



The Office of the National Coordinator for
Health Information Technology



HIT Safety: Progress Made and Challenges Ahead

Health IT Week

September 19, 2014



- ONC welcomes our featured speakers
 - Zia Hydari – Carnegie Mellon University
 - Tammy Williams – University Health System Consortium
 - Karen P. Zimmer – ECRI Institute and PSO

Crucial Role of HIT Safety at ONC

- National Quality Strategy – “Making care safer” is DHHS priority
 - Health IT provides the infrastructure
- IOM Report - 2011
- ONC Health IT Safety Plan - 2013
 - Use Health IT to make care safer
 - Continuously improve the safety of Health IT
 - Certification Criteria
- ONC Office of Clinical Quality and Safety - 2014

Active role of ONC in Health IT Safety

– Learn

- Increase the quantity and quality of data and knowledge

– Improve

- Develop resources and use corrective actions

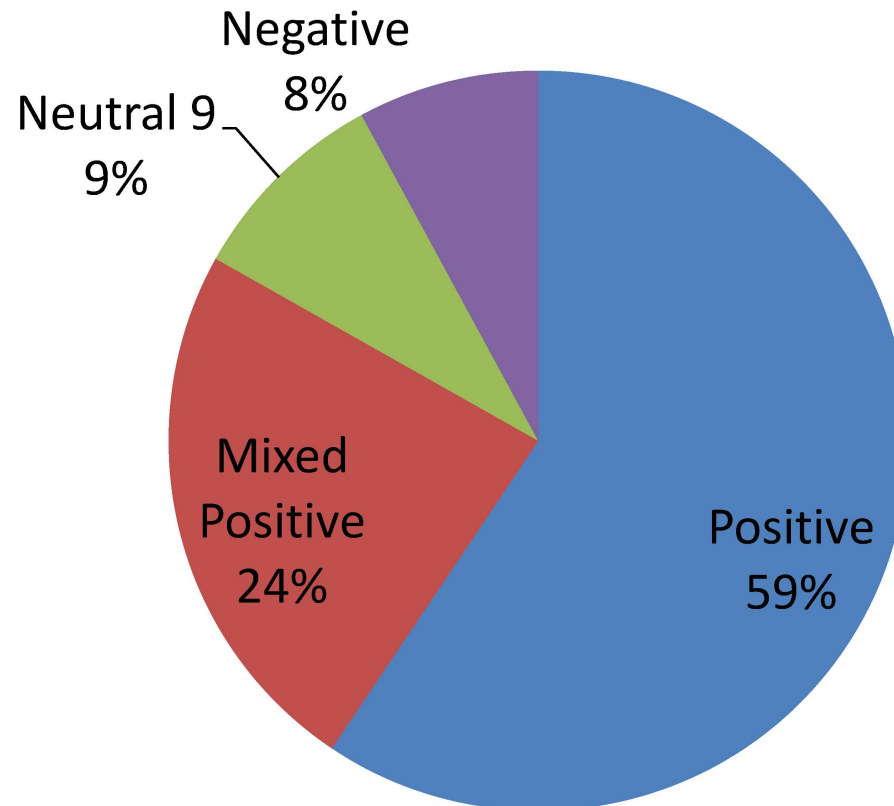
– Lead

- Promote shared responsibility
- Establish Health IT Safety Center

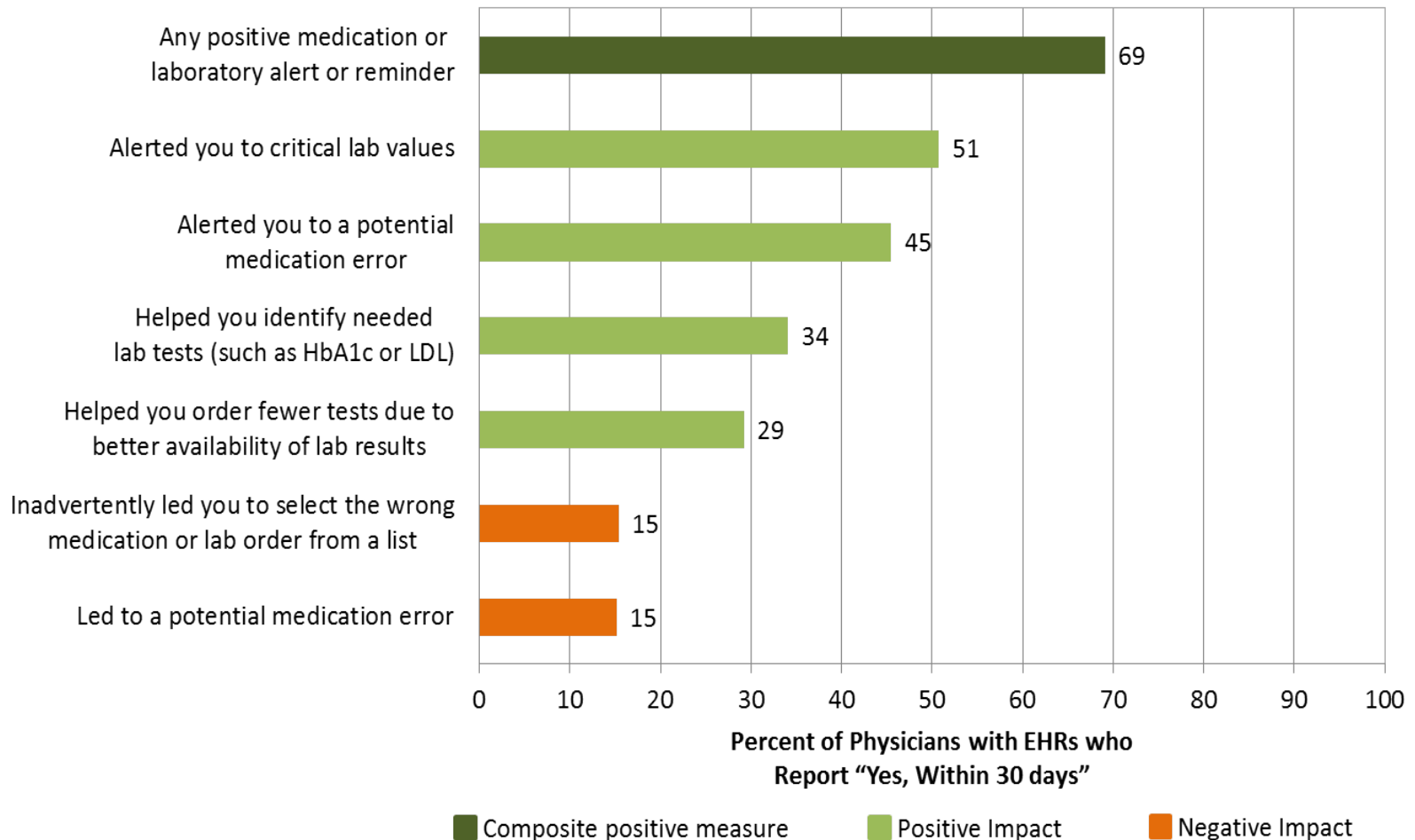
ONC HIT Safety Program Highlights - Promoting Safe Use of EHRs: 2013 - 2014

- SAFER Guides released
- Safety Enhanced Design 2014 EHR Certification Criteria
 - Usability Testing Reports on CHPL
- ONC-ACB surveillance of safety
- HIT developers "How to work with a Patient Safety Organization"

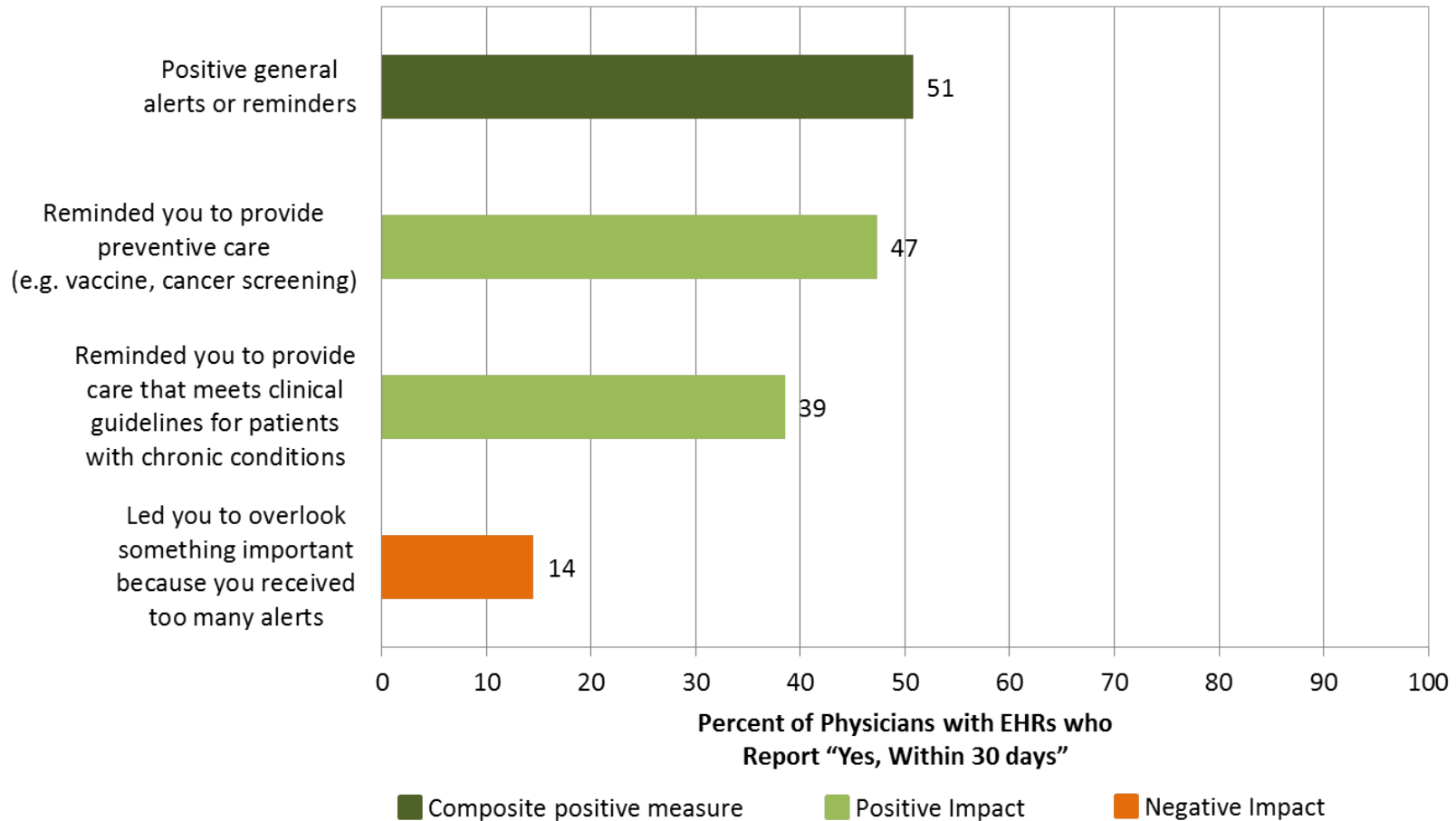
Meaningful Use Functionalities have Positive Effects on Health Care Quality, Safety and Efficiency



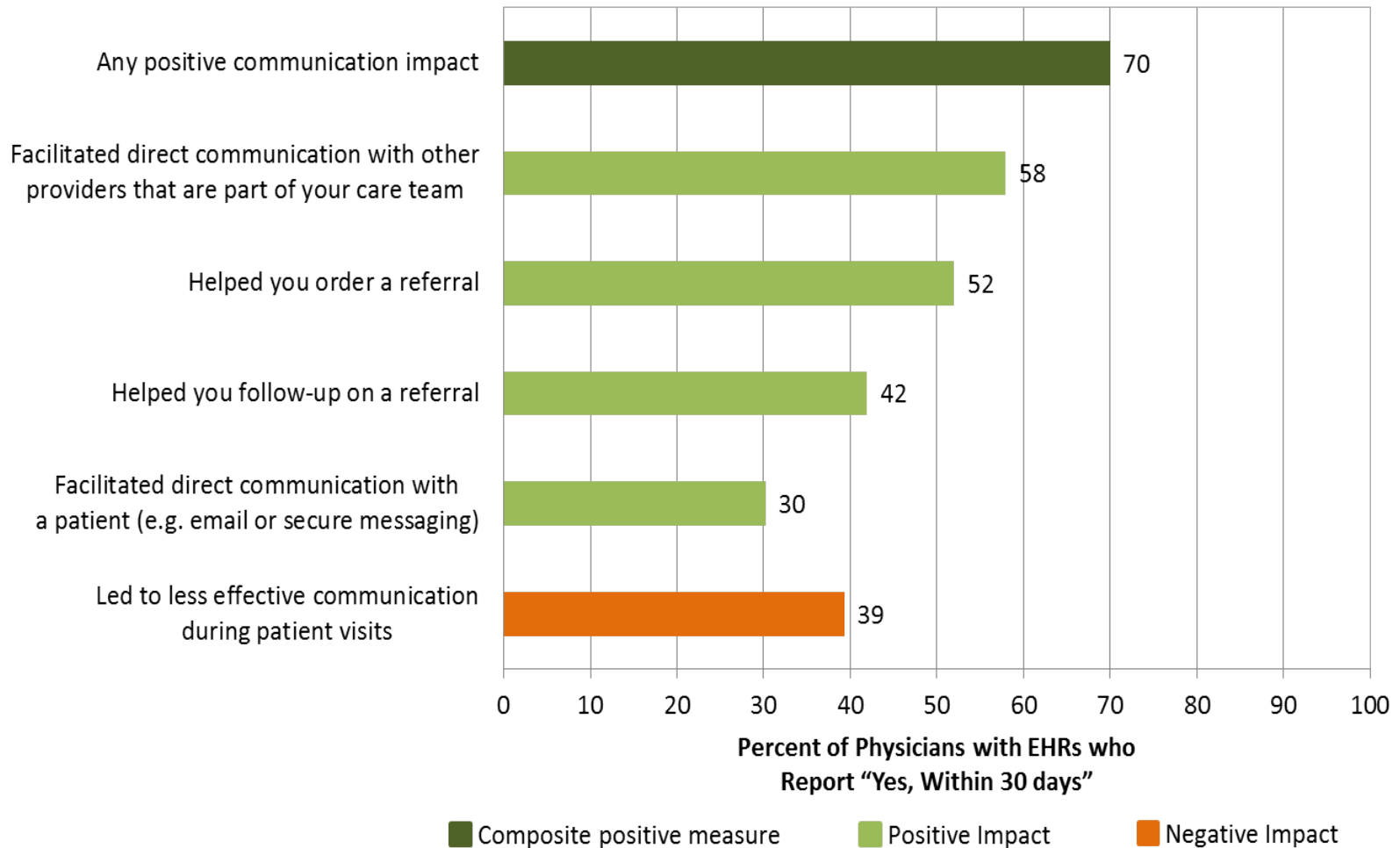
Three times as many physicians reported that their EHR prevented a potential medication error than caused one



More than half of all physicians using EHRs reported positive impacts associated with their EHRs' general alerts and reminder functions



Seven in ten physicians using EHRs reported positive impacts from EHR-facilitated communication with patients or care team members



ONC EHR Certification Criteria Improves Safety and Quality

- Physicians with *meaningful use-enabled EHRs* reported their systems were: 26% more likely generate general alerts and reminders that improve patient care,
- 22% more likely to demonstrate positive medication or laboratory impacts
- 9% more likely to enhance communication
- http://www.healthit.gov/sites/default/files/safetyqualitybrieffinal_sept2014_final.pdf

Meaningful Use Measures Decrease Adverse Drug Events

- Hospitals adopting all five core measures of meaningful use for medication management in 2010 had 52 percent reduction in adverse drug events
- AHRQ funded study of Florida hospitals



Saving Patient Ryan

Can Hospital IT Make Patient Care Safer? Evidence from
Pennsylvania Hospitals

Muhammad Zia Hydari
Carnegie Mellon University, and
Living Analytics Research Centre (LARC)

Professor Rahul Telang
Carnegie Mellon University

William M. Marella
Pennsylvania Patient Safety Authority

The Problem—Patient Safety

“Patient safety” can be defined as freedom, as far as possible, from harm, or risk of harm, caused by medical management (as opposed to harm caused by the natural course of the patient’s original illness or condition).¹

Pennsylvania (PA) Population	12 million
Reported PA Patient Safety Events, (2005—2012)	1.7 million ²
Reported PA Deaths (due to patient safety event, 2005—2012)	2,500

(1) Great Britain House of Commons Committee, Patient Safety, Sixth Report, (2) Pennsylvania law requires hospitals to report events to the Patient Safety Authority, (3) Harvard Professor and MD Lucian Leape popularized the expression that US patient safety problem is comparable to “3 jumbo jet crashes every two days” [Error In Medicine, JAMA 1994], (4) PHC4 reported roughly 7 million inpatient days per year during 2005-2012.

Do Advanced Electronic Medical Records (EMR) make patient care safer?

Dranove et al defined “Advanced EMR” as CPOE or Physician Documentation; multiple authors have used this definition in their studies.

Dranove, David, Christopher Forman, Avi Goldfarb, and Shane Greenstein. “The Trillion Dollar Conundrum: Complementarities and Health Information Technology.” *American Economic Journal: Economic Policy*, 2014. https://www.aeaweb.org/forthcoming/output/accepted_POL.php.

Data

Item	Source	Description
Patient Safety Events	PSA	All patient safety events for 2005-2012 in Pennsylvania Hospitals
EMR Adoption	HIMSS	Adoption of Basic EMR (CDR, CDSS) and Advanced EMR (CPOE, Physician Documentation) and non-Clinical IT for 2005-2012
Hospital Controls	PHC4, AHA, CMS	In-patient days, teaching status, residency status, JCAHO, medical school, transfer-adjusted case mix index
County Controls	AHRF	Population; percent white; percent over 65; unemployment, household income

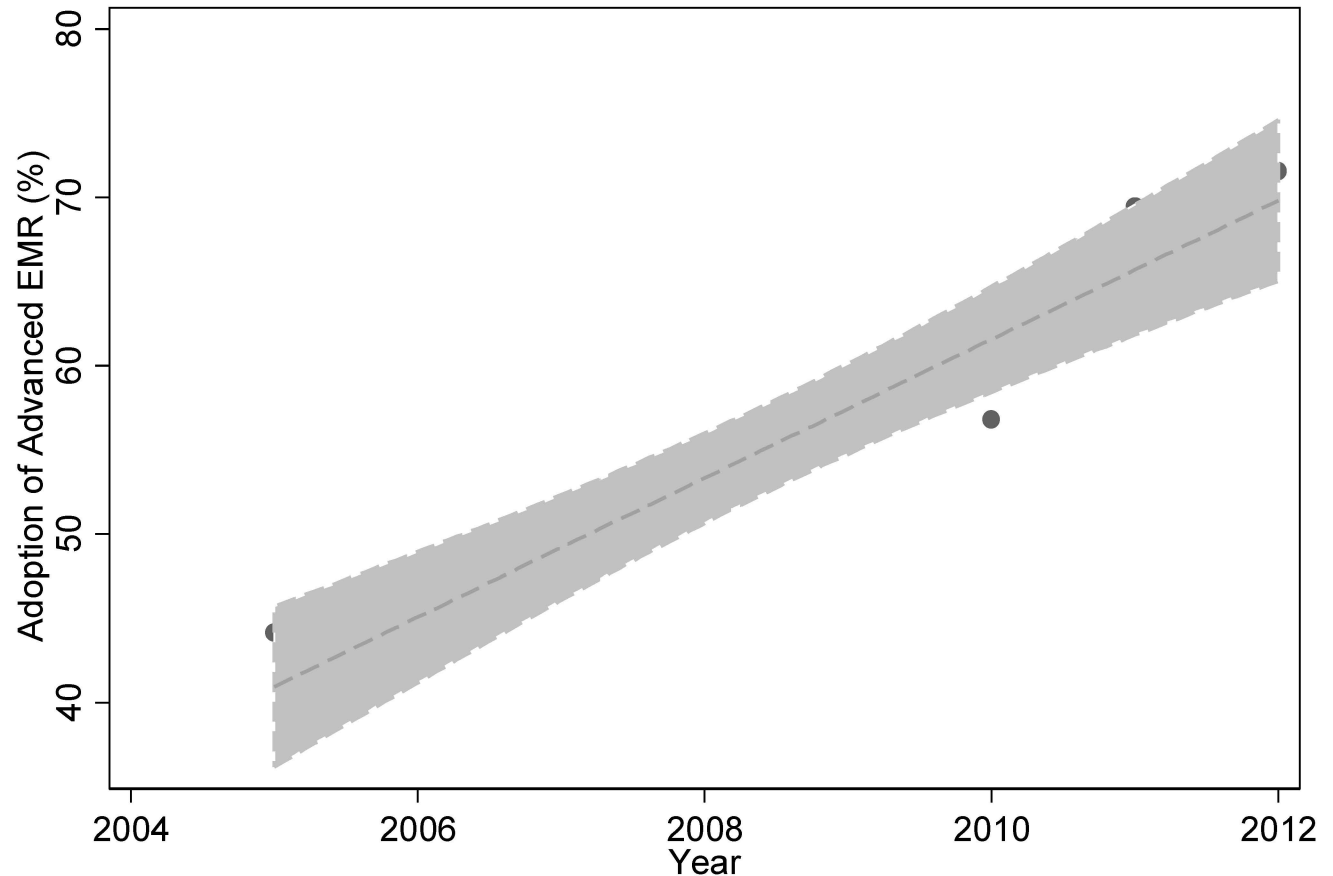
Methods

- Hospital-year as unit of analysis
- Outcome is log of reported patient safety events
- Differences-in-differences identification strategy
 - Exploit within-variation in hospitals' EMR adoption and patient safety events
 - Control for hospital and year FE
- Time-varying hospital controls
 - Inpatient days, case mix index¹
- “Time-invariant” controls, interacted w/ linear time trend
 - County: population, household income, age over 65 years
 - Hospital: teaching, residency, medical school, JCAHO

*Identification Assumption:
EMR Adoption is random, conditional on the controls*

¹. Case Mix Index used in robustness check

EMR Adoption in Pennsylvania Hospitals



Advanced EMR

- CPOE
- Physician Documentation

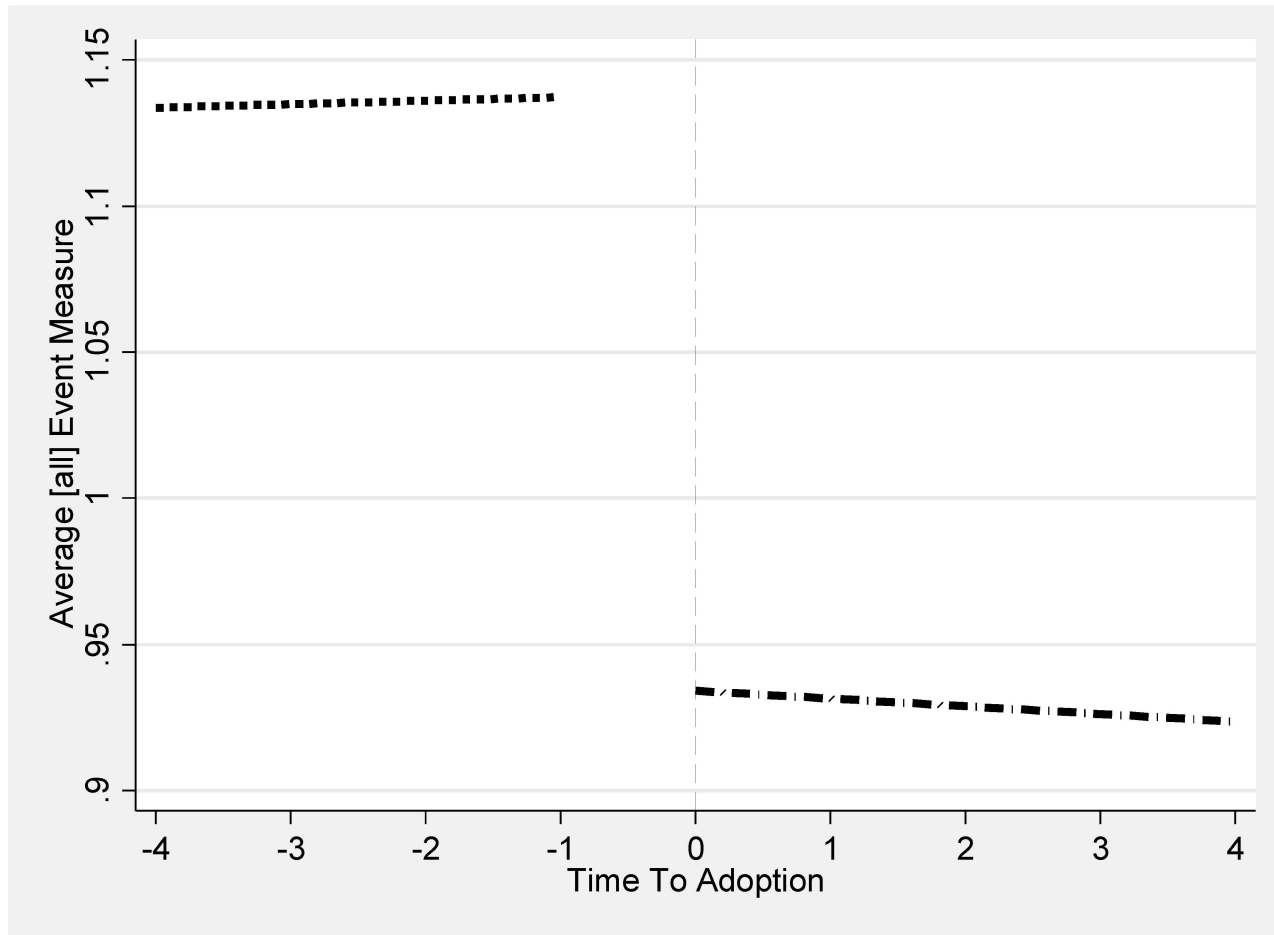
{Dranove et al 2012}

Includes only hospitals with observations for all years.

CDR: Clinical Data Repository; CDSS: Clinical Decision Support System; CPOE: Computerized Physician Order Entry;

Dranove, David, Christopher Forman, Avi Goldfarb, and Shane Greenstein. "The Trillion Dollar Conundrum: Complementarities and Health Information Technology." *American Economic Journal: Economic Policy*, 2014. https://www.aeaweb.org/forthcoming/output/accepted_POL.php.

Patient Safety Events Before and After Adoption



- 1. Suggests 15%–20% drop in average event measure*
- 2. Upward sloping before, downward sloping after*

Vertical axis measure is calculated from the residual of a regression that factors out control variables, hospital fixed effects, and year fixed effects from log of events. Residual is the difference between the expected value predicted by the factors and the actual value.

Summary of Main Results

Advanced EMR adoption leads to:

- 27% decline in all (aggregated) events
- 30% decline in medication events
- 25% decline in complication of procedure ,
test, or treatment

Medication events include incorrect medication lists, unauthorized drugs, omitted/extra/wrong dosage, prescription delays, monitoring errors, or inadequate pain management (but not adverse drug reactions).

Complications of procedure, test, or treatment include complication following surgery or invasive procedure, anesthesia event, emergency department, maternal complication, neonatal complication, nosocomial infection, cardiopulmonary arrest outside ICU, IV site complication, extravasation of drug or radiologic contrast, catheter or tube problem, onset of hypoglycemia, and complication spinal therapy

Robustness Checks

Concern	Check
Selection	<ul style="list-style-type: none">• No effect on skin integrity events (falsification test with placebo outcome)
Unobserved hospital ability correlated with IT adoption and patient safety	<ul style="list-style-type: none">• No effect of non-clinical IT• Effect of Advanced EMR persists with non-clinical IT as covariates
Reverse causality (regression to mean)	<ul style="list-style-type: none">• Lagged events (and changes) do not predict Advanced EMR adoption• No anticipation effect of EMR adoption
Functional form dependence	<ul style="list-style-type: none">• Similar effects from non-linear specifications
Sample issues (outliers etc.)	<ul style="list-style-type: none">• Similar effects with balanced panel and balanced panel with basic EMR throughout study
Measurement error	<ul style="list-style-type: none">• Similar effects with corrected sample in which EMR adoption persists

Skin integrity events include pressure ulcers, burns, rashes / hives, abrasions, lacerations, blisters, and skin tears. These events are problems with patient positioning, movement, or manipulation; or physical environment; or use of devices near or on patients—so no expected effect from IT

Non-clinical IT includes revenue cycle management, general financials, financial decision support, human resources, and supply chain management.

Events by Harm Score

- Events categorized into (i) Adverse Events, (ii) Reached Patient, No Harm, and (iii) Near Misses
- Advanced EMR leads to decline in all categories but statistically significant decline (28%) for (ii) only
- CPOE leads to a statistically significant (14%) decline in (i)
- Physician documentation leads to statistically significant (29%) declines in both (ii) and (iii)

Next Steps

- Advanced EMR adoption and thematic changes in medication errors
 - Distribution changes in event subtypes
 - Latent topics and topic evolution in unstructured text reports
- Differences in benefits
 - Hospital organization hierarchy
 - All vs. (a priori) good hospitals
 - Over time



Health IT-Related Patient Safety Events

Findings in the UHC Safety
Intelligence™ Patient Safety
Organization (PSO) Database

September 19, 2014

Background

- This project supports the 2013 ONC *Health IT Patient Safety Action and Surveillance Plan*
- The analysis of a large database of reported safety events can
 - Increase knowledge about the types, frequencies, and underlying causes of health IT-related safety problems
 - Guide the development of evidence-based programs and policies
 - Improve measurement and reporting of health IT-related safety events
- ONC contracted with Westat to engage AHRQ-listed PSOs to conduct analysis
- Westat subcontracted with UHC, an established PSO with a large historical database of patient safety events

Objective of Analysis of Health IT Safety Events

- Identify the types and characteristics of patient safety events that have health IT involvement
- Describe the specific nature of health IT-related events
- Ascertain the ability of the AHRQ Common Formats to identify health IT events

Aggregate Analysis of Events Reported to UHC Intelligence™ Databases

2 Separate Groups of Data in Aggregate analyses

- 40 PSO organizations only
- All 81 organizations in PSO and Non-PSO

Data were obtained for a 2 ½-year period of time

- January 1, 2011 to June 30, 2013

Aggregate analysis focused on responses to question “Was health information technology implicated in event?”

- AHRQ Common Formats event type categories
- Harm Scale v 1.1
- Preventability
- Age, Gender, Ethnicity, Race
- Contributing Factors

Key Findings in Aggregate Data

Item	PSO Database	PSO and Non-PSO Database Combined
Total # of Events in Database	451,195	924,281
Health IT Question Answered	229,248 (51%)	438,568 (47%)
Health IT Involved (Answer “Yes”)	9,726 (4.2%)	20,758 (4.7%)

Most common AHRQ categories tagged health IT-related

- Other (55%)
- Medication-related (33%, 36%)
- All others 1-3% or less

60% of Health IT-related events reached the patient

- Less likely to result in harm when compared to those events that were not health IT-related

About 75% of events were considered preventable*

- More likely to be preventable when compared to events that were not health IT-related (about 50% considered preventable)

Events Categories Selected for In-Depth Review and Their Sample Sizes

Event Category	Total health IT-tagged events in category	Sample size (# events reviewed)	Sample size as a % of total events
1. Medication-related	3,206	300	9
2. Medical records/patient identification [†]	1,224	300	25
3. Care coordination/communication [†]	1,036	300	29
4. Laboratory test [†]	1,036	300	29
5. Device/supply	306	300	98
6. Radiology/imaging [†]	242	242	100
7. Omissions/errors in diagnosis, assessment and monitoring [†]	218	218	100
8. Blood/Blood Product	151	151	100
9. Infrastructure failure [†]	149	149	100
Other Event Categories Reviewed*			
Falls	280	50	18
Surgery or anesthesia	196	50	25

[†]These event types were captured using UHC's proprietary taxonomy, but would map to "other" category in Common Formats.

*These were event types assumed to have a high rate of false tagging; therefore, a small sample was reviewed to ensure important information was not overlooked in these categories.

Type of Health Information Technology Involved

Type of Health IT	N	%
*EHR - Clinical documentation system	657	42.1
*EHR - Computerized Prescriber Order Entry - Other	296	19.0
*EHR - Computerized Prescriber Order Entry - Medication	171	11.0
*Administrative	168	10.8
*Laboratory information system (LIS)	159	10.2
*EHR - Electronic medication administration record (eMAR)	83	5.3
*Radiology Information System (RIS) / Picture Archiving & Communication System (PACS)	79	5.1
*EHR - Pharmacy system	45	2.9
Blood Management System	38	2.4
*Human interface device (e.g. keyboard, mouse, monitor, printer)	26	1.7
EHR - Entire system	16	1.0
*Automated Dispensing Machine	14	0.9
*EHR - Clinical decision support system	8	0.5
Operating Room Information System	6	0.4
Cardiovascular Information System (CVIS)	4	0.3
*Billing - Coding/billing system	3	0.2

*Asterisk indicates field in AHRQ Common Formats v.1.2

More than one type of technology may have been selected in one event

Total number of health IT events = 1,559

Health IT-related Taxonomy: Computer-related Issues

Computer-Related Categories		
Level 1 Category†	N	%
Data output/display error	392	25.1
*Software functionality or configuration issue	274	17.6
*Issue in the interface between software	247	15.8
Computer/system/software was down/unavailable/slow	187	12.0
*Issue in software interface with a device	169	10.8
*Network failure/problem	31	2.0
*Problem associated with maintenance or upgrades	24	1.5
*Hardware failure/problem	22	1.4
*Security, virus, or malware issue	4	0.3

†Subcategories of taxonomy not shown

*Asterisk indicates field in AHRQ Common Formats v.1.2

Total number of selections under computer-related = 1,350

Total number of health IT events = 1,559

More than one taxonomy category may have been selected in one event

Health IT-related Taxonomy: Human-Computer Interface

Human-Computer Interface		
Level 1 Category†	N	%
*Data entry errors	827	53.0
Missed/overlooked information	199	12.8
Did not review /seek out info in record	138	8.8
*Design of user interface/display of information/interpretation	56	3.6
Access issue (unable to log in, multiple user issue)	39	2.5
User ignored or overrode an alert	12	0.7

*Asterisk indicates field in AHRQ Common Formats v.1.2

†All categories/subcategories are not shown

Total number of selections under human-computer interface = 1,676

Total number of health IT events = 1,559

More than one taxonomy category may have been selected in one event

Overview of Findings

Both computer-related and human-computer interface health IT issues are mainly the result of human error

- Exceptions such as hardware failures or power failures
- *Blunt end*: design/format of software, its functionality/configuration
- *Sharp end*: errors by healthcare providers during processes of care

Errors occurred at each stage of the care delivery process for the most part

- Medication: order, transcribe, dispense, administer, monitor
- Lab/Blood/Radiology: order, specimen collection, administration of treatment or tests, and interpretation or results reporting

Most common health IT-related issues

- Entry errors
- Data output/display errors
- Software functionality or configuration issue
- Software interface between various software products

Prevention Strategies

- Decision support and/or alerts/prompts may help prevent order entry errors for
 - Incomplete entries, expiring medication orders, duplicate orders for medications and tests, out of range weights and medication doses, contraindications for treatment or tests
- Stronger action to prevent wrong patient errors and duplicate records
 - Policies, procedures, and functionality that forces staff to search for records a particular way may help prevent wrong patient errors and the creation of duplicate records (e.g. required fields, specific sequence of search elements)
- Organizations should monitor for duplicate records
- Policies and procedures requiring verbal communication in error-prone situations

Strengths

- Large sample size representing organizations nationally
- Rich information on the characteristics of health IT events including:
 - Computer-related aspects
 - Human-computer interface aspects
 - When health IT-related issues occurred in the course of care
- Provides actionable content
- Interrater reliability was high on whether events were truly health IT-related and on agreement on at least 1 type of health IT involved and on 1 taxonomy classification

Limitations

There are limitations inherent in voluntarily incident reporting

- Not representative of all cases
- Categorization of the event may not be accurate
- Information in event description may be limited or not exact
- Cause of the IT issue may not have been identified

Interrater reliability lower for exact agreement on taxonomy

- Large number of categories with some similar, interrelating, and overlapping themes, making it challenging for 2 reviewers to select exactly the same choices

Findings may not be generalizable across software products

Health IT Safety: Progress Made and Challenges Ahead

September 19th

Karen P. Zimmer, MD, MPH, FAAP

Medical Director, Patient Safety, Risk, & Quality, ECRI Institute

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Two ONC-Sponsored Works:

1. Anticipating Unintended Consequences of Health Information Technology and Health Information Exchange: How to Identify and Address Unsafe Conditions Associated with Health IT. (#HHSP23320095655WC)



2. Patient Safety Through Effective Health IT Risk Management (#HHSP23320095649WC)



- Reduce medication errors
- Eliminate illegible writing
- Enable computerized provider order entry
- Achieve best practices using clinical decision support tools (CDS)
- Preventive care recommendations
- Track immunizations, testing, and referrals
- Centralize patient records (availability, timeliness)
- Allow access across a variety of settings for care coordination

How to Identify Unsafe Conditions Associated with Health IT



*Anticipating Unintended Consequences
of Health Information Technology
and Health Information Exchange*

How to Identify and Address Unsafe Conditions Associated with Health IT

September 19, 2013

**Reporting is
easier said than
done.**

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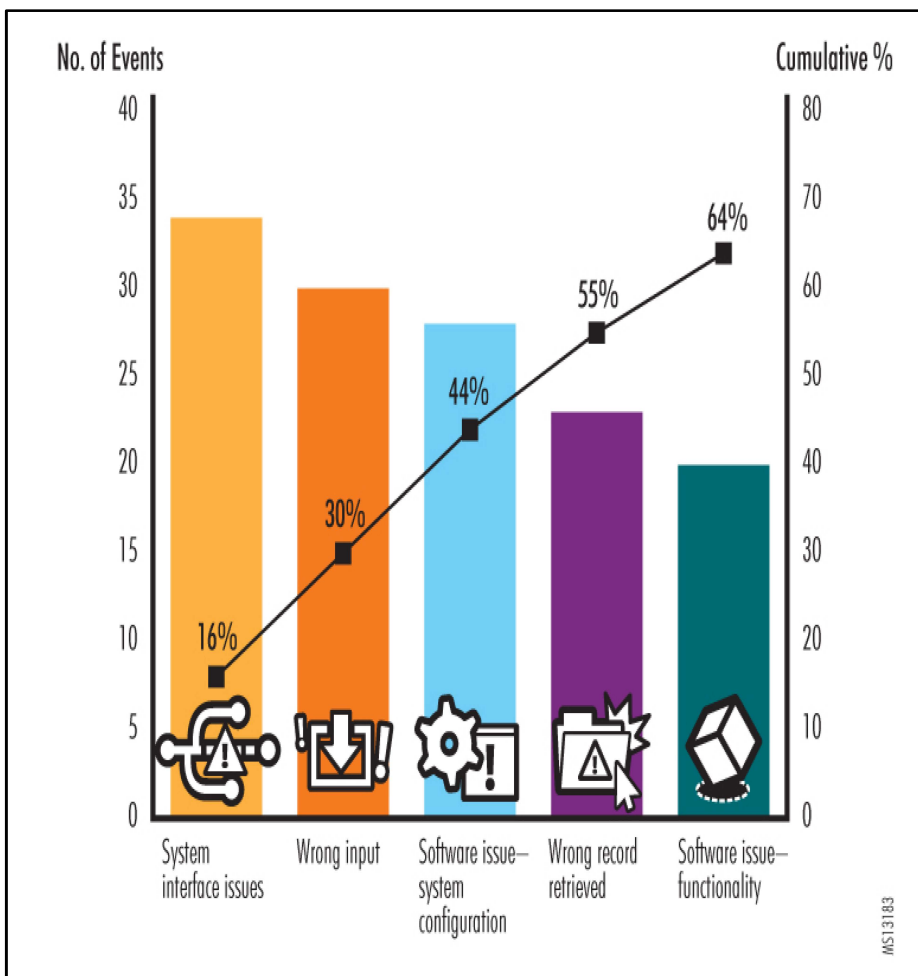
Rockville, MD 20850-3129

(301) 251-1500

Contract No: HHSP23320095655WC

Task Order: HHSP23337003T

**Do the clinical users
and risk managers
SEE the role of
health IT in adverse
events?**



1. System interface issues
2. Wrong input
3. Software issue – system configuration
4. Wrong record retrieved
5. Software issue – functionality

Human-computer

- A patient was not identified properly, and all clinical information was entered into the wrong record.
- Data were entered incorrectly into the electronic record due to multiple records being open.
- The system failed to alert the user of an identified concern with a flag or pop up.
- The user ignored or overrode an alert.
- Data were not entered into the system.
- Data were incomplete and missing from the entry.

Computer-related

- Data were not displaying properly in the system.
- The network was down or slow.
- Interface issues with the laboratory system caused delays in the ability to retrieve data.
- The software was not up to date.
- Software did not meet the needs of the specialty provider.
- The software was not functioning properly.
- Data were lost.

- Identified how the implementation and use of health information technology (health IT) impacts patient safety
- Described high reliability and culture of safety principles to support reporting in healthcare organizations of errors, near misses, and unsafe conditions with health IT systems.
- Identified tools and methodologies to assist healthcare organizations in developing reporting systems to capture health IT events.
- Listed the advantages for healthcare organizations to partner with EHR developers and PSOs in learning about and analyzing health IT events.

Standardized tools:

- AHRQ Common Format for Health IT Event



AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Health Care Information | For Patients & Consumers | For Professionals | For Policymakers | Research Tools & Data | Funding & Grants | Centers, Portfolios & Initiatives | News & Events

Home > News & Events > Newsletters > Research Activities Newsletter

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 - AHRQ Patient Safety Network
 - AHRQ Web M&M
 - Health Care Innovations Exchange
 - EHC Inside Track
 - Electronic Newsletter
 - Patient Safety Newsletter
 - Research Activities

New Health IT Common Format for adverse event reporting

Publication # 11-RA003

Go to Online Store

Research Activities, December 2010, No. 364

The Agency for Healthcare Research and Quality (AHRQ) has released a new Common Format designed to help health care providers collect information about adverse events related to health information technology and devices. This Common Format, titled *Device or Medical/Surgical Supply including HIT Device*, is currently available as a beta version for public review and comment. The format will be revised based on feedback and released with AHRQ's Common Formats, Version 1.2 in August 2011.

To access AHRQ's full set of Common Formats (Version 1.1) along with technical specifications, and accompanying user information, visit the AHRQ's Patient Safety Organization Web site at <http://www.pso.ahrq.gov>.

Any questions or comments, contact:
Gail Makulowich
Managing Editor
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Email: gail.makulowich@ahrq.hhs.gov

Research Activities Online Newsletter
Archive, 1995-2009

Event ID: _____
Initial Report Date (HERF Q4) _____

Patient Safety Event Report – Hospital:

H **DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)**

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of (1) an implantable device or (2) an item of medical equipment.

For defects or events discovered prior to market approval or clinical deployment, do not use this form. If the event also involves a medication or other substance, please complete the Medication or Other Substance form in addition to this form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). **Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).**

- Which of the following best describes the event or unsafe condition? CHECK ONE:
 - Device defect or failure, including HIT
 - Use error
 - Combination or interaction of device defect or failure and use error
 - Unknown
- What type of device was involved in the event or unsafe condition? CHECK ONE:
 - Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)
 - Medical equipment (e.g., walker, hearing aid)
 - Medical/surgical supply, including disposable product (e.g., incontinence supply)
 - HIT device
- At the time of the event, was the device placed within the patient's tissue? CHECK ONE:
 - Yes
 - No
 - Unknown
- Did the event result in the device being removed? CHECK ONE:
 - Yes
 - No
 - Unknown

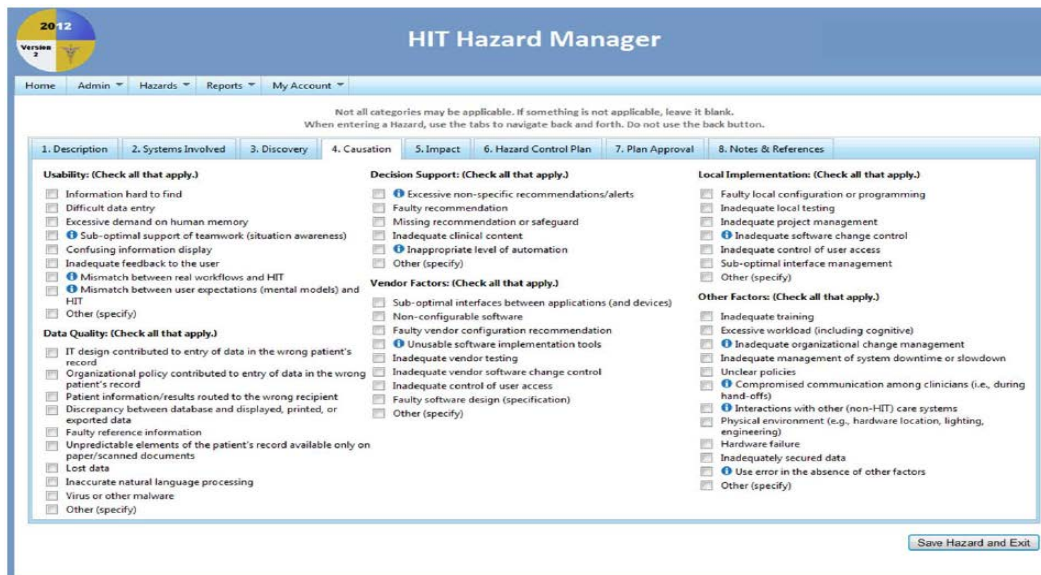
5. What is the name (brand or generic) of the device, product, software, or medical/surgical supply?

6. What is the name of the manufacturer?

AHRQ Common Formats - Hospital Version 1.2 - April 2012
Page 1 of 4
Device or Medical/Surgical Supply, Including Health Information Technology (HIT)

Standardized tools:

- AHRQ Health IT Hazard Manager



2012
Version 2

HIT Hazard Manager

Home Admin Hazards Reports My Account

Not all categories may be applicable. If something is not applicable, leave it blank.
When entering a Hazard, use the tabs to navigate back and forth. Do not use the back button.

1. Description 2. Systems Involved 3. Discovery 4. Causation 5. Impact 6. Hazard Control Plan 7. Plan Approval 8. Notes & References

Usability: (Check all that apply.)

- Information hard to find
- Difficult data entry
- Excessive demand on human memory
- Sub-optimal support of teamwork (situation awareness)
- Confusing information display
- Inadequate feedback to the user
- Mismatch between real workflows and HIT
- Mismatch between user expectations (mental models) and HIT
- Other (specify)

Data Quality: (Check all that apply.)

- IT design contributed to entry of data in the wrong patient's record
- Organizational policy contributed to entry of data in the wrong patient's record
- Patient information/results routed to the wrong recipient
- Discrepancy between database and displayed, printed, or exported data
- Faulty reference information
- Unpredictable elements of the patient's record available only on paper/scanned documents
- Lost data
- Inaccurate natural language processing
- Virus or other malware
- Other (specify)

Decision Support: (Check all that apply.)

- Excessive non-specific recommendations/alerts
- Faulty recommendation
- Missing recommendation or safeguard
- Inadequate clinical content
- Inappropriate level of automation
- Other (specify)

Vendor Factors: (Check all that apply.)

- Sub-optimal interfaces between applications (and devices)
- Non-configurable software
- Faulty vendor configuration recommendation
- Unusable software implementation tools
- Inadequate vendor testing
- Inadequate vendor software change control
- Inadequate control of user access
- Faulty software design (specification)
- Other (specify)

Local Implementation: (Check all that apply.)

- Faulty local configuration or programming
- Inadequate local testing
- Inadequate project management
- Inadequate software change control
- Inadequate control of user access
- Sub-optimal interface management
- Other (specify)

Other Factors: (Check all that apply.)

- Inadequate training
- Excessive workload (including cognitive)
- Inadequate organizational change management
- Inadequate management of system downtime or slowdown
- Unclear policies
- Compromised communication among clinicians (i.e., during hand-offs)
- Interactions with other (non-HIT) care systems
- Physical environment (e.g., hardware location, lighting, engineering)
- Hardware failure
- Inadequately secured data
- Use error in the absence of other factors
- Other (specify)

Save Hazard and Exit

- Staff Feedback
 - Analysis of event(s)
 - Error-prevention strategies
- Monitoring
 - Organizations must monitor the effectiveness of their event reporting programs to ensure staff know:
 - How to use the program
 - That the program is capturing the data needed for continuous improvement

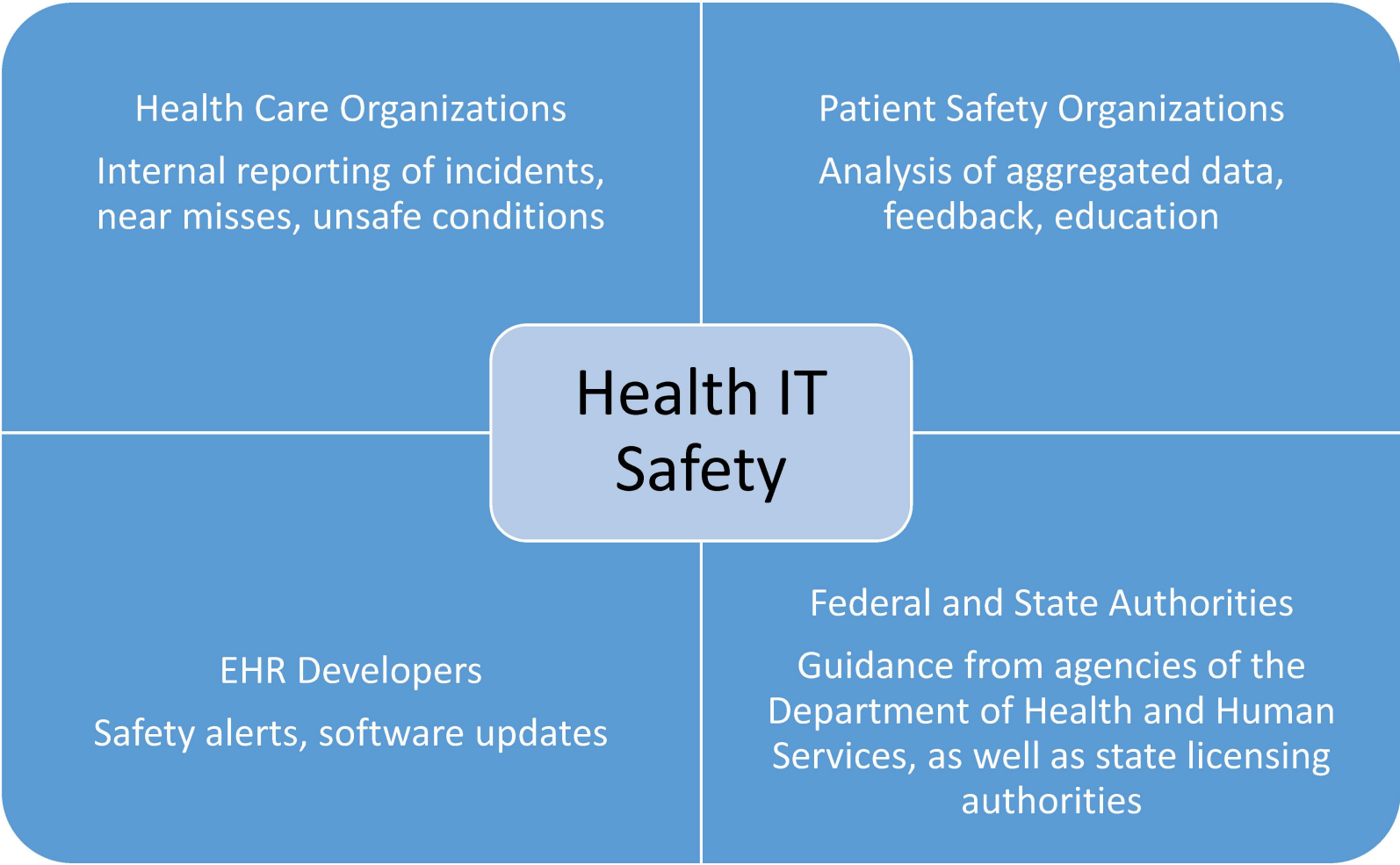
- Other sources of information:
 - Discussion with users
 - Helpdesk logs maintained by the IT Department
 - Medical chart reviews
 - Claims data
 - Executive staff walk-arounds

The Eight Dimensions of the Socio-Technical Model

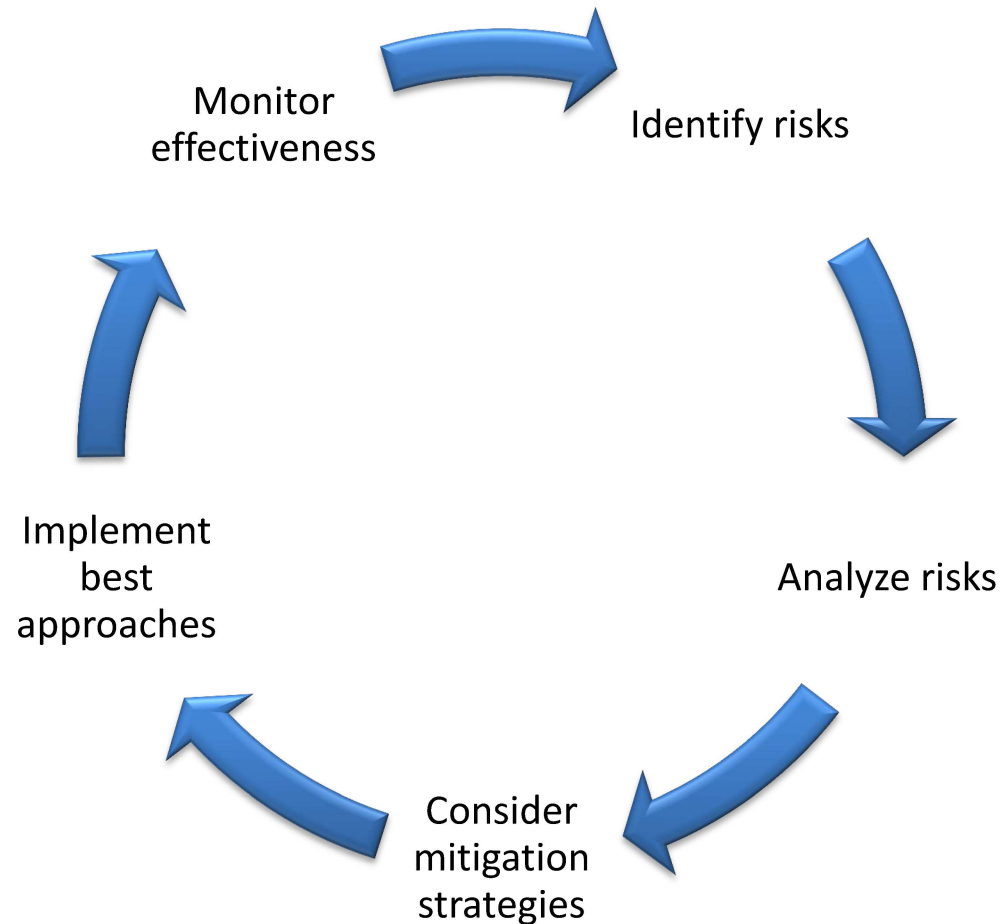


- 1 Hardware and software
- 2 Clinical content
- 3 Human-computer interface
- 4 People
- 5 Workflow and communication
- 6 Internal organizational policies, procedures, environment, and culture
- 7 External rules, regulations, and pressures
- 8 System measurement and monitoring

Guide: Health IT Safety – A Shared Responsibility



Continuous Feedback Approach to Health IT System Safety



Promoting Patient Safety Through Effective Health IT Risk Management

Sponsor: Office of the National Coordinator for Health Information
Technology (#HHSP23320095649WC)

- The potential for health IT to improve the safety of health care delivery has been appreciated for decades
- Role of health IT in introducing safety risks has become apparent more recently
 - Malfunctioning hardware/software
 - Data corrupted or lost
 - Complex organizational demands

- To develop and test a prototype safety improvement approach for organizations implementing health IT systems
 - Enable them to identify safety risks attributable to health IT systems
 - Begin to mitigate those risks

- 9-month process improvement project
- Diverse group of hospitals and ambulatory practices
- Patient Safety Organization (ECRI Institute) recruited sites and facilitated improvement projects
- Expert input: Hardeep Singh & Dean Sittig
- Evaluation: RAND team

- Sites developed work plans:
 - Select a safety topic area
 - Ex: CPOE
 - Identify specific risks within that area
 - Ex: nurses fail to acknowledge orders in the EHR
 - Design and deploy mitigation actions
 - Ex: standardizing work flow and training nurses
 - Identify metrics and collect data
 - Ex: percent of orders not acknowledged within time frame

Overview of sites

Site	Interview?	Project leader's department	Reporting to PSO?	Selected topic area
Hosp 1	No	Quality	Yes	Organizational activities and responsibilities
Hosp 2	Yes	Risk management	No	Clinician communication
Hosp 3	Yes	Risk management	Yes	Test result reporting and follow-up
Hosp 4	Yes	Quality/risk mgmt	No	CPOE
Hosp 5	No	Quality	Yes	Clinician communication
Hosp 6	No	IT	No	EHR downtime
Hosp 7	No	Risk management	Yes	Clinician communication
Amb 1	Yes	Multiple roles	No	CDS
Amb 2	No	Operations	No	Patient identification
Amb 3	Yes	Risk management	No	Test result reporting and follow-up
Amb 4	Yes	Practice owner	No	Test result reporting and follow-up

- Interviews with representatives of hospitals and ambulatory practices
- Interviews covered:
 - background and context
 - health IT adoption
 - existing health IT safety and risk management practices
 - process improvement experience
 - barriers and facilitators
 - usefulness of resources

- Most sites found it difficult to identify and mitigate health IT safety risks within the 9-month project period
- Most sites implemented risk mitigation activities
- One site demonstrated improvement on its selected metric
- Several sites found reporting to PSO using the Common Formats to be challenging

1. Organizations with the highest level of readiness had in-house expertise and prior experience in QI and risk management
2. Projects aligned with organizational priorities, current initiatives, and federal policy directives (e.g., MU) were more likely to make progress
3. Organizations with project teams that were closely involved in executive leadership were more likely to make progress

4. Health care organizations had limited capacity to join and sustain an externally-initiated health IT risk management initiative
5. Organizations tended to view health IT as a solution to patient safety problems, rather than a contributor to problems

6. A key determinant of project success was the availability of resources – especially staff effort – to commit to the health IT safety project
7. Practical, easy-to-use tools could help organizations identify risks and set priorities for addressing them

- **Raising awareness:**
 - Integrate health IT safety agenda with the broader patient safety agenda
 - Engage front-line clinicians—they have direct experience with the risks
- **Fostering collaboration:**
 - Disseminate best practices and project guides
 - Provide training related to safe use of health IT to staff in several distinct disciplines (medical, IT, risk management)

- **Increase the availability of consultation services:**
 - Especially important in rural hospitals and small ambulatory practices
 - REC and PSO programs
 - Develop a “facilitator” workforce
- **Develop and refine tools and metrics:**
 - Adaptation or extension of diagnostic tools, SAFER Guides, AHRQ Common Formats

- **Strengthen incentives for health IT system designers:**
 - Consider use of MU standards and EHR certification programs to provide incentives for EHR developers and clients to optimize safe use of health IT
 - Use surveillance associated with certification to identify and address unsafe features

- The prototype safety improvement approach confronted barriers—all are potentially remediable
 - Limited awareness, competing priorities
 - Cross-department, inter-professional coordination
 - Identifying health IT-related safety risks
 - Metrics for improvement
 - Mitigation strategies



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Consumer eHealth

Health IT and Safety

▶ Health IT and Patient Safety Tools and

Health IT and Safety

Health IT makes new improvements in health care quality and safety possible, compared to paper records. Yet, if not designed and used correctly, it can also introduce new risks of harm. The Office of the National Coordinator (ONC) is taking actions on health IT and patient safety as described in our [Health IT Patient Safety Action and Surveillance Plan](#) by **Improving** the safe use of health IT, **Learning** more about the impact of health IT on patient safety, and **Leading** to create a culture of shared responsibility among all users of health IT.

IMPROVE: ONC is creating resources to improve health IT safety and patient safety

- SAFER Guides: The SAFER Guides are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of electronic health records (EHRs). The SAFER Guides were developed based on the best evidence available including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems.. Each of the nine SAFER Guides begins with a checklist of "recommended practices."



Recently Updated

May 2014

- [Promoting Patient Safety Through Effective Health Information Technology Risk Management \[PDF - 1.95 MB\]](#)

July 19, 2013

- ONC released the guide [EHR Contracts: Key Contract Terms for Users to Understand \[PDF - 501 KB\]](#).

Spotlight on the Literature

- [Improving Adherence for Management of Acute Exacerbation of Chronic Obstructive Pulmonary Disease.](#) Sonstein L, Clark C, Seidensticker S, Zeng L, Sharma G.
- [Development and testing of tools to detect ambulatory surgical adverse events.](#) Mull HJ, Borzecki AM, Hickson K, Itani KM, Rosen AK.

- **ONC sponsored analysis of HIT related safety events**
 - University Health System Consortium
 - ECRI
 - The Joint Commission
- **Tools and Interventions**
 - Health IT Developers Guide to Working with High Reliability Organizations
 - How to Identify Unsafe Conditions Related to Health IT
 - Promoting Patient Safety Through Effective Health IT Risk Management
- **Certified Health Product List (CHPL)**
 - Usability Testing Reports

Certified Health IT Product List

The Office of the National Coordinator for Health Information Technology

The Certified Health IT Product List (CHPL) provides the authoritative, comprehensive listing of Complete Electronic Health Records (EHRs) and EHR Modules that have been tested and certified under the ONC HIT Certification Program, maintained by The Office of the National Coordinator for Health Information Technology (ONC).

Each Complete EHR and EHR Module listed on CHPL has been tested and certified by an authorized testing and certification body against applicable standards and certification criteria adopted by the HHS Secretary. EHR technologies that have been certified under the ONC HIT Certification Program are eligible to be used for the Centers for Medicare and Medicaid (CMS) EHR Incentive Programs. The CHPL provides CMS EHR Certification ID for qualified products to be used in the CMS EHR Incentive Programs.

In FY/CY 2013, beginning January 2, 2013:

Eligible providers will have the ability to use EHR technology that is certified to 2011 edition certification criteria, 2014 edition certification criteria, and a combination of 2011 and 2014 edition certification criteria to generate CMS EHR Certification ID that is submitted to CMS as part of attesting to meaningful use of certified EHR technology.

Please send suggestions and comments regarding the Certified Health IT Product List (CHPL) to ONC.certification@hhs.gov, with "CHPL" in the subject line.

Vendors or developers with questions about their product's listing should contact their certification body that certified their product.

STEP 1: TO WHICH EDITION OF ONC HIT EHR CERTIFICATION ARE YOU ATTESTING?

[2011 Edition](#)

[Combination of 2011 and 2014 Edition](#)

[2014 Edition](#)

USING THE CHPL WEBSITE

To browse the CHPL and review the comprehensive listing of certified EHR products, follow the steps outlined below:

1. Select the EHR Certification Criteria Edition for attestation (2011 Edition, Combination of 2011 and 2014 Edition, 2014 Edition)
2011 Edition – List of EHR products that are certified to 2011 Edition certification criteria.
2014 Edition – List of EHR products that are certified to 2014 Edition certification criteria.
Combination of 2011 and 2014 Edition – List of EHR products that are certified to 2011 Edition certification criteria AND/OR equivalent 2014 Edition certification criteria.
2. Select Practice Type (Ambulatory or Inpatient). Practice Type selection available only for '2011 Edition' and 'Combination of 2011 and 2014 Edition' attestation
3. Select the "Browse" button to view the list of all CHPL products

To obtain a CMS EHR Certification ID, follow the steps outlined below:

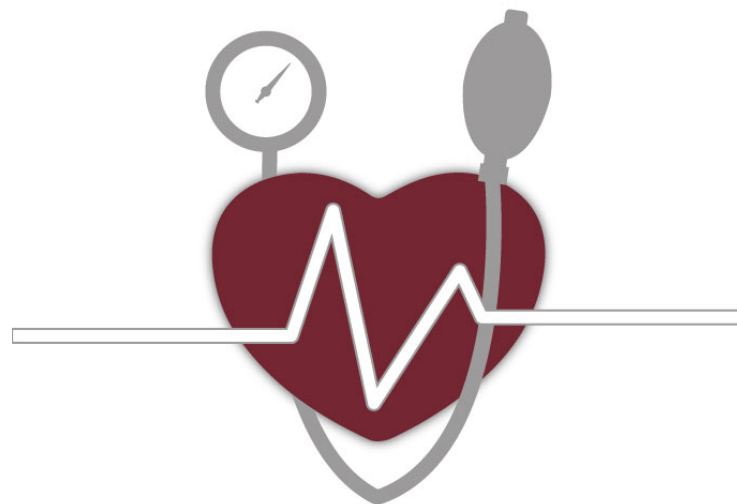
1. Select the EHR Certification Criteria Edition for attestation (2011 Edition, Combination of 2011 and 2014 Edition, 2014 Edition)
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3. Search for certified complete EHR products or EHR modules by browsing all products, searching by product name, CHPL product number, vendor name, product classification, or criteria met. A search by clinical quality measures (CQMs) is available only for 2014 Edition attestation
4. Add certified complete EHR product(s) or a combination EHR module(s) to cart to determine if selected product(s) meet 100% of the required criteria to demonstrate meaningful use
5. Request a CMS EHR Certification ID for CMS registration or attestation

- IOM 2012: More research is needed to improve the safety of health IT
- AHRQ 2014 appropriation: \$4 million for new research grants
- February 2014: Two funding notices posted
- September 2014: Four new grants awarded
- Dr. David Bates will be improving the CPOE Evaluation Tool currently used by Leapfrog

EHR Innovations for Improving Hypertension Challenge

- Identify the most successful tools and approaches for blood pressure treatment and control used by individual practices (Phase 1: Submissions due October 6, 2014)
- Spread these to new practices and demonstrate success (Phase 2: Submissions Due July 31, 2015)
- Hypertension Challenge URL - <http://challenge.sites.usa.gov/challenge/ehr-innovations-for-improving-hypertension-challenge/>

EHR INNOVATIONS FOR
IMPROVING
HYPERTENSION



CHALLENGE





Build the foundation and develop a roadmap for an ONC Health IT Safety Center

- Engage Stakeholders
- Public – Private Partnership
- Identify Highest Priority Activities to Promote Safe Use of EHRs
 - Review evidence on HIT Safety Related Events
 - Provide education on identifying and preventing HIT related safety events
 - Develop resources and tools to improve Health IT Safety and promote the safe use of EHRs
 - Evaluate progress on HIT safety

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- **Contact us at:** onc.request@hhs.gov



Office of the National Coordinator for Health Information Technology

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HIT Safety: Progress Made and Challenges Ahead

Health IT Week

September 19, 2014

