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Webinar Series 2014

The presentation will begin shortly.

AHA Webinar

ONC SAFER Guides for Improving EHR Safety

December 3, 2014

Hardeep Singh, MD MPH & Dean F. Sittig, PhD

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

Baylor College of Medicine

GIVING LIFE TO POSSIBLE

UTHealth | School of Biomedical Informatics

The University of Texas Health Science Center at Houston

Agenda

- Discuss the need for SAFER *(Safety Assurance Factors for EHR Resilience)* Guides
  - Review R&D methods
  - Development Approach and Guide Review
  - Q&A/Discussion

SAFER Project Goal…

To develop and validate proactive, self-assessment tools to ensure that EHR-enabled clinical work systems are safe and effective

Health IT risks exist

Aug 27, 2013, 2:57pm PDT | **UPDATED:** Aug 27, 2013, 6:13pm PDT

Sutter electronic records system crashed Monday

Kathy Robertson
Senior Staff Writer-
Sacramento Business Journal
Email | Twitter | LinkedIn | Google+

At about 8 a.m. Monday, the electronic health record system at seven East Bay hospitals, medical offices and clinics went dark. The meltdown continued through late afternoon or early evening, according to early reports from the California Nurses Association.

Srdjan Srdjanov

The electronic health record system at seven East Bay hospitals, medical offices and clinics went dark on Monday

Be Prepared!

The more Health IT you have,
the more prepared you need to be!

This can happen anywhere…

- **Survey of Scottsdale Institute Membership**
  - 95% had at least 1 unplanned downtime in past 3 yrs
  - 79% or organizations had at least one unplanned downtime of at least 8 hours
    - 13% had 24+ hours of downtime
  - 1 organization had an injury to a patient or staff member during a planned downtime
  - 2 organizations had an injury to a patient or staff member during an unplanned downtime

Contingency Planning for EHR-based Care Continuity: A Survey of Recommended Practices. Sittig et al Int J Med Inform. 2014 Nov;83(11):797-804.

We did a survey of ASHRM and AHLA members

- August - September 2012; 369 respondents
- Survey topic areas included:
  - Frequency of EHR-related serious safety events
  - Factors affecting EHR-related serious safety events
  - Best practices to avoid EHR-related serious safety events
  - Tracking of EHR-related safety measurements

EHR-Related Safety Concerns: A Cross-Sectional Survey. J Healthc Risk Manag. 2014;34(1):14-26.

Frequency of serious safety events in the last 5 years

- 53% admitted to at least one EHR-related serious safety event in the previous five years;
  - 10% experienced more than 20 events

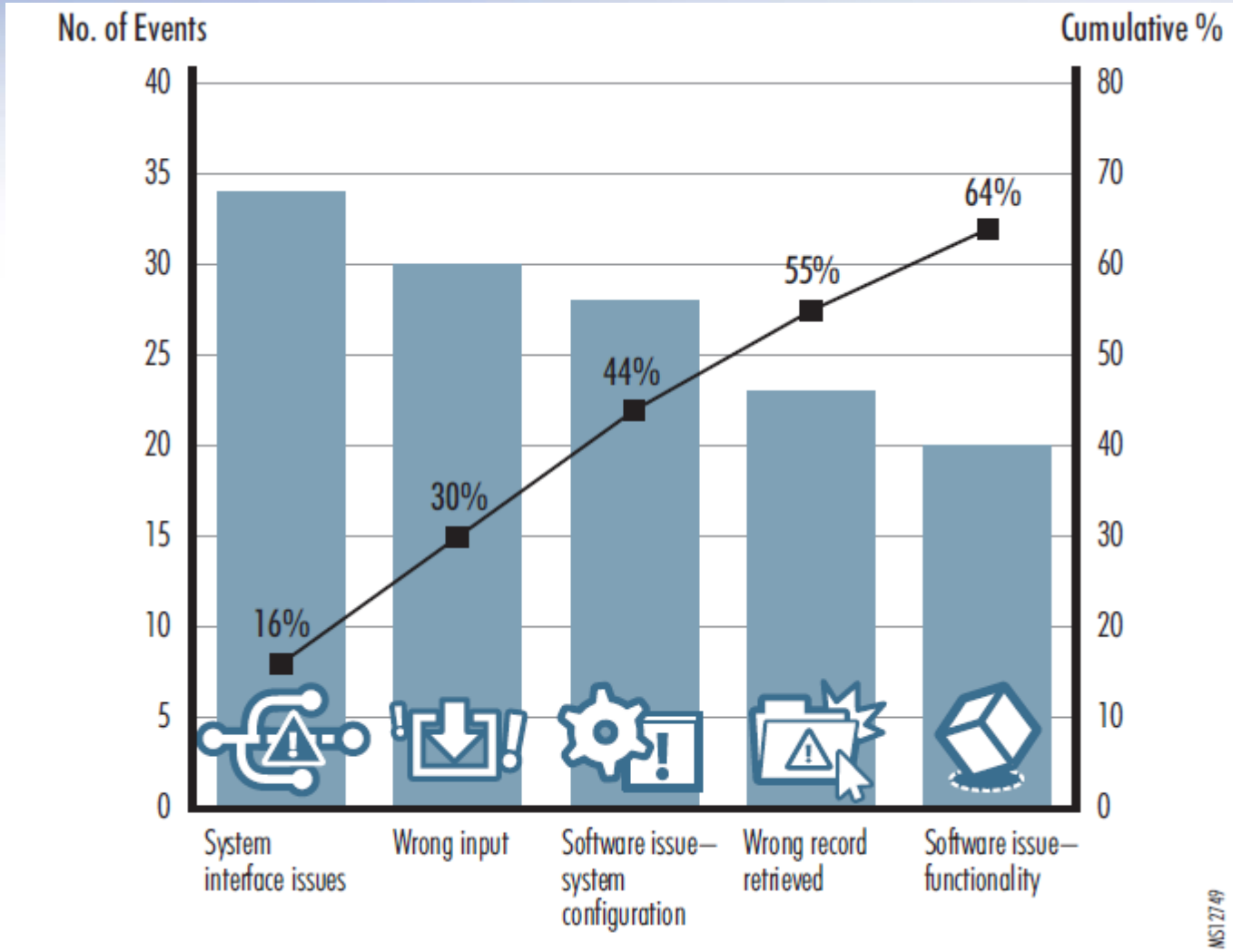
EHR-Related Safety Concerns: A Cross-Sectional Survey. J Healthc Risk Manag. 2014;34(1):14-26.

Type and frequency of health IT-related safety events in the past 5 years

Type of safety event	Frequently + Occasionally - %
Data is incomplete, missing or misleading	52
Open or incomplete patient orders	51
Procedures and policies are ineffective	46
Failure to follow up abnormal test results	44
Confusing one patient with another	43
Reliance upon inaccurate or incomplete patient data	39
Intentionally or accidently subverting CDS	34
Automatic discontinuation of a prescription	29
Data aggregation leading to erroneous data reporting	27
Prolonged EHR downtime	20
Errors resulting from implementing legal mandates	17

EHR-Related Safety Concerns: A Cross-Sectional Survey. J Healthc Risk Manag. 2014;34(1):14-26.

Results of the ECRI deep dive



ECRI Institute PSO Deep Dive: Health Information Technology. Plymouth Meeting, PA (2012).

National initiatives should be accompanied by guidance for the frontlines

- Clinicians/institutions unaware of best practices for safe EHR implementation & use
- Difficult to identify errors embedded in flawed interfaces between components of the EHR
- Solutions cannot be addressed through improvements in technology alone

The SAFER Guides: Empowering Organizations to Improve the Safety and Effectiveness of Electronic Health Records. Sittig, Ash, Singh. Am J Manag Care. 2014 May;20(5):418-23.

Defining Major types of HIT-related Safety Concerns

Type of HIT-related safety concern	Examples
1. Instances in which HIT fails during use or is otherwise not working as designed.	Broken hardware or software "bugs"
2. Instances in which HIT is working as designed, but the design does not meet the user's needs or expectations.	Usability issues
3. Instances in which HIT is well-designed and working correctly, but was not configured, implemented, or used in a way anticipated or planned for by system designers and developers.	Duplicate order alerts that fire on alternative PRN pain medications

5 Major types of HIT-related Safety Concerns

Type of HIT-related safety concern	Examples
4. Instances in which HIT is working as designed, and was configured and used correctly, but interacts with external systems (e.g., via hardware or software interfaces) so that data is lost or incorrectly transmitted or displayed.	Medication order for extended release morphine inadvertently changed to immediate release morphine by error in interface translation table
5. Instances in which specific safety features or functions were not implemented or not available (i.e., HIT could have prevented a safety concern).	Hospitalized patient inadvertently receives 5 grams of acetaminophen in 24 hours because maximum daily dose alerting was not available

Sittig, Classen, Singh. J Am Med Inform Assoc. 2014 Oct 20.

Methods for Development

- Literature review to identify best practices
- Expert panel meetings
- Stakeholder engagement
- Fieldwork at purposively selected sites
- Cognitive interviews reviewing the guides
- Pilot testing the guides

Safety Assurance Factors for Electronic Health Record Resilience (SAFER): study protocol.
BMC Med Inform Decis Mak. 2013 Apr 12;13:46.

Stakeholder Engagement

- American College of Physicians
- American Health Information Management Association
- American Hospital Association
- American Medical Informatics Association
- American Society for Healthcare Risk Management
- Association of Medical Directors of Information Systems
- CDC's Laboratory Health IT Panel
- Health Information Management Systems Society
- Institute for Healthcare Improvement
- Medical Group Management Association
- Patient Safety Organizations
- The Scottsdale Institute
- Summer Institute for Nursing Informatics
- Texas Medical Association
- The Joint Commission

Site Visits

- Learn about new best practices
- Discover differences across kinds of sites
- Interview and observe to find out who would use the guides, how, and when
- To find out what would be most useful to them
- Iteratively refine the guides

Pilot Testing

- Who can answer the questions (team?)
- Is guide user-friendly?
- Are questions user-friendly?
- Completion time
- Synchronous or asynchronous completion?

Agenda

- Discuss the need for SAFER *(Safety Assurance Factors for EHR Resilience)* Guides
  - Review R&D methods
  - Development Approach and Guide Review
  - Q&A/Discussion

Used a Multifaceted Approach

- Design, development, implementation, use, and evaluation of health IT is complex and prone to failure

- Need new scientific "conceptual models" to get this right!

Sittig & Singh. JAMA. 2009 Sep 9;302(10):1111-3.

8-dimensional Socio-Technical Model of Safe & Effective EHR Use

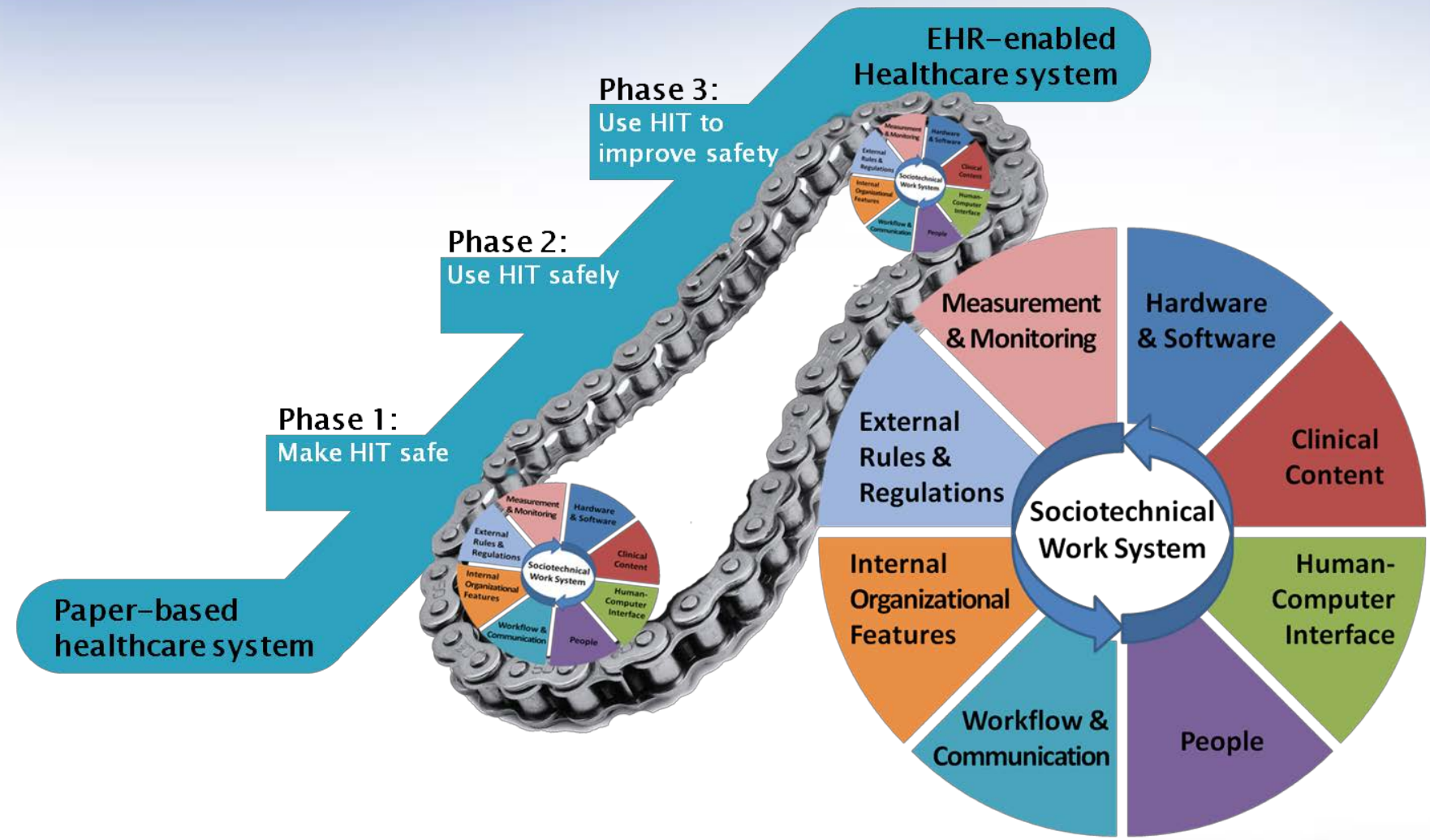
(Sittig & Singh. Qual Saf Health Care. 2010 Oct;19 Suppl 3:i68-74.)

Evolution of Safety (and Risks) – Phases of HIT Safety

- Safe IT:
  - events unique/specific to EHRs; more likely early in implementation
- Using IT safely:
  - unsafe or inappropriate use of technology
  - unsafe changes in workflows that emerge from technology use
- Using IT to improve/monitor safety
  - monitor health care processes and patient outcomes to identify potential safety concerns before harm

Sittig & Singh N Engl J Med. 2012 Nov 8;367(19):1854-60.

SAFER Conceptual Model



Meeks et al J Am Med Inform Assoc. 2014 Feb;21(e1):e28-34.

6 SAFER Principles in 3 Phases

- **Phase 1** *Safe Health IT: Address Safety Concerns Unique to EHR Technology*
    1. Data Availability
    2. Data Integrity
    3. Data Confidentiality
- **Phase 2** *Using Health IT Safely: Optimize the Safe Use of EHRs*
    4. Complete/Correct EHR Use
    5. EHR System Usability
- **Phase 3** *Monitoring Safety: Use EHRs to Monitor and Improve Patient Safety*
    6. Safety Surveillance, Optimization, and Reporting

Sittig et al. J Am Health Inform Management Association, 2014

Nine SAFER Guides

- **Foundational Guides**
  - High Priority Practices
  - Organizational Responsibilities
- **Infrastructure Guides**
  - System Configuration
  - System Interfaces
  - Contingency Planning
- **Clinical Process Guides**
  - Patient Identification
  - Computerized Provider Order Entry with CDS
  - Test Results Reporting and Follow-up
  - Clinician Communication

Start with Practices

- Each SAFER Guide has between 10-25 “recommended practices”
  - “What” to do to optimize the safety and safe use of the EHR
- Practices assessed as “fully implemented,” “partially implemented,” or “not implemented”

Planning Worksheets are Extra Help

- *Help* organizations/practices <u>set goals and track progress</u>
- *Provide* <u>Rationale</u> to explain "why" each recommended practice is important
- *Provide* <u>Examples</u> to operationalize each recommended practice
  - Examples illustrate "how" the recommended practices could be implemented

Which Guide to Begin With and How?

- The *High Priority Practices SAFER Guide* identifies "high risk" areas and "high priority" safety practices
- Multi-disciplinary team recommended to help focus on most important safety challenges and risks
- Requires engagement of people both within and outside practice/organization (e.g. EHR technology developers and diagnostic services providers)
- Collaboration between clinicians and staff members

SAFER Walkthrough

SAFER Self Assessment High Priority Practices | Checklist

> Table of Contents | > *About* the Checklist | > Team Worksheet | > *About* the Practice Worksheets | > Practice Worksheets

Recommended Practices for ***Phase 1 — Safe Health IT***

			Implementation Status			
			Fully in all areas	Partially in some areas	Not implemented	
1	Data and application configurations are backed up and hardware systems are redundant.	*Worksheet 1*				reset
2	EHR downtime and reactivation policies and procedures are complete, available, and reviewed regularly.	*Worksheet 2*				reset
3	Allergies, problem list entries, and diagnostic test results (including interpretations of those results, such as "normal" and "high"), are entered/stored using standard, coded data elements in the EHR.	*Worksheet 3*				reset
4	Evidence-based order sets and charting templates are available for common clinical conditions, procedures, and services.	*Worksheet 4*				reset

SAFER Worksheet – Practice 3

SAFER Self Assessment High Priority Practices | Recommended Practice 3 Worksheet | *Phase 1 – Safe Health IT*

> Table of Contents | > *About* the Checklist | > Team Worksheet | > *About* the Practice Worksheets | > Practice Worksheets

Recommended Practice

3 Allergies, problem list entries, and diagnostic test results (including interpretations of those results, such as "normal" and "high"), are entered/stored using standard, coded data elements in the EHR.[7,12-21] Meaningful Use *Checklist*

Implementation Status

Rationale for Practice or Risk Assessment

Free text data cannot be used by clinical decision support logic[22] to check for data entry errors or notify clinicians about important new information.

Assessment Notes

Suggested Sources of Input

Clinicians, support staff, and/or clinical administration

EHR developer

Examples of Potentially Useful Practices/Scenarios

- RxNorm is used for coding medications and NDF-RT for medication classes.
- SNOMED-CT is used for coding allergens, reactions, and severity

SAFER Worksheet – Practice 3

SAFER Self Assessment High Priority Practices | Recommended Practice 3 Worksheet | *Phase 1 – Safe Health IT*

> Table of Contents | > *About* the Checklist | > Team Worksheet | > *About* the Practice Worksheets | > Practice Worksheets

Recommended Practice

Implementation Status

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Rationale for Practice or Risk Assessment

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Assessment Notes

SAFER Worksheet – Practice 3

SAFER Self Assessment High Priority Practices | Recommended Practice 3 Worksheet | *Phase 1 – Safe Health IT*

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SAFER Worksheet – Practice 3

SAFER Self Assessment High Priority Practices

Recommended Practice 3 Worksheet

Phase 1 – Safe Health IT

> Table of Contents | > *About* the Checklist | > Team Worksheet | > *About* the Practice Worksheets | > Practice Worksheets

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Free text data cannot be used by clinical decision support logic[22] to check for data entry errors or notify clinicians about important new information.

Suggested Sources of Input

Clinicians, support staff, and/or clinical administration

EHR developer

Examples of Potentially Useful Practices/Scenarios

- RxNorm is used for coding medications and NDF-RT for medication classes.
- SNOMED-CT is used for coding allergens, reactions, and severity

Assessment Notes

SAFER Worksheet – Practice 3

Examples of Potentially Useful Practices/Scenarios

- RxNorm is used for coding medications and NDF-RT for medication classes.
- SNOMED-CT is used for coding allergens, reactions, and severity.
- SNOMED-CT, ICD-10, or ICD-9 is used for coding clinical problems and diagnoses.
- LOINC and SNOMED-CT are used for coding clinical laboratory results.
- Abnormal laboratory results are coded as such.

See the *Computerized Provider Order Entry with Decision Support Guide* and *Test Results Reporting and Follow-Up Guide* for related recommended practices.

Interactive Section of Worksheet

Follow-up Actions

Person Responsible for Follow-up Action

reset page

Click on a link below to view the topic online:

»References »Phases & Principles »Meaningful Use »HIPAA

Supported by References

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

References: High Priority Practices

References from the literature are included to support the recommended practices and to provide additional resources.

1. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J Am Med Inform Assoc*. 2004;11:104-112.

2. Harrington L, Kennerly D, Johnson C. Safety issues related to the electronic medical record (EMR): synthesis of the literature from the last decade, 2000-2009. *J Healthc Manag*. 2011;56:31-43.

3. Singh H, Wilson L, Petersen LA, et al. Improving follow-up of abnormal cancer screens using electronic health records: trust but verify test result communication. *BMC Med Inform Decis Mak*. 2009;9:49.

4. Singh H, Thomas EJ, Mani S, et al. Timely follow-up of abnormal diagnostic imaging test results in an outpatient setting: are electronic medical records achieving their potential? *Arch Intern Med*. 2009;169:1578-1586.

5. Singh H, Thomas EJ, Sittig DF, et al. Notification of abnormal lab test results in an electronic medical record: do any safety concerns remain? *Am J Med*. 2010;123:238-244.

6. Sittig DF, Classen DC. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *JAMA*. 2010;303:450-451.

7. Sittig DF, Singh H. Electronic health records and national patient-safety goals. *N Engl J Med*. 2012;367:1854-1860.

Interactive Section of Worksheet

Follow-up Actions

Person Responsible for Follow-up Action

reset page

Click on a link below to view the topic online:

»References »Phases & Principles »Meaningful Use »HIPAA

SAFER Phases and Principles

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

SAFER Phases and Principles

The SAFER Guides are designed to optimize the safety and safe use of EHRs. Eight of the guides (all except the Organizational Responsibilities SAFER Guide) are organized according to Phases and Principles described below. Phases remind organizations "which" aspect of health IT safety is being addressed as they adopt EHRs and build health IT safety programs. Phases overlap and build upon each other. In general, the higher phases assume that Phase 1 recommended practices on safety concerns unique to EHRs have been considered and are being addressed. Once the EHR is in clinical use, organizations should consider how to integrate the recommended practices in all phases into routine operations, based upon assessment of those practices. Within each phase, the recommended practices address principles that suggest "why" the recommended practices are needed, although any given recommended practice may support several principles that support health IT safety.

The recommended practices in the Organizational Responsibilities SAFER Guide are organized under a different set of principles relevant for patient safety programs at any phase of EHR adoption and implementation. These principles are described in the guide itself.

Phase 1 | Safe Health IT — Address Safety Concerns Unique to EHR Technology

Principle: Data Availability

EHRs and the data or information contained within them are accessible and usable upon demand by authorized individuals.

Principle: Data Quality and Integrity

Data or information in EHRs is accurate and created appropriately and have not been altered or destroyed in an unauthorized manner.

Principle: Data Confidentiality

Data or information in EHRs is only available or disclosed to authorized persons or processes.

SAFER Phases and Principles

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

Phase 2 | Using Health IT Safely — Optimize the Safe Use of EHRs

Principle: Complete/Correct EHR Use

EHR features and functionality are implemented and used as intended.

Principle: EHR System Usability

EHR features and functionality are designed and implemented so that they can be used effectively, efficiently, and to the satisfaction of the intended users to minimize the potential for harm. For information in the EHR to be usable, it should be easily accessible, clearly visible, understandable, and organized by relevance to the specific use and type of user.

Phase 3 | Monitoring Safety — Use EHRs to Monitor and Improve Patient Safety

Principle: Safety Surveillance, Optimization, and Reporting

As part of ongoing quality assurance and performance improvement, mechanisms are in place to monitor, detect, and report on the safety and safe use of EHRs, and to optimize the use of EHRs to improve quality and safety.

HIPAA References

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

HIPAA: High Priority Practices

HIPAA references that support recommended principles are identified below.

Recommended Practice 1

Data and application configurations are backed up and hardware systems are redundant.[8-10]

Security Rule – Administrative Safeguards
45 C.F.R. § 164.308 (a)(7) – Contingency plan

Security Rule – Physical Safeguards
45 C.F.R. § 164.310(d)(2)(iv) – Data backup and storage

Meaningful Use References

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

Meaningful Use: High Priority Practices

Recommended Practices that support Meaningful Use are identified below.

Recommended Practice 13

The EHR is used for ordering medications, diagnostic tests, and procedures.[7]

Meaningful Use:

- 42 CFR 495.6(j)-(m) Stage 2 Core Objective: Use CPOE for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines.
- 42 CFR 495.6(j)-(m) Stage 2 Core Measure: More than 60% of medication, 30% of laboratory, and 30% of radiology orders created by the EP or authorized providers of the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.

See Also: CMS FAQs 2771, 2851, 3057, 7623, 7693, 7709, and 9058 at https://questions.cms.gov/

Thank You

- Funding Acknowledgement: **ONC**

- SAFER Guides http://www.healthit.gov/safer

- Hardeep Singh – Hardeeps@bcm.edu
  http://www.houston.hsrd.research.va.gov/bios/singh.asp
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Additional support: **VA, AHRQ**

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