SAFER Guides:
Safety Assurance Factors for EHR Resilience

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January 30, 2014

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ONC and Health IT Patient Safety

- Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Better Care* (2011)
- *Health IT Patient Safety Action and Surveillance Plan (2013)*
  - *Use health IT to make care safer*
  - *Continuously improve the safety of health IT*
- SAFER Guides – health IT safety tool, designed for all settings, from small practices to large systems
- Requires organizational leadership and a team
- Requires shared responsibility and engagement by EHR technology developers/vendors, diagnostic services providers, and others

SAFER Guides -- Development

- 2 years in development; based on best available evidence

- Content development led by an exceptional team
  - Joan Ash, PhD MLS MBA, Prof. and Vice-Chair Informatics at Oregon Health & Science University
  - Hardeep Singh, MD, MPH, Houston VA Center for Innovations in Quality, Effectiveness and Safety, and Baylor College of Medicine
  - Dean Sittig, PhD, University of Texas School of Biomedical Informatics; UT-Memorial Hermann Center for Healthcare Quality and Safety

Why We Need the SAFER Guides

Dean F. Sittig, PhD

University of Texas School of Biomedical Informatics at Houston

UT - Memorial Hermann Center for Healthcare Quality & Safety

SAFER Project Goal…

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

Agenda

- Discuss need for SAFER guides

- Review R&D methods

- Describe how and why the guides are organized as they are

- Q&A and review the guides

- Goal is to have lively, interactive discussion

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.

⊞ Enlarge

Srdjan Srdjanov

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

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Be Prepared!

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

- **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.
J Am Med Inform Assoc. 2013 (in preparation)

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 (in press)

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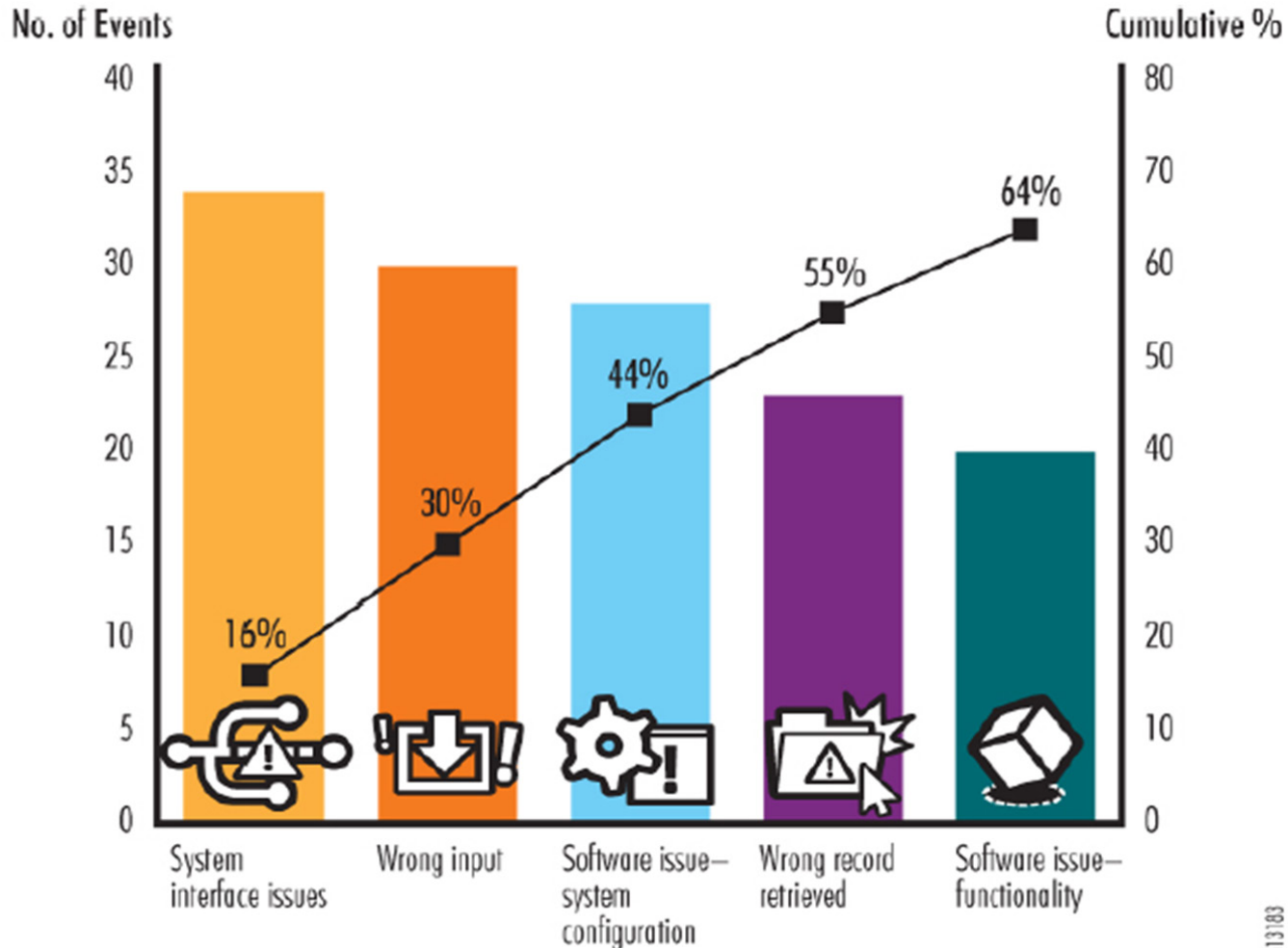 - 10% experienced more than 20 events

EHR-Related Safety Concerns: A Cross-Sectional Survey. J Healthc Risk Manag. 2014 (in press)

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 (in press)

Results of the ECRI deep dive

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

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- 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. J Am Med Inform Assoc. 2013 (under review)

SAFER: Safety Assurance Factors for EHR Resilience

- **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

Developing the SAFER Guides

Joan S. Ash, PhD, MLS, MBA
Professor and Vice-Chair, Informatics
Oregon Health & Science University
Portland, Oregon

Methods we used for developing truly useful guides

- 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 has been ongoing

- 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

The purpose of site visits was to

- 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

We gathered a lot of data

	Geisinger Health System	Family Physicians Group	The Alliance of Chicago	Four Independent Colorado Clinics	Partners HealthCare
Location	Danville, PA	Orlando, FL	Chicago, IL	Lakewood and Colorado Springs, CO	Boston, MA
Characteristics of setting	Community Health System	Large Primary Care Practice	30+ Federally Qualified Health Centers across U.S.	Small independent private clinics	Academic and community health system
Type of EHR	Commercial (Epic)	Commercial (GE Centricity)	Commercial (GE Centricity)	Four ambulatory commercial systems	Locally developed and commercial
Date of Visit	6/12	7/12	8/12	9/12	10/12
Hours observing	NA	15	28	6	20
Num. clinics observed	NA	3	3	4	4
Num. interviews	20	12	16	14	30
Num. pages of data	303	140	439	411	872

We pilot tested the tools at five sites

- Who can answer the questions (team?)

- Is guide user-friendly?

- Are questions user-friendly?

- Completion time

- Synchronous or asynchronous completion?

Lessons learned

- **Organization of the Guides**
  - Development and incorporation of the over-arching principles
  - Development of the rationale section of the guides
- **Implementation and Use of the Guides**
  - Multi-disciplinary teams are best suited to work on the guides
  - Elimination of the idea of "scoring" the practices within a guide
  - Reduction of the 5-point assessment scale for each practice to a 3-point scale
  - Recommended practices applied to both ambulatory and large system practices
- **Content of the Guides**
  - Development of a High Priority Guide
  - Addition of the references
  - Addition of new and significantly refined practices

The Conceptual Evolution of the SAFER Guides

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Hardeep Singh, MD, MPH

Chief, Health Policy Quality and Informatics Program,
Houston Veterans Affairs Center for Innovations in Quality, Effectiveness and Safety
Michael E. DeBakey VA Medical Center & Baylor College of Medicine
Director, Houston VA Patient Safety Center of Inquiry

Multifaceted approach needed

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

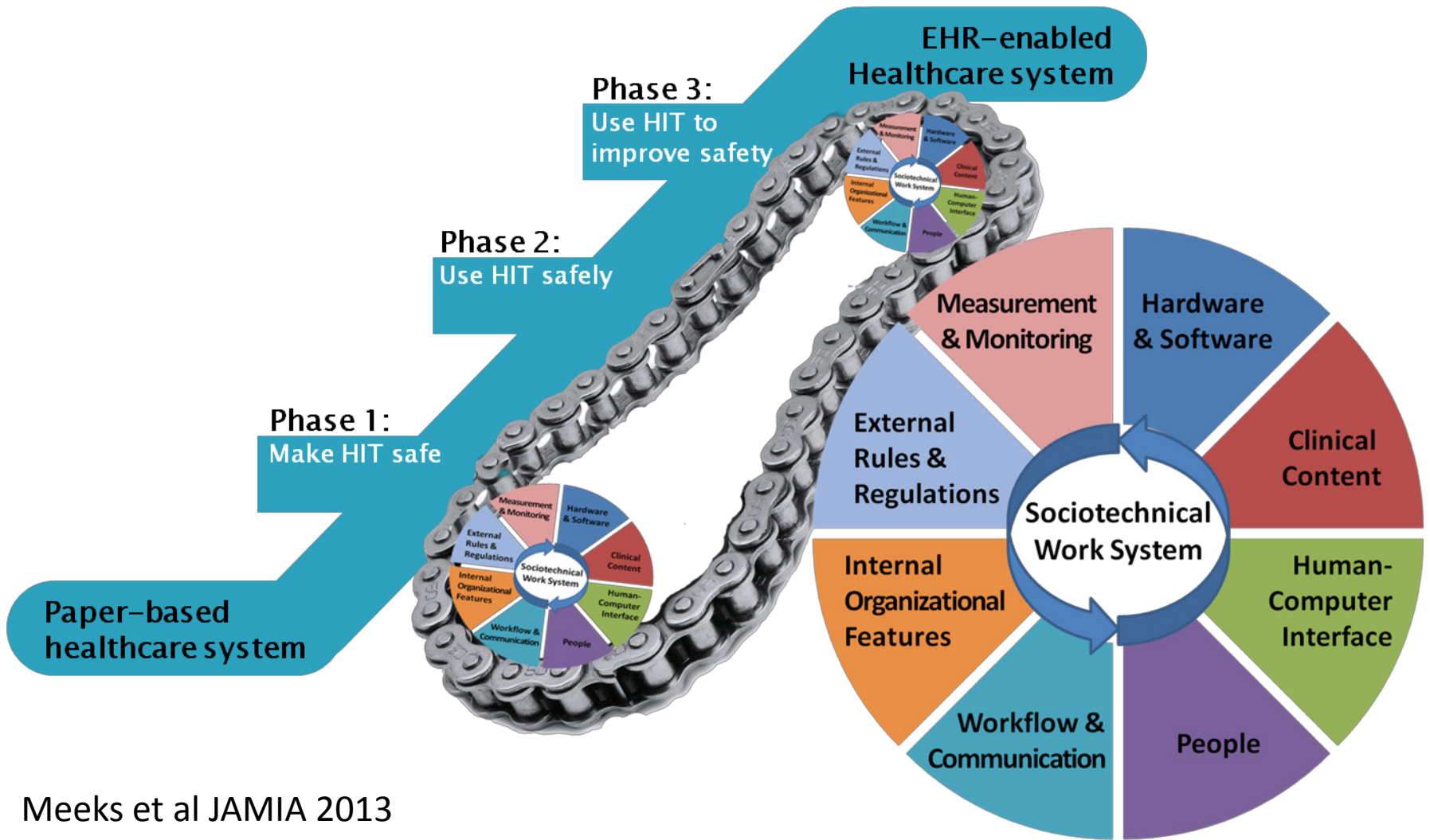- Need new scientific "conceptual models" to get this right!

Sittig & Singh *JAMA* 2009

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

(Sittig & Singh QSHC 2010)
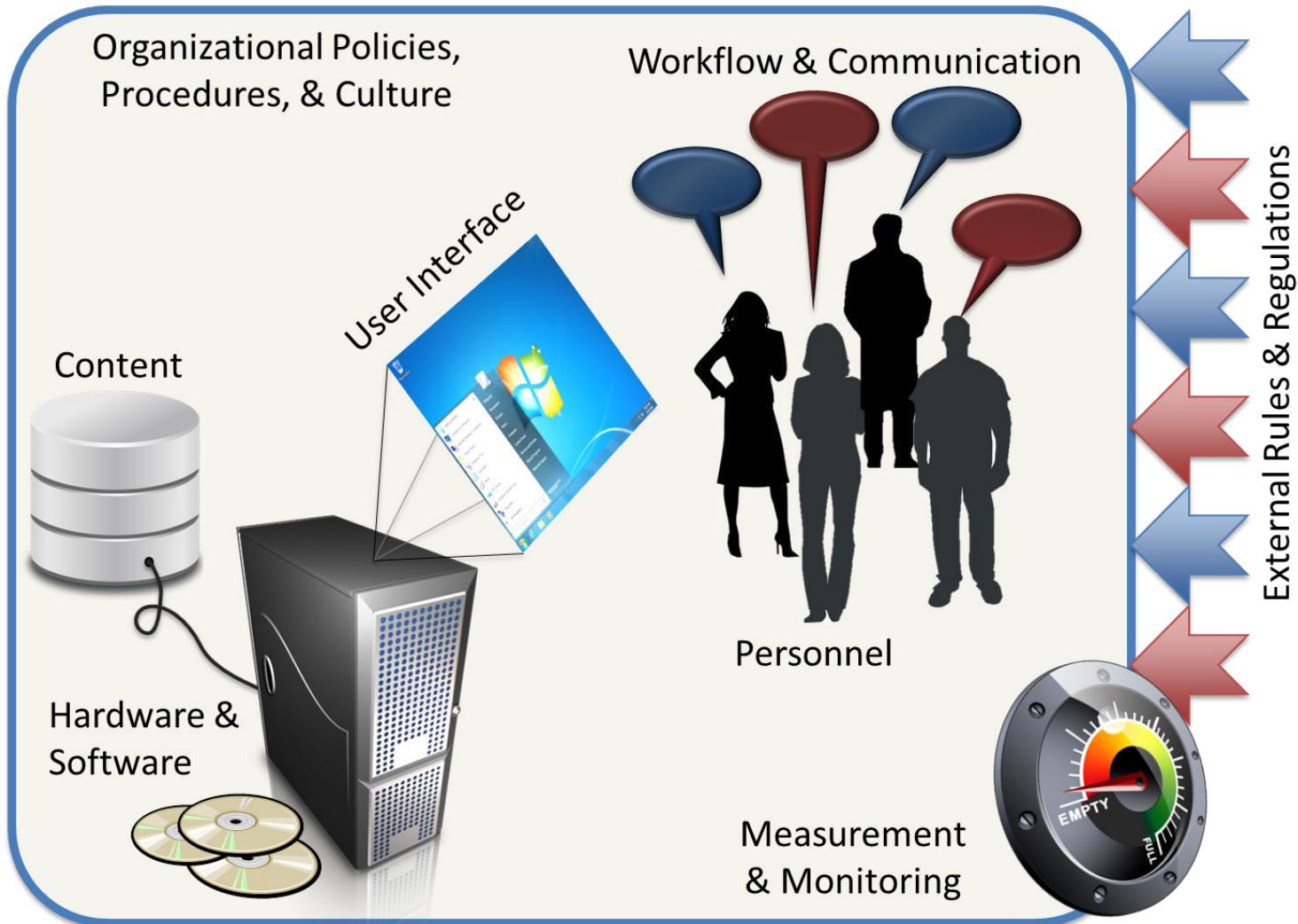
- Safe IT:
  - events unique/specific to EHRs; more likely early in implementation
- Using IT safely:
  - unsafe or inappropriate use of technology
  - unsafe changes in the workflows that emerge from technology use
- Using IT to improve/monitor safety
  - monitor health care processes and patient outcomes to identify potential safety concerns before harm

Sittig & Singh NEJM Nov 2012

"SAFER" conceptual model

Phase 3:
Use HIT to improve safety

EHR–enabled Healthcare system

Phase 2:
Use HIT safely

Phase 1:
Make HIT safe

Paper–based healthcare system

Sociotechnical Work System

- Measurement & Monitoring
- Hardware & Software
- Clinical Content
- Human-Computer Interface
- People
- Workflow & Communication
- Internal Organizational Features
- External Rules & Regulations

Meeks et al JAMIA 2013

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- **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 Under Review

- 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

- *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

Where to Begin?

- The *High Priority Practices SAFER Guide* identifies "high risk" areas and "high priority" safety practices

- Multi-disciplinary safety 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 checklists

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 interpreta-tions 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.

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

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SAFER Worksheet – Practice 3

SAFER Self Assessment
High Priority Practices

Recommended Practice 3
Worksheet

Phase 1 —
Safe Health IT

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Assessment Notes

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Assessment Notes

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Assessment Notes

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SAFER Worksheet – Practice 3

SAFER Self Assessment
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Assessment Notes

SAFER Worksheet – Practice 3

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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.

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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 Reference page

SAFER Safety Assurance Factors for EHR Resilience

The Office of the National Coordinator for Health Information Technology

References: <u>High Priority Practices</u>

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

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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.

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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.

Interactive section of worksheet

Follow-up Actions

Person Responsible for Follow-up Action

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»References   »Phases & Principles   »Meaningful Use   »HIPAA

SAFER Safety Assurance Factors for EHR Resilience

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Health Information Technology

HIPAA: High Priority Practices

HIPAA references the 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

SAFER Worksheet – Practice 13

SAFER Self Assessment
High Priority Practices

Recommended Practice 13 Worksheet

Phase 2 —
Using Health IT Safely

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

Recommended Practice

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

Checklist

Implementation Status

Rationale for Practice or Risk Assessment

Partial EHR use means that clinicians must look in two separate places to find the most recent orders, which increases the potential to miss or delay filling critical orders. Hybrid systems, part electronic and part paper, are particularly hazardous.[53]

Suggested Sources of Input

Clinicians, support staff, and/or clinical administration
Diagnostic services

Health IT support staff
Pharmacy

Examples of Potentially Useful Practices/Scenarios

- The CPOE rate (i.e., the number of orders electronically entered by clinicians divided by the total number of orders entered) is monitored.

Assessment Notes

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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 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/

SAFER Worksheet – Practice 17

SAFER Self Assessment
High Priority Practices | Recommended Practice 17 Worksheet | *Phase 3 — Monitoring Safety*

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

Recommended Practice

Status

17 EHR-related patient safety hazards are reported to all responsible parties, and steps are taken to address them.

Checklist

Rationale for Practice or Risk Assessment

Ensuring that EHR-related patient safety hazards are systematically identified, reported, and addressed is essential to improving the safety of EHRs.

Suggested Sources of Input

Clinicians, support staff, and/or clinical administration

EHR developer

Health IT support staff

Examples of Potentially Useful Practices/Scenarios

- The organization clearly identifies through policies and procedures how to address reports of EHR safety hazards.

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Examples of Potentially Useful Practices/Scenarios

- The organization clearly identifies through policies and procedures how to address reports of EHR safety hazards.

- The organization ensures that reports of hazards and adverse events are reported, as appropriate, to EHR developers as well as senior leadership and boards.

- The organization has a relationship with a patient safety organization experienced in investigating and addressing EHR-related patient safety incidents.

- The total number of EHR-related software errors (i.e., bugs) reported is monitored.

- The serious EHR error fix rate (i.e., the number of errors with potential for causing direct patient harm fixed within 3 months divided by the total number of errors reported) is monitored.

See the *Organizational Responsibilities Guide* for related recommended practices.

Phase 3 —
Monitoring Safety

>Practice Worksheets

Status

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EHR developer

Health IT support staff

ially Useful Practices/Scenarios

learly identifies through policies and
address reports of EHR safety hazards.

SAFER Project Team

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- Dean F. Sittig – Dean.F.Sittig@uth.tmc.edu

- SAFER Guides – www.healthit.gov
- http://www.healthit.gov/saferguide