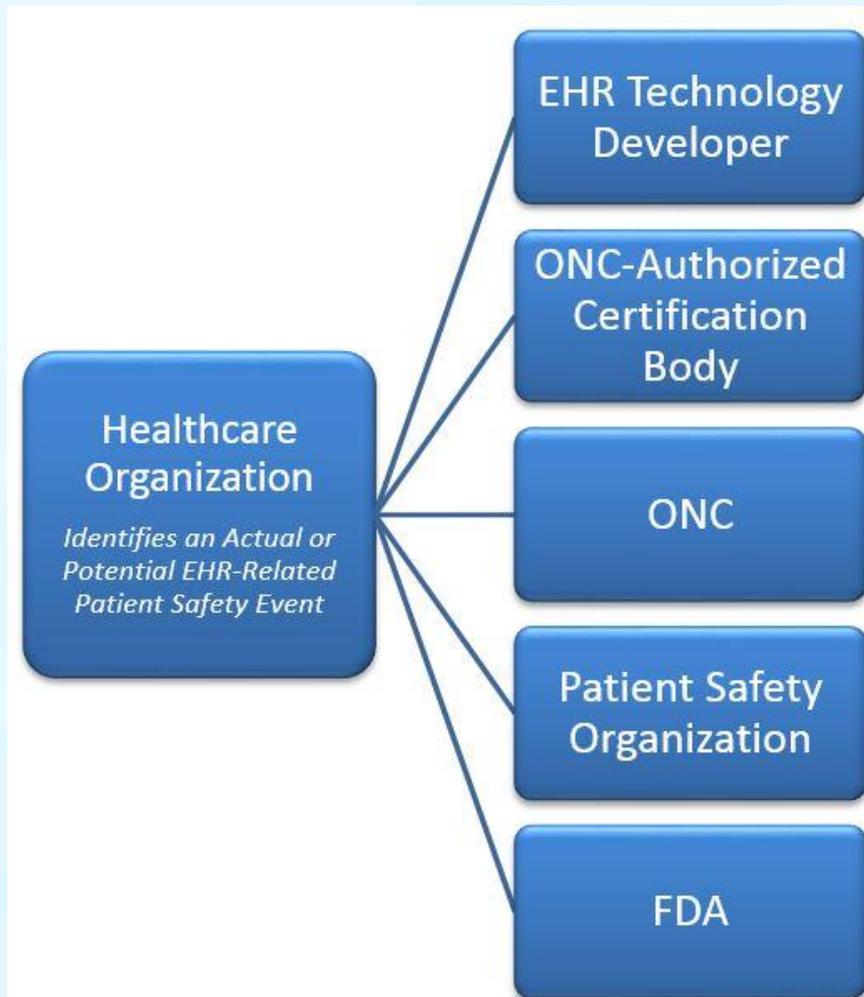


Figure 1: Health Information Exchange in the Healthcare System

IOM: Health IT and Patient Safety: Building Safer Systems for Better Care (2012)

- ❑ *Users and researchers need to be encouraged to provide specific descriptions of safety problems associated with particular health IT products in order to provide potential users with credible data regarding which IT products are safer than others.*

Reporting Options for Actual or Potential (near-miss) EHR-Related Patient Safety Events



Reporting Safety Related Concerns

- ❑ **EHR Technology Developer**
- ❑ **EHR Certification Body**
- ❑ **Office of the National Coordinator for Health IT**
- ❑ **Patient Safety Organization**
- ❑ **U.S. Food & Drug Administration**

Events reported to FDA with keyword: “Electronic Health Record” or EHR as of May 3, 2016

	Death	Injury	Malfunction	Other/ NA	Total
2006-2009	--	--	--	--	0
2010	--	10	2	5	17
2011	1	3	4	--	8
2012	--	3	12*	2	17*
2013	1	6	1*	--	8*
2014	--	24	4	4	32
2015	1	15	--	--	16
2016	--	8	--	2	10
Total	3	85	23	13	108

Data queried from the FDA MAUDE Database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>

*Note: In 2012 and 2013, the data has been adjusted to reflect a single root cause identified by one EHR vendor for one customer. A retrospective review of all impacted patient was conducted by the customer and the vendor submitted a report to the FDA for every patient study day over a two year period. The total number of reports identified under the category “Malfunction” with the same leading FDA Report Number from this vendor in 2012 and 2013 were consolidated for the purpose of presenting the adjusted data in this chart. For 2012, 44 of 55 Malfunction reports were consolidated to represent one root cause. For 2013, 633 of 633 Malfunction reports were consolidated to represent one root cause. The original number of total event records for 2012 and 2013 were 60 and 641, respectively.

Deaths Reported to FDA including keyword “EHR” 2011 - May 3, 2016

□ 3 deaths

- Across three different large EHR vendors
- Root causes
 - 2011: Unaware of new laboratory result indicating renal failure
 - 2013: Undetected low blood pressure before dialysis
 - 2015: Unscheduled downtime (lack of access) causing delays
 - Clinical cause of unanticipated patient death was not stated

Injuries Reported to FDA including keyword “EHR” 2011 - May 3, 2016

□ 85 injuries

- Preliminary data suggest “Notifications” are a high risk area
 - Data of consequence deposited in the record without notification
 - Example: Patient with standing potassium orders with new reports of normal or elevated potassium results going unnoticed, leading to overdose
- Examples cited in CDC’s Report, *“The Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems”*
 - Unconventional results display causes abnormal pap smear to be missed; outcome is hysterectomy in woman of child bearing age
 - Unexpected interpretation of “daily” causes delayed anticoagulant therapy testing; outcome is delayed adjustment in medication causing increased risk for abnormal bleeding, such as stroke
- Report also includes examples of interoperability and display issues, as well as innovative clinical decision support opportunities that can save lives and healthcare dollars
 - Delayed detection of emergent conditions in a child (sepsis) resulting in death

New LRI Test Method Use Case for CLIA Compliance

Take the Challenge!

- ❑ **New use case to ensure laboratory data includes required elements by:**
 - Federal CLIA Regulations
 - Laboratory accreditors (CAP, The Joint Commission, COLA, AABB, AOA, ASHI, VA/DoD, exempt states [WA, NY])
- ❑ **Creates two-stage test method for “corrected reports”**
 - Wrong patient scenario: CBC on pediatric male reported as adult female
 - Critical result flags and corrected report identifier were integrated into existing use cases
- ❑ **Tests methods help to ensure laboratory data can be interpreted correctly**
- ❑ **CDC poster presented at August 2016 Public Health Informatics Conference: <http://www.cdc.gov/labhit/>**
- ❑ **Updated LRI Validation Tool: <http://hl7v2-lab-r2-testing.nist.gov/lri-r2/#/home>**

Resources

- ❑ *The Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems (May 2014):*
 - http://www.cdc.gov/labhit/labhit_paper.html
- ❑ Simplifying data display
 - Wired Magazine: The Blood Test Gets a Makeover
 - http://www.wired.com/2010/11/ff_bloodwork/
 - Thomas Goetz: 16 minute Ted Talk on simplifying medical data:
 - http://www.ted.com/talks/thomas_goetz_it_s_time_to_redesign_medical_data
 - Alan Siegel: 4 minute Ted Talk on simplifying legal forms (paper and online); hired by IRS to simplify documents:
 - http://www.ted.com/talks/alan_siegel_let_s_simplify_legal_jargon?language=en
- ❑ Sepsis
 - AHRQ Statistical Brief #161
 - <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb161.pdf>
 - Sepsis Fact Sheet
 - http://www.sepsisalliance.org/downloads/2016_sepsis_facts_media.pdf
 - Mining EHRs to Improve the Quality and Safety of Care
 - <http://tinyurl.com/miningforsepsis>

Thank you!

For more information please contact Centers for Disease Control and Prevention

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.