SAFER Electronic Health Records

Safety Assurance Factors for EHR Resilience

Editors

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

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INTRODUCTION

Electronic health records (EHRs) have the potential to improve the quality and safety of health care [1]. Since the enactment of the Health Information Technology for Economic and Clinical Health Act (HITECH) [2], organizations are adopting EHRs at an unprecedented rate [3]. While the challenges of rapid EHR implementation can be numerous and disruptive, most clinicians prefer EHRs over paper records [4] in the hopes of improving care with better access to information at the point-of-care [5], advanced clinical decision support [6], and more reliable mechanisms for provider-to-provider communication [7]. Clinicians' willingness to adopt EHRs is reassuring, especially in these early stages of an EHR-enabled health system where benefits thus far have been difficult to achieve on a broad scale. However, implementation of EHRs and other new technologies carries unintended consequences that need to be addressed [8]. Clinicians have also experienced safety concerns from EHR design and usability features that are not optimally adapted for the complex workflow of real-world practice settings [9,10,11]. To respond to these challenges, the Office of the National Coordinator for Health Information Technology (ONC) commissioned the 2012 Institute of Medicine Report *Health IT and Patient Safety: Building Safer Systems for Better Care* [12] and recently released the *Health Information Technology Patient Safety Action and Surveillance Plan* that lays out their proposed response to these issues [13].

National initiatives needed to improve the safety of EHRs must be accompanied by practical and helpful strategies for clinicians on the frontlines of EHR-enabled care delivery. Although organizations are accustomed to developing and using practice standards, clinical guidelines, and evidence-based medicine to provide the best possible care for their patients, they are often unaware of best practices for safe EHR implementation and use. For example, they often have minimal guidance to handle problems such as too many alerts [14,15], an EHR that is too slow, or an

EHR that requires an excessive number of "clicks" to complete simple tasks. These are not skills routinely expected of healthcare providers in the past [16]. Clinicians are also not privy to other safety concerns embedded in flawed interfaces between the various components of the EHR and in the way the EHR system is configured. Solutions to these problems are often multifaceted, involving analysis and redesign of workflow and organizational processes and procedures that cannot be addressed through improvements in technology alone. Addressing EHR-related safety concerns is thus inherently complex and involves a comprehensive and multifaceted systems-based approach. Organizations must be active in finding and demanding solutions, but they need practical and useful guidance for EHR safety.

With support from the ONC, we used a rigorous, iterative process to develop a set of nine self-assessment guides to optimize the safety and safe use of EHRs (see Table 1) [17]. These guides, referred to as the Safety Assurance Factors for EHR Resilience (SAFER) guides, are designed to help organizations self-assess the safety and effectiveness of their EHR implementations, identify specific areas of vulnerability, and change their cultures and practices to mitigate risks.

The goal of this book is to provide EHR designers, developers, implementers, users, and policy makers with the requisite historical context, clinical informatics knowledge, and real-world, practical guidance to enable them to utilize the SAFER Guides to proactively assess the safety and effectiveness of their EHR implementations. The first five chapters are designed to provide readers with the conceptual knowledge required to understand why and how the guides were developed. The next nine chapters consist of 1–3 articles that focus on the underlying informatics concepts, key research activities, or methods used to develop each of the guides. Each of these chapters concludes with a copy of the guide itself. The final chapter provides a vision for the future of how we can create the required socio-technical infrastructure necessary to oversee the work required to ensure that future generations of EHRs are designed, developed, implemented, and used to improve the overall safety of the EHR-enabled healthcare system.

TABLE 1: Electronic Health Record-Related Structures and/or Processes addressed by SAFER guides.

Name of Guide	Description of each guide
High Priority Practices	The subset of processes determined to be "high risk" and "high priority" meant to broadly cover all areas that have a role in EHR safety
Computerized provider order entry (CPOE) with clinical decision support	Processes pertaining to electronic ordering of medications and diagnostic tests and aiding the clinical decision making process at the point of care
Test result reporting and follow-up	Processes involved in delivering test results to the appropriate providers
Communication between providers	Communication processes in three high-risk areas: consultations or referrals, discharge-related communications, and patient-related messaging between clinicians
Patient identification	Processes related to creation of new patients in the EHR, patient registration, retrieval of information on previously registered patients, and other patient identification processes
Contingency planning for EHR-based care continuity	Processes and preparations that should be in place in the event that the EHR experiences a hardware, software, or power failure
EHR customization and configuration	Processes required to create and maintain the physical environment in which the EHR will operate, as well as the infrastructure related to the hardware and software that are required to run the EHR
System-system data interfaces	Processes that enable different hardware devices and software applications to be connected both physically and logically so they can communicate and share information
Organizational activities and responsibilities	The organizational activities, processes, and tasks that people must carry out to ensure safe and effective EHR implementation and continued operations

DETAILED OVERVIEW OF EACH CHAPTER

Chapter 1 describes the context of EHR Safety and the need for proactive risk assessment. It begins with an article that defines health information technology-related errors. Interestingly, while many EHR researchers and users commonly discuss EHR-related safety concerns, there is still no widespread agreement on exactly how these concerns are defined. The second article provides a high-level overview of our 8-dimension

socio-technical model while discussing what must be done within each of these dimensions if we are to achieve the safe and effective EHR-enabled healthcare system that will transform healthcare from a cottage industry into the evidence-based, high-reliability, scientifically-sound, interoperable healthcare ecosystem that is required to address the healthcare needs of our modern society. The final article in this chapter describes the results of a cross-sectional survey that focused on EHR-related safety concerns. It provides the background to help explain why there is such a widespread interest in improving the safety and effectiveness of current EHRs.

Chapter 2 consists of three articles that focus on various methods for, and results of, analyzing EHR-related safety events. The first article focuses on an analysis of the EHR-related safety events that have been reported through the US Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. The second article explores the socio-technical intersection of patient safety and EHR implementation as experienced in twelve National Health Service (NHS) hospitals in the United Kingdom. The final article analyzes 100 consecutive EHR-related safety events that were extracted from a non-punitive, voluntary reporting system maintained by the US Veterans Health Administration (VA).

Chapter 3 provides an overview of the user context required to ensure safe and effective EHR use. The first article focuses on the rights and responsibilities of physician users of EHRs. The second article focuses on the additional rights and responsibilities of the sub-set of EHR users that care for children. Taken together, these two articles describe specific EHR features, functions and user privileges that are critical for physicians if they are to provide the highest quality, safest and most cost-effective care. Each of these "rights" is also accompanied by a corresponding responsibility of physicians, without which the ultimate goal of improving the quality of health care might not be achieved.

Chapter 4 describes the conceptual foundation of the SAFER guides. It begins with an in-depth review of an eight-dimension socio-technical model that we have used extensively to study various aspects of health information technology. The second article presents a three-phase approach to ensure that EHRs are implemented and used safely and effectively that focuses on: 1) Ensuring that the EHR itself is working appropriately; 2)

Ensuring that the EHR is uses correctly and completely; and 3) Ensuring that the EHR is used to improve the safety of the healthcare delivery system.

Chapter 5 describes the research methods we used to develop the SAFER guides. It includes a description of how we solicited input from various subject matter experts and relevant stakeholders and created the first iteration of the guides that focused on nine specific risk areas. It goes on to describe how we pilot and beta tested the guides with individuals representative of likely users. It concludes with the methods our multidisciplinary team used to assess the content validity and perceived usefulness of the draft SAFER guides, including interviews, naturalistic observations, and document analysis.

Chapter 6 provides an overview of the high priority items from each of the SAFER guides. It begins with an overview of how these guides can be used to empower organizations to improve the safety and effectiveness of their EHRs. The second article describes a red-flag-based approach that we developed based on the SAFER recommendations to help organizations identify various safety issues. The final section of this chapter includes the High Priority SAFER guide. This self-assessment guide is intended to increase awareness of characteristics that can improve the safety of EHRs and support the proactive evaluation of selected risk areas. It helps organizations identify and evaluate where breakdowns may occur in their healthcare delivery system. This assessment focuses on processes determined to be "high risk" and "high priority" and is meant to broadly cover all areas that have a role in EHR safety. Thoughtful use of this assessment by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. When assessing EHRs at repeated intervals, (such as initially, annually and when changes are made), the assessment can be used to establish a baseline for measuring the effect of interventions designed to improve EHR safety. The assessment works for small, ambulatory physician practices and larger outpatient settings as well as for hospitals.

Chapter 7 provides an overview of a survey of recommended practices that we developed to help organizations assess their contingency planning activities for EHR downtimes. Failures in Electronic Health Record (EHR) software and the hardware infrastructure that supports them, not to

mention both natural and man-made disasters are inevitable. The potential consequences of EHR-related failures becomes of increasing concern as large-scale EHR systems are deployed across multiple facilities within a health care system, often across a wide geographic area . This chapter concludes with the self-assessment guide that focuses on processes and preparations that should be in place in the event that the EHR experiences a downtime or if a power outage occurs. It helps organizations proactively identify and evaluate if their practice or organization is prepared to deliver safe health care when the EHR is not available and can help manage downtime procedures adequately. Thoughtful use of this assessment by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. The assessment guide works for ambulatory physician practices and other outpatient settings as well as for hospitals, although the patient safety risks in these settings might vary.

Chapter 8 discusses how an organization can learn how to safely configure and maintain the system-to-system interfaces required to implement a state-of-the-art EHR. It begins with a report of a field study that we conducted to assess the utility of the system-to-system interface SAFER guide. It concludes with both the "System interfaces and System configuration guides." Briefly, the System Interfaces SAFER Guide identifies recommended safety practices intended to optimize the safety and safe use of system-to-system interfaces between EHR-related software applications. Many healthcare organizations are involved in planning, implementing, or maintaining enterprise- or community-wide clinical information systems that require integration [18]. Such integration occurs most often via interfaces between software applications, often from different system developers. These interfaces send and receive information, enabling disparate systems to operate on the same data. System interface projects are complex because they involve many stakeholders (e.g., clinicians, administrators, and information technologists) in various departments, often with differing agendas. Stakeholders must work with hardware devices and software applications that are developed independently, while integrating them flawlessly with complex clinical work processes. Well-designed and well-developed system interfaces enable reliable physical and logical connection of different systems. System interfaces require physical equipment

(e.g., hardware such as plugs, cables, and cards), software that controls the data and information that is exchanged, and concepts (e.g., data protocols and controlled vocabularies) that control the interactions between systems. In addition to these technical issues, interfaces involve social and organizational factors, such as agreements to provide data in a consistent format and to use data to refer to concepts in a consistent manner (i.e., multiple systems must manage and coordinate any change to the meaning of a data item). Processes and preparations must be in place to ensure appropriate configuration and maintenance of interfaces [19]. For example, a mapping error between the order entry system and the pharmacy can cause dispensing of the wrong drug [20]. Similarly, researchers have identified errors in the transmission of free-text comment fields between the order entry application and the pharmacy system [21].

The second SAFER guide in this chapter describes how configuration of an EHR includes creating and maintaining the physical environment in which the EHR will operate as well as the infrastructure related to the various aspects of the hardware and software which are required by the EHR. Configuring EHRs and their hardware and software components into their associated environment is complex and vulnerable to errors. It is a continuous process that must be sustained and reliable over time. In the EHR-enabled healthcare environment, we rely upon technology to support and manage many complex clinical and administrative processes. EHR safety and effectiveness can be improved by establishing proper configuration policies and practices and then embedding these concepts within the EHR to ensure that they are carried out. This self-assessment guide is intended to increase awareness of characteristics that can improve the safety of EHR configuration and support the proactive evaluation of selected risk areas. It helps you identify and evaluate where configuration issues may occur in your healthcare delivery system. Thoughtful use of this assessment guide by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. These guides work for both large and small ambulatory physician practices as well as for large and small hospitals.

Chapter 9 helps organizations learn how to assess their patient identification-related practices. It begins with a report of an investigation into matching patient identifiers that lead to significant numbers of duplicate

patient records. Processes related to patient identification are complex and vulnerable to breakdown. In the EHR-enabled healthcare environment, we rely upon technology to help support and manage these complex identification processes and thus EHRs should optimize how information related to patient identification is displayed and communicated. Technology configurations alone cannot ensure accurate patient identification. Staff must also be supported with adequate training and procedures. This self-assessment is intended to increase awareness of EHR system characteristics related to design, configuration, and implementation decisions related to patient identification. This assessment can help identify and evaluate where breakdowns related to patient identification may occur in your healthcare delivery system. It focuses on the processes related to creation of new patients in the EHR, patient registration, and retrieval of information on previously registered patients and other types of patient identification processes in the EHR with the goal being to mitigate problems that arise from duplicative records and patient mix-ups. Thoughtful use of this assessment by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. The assessment works for ambulatory physician practices and other outpatient settings as well as for hospitals.

Chapter 10 includes a report of the development and field assessment of the SAFER guide that addresses computer-based provider order entry (CPOE) with clinical decision support. CPOE practices are complex and vulnerable to breakdown. In the EHR-enabled healthcare environment, we rely upon technology to support and manage these complex workflow processes. EHRs that incorporate standardized and automated features can improve the safety and effectiveness of how order entry information is communicated. This self-assessment guide is intended to increase awareness of characteristics that can improve the safety of EHRs and support the proactive evaluation of select risk areas. It helps organizations identify and evaluate where CPOE breakdowns may occur in your healthcare delivery system. It focuses on processes pertaining to electronic medication and laboratory test ordering. Thoughtful use of this assessment guide by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. In addition, this guide discusses processes related to Clinical Decision Support (CDS),

which are also complex and vulnerable to breakdown. It helps you identify and evaluate where CDS breakdowns may occur in your healthcare delivery system. The guide works for ambulatory physician practices and other outpatient settings as well as for hospitals.

Chapter 11 includes three articles that discuss various aspects of improving the follow-up of abnormal diagnostic test reporting. The first is a case report of the investigation of a software configuration error, among several other errors, that lead to failure to follow-up on numerous abnormal cancer screening tests. The second is an editorial regarding a systematic review of studies that focused on abnormal test result follow-up that concludes that alerts alone are not sufficient to solve this difficult problem. The third article describes ten strategies that can be used to improve the management of the abnormal test result alerts within the EHR-enabled work system. The chapter concludes with a self-assessment guide that is intended to increase awareness of characteristics that can improve the safety of EHRs and support the proactive evaluation of select risk areas. It helps organizations identify and evaluate where test result reporting and follow-up breakdowns may occur in their healthcare delivery system. It focuses on processes after tests have been performed, when providers are notified electronically of the results and are then responsible for reviewing the results and follow-up with patients, as appropriate. EHRs that incorporate standardized and automated features can improve the safety and effectiveness of how information from diagnostic reports is communicated. Thoughtful use of this assessment guide by EHR users is intended to stimulate implementation of the recommended practices, as well as sustain those that are already present. The guide works for ambulatory physician practices and other outpatient settings as well as for hospitals.

Chapter 12 focuses on the assessment of clinician-to-clinician electronic communication. Communication is a key aspect of nearly all patient care processes and has enormous potential to impact patient safety [22–26]. Communication breakdowns between clinicians are one of the most common causes of medical errors and patient harm. Communication processes have become increasingly integrated into EHRs [27]. These include sending and receiving referral and consult communication, communication about transitioning a patient from the inpatient to the outpatient setting, and communicating clinical messages with the EHR. Several at-

tributes of EHR-based communication can result in a disconnect between the sender and the receiver of clinical information, including the sender's uncertainty about whether or when a message has been received, and a mismatch between single patient vs. multiple patient interactions. Messages may be incomplete, misdirected, or directed to an unavailable clinician, and may overload the recipient. The guide works for ambulatory physician practices and other outpatient settings as well as for hospitals.

Chapter 13 includes an evaluation of a novel tablet-based, handheld computing device designed to support primary care practice in rural India. Based on our 8-dimension conceptual model, we developed an assessment guide for the tablet system that was informed by literature review, interviews, and observations of health workers and supervisors. This article includes a SAFER-like guide that can be used to proactively assess similar handheld computing devices.

Chapter 14 discusses how organizations can increase their resilience, or their ability to recover from difficulties. Given the rapid adoption of EHRs by many organizations that are still early in their experiences with EHR safety, it is important to understand practices for maintaining resilience used by organizations with a track record of success in EHR use.

The chapter concludes with a SAFER guide that articulates general principles and practices relevant to any organization that provides health care, whether inpatient or ambulatory, large or small. The universal, minimum goal is to assure that the EHR does not negatively impact care. Thoughtful use of this assessment guide by EHR stakeholders is intended to introduce or sustain safety practices that are already present. The focus here is on activities, processes, and tasks, rather than on individual roles or titles. Some of the recommended activities are best conducted by teams or committees rather than one individual.

Chapter 15 offers our vision of, and the need for, an oversight infrastructure for EHR-related patient safety hazards. Specifically, we propose the creation of a national EHR oversight program to provide dedicated surveillance of EHR-related safety hazards and to promote learning from identified errors, close calls, and adverse events. The program calls for data gathering, investigation/analysis, and regulatory components. The final article describes our vision for the recently proposed federal health information technology safety center.

Taken together, the information provided in this book should help any organization, whether large or small, well on their way or just beginning their EHR journal to improve the safety and effectiveness of their EHR-enabled healthcare system.

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CHAPTER 1

THE CONTEXT OF EHR SAFETY AND THE NEED FOR RISK ASSESSMENT

DEFINING HEALTH INFORMATION TECHNOLOGY-RELATED ERRORS: NEW DEVELOPMENTS SINCE *TO ERR IS HUMAN*

Dean F. Sittig and Hardeep Singh

1.1.1 INTRODUCTION

Two Institute of Medicine (IOM) reports have recommended the use of information technologies to improve patient safety and reduce errors in health care [1,2]. Broadly speaking, health information technology (HIT) is the overarching term applied to various information and communication technologies to collect, transmit, display, or store patient data.

Despite HIT's promise in improving safety, recent literature has revealed potential safety hazards associated with its use, often referred to

Sittig DF and Singh H. Defining Health Information Technology-related Errors: New Developments Since To Err is Human. Archives of Internal Medicine **171**,14 (2011).

as e-iatrogenesis [3,4]. For example, Koppel et al. described 22 types of errors facilitated by a commercially-available EHR system's computerized provider order entry (CPOE) application [5]. In response to similar emerging concerns, the Office of the National Coordinator for HIT recently sponsored an IOM committee to "review the available evidence and the experience from the field" on how HIT use affects patient safety. Given the national impact of HIT, this initiative is a major step forward in ensuring safety and well-being of our patients. However, the field currently lacks acceptable definitions of HIT-related errors and it's unclear how best to measure or analyze "HIT errors".

The goal of this manuscript is to advance the understanding of HIT-related errors and explain how adverse events, near misses, and patient harm can result from problems with HIT itself or from interactions between HIT, its users, and the work system. HIT errors almost always jeopardize patient outcomes and have high potential for harm [6]. This is because many of these errors are latent errors that occur at the "blunt end" of the healthcare system [7], with potential to affect large numbers of patients if not corrected. Furthermore, if important structural or process-related HIT problems are not addressed proactively, care of millions of patients may be affected due to impending widespread adoption and implementation of EHRs [8]. We thus focus this manuscript heavily on errors related to the use of EHR systems.

1.1.2 GENERAL CRITERIA FOR A HIT ERROR

We define the "HIT work system" as the combination of all the hardware and software required to implement the HIT, as well as the social environment in which it is implemented. We thus propose that HIT errors should be defined from the socio-technical viewpoint of end users (including patients, when applicable), rather than the purely technical view of manufacturers, developers, vendors, and personnel responsible for implementation. HIT-related error occurs anytime the HIT system is unavailable for use, malfunctions during use, is used by someone incorrectly, or when HIT interacts with another system component incorrectly, resulting in data be-

ing lost or incorrectly entered, displayed, or transmitted [9,10]. HIT errors may involve failures of either structures or processes and can occur in the design and development, implementation and use, or evaluation and optimization phases of the IT lifecycle [11]. This approach is consistent with the currently recommended systems and human factors approaches used to understand and reduce error [1].

The HIT system is considered to be *unavailable* for use if for any reason the user cannot enter, review, transmit or print data (e.g., patient's medication allergies or most recent laboratory test results). Reasons could include unavailable *computer hardware* (e.g., missing keyboard, or problems with the computer's monitor, the network routers that connect the computer to the data servers and printers, or the server where data is stored), *software* (e.g., problems with the operating system that manages either the computer applications such as the internet browser and EHR, or the interface between an EHR and the information system of an ancillary service such as radiology or lab), and *power sources* (e.g., a power outage that results in hospital-wide computer failure) [4].

The HIT system is considered to be *malfunctioning* (i.e., available, but not working correctly) whenever a user cannot accomplish the desired task despite using the HIT system as designed. In this situation, error results from any hardware or software defect (or "bug") that prohibits a user from entering or reviewing data, or any defect that causes the data to be entered, displayed, transmitted, or stored incorrectly. For example, the clinician enters the patient's weight in pounds and the weight-based dosing algorithm fails to convert it to kilograms before calculating the appropriate dose, resulting in a 2-fold overdose.

Finally, errors can occur even when hardware and software are functioning as designed. For instance, errors may result when users do not use the hardware or software as intended. For example, users might enter free-text comments (e.g., take 7.5mg Mon-Fri only) that contradict information contained in the structured section of the medication order (e.g., Warfarin tabs 10mg QD) [12]. Errors may also arise when two or more parts of the HIT system (e.g., CPOE application and the pharmacy's medication dispensing system) interact in an unpredicted manner, resulting in inaccurate, incomplete, or loss of data during entry, display, transmission or storage [13].

TABLE 1.1.1: Examples of the types of errors that can occur within each dimension of the socio-technical model16 and corresponding suggested mitigating procedures.

Socio-technical model dimension	Examples of types of errors that could occur in each dimension	Examples of potential ways to reduce likelihood of these errors…
Hardware and Software - required to run the healthcare applications	Computer or network is not functioning	Provide redundant hardware for all essential patient care activities
	Input data truncated (ie, buffer overflow) – some entered data lost	Warn users when data entered exceeds amount that can be stored
Clinical Content – data, information, and knowledge entered, displayed, or transmitted	Allowable item can't be ordered(eg., no "amoxicillin" in the antibiotic pick-list) [5]	Conduct extensive pre-release testing on all system-system data and human-computer interfaces to insure that new features are working as planned and that existing features are working as before
	Incorrect default dose for given medication [5]	
Human Computer Interface - aspects of the system that users can see, touch, or hear	Data entry/review screen does not show the patient name, medical record number, birthdate, etc.	Encourage and provide methods for clinicians to report when patient-specific screens do not contain key patient demographics so that the software can be fixed
Human Computer Interface (cont.)	Wrong decision about KCl administration based on poor data presentation on the computer screen	Improve data displays and train users to routinely review and cross-validate all data values for appropriateness before making critical decisions.
	Two buttons with same label, but different functionality	Pre-release inspection of all screens for duplicate button names
People - the humans involved in the design, development, implementation, and use of HIT	Two patients with same name; data entered on wrong patient	Alert providers to potential duplicate patients and require re-confirmation of patient ID before saving data (eg, display patient photo before signing)
	Incorrect merge of two patient's data	Develop tools to compare key demographic data and calculate a probability estimate of similarity

TABLE 1.1.1: *Cont.*

Socio-technical model dimension	Examples of types of errors that could occur in each dimension	Examples of potential ways to reduce likelihood of these errors…
	RNs scan duplicate patient barcode taped to their clipboard rather than barcode on patient to save time	Improve user training, user interfaces, work processes, and organizational policies to reduce need for work-arounds
Workflow and Communication - the steps needed to ensure that each patient receives the care they need at the time they need it	Computer discontinues a medication order without notifying a human	Implement fail-safe communication (eg, re-send message to another hospital designee if no response from MD or RN) for all computer-generated actions ,
	Critical abnormal test result alerts not followed up	Implement robust quality assurance systems to monitor critical alert follow-up rates ; use “dual notification” for alerts judiciously
Organizational Policies and Procedures - internal culture, structures, policies, and procedures that affect all aspects of HIT management and healthcare	Policy contradicts physical reality (eg, required Barcode med administration readers not available in all patient locations) [21]	
Conduct pre- and post-implementation inspections, interviews, and monitor feedback from users in all physical locations		
	Policy contradicts personnel capability (eg, 1 pharmacist to verify all orders entered via CPOE in large hospital)	
	Conduct pre- and post-implementation interviews with all affected users to better gauge workload	

TABLE 1.1.1: ***Cont.***

Socio-technical model dimension	Examples of types of errors that could occur in each dimension	Examples of potential ways to reduce likelihood of these errors…
	Incorrect policy allows "hard-stops" on clinical alerts causing delays in needed therapy	Disallow "hard-stops" on alerts; users should be able to override the computer in all but the most egregious cases (eg, ordering promethazine as IV push by peripheral vein)
External Rules, Regulations, and Pressures - external forces that facilitate or place constraints on the design, development, implementation, use, and evaluation of HIT in the clinical setting	Billing requirements lead to inaccurate documentation in EHR (eg, inappropriate copy & paste)	Highlight all "pasted" material and include reference to source of material
	Joint Commission required medication reconciliation processes causing rushed development of new medication reconciliation applications that were difficult to use and caused errors ; rescinded safety goal only to reinstate it 7/1/2011	Carefully consider potential adverse unintended consequences before making new rules or regulations; conduct interviews and observations of users to gauge effects of rules and regulations on patient safety, quality of care, and clinician work-life
System Measurement and Monitoring - of system availability, use, effectiveness, and unintended consequences of system use	Incomplete or inappropriate (eg, combining disparate data) data aggregation leads to erroneous reporting	Increase measurement and monitoring transparency by providing involved stakeholders with access to raw data, analytical methods, and reports
	Incorrect interpretation of results	

1.1.3 ORIGIN-SPECIFIC TYPOLOGY FOR AN HIT ERROR

Leveson [14] proposes that new technologies have fundamentally altered the nature of errors and asserts that these changes necessitate new models and methods for investigating technology-related errors. Thus, technological advances could potentially give rise to increasingly complex and multifaceted errors in healthcare. In view of the resultant expanding and evolving context of safe HIT implementation and use, we illustrate how a new socio-technical model for HIT evaluation and use can provide an origin-specific typology for HIT errors [15]. The model's 8 dimensions (Table 1.1.1) comprehensively account for the technology, its users and their respective workflow processes and how these two elements interface with the technology, the work system context including organizational and policy factors that affect HIT, and notably, the interactions between all of these factors [16]. Table 1.1.1 provides examples of specific EHR-related errors that can occur within each of the 8 dimensions of the socio-technical model, along with examples of potential ways that the likelihood of each error could be reduced. Thus, the model not only illustrates the complex relationships between active and latent errors but also lays a foundation for error analysis.

1.1.4 CONCLUSION

Rapid advances in HIT development, implementation, and regulation have complicated the landscape of HIT-related safety issues. Erroneous or missing data, or the decisions based on them, increase the risk of an adverse event and unnecessary costs. Because these errors can and frequently do occur post-implementation, simply increasing oversight of HIT vendors' development processes will not address all HIT–related errors. Comprehensive efforts to reduce HIT errors must start with clear definitions and an origin-focused understanding of HIT errors that addresses important socio-technical aspects of HIT use and implementation. To this end, we believe this commentary provides a much needed foundation for coordinating safety initiatives of HIT designers, developers, implementers, us-

ers, and policy-makers, who must continue to work together to achieve a high-reliability HIT work system for safe patient care.

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EIGHT RIGHTS OF SAFE ELECTRONIC HEALTH RECORD USE

Dean F. Sittig and Hardeep Singh

Computers can improve the safety, quality, and efficiency of health care [1]. The pressure on hospitals and physicians to adopt electronic health records (EHRs) has never been greater [2,3]. However, concerns about the immaturity and rigidity of currently available clinical application software, the inexperience of clinicians and information technologists in implementation and use of EHRs, and potentially harmful side effects of EHRs like provider order-entry, have raised questions regarding the safe use of EHRs [4,5,6].

President Obama has often referred to EHRs as a solution to reduce medical errors. To avoid these pitfalls and achieve the promise of EHRs, we propose eight "Rights of Safe EHR Use" grounded in Carayon's systems engineering initiative for patient safety model [7].

1.2.1 RIGHT HARDWARE/SOFTWARE

An EHR must be capable of supporting required clinical activities. For instance, it should calculate the medication dose based on the patient's weight, transmit the order to the appropriate ancillary department, and notify the nurse that an order has been placed. A medication error could eas-

Sittig DF and Singh H. Eight Rights of Safe Electronic Health Record Use. Journal of the American Medical Association ***302****,10 (2009).*

ily follow a breakdown in any of these functions. Furthermore, if hardware or software is inadequately sized, configured, or maintained, the EHR will function poorly. Anything that slows or disrupts the clinician's workflow has the potential to negatively affect patient safety.

Local software oversight committees are one way to ensure that hardware and software are functioning safely [8]. Another solution may be "cloud computing," reliable computing services that are accessible from remote locations via the Internet; potentially reducing hardware procurement, configuration, and maintenance burdens for healthcare organizations. Before clinicians can rely on EHRs in the "cloud", internet speed, reliability, and access must be improved.

1.2.2 RIGHT CONTENT

Right content includes standard medical vocabularies used to encode clinical findings and the clinical knowledge used to create specialty-specific features (e.g., post-transplant orders) and functions (e.g., health maintenance reminders). Content must be evidence-based, carefully constructed, monitored, complete, and error-free.

The federal government has taken a significant positive step towards advancing a controlled vocabulary with its strong support of SNOMED-CT; the most comprehensive, multilingual clinical healthcare terminology in the world. Through its membership in The International Health Terminology Standards Development Organization, SNOMED-CT is free. Adoption of a standard vocabulary is prerequisite to implementing advanced clinical decision support (CDS). In an effort to increase access to a standards-based set of validated, evidence-based CDS, an open-access clinical knowledge base of interventions should be developed that primarily focuses on helping clinicians achieve the quality and safety targets for "meaningful" EHR use. These interventions could be downloaded and utilized directly, or perhaps accessed over the internet as a service, by any EHR.

1.2.3 RIGHT HUMAN-COMPUTER USER-INTERFACE

The right user-interface allows clinicians to quickly learn and utilize a complex EHR safely and efficiently. The interface should present all the relevant patient data in a format allowing clinicians to rapidly perceive problems, formulate responses, and document their actions. A key design consideration is the trade-off between clinicians' desire to "see everything on one screen" and limited screen space. Clinicians miss crucial information in applications that overload information on one screen, leading to subsequent errors. On the other hand, systems that offer users too many nested menu options, or multiple, step-wise pathways can be difficult to learn and time consuming to use. The physical aspects of the interface (e.g., the keyboard, mouse, or touch screen) may also interfere with the data-entry process and make input or selection of information error prone.

A particularly difficult problem facing busy clinicians is the requirement to navigate different EHR interfaces safely and efficiently at different practice sites. Although a complex undertaking, the federal government along with the EHR vendors, should develop common user interface standards for healthcare applications.

1.2.4 RIGHT PEOPLE

As emphasized in Carayon's model of patient safety, trained and knowledgeable people are essential to safe EHR use. Clinicians require not only basic computing skills but also knowledge of how to integrate the EHR into their workflows, which may necessitate one-on-one training sessions; and how to function when the EHR is unavailable.

We must have adequately trained EHR software designers, developers, trainers, and implementation/maintenance staff. System developers should posses extensive software engineering skills, be able to design effective user interfaces, utilize existing standardized clinical vocabularies, and have a sound understanding of the practice of clinical medicine. EHR trainers, implementers, and maintenance staff should have clinical expe-

rience, understanding of EHR capabilities and limitations, and excellent project management skills. Close interaction among informatics experts, clinical application coordinators, and end users is essential for safe design and use.

In an attempt to create the "right people," the American Medical Informatics Association (AMIA) has created the "10x10 Training Programs" [10] and identified the knowledge and skills necessary for clinical informatics subspecialty fellowship programs [11]. Similar programs need to be bolstered nationwide.

1.2.5 RIGHT WORKFLOW / COMMUNICATION

Any disruption in workflow or information transfer is fertile ground for error. Prior to system implementation, a careful workflow analysis that accounts for EHR use could lead to identification of potential breakdown points. For example, vulnerabilities in hand-offs could be exposed in such an analysis [12], and communication tasks deemed critical could be required to have a traceable electronic receipt acknowledgement.

Errors also perpetuate if CDS interventions (i.e., alerts and reminders) are not well-focused or judiciously delivered at the point in the workflow that best supports the clinician's decision making or data entry. Delivering CDS interventions streamlined with clinicians' electronically-enabled workflow through a standard set of EHR functions (e.g., pop-up alerts, pick lists, or order sets) can lead to safer care.

1.2.6 RIGHT ORGANIZATIONAL CHARACTERISTICS

Organizational factors including a, culture of innovation, exploration, and continual improvement just as in other safety models, are key to safe EHR use. Organizations should adopt and actively encourage methods for users to report errors, or barriers to care, resulting from EHR use even if the findings are used for local or internal improvement. Organizations must also carefully review their existing policies and procedures before EHR imple-

mentation. For instance, EHRs can improve transmission of critical information through electronic notifications, but may do more harm than good if there are no standard operating procedures regarding information follow-up [13]. We believe the Veterans Affairs health system exhibits many model organizational features, including a fair amount of central control, standardized procedures for collecting error data and implementing upgrades, and a recent emphasis on studying innovations from field-users.

1.2.7 RIGHT STATE AND FEDERAL RULES AND REGULATIONS

State and federal regulations act as barriers or facilitators for achieving safe use of EHRs.

The American Recovery and Reinvestment Act (ARRA) stipulates that clinicians and healthcare organizations can receive incentive payments for "meaningful use" of EHRs. Depending on the definition and timeline for "meaningful use", this legislation could result in a rush to implement systems that have the potential to decrease patient safety.

Furthermore, ARRA includes language designed to protect patients' privacy that will require significant modifications to existing EHRs. For example, one provision requires organizations to provide a list of data disclosures to third parties for patients. Identifying and reporting such disclosures will be difficult and expensive given current technical constraints.

Regulations to safeguard patient privacy are clearly important but may also have the greatest unintended consequence on national EHR implementation. Policies must address safety and effectiveness of national health information exchange, which may call for reopening the unique national patient identifier debate. Currently used probabilistic patient matching algorithms, used to link patient information from disparate healthcare organizations, are prone to error, and many matches are never made. We recommend that state and federal governments create a regulatory environment compatible with widespread EHR use and interoperability. This will enable systems to continue evolving while maintaining appropriate safety and privacy oversight.

1.2.8 RIGHT MONITORING

The creation of the Certification Commission for Health Information Technology is a significant step towards accelerating EHR adoption, but an equally detailed post-implementation usability inspection process is also needed. Several recent reports have described serious errors related to the use or misuse of EHR systems, many of which were the result of faulty system design, configuration or implementation processes [14]. Organizations must continually evaluate the usability and performance of EHRs after implementation and reliably measure benefits, and potential iatrogenic effects of EHRs Furthermore, the federal government should mandate the development and use of a vendor-independent EHR hazard reporting database [1] and a national EHR implementation accreditation test. An EHR accreditation test would help ensure that EHRs are functioning as designed and are safe to use. The LeapFrog clinical decision support functionality test is an example for how such a test could be constructed.

SUMMARY

EHR developers have encountered many roadblocks on their journey to achieving safe and effective EHRs for all. If we are to succeed in the next 10 years we must have a coordinated multi-disciplinary research and development effort, much like the formation of NASA following President Kennedy's promise of a moon landing. This effort must bring the best scientists, engineers, and clinicians together to address the myriad problems described in this and other publications. Our efforts must move beyond the lone informatics researcher in an isolated laboratory if we are to truly understand and address the complex interaction of organizational, technical, and cognitive factors that affect the safety of EHRs. Without this understanding, any solutions are sure to be far from optimal. But without high-quality, well-designed and carefully implemented EHRs, we may never achieve highly reliable, safe health care.

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ELECTRONIC HEALTH RECORD-RELATED SAFETY CONCERNS: A CROSS-SECTIONAL SURVEY

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1.3.1 INTRODUCTION

The Health Information Technology for Economic and Clinical Health (HITECH) Act has encouraged the adoption of health information technology (HIT) [1] through incentive payments to physicians and healthcare organizations for meaningful use of electronic health records (EHRs). [2] As a result, recently there has been a significant increase in EHR implementation. [3] Nearly three-quarters of office-based physicians now use some form of an EHR system. Since 2009, physicians' capability to prescribe electronically has more than doubled. [4] To date, physicians, hospitals, and other healthcare providers have received over $12.6 billion in incentive payments under the provisions of the HITECH Act. [5]

The widespread adoption of EHRs is expected to transform healthcare through benefits such as complete availability of patient records and clinical decision support. [6] Despite the benefits of EHRs, there is a growing concern regarding risks associated with use of these technologies. [7–11] Because HIT is implemented in highly complex healthcare settings, new and unanticipated sources of errors are beginning to emerge. [9,10,12,13] For example, partial use of EHRs can result in loss of critical information or documentation between the twin worlds of paper and electronic records. The introduction of EHRs could also alter preexisting workflows and introduce new types of cognitive challenges and unsafe workarounds. [14] For instance, several types of errors have been associated with incorrect entry of information into the EHR and inadequate provider training. [15] Finally, even long after implementation, there are potential risks related to system-wide EHR downtimes that could result in widespread adverse effects on clinical care. [16]

Electronic Health Record–Related Safety Concerns: A Cross-Sectional Survey, Menon S, Singh H, Meyer AND, Belmont E, and Sittig DF, Journal of Healthcare Risk Management **34**,1.

Although there is emerging evidence of these safety concerns, comprehensive data on EHR-related safety events are lacking, partly because of limited disclosure of HIT-related medical errors. [7] The Pennsylvania Patient Safety Authority [17] recently identified EHR-related errors and problems through an analysis of HIT-related incident reports. The 2012 Institute of Medicine report on HIT and patient safety identified the lack of risk reporting and hazard data on HIT as a major barrier in building safer systems. [7] Given the increasing number of EHR implementations, as well as the proliferation of EHR vendors with different clinical information systems, additional data are needed to identify the extent of EHR-related safety concerns.

EHR-related safety concerns might not always be visible to users, or users can be unaware of the origin of the problem. Conversely, risk managers and healthcare system lawyers have access to quality and safety data from multiple sources and are often privy to additional safety data from sources unavailable to HIT personnel and clinicians (e.g., malpractice claims). In order to gain new knowledge and learn about their experiences, we conducted a cross-sectional survey of risk managers and health lawyers to obtain exploratory data about EHR-related serious safety events. Our study objectives were to identify (1) the most frequent types of EHR-related serious safety events reported by these respondents, (2) possible factors they believed to be associated with EHR-related serious safety events, and (3) patterns of measurement related to tracking and reporting of EHR-related safety concerns within their institutions.

1.3.2 METHODS

1.3.2.1 PARTICIPANTS

Members of the American Health Lawyers Association (AHLA) and the American Society for Healthcare Risk Management (ASHRM) participated in the survey. The membership of these 2 associations includes individuals who represent large and small hospital systems and long-term care facilities. Members include patient safety professionals, such as risk managers and attorneys practicing healthcare law. The risk managers are re-

sponsible for promoting risk management policies and programs through education and communication among senior management and governing bodies, medical staff members, and employees at all levels of the organizations. The health lawyers represent and counsel hospital systems, physicians, managed care organizations, and other healthcare entities on health-related legal issues. All registered AHLA and ASHRM members were invited to participate in the survey through an e-mail invitation that was distributed by the organizations using their mailing lists. The one-time invitation informed potential participants about the purpose of the study and assured confidential and voluntary participation. An independent survey firm managed survey administration and data collection, all of which was conducted using a secure Web-based platform.

1.3.2.2 SURVEY DEVELOPMENT

We performed a literature search to identify previously developed surveys about EHR implementations and their impact on healthcare practices. We did not find any surveys that specifically addressed the frequency and nature of EHR-related serious safety events. Therefore, we developed a new survey to address the study questions. The survey focused on 5 content areas:

1. *Degree of EHR implementation at the respondents' healthcare organization* (ie, for a lawyer, where the respondent was hired for legal representation). We asked respondents to indicate the extent of EHR implementation defined as the percentage of patient health records that were maintained in electronic form. [18] The response categories were none, 1%–10%, 11%–25%, 26%–50%, 51%–75%, 76%–99%, and 100%.
2. *Frequency of EHR-related serious safety events.* Participants rated the frequency of 11 types of EHR-related serious safety events, such as hardware and software malfunctioning, issues related to data display, incorrect patient identification, subversion of clinical decision support protocols, and issues related to data aggregation. [19] Frequencies were reported on a 5-point Likert scale with the following categories: frequently, occasionally, seldom, never, and

don't know. A separate item asked respondents to indicate their concern about the potential occurrence of EHR-related serious safety events over the next 5 years, rated on a 5-point scale as very concerned, moderately concerned, somewhat concerned, slightly concerned, or not at all concerned.

3. *Factors affecting EHR-related serious safety events*. Respondents chose from a list of 7 EHR characteristics (eg, EHR workflow process, type of users, degree of integration of new EHR) that might have affected the type or frequency of EHR-related serious safety events they had witnessed in the past. [14,20]
4. *Best practices to avoid EHR-related serious safety events*. Participants rated 12 good clinical practices (eg, prompt vendor and organization-level response to EHR-related system errors, EHR downtime training, oversight and accountability structure) that can be used to avoid occurrences of serious safety events related to use of or transition to EHRs. Respondents rated each practice as very important, important, moderately important, somewhat important, or not important. [16]
5. *Tracking of EHR-related safety measurements*. [21] Respondents were asked to indicate whether any of 12 EHR-related safety measures (eg, EHR-related serious safety events, EHR system response time, open or incomplete patient orders, EHR system uptime rate) were tracked and reported at their facility. Separately, respondents were asked to indicate which tracked measures were routinely shared with the governing boards of their healthcare organizations.

Most survey items were closed-ended. For each closed-ended question, we used expert opinion and an extensive literature review to generate a list of responses.

1.3.2.3 ANALYSIS

We used IBM SPSS Statistics software to analyze the survey data. We used descriptive statistics to summarize frequencies of degree of EHR implementation, types of EHR-related serious safety events, factors affecting EHR-related serious safety events, and tracking of EHR-related safety measurements. We also investigated whether EHR-related safety measures that were tracked were successively shared with the governing body of healthcare

organizations represented by the respondents. Additionally, we compared frequency of EHR-related serious safety events experienced in the past 5 years and concerns expressed about future EHR use and potential for serious safety events. Because we were interested in highlighting most common types of EHR-related serious safety events experienced in the past, we combined frequently and occasionally response categories. Similarly, we were interested in highlighting the presence of relatively greater concern, and thus combined very concerned and moderately concerned response categories to represent respondents who had expressed more concern about future EHR use and potential for serious safety events.

1.3.3 RESULTS

The online survey was open to 15,400 AHLA and ASHRM members between August and September 2012. We were unable to get a more accurate denominator for respondents (ie, the number of members eligible to answer the survey) because many AHLA and ASHRM members' institutions either do not have an EHR or the members do not directly work on clinical issues related to the EHR. We estimated that about one-third of members were affiliated with institutions with EHRs, based on the most recent national EHR adoption rates available. [22] Based on input from senior members, we further assumed that only one-half of those remaining were working closely enough with an EHR to be able to respond to the survey. Thus, we estimated that approximately 2500 members were eligible to participate. Three hundred sixty-nine respondents completed the survey, and hence our estimated response rate was about 15%. Most respondents were risk managers (53%), followed by an equal proportion of patient safety officers and attorneys exclusively practicing healthcare law (14%). Other participants included attorneys who practiced law within and outside healthcare (about 10%), compliance officers (9%), and vice presidents of quality (4%). Two-thirds of respondents (66%) worked for hospitals or healthcare systems. Other respondents represented physician practice groups (18%), long-term care facilities (5%), and health plans (5%). As shown in Figure 1.3.1, healthcare organizations represented in the survey had variable degrees of EHR implementation, with about half having at least 76% of their medical records maintained in electronic form and 2% having no electronic records.

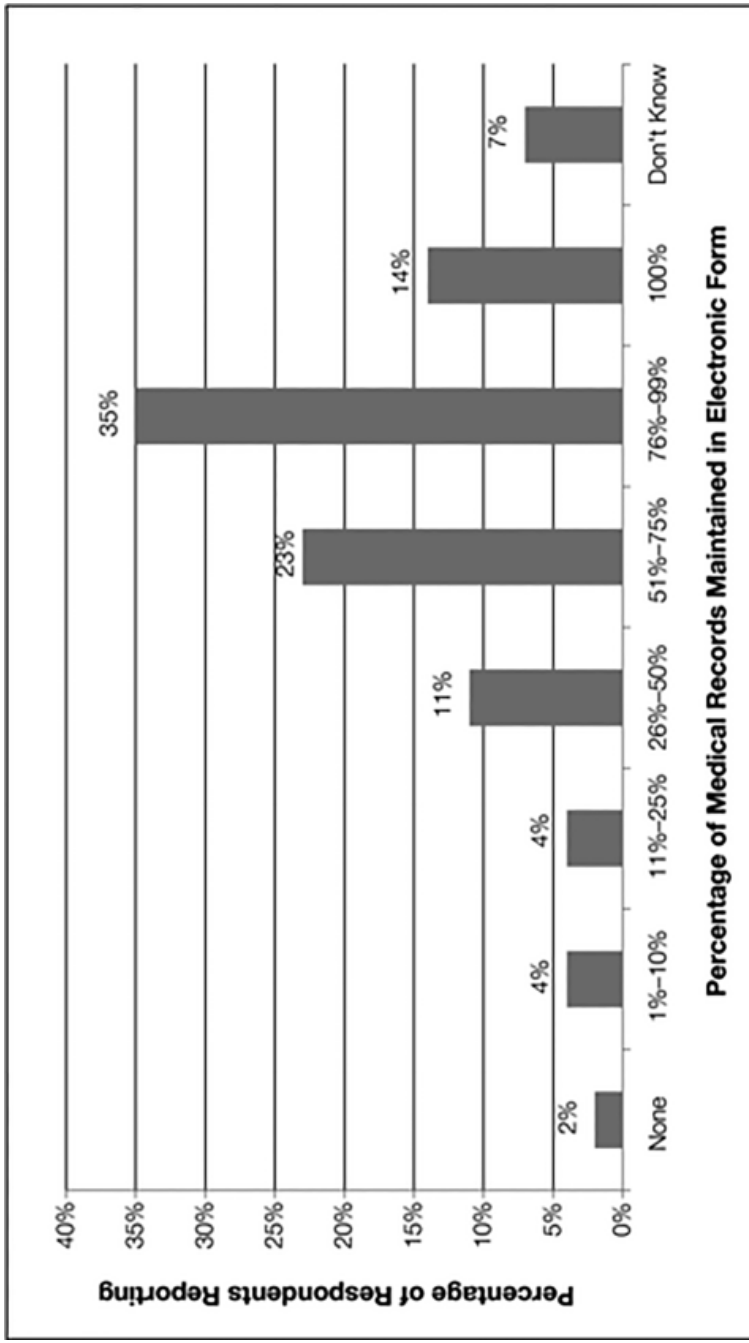

FIGURE 1.3.1: Percentage of Medical Records Maintained in Electronic Form

TABLE 1.3.1: Type and Frequency of Safety Events in the Past 5 Years

Survey question: For each of the following types of serious safety events, please indicate how frequently the healthcare organization for which you are employed or provide legal representation has experienced those events in the past 5 years—frequently, occasionally, seldom, never, don't know						
	Frequently		Occasionally		Sum of Fequently and Occasionally	
	N	(%)	N	(%)	N	(%)
Type of safety event						
Some aspect of data display in the hardware is incomplete, missing, or misleading	55	(15.4)	130	(36.5)	185	(52.0)
Open or incomplete patient orders	40	(11.3)	140	(39.7)	180	(51.0)
Procedures and policies that are ineffective given equipment and/or staffing realities	48	(13.5)	115	(32.3)	163	(45.8)
Failure to follow up abnormal test results due to computer or user input error	26	(7.3)	133	(37.4)	159	(44.7)
Confusing one patient with another because of similar names, incorrect input or other errors	20	(5.7)	130	(36.9)	150	(42.6)
Reliance upon inaccurate or incomplete patient-generated health data (eg, personal health records)	31	(8.7)	105	(29.6)	136	(38.3)
Intentionally or accidentally subverting clinical decision support protocols that issue an alert based on the entry of a certain clinical finding, result, or adverse drug interaction	29	(8.1)	93	(26.1)	122	(34.3)
Automatic discontinuation of a prescription	14	(4.0)	87	(24.8)	101	(28.8)
Data aggregation leading to erroneous data reporting and/or incorrect interpretation of data	19	(5.4)	75	(21.1)	94	(26.5)
Prolonged downtime of EHR systems resulting in unavailability of patient information	11	(3.1)	59	(16.6)	70	(19.7)
Errors resulting from implementing accrediting body, regulatory, or legal mandates	10	(2.8)	50	(14.1)	60	(16.9)

1.3.3.1 FREQUENCY OF SERIOUS SAFETY EVENTS IN THE PAST 5 YEARS

More than half (53%) of respondents surveyed admitted to having at least one EHR-related serious safety event in the previous 5 years; 10% of all respondents experienced more than 20 such events in the same time frame. About half (47%) reported that they had not experienced or were unaware of any EHR-related serious safety events in their organization in the past 5 years.

The 2 most common types of EHR-related safety concerns identified by the respondents related to data display and open or incomplete patient orders (Table 1.3.1). These were followed closely by failure to follow up on abnormal test results and wrong patient identification. Errors due to unavailability of patient data during downtime and errors resulting from implementing accrediting body, regulatory, or legal mandates were perceived as less common.

When asked about the variables that have affected the type and frequency of EHR-related serious safety events in the past, the 3 most frequently reported variables included EHR workflow processes, user familiarity with and training on the EHR, and degree of integration of the new EHR system (Figure 1.3.2). Vendor-specific variables, such as EHR vendor reliability and contractual protection such as acceptance testing or uptime guarantees, were less often endorsed as contributing to EHR-related serious safety events.

A majority of respondents indicated that serious EHR-related adverse events were tracked in their respective institutions; other EHR-related measures were tracked less frequently and with considerable variability (Table 1.3.2). For instance, a number of potentially hazardous EHR-related safety measures such as “open or incomplete patient orders,” “incorrect reporting of laboratory and other diagnostic test results,” and “alert override and adjustment rate” were reported as being used by less than half of the respondents. Change in mortality rate following EHR system implementation was the least tracked measure. Even when EHR-related measures were tracked, they were not automatically reported to the leadership. Compared to overall tracking rates, rates of reporting these measures

to the institutional or system governing boards were consistently lower, sometimes markedly, for all of the measures we assessed.

TABLE 1.3.2: Tracking and Reporting of EHR-Related Safety Measures

Survey question 1: What measures does the healthcare organization for which you are employed or provide legal representation track relating to its EHR system(s)? (Check all that apply) Survey question 2: For which of the following measures is tracking information shared with the governing board of healthcare organization for which you are employed or provide legal representation? (Check all that apply)				
	Question 1: Tracked		Question 2: Shared	
	N	(%)	N	(%)
EHR-Related Measure†				
All serious EHR-related adverse events	229	(62.1)	173	(46.9)
Open or incomplete patient orders after a set period	182	(49.3)	45	(12.2)
Laboratory and other diagnostic test results incorrectly reported	159	(43.1)	50	(13.6)
Alert override and adjustment rate	150	(40.7)	43	(11.7)
Results of network penetration to assess the confidentiality, integrity, and availability of e-Protected Health Information (PHI)	149	(40.4)	67	(18.2)
EHR system uptime rate	134	(36.3)	40	(10.8)
Adherence to the Joint Commission Sentinel Event Alert #42—Safely Implementing Health Information and Converging Technologies	129	(35.0)	63	(17.1)
Adherence to clinical decision support protocols	105	(28.5)	32	(8.7)
EHR system response time	101	(27.4)	25	(6.8)
Clinical user satisfaction survey	98	(26.6)	46	(12.5)
Serious EHR fix rate	93	(25.2)	32	(5.7)
Change in mortality rate following EHR systems implemented	48	(13.0)	24	(6.5)
None of the above	51	(13.8)	0	0.0

†Questions 1 and 2: Respondents could choose all measures that are tracked and shared. The total for each measure represents number of respondents who chose that measure.

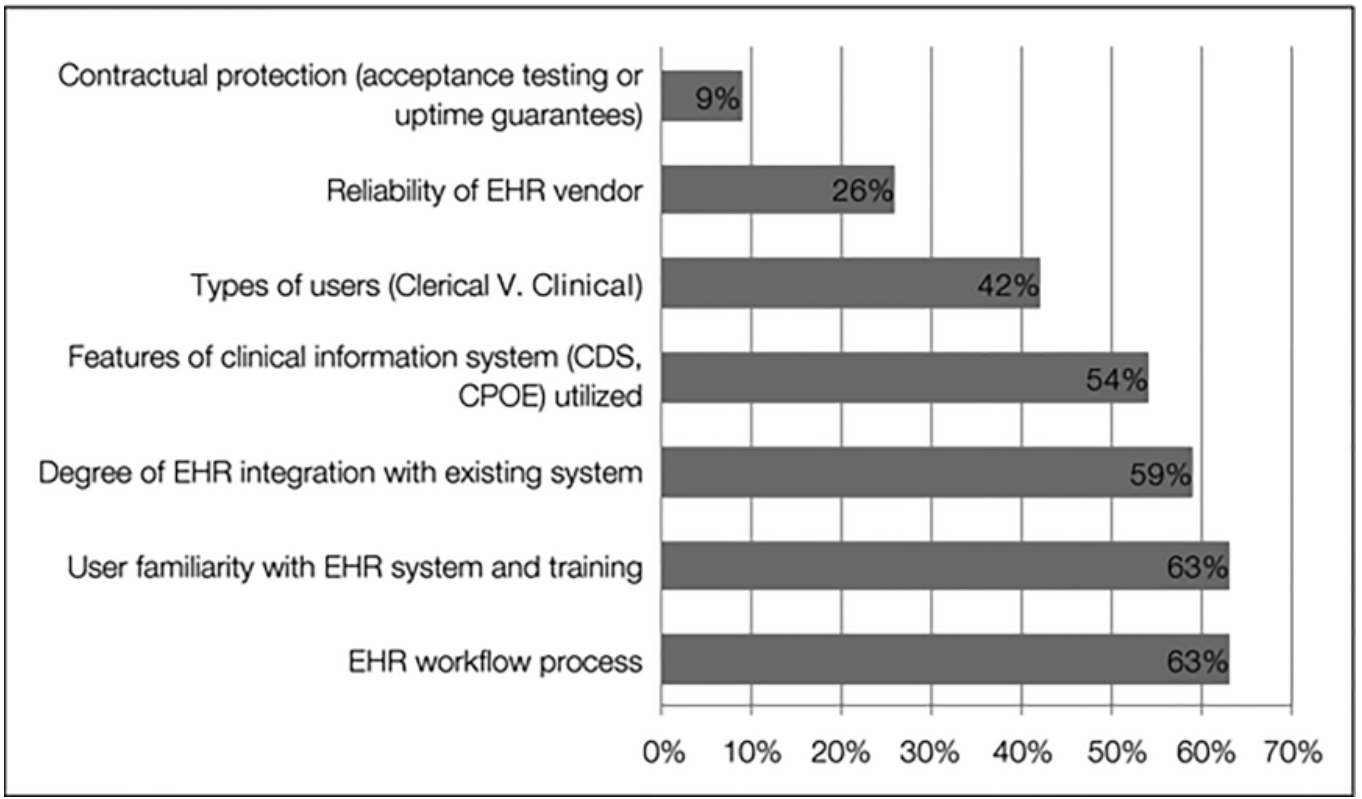

FIGURE 1.3.2: Percentage Distribution of Variables Affecting EHR-Related Serious Safety Events

TABLE 1.3.3: Concerns About Future EHR Use and Potential for Serious Safety Events and Frequency of Safety Events Experienced in the Past 5 Years

Survey question 1: Concerns about future EHR use and potential for serious safety events (very/moderately concerned)

Survey question 2: Frequency of safety events in the past 5 years (frequent/occasional)

	Question 1: Future Concerns		Question 2: Frequency of Past Concerns	
	N	(%)	N	(%)
Type of Serious Safety Events				
Failure to follow up on abnormal test results due to computer or user input error	291	(59.3)	159	(43.1)
Some aspect of data display is incomplete, inaccurate, or misleading	205	(55.6)	185	(50.1)
Reliance upon inaccurate or incomplete patient-generated health data (eg, personal health record)	196	(53.1)	136	(36.9)
Open or incomplete patient orders	189	(51.2)	180	(48.8)
Intentionally or accidentally subverting clinical decision support protocols that issue an alert based upon the entry of a certain clinical finding, result or adverse drug interaction	184	(49.9)	122	(33.1)
Confusing one patient with another because of similar names, incorrect input, or other error	176	(47.7)	150	(40.7)
Procedures and policies that are ineffective given equipment and/or staffing realities	174	(47.2)	163	(44.2)
Prolonged downtime of EHR systems resulting in the unavailability of patient information	145	(39.3)	70	(19.0)
Automatic discontinuation of prescription	132	(35.8)	101	(27.4)
Data aggregation leading to erroneous data reporting and/or incorrect interpretation of data	120	(32.5)	94	(25.5)
Errors resulting from implementing accrediting body, regulatory, or legal mandates	9	(26.3)	60	(16.3)

When asked how concerned they were about future EHR use and potential for serious safety events, more than half of respondents indicated they were very or moderately concerned about the following 3 serious

safety events: (1) failure to follow up on abnormal test results due to computer or user input error; (2) some aspect of EHR data display that is incomplete, inaccurate, or misleading; and (3) reliance on inaccurate or incomplete patient-generated health data (Table 1.3.3). To understand how serious safety events experienced in the past might affect the respondent's perceptions about potential problems in the future, we looked at the frequency of EHR-related serious safety events reported in the past 5 years. As shown in Table 1.3.3, concerns about future EHR-related serious safety events were not entirely consistent with past experiences with serious safety events. For instance, although 37% of respondents reported inaccurate patient-generated health data as a common safety event in the past, over half of respondents expressed concern about this safety risk, perhaps due to an anticipated increase in patients' involvement in managing their health records. Similarly, though only 19% of respondents reported prior frequent events related to unavailability of patient information due to prolonged downtime, a much higher number of respondents (39%) were concerned about this issue arising in the future.

1.3.4 DISCUSSION

We conducted a Web-based survey of members of the AHLA and ASHRM to elicit information about factors associated with EHR-related serious safety events. More than half of respondents reported that their facilities had experienced at least 1 EHR-related serious safety event in the previous 5 years. Issues related to data display, open or incomplete patient orders, and failure to follow up on abnormal test results were the 3 most common types of EHR-related serious safety events. Although a majority of respondents stated that all EHR-related serious safety events were tracked at their facilities, fewer reported regular monitoring of EHR safety measures that could have flagged hazardous conditions. Only a few measures were reported to the leadership/governing boards of the healthcare organizations.

A growing body of literature suggests that EHRs and other forms of HIT can introduce new types of errors. [7–11] Although these errors can have serious implications for patient safety, [23] few reports about the nature and magnitude of these errors have been published. This is largely

due to the fact that EHR-related errors are not clearly defined [13] and are rarely reported. [7] Whereas some prior studies have used reported events to classify errors, [17] there is little empirical data on the frequency and types of EHR-related errors in real practice. [17] Our survey offers additional insights to understand the risks posed by using EHRs.

Respondents viewed EHR workflow processes, user familiarity with EHR system and training, and degree of integration of new EHRs as the most significant factors affecting EHR-related serious safety events. These findings lend support to the argument that EHR implementation invariably alters existing workflows and introduces new types of risks, and that organizations must work closely with their EHR vendor and frontline clinicians to create new EHR-enabled clinical workflows that are both efficient for clinicians and safe for patients. [14] Specific features and configurations of new clinical information systems (clinical decision support, computerized provider order entry [CPOE]), along with their degree of integration with existing legacy systems, also contribute to serious safety events. In addition, we found that respondents considered user training and familiarity with EHR systems to be important variables linked to EHR safety events. In the current regulatory environment that encourages rapid implementation of EHR systems to meet time-sensitive criteria for monetary incentives, these findings serve as a cautionary note.

Our findings regarding types of EHR-related errors support the Pennsylvania Patient Safety Authority's report that found inaccurate data display as one of the most frequently reported safety events. For example, this report [17] found that "wrong data"–related events (data are missing, not updated, not entered, or incorrectly entered) were involved in a majority of EHR-related error reports. Clinical data entered into the EHR are among the most important components of the patient record, and the ability of EHR systems to share these data within and among healthcare organizations magnifies the risks associated with inaccurate data. Our study also found that more than half of respondents indicated that open or incomplete patient orders were the second most frequent type of serious safety event. A patient order is considered incomplete when important components such as date and time of order, drug name, drug dose, drug route, schedule, and duration are not entered. Incomplete patient orders can lead to serious medication errors and resulting harm. In addition to CPOE risks

identified by Koppel et al, [24] about 81% of HIT events reported in the Pennsylvania Patient Safety Study involved medication errors and many of these involved medication orders. Additionally, risks related to follow-up of abnormal test results in EHRs (the third most common EHR-related serious safety event) have been identified in other studies as well. [25,26]

Safety risks associated with EHR use can be mitigated with use of a comprehensive monitoring mechanism. [27,28] For instance, tracking of EHR-related safety measures can provide information about potentially hazardous practices within an organization. To change these practices, this information must be shared with the organization's leadership. However, data about EHR safety measures is rarely available, and EHR-related serious safety events are underreported. [28] Measurement in this area is clearly underdeveloped; only some institutions appear to be monitoring EHR-related safety measures (Table 1.3.2). Furthermore, much of the data about safety measures were not consistently shared with the leadership. To enable EHR safety-related improvement, sharing data with organizational leadership is important; what cannot be measured cannot be improved.

This study has several limitations. A low response rate was an obvious limitation. While the estimated 15% response rate is significantly lower than what we expected, the relatively large number of total responses (369) represents one of the largest samples to date of organizations reporting EHR-related serious safety events. The knowledge of EHR-related safety concerns is still evolving, and it is possible that by providing a list of potential EHR-related patient events created by survey developers, we biased the respondents. However, some of the findings, such as data-related errors and errors related to follow-up of test results, have also been found in other studies.

1.3.5 CONCLUSION

Although EHR-related patient safety concerns are difficult to detect and measure, some risk managers and health lawyers appear to be witnessing serious EHR-related safety concerns in their respective organizations and could provide useful data on areas of improvement. Data display, open or incomplete patient orders, and failure to follow up on abnormal test

results were identified as common types of EHR-related serious safety events. Most respondents did not use EHR safety measures comprehensively, and of the safety data that were being measured, relatively little was shared with their leadership. Because EHR-related serious safety events are underreported and understudied, organizations should consider implementing robust measures within their institution for mitigating risks from EHR-related safety concerns.

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There are several supplemental files that are not available in this version of the article. To view this additional information, please use the citation provided.

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EIGHT RIGHTS OF SAFE ELECTRONIC HEALTH RECORD USE

Dean F. Sittig and Hardeep Singh

Computers can improve the safety, quality, and efficiency of health care

[1]. The pressure on hospitals and physicians to adopt electronic health

records (EHRs) has never been greater [2,3]. However, concerns about

the immaturity and rigidity of currently available clinical application

software, the inexperience of clinicians and information technologists in

implementation and use of EHRs, and potentially harmful side effects of

EHRs like provider order-entry, have raised questions regarding the safe

use of EHRs [4,5,6]. President Obama has often referred to EHRs as a solution to reduce

medical errors. To avoid these pitfalls and achieve the promise of EHRs,

we propose eight “Rights of Safe EHR Use” grounded in Carayon’s sys

tems engineering initiative for patient safety model [7].

1.2.1 RIGHT HARDWARE/SOFTWARE

An EHR must be capable of supporting required clinical activities. For

instance, it should calculate the medication dose based on the patient’s

weight, transmit the order to the appropriate ancillary department, and no

tify the nurse that an order has been placed. A medication error could eas

or software is inadequately sized, configured, or

maintained, the EHR will

function poorly. Anything that slows or disrupts the clinician’s workflow

has the potential to negatively affect patient safety. Local software oversight committees are one way to ensure that hard

ware and software are functioning safely [8]. Another solution may be

“cloud computing,” reliable computing services that are accessible from

remote locations via the Internet; potentially reducing hardware procure

ment, confi guration, and maintenance burdens for healthcare organiza

tions. Before clinicians can rely on EHRs in the “cloud”, internet speed,

reliability, and access must be improved.

1.2.2 RIGHT CONTENT

Right content includes standard medical vocabularies used to encode clin

ical findings and the clinical knowledge used to create specialty-specific

features (e.g., post-transplant orders) and functions (e.g., health mainte

nance reminders). Content must be evidence-based, carefully constructed,

monitored, complete, and error-free. The federal government has taken a signifi cant positive step towards ad

vancing a controlled vocabulary with its strong support of SNOMED-CT;

the most comprehensive, multilingual clinical healthcare terminology in the

world. Through its membership in The International Health Terminology

Standards Development Organization, SNOMED-CT is free. Adoption of a

standard vocabulary is prerequisite to implementing advanced clinical de

cision support (CDS). In an effort to increase access to a standards-based

set of validated, evidence-based CDS, an open-access clinical knowledge

base of interventions should be developed that primarily focuses on helping

clinicians achieve the quality and safety targets for “meaningful” EHR use.

These interventions could be downloaded and utilized directly, or perhaps

accessed over the internet as a service, by any EHR.

The right user-interface allows clinicians to quickly learn and utilize a

complex EHR safely and efficiently. The interface should present all the

relevant patient data in a format allowing clinicians to rapidly perceive

problems, formulate responses, and document their actions. A key design

consideration is the trade-off between clinicians’ desire to “see everything

on one screen” and limited screen space. Clinicians miss crucial informa

tion in applications that overload information on one screen, leading to

subsequent errors. On the other hand, systems that offer users too many

nested menu options, or multiple, step-wise pathways can be difficult to

learn and time consuming to use. The physical aspects of the interface

(e.g., the keyboard, mouse, or touch screen) may also interfere with the

data-entry process and make input or selection of information error prone. A particularly diffi cult problem facing busy clinicians is the require

ment to navigate different EHR interfaces safely and effi ciently at differ

ent practice sites. Although a complex undertaking, the federal govern

ment along with the EHR vendors, should develop common user interface

standards for healthcare applications.

1.2.4 RIGHT PEOPLE

As emphasized in Carayon's model of patient safety, trained and knowl

edgeable people are essential to safe EHR use. Clinicians require not only

basic computing skills but also knowledge of how to integrate the EHR

into their workflows, which may necessitate one-on-one training sessions;

and how to function when the EHR is unavailable. We must have adequately trained EHR software designers, develop

ers, trainers, and implementation/maintenance staff. System developers

should posses extensive software engineering skills, be able to design ef

fective user interfaces, utilize existing standardized clinical vocabularies,

and have a sound understanding of the practice of clinical medicine. EHR

trainers, implementers, and maintenance staff should have clinical expe

project management skills. Close interaction among informatics experts,

clinical application coordinators, and end users is essential for safe design

and use. In an attempt to create the “right people,” the American Medical Infor

matics Association (AMIA) has created the “10x10 Training Programs”

[10] and identifi ed the knowledge and skills necessary for clinical infor

matics subspecialty fellowship programs [11]. Similar programs need to

be bolstered nationwide.

1.2.5 RIGHT WORKFLOW / COMMUNICATION

Any disruption in workflow or information transfer is fertile ground for

error. Prior to system implementation, a careful workflow analysis that

accounts for EHR use could lead to identification of potential breakdown

points. For example, vulnerabilities in hand-offs could be exposed in such

an analysis [12], and communication tasks deemed critical could be re

quired to have a traceable electronic receipt acknowledgement. Errors also perpetuate if CDS interventions (i.e., alerts and reminders)

are not well-focused or judiciously delivered at the point in the workfl ow

that best supports the clinician’s decision making or data entry. Deliver

ing CDS interventions streamlined with clinicians’ electronically-enabled

workfl ow through a standard set of EHR functions (e.g., pop-up alerts,

pick lists, or order sets) can lead to safer care.

1.2.6 RIGHT ORGANIZATIONAL CHARACTERISTICS

Organizational factors including a, culture of innovation, exploration, and

continual improvement just as in other safety models, are key to safe EHR

use. Organizations should adopt and actively encourage methods for users

to report errors, or barriers to care, resulting from EHR use even if the find

ings are used for local or internal improvement. Organizations must also

carefully review their existing policies and procedures before EHR imple

mation through electronic notifications, but may do more harm than good if

there are no standard operating procedures regarding information follow-up

[13]. We believe the Veterans Affairs health system exhibits many model

organizational features, including a fair amount of central control, standard

ized procedures for collecting error data and implementing upgrades, and a

recent emphasis on studying innovations from field-users.

1.2.7 RIGHT STATE AND FEDERAL RULES AND REGULATIONS

State and federal regulations act as barriers or facilitators for achieving

safe use of EHRs. The American Recovery and Reinvestment Act (ARRA) stipulates that

clinicians and healthcare organizations can receive incentive payments for

“meaningful use” of EHRs. Depending on the defi nition and timeline for

“meaningful use”, this legislation could result in a rush to implement sys

tems that have the potential to decrease patient safety. Furthermore, ARRA includes language designed to protect patients’

privacy that will require signifi cant modifi cations to existing EHRs.

For example, one provision requires organizations to provide a list of

data disclosures to third parties for patients. Identifying and reporting

such disclosures will be diffi cult and expensive given current technical

constraints. Regulations to safeguard patient privacy are clearly important but may

also have the greatest unintended consequence on national EHR imple

mentation. Policies must address safety and effectiveness of national

health information exchange, which may call for reopening the unique na

tional patient identifi er debate. Currently used probabilistic patient match

ing algorithms, used to link patient information from disparate healthcare

organizations, are prone to error, and many matches are

never made. We

recommend that state and federal governments create a regulatory envi

ronment compatible with widespread EHR use and interoperability. This

will enable systems to continue evolving while maintaining appropriate

safety and privacy oversight.

The creation of the Certification Commission for Health Information

Technology is a significant step towards accelerating EHR adoption, but

an equally detailed post-implementation usability inspection process is

also needed. Several recent reports have described serious errors related

to the use or misuse of EHR systems, many of which were the result of

faulty system design, configuration or implementation processes [14]. Or

ganizations must continually evaluate the usability and performance of

EHRs after implementation and reliably measure benefits, and potential

iatrogenic effects of EHRs Furthermore, the federal government should

mandate the development and use of a vendor-independent EHR hazard

reporting database [1] and a national EHR implementation accreditation

test. An EHR accreditation test would help ensure that EHRs are function

ing as designed and are safe to use. The LeapFrog clinical

decision support

functionality test is an example for how such a test could be constructed.

SUMMARY

EHR developers have encountered many roadblocks on their journey to

achieving safe and effective EHRs for all. If we are to succeed in the next

10 years we must have a coordinated multi-disciplinary research and de

velopment effort, much like the formation of NASA following President

Kennedy’s promise of a moon landing. This effort must bring the best sci

entists, engineers, and clinicians together to address the myriad problems

described in this and other publications. Our efforts must move beyond the

lone informatics researcher in an isolated laboratory if we are to truly un

derstand and address the complex interaction of organizational, technical,

and cognitive factors that affect the safety of EHRs. Without this under

standing, any solutions are sure to be far from optimal. But without high

quality, well-designed and carefully implemented EHRs, we may never

achieve highly reliable, safe health care.

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American Society for Healthcare Risk Management of the American Hospital Association.

A CROSS-SECTIONAL SURVEY

Shailaja Menon, Hardeep Singh, Ashley N.D. Meyer,

Elisabeth Belmont, and Dean F. Sittig

1.3.1 INTRODUCTION

The Health Information Technology for Economic and Clinical Health

(HITECH) Act has encouraged the adoption of health information tech

nology (HIT) [1] through incentive payments to physicians and healthcare

organizations for meaningful use of electronic health records (EHRs). [2]

As a result, recently there has been a significant increase in EHR imple

mentation. [3] Nearly three-quarters of office-based physicians now use

some form of an EHR system. Since 2009, physicians' capability to pre

scribe electronically has more than doubled. [4] To date, physicians, hos

pitals, and other healthcare providers have received over $12.6 billion in

incentive payments under the provisions of the HITECH Act. [5] The widespread adoption of EHRs is expected to transform healthcare

through benefi ts such as complete availability of patient records and clini

cal decision support. [6] Despite the benefi ts of EHRs, there is a growing

concern regarding risks associated with use of these technologies. [7–11]

Because HIT is implemented in highly complex healthcare settings, new

and unanticipated sources of errors are beginning to emerge. [9,10,12,13]

For example, partial use of EHRs can result in loss of critical information

or documentation between the twin worlds of paper and electronic records.

The introduction of EHRs could also alter preexisting workfl ows and in

troduce new types of cognitive challenges and unsafe workarounds. [14]

For instance, several types of errors have been associated with incorrect

entry of information into the EHR and inadequate provider training. [15]

Finally, even long after implementation, there are potential risks related

to system-wide EHR downtimes that could result in widespread adverse

effects on clinical care. [16]

prehensive data on EHR-related safety events are lacking, partly because

of limited disclosure of HIT-related medical errors. [7] The Pennsylvania

Patient Safety Authority [17] recently identifi ed EHR-related errors and

problems through an analysis of HIT-related incident reports. The 2012

Institute of Medicine report on HIT and patient safety identifi ed the lack

of risk reporting and hazard data on HIT as a major barrier in building

safer systems. [7] Given the increasing number of EHR implementations,

as well as the proliferation of EHR vendors with different clinical infor

mation systems, additional data are needed to identify the extent of EHR

related safety concerns. EHR-related safety concerns might not always be visible to users, or

users can be unaware of the origin of the problem. Conversely, risk man

agers and healthcare system lawyers have access to quality and safety data

from multiple sources and are often privy to additional safety data from

sources unavailable to HIT personnel and clinicians (e.g., malpractice

claims). In order to gain new knowledge and learn about their experiences,

we conducted a cross-sectional survey of risk managers and health law

yers to obtain exploratory data about EHR-related serious safety events.

Our study objectives were to identify (1) the most frequent types of EHR

related serious safety events reported by these respondents, (2) possible

factors they believed to be associated with EHR-related serious safety

events, and (3) patterns of measurement related to tracking and reporting

of EHR-related safety concerns within their institutions.

1.3.2 METHODS

1.3.2.1 PARTICIPANTS

Members of the American Health Lawyers Association (AHLA) and the

American Society for Healthcare Risk Management (ASHRM) partici

pated in the survey. The membership of these 2 associations includes indi

viduals who represent large and small hospital systems and long-term care

facilities. Members include patient safety professionals, such as risk man

agers and attorneys practicing healthcare law. The risk managers are re

education and communication among senior management and governing

bodies, medical staff members, and employees at all levels of the orga

nizations. The health lawyers represent and counsel hospital systems,

physicians, managed care organizations, and other healthcare entities on

health-related legal issues. All registered AHLA and ASHRM members

were invited to participate in the survey through an e-mail invitation that

was distributed by the organizations using their mailing lists. The one-time

invitation informed potential participants about the purpose of the study

and assured confidential and voluntary participation. An independent sur

vey firm managed survey administration and data collection, all of which

was conducted using a secure Web-based platform.

1.3.2.2 SURVEY DEVELOPMENT

We performed a literature search to identify previously developed surveys

about EHR implementations and their impact on healthcare practices. We

did not find any surveys that specifically addressed the frequency and na

ture of EHR-related serious safety events. Therefore, we developed a new

survey to address the study questions. The survey focused on 5 content

areas: 1. Degree of EHR implementation at the respondents' healthcare organization (ie, for a lawyer, where the respondent was hired for legal representation). We asked respondents to indicate the extent of EHR implementation defined as the percentage of patient health records that were maintained in electronic form. [18] The response categories were none, 1%–10%, 11%–25%, 26%–50%, 51%–75%, 76%–99%, and 100%. 2. Frequency of EHR-related serious safety events. Participants rated the frequency of 11 types of EHR-related serious safety events, such as hardware and software malfunctioning, issues related to data display, incorrect patient identification, subversion

of clinical decision support protocols, and issues related to data aggregation. [19] Frequencies were reported on a 5-point Likert scale with the following categories: frequently, occasionally, seldom, never, and concern about the potential occurrence of EHR-related serious safety events over the next 5 years, rated on a 5-point scale as very concerned, moderately concerned, somewhat concerned, slightly concerned, or not at all concerned. 3. Factors affecting EHR-related serious safety events. Respondents chose from a list of 7 EHR characteristics (eg, EHR workflow process, type of users, degree of integration of new EHR) that might have affected the type or frequency of EHR-related serious safety events they had witnessed in the past. [14,20] 4. Best practices to avoid EHR-related serious safety events. Participants rated 12 good clinical practices (eg, prompt vendor and organizationlevel response to EHR-related system errors, EHR downtime training, oversight and accountability structure) that can be used to avoid occurrences of serious safety events related to use of or transition to EHRs. Respondents rated each practice as very important, important, moderately important, somewhat important, or not important. [16] 5. Tracking of EHR-related safety measurements. [21] Respondents were asked to indicate whether any of 12 EHR-related safety measures (eg, EHR-related serious safety events, EHR system response time, open or incomplete patient orders, EHR system uptime rate) were tracked and reported at their facility. Separately, respondents were asked to indicate which tracked measures were routinely shared with the governing boards of their healthcare organizations. Most survey items were closed-ended. For each closed-ended ques

tion, we used expert opinion and an extensive literature review to generate

a list of responses.

1.3.2.3 ANALYSIS

We used IBM SPSS Statistics software to analyze the survey data. We used

descriptive statistics to summarize frequencies of degree of EHR implemen

tation, types of EHR-related serious safety events, factors affecting EHR

related serious safety events, and tracking of EHR-related safety measure

ments. We also investigated whether EHR-related safety measures that were

tracked were successively shared with the governing body of healthcare

frequency of EHR-related serious safety events experienced in the past 5

years and concerns expressed about future EHR use and potential for seri

ous safety events. Because we were interested in highlighting most common

types of EHR-related serious safety events experienced in the past, we com

bined frequently and occasionally response categories. Similarly, we were

interested in highlighting the presence of relatively greater concern, and thus

combined very concerned and moderately concerned response categories to

represent respondents who had expressed more concern about future EHR

use and potential for serious safety events.

1.3.3 RESULTS

The online survey was open to 15,400 AHLA and ASHRM members be

tween August and September 2012. We were unable to get a more accurate

denominator for respondents (ie, the number of members eligible to answer

the survey) because many AHLA and ASHRM members' institutions either

do not have an EHR or the members do not directly work on clinical issues

related to the EHR. We estimated that about one-third of members were

affiliated with institutions with EHRs, based on the most recent national

EHR adoption rates available. [22] Based on input from senior members,

we further assumed that only one-half of those remaining were working

closely enough with an EHR to be able to respond to the survey. Thus, we

estimated that approximately 2500 members were eligible to participate.

Three hundred sixty-nine respondents completed the survey, and hence our

estimated response rate was about 15%. Most respondents were risk man

agers (53%), followed by an equal proportion of patient safety officers and

attorneys exclusively practicing healthcare law (14%). Other participants

included attorneys who practiced law within and outside healthcare (about

10%), compliance officers (9%), and vice presidents of quality (4%). Two

thirds of respondents (66%) worked for hospitals or healthcare systems.

Other respondents represented physician practice groups (18%), long

term care facilities (5%), and health plans (5%). As shown in Figure 1.3.1,

healthcare organizations represented in the survey had variable degrees of

EHR implementation, with about half having at least 76% of their medical

records maintained in electronic form and 2% having no electronic records. F I G U R E 1 . 3 . 1 : P e r c e n t a g e o f M e d i c a l R e c o r d s M a i n t a i n e d i n E l e c t r o n i c F o r m

Survey question: For each of the following types of serious safety events, please indicate how

frequently the healthcare organization for which you are employed or provide legal representation

has experienced those events in the past 5 years--frequently, occasionally, seldom, never, don't

know

Frequently Occasionally Sum of Fequently and Occasionally

N (%) N (%) N (%)

Type of safety event

Some aspect of data display in

the hardware is incomplete, miss

ing, or misleading 55 (15.4) 130 (36.5) 185 (52.0)

Open or incomplete patient

orders 40 (11.3) 140 (39.7) 180 (51.0)

Procedures and policies that are

ineffective given equipment and/

or staffing realities 48 (13.5) 115 (32.3) 163 (45.8)

Failure to follow up abnormal

test results due to computer or

user input error 26 (7.3) 133 (37.4) 159 (44.7)

Confusing one patient with an

other because of similar names,

incorrect input or other errors 20 (5.7) 130 (36.9) 150

(42.6)

Reliance upon inaccurate or in

complete patient-generated health

data (eg, personal health records) 31 (8.7) 105 (29.6) 136 (38.3)

Intentionally or accidentally sub

verting clinical decision support

protocols that issue an alert based

on the entry of a certain clinical

finding, result, or adverse drug

interaction 29 (8.1) 93 (26.1) 122 (34.3)

Automatic discontinuation of a

prescription 14 (4.0) 87 (24.8) 101 (28.8)

Data aggregation leading to

erroneous data reporting and/or

incorrect interpretation of data 19 (5.4) 75 (21.1) 94 (26.5)

Prolonged downtime of EHR sys

tems resulting in unavailability of

patient information 11 (3.1) 59 (16.6) 70 (19.7)

Errors resulting from implement

ing accrediting body, regulatory,

or legal mandates 10 (2.8) 50 (14.1) 60 (16.9)

PAST 5 YEARS

More than half (53%) of respondents surveyed admitted to having at least

one EHR-related serious safety event in the previous 5

years; 10% of all

respondents experienced more than 20 such events in the same time frame.

About half (47%) reported that they had not experienced or were unaware

of any EHR-related serious safety events in their organization in the past

5 years. The 2 most common types of EHR-related safety concerns identifi ed

by the respondents related to data display and open or incomplete patient

orders (Table 1.3.1). These were followed closely by failure to follow up

on abnormal test results and wrong patient identifi cation. Errors due to

unavailability of patient data during downtime and errors resulting from

implementing accrediting body, regulatory, or legal mandates were per

ceived as less common. When asked about the variables that have affected the type and fre

quency of EHR-related serious safety events in the past, the 3 most fre

quently reported variables included EHR workfl ow processes, user famil

iarity with and training on the EHR, and degree of integration of the new

EHR system (Figure 1.3.2). Vendor-specifi c variables, such as EHR ven

dor reliability and contractual protection such as acceptance testing or up

time guarantees, were less often endorsed as contributing to EHR-related

serious safety events. A majority of respondents indicated that serious EHR-related adverse

events were tracked in their respective institutions; other EHR-related

measures were tracked less frequently and with considerable variability

(Table 1.3.2). For instance, a number of potentially hazardous EHR-relat

ed safety measures such as “open or incomplete patient orders,” “incor

rect reporting of laboratory and other diagnostic test results,” and “alert

override and adjustment rate” were reported as being used by less than

half of the respondents. Change in mortality rate following EHR system

implementation was the least tracked measure. Even when EHR-related

measures were tracked, they were not automatically reported to the leader

ship. Compared to overall tracking rates, rates of reporting these measures

sometimes markedly, for all of the measures we assessed.

TABLE 1.3.2: Tracking and Reporting of EHR-Related Safety Measures

Survey question 1: What measures does the healthcare organization for which you are employed

or provide legal representation track relating to its EHR system(s)? (Check all that apply)

Survey question 2: For which of the following measures is tracking information shared with the

governing board of healthcare organization for which you are employed or provide legal represen

tation? (Check all that apply)

Question 1: Tracked Question 2: Shared

N (%) N (%)

EHR-Related Measure†

All serious EHR-related adverse events 229 (62.1) 173 (46.9)

Open or incomplete patient orders after a set period 182 (49.3) 45 (12.2)

Laboratory and other diagnostic test results incor

rectly reported 159 (43.1) 50 (13.6)

Alert override and adjustment rate 150 (40.7) 43 (11.7)

Results of network penetration to assess the confi

dentiality, integrity, and availability of e-Protected

Health Information (PHI) 149 (40.4) 67 (18.2)

EHR system uptime rate 134 (36.3) 40 (10.8)

Adherence to the Joint Commission Sentinel Event

Alert #42--Safely Implementing Health Informa

tion and Converging Technologies 129 (35.0) 63 (17.1)

Adherence to clinical decision support protocols 105 (28.5) 32 (8.7)

EHR system response time 101 (27.4) 25 (6.8)

Clinical user satisfaction survey 98 (26.6) 46 (12.5)

Serious EHR fix rate 93 (25.2) 32 (5.7)

Change in mortality rate following EHR systems

implemented 48 (13.0) 24 (6.5)

None of the above 51 (13.8) 0 0.0

†Questions 1 and 2: Respondents could choose all measures that are tracked and shared.

The total for each measure represents number of respondents who chose that measure. F I G U R E 1 . 3 . 2 : P e r c e n t a g e D i s t r i b u t i o n o f V a r i a b l e s A f f e c t i n g E H R R e l a t e d S e r i o u s S a f e t y E v e n t s

and Frequency of Safety Events Experienced in the Past 5 Years

Survey question 1: Concerns about future EHR use and potential for serious safety events (very/

moderately concerned)

Survey question 2: Frequency of safety events in the past 5 years (frequent/occasional)

Question 1: Future Concerns Question 2: Frequency of Past Concerns

N (%) N (%)

Type of Serious Safety Events

Failure to follow up on abnormal test re

sults due to computer or user input error 291 (59.3) 159 (43.1)

Some aspect of data display is incomplete,

inaccurate, or misleading 205 (55.6) 185 (50.1)

Reliance upon inaccurate or incomplete

patient-generated health data (eg, personal

health record) 196 (53.1) 136 (36.9)

Open or incomplete patient orders 189 (51.2) 180 (48.8)

Intentionally or accidentally subverting

clinical decision support protocols that

issue an alert based upon the entry of a

certain clinical finding, result or adverse

drug interaction 184 (49.9) 122 (33.1)

Confusing one patient with another because

of similar names, incorrect input, or other

error 176 (47.7) 150 (40.7)

Procedures and policies that are ineffective

given equipment and/or staffing realities 174 (47.2) 163 (44.2)

Prolonged downtime of EHR systems

resulting in the unavailability of patient

information 145 (39.3) 70 (19.0)

Automatic discontinuation of prescription 132 (35.8) 101 (27.4)

Data aggregation leading to erroneous data

reporting and/or incorrect interpretation

of data 120 (32.5) 94 (25.5)

Errors resulting from implementing accred

iting body, regulatory, or legal mandates 9 (26.3) 60 (16.3) When asked how concerned they were about future EHR use and po

tential for serious safety events, more than half of respondents indicated

they were very or moderately concerned about the following 3 serious

computer or user input error; (2) some aspect of EHR data display that is

incomplete, inaccurate, or misleading; and (3) reliance on inaccurate or

incomplete patient-generated health data (Table 1.3.3). To understand how

serious safety events experienced in the past might affect

the respondent’s

perceptions about potential problems in the future, we looked at the fre

quency of EHR-related serious safety events reported in the past 5 years.

As shown in Table 1.3.3, concerns about future EHR-related serious safe

ty events were not entirely consistent with past experiences with serious

safety events. For instance, although 37% of respondents reported inac

curate patient-generated health data as a common safety event in the past,

over half of respondents expressed concern about this safety risk, perhaps

due to an anticipated increase in patients’ involvement in managing their

health records. Similarly, though only 19% of respondents reported prior

frequent events related to unavailability of patient information due to pro

longed downtime, a much higher number of respondents (39%) were con

cerned about this issue arising in the future.

1.3.4 DISCUSSION

We conducted a Web-based survey of members of the AHLA and ASHRM

to elicit information about factors associated with EHR-related serious

safety events. More than half of respondents reported that their facilities

had experienced at least 1 EHR-related serious safety event in the previous

5 years. Issues related to data display, open or incomplete patient orders,

and failure to follow up on abnormal test results were the 3 most common

types of EHR-related serious safety events. Although a majority of respon

dents stated that all EHR-related serious safety events were tracked at their

facilities, fewer reported regular monitoring of EHR safety measures that

could have flagged hazardous conditions. Only a few measures were re

ported to the leadership/governing boards of the healthcare organizations. A growing body of literature suggests that EHRs and other forms of

HIT can introduce new types of errors. [7–11] Although these errors can

have serious implications for patient safety, [23] few reports about the

nature and magnitude of these errors have been published. This is largely

rarely reported. [7] Whereas some prior studies have used reported events

to classify errors, [17] there is little empirical data on the frequency and

types of EHR-related errors in real practice. [17] Our survey offers addi

tional insights to understand the risks posed by using EHRs. Respondents viewed EHR workfl ow processes, user familiarity with

EHR system and training, and degree of integration of new EHRs as the

most signifi cant factors affecting EHR-related serious safety events. These

fi ndings lend support to the argument that EHR implementation invari

ably alters existing workfl ows and introduces new types of risks, and that

organizations must work closely with their EHR vendor and frontline cli

nicians to create new EHR-enabled clinical workfl ows that are both ef

fi cient for clinicians and safe for patients. [14] Specifi c features and con

fi gurations of new clinical information systems (clinical decision support,

computerized provider order entry [CPOE]), along with their degree of

integration with existing legacy systems, also contribute to serious safety

events. In addition, we found that respondents considered user training

and familiarity with EHR systems to be important variables linked to EHR

safety events. In the current regulatory environment that encourages rapid

implementation of EHR systems to meet time-sensitive criteria for mon

etary incentives, these fi ndings serve as a cautionary note. Our fi ndings regarding types of EHR-related errors support the Penn

sylvania Patient Safety Authority's report that found inaccurate data dis

play as one of the most frequently reported safety events. For example, this

report [17] found that "wrong data"-related events (data are missing, not

updated, not entered, or incorrectly entered) were involved in a majority of

EHR-related error reports. Clinical data entered into the EHR are among

the most important components of the patient record, and the ability of

EHR systems to share these data within and among healthcare organiza

tions magnifi es the risks associated with inaccurate data. Our study also

found that more than half of respondents indicated that open or incom

plete patient orders were the second most frequent type of serious safety

event. A patient order is considered incomplete when important compo

nents such as date and time of order, drug name, drug dose, drug route,

schedule, and duration are not entered. Incomplete patient orders can lead

to serious medication errors and resulting harm. In addition to CPOE risks

Pennsylvania Patient Safety Study involved medication errors and many

of these involved medication orders. Additionally, risks related to follow

up of abnormal test results in EHRs (the third most common EHR-related

serious safety event) have been identifi ed in other studies as well. [25,26] Safety risks associated with EHR use can be mitigated with use of a

comprehensive monitoring mechanism. [27,28] For instance, tracking of

EHR-related safety measures can provide information about

potentially

hazardous practices within an organization. To change these practices, this

information must be shared with the organization’s leadership. However,

data about EHR safety measures is rarely available, and EHR-related se

rious safety events are underreported. [28] Measurement in this area is

clearly underdeveloped; only some institutions appear to be monitoring

EHR-related safety measures (Table 1.3.2). Furthermore, much of the data

about safety measures were not consistently shared with the leadership. To

enable EHR safety-related improvement, sharing data with organizational

leadership is important; what cannot be measured cannot be improved. This study has several limitations. A low response rate was an obvious

limitation. While the estimated 15% response rate is signifi cantly low

er than what we expected, the relatively large number of total responses

(369) represents one of the largest samples to date of organizations re

porting EHR-related serious safety events. The knowledge of EHR-related

safety concerns is still evolving, and it is possible that by providing a list

of potential EHR-related patient events created by survey developers, we

biased the respondents. However, some of the fi ndings, such as data-re

lated errors and errors related to follow-up of test results, have also been

found in other studies.

1.3.5 CONCLUSION

Although EHR-related patient safety concerns are difficult to detect and

measure, some risk managers and health lawyers appear to be witnessing

serious EHR-related safety concerns in their respective organizations and

could provide useful data on areas of improvement. Data display, open

or incomplete patient orders, and failure to follow up on abnormal test

events. Most respondents did not use EHR safety measures comprehen

sively, and of the safety data that were being measured, relatively little was

shared with their leadership. Because EHR-related serious safety events

are underreported and understudied, organizations should consider imple

menting robust measures within their institution for mitigating risks from

EHR-related safety concerns.

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2 Chapter 2: ANALYSIS OF EHR SAFETY

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SAFETY AND ELECTRONIC HEALTH RECORD IMPLEMENTATION

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2.2.1 BACKGROUND

The USA federal government, through stimulus spending and the Afford

able Care Act, is encouraging widespread implementation of health infor

mation technology (HIT) to improve healthcare quality and patient safety.

[1] These efforts are founded on expectations of increased coordination of

care, improved follow-up, and increased efficiency throughout the con

tinuum of care. [2] However, research suggests that technology may lead

to new uncertainties and risks for patient safety through disrupting es

tablished work patterns, creating new risks in practice, and encouraging

workarounds. [3–10] In particular, the increasing adoption of electronic

health records (EHR) has revealed potential safety implications related to

EHR design, implementation, and use. [11–15] These risks are not related

solely to the technological features of the EHR but may involve EHR us

ers and their workflows, aspects of the organizations in which they func

tion, and the rules and regulations that govern or oversee their activities.

Furthermore, patient safety risks associated with EHR may vary along the

EHR adoption and implementation timeline. Given the complexity and

multifaceted nature of EHR-related safety risks, a comprehensive model is

needed to understand and anticipate these risks in a sociotechnical context.

Sittig and Singh [16,17] developed an eight-dimensional sociotech

nical model to study the safety and effectiveness of HIT at all levels of

design, development, implementation, use, and evaluation. Four earlier

sociotechnical models informed the development of the eight-dimensional

risk and safety of Vincent et al, [1,9] the systems engineering initiative

of patient safety of Carayon et al, [20] and the interactive sociotechnical

analysis of Harrison et al. [2,1] The model’s dimensions represent inter

dependent domains of an EHR-enabled healthcare system: hardware and

software; clinical content; human–computer interface; people; workfl ow

and communication; internal organization policies, procedures, and cul

ture; external rules, regulations, and pressures; system measurement and

monitoring (Figure 2.2.1). [16,17] For example, failure to follow up a

critical laboratory result could be attributable to a software error that pre

vented transmission of the laboratory result to the correct provider (hard

ware and software), faulty display of information in the provider's EHR

window (human–computer interface), or inadequate coordination of roles

within the clinical care team (workfl ow and communication). [22] Efforts

to improve EHR-related patient safety rely on identifi cation of underlying

risks as well as an appreciation of contributing areas of vulnerability (eg,

people, organization policies and procedures, or system measurement). [23]

The sociotechnical intersection of patient safety and EHR is complex.

First, this intersection conceptualizes the healthcare system as an evolving,

complex adaptive system in which safety risks often emerge from users' in

teractions with the EHR that lead to new clinical workfl ow processes. These

new workfl ow processes involve different environmental (eg, human inter

action with physical devices and their workspace), [24] cultural (eg, role

changes of clinicians in the EHR-enabled workfl ow), [25] or even sociopo

litical (eg, clinical power structure) factors. [26] Second, these safety risks

are multifactorial and rarely involve a single contributing factor. Third, im

proving patient safety within an EHR-enabled healthcare system requires a

journey in which the sociotechnical infrastructure and functionalities evolve

over time. The sociotechnical model does not itself convey how it fi ts into

the continuum of HIT safety that includes safe transition from paper to fully

integrated EHR. Therefore, to understand the intersection of EHR and pa

tient safety, Sittig and Singh [27] further proposed a three-phase model to

account for the variation in the stages of implementation, levels of complex

ity, and related patient safety concerns within an EHR-enabled healthcare

system. The fi rst phase is concerned with safety events that are unique and

specifi c to technology (ie, unsafe technology), which often emerge early

inappropriate use of technology as well as unsafe changes in the overall

workfl ow that emerge due to technology use. The third phase addresses use

of technology proactively to identify and monitor potential safety concerns

before harm occurs to the patient. While the boundaries between the phases

may not always be distinct, the three-phase model could be

useful for goal

setting and identifi cation of threats to patient safety. [27]

In light of emerging and often novel risks associated with EHR, compre

hensive models such as those described above are needed to assess the variety

of safety threats and near misses. Such efforts will advance the understand

ing of EHR-related safety events to allow for the planning of safer systems

and processes. Previously, we conducted a longitudinal, sociotechnical

evaluation of the implementation and adoption of EHR in English National

Health Service (NHS) hospitals. [28,29] As part of that study, we conducted

interviews that yielded a large volume of open-ended comments, some of

which refl ected concerns about patient safety. That study demonstrated the

importance of considering the sociotechnical context of EHR implementa

tion, although the UK investigators did not apply a formal framework to

assess patient safety until now. [30] Our aim was to explore and illustrate the

application of the eight-dimensional sociotechnical and three-phase EHR

safety models to organize and interpret EHR-related patient safety concerns

elicited during evaluation. Rather than conduct hypothesis testing, our goal

was to highlight the ‘real-world’ usefulness of practical sociotechnical ap

proaches to ensuring safe and effective EHR implementation and future use.

2.2.2 MATERIALS AND METHODS

2.2.2.1 SETTING AND DESIGN

In 2002, the UK Department of Health decided to implement three centrally

procured national EHR applications, both made to order and commercially

available, in the English NHS hospitals. Implementation was supported by a

small number of centrally contracted local service providers, each responsible

for delivering standard software systems to local hospitals, ensuring system

integration, interoperability, and national connectivity within a geographical

tive to transform the NHS’s HIT infrastructure into an integrated set of elec

tronic systems connected to national databases and a messaging service (the

‘NHS spine’). [30] The data presented here were extracted from a 30-month

(September 2008 to March 2011) prospective, longitudinal, and real-time case

study-based evaluation during EHR implementation and adoption in 12 hos

pitals (nine acute and three mental health). [31] The original research proposal

was approved as a service evaluation by a NHS ethics committee.

2.2.2.2 DATA COLLECTION

The methods of data collection have been described elsewhere. [28–30]

Interviews were conducted at all stages of EHR implementation and adop

tion from initial awareness and planning to sustained use. In order to ex

plore the implementation processes across hospitals, interviewers sought

to determine the organizational activities undertaken and their conse

quences for professional roles, workflows, and clinical practices. Partici

pating hospitals were purposefully selected according to their projected

implementation timelines and included a range of hospital types (ie, teach

ing, non-teaching, acute care, and mental health) to allow comparisons.

The original investigators conducted semistructured interviews with

a broad range of stakeholders: managers, implementation team members,

information technology (IT) staff, junior and senior physicians, nurses,

allied health professionals, administrative staff, external implementation

related stakeholders, and software developers. The six interviewers did not

explicitly ask interviewees questions regarding patient safety. Interviews

were audio-recorded and transcribed verbatim. Data were anonymized by

redacting information that identifi ed the individual

participant or site.

2.2.2.3 DATA ANALYSIS

One author (AT) asked the original UK investigators to review transcripts

for content related to patient safety. Out of 480 interviews conducted in the

evaluation, AT confirmed 49 interviews in which patient safety content was U R E 2 . 2 . 1 : D i a g r a m i l l u s t r a t i n g t h e i n t e r a c t i o n b e t w e e n t h e e i g h t d i m e n s i o n s o c i o t e c h n i c a l a n d t h r e e p h a s e e l e c t r o n i c h e a l t h r e c o r d R) s a f e t y m o d e l s . T h e g o a l i s f o r o r g a n i z a t i o n s t o m o v e f r o m a p a p e r b a s e d m e d i c a l r e c o r d s y s t e m ’ u p t h e e s c a l a t o r ’ t o b e c o m e a n E H R

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a qualitative research method that has pre-set aims but accommodates new

themes from the data. [32] Framework analysis has five stages: familiar

ization; thematic analysis; indexing (coding); charting; and mapping and

interpretation. We began by reviewing and summarizing

relevant quotes re

garding EHR-related patient safety concerns. Using the eight dimensions of

the sociotechnical model as the framework, three reviewers (DWM, DFS,

and HS) indexed the data. While acknowledging the interrelatedness of the

models, for clarity we coded the dimension and phase most directly impli

cated in the safety concern. The data were then arranged according to the

three-phase model (charting). This analysis was performed iteratively until

consensus was obtained among the reviewers. Interrater reliability was not

assessed as the aim of the study was to explore themes of patient safety and

EHR implementation (mapping and interpretation), not rigorous classifica

tion with the two models. ATLAS.ti 6 by ATLAS.ti Scientific Software De

velopment (http://www.atlasti.com) was used for data management.

2.2.3 RESULTS

The interviewees' roles in EHR implementation and the number of hospital

represented are shown in Table 2.2.1. The sociotechnical domains were not

mutually exclusive, but were seen to interact in the data; however, they are

presented within the domain judged to be most involved with the safety con

cern. Some dimensions of the sociotechnical model are

better represented

than others in the dataset, as demonstrated by the mappings of phases and

dimensions in Table 2.2.2. Similarly, most data were mapped to phases one

and two of the three-phase model. Table 2.2.3 provides a high-level sum

mary of the safety concerns present in the data. This table reveals that certain

dimensions have heterogeneity while others have more homogeneous con

cerns expressed. For instance, in hardware and software concerns regarding

EHR availability were prominent in phase one; data sharing and system–

system interface issues were also seen. Conversely, in clinical content, most

(perceived or actual) with order entry through the EHR. We present the data

according to the three-phase model to illustrate safety risks that emerged as

most relevant to each phase of implementation.

TABLE 2.2.1: Interviewee role and hospital representation

Interviewee role No of interviewees No of hospitals represented

Senior manager 7 6

EHR implementation/IT team 9 6

Healthcare practitioners 16 6

Clinical managers 6 5

Administrators 3 5

Strategic health authorities 3 N/A

Local IT service providers 2 N/A

EHR software developers 3 N/A

Total 49 N/A

EHR, electronic health record; IT, information technology.

TABLE 2.2.2: Types of safety concerns categorized by sociotechnical dimensions and

phases of EHR implementation and use Phase 1 Phase 2 Phase 3

Hardware and software 11 2 0

Clinical content 3 7 0

Human–computer interface 4 4 0

People 1 4 0

Workflow and communication 1 6 0

Internal organization policies, procedures, and cul

ture 3 0 0

External rules, regulations, and pressures 2 0 0

System measurement and monitoring 0 0 1

EHR, electronic health record.

dimension

Sociotechnical

dimension Phase of use Summary of safety concern

Hardware and software Phase one Problems with EHR availability (login or network access) (n=4) Lack of basic EHR functionality (n=4) Problems related to data maintenance, sharing, or security (n=3) Phase two Problems with accessing appropriate clinical information Problem with system–system interfaces

Clinical content Phase one Undeveloped or non-standardized clinical content in the EHR (n=3) Phase two Parallel use of paper and EHR Problems or difficulties with use of order

entry (n=6)

Human–computer

interface Phase one User interface too burdensome or error prone for data entry (n=4) Phase two User interface does not support clinical workflow (n=3) Risk of copy and paste functionality

People Phase one Data security concerns Phase two Users sharing EHR access (n=3) Poor training leads to improper use

Workflow and

communication Phase one Errors related to appointment scheduling applications Phase two EHR not integrated into clinical workflow EHR causes delays in work (n=3) Laboratory result routing unreliable (n=2)

Internal organizational

policies, procedures,

and culture Phase one Multiple medical record numbers per patient increase risk of wrong selection Data confidentiality risks Local IT budget must support ongoing IT infrastructure requirements

External rules, regula

tions, and pressures Phase one National IT budgeting important for safe EHR use after implementation Complexity of software and business models of vendors may affect future use

System measurement

and monitoring Phase three Challenges and benefits of EHR-based quality reporting

EHR, electronic health record; IT, information technology.

In accordance with the model, phase one EHR safety concerns were unique

and specific to technology. Within the framework of the sociotechnical

model, specific comments were frequently mapped to the

domains of hard

ware and software, clinical content, and human–computer interface. An ex

ample of a phase one safety concern regarding hardware and software was

the acknowledgment of an insufficient data center and back-up procedures. The danger with [hospitals] doing their own thing is that instead of having a proper data centre meeting certain standards you get it sort of in a shed out the back sort of thing and it's not 24/7, it's not resilient, it doesn't have a fail over site that it can go to, it doesn't have a fail over within, guaranteed two hours service level and it's up to what they can negotiate with the supplier, so cost effectively it's not as cost effective and from a resilience and safety point of view it's not as good. I think the safety is probably one of the key things that doing it centrally and nationally is a lot more secure. IT Manager, Site H Sociotechnical model: hardware and software

A recurring safety concern, also related to hardware and software, was

implementation of an EHR without necessary software features to support

a clinical workfl ow that demanded those features. If you think someone's at risk of suicide and you kind of tick the box there and put some text in, you expect that will bounce through to the care plan module so they could then put a response to it and it stops things getting lost and what have you. It doesn't do anything like that. When you identify needs it doesn't bounce it through to the care planning functionality so that it's already there so that you know what you've got to address, and if you forget to transfer the fact that this person is at risk of stabbing someone, then the system doesn't offer any safeguards to drag it through. Healthcare provider, Site G Sociotechnical model: hardware and software

implementation they perceived to be error prone. For instance, users de

scribed EHR hardware and software issues or human–computer interface

problems that contributed to patient safety concerns. We've

had a couple of instances in Radiology where we've not been able to cancel requests and patients have been scanned twice, so they've had a double exposure of radiation. Director, Site E Sociotechnical model: hardware and software …[It's] terribly easy to make a mistake, because you can bring up several Maria Smiths and if you are not careful and you don't look at the date of birth, because they are just a list and they are right on top of each other, you could pick the wrong one. Receptionist, Site E Sociotechnical model: human–computer interface

2.2.3.2 PHASE TWO

In this phase patient safety is compromised through unsafe use of tech

nology or unsafe changes in workflow. The most common dimensions in

this phase were workflow and communication, people, human–computer

interface, and clinical content. The prevailing theme from the data was the

risk introduced when EHR was placed within a clinical context that did

not facilitate safe use. For instance, a phase two concern was the improper

integration of computers into clinical encounters in which EHR use can

not occur simultaneously with delivery of care (ie, in procedural or sterile

areas). Another example was the barrier associated with the requirement to

sign into the EHR, which resulted in password sharing and generic pass

word use. …you go to your colleague and you say, log me in and then you use other people's cards. They had to have this generic access in situation. It broke all the rules for information and governance and data protection. Manager, Site E Sociotechnical model: people

Certain EHR features, such as copy and paste, were

recognized as

safety risks due to inappropriate use. In the example below, pathology

specimens were mislabeled and the EHR was understood, in this instance,

to increase risk of patient harm. The ability to copy and paste in fields is dangerous. Incorrect details are being pasted into incorrect patient fields (i.e., prostate as specimen details in female patient request or missed miscarriage in clinical details for male patient). Healthcare provider, Site D Sociotechnical model: human–computer interface

Some workfl ow and communication problems were specifi c to certain

practice areas for which use of the EHR, as implemented, was thought

to be particularly ill suited. For instance, EHR users in the mental health

hospitals felt the effort needed to document in the EHR was not only po

tentially unsafe, but impeded the ability to see patients in a timely manner. The psychiatric assessments are quite lengthy and there are quite a lot of notes that go with it. Doctors are not going to be able to do it while they are with the patient, because of issues like risk… So it's going to increase the time spent and you are then delayed seeing the next patient which is I think the big anxiety. Doctor, Site M Sociotechnical model: workflow and communication

Finally, as clinical workfl ow and communication was noted to become

error prone when the medical record was in transition from paper to elec

tronic form, clinical content also arose as an area of potential risk. because not everyone is on [software X]… But I can also see the fact that when everyone is on it you won't have to do it. Healthcare provider, Site H Sociotechnical model: clinical content

2.2.3.3 PHASE THREE

This phase addresses EHR use to monitor and identify safety concerns be

fore patients are harmed. This ultimate use of technology was reflected in

only one interview. The participant noted the difficulty in reporting quality

measures before EHR implementation and the potential advantages of an

EHR-enabled healthcare system. If everybody is using the same system, they have the same functionality available to them. There is only a limited amount of ways that you can record information from reporting and performance indicator and assessment sort of point of view. We often have difficulty meeting certain targets, because we don't have a way of reporting it. It's a real struggle. But, at least if everybody has the same struggle then you are comparable to everybody else and there aren't these gaps. You are more easily able to make a comparison across organizations. I think that's an advantage. Manager, Site M
Sociotechnical model: system measurement and monitoring

2.2.4 DISCUSSION

IT and EHR could potentially have large quality and safety benefits. How

ever, there is increasing acknowledgement that the use of EHR could in

troduce unintended risks, and simultaneous efforts are needed to establish

safe EHR design and implementation. [14] As with other patient safety

issues, a piecemeal, reactive approach to identifying and correcting EHR

related safety issues is unlikely to be efficient or effective. Systematic

text that accounts for the evolving sociotechnical infrastructure and func

tionality that defines the journey to a safe EHR-enabled healthcare system.

In this analysis from the evaluation of the NHS's implementation of EHR,

we attempted to demonstrate the 'real-world' usefulness of analyzing

spontaneously reported safety concerns through two operational models

related to HIT: an eight-dimension sociotechnical model and a three-phase

EHR safety model. A sociotechnical approach may allow developers, IT

managers, administrators, clinicians, and others to understand risks in the

development, implementation, and use of EHR and HIT while account

ing for complex interactions of technology within the healthcare system.

Further application of these models may be helpful as government bodies

make HIT safety a greater priority within clinical environments. [33]

The three-phase model was useful to understand the context of safety

risks given that our sites were still early in their EHR implementation jour

ney, and therefore both phases one and two were suffi ciently represented.

Unfortunately, we were unable to identify many activities within phase

three of the model. Furthermore, the eight-dimension model was found to

have face validity to understand and classify EHR-related safety concerns

within the technical, social, or clinical context in which they occur. Appli

cations of such models could be useful to inform or prioritize implementa

tion efforts. For example, we found, as anticipated, that phase one safety

concerns arose most commonly in the hardware and software domains

of the sociotechnical model. Therefore, organizations should ensure that

proper hardware requirements are in place before EHR implementation

(eg, adequate number of workstations, appropriate data center). Phase

two concerns were frequently mapped to clinical content and workfl ow

and communication. Phase two priorities could therefore involve under

standing and changing the clinical workfl ow or the EHR confi guration to

facilitate safe care. Organizational and leadership factors are commonly

recognized as important for success, [34] but we suggest that understand

ing the local culture, workfl ow, and potential impact on productivity is

equally necessary. [31,35] Our combined model also suggests that as an

organization evolves, both patient safety improvement activities and pa

tient safety hazards also evolve from concerns about safe functionality and

ensuring safe and appropriate use, to using the EHR itself

to provide ongo

this evolution could inform sociotechnical approaches to improving safety

in future large-scale EHR implementations.

The strengths of this qualitative analysis include the large scale of the

EHR implementation and evaluation involving simultaneous interviews.

Other qualitative investigations have analyzed EHR implementations, but

primarily focused on barriers to implementation, system-wide challenges,

or overall benefi ts and concerns rather than patient safety. [35–39] Our

high-level approach differs from that of other classifi cation systems, nota

bly that of Magrabi and colleagues, [40,41] which includes both technical

and human elements. [42] For instance, the human elements it encompass

es are generally related to the direct use of the computer, and to actions

closely linked in time to the error at hand. By contrast, the model used

in this paper encompasses a broader range of sociotechnical factors (eg,

workfl ow and organizational factors) that are more temporally dissociated.

Each approach might have its own advantages and limitations depending

on what type of data is available for analysis, the depth and breadth of

available data, and the rationale of why the analysis was

undertaken.

We also build on previous work demonstrating the use of sociotechni

cal models. For instance, in our previous work, we found this sociotech

nical model applicable in specifi c clinical contexts (eg, test results and

referral communication), [43–48] but until this analysis, a formal model to

study patient safety issues with EHR implementation was lacking (includ

ing within the previous body of work done by the UK investigators). Our

sociotechnical model was adapted by the Institute of Medicine in their

report on HIT safety albeit without the detailed technology dimensions

that we believe are essential to appreciate the nuances involved with EHR

use. [14]

To our knowledge, there are few if any practical models that are specif

ic to HIT that provide guidance in this area. The combination of the socio

technical model with the three-phase model allows us to view EHR safety

from a systems engineering perspective. Through this lens, interaction of

the two models is considered from four fundamental perspectives of com

plex systems: scale (quantitative size); function (the reason for existence);

structure (the interconnection of system elements); and

temporality (scales

of time). [49] In our combined model (Figure 2.2.1), the phases differ in

each phase, the eight-dimensional sociotechnical model can be used to

understand unique safety issues. For instance, a phase one software prob

lem may encompass a single function such as inappropriate matching of

blood products due to a software coding or content error. While in phase

three, errors in blood typing would be identifi ed in real time through an

organization-wide monitoring program that alerts clinicians whenever the

blood type of a patient has ‘changed’. In other words, in phase one, we

view the sociotechnical scale of the problem to be much more isolated and

contained, while in the latter phases, the scale increases signifi cantly: in

cluding users and the physical environment in phase two and, potentially,

the entire organization in phase three.

Another example is the different skills and roles of people involved in

phase one who are responsible for confi guring the hardware (eg, moving

database servers to a physically secure location) and software (eg, set

ting up encryption keys on the periodic back-up systems) to ensure pa

tient confi dentiality. While in phase three, people

ensuring patient safety

would probably include informaticians developing surveillance and moni

toring capabilities to identify potential breaches of patient confi dentiality

or health information management and human resource professionals to

investigate these potential breaches and enforce policies to protect health

information. [50,51]

The limitations of this study include the interview protocol’s lack of

specifi city to patient safety issues and the inability to assess impact on

patient safety. The interviewers broadly focused on EHR implementa

tion and did not intentionally seek detailed responses about patient safety.

While safety concerns arose in several interviews, the interviews did not

necessarily elicit the full range of potential EHR-related safety concerns.

Although the concerns of those involved during implementation appeared

appropriate, no additional effort was made to validate these concerns. As

this was a secondary analysis of previously collected data, interview data

regarding safety potentially could have been overlooked during the initial

review by the original UK investigators because the data collection did not

anticipate this use. The case study design may have reduced

the generaliz

ability of the fi ndings, but despite different EHR software, cultures, and

methods of healthcare delivery, we believe the usefulness of our analysis

concerns and priorities to address them.

2.2.5 CONCLUSION

Examining the intersection of HIT and patient safety with practical con

ceptual models can advance the EHR-enabled healthcare system towards

the goal of improving patient safety. ‘Safe technology’ and ‘safe use of

technology’ are necessary for efforts to improve and monitor patient safe

ty; for example, phase three of the EHR-enabled healthcare system. We

demonstrated how the combined use of two models has face validity to

facilitate understanding of the sociotechnical aspects of safe EHR imple

mentation and the complex interactions of technology within the evolving

healthcare system. Our sociotechnical approach, along with other existing

frameworks, may be beneficial to help stakeholders understand, synthe

size, and anticipate risks within the continuum of HIT safety that includes

safe transition from paper to integrated EHR.

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AN ANALYSIS OF ELECTRONIC HEALTH RECORD-RELATED

SAFETY CONCERNS

Derek W. Meeks, Michael W. Smith, Lesley Taylor, Dean F. Sittig,

Jeanie Scott, and Hardeep Singh

2.3.1 BACKGROUND AND SIGNIFICANCE

Investments in health information technology (HIT) can enhance the

safety and efficiency of patient care and enable knowledge discovery.[1]

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safety concerns and other unintended consequences due to usability is

sues, disruptions of clinical processes, and unsafe workarounds to circum

vent technology-related constraints.[2-14] In particular, rapid adoption of

electronic health records (EHRs) has revealed potential safety concerns

related to EHR design, implementation, and use.[13,15-18] Patient safety

concerns are broadly defined as adverse events that reached the patient,

near misses that did not reach the patient, or unsafe conditions which in

crease the likelihood of a safety event.[19,20] Detecting and preventing

EHR-related safety concerns is challenging because concerns are often

multifaceted, involving not only potentially unsafe technological features

of the EHR but also EHR user behaviors, organizational characteristics,

and rules and regulations that guide EHR-related activities. Thus, com

prehensive and newer “sociotechnical” approaches that account for these

elements are required to address the complexities of EHR-related patient

safety.[21-24]

Despite a clear need to defi ne and understand EHR-related safety

concerns,[25] data that describe the nature and magnitude

of these con

cerns are scarce. A few studies have attempted to quantify and classify

HIT-related safety concerns by mining patient safety incident reporting

databases.[16,26-28] In addition, conceptual frameworks or models have

been developed to incorporate the breadth of technical and nontechnical

factors into the analysis of HIT safety and effectiveness.[22,24,29-31] For

instance, we previously developed a sociotechnical model that proposes

eight interdependent dimensions that are essential to understand EHR-re

lated safety (Table 2.3.1).[21,32] The model accounts for the complexities

of technology, its users, the involved workfl ow, and the larger external or

organizational policies and context in assessment of EHR-related safety

concerns.[33,34]

We conducted a qualitative “sociotechnical analysis” of completed

EHR-related safety investigations from voluntary reports within a large,

integrated healthcare system. Using Sittig and Singh’s sociotechnical

model as a guiding framework, our aim was to describe common EHR

related safety concerns and understand the nature and context of these

safety concerns in order to build a foundation for future

work in this area.

2.3.2.1 DESIGN AND SETTING

We performed a retrospective analysis of completed investigation reports

about EHR-related safety concerns from healthcare facilities within the

Department of Veterans Affairs (VA). The VA operates the largest inte

grated healthcare system in the United States with over 1700 sites of care

(e.g., hospitals, clinics, community living centers, domiciliaries, readjust

ment counseling centers).[35] A comprehensive EHR, nationally man

dated in 1999, is used at all its facilities to provide care to approximately

8.3 million Veterans.[36] The VA is considered a leader in the design,

development, and use of EHRs to address healthcare quality.[37-39] The

established HIT infrastructure is comprised of internally developed and

commercially procured systems that provide a range of applications (e.g.

laboratory, pharmacy, radiology, patient record, scheduling, registration,

billing). VA facilities have the ability to customize the available admin

istrative, financial, and clinical applications to match local processes and

practice conditions while the core functionality is centrally updated and

distributed. In conjunction with other patient safety

initiatives such as

sentinel event monitoring, root cause analysis, and proactive risk assess

ment, the VA created an Informatics Patient Safety (IPS) Office in 2005

to establish a mechanism for non-punitive, voluntary reporting of EHR

related safety concerns.

The IPS reporting system, which includes only health IT-related re

ports, is the foundation for a rigorous approach that includes not only event

investigation and analysis, but also feedback to reporters and developers

of solutions to mitigate future risks to patients. Clinical or administrative

EHR users along with EHR developers can report EHR-related patient

safety concerns through an intranet website or by using the national VA

information technology helpdesk system. The most common process for

clinical users to report a safety concern is by notifi cation of local IT staff.

The local IT staff investigate the safety concern, determine if national sup

port is needed, and report the incident to the helpdesk. At the national

level, if the event is patient safety related, an initial IPS report is populated

the applications in use at the time of the event, any harm or potential for

harm, and any known corrective actions. IPS analysts with

healthcare,

safety, and informatics training and human factors specialists investigate

reports; at an average, it takes about 30 days per incident. The goals of

analysis are understanding user actions that immediately preceded the

safety concern, identifying the underlying root causes, and, if possible,

safely replicating the event with “test” patients in the “live” EHR system.

At a minimum, an account of the incident is elicited from the person who

detects it, and this account is further reviewed by an IPS patient safety and

informatics specialist with expertise in human factors. Most incidents are

then subjected to attempts to replicate the incident in the EHR, reviews of

logs, discussions with technical specialists, or other efforts to determine

the exact nature of the incident. The reports are analyzed and scored ac

cording to potential severity, frequency, and detectability. The score pri

oritizes the need for solution development: a solution could be considered

depending on resources but is not mandatory (low), a solution required an

action plan such as training or request for software modifi cation (inter

mediate), a solution required an immediate action (high), such as a soft

ware patch. After analysis, the IPS makes recommendations to software

developers, individual medical facilities, or other relevant stakeholders

within the VA healthcare system to mitigate the risk of error or harm.[40]

Investigation-related information is maintained in a database and tracked

until the investigation is “closed.” The fi nal, closed investigation for each

report contains a narrative as provided by the initial reporter, the technical

narrative by IPS and information technology staff that includes details of

the investigation, and any solution that might have been identifi ed.

2.3.2.2 DATA COLLECTION

We searched the IPS database for closed investigations that contained full

analyses and narratives that provided meaningful information, excluding

duplicate entries. We also excluded safety concerns related to erroneous

editing or merging of patient records resulting in co-mingled or overlaid

records. Although these are known safety concerns,[41] they were ex

primarily by a separate office in the VA. We extracted 100 consecutive

records that met our search criteria. Previous exploratory studies in patient

safety have been able to shed powerful light on contributory factors with

a similar sample size and, given the rich nature of the qualitative data, we

believed this number was both valuable and feasible.[42]

2.3.2.3 DATA ANALYSIS

We analyzed narrative data in the completed investigation reports using

a framework analysis method, which allows emerging themes to be in

corporated into a previously established framework.[43,44] Framework

analysis consists of five stages: familiarization, thematic analysis, index

ing, charting, and mapping and interpretation. First, two authors (D.W.M.

and M.W.S.) independently reviewed and summarized the investigation

reports to become familiar with the data, but at this secondary stage of

analysis, we made no further effort to replicate the investigation, deter

mine additional causes, or offer additional solutions. Thematic analysis

was guided primarily by the application of the eight-dimension sociotech

nical model. A coding scheme was created so that each concern could be

described and indexed according to one or more sociotechnical dimen

sions that underlay or contributed to the safety concern. Additionally, we

categorized incidents by “phases” of safe EHR implementation and use:

incident related to inherently unsafe technology or

technology failures

(“phase 1”), incidents related to unsafe or inappropriate use of technology

(“phase 2”), and incidents related to lack of monitoring of potential safety

concerns before harm occurs (“phase 3”).[45]

Our coding scheme allowed a safety concern to be classifi ed in multi

ple dimensions from the sociotechnical model, but in only one of the EHR

safety phases. When more than one sociotechnical dimension was involved

in a safety incident we noted this interaction by counting co-occurring

dimensions. The two coding authors (i.e., a physician with informatics

training and a human factors engineer) independently indexed each safety

concern after analyzing the results of the IPS investigation. Discrepancies

in coding were resolved by consensus. The emergent safety concerns were

results. This included re-reading and re-arranging the data (charting) with

members of our multidisciplinary project team whose areas of expertise

included clinical medicine, patient safety, informatics, human factors, and

information technology. Finally, emergent and recurring safety concerns

were identifi ed and described (mapping and interpretation) according to

their sociotechnical origins and EHR safety phase.

We used the software package Atlas.ti version 6.2 to facilitate coding

of the investigation narratives and Microsoft Excel to arrange and struc

ture the data.

2.3.3 RESULTS

We extracted 100 consecutive, unique, closed investigations between Au

gust 2009 and May 2013 from 344 reported incidents. The selected incidents

were reported from 55 unique VA facilities. The priority scores for solution

development were 48 low priority, 38 intermediate priority, and 14 high pri

ority incidents. Table 2.3.1 summarizes our analysis of the safety concerns

along the sociotechnical model's dimensions and EHR safety phases. Ap

proximately three-fourths of safety concerns were categorized as phase 1

(i.e., concerns related to unsafe technology). Sociotechnical dimensions of

phase 1 concerns most commonly involved hardware and software, work

flow and communication, and clinical content. One-quarter were classified

as phase 2 (i.e., unsafe EHR use) and most commonly involved the dimen

sions of people, clinical content, workflow and communication, and human

computer interface. Only one safety concern involving phase 3 (i.e., failure

to use the EHR to monitor patient safety) was represented in our analysis.

Incidents frequently reflected occurrence of more than one sociotechnical

dimension: 40 incidents were classified with two sociotechnical dimensions,

23 incidents had three, and 7 involved four dimensions.

During charting, mapping, and interpretation of the interactions of so

cial and technical components of EHR use, several distinct (although not

mutually exclusive) safety concerns emerged. We classifi ed these concerns

into four types: unmet display needs in the EHR, safety concerns with

software modifi cations or upgrades, concerns related to data transmis

in distributed systems (i.e., when one EHR component unexpectedly or

unknowingly is affected by the state or condition of another). Table 2.3.2

provides defi nitions and examples of these four types of concerns, which

accounted for 94% of the incidents analyzed. All four types of safety con

cerns affected or had the potential to affect multiple patients although we

did not further analyze outcomes data except as noted below.

TABLE 2.3.1 EHR-related Safety Concerns Categorized by Sociotechnical Dimensions

and Phases of EHR Implementation and Use

Sociotechnical Dimension Phase 1 Unsafe technology or technology failures (n=74) Phase 2 Unsafe or

inappropriate use of technology (n=25) Phase 3 Lack of monitoring of safety concerns (n=1) Total

Hardware and software:

The computing infrastructure

used to power, support, and

operate clinical applications

and devices 67 9 0 76

Clinical content: The text,

numeric data, and images that

constitute the “language” of

clinical applications 22 15 1 38

Human-computer interface:

All aspects of technology that

users can see, touch, or hear

as they interact with it 16 12 1 29

People: Everyone who

interacts in some way with

technology, including devel

opers, users, IT personnel, and

informaticians 5 15 0 20

Workflow and Communi

cation: Processes to ensure

that patient care is carried out

effectively 24 11 0 35

Sociotechnical Dimension Phase 1 Unsafe technology or technology failures (n=74) Phase 2 Unsafe or inappropriate use of technology (n=25) Phase 3 Lack of

monitoring of safety concerns (n=1) Total

Internal Organizational

Features: Policies, proce

dures, work-environment and

culture 4 2 0 6

External Rules and Regula

tions: Federal or state rules

that facilitate or constrain

preceding dimensions 1 1 0 2

System Measurement and

Monitoring: Processes to

evaluate both intended and

unintended consequences of

health IT implementation and

use 1 0 0 1

TABLE 2.3.2 EHR-related Safety Concerns with Definitions and Examples

Category of

Concern Definition Examples

Unmet display

needs (n=36) Information needs and content display mismatch User required to review multiple screens to determine status of orders or review active medications User working on two patients with two instances of EHR orders medication for wrong patient User interface wording and function inconsistent throughout EHR Order entry dialog allows conflicting information to be entered

Software

modifications

(n=24) Concerns due to upgrades, modifications, or configuration Software designed at remote facility conflicts with local software use Despite testing, a new feature allows unauthorized users to sign orders Corrupted files or databases prevent entry of diagnoses, orders Corrupted files or databases prevent retrieval of complete patient information

Category of

Concern Definition Examples

Hidden

dependencies

in distributed

system

(n=17) One component of the EHR is unexpectedly or unknowingly affected by the state or condition of another component Transition of patients between wards or units not reflected in EHR, resulting in missed medications or orders Bulk ordering of blood products results in prolonged delay due to matching algorithm Template completion depends on remote data and user is unaware that network delays have caused failure User assigns surrogate signer for patient alerts, but alerts not forwarded due to logical error not seen by user

System-sys

tem interface

(n=17) Concerns due to failure of interface between EHR systems or components Failure of patient context manager Remote internal server failure prevents relevant patient data to be retrieved Radiology studies canceled in EHR remain active in Picture Archiving and Communication System (PACS) workflow Interface flaw causing duplicate patient record creation from external source

2.3.3.1 CONCERNS RELATED TO UNMET DATA DISPLAY

NEEDS IN THE EHR

Unmet display needs was the most common type of concern observed

(36 incidents). This category represented a pattern of hazards in which

human-EHR interaction processes did not adequately support the tasks

of the end-users. These events reflected a poor fit between information

needs and the task at hand, the nature of the content being presented (e.g.,

patient specific information requiring action, such as drug-allergy warn

ings or information required for successful order entry), and the way the

information was displayed. As a result of these conditions, the displayed

information available to the end-user failed to reduce uncertainty or led to

increased potential for patient harm.

As an example, one incident described a situation in which a patient

was administered a dose of a diuretic that exceeded the prescribed amount.

First, a pharmacist made a data entry error while approving the order for

a larger-than-usual amount of diuretic. Although a dose error warning ap

peared upon order entry, this particular warning was known to have a high

false positive rate. Due to diminished user confi dence in the warning’s

reliability, the warning was overridden. The override released the incor

rect dose for administration by nursing staff. The nurse, unaware of the

discrepancy between the prescribed amount and the amount approved by

the pharmacist, administered the larger dose. This event highlights com

plex interactions between the hardware and software, human-computer

interface, people, and workfl ow and communication dimensions, which

served to either prevent or obscure the users' receipt of appropriate infor

mation. Across the 36 concerns within this concern type, the contributory

dimensions were hardware and software (22 incidents), human-computer

interface (22 incidents), workfl ow and communication (10 incidents),

clinical content (9 incidents), people (9 incidents), organizational policies

and procedures (2 incidents), and system measurement and monitoring (1

incident). Most (22 of 36) of these concerns were classifi ed as phase one

issues, followed by phase two, and 1 phase three.

2.3.3.2 CONCERNS RELATED TO BOTH INTENDED AND UNINTENDED SOFTWARE MODIFICATIONS

The second most frequent concern type involved upgrades to the EHR or

one of its components, or improperly configured software (24 incidents).

One configuration error included a disease management package that, af

ter local implementation, was found to have erroneously

escalated user

privileges to place and sign orders. Another concern involved “legacy”

software (i.e., an older system that has not evolved despite newer tech

nologies[46]) that needed an upgrade or maintenance, but support staff

did not have sufficient knowledge of these systems. For example, one in

cident described an inadvertent change to a configuration file during an

update to the EHR that prevented the EHR from communicating with the

printing system used to label laboratory specimens. Since these printers

configuration error was not immediately recognized. The main contrib

uting sociotechnical dimensions of this concern type were hardware and

software (21 incidents), clinical content (10 incidents), and workflow and

communication (5 incidents). This concern type was most often associated

with phase one EHR safety (21 incidents). Three concerns were classified

as phase two, and none were phase three.

2.3.3.3 CONCERNS RELATED TO SYSTEM-SYSTEM INTERFACES

We analyzed 17 cases where the primary safety concern involved, system

system interfaces, the means by which information is transferred from one

EHR component to another. Patient safety concerns in this category of

ten involved maintaining a unique patient’s context, a process designed to

keep various individual EHR components centered on a single patient as

the user traverses the EHR components.[47] For example, if patient con

text is not maintained between the user’s EHR screen and the radiology

viewing screen, a different patient’s data will be shown in the two EHR

components and the user may incorrectly assume the data is associated

with the original patient. Patient context-related concerns were caused by

network failures, conflicts created by non-EHR software, and EHR up

grades that were not compliant with context protocols.

Another example of a system-system interface concern occurred when

a patient who was allergic to angiotensin converting enzyme (ACE) inhib

itors presented to an emergency department with elevated blood pressure.

The patient was prescribed an ACE inhibitor and subsequently required

treatment for allergic reactions and angioedema. Although the patient’s

medication allergy list at a remote facility included ACE inhibitors, a net

work problem prevented remote allergy checking. As highlighted in this

example, the system-system interface concern involved interactions from

multiple sociotechnical dimensions: hardware and software (17 incidents),

workfl ow (6 incidents), and content (5 incidents). All incidents of this con

cern category were coded as phase one EHR use.

DISTRIBUTED SYSTEMS

Concerns may develop not only because the EHR fails to support a partic

ular task, but also because other processes within the EHR system conflict

with the safe execution of that task. The concern of hidden dependencies

or “cascading” effects[48] occurs if one component of the EHR system

is unexpectedly or unknowingly affected by the state or condition of an

other component. While safety concerns involving hidden dependencies

and system-system interfaces are not mutually exclusive, system-system

interfaces are usually known and therefore potential points of failure and

possible safety concerns may be more readily identified. For example,

one safety concern involved medications that were ordered for a patient

who was admitted to the hospital, but temporarily placed in an outpatient

unit. Once the patient was transferred to the regular inpatient unit, certain

medications were automatically removed from the active medication list

because they were previously ordered on an “outpatient” status. This “hid

den dependency” (i.e., between the patient’s physical location and medica

tion order status) can be potentially harmful to the patient because there

was no clear expectation that medications would need to be re-ordered.

Another example of a hidden dependency was a blood product compat

ibility matching algorithm that was not equipped to handle an incoming

bulk order, which exponentially delayed the processing of blood products.

This delay resulted in a disruption of the blood bank workflow by prevent

ing further entry of blood product orders through the EHR and delaying

release of blood products to the requesting clinical services.

The concerns of hidden dependencies primarily involved the dimen

sions of hardware and software (14 of 17 incidents), workfl ow (14 inci

dents), clinical content (9 incidents), and people (5 incidents). Incidents in

this category were also noted to be largely dependent on multiple interac

tions between these dimensions, and only one incident was coded with a

single dimension. These incidents also spanned both phase one (n=11)

and phase two (n=6) of EHR safety.

We analyzed 100 unique, consecutive investigations of EHR-related

safety concerns reported to and investigated by the VA's Informatics Pa

tient Safety Office. Although the reports documented a variety of EHR

related safety incidents, four broad types of safety concerns were promi

nent. These were unmet data display needs within the EHR, problems

with software modifications or upgrades, concerns related to system

system interfaces, and hidden dependencies within the EHR. Safety con

cerns typically emerged from complex interactions of multiple socio

technical aspects of the EHR system. Although it is challenging to detect

these concerns, let alone prevent them, our findings may be useful in

guiding proactive efforts to monitor and improve safety as more institu

tions adopt EHRs.[49,50]

A novel feature and strength of our study is the use of an information

rich data source. Previous studies have largely used isolated event reports

without benefi t of an independent human factors investigation to analyze

or replicate the event in the EHR.[16,26-28] Conversely, we analyzed the

contents of both initial incident reports as well as the fi ndings of the de

tailed safety investigations and analysis conducted by the VA’s IPS offi ce.

Our data sources included detailed narratives that explained the circum

stances in which safety concerns arose, the actions of users and EHR sys

tems at the time of the concerns, and, when possible, the fi nal determina

tion of causes or preventive strategies. This level of detail enabled a more

robust analysis in terms of understanding the larger sociotechnical context

in which an event occurred.

Our sociotechnical analysis of completed IPS investigations provides

additional opportunities for safety improvement. Other large reports of

HIT-related safety concerns have focused on incident reports.[26,51] How

ever, our study involved incident reports that had received further detailed

investigation by informaticians and human factors experts. While studies

using self-reported data, including this one, are limited by the possibility

of reporters’ recall bias or knowledge, [52] our methods may allow for a

more complete representation of an incident and the underlying safety con

of our sample of EHR-related safety events and the relatively sophisticated

implementation and use of the EHR across the VA healthcare system.[37]

As an early adopter of EHRs, the VA has evolved into a “learning system”

that dedicates resources to investigating safety concerns and making EHR

related safety improvements decades after fi rst launch.[40]

TABLE 2.3.3 EHR-related Safety Concerns and Suggested Mitigating Procedures

Category of Concern Mitigating Procedures

Unmet display needs • Testing information display in context of "real-world" tasks • Validating display with all expected information and reasonable unexpected information • Ensuring essential information is complete and clearly visible on the screen • System messages and labels are unambiguously worded

Software modifications • Availability and testing of appropriate hardware and software occurs at the unit level and as-installed before go-live • Testing changes with full range of clinical content • Exploring impact of changes on workflows

System-system interface • Understanding, documenting, and testing content and workflow requirements on both sides of interface. • Ensuring communication is complete (disallow partial transmission of information) • Developing workflows that incorporate back-up methods to transmit information

Hidden dependencies in

distributed system • Documenting ideal actions of EHR or components • Documenting assumptions or making dependencies explicit in software, workflows • Establishing monitoring and measurement practices with systemwide scope

Our fi ndings underscore the importance of continuing the process of

detecting and addressing safety concerns long after EHR implementation

and “go-live” has occurred. Having a mature EHR system clearly does

cidents were phase 1 or unsafe technology. However, few healthcare sys

tems have robust reporting and analytic infrastructure similar to the VA’s

IPS. In light of increasing use of EHRs, activities to achieve a resilient

EHR-enabled healthcare system should include a reporting and analysis

infrastructure for EHR-related safety concerns as well as proactive risk

assessments to identify safety concerns.[49]

Although we cannot make specifi c claims about the prevalence of vari

ous EHR-related concerns, it is notable that the vast majority of incidents

could be classifi ed into one of four types of concern. The categories that

emerged from our analysis appear to represent common and signifi cant

safety concerns that need to be addressed with current and future EHR

implementations. Some safety concerns had relatively straightforward ori

gins, such as simultaneous use of multiple instances of an EHR application

by a single user, leading to order entry on the wrong patient. Other prob

lems had more complex origins, such as user misinterpretation of informa

tion presented through the EHR’s user interface. Our study suggests that

technology-based solutions alone will only partially mitigate concerns and

that interventions to improve EHR-related safety should encompass the

people, organizations, systems, and policies that infl uence how EHRs are

used. We list several general mitigating procedures that could be used to

address these concerns in Table 2.3.3.

This study has several limitations. All incidents were related to use

of the same EHR within a single, albeit very large, healthcare system.

Although the sample size is smaller than that of some other studies, the

case descriptions were rich (i.e., 2-4 single-spaced pages), spanned a pe

riod of 3 years, and represented a continuum of care from home-based

primary care to large, urban medical centers. Nevertheless, our fi ndings

may not represent all types of EHR-related safety concerns and might not

be generalizable to other institutions with different organizational charac

teristics, HIT infrastructure, or patient safety reporting mechanisms. The

data used for our analysis were composed of safety concerns that ranged

from unsafe conditions to patient harm. Although the analysis of unsafe

conditions or near misses is useful to illustrate concerns in EHR-enabled

care, we acknowledge that their circumstances or implications may be dif

ferent from adverse events that result in patient harm. All four emergent

but we did not analyze additional data on patient outcomes as a result of

these concerns. In general, less than 10% of medical errors are captured

through reporting and such data does not allow us to calculate prevalence

rates.[52-54] Despite capturing a low percentage of errors, we were able

to gain insight about non-technical aspects of EHR-related safety concerns

that may not be routinely considered in technology-focused investigations.

In conclusion, our study demonstrates the potential utility of analyz

ing patient safety concerns using a sociotechnical approach to account for

the complexities of using health information technology. We found that

even within a well-established HIT infrastructure, many signifi cant EHR

related safety concerns related to both unsafe technology and unsafe use

of technology remain. The predominant concerns we identifi ed can help

to focus future safety assessment activities and, if confi rmed in other stud

ies, can be used to prioritize ongoing interventions or further research.

Safety concerns we identifi ed had complex sociotechnical origins and

would need multifaceted strategies for improvement. Thus, institutions

with long-standing EHRs as well as those currently implementing EHRs

should consider building a robust infrastructure to monitor and learn from

EHR-related safety concerns.

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3 Chapter 3: USER CONTEXT OF SAFE AND EFFECTIVE EHR USE

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RIGHTS AND RESPONSIBILITIES OF EHR USERS CARING

FOR CHILDREN

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Establishing a safe and effective electronic health record-enabled (EHR)

healthcare delivery system is complex and challenging. In addition to sup

port from executive leadership, a robust EHR from a reputable vendor,

sionals, clinician support is instrumental in overcoming the challenges. While

there is an increasing breadth of knowledge about good clinical practices

needed to address EHR implementation and use in the general population,

clinicians responsible for the care of neonates, children, and adolescents face

a unique set of additional challenges. For example, children have unique EHR

requirements related to dosing of medications as well as specific needs related

to their growth and development that the EHR needs to facilitate [1]. In order to encourage a dialogue between clinicians and other stakehold

ers to help address and overcome these challenges, we previously proposed

that front-line practicing clinicians be given certain “professional rights” for

“must have” EHR features, functions, and user privileges that are critical to

provide high quality and safe care. We also proposed that each “right” be

accompanied by a corresponding user responsibility. Because of the unique

circumstances involving the safe and effective care of children and that fact

that most children are not cared for in facilities where the EHR has been de

signed exclusively for children, in this paper we propose “pediatric amend

ments” to our previously proposed “Rights and Responsibilities of Users of

EHRs” [2]. All previously identifi ed rights and responsibilities still apply

along with these new pediatric-specifi c items discussed below.

3.2.1 SUPPORT FOR MEDICATION PRESCRIBING IN CHILDREN

The epidemiology of harm associated with medication prescribing for ne

onates and children is very different than adult patients. Both hospitalized

and ambulatory patients are at higher risk of harm from drug dosing errors

than from drug-drug interactions. [3,4] Clinicians seeing pediatric patients

have the right to both inpatient and ambulatory electronic prescribing sys

tems that are safer and more effective for children and include weight

based dosing recommendations, age appropriate dosing calculators, dose

range checking, and pediatric-specific drug-drug interaction alerts. [5,6] Clinicians seeing pediatric patients have the responsibility to consis

tently and reliably document patient weights, and should maintain famil

iarity with medication dosing guidelines to mitigate the effect of automa

tion bias [7].

Visual display of patient information is an important decision support tool.

Clinicians should have the right to view their young patients' anthropometric

data using growth charts [8] that display age-based percentiles for weight,

height, head circumference, and body mass index (BMI) within their EHR [9]. All of these age-appropriate displays require up-to-date, accurate data

capture; therefore, clinicians have the responsibility to record or facilitate

the recording of patient's height, weight, and head circumference. Addi

tionally, they should use this information to apply the appropriate age

specifi c clinical guidelines and provide copies of these charts to parents.

3.2.3 CHILD-FRIENDLY, EHR-EQUIPPED EXAM ROOM

While not a specific feature or function of the EHR, clinicians caring for

children have the right to an EHR-equipped exam room that

is designed

using appropriate human factors principles [10]. For example, rooms

should have a layout that provides adequate room for the patient, a parent

and the clinician to move around [11]. In addition, keyboards and touch

screens should be cleaned and disinfected on a regular basis [12]. Finally,

the computer, if wall-mounted, should be sturdy enough to withstand a

child swinging from the support arm. Clinicians have the responsibility for positioning the monitor so that

he/she, as well as the parent and the patient can see the screen simultane

ously. This is particularly important in pediatrics, as children cannot ratio

nalize the use of a computer in the exam room and may unintentionally

misinterpret the intention [13].

3.2.4 USER INTERFACE THAT SUPPORTS CORRECT

IDENTIFICATION OF PATIENTS

Several studies have suggested that pediatric patients in general and neo

nates in particular are at higher risk for misidentification because of nam

ing issues during the newborn period and siblings being treated simultane

to an EHR user interface which minimizes wrong-patient errors. Such

functionality may include limiting users to one open chart at a time, avail

ability of patient pictures within the EHR, and including additional patient

verification processes with computerized order entry systems. [15,16] Electronic systems themselves may actually carry the unintended con

sequence of increasing the risk for wrong-patient errors [17]. Users of

these systems have a responsibility to ensure that processes are setup to

capture patient photographs in the EHR, and that misidentifi cation errors

are appropriately reported and fi xed.

3.2.5 AN EHR THAT SUPPORTS ADOLESCENT CONFIDENTIALITY

Although exact legal requirements vary, most countries acknowledge that

adolescents have the right to keep mental, behavioral, and sexual healthcare

confidential from their parents or guardians. Unfortunately, many commer

cial EMR’s do not yet provide the functionality needed to respect these legal

and ethical positions [18]. Pediatric users have the right to EHR software

which includes default settings for adolescent privacy, customizable point

of-care privacy controls for clinicians, clear on-screen labeling of confiden

tial data elements, patient-adjustable proxy access capabilities for patient

portals, and suppression capabilities for specific items on post-visit summa

ries, bills, and post-visit surveys. In addition, adolescent privacy standards

must be built into health information exchange data sharing agreements. Clinicians seeing adolescent patients have the responsibility to un

derstand local adolescent confi dentiality regulatory requirements. They

should also review the entire patient experience from registration to post

clinic surveys to ensure that the adolescent’s confi dentiality is maintained

in light of these requirements.

3.2.6 EHR CONTENT THAT SUPPORTS PEDIATRIC PRACTICE

To deliver appropriate preventative well-child care, pediatricians have the

right to an EHR with content that supports the care of children. This in

as administration of immunizations and linkages to immunization regis

tries as well as content for pediatric normative values (e.g. laboratory test

values) that frequently change with age [19]. Furthermore, EHRs must be

optimized to support recording of quality measures for pediatrics. Pediatricians have the responsibility to review decision support rules

(e.g. do they match local vaccination schedules) and record key data that

would lead to the generation of appropriate decision support.

3.2.7 SUMMARY

The care of children and neonates presents complex challenges for the

design and operation of healthcare facilities and EHRs worldwide. For

clinicians to provide the highest quality, safe and effective care to children,

EHRs providing care to children must be properly designed and config

ured and clinicians must use them correctly. Organizations that provide

their clinicians with state-of-the-art EHRs and grant them the “professional

rights” we previously identified along with these “pediatric amendments”

could see dramatic improvements in clinician usage of their EHRs. This

will lead us closer to the ultimate goal of improving the quality, safety, and

effectiveness of care delivered to children.

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4 Chapter 4: CONCEPTUAL FOUNDATION OF SAFER GUIDES

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ELECTRONIC HEALTH RECORDS AND NATIONAL PATIENT

SAFETY GOALS

Dean F. Sittig and Hardeep Singh

Electronic health records (EHRs) are essential to improving patient safety

[1]. Hospitals and healthcare providers are implementing electronic health

records (EHRs) at an unprecedented pace in response to the American

Recovery and Reinvestment Act of 2009 (ARRA) [2-4]. Meanwhile, the

number of certifi ed EHR vendors in the US has increased

from 60 [5,6],

From The New England Journal of Medicine, Sittig DF and Singh H, Electronic Health Records and

cant and often unexpected risks resulting from the use of EHRs and other

health information technology [8–12]. These concerns are compounded by

the extraordinary pace of EHR development and implementation. Thus,

the unique safety risks posed by the use of EHRs should be considered

alongside the potential benefi ts of these systems. At a time when institutions are focused heavily on achieving meaningful

use requirements, we propose that clearer guidance be provided for them to

align their patient safety activities with those required for an EHR-enabled

healthcare system [13]. A set of EHR-specifi c safety goals, modeled after the

Joint Commission's National Patient Safety Goals (NPSGs), may provide or

ganizations with unique focus areas for sustained improvements in organiza

tional infrastructure, processes, and culture as they adapt to new technology. EHR implementation is still highly variable across healthcare systems and

providers, with equally variable implications for patient safety. For instance,

the key patient safety priorities for an organization in the midst of an EHR

rollout are somewhat distinct from those of an organization that has used a

fully integrated EHR for fi ve or more years. To account for variation in stages

of implementation and levels of complexity across clinical practice settings,

we propose a three-phase framework for development of EHR-specifi c patient

safety goals (e-PSGs). The fi rst phase of the framework, aimed at all EHR us

ers but especially at recent and future adopters, includes goals to mitigate risks

that are unique and specifi c to the use of technology [14] (e.g., unavailable or

malfunctioning hardware or software). The second phase addresses issues cre

ated by failure to use or misuse of appropriate technology [15]. The fi nal phase

focuses on uses of technology to monitor safety events and identify potential

safety issues before they can harm patients [16]. In the following sections,

we illustrate how this framework can lay the foundation for development of

e-PSGs within the context of EHR-enabled healthcare.

4.2.1 PHASE 1: DEVELOP GOALS TO ADDRESS SAFETY

CONCERNS UNIQUE TO TECHNOLOGY

Device failures and natural or man-made disasters are inevitable. The po

tential consequences of an EHR failure become increasingly significant as

care system, often across a wide geographical area. These

broadly distrib

uted systems may be tightly coupled and lightning fast; hence, a malfunction

can rapidly affect not only a single department or institution but possibly

an entire community [17]. Furthermore, the operations of such systems are

often decentralized and relatively opaque to end users [18] such that prob

lems evade easy detection and solution. As a recent example, on April 21,

2010, one-third of hospitals in Rhode Island were forced to postpone elec

tive surgeries and divert non-life-threatening emergencies [19] when an er

roneous automatic anti-virus software update set off a chain of events that

caused “uncontrolled [computer] restarts and loss of networking functional

ity.” [20] A potential goal, therefore, should be to reduce the impact of EHR

downtime on clinical operations and patient safety. Table 4.2.1 lists some of

the activities that organizations could undertake to achieve this goal. Safety can also be compromised as the result of miscommunication

between components of an EHR system. For example, it is not uncom

mon for data translation tables, used to encode and decode orders between

disparate systems, to have mismatched data fi elds [34]. These errors may

result in inadvertent changes to orders that are virtually undetectable by

the computer or by humans not privy to the original sender’s intentions.

An example of such an error is an order for 30 mg oxycodone sustained

release that is correctly entered in the computer-based provider order entry

(CPOE) system but erroneously mapped to 30 mg oxycodone immediate

release in the pharmacy management system and incorrectly dispensed.

Errors related to system-to-system information transfer may be detected

by testing interacting components within the “live EHR” environment.

However, this process is resource intensive and therefore may not receive

adequate effort and attention. Therefore, an e-PSG could focus on reduc

ing miscommunication of data transmitted between different safety-criti

cal components of the EHR. Recent evidence has identifi ed both problem areas above (EHR acces

sibility and information transfer) as the most common issues in reported

EHR-related safety events [9,11,12].

(e-PSGs).

Potential Goal Rationale Suggestions to Achieve the Goal

Phase 1: Safety Concerns Unique to Technology

Reduce the impact

of EHR downtime

on patient safety A robust computing infrastructure should

include a plan for when the computer is unexpectedly unavailable. • Maintain backup paper forms for ordering and clinical documentation in clinical areas • Employ clearly marked, easily activated, password protected, read-only backup systems that contain the most recent clinical results and orders • Ensure complete, encrypted, daily, off-site storage of all patient data • Use redundant hardware (e.g., database servers) for mission-critical applications • Maintain uninterrupted power supplies capable of maintaining computer operations until generators come on-line • Develop downtime (and re-activation) policies and procedures to operationalize plans and train personnel on these plans • Report EHR uptime rates to organization’s board of directors on regular basis

Reduce miscom

munication of

data transmitted

between different

components of

EHRs Miscommunication can be problematic when sending remotely generated, “asynchronous” orders through multiple components of an EHR system. • Mandate regression testing (i.e., testing to ensure that intended changes are correct and did not corrupt any other parts of the system) of all mission-critical applications after every modification • Reduce the number of interfaces between mission-critical systems (e.g., between CPOE and pharmacy management systems) developed by different software vendors

Phase 2: Address Failure to Use EHRs Appropriately

Mandate computer

based provider

order entry for all

medications, labo

ratory, and radiol

ogy test orders CPOE with advanced clinical decision

support has been shown to reduce errors of omission and commission. • Create order sets for the most common condition-, task-, and service-specific clinical scenarios • Make clinician login privileges conditional on training and testing in order entry • Report CPOE rates to organization’s board of directors on regular basis

Potential Goal Rationale Suggestions to Achieve the Goal

Reduce alert

fatigue Alerts with low specificity result in a high rate of clinician overrides and lead to “alert fatigue.” Clinicians thus may inadvertently ignore important information. • Implement drug-drug interaction checking only for life-threatening combinations • Focus CDS interventions on key organizational safety goals • Ensure that timing, content, and delivery of CDS interventions are appropriate to recipients and workflows • Monitor the number and override rate of all alerts • Report Alert override rates to organization’s board of directors on regular basis

Enter all medica

tions, allergies,

diagnostic test

results, and clini

cal problems as

structured or coded

data Structured data is needed to realize the full potential of computer-generated decision support (e.g., drug-allergy checking, automated abnormal test result notification , or drug-condition reminders) • Use standard clinical vocabularies • Implement two-way, system-system interfaces with all ancillary information systems both within and outside the organization to facilitate the capture and use of coded data • Develop order entry templates

Phase 3: Use EHRs to Monitor and Improve Patient Safety

Use EHR-based

“triggers” to moni

tor and improve

patient safety Current incident reporting systems capture a small proportion of events or only specific types of events . Safety trends cannot be measured reliably at present. • Identify high-risk target conditions relevant to their clinical contexts • Develop search criteria to identify them (e.g., patients in need of particular tests, follow-up actions, or those experiencing specific safety events) • Query the EHR regularly to detect events based on search criteria • Assign staff to take action on identified events

4.2.2 PHASE 2: DEVELOP GOALS TO MITIGATE SAFETY

CONCERNS FROM FAILURE TO USE EHRS APPROPRIATELY

One rationale for widespread use of EHRs is that certain types of patient

harm can be prevented when EHRs are used appropriately. For instance,

EHRs facilitate and/or standardize the transfer of information between

TABLE 4.2.1: Cont.

who order tests are notified promptly of abnormalities. However, these

benefits are predicated on the assumption that EHRs are used correctly

and as intended in routine practice [35]. For example, if CPOE were used

on some nursing units but not others, clinicians would need to check for

orders and test results in multiple locations, increasing the opportunity

to miss information. Other partial uses of CPOE (e.g., used for ordering

medications but not laboratory tests) could leave the non-computerized

processes more vulnerable to error, with no way of ensuring closed-loop

electronic communication of test results to the ordering providers and po

tentially leading to more missed results [36]. Another hazard can arise if

providers bypass structured data fields in CPOE and instead use EHR

based free-text communication to prescribe or discontinue medications,

since free-text orders are not standardized and vulnerable to miscommu

nication [37]. To reduce these safety concerns, another e-PSG could man

date use of CPOE for all medication, laboratory, and radiology test orders.

Table 4.2.1 lists several potential strategies to help achieve this goal. Second, implementation and use of complex clinical decision support

(CDS) embedded within EHR systems are prone to human error and cogni

tive constraints [38,39]. Thus, decisions related to various aspects of CDS

interventions must be periodically evaluated [40]. For example, although

point-of-care, CDS interventions are necessary to achieve the full benefi ts

of EHRs and “meaningful use” payments [41], interruptive alerts must be

used judiciously. Many organizations turn on alerts with low specifi city,

resulting in high rates of clinician overrides [24]. Frequent overrides are

associated with “alert fatigue,” which may cause clinicians

to inadvertent

ly ignore important information. Thus, another potential e-PSG could be

to reduce alert fatigue. Alerts with override rates above a certain threshold

should be discontinued or modifi ed to increase their specifi city [42]. Simi

larly, hard stops (i.e., when users cannot proceed with the desired action)

must be used only for the most egregious errors [43]. Having such a goal

will stimulate a multidisciplinary approach to reducing alerts that involves

bringing cognitive scientists, human factors engineers and informaticians

[44,45], to work on these complex issues with the clinicians. Some addi

tional suggestions to achieve this goal are listed in Table 4.2.1.

reports and scanning images of test results into EHRs including improved

legibility and rapid access [46], many institutions are not currently coding

certain critical data. A lack of structured or coded data prevents the sys

tem from being able to provide meaningful feedback or interpretation of

results to the user (i.e. no alert for lisinopril will be generated if captopril

angioedema was not previously entered as coded allergy data). Therefore,

to realize the full safety benefi ts of complex CDS tools [47] (e.g., drug

allergy checking [48], automated abnormal test result notifi cation [28], or

drug-condition reminders [29]) another e-PSG could focus on ensuring

that critical data such as medications, allergies, diagnostic test results, and

clinical problems are entered as structured or coded data in the EHR [49].

Strategies to help achieve this goal are summarized in Table 4.2.1.

4.2.3 PHASE 3. DEVELOP GOALS RELATED TO USE OF EHRS TO MONITOR AND IMPROVE PATIENT SAFETY

To achieve the goals of many national stakeholders and initiatives to

improve patient safety, including Agency for Healthcare Research and

Quality (AHRQ), The Joint Commission and the recent "Partnership for

Patients" [50]. Current methods to measure safety events over rely on in

cident reports, which have several limitations including detection of only a

small proportion of events [32]. In contrast, systems can be programmed to

automatically detect easily overlooked and underreported errors of omis

sion, such as patients who are overdue for medication monitoring, patients

who lack appropriate surveillance after treatment, and patients who do not

receive follow-up for abnormal laboratory or radiology tests [51]. EHR

based trigger approaches [33] can also be used to detect

errors of commis

sion such as adverse drug events [52], postoperative complications [53],

and errors related to misidentification of patients [54]. Organizations must

leverage EHRs for purposes of improving rapid detection of common er

rors (including EHR-related errors), to monitor for high-priority safety

events and to more reliably track trends over time. EHRs could also play

a role in improving the existing infrastructure of reporting and analysis by

scribing particular safety events using the AHRQ common format v1.2 [55].

Thus, an e-PSG could relate to the use of the EHR to monitor, report, and

identify potential safety issues and events. This would make detection and

reporting more efficient and help shift resources towards investigation and

action. Strategies to help achieve this goal are summarized in Table 4.2.1.

4.2.4 APPLICATION OF THE THREE-PHASE E-PSG FRAMEWORK

Given that only 48% of all eligible hospitals and only 20% of eligible phy

sicians have currently received Stage 1 meaningful use payments [56], the

development and application of e-PSGs could partially address the Institute

of Medicine’s recent recommendation to the ONC to create an EHR safety

action and surveillance plan [8]. Such a plan should be

tailored to the appro

priate stage of EHR implementation. Recent adopters of EHRs could focus

on Phase 1 goals in our safety framework, making sure that the technol

ogy is safe to use, whereas organizations that have already achieved stage 1

meaningful use criteria and have been using EHRs for several years would

aim for goals from all phases. Measurements related to e-PSGs would allow

tracking and benchmarking of EHR-related safety performance nationally

[57]. Policymakers and EHR vendors could collaborate on development and

certification of automated methods to measure and report new indicators

from “meaningful use” certified EHRs in eligible hospitals annually. Exam

ples of potential measures for e-PSGs might include EHR uptime rate (e.g.,

minutes the EHR was available to clinicians divided by number of minutes

in a year [23]), CPOE rate (e.g., number of orders electronically entered

divided by the total number of orders during the year [23], and alert override

rate (e.g., number of point-of-care alerts ignored divided by the total number

of point-of-care alerts generated [23]). These goals will also need to be reviewed regularly and updated as

needed based on national priorities and research on EHR-related patient

safety. In addition, many strategies not addressed in this paper could be

considered as recommendations or good clinical practices and progress in

a step-wise fashion to future e-PSGs.

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EHR-RELATED SAFETY CONCERNS

Dean F. Sittig and Hardeep Singh

6.2.1 INTRODUCTION

Although electronic health records (EHRs) have a significant potential

to improve patient safety, EHR-related safety concerns have begun to

emerge. For instance, some unique risks of EHRs are inherent to the tech

nologies themselves, whereas others are related to how these technologies

are applied and used [1].

We previously conducted a web-based survey of the memberships of

the American Society for Healthcare Risk Management and the American

Health Lawyers Association between August and September 2012. A 17

item survey was developed to capture information about four content ar

eas: (1) extent of EHR use at the primary facility of practice; (2) frequency

of EHR-related serious safety events; (3) variables affecting EHR-related

serious safety events; and (4) tracking of EHR-related safety measure

ments. Of 15,400 member e-mail invitations, the survey was completed

by 369 respondents (2.4%), a majority of whom worked for large hospitals

and healthcare systems. Based on this survey and supplemented by our

previous work in EHR-related patient safety, we identifi ed the following

common EHR-related safety concerns:

1. Incorrect patient identification

2. Extended EHR unavailability (either planned or unplanned)

3. Failure to heed a computer-generated warning or alert

5. Failure to identify, find, or use the most recent patient data

6. Misunderstandings about time

7. Incorrect item selected from a list of items

8. Open or incomplete orders

Guidance for risk managers on how they should approach these safety

concerns is limited. Many EHR-related safety concerns are not visible or

apparent to end users. Others are distributed such that one user is often un

aware of the broader signifi cance of the safety concern (e.g., errors in sys

tem interfaces between the EHR and ancillary systems may not be visible

since the person entering the order rarely sees what the ancillary system

receives). Thus, voluntary detection and reporting of EHR-related safety

problems may be an inadequate strategy. In this chapter, we present a “red

fl ag”-based approach that can be used by risk managers to identify poten

tial EHR safety concerns in their institution. Red fl ags are indications that

something may be wrong and should be given additional consideration or

evaluation. In medicine, clinicians commonly look for red fl ags indicat

ing that a seemingly minor problem may be more serious. For example,

a 60-year-old otherwise healthy patient who complains of a cough for a

week may be given a diagnosis of upper respiratory infection and a pre

scription for cough syrup. However, if the same patient indicated he is

coughing up blood, that would warrant special attention, perhaps a chest

x-ray [2], because the blood in sputum at that age is a “red fl ag” that could

suggest a serious problem such as a lung cancer.

Risk managers routinely collect quality and safety data from multiple

sources and are often privy to data from sources unavailable to informa

tion technology (IT) specialists or clinicians. Thus, risk managers are in a

unique position to conduct a red-fl ag based analysis. In order to develop

these red fl ags, we conducted an extensive literature search and relied

heavily on our extensive experience in EHR-related patient safety re

search. In the following sections, we defi ne each error type and list several

“red fl ags” that risk managers or other interested parties can use to identify

potential EHR-related safety issues within their organizations.

There are two types of patient identification errors. A duplicate record exists

when a single patient has more than one medical record. A co-mingled record

exists when a single medical record contains information about two or more

patients. Duplicate records are created when users create a new record for a

patient with an existing record or when patient records from disparate systems

are combined without checking for matching records. Co-mingled records re

sult from incorrect patient selection and subsequent use [3]. The likelihood of

such events is greatly increased when a) looking up patients in large, multi

institutional healthcare systems that may have over a million patient records;

b) looking for patients with “common” names (e.g., Smith, Williams, Jones,

Garcia, Rodriguez, etc.); c) attempting to merge patient records from two or

more disparate systems without using state-of-the-art patient record matching

algorithms; and d) allowing clinicians to open two or more patient records

(i.e., either multiple tabs or windows) on the same device.

6.2.2.1 RED FLAGS FOR INCORRECT PATIENT IDENTIFICATION

1. Key patient identifying information (i.e., first and

last name, date of birth, gender, medical record number, inpatient location or home address, picture) is missing from EHR screens or printouts [5].

2. Absence of documented processes and procedures for checking patient ID at essential stages of a patient visit (e.g., when patients are called back for rooming, at entering of vital signs, prior to labs, procedures or medication administration, at checkout, etc.).

3. A large number of clinician calls (e.g., > 1/1000 orders or notes entered) request “help desk” or IT support to move their erroneous EHR entries from patient A (the wrong patient) to patient B (the right patient). Incorrect entries could include orders, order sets, clinical notes, or test results.

4. Nurses use copies of one or more patient barcode identification bands taped to their clipboard as a work-around when performing barcoded medication administration [6]. back to an order entered on the wrong patient.

6. Greater than expected number of “erroneous notes” in the EHR (i.e., notes entered incorrectly on another patient) as identified by an automated scan of all notes in the system [7].

6.2.3 EXTENDED EHR UNAVAILABILITY (EITHER PLANNED

OR UNPLANNED)

Extended (i.e., > 4 hours) EHR unavailability means that some portion, or

more likely, all of the patient’s medical records are unavailable for review.

It results from total or partial failure or planned downtime in any part of

the EHR computing infrastructure (e.g., electrical power, network connec

tions, database servers, computer-to-computer interfaces, computer termi

nals on patient care units, software upgrades, etc.) [8]. These problems can

lead to temporary, or even permanent, loss of data or inability to send or

receive information from others [9]. The organization must do everything

it can to reduce the likelihood of these events as well as prepare to con

tinue providing care in the event a system failure does occur [10].

6.2.3.1 RED FLAGS FOR EXTENDED EHR UNAVAILABILITY

1. Absence of documented EHR downtime and reactivation procedures.

2. Absence of notification procedures for scheduled downtimes, suggesting poor preparedness for downtimes lasting longer than anticipated.

3. No regular off-site backup of all data required to continue caring for patients (i.e., demographic, clinical, and financial).

4. No pre-printed paper order sheets or clinical documentation forms in clinical care areas.

5. Critical clinical computing hardware devices are not configured in a redundant manner (i.e., if one device fails, a backup device does not take over the work). available on a standalone computer connected to the “red” electrical plug in clinical areas.

6.2.4 FAILURE TO HEED A COMPUTER-GENERATED WARNING

OR ALERT

Critical information, even if sent to the correct person at the right time

and displayed prominently on the computer screen, can be overlooked

amidst an overabundance of other false positive information (i.e., items

that indicate a given condition exists, when it actually does not). Warn

ings or alerts can occur either synchronously (i.e., during the activity

that the alert pertains to, such as a drug-drug interaction alert during

order entry) or asynchronously (i.e., while the user is not engaged in the

activity that generated the alert, such as an alert for an abnormal labo

ratory test result). These missed data can lead to erroneous or delayed

diagnoses or treatments.

6.2.4.1 RED FLAGS FOR FAILURE TO HEED A COMPUTER

GENERATED WARNING OR ALERT

1. Reports show widespread non-adherence to computer-generated alerts that are based on recommended guidelines [11].

2. Clinicians report receiving too many irrelevant alerts during order entry or as asynchronous messages in their inboxes [12].

3. Clinicians report intrusive alerts used to present information that is not critical (e.g., a pop-up message reading “Are you sure you want to send this prescription as an e-script?”).

4. Clinicians report working at home, staying late after work, or working on weekends to complete all the work in their inboxes (e.g., abnormal laboratory test results, prescription refills, orders to cosign) . ate an alert.

6.2.5 SYSTEM-TO-SYSTEM INTERFACE ERRORS

Errors caused by miscommunication (or non-communication) between ap

plications can result in data from one application (e.g., a laboratory sys

tem) failing to reach or being corrupted before reaching another applica

tion (e.g., the EHR). These errors can occur due to mistakes in the data

translation tables (i.e., used to encode and decode orders and results) that

are used to transmit information between components of an EHR or be

tween disparate clinical systems. [14] Mismatched data fields may affect

orders or results by introducing inadvertent changes (or outright data loss)

that are virtually undetectable by the computer, or by the people not privy

to the original sender’s intentions.

6.2.5.1 RED FLAGS FOR SYSTEM-TO-SYSTEM INTERFACE

ERRORS

1. Orders or test results are reported to be missing for certain patients.

2. The “error log” of the interface between components of an EHR contains orders or results that were not able to be transmitted automatically between different components of the EHR system.

3. Laboratory reports in the EHR are reported to be incomplete (e.g., missing measurement units, reference ranges, date and time of result, or comments).

4. Any report of patient receiving incorrect or unnecessary medications.

5. Clinicians report errors or inconsistencies between the structured data fields and free-text comment fields or comments that fail to transfer from system-to-system [15].

6. The organization does not have a method for sending or receiving laboratory tests performed by an outside laboratory through a direct interface to the EHR, (i.e., requiring orders or results to be transmitted via mail or fax) [16].

PATIENT DATA

Failure to find or use the most recent patient data (e.g., medication orders,

laboratory or radiology results) can cause clinicians to make erroneous

clinical decisions and lead to incorrect, unnecessary, or delayed tests, pro

cedures, or therapies. These failures often result from difficulties navigat

ing, seeing, understanding or interacting with user interfaces.

6.2.6.1 RED FLAGS FOR FAILURE TO IDENTIFY, FIND, OR

USE THE MOST RECENT PATIENT DATA

1. EHR displays require either horizontal or vertical scrolling to see the most recent orders or results (i.e., data sorted chronologically [earliest to latest] rather than in reverse chronological order [most recent results first]).

2. EHR displays require users to widen data display fields, or columns, to see the complete text of the order or result.

3. Clinicians repeatedly order new diagnostic tests within a short time of the previous result [17].

4. Clinicians take inappropriate therapeutic actions due to missing recent test results (e.g., administering potassium when most recent potassium levels are high) [18].

5. Diagnostic test results are displayed in multiple locations (i.e., different screens or tabs) in the EHR.

6.2.7 EHR TIME MEASUREMENT TRANSLATIONAL CHALLENGES

Translational challenges as a result of the inability of computers to prop

erly translate time measurements as they are conceived and entered by

users can lead to many different kinds of errors. For example, users may

fail to understand how much time has passed since a displayed date (e.g.,

patient born 11/23/62 is now 50-years-old and due for a colonoscopy). Us

This can be difficult for others to interpret, especially at a later date (e.g.,

surgery scheduled for tomorrow), when historical information is entered

with current time stamp, or when the computer is instructed to carry out a

specific action at a future date and time without notifying the clinicians or

patients affected.

6.2.7.1 RED FLAGS FOR EHR TIME MEASUREMENT

TRANSLATIONAL CHALLENGES

1. Routine tests, medications, or procedures ordered “daily” continue long after they are clinically indicated (i.e., no stop date is documented). Examples include daily chest X-rays for previously intubated patient and prophylactic antibiotics continued after 10 days with no sign of infection.

2. Repeated delays in administration of time-sensitive medications (e.g., antibiotics) ordered as “next routine administration time,” or double doses are given when a multi-day course of medication is ordered to begin “now” and then inadvertently repeated when the “next routine administration time” occurs soon after the order time [19].

3. Clinicians report that critical medications have been cancelled automatically with no notice to clinicians [20].

4. Clinicians are unable to create reminders for future important actions within the EHR [21].

5. “Urgent” or “STAT” flags on orders are overused (e.g., more than 50% of orders placed as STAT on acute care hospital units) or any other evidence that clinicians are not confident in the EHR’s ability to communicate their routine instructions in a timely manner.

6.2.8 INCORRECT ITEM SELECTED FROM A LIST OF ITEMS

Juxtaposition errors occur when an EHR user inadvertently selects a listed

item that is directly adjacent to the item he or she intended to select. These

between items or simply selects the incorrect item.

6.2.8.1 RED FLAGS FOR INCORRECT ITEM SELECTED FROM

A LIST OF ITEMS

1. Drop-down or static selection lists are too narrow to display the complete text of all items, include too many items, or items are too close together [24].

2. Drop-down or static selection lists are sorted alphabetically (i.e., rather than grouped by similarity of concept) or consist of all CAPITAL LETTERS.

3. Clinicians or members of ancillary services report patient orders for wrong medications, diagnostic tests, or therapeutic procedures.

4. A large number of orders are discontinued soon after they are entered.

5. The EHR user interface has multiple cascading or fly-out submenus (i.e., secondary and tertiary menus displayed on demand from within the primary menu) [25].

6.2.9 OPEN OR INCOMPLETE ORDERS

Open or incomplete orders can result from failure to complete the order

entry process including signing and submitting the order(s), or from fail

ure of supervising physicians to co-sign orders that require co-signatures

before becoming active. Although these errors may result from clinician

oversight, they can also result from user interfaces that make it difficult to

understand the current state of user actions.

6.2.9.1 RED FLAGS FOR OPEN OR INCOMPLETE ORDERS

1. Orders requiring co-signature in a queue that are overdue according to the organization’s policy (e.g., 24-48 hours old). (e.g., unsigned orders, discharge summaries, dictated notes, etc.)

3. Clinicians complain that the system is “losing” their orders (i.e., orders that they have entered are not carried out).

4. Some providers use a high percentage of “verbal” orders, rather than entering them into the computer themselves.

5. Referring providers do not receive notification back from specialists about consultations that are completed.

6.2.10 DISCUSSION

We have provided a list of red flags that risk managers can consider using

in their ongoing activities to improve patient safety within the context of

EHR-enabled healthcare delivery. Identifying that one or more common

EHR-related safety concerns has occurred is only the first step in resolv

ing a problem. In most cases, the risk manager or other responsible party

should convene a multi-disciplinary group, including members of the IT

department and affected clinicians, to investigate the causes of the prob

lem. It may be necessary to work with the EHR vendor to identify the

cause of the problem and potential solutions.

While we discussed many types of EHR-related safety concerns, these

concerns likely represent only the tip of the iceberg. There might be other

concerns we have missed. For instance, adoption of EHRs is still less than

50% of physicians [26] and currently, comprehensive closed claims analy

sis of EHR-related safety concerns is not available. Thus, the red fl ags

listed could represent only a fraction of the possible factors that can be

used to detect EHR-related problems. An organization that routinely con

ducts EHR-related surveillance activities, such as the ones proposed here,

can signifi cantly reduce the risks associated with EHR implementations.

6.2.11 CONCLUSION

EHRs represent one of the most important tools available to improve pa

tient safety in healthcare organizations. Nevertheless, without careful and

can arise. Organizations can dramatically reduce both the number and se

verity of EHR-related serious safety events by addressing these red flags.

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T Y S A F E R G u i d e s R e c o m m e n d e d P r a c t i c e s R a t i o n a l e f o r P r a c t i c e o r R i s k A d d r e s s e d E x a m p l e s o f P o t e n t i a l l y U s e f u l P r a c t i c e s / S c e n a r i o s P h a s e 1 - M a k e H e a l t h I T S a f e r P r i n c i p l e : D a t a A v a i l a b i l i t y (E H R s a n d t h e d a t a c o n t a i n e d w i t h i n t h e m a r e a v a i l a b l e t o a u t h o r i z e d i n d i v i d u a l s w h e r e a n d w h e n r e q u i r e d t o s u p p o r t h e a l t h c a r e d e l i v e r y a n d b u s i n e s s o p e r a t i o n s .) 1 . D a t a a n d a p p l i c a t i o n c o n f i g u r a t i o n s a r e b a c k e d u p a n d h a r d w a r e s y s t e m s a r e r e d u n d a n t . [8 1 0] C , I T , H H a r d w a r e a n d s o f t w a r e f a i l u r e s a r e i n e v i t a b l e . W i t h o u t r e d u n d a n t b a c k u p h a r d w a r e , d e l a y s i n r e s t o r i n g s y s t e m o p e r a t i o n c a n a f f e c t b u s i n e s s c o n t i n u i t y . W i t h o u t d a t a b a c k u p s , k e y c l i n i c a l a n d a d m i n i s t r a t i v e i n f o r m a t i o n c a n b e l o s t . • M i s s i o n c r i t i c a l h a r d w a r e s y s t e m s (e . g . , d a t a b a s e s e r v e r s , n e t w o r k r o u t e r s , c o n n e c t i o n s t o t h e i n t e r n e t) a r e d u p l i c a t e d . • D a t a a r e e n c r y p t e d a n d b a c k e d u p f r e q u e n t l y , a n d t r a n s f e r r e d t o a n o f f s i t e s t o r a g e l o c a t i o n a t l e a s t w e e k l y . • S y s t e m b a c k u p s a r e t e s

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Recommended Practices Rationale for Practice or Risk

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Safetyinciple:SafetySurveillan
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ementsinsafety.•EHRuptimerate–minutestheEHRwasavailabletocliniciansdividedbynumberofminutesinthereportingperiod.[52]•Systemresponsetime–meantimetodisplayarecentCBCresultonatestpatient,measuredeverydayinthereportingperiod.•SeriousEHRrelatedadverseevents–listofreportedEHRrelatedadverseevents(whethertheyresultedinpatientharmornot,includesanyreportedbreachesofpatientconfidentiality).•Potentialwrongpatienterrorrate–Requeststo“change”orderthatresultincancellationof1storderandcreationofanorderforthesameitemonadifferentpatientbythesameuser.

Recommended Practices Rationa

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s 1 7 . E H R r e l a t e d p a t i e n t s a f e t y h a z
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n c e d i n i n v e s t i g a t i n g a n d a d d r e s s i
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f i x r a t e (i . e . , t h e n u m b e r o f e r r o r s

with potential for causing direct patient harm fixed within 3 months divided by the total number of errors reported) is monitored. 18. Activities to optimize the safety and safe use of EHRs include clinician engagement. C, Ev, Dx, IT, Rx Unless clinicians are included in decisions that affect the ir use of the EHR, they may not understand or accept changes, which increases risks. Clinicians should be engaged in identifying opportunities for the EHR to support safe and effective clinical use. Representatives from the following groups are involved in decision making about EHR safety: clinicians, administrators, patients, IT/informatics, board and CEO, quality, and legal staff.

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DOWNTIME

SAFER Guides

Recommended Practices Rationale for Practice or Risk Addressed Examples of Potentially Useful Practices/Scenarios

Phase 1 – Make Health IT Safer

Principle: Data Availability (EHRs and the data contained within them are available to authorized

individuals where and when required to support healthcare delivery and business operations.)

1. Hardware that runs ap

plications critical to the

organization’s operation

is duplicated. C, Ev, IT Organizations should take steps to prevent and minimize impact of technology failures. A single point of failure greatly increases risk. • The organization has a remotely located (i.e., > 50 miles away and > 20 miles from the coastline) “warm-site” (i.e., a site that can be activated in less than 8 hours) backup facility that can run the entire EHR. dressed Practices/Scenarios • The warm-site is tested at least quarterly. • The organization maintains a redundant path to the internet consisting of two different cables, in different trenches (a microwave or other form of wireless connection is also acceptable), provided by two different internet providers.5

2. An electric generator

and sufficient fuel are

available to support the

EHR during an extended

power outage. C, IT Most health care organizations must be able to continue running their health IT infrastructure and preserve data and communication capabilities in cases of sustained power outage. • Organizations evaluate the consequences to patient safety and to business operations due to loss of power that shuts down the EHR, and implement concrete plans to keep the EHR running to the extent needed to avoid unacceptable consequences • In the event of a power failure, there is an uninterruptible power supply (UPS)), either batteries or a "flywheel," capable of providing instantaneous power to maintain the EHR for at least 10 minutes. • The UPS is tested regularly (optimally on at least a monthly basis). • The on-site,

backup electrical generator is capable of maintaining EHR functionality critical to the organization’s operation (e.g., results review, order entry, clinical documentation). • The organization maintains 2 days of fuel for the generator on-site. • The generator is tested regularly (optimally at least on a monthly basis). • The UPS and the generator are housed in secure locations not likely to flood. dressed Practices/Scenarios

3. Paper forms are avail

able to replace key EHR

functions during down

times. C Clinical and administrative operations need to continue in the event of a downtime. • The organization maintains enough paper forms to care for patients on the unit for at least 8 hours. Paper forms could include those required to enter orders and document the administration of medications, labs, radiology on each unit.10 • There is a process in place to ensure that the information recorded on paper during the downtime gets entered and reconciled into the EHR following its reactivation (e.g., could be entering in data as coded data or scanning of documents).10

Phase 1 – Make Health IT Safer

Principle: Data Integrity (Data are accurate, consistent and not lost, altered or created inappropri

ately.)

4. Patient data and soft

ware application con

figurations critical to the

organization’s operations

are backed-up.* C, Ev, IT Backup of mission-critical patient data and EHR system configuration allows system restoration to a “pre-failure” state with minimal data loss. • The organization has a daily, off-site, complete, encrypted backup of patient data.* • The offsite backup is tested regularly (optimally on at least a monthly basis, i.e., complete restore).* • The content required to configure the system is backed up on a regular basis

(optimally on a monthly basis and before every system upgrade). • The organization maintains multiple backups, created at different times. • The organization maintains multiple backups, created at different times. • Backup media are physically secured.* • Backup media are rendered unreadable (i.e., use software to scramble media contents or better yet, physically destroy/shred media) before disposal.* dressed Practices/Scenarios • The organization has a “readonly” backup EHR system that is updated frequently (optimally at least hourly). • The read-only EHR system is tested regularly (optimally at least a weekly basis). • Users can print from the readonly EHR system. • If there is a “unit-level” readonly backup EHR system, it is connected to a local UPS or “red plug.”

Phase 1 – Make Health IT Safer

Principle: Data Confidentiality (Patient data is only available to those authorized to see it.)

5. Processes and pro

cedures are in place to

ensure accurate patient

identification when pre

paring for, during, and

after downtimes.*C, Ev Without policies, procedures, and processes in place to manage patient identification during downtimes, mismatches and lost records could compromise patient confidentiality and safety. Patient confidentiality and careful identification should be maintained, to the extent possible, at all times. • The read-only EHR system should have user-specific passwords (i.e., should not use a generic password for all users). • There is a mechanism in place to register new patients during downtime including assignment of unique temporary patient record numbers along with a process for reconciling these new patient IDs once the EHR comes back on-line.* • Ensure that paper documents created during downtime are protected using standard HIPAA safeguards and policies.*

Phase 2 – Safer Application and Use of IT

Principle: Complete/Correct EHR Use (Correct system usage [i.e., features and functions used

as designed, implemented, and tested] is required for mission-critical clinical and administrative

processes throughout the organization.)

6. Staff are trained and

tested on downtime and

recovery procedures.*C In organizations that have not had a significant downtime in over a year, there is an increased risk of having employees who do not know how to function in a paperbased environment. • Organizations establish and follow training requirements so that each employee knows what to do to keep the organization operating safely during EHR downtimes. • Clinicians are trained in use of the paper-based ordering and charting tools.* dressed Practices/Scenarios • The organization conducts unannounced EHR “downtime drills” at least once a year. • Clinicians have been trained on how and when to activate the “read-only” backup EHR system.

7. A communication

strategy that does not

rely on the computing

infrastructure exists for

downtime and recovery

events.*C, IT Institutions need to be prepared to communicate with key personnel without use of the computer. • The organization has methods other than electronic-based (i.e., NOT email, twitter, voiceover-IP, etc.) to notify key organizational administrators and clinicians about times when the EHR is down (either planned or unplanned).* • The organization has a mechanism in place to activate the read-only backup EHR system and notify clinicians how to access it. • The organization has a mechanism in place to notify clinicians when the EHR is back on-line (either planned or unplanned).

8. Written policies and

procedures on EHR

downtimes and recovery

processes ensure conti

nuity of operations with

regard to safe patient care

and critical business op

erations. C, IT Policies and procedures on EHR downtime and recovery keep everyone “on the same page” so they are able to care for patients and maintain critical business operations during inevitable downtimes, whether planned or unplanned. • The organization has a written downtime and recovery policy that describes key elements such as when a downtime should be called; how often further communication will be delivered; who will be in-charge during the downtime (both on the clinical and technical side); how everyone will be notified; and how information collected during the downtime is entered into the EHR. • The downtime policy is reviewed at least every 2 years. • The EHR downtime policy describes when the warm-site backup process should be activated (ideally, before the system has been down for 2 hours). dressed Practices/Scenarios • A paper-based copy of the current downtime and recovery policy is available on clinical units. • A paper copy of the current downtime and recovery policy is stored in a safe, off-site location.

Phase 2 – Safer Application and Use of IT

Principle: System Usability (All EHR features and functions required to manage the treatment,

payment, and operations of the healthcare system are designed, developed, and implemented in

such a way to minimize the potential for errors. In addition all information in the system must be

clearly visible, understandable, and actionable to authorized users.)

9. The user interface of

the locally-maintained

backup, read-only EHR

system is clearly differ

entiated from the live/

production EHR system.

C, Ev When the usual system is unavailable, a read-only copy can enable access to patient records, though it can’t support adding or editing patient data. If it looks the same to users it could easily result in attempts to enter data that will not be recorded. • Access to the “read-only” backup EHR is disabled (e.g., icons on the computer screens are “greyed out” or not available) during periods of normal EHR operations. • The user interface of the readonly backup EHR system is visibly different than the fully operational system (e.g., there is a different background color for screens, a watermark across screens, or data entry fields are greyed out). • Clinicians are trained on appropriate use of the read-only backup EHR.

Phase 3 – Leverage IT to Facilitate Oversight and Improvement of Patient Safety

Principle: Safety Surveillance and Optimization (Monitor, detect and report on safety-critical clini

cal and administrative aspects of EHRs and healthcare processes and make iterative refinements

to optimize safety.)

10. There is a compre

hensive testing and mon

itoring strategy in place

to prevent and manage

downtime events. C, Ev,

IT Comprehensive testing and monitoring strategies can prevent and minimize impact of future technology failures. • The organization regularly monitors and reports on system downtime events. • The organization regularly monitors and reports on system response time (optimally under 2 seconds). • The organization has a written policy describing the different hardware, software, process, and people-related testing procedures. dressed Practices/Scenarios • The organization maintains a log of all testing activities. • Unplanned downtimes and the

effectiveness of follow- up to prevent them from recurring are monitored by the top leadership.

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8 Chapter 8: SAFELY CONFIGURING AND MAINTAINING EHRS AND SYSTEM-TO-SYSTEM INTERFACES

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ESSAFERGuidesRecommendedPracti
cesRationaleforPracticeorRiskA
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sefulPractices/ScenariosPhase1
-MakeHealthITSaferPrinciple:Da
taAvailability(EHRsandthedatac
ontainedwithinthemareavailable
toauthorizedindividualswherean
dwhenrequiredtosupporthealthca
redeliveryandbusinessoperation
s.)1.TheEHRsupportsandusesstan
dardizedprotocolsforexchanging
datawithothersystems.C,Dx,Ev,I
T,RxStandardssuchasthosedevelo
pedbyHL7greatlysimplifytheesta
blishmentandmaintenanceofsafea
ndeffectiveinterfacesbetweenex
ternalsystems(e.g.,ancillaries
likeLaboratory,Radiology,orPha
rmacy)therebyreducingerrorsofm
isscommunication.•Ataminimum,t
heEHRsatisfiesONC'scertificati
onrequirementsrelatedtoelectro
nicexchangeofinformation.•TheE
HRiscapableofsendingandreceivi
ngclinicalandadministrativedat
ausingHL72.xmessageswherethese
ndingandreceivingsystemsusethe
sameversion.•TheEHRhas2way,HL7
v2.xcompatibleinterfacestomiss
ioncriticalancillarysystems(at
aminimum:Pharmacy,Laboratory,B
loodBank,Radiology).•TheEHRisc
apableofgenerating,exporting,i
mporting,anddecodingclinicalpa
tiensummarydocumentsencodedint
heContinuityofCareDocument(CCD
)standard.Thisincludesprocedur
essuchasplacingthecorrectlydec
odedclinicaldataintotheproperl
ocationintheEHR,ratherthanjust
addingahumanreadableversionoft
hedocumenttothepatient'slistof
freetextreports.•Iftheorganiza
tionhasan“interfaceengine”,the

hardwarerunningthisapplication
iduplicated(i.e.,operationalba
ckuphardwareisinstalled.• Botht
hesendingandreceivingsideofthe
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cientdetailtoallowbothsidestov
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ceforuse.• TheEHRhaslinkstoexte
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dExamplesofPotentiallyUsefulPr
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y(Dataareaccurate,consistentan
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ropriately.)Systemtosysteminfa
cessupportthestanrdclinicalvoc
abulariesedbytheconnectedplica
tions.Ev,ITUseofstandardclinic
alvocabulariesisessentialtoens
uresemanticinteroperability(i.
e.,consistentinterpretationoft
hemeaningofterms)betweensystem
s.• Theinterfacesupportsandenco
uragesuseofclinicalvocabularie
sfromONC'scertificationrequire

ments, for example: Rx Norm for medi
cation names, SNOMED CT for clinica
l problems, and LOINC for laborator
y tests. • A process is in place to ens
ure that standard clinical vocabul
aries are updated and consistent in
all interfaced software applicati
ons. • Organizations evaluate inte
rfaced software prior to purchase t
o ensure that it uses compatible ver
sions of standard clinical vocabul
aries. System to system er faces are
properly nfigured and tested ensur
e that both ded and free text data men
ts are transmit without loss of oran
ges to information ntent. Ev, IT Mai
ntaining a system to system interfa
ce within a rapidly evolving clinic
al information system is challengi
ng in part because many changes are r
equired. Without the ability to imp
lement and test these changes prior
to go live, patients would be placed
at significant ly increased risk of
data loss, corruption or the ft. Fai
lure to test system interface compo
nents is

one of the leading causes of EH

R

related patient safety events. • Sy
stem to system interfaces are teste
d going into production and after ch
anges to hardware, software, or con
tent (i.e., the allowable list of da
ta elements to be exchanged) on eith
er side of the interface. • Free text
data fields accessible to clinical
end users of one system are transfer
red intact (i.e., no changes or trun
cation of characters) to the second
ary system. • The organization (or i
nterface developer) should develo
p a reference or validation dataset
that includes boundary cases (i.e.
, data that are slightly below, at, a
nd slightly above key thresholds).
These test data are run through the i

n t e r f a c e r e p e a t e d l y a f t e r a n y c h a n
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s 5 . T h e i n t e n s i t y a n d t h e e x t e n t o f i
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c o m p l e x i t y a n d w i t h t h e i m p o r t a n c e
o f t h e a c c u r a c y , t i m e l i n e s s , a n d r e
l i a b i l i t y o f t h e d a t a t h a t t r a v e r s e
s t h e i n t e r f a c e . C , D x , E v , I T , R x W h i
l e i d e a l l y e v e r y t h i n g s h o u l d b e c a r
e f u l l y t e s t e d , t h e d e m a n d s o f t e s t i
n g m u s t a l s o b e r e a s o n a b l e . T h e m o r e
i m p o r t a n t t h e d a t a i s t o p a t i e n t s a f
e t y t h e m o r e i n t e r f a c e t e s t i n g t h a t
s h o u l d b e c o n d u c t e d . • W h e n t e s t i n g
a n i n t e r f a c e , b o t h a n t i c i p a t e d a n d
u n a n t i c i p a t e d t y p e s o f d a t a (e . g . ,
t e x t c h a r a c t e r s i n a n u m e r i c f i e l d)
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e n s u r e t h a t t h e i n t e r f a c e d o e s n o t r
e s p o n d i n c o r r e c t l y i n e i t h e r c a s e .
• O r g a n i z a t i o n s , t h r o u g h p o l i c i e s
a n d / o r j o b d e s c r i p t i o n s , a d d r e s s r
e s p o n s i b i l i t y f o r e v a l u a t i o n o f t h
e i n t e n s i t y a n d e x t e n t o f i n t e r f a c e
t e s t i n g f o r a l l n e w s o f t w a r e p u r c h a
s e s o r u p g r a d e s o f s y s t e m s t h a t m u s t
b e i n t e r f a c e d . • O r g a n i z a t i o n s a d d
r e s s t h e r o l e o f E H R t e c h n o l o g y d e v e
l o p e r s i n t h e t e s t i n g o f i n t e r f a c e s
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o n t r a c t u a l a n d s e r v i c e o b l i g a t i o n
s 6 . A t t h e t i m e o f a n y m a j o r s y s t e m c h
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e r s (c l i n i c i a n s o r a d m i n i s t r a t o r s
) o n b o t h s i d e s o f t h e i n t e r f a c e c o r r
e c t l y u n d e r s t a n d a n d u s e i n f o r m a t i
o n t h a t m o v e s o v e r t h e i n t e r f a c e . C ,
D x , E v , I T , R x A t t h e t i m e o f m a j o r s y s
t e m c h a n g e s , s o c i a l f a c t o r s c a n i n t
e r a c t w i t h t e c h n i c a l f a c t o r s t o c r e
a t e n e w r i s k s . I n f o r m a t i o n , e v e n w h
e n c o r r e c t l y e n c o d e d a n d t r a n s m i t t
e d , c a n b e m i s i n t e r p r e t e d b e c a u s e o
f d i f f e r e n c e s i n h o w u s e r s c o n c e p t u
a l i z e t h e i r w o r k . • T e s t i n g u s e s a w i
d e r a n g e o f c a s e s a n d s c e n a r i o s i n c l
u d i n g t h o s e w h e r e u s e r s o f t h e e x t e r
n a l a p p l i c a t i o n o r u s e r s i n t h e e x t e
r n a l f a c i l i t y o r s e r v i c e m a y i n t e r p

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a24/7facilityanda95facility;if
“homephone”meansthesamethingfo
racollegecampusclinic,anursing
home,anurban“safetynet”communi
tyclinic,andaprivatephysicianp
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ouldincluderealworld,clinicals
cenariosofinformationexchange,
suchas:scheduleanappointment;a
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essorderinancillarylab;reportr
esults;recordmedicationadminis
tration.7.Changestohardwareors
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senderroneousrandomdatathrough
theinterfacetoinduceunexpected
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anhandletherequiredloadatpeakt
imesandwhenconfrontedwitherron
eousdata.commendedacticesRatio

nale for Practice or Risk Addressed
Examples of Potentially Useful Pra
ctices / Scenarios There is a hardwa
red software environnt for interfa
ce test that is physically parate fr
om the live vironment. Ev, ITEHR san
d the many applications they must in
terface with are continually chang
ing. System administrators and app
lication developers need a “safe” p
lace to develop and test their chang
es without fear of causing harm to pa
tients. • Changes to applications (
or the content to be exchanged) one i
ther side of the interface, or to the
interface itself, are implemented
and tested in the test / development
environment before being put into p
roduction. • Develop and test batch
processing jobs for applications a
nd interfaces. • Regression testin
g (i.e., to ensure that all previous
functionality is still working app
ropriately) is conducted in the tes
t environment before the changes ar
e moved to production. Policies and
produres describe hows to and rest
art exchange of data ross the inter f
ace in orderly manner. Dx, , IT, R x Fa
ilure to stop and restart an interfa
ce properly can result in “in transi
t” data being lost or corrupted with
out any warning to users. • Ensure th
at all system interface buffers are
empty prior to stopping or restarti
ng the system. • If the interface mus
t be disconnected while the sending
system continues to produce data fo
r transmission, e.g. lab tests orde
red through CPOE, the buffers are of
adequate size and behavior to preve
nt any loss of data • The organizatio
n has a method of communicating to us
ers when a clinical interface is not
functioning properly (e.g., alert
on the login page, or alert in the EHR
whenever data retrieval or transmi
ssion is attempted but not complete
d). • Ensure reliable procedures ar
e in place and used for stopping and s

tartingsysteminterfaces.Theprocedureareavailableandconsulteddduringhardware/softwareupgrades.ase1-MakeHealthITSafer inciple:DataConfidentiality(Patientdataisonlyavailabletothoseauthorizedtoseeit.)

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s10.Physicalandlogicalsecurity proceduresareestablishedbasedo nuserrolesformanagingdifferent aspectsoftheinterfaceordataexc hange(e.g.,contentmappingappli cations,errorlogs,andclinicald ata).Ev,ITTheintegrityandconfi dentialityofdatawithinapplicat ionsarewellprotected.Whendatam ovesbetweensystemsthereisaninc reasedriskofdataloss,corruptio n,ortheft.Bothphysicalandlogic alsecuritycontrolsarerequiredo verthisexchangeofdataarerequir edtopreventunintendedchanges.• Theserverhostingthe“interfacee ngine”ismaintainedinaphysicall ysecure(i.e.,lockedroom)locati on.• Theserverhostingtheinterfa cehardwareandsoftwareismaintai nedinaphysicallysecure(i.e.,lo ckedroom)location.• Theserverho stingthe“interfaceengine”hasas ecureadministratorlogintopreve ntunauthorizedchangestotheinte rfaceconfigurationoraccesstoth edataasitcrossestheinterface.• Systemsecurityistestedtoensure thatunauthorizedindividualsora pplicationscannotgainaccesstop rotectedhealthinformation.• The securityproceduresidentifyandp rotectkeydesignatedaspectsofth einterfaces,includingcontentma ppingapplications,thecontentma psthemselves,errorlogs,andclin icaldata.Phase2-SaferApplicati onandUseofITPrinciple:Complete /CorrectEHRUse(Correctsystemus age[i.e.,featuresandfunctionsu sedasdesigned,implemented,andt ested]isrequiredformissioncrit icalclinicalandadministrativep rocessesthroughouttheorganizat ion.)11.Theorganizationhasacce sstopersonnelwiththeskillsrequ iredtoconfigure,test,andmanage systemtosysteminterfaces.ITCon figuring,testing,andmanagingsy stemtosysteminterfacesarecompl

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leforPracticeorRiskAddressedEx
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ionregardingthemeaningandtimin
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ding:allowablevalues(e.g.,text
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resentationofunitsonmeasuremen
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imatedmeanandmaximumamountsofd
ataexpectedtocrosstheinterface
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rorsgenerated.•Theorganization
maintainsacomprehensivedatadic
tionarythatincludesforeachdata

element:oDatatype(e.g.,coded,freetext,numeric)oDatadefinitionoMetadata-creator,datecreated,users•Theorganizationmaintainsacomprehensiveinterfacedatamapthatincludesdatarecodesorconversions,asrequired.•Theorganizationmaintainsasetofinterfacessystemperformancerequirementsincludingtheexpectedthroughputofthesystem,uptimerequirements,andprotocolssupported..TheorganizationtifiespeopleinvolvedmaintenanceorusesysteminterfaceschangesaredethataffectthententoftheStandardtafilesorallowableluestransmittedviainterface(e.g.,thederablecatalogorargemaster).Dx,Ev,,RxEHRrelatedhardwareandsoftwarechangefrequently.Failuretonotifyallpartiesinvolvedinthemaintenanceoruseofthesysteminterfacesoftenresultsininterfaceerrors.Someofthseerrorsmaybesubtleanddifficulttoidentify.Failuretoaccountforandmanagethesechangescanleadtoseriouspatientsafetyevents.•Changesareclearlycommunicatedandtestedpriortogolive,includingchangesto:conversionprograms,interfaces,databases,screens(e.g.,lengthofdataentryordisplayfields),tables(e.g.,datainterpretation,numericvalues,times,dates,ortextbaseddatafields),andvocabularies•Documentationthatappropriatetestinghasoccurredafterallsystemmodificationsisavailable.•Thereisapolicydescribingconfigurationcontrolproceduresthatincludes:whomustbenotifiedbeforeanychangeismade,whocanmakethechanges,whoisresponsibleforTestingthechanges,whoisresponsibleforapprovingthechanges,andwhencanthechangesbeimplementedinthelivesystem.RecommendedPractices Rationalefor Practiceor Risk Addressed Examplesof Potential

lyUsefulPractices/ScenariosPha
se2-SaferApplicationandUseofIT
Principle:SystemUsability(AllE
HRfeaturesandfunctionsrequired
tomanagethetreatment,payment,a
ndoperationsofthehealthcaresys
temaredesigned,developed,andim
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clinicaluse,suchasknowingwhent
heinterfacecannottransmitorrec
eivemessages,alerts,orcruciali
nformation.Ev,ITUsersmustbenot
ifiedwhentheinterfacebetweencl
inicalsystemsisnotfunctioningp
roperly.Failuretodistinguishbe
tween“therearenoresults”and“th
einterfacetothesystemcontainin
gtheresultsisnotfunctioning”co
uldleadtodiagnosticortherapeut
icdelays.•Theuserisinformedwhe
nthe interfacecannottransmitame
ssage.•Theuserisinformedwhenth
eremotesystemfromwheretheyarer
equestinginformationisunavaila
bleeitherduetoerrorsintheinter
faceortheremotesystemitself.•T
heuserisnotifiedwhendrugallerg
ytestingisperformedonlocalmedi
cationsonlynotthoseidentifiedb
yremotepharmacyorhealthinforma
tionexchanges.•EHRapplications
thatdependonsysteminterfacessh
ouldreportthe interfacestatuswh
eninuse(e.g.,whilereviewingima
gingstudies,theEHRshowslastupd
atetimeocurrentconnectionwithP
ACSsystem).15.Theinterfaceisab
letotransmitcontextualinformat
ion,suchasunitsformeasuresorso
urcesofinformation,toenablecli
nicianstoproperlyinterpretinfo
rmation.Dx,Ev,IT,RxFailuretotr

ansmittherelevantmetadata(i.e.,contextordetails)relatedtothedata,andnecessaryforitsinterpretation,canleadtomisunderstandingsanderroneousdecisions.• Theinterfacecantransmitthe“units”formeasurementsalongwiththemeasurements,andtheunitsarestoredinstructureddatafields(e.g.,175lbs.or500mg)• Theinterfacecantransmitinformationassociatedwithaparticularmeasure(e.g.,fractionofinspiredoxygenalongwiththarterialbloodgasresultstoallowcliniciantointerpretthebloodgasvaluesinthepropercontext).commendedacticesRationaleforPracticeorRiskAddressedExamplesofPotentiallyUsefulPractices/Scenarios.Interfaceproblemssociatedwithknownsteminterfaceriskssddatafieldsizeitsaremanagedtooidreadilypreventleerrors.Dx,Ev,,RxPhysicalandlogicalinterfaceshavelimitations.Failuretoacknowledgeandplanfortheselimitationsoftenresultsinpatientsafetyevents.• Thesendingsystemidentifiesandrestrictsmessagesthatarenottransmittable(e.g.,incorrectdatatype).• Theuserisnotifiedifwhattheyaretypingexceedsthebuffersizeforeitherthestoragelocationorthesystemtosysteminterface.• Theorganizationhasaprocessformanagingandminimizingknownrisksassociatedwithinterfaceproblems,suchastwosystemswithdifferentfieldsizelimits.Thesystemwiththesmallerlimitcancausedatatobetruncatedunlessthereisaddressedproperlyase3-LeveragelTtoFacilitateOversightandImprovementofPatientSafetyinciple:SafetySurveillanceandOptimization(Monitor,detectandreportonsafetycriticalclinicalandadministrativeaspectsofEHRsandhealthcareocessesandmakeiterativerefinementstooptimizesafety.).T

h e o r g a n i z a n m o n i t o r s t h e r f o r m a n c e a n d u s e s y s t e m i n t e r f a c e s u l a r l y , i n c l u d i n g n i t o r i n g t h e i n t e r e e r r o r l o g a n d t h e l u m e o f t r a n s a c t i o n s e r t h e i n t e r f a c e . D x , , I T , R x S y s t e m t o s y s t e m i n t e r f a c e s a r e c o m p l e x a n d m a n y o f t h e i r a c t i o n s a r e n o t d i r e c t l y v i s i b l e . E x t e n s i v e s y s t e m m o n i t o r i n g i s r e q u i r e d t o h e l p i d e n t i f y a n d t r a c k h i d d e n e r r o r s b e f o r e t h e y a f f e c t p a t i e n t s . • T h e s y s t e m t o s y s t e m i n t e r f a c e e r r o r l o g i s a u t o m a t i c a l l y m o n i t o r e d a n d a l l f a i l e d t r a n s a c t i o n s a r e b r o u g h t t o t h e a t t e n t i o n o f t h e a p p r o p r i a t e s u p e r v i s o r , i n v e s t i g a t e d a n d f i x e d w i t h i n o n e w e e k . • T h e n u m b e r o f t r a n s a c t i o n s c r o s s i n g t h e i n t e r f a c e i s m o n i t o r e d t o e n s u r e t h a t t h e n u m b e r o f t r a n s a c t i o n s i s “ n o r m a l ” (e . g . , d i s p l a y e d i n c o n t r o l c h a r t s h o w i n g t h e m e a n a n d r e a s o n a b l e u p p e r a n d l o w e r b o u n d s (e . g . , 2 o r 3 s t a n d a r d d e v i a t i o n s f r o m t h e m e a n) . . W h e n i n t e r f a c e o r s a r e d e t e c t e d , t h e y a r e r e p o r t e d , f i x e d , d u s e d t o c o n s t r u c t w t e s t c a s e s t o p r o v e t h e i n t e r f a c e

t i n g . D

x , E v , I T , R

x F a i l u r e t o f i x i n t e r f a c e e r r o r s i n a t i m e l y m a n n e r c a n l e a d t o p a t i e n t h a r m o r t o l o s s o f c l i n i c i a n s ’ c o n f i d e n c e i n t h e d a t a . • A f t e r a n y i n t e r f a c e e r r o r i s d e t e c t e d a n d f i x e d , a d d i t i o n a l t e s t d a t a a r e a d d e d t o t h e s t a n d a r d s e t o f t e s t s t o c h e c k f o r t h e s a m e e r r o r i n f u t u r e r e l e a s e s .

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HARDWARE/SOFTWARE CONFIGURATION

SAFER Guides

Legend Key Facilitators of Practice Implementation

C Clinicians, support staff, and/or clinical administration
(e.g., Medical Records and Risk Managers)

Dx Diagnostic services, such as laboratory or
radiology—could be local or remote

Ev EHR vendor

IT IT support staff, could be local or contracted.
Responsible for maintaining the EHR and infrastructure

Rx Pharmacy – could be local or remote

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s P h a s e 1 – M a k e H e a l t h I T S a f e r P r i n c i p l e : D a t a A v a i l a b i l i t y (E H R s a n d t h e d a t a c o n t a i n e d w i t h i n t h e m a r e a v a i l a b l e t o a u t h o r i z e d i n d i v i d u a l s w h e r e a n d w h e n r e q u i r e d t o s u p p o r t h e a l t h c a r e d e l i v e r y a n d b u s i n e s s o p

erations.)1.Thereareanadequate
numberofEHRaccesspointsinallcl
inicalareas.C,ITRapid,reliable
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and,ifthereare waittimes,theyar
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ase1-MakeHealthITSaferinciple:
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consistentandnotlost,alteredor
createdinappropriately.)Theorg
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ectedusingstrongthenticationme
chams.ITFailuretoimplementandm
anageauthenticationaccesstoany
systemordata(e.g.,strongpasswo
rds,fingerprints,androlebaseda
ccess)isanavoidablesourceoferr
oneousdatathatcanleadtopatient
harm.•Organizationshavepolicie
sandproceduresandconductregula
rriskassessmentstodefine,imple

ment, and monitor personauthentic ation. • Access to the organization's "backbone network" via wireless devices is password protected.

Recommended Practices Rationale for Practice or

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u i r e d f o r r e m o t e a c c e s s t o t h e s e r v e
r s ’ “ a d m i n i s t r a t i v e ” a c c o u n t s [e .
g . , r o o t p r i v i l e g e s o n U n i x] a n d c l i
n i c i a n s r e m o t e a c c e s s t o p a t i e n t d a
t a . T w o f a c t o r a u t h e n t i c a t i o n i n v o
l v e s u s i n g a t l e a s t 2 m e a n s o f i d e n t i
f i c a t i o n , i n f o r m a t i o n o n e k n o w s [i
. e . , p a s s w o r d] , i n f o r m a t i o n o n e h a
s [i . e . , e l e c t r o n i c I D o r r a n d o m n u m
b e r t o k e n] , o r i n f o r m a t i o n u n i q u e t
o a p e r s o n [e . g . , i r i s o r f i n g e r p r i n
t s c a n]) . • A l l u s e r s h a v e a u n i q u e u s
e r n a m e a n d “ s t r o n g ” p a s s w o r d (i . e .
, c o n t a i n s l e t t e r s , n u m b e r s , a n d s p
e c i a l c h a r a c t e r s (e . g . , $, % , &) . • P
e r i o d i c c h a n g e s t o p a s s w o r d s a r e r e
q u i r e d) . • E m p l o y e e l o g i n c r e d e n t i
a l s a r e r e v o k e d a s s o o n a s t h e i r e m p l
o y m e n t e n d s . • T h e o r g a n i z a t i o n h a s
i m p l e m e n t e d a “ s i n g l e s i g n o n ” s o l u
t i o n t h a t a l l o w s a u t h o r i z e d c l i n i c
i a n s t o r a p i d l y m o v e b e t w e e n d i s p a r
a t e c l i n i c a l a p p l i c a t i o n s w i t h o u t
r e q u i r i n g a n a d d i t i o n a l l o g i n i n f o
r m a t i o n . 4 . S y s t e m h a r d w a r e a n d s o f
t w a r e r e q u i r e d t o r u n t h e E H R (e . g . ,
o p e r a t i n g s y s t e m) a n d t h e i r m o d i f i
c a t i o n s a r e t e s t e d i n d i v i d u a l l y a n
d a s i n s t a l l e d b e f o r e g o i n g l i v e a n d
a r e c l o s e l y m o n i t o r e d a f t e r g o l i v e
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e m h a r d w a r e a n d s o f t w a r e c a n l e a d t o
s u b o p t i m a l p e r f o r m a n c e a s m e a s u r e
d b y r e s p o n s e t i m e , r e l i a b i l i t y , a n
d e r r o r f r e e o p e r a t i o n . • C r i t i c a l s
y s t e m i n f r a s t r u c t u r e c o m p o n e n t s ,
s u c h a s d a t a b a s e s e r v e r s , n e t w o r k r
o u t e r s , a n d e n d u s e r t e r m i n a l s , a r e
r e g u l a r l y l o a d t e s t e d . • A l l s y s t e m
s o f t w a r e u p d a t e s a r e i n s t a l l e d a n d
t e s t e d i n t h e “ t e s t ” e n v i r o n m e n t b e
f o r e t h e y a r e m o v e d i n t o t h e p r o d u c t
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t e d . • T h e o r g a n i z a t i o n m o n i t o r s t h
e s y s t e m d o w n t i m e a n d r e s p o n s e t i m e
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c e d u r e s a d d r e s s p o s t i n s t a l l a t i o n
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tatoensurethatitisnotinadvertentlyormaliciouslyviewed,changed,ordeletedisvitaltoensuringsafeandeffectiveuseofclinicalapplications.• Terminalsusedtoaccesspatientdatainpubliclyaccessiblelocationshaveanautomaticscreenlockingfeatureset,appropriatetotheclinicalsetting(e.g.,lockafteridleforthreeminutes).• Devicesusedtoaccesspatientdatahavetheirscreensfacingawayfrompubliclyaccessiblelocationsand/orhave"privacyfilters"(i.e.,filtersthatrestrictscreenviewingangles).• Publicdisplaysofpatientnamesonehrsaremasked(i.e.,onlyaportionofthepatient'snameisvisibleinpublicareas,e.g.,EDandwaitingrooms).• Theserverroomhasphysicalsecuritycontrolsinplace(e.g.,roomislocked,thereisnonwaterbasedfiresuppression,roomisabovegroundtopreventflooding,andbackupsarekeptinadifferentlocation).• Allportablecomputingdevicesusedtoaccessehrdatahaveencrypteddrives.• Backupscontainingpatientidentifiabledataareencrypted.

Recommended Practic

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s 7 . T h e r e a r e p r o c e s s e s i n p l a c e t o e
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e r m a j o r s y s t e m c h a n g e s , s u c h a s u p g
r a d e s t o h a r d w a r e , o p e r a t i n g s y s t e
m s , o r b r o w s e r s . M a j o r s y s t e m c h a n g
e s c r e a t e t h e r i s k o f l o s s o r c o r r u p t
i o n o f p a t i e n t d a t a . D a t a p e r s i s t e n
c e m u s t b e e n s u r e d i n d e p e n d e n t o f h a
r d w a r e a n d s o f t w a r e c h a n g e s t o m a i n
t a i n c o n t i n u i t y o f c a r e . L o s i n g d a t
a d u e t o " i m p r o v e m e n t s " i n t h e u n d e r
l y i n g s y s t e m s i s u n a c c e p t a b l e . • O r
g a n i z a t i o n s h a v e c h a n g e m a n a g e m e n
t a n d i n t e r n a l c o n t r o l p o l i c i e s a n d
p r o c e d u r e s i n p l a c e , d e s i g n e d t o e n
s u r e d a t a i n t e g r i t y , w h i c h a p p l y t o
a l l m a j o r s y s t e m c h a n g e s . M a j o r s y s
t e m c h a n g e s i n c l u d e , a t a m i n i m u m , o
p e r a t i n g s y s t e m o r b r o w s e r v e r s i o n
u p g r a d e s , o r a d d i n g n e w s y s t e m s o f t
w a r e (e . g . , v i r u s p r o t e c t i o n u p g r a
d e s) . • T h e r e a r e p r o c e s s e s i n p l a c e
t o m i g r a t e e x i s t i n g d a t a t o t h e n e w s

ystemwhileensurinitremainsaccu
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m b e r a n d s i z e o f d a t a b a s e s e r v e r s d e
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s w o r d s t r e n g t h , s y s t e m t i m e o u t s , a
n d o t h e r s i m i l a r s e t t i n g s . O r g a n i z
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s t h a t i d e n t i f y t h e k e y c o n f i g u r a t i
o n s e t t i n g s a n d t h e p e r s o n s r e s p o n s
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s • S y s t e m r e s p o n s e t i m e i s m e a s u r e d a n d r e p o r t e d r e g u l a r l y . • T h e i n t e r f a c e e r r o r l o g i s r e g u l a r l y r e v i e w e d a n d a l l e r r o r s a r e i d e n t i f i e d a n d f i x e d p r o m p t l y . • T h e a l e r t o v e r r i d e r a t e i s m o n i t o r e d a n d r e g u l a r l y r e v i e w e d . A l e r t s t h a t a r e i g n o r e d 1 0 0 p e r c e n t o f t h e t i m e (o r n e a r l y s o) a r e r e e v a l u a t e d a n d f i x e d o r d i s a b l e d . 8 • C l i n i c a l d e c i s i o n s u p p o r t i s m o n i t o r e d u s i n g s t a t i s t i c a l p r o c e s s e s (e . g . , c o n t r o l c h a r t s) t o i d e n t i f y m a l f u n c t i o n s . 9

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9 Chapter 9: ASSESSMENT OF PATIENT IDENTIFICATION RELATED PRACTICES

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SAFER SELF-ASSESSMENT: PATIENT IDENTIFICATION

SAFER Guides

OVERVIEW

Processes related to patient identification are complex and vulnerable to

breakdown. In the EHR-enabled healthcare environment, we rely upon

cesses and thus EHRs should optimize how information related to patient

identification is displayed and communicated. Technology configura

tions alone cannot ensure accurate patient identification.

Staff must also

be supported with adequate training and procedures. This self-assessment

is intended to increase awareness of EHR system characteristics related

to design, configuration, and implementation decisions related to pa

tient identification. This assessment can help identify and evaluate where

breakdowns related to patient identification may occur in your healthcare

delivery system. It focuses on the processes related to creation of new

patients in the EHR, patient registration, retrieval of information on previ

ously registered patients and other types of patient identification processes

in the EHR with the goal being to mitigate problems that arise from dupli

cative records and patient mix-ups. Thoughtful use of this assessment by

EHR users is intended to stimulate implementation of the recommended

practices, as well as sustain those that are already present. When assessing

EHRs at repeated intervals, (such as initially, annually and when changes

are made), the assessment can be used to establish a baseline for measur

ing the effect of interventions designed to improve the safety of patient

identification. The assessment works for ambulatory physician practices

and other outpatient settings as well as for hospitals.

EXPECTATIONS

Healthcare professionals should use this assessment to aid in identifying

and prioritizing patient safety issues related to EHR enabled patient iden

tification. For example, you should consider both the frequency and sever

ity of a safety event that might result in absence of these practices. We

anticipate this to be a useful tool in ongoing safety and risk management

programs, allowing you to address new risks that arise in EHR-enabled

healthcare settings and helping you take advantage of the safety benefits

of EHR-enabled healthcare settings. Please refer to the Guide for addi

tional information, including the specific risks and rationales addressed by

the recommended practices, and example strategies implemented in other

clinical settings to support the recommended practices.

C Clinicians, support staff, and/or clinical administration (e.g., Health Information Management and Risk Managers)

Dx Diagnostic services, such as laboratory or radiology—could be local or remote

Ev EHR vendor

IT IT support staff, could be local or contracted. Responsible for maintaining the EHR and infrastructure

Rx Pharmacy – could be local or remote

PATIENT IDENTIFICATION

Wrong patient errors are likely one of the most common types of errors in

the modern EHR-enabled healthcare system. Accurate identification of the

patient during registration coupled with on-going selection and use of the

correct electronic record for each patient is the cornerstone upon which the

entire electronic healthcare record (EHR) is based. Failure to identify that

an existing patient record exists for a patient during registration can result

in the creation of a duplicate record. A far more dangerous problem occurs

when the wrong patient’s record is used during the data review process

or when recording new data. These so-called, co-mingled (or overlay) re

cords are much more difficult to detect and once detected are very difficult

to fix. A number of approaches to managing duplicate records have been

described. The first approach is prevention, where institutions try to keep

duplicate records from occurring. Prevention approaches include effective

training, centralized registration, and notifications to users when creating

a new record that is similar to an existing record, and use of master patient

index (MPI) technology. When prevention is not implemented or is insuf

ficient, institutions must have methods in place to detect

and resolve dupli

cate records. Detection methods include automated (e.g., deterministic or

probabilistic) and manual reviews for similarity. After potential duplicate

records have been detected and confirmed as actual duplicates, they must

be merged. Finally, institutions should adopt error mitigation approaches,

to prevent or reduce patient harm when duplicate or potentially duplicate

patient records persist within systems. Methods for mitigating errors in

clude notifying users who access a record that is similar to another record,

vein pattern matching) identification during patient registration, and in

cluding an up-to-date picture of the patient in the record.

Recommended

Practices Rationale for Practice or Risk Addressed Examples of Potentially Useful Practices/Scenarios

Phase 1 – Make Health IT Safer

Principle: Data Availability (EHRs and the data contained within them are available to authorized

individuals where and when required to support healthcare delivery and business operations.)

1. An enterprise-wide

master patient index

that includes patient’s

demographic informa

tion and medical

record number(s)

from different parts of

the same organiza

tion (and, if avail

able, from external

organizations) is used

to identify patients

before importing

data. IT Duplicate patient records are a common problem and can cause harm when clinicians lack complete records. Likewise, when two patients' records are commingled harm can result. An enterprise-wide master patient index reduces the occurrence of duplicate patient records by increasing the likelihood that patients with previous encounters are identified. • The master patient index employs a probabilistic matching algorithm that uses patient's first and last names, date of birth, gender, and zip code or telephone number or social security number. • Organizations have policies and procedures to identify and prevent duplicate patient records and to integrate unintentional duplicate records into one complete record. • Organizational policies address how to ensure correct patient identification of information from external sources, and monitor compliance with those policies. • Organizations update policies on patient identification related to the master patient index as best practices change.

2. Clinicians can

select patient records

from electronically

generated lists based

on specific criteria

(e.g., user, location,

time, service). Ev, IT Selecting a patient from a short

list of relevant patients reduces the risk of selecting the wrong patient. • Patient lists can be automatically generated in several formats: Person-specific (e.g., all patients a clinician is responsible for), location-specific (e.g., all patients on a particular nursing unit or clinic), time-specific (e.g., all patients on today's schedule), and service-specific (e.g., all patients being cared for by a particular specialty or service). • Clinicians can view (read), edit (write: create, modify, delete), and use (execute: select a patient) patient lists.

Practices dressed Practices/Scenarios • Patient lists should by sorted in a clinically relevant order by default (e.g., by room number or appointment time), rather than alphabetically, to reduce the chance of look-alike or sound-alike names appearing close together. • There are 2 or more patient identifiers included with each patient on the list (e.g., name & date of birth, Medical record number, gender).

Phase 1 – Make Health IT Safer

Principle: Data Integrity (Data are accurate, consistent and not lost, altered or created inappropri

ately.)

3. Information

required to accurately

identify the patient is

clearly displayed on

all computer screens,

wristbands, and print

outs. Ev, IT Providing medical services to the wrong patient is one of the most common preventable sources of patient harm. Steps should be taken to ensure that the person using an EHR to care for a patient is addressing the intended patient. Doing so reduces the risk of wrong patient errors. • Organizational policies and all computer-generated displays incorporate the following information to facilitate patient identification: o LAST name o First name o Date of birth (with calculated age) o Gender o Medical record number o in-patient location

(or home address) o Recent photograph (recommended) o Responsible physician (optional) • Organizational policies and workflows incorporate use of the EHR into ensuring correct patient identification

4. Patient names on

adjacent lines in the

EHR display are visu

ally distinct. Ev, IT Keeping patient names visually distinct in the EHR reduces the likelihood of unintentionally selecting the wrong patient. This is a basic good usability practice. • On all patient lists containing two or more patients with the same last name, the names in common are displayed in a visually distinct manner (e.g., bold, italics, different color).

Practices dressed Practices/Scenarios • Use alternate line colors for adjacent patients

5. Medical record

numbers incorporate a

“check digit” to help

prevent data entry

transposition errors.

Ev, IT A check digit greatly reduces data entry transposition errors . • Organizational policies optimize automated processes in the EHR to prevent common errors, including transposition errors, which can result in poor patient identification • The “Verhoeff algorithm” works with strings of decimal digits of any length and detects all singledigit errors and all transposition errors involving two adjacent digits .

6. Users are warned

when they attempt to

create a new record

for a patient (or look

up a patient) whose

first and last name is

the same as another

patient. Ev, IT Using automated EHR processes to prevent duplicate records can prevent unintentional human errors that could lead to patient harm. Creating a duplicate (split) record or commingling two different patient records results in a serious patient safety risk. • System generates a pop-up alert when a user attempts to create a record for a new patient or looks up an existing patient with the same first and last name as an existing patient. • System generates an alert when a user attempts to create a record for a new patient or looks up an existing patient with a similar sounding first and last name as an existing patient, using a phonetic algorithm such as Soundex. • System monitors for similar names (nicknames), or changed last names (e.g., marriage, divorce, adoption), when other demographics match. • Alert provides additional demographic information context for the existing patient to help the user confirm or rule out that it is the same patient.

Phase 2 – Safer Application and Use of IT

Principle: Complete/Correct EHR Use (Correct system usage [i.e., features and functions used

as designed, implemented, and tested] is required for mission-critical clinical and administrative

processes throughout the organization.)

Practices dressed Practices/Scenarios

7. Patients are

registered using a

centralized, common

database using stan

dardized procedures.

C, Ev, IT Nonstandard registration practices and lack of access to a common database are common causes of duplicate medical records on the same patient. • The organization requires a picture ID or uses biometric

authentication (e.g., iris or vein scan) when authenticating new patients. • Organizational policy establishes standardized registration procedures involving the EHR and a common database to serve as the “source of truth” on whether a record already exists on a person who presents for services. • The organization requires a picture ID19 or uses biometric authentication (e.g., iris or vein scan) when authenticating new patients. • Registration clerks are trained to look up patients using the enterprise master patient index before creating a new record. • When new patient records are being created during the registration process, the registrar is prompted to consider other potential matches in the existing database.

8. The user interfaces

of the training, test,

and read-only backup

versions of the EHR

are clearly different

from the production

(“live”) version to

prevent incorrect

entry or review of

patient information

in the wrong system.

Ev, IT If a clinician logs into and begins using the training, test, or read-only backup versions of the EHR by mistake, any information they attempt to enter will be lost. • The screen background color on the production (“live”) EHR is different from all other EHR environments. • EHR users are trained to understand the meaning of the visual differences between the different environments

Practices dressed Practices/Scenarios

9. The organization

has a process to assign

a “temporary” unique

patient ID (which is

later merged into a

permanent ID) in the

event that either the

patient registration

system is unavailable

or the patient is not

able to provide the

required information.

Ev, IT Inevitably, in certain cases, care must be delivered to patients who are not yet registered. Processes must be in place to ensure that they soon have a permanent ID and to merge records to avoid duplicate or incomplete records. • A process (automated or manual, such as naming conventions) is in place to assign temporary IDs to newborns and patients arriving at the Emergency Department unable to provide their demographic information. • Staff members are trained in areas where temporary IDs may be required to ensure that temporary records are integrated into permanent ones. • Any downstream use of a temporary ID, such as in billing or in transfers between facilities, is tracked and corrected in all electronic systems, including at transfer facilities. • Organizations monitor resolution of temporary IDs.

10. Patient identity is

verified at key points

or transitions in the

care process (e.g.,

rooming patient, vital

sign recording, order

entry, medication

administration, and

check-out). C To avoid wrong patient errors, care must be taken to check the patient’s identification at all critical points in the healthcare process and to ensure that EHR use is integrated into workflows that support correct patient identification. • Before opening a specific patient record or signing an order, the user is shown a picture, or the name, gender and age of the patient . • Clinicians are asked to “reenter” the patient’s initials before signing an order. • Workflow related to verification of patient identity is evaluated to optimize use of the EHR to prevent wrong patient errors.

Phase 2 – Safer Application and Use of IT

Principle: System Usability (All EHR features and functions required to manage the treatment,

payment, and operations of the healthcare system are designed, developed, and implemented in

such a way to minimize the potential for errors. In addition all information in the system must be

clearly visible, understandable, and actionable to authorized users.)

Practices dressed Practices/Scenarios

11. The EHR limits

the number of patient

records that can be

displayed on the same

computer at the same

time to one , unless

all subsequent patient

records are opened

as “Read Only” and

clearly differentiated

to the user. Ev, IT Distractions while documenting or reviewing information in the EHR are common. EHRs should be designed to reduce the likelihood of working with the wrong patient's record as the re- sult of distractions. When working on multiple patients, poten- tial gains in efficiency are outweighed by the risks associated with entering or reviewing data on the wrong patient. • Clinicians are engaged in developing EHR configuration and policies to prevent errors due to distractions and the resulting danger of working on the wrong patient chart when more than one is open. • Workflow is evaluated to ensure that clinicians are able to respond to urgent situations in which they may need to look at a new record without completing review of a first patient. The practice environment should be designed to minimize the need to open and actively use more than one patient's records on the same computer. • Before allowing the user to change the current patient, the system checks that all entered data has been saved (i.e., signed) before allowing the system to display a different patient's data .

12. Patients who are

deceased are clearly

identified as such.

Ev, IT In many instances, selection of a deceased patient represents a "wrong patient" error. Clinicians should be reminded that the patient they have selected is dead. • The system displays either a pop-up alert when opening the record or a different background color for the deceased patient header in the EHR.

13. The use of

test patients in the

production (i.e.,

"live") environment is

carefully monitored.

When they do exist,

they have unambigu

ously assigned “test”

names (e.g., including

numbers or multiple

ZZ’s) and are clearly

identifiable as test

patients (e.g., different

background color for

patient header). IT Test patients in the production system are necessary to facilitate end-to-end testing, but care must be taken to ensure that they are not mistaken for “real” patients. • Test patients should have names that clearly identify them as such: BWH17, ZZZOrders or MGH23zz, ZResults (examples are Last, First). • “Cute” names, e.g., “Marcus Welby” or “Jim Test” should not be used since there are real patients with those names.

Practices dressed Practices/Scenarios

Phase 3 – Leverage IT to Facilitate Oversight and Improvement of Patient Safety

Principle: Safety Surveillance and Optimization (Monitor, detect and report on safety-critical

clinical and administrative aspects of EHRs and healthcare processes and make iterative refine

ments to optimize safety.)

14. The organization

regularly monitors

their patient database

for erroneous patient

identification errors.

,10 Ev, IT Organizations must be prepared to monitor their system for potential patient ID errors and to investigate their causes. • The order – retract – reorder algorithm

can be used to estimate erroneous orders due to patient ID errors. • The “inconsistent gender algorithm” can be used to estimate the number of erroneous freetext notes due to patient ID errors. • Duplicate records are detected and merged. • Industry standards for duplicate error rates are available. The organization consistently monitors its own duplicate error rate, and ensures that it remains at or below industry standards

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10 Chapter 10: ASSESSMENT OF COMPUTER-BASED PROVIDER ORDER ENTRY WITH CLINICAL DECISION SUPPORT

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DECISION SUPPORT

SAFER Guides

Recommended Practices Rationale for Practice or Risk Addressed Examples of Potentially Useful Practices/Scenarios

Phase 1 – Make Health IT Safer

Principle: Data Availability (EHRs and the data contained within them are available to authorized

individuals where and when required to support healthcare delivery and business operations.)

1. Coded allergen and re

action information (or No

Known Allergies [NKA])

are entered and updated in

the EHR prior to any order

entry.39 C, Ev One of the main purposes of CDS is automated drug/allergy checking, which requires coded entry of allergies in the EHR. • Users are reminded to enter patients' allergies or "no known allergies" before entering any medication orders. • A standard, controlled vocabulary of allergens and reactions (e.g., SNOMED-CT) is available and used. • There is a defined hierarchy of authority to edit or remove allergy-related information from a patient's EHR. • The EHR system permits entry of medication intolerances, separate from true allergies. Addressed Practices/Scenarios

2. Evidence-based order

sets are available in the

EHR for common tasks/

conditions and are updated

regularly.38 C, Dx, Ev, Rx Order sets minimize errors of omission through standardization. Requiring clinicians to enter each of the individual orders for routine clinical practices increases risk of overlooking one or more items.

• Order sets for medications, diagnostic tests, and procedures are developed on the basis of Institute For Safe Medical Practices guidelines. [40] • Order sets exist for top the 10 most common clinical conditions (e.g., management of chest pain), procedures (e.g., insulin administration and monitoring), and clinical services (e.g., admission to labor & delivery). [41] • Clinical content is developed or modified based on evidence from authoritative sources, such as those in the ARHQ CDS initiative or by specialists within the organization. • EHR developer-provided clinical content is based on authoritative sources and is updated whenever those sources are updated. • Order sets for medications include complete pre-written medication orders (aka, order sentences) that include dose, dose form when necessary, route of administration, frequency, and a PRN flag and indication, if appropriate. [39] • Pre-written medication orders use doses that are weight- based, when appropriate. • Personalized order sets are not used. If an institution permits them, there is an annual review process, (e.g., clinical quality committee or medical director approval). • Medications requiring complex dosing guidelines e.g., insulin sliding scale, are standardized and available electronically. • CPOE list of orderable items (i.e., medication dictionary or orderable catalog) includes all formulary medications. Addressed Practices/Scenarios • CPOE list of orderable items includes acceptable, non-formulary medications, which are clearly marked, that users can order for out of formulary fulfillment. • Prescribing systems for children use weight-based dosing recommendations, age-appropriate dosing calculators and dose-range checking, and pediatric-specific drug-drug interaction alerts.

3. User entered orderable

items are matched to (or

can be looked up from) a

list of standard terms. 42

C, Dx, Ev, Rx CDS is important to patient safety. CDS can be supported by orders of standardized items, but not on free text orders • Users can look-up all orderable items (e.g., medications, laboratory and radiology tests) and pick terms from lists instead of entering free-text. This should support various word orders (e.g., “abdominal ultrasound” or “ultrasound, abdominal”), various names (e.g., generic or brand, synonym), and should be able to

be browsed alphabetically. [43]

Phase 1 – Make Health IT Safer

Principle: Data Integrity (Data are accurate, consistent and not lost, altered or created inappropriately.)

4. The EHR can facilitate

both cancellation and ac

knowledgement of receipt

of an orders for laboratory,

radiology, and pharma

cy.38 Dx, Ev, Rx, IT Communication errors, especially related to medication orders and diagnostic services, are frequent occurrences. Order tracking can reduce these errors. • The user can look up whether the lab has received the specimen for testing or not • When medication orders are canceled, information is received and acted upon appropriately by the responsible pharmacy. • The 2-way interfaces that facilitate order tracking are tested pre- and post- go-live.

5. CDS alerts are displayed

in the relevant clinical

context.44-49 Ev, C, IT CDS to improve diagnostic or therapeutic decision-making should be accessible in real time at the point of care, otherwise, the advice generated may be useless or under-utilized.50 Risks include information overload and clinician dissatisfaction.3,31,32 • A process is in place to identify and remove alerts that do not make sense in the particular clinical context. In some cases the process may require communication with the EHR developer. Addressed Practices/Scenarios • Ambulatory alerts for cancer screening protocols should not be presented in the inpatient setting. [51,52] • Alerts for diabetic foot screening should not be presented on patients with bi-lateral below the knee amputations.

6. CDS incorporates

current “best practices”

and guidelines from au

thoritative sources, such as

national organizatons and

medical specialty profes

sional associations.53 C,

Ev, IT Out of date or incorrect knowledge provided by the CDS system may be harmful.3,31,32 • For organizations that rely on EHR developer-provided CDS, a process is in place to ensure that CDS is based on authoritative sources and is regularly updated. • The expertise supporting CDS is demonstrated to EHR users before adoption. • Examples of authoritative sources include AHRQ's CDS Initiative and professional associations. • Colon cancer screening reminder follows U.S. Preventive Services Task Force guidelines [54] • Vaccination reminders use the latest recommendations from the Advisory Committee on Immunization Practices [55]

Phase 2 – Safer Application and Use of IT

Principle: Complete/Correct EHR Use (Correct system usage [i.e., features and functions used

as designed, implemented, and tested] is required for mission-critical clinical and administrative

processes throughout the organization.)

7. Clinicians are trained

and tested on CPOE opera

tions before being issued

login credentials. C, Dx,

Ev, IT, Rx • CPOE is a complex tool. In order to maximize its safe and effective use, clinicians must trained rigorously and should not be expected to "learn the basics on the job." • Incentives such as continuing education (CME or CEU) credits are awarded for clinicians getting trained on CPOE. • Clinicians are required to demonstrate basic CPOE skills before getting their login credentials. [56] • Organizations evaluate whether specialized CPOE training should be required in high risk areas. • Training is reinforced periodically especially

with changes/ upgrades. Addressed Practices/Scenarios

8. Clinicians are en

gaged in implementing,

reviewing and updating

CDS related interven

tions.53,57-61 C, Rx, Dx • Failure to include clinicians in decisions that affect their clinical work environment, their decision-making capabilities, or how their decisions are communicated and recorded significantly increases the risk of hazardous events. CDS systems can be optimized through monitoring of use, overrides, and clinical satisfaction. • Clinicians are involved in making the content consistent with updated guidelines and algorithms.There is an internal regulatory process (that involves clinicians) to evaluate and prioritize CDS for priority clinical conditions. [53,60-63] • Clinicians are involved in making (and keeping) the CDS content consistent with updated guidelines and algorithms. There is a process (that involves clinicians) to manage, • evaluate, and prioritize CDS updates. [53,60-63] • Clinician-provided feedback is reviewed and used for refinement and maintenance of CDS and the relevant clinical content. [53,5961,63] • Clinician overrides (i.e., decisions not to follow a computergenerated suggestion) for high-priority CDS elements are logged and available for review and reporting. [64-66] • For EHR developer provided or controlled CDS, a process is in place to communicate about the need for CDS improvements with the developer.

9. EHR is used for

ordering medications,

diagnostic tests, and pro

cedures for which CPOE

is available. [38] (MU) C,

Dx, Ev, IT, Rx • While full use of CPOE with advanced clinical decision support has been shown to reduce errors, [50] partial use of CPOE can introduce errors. • Except in unusual situations providers are required to enter their orders into the CPOE system. • Exceptions (e.g., emergency

orders in resuscitation situations) are clearly defined, and processes are in place (and followed) for their proper documentation in the EHR.

10. There is minimal use

of free-text order-entry.

Orders are entered and

stored in standardized,

coded form. [38,67] C,

Ev, IT Free-text data can introduce errors if it is inconsistent with structured data or is not used or communicated properly. Free-text orders cannot be effectively supported with CDS. • Organizational policy addresses safety precautions to be undertaken when free text ordering is allowed. Addressed Practices/Scenarios • When medications are entered using standardized, coded terms, corresponding narrative text is minimized. Processes are in place to ensure timely use and review of any narrative text. • When medications must be ordered using free text, as constrained by organizational policy, a pharmacist reviews the order to identify and address any drugdrug or drug-allergy interactions.

11. Order entry information

is electronically commu

nicated, such as through

the computer/mobile

messaging, to the people

responsible for carrying

out the order. [68] (MU)

C, Ev, IT To have effective CPOE, orders must be electronically communicated. An automated process minimizes lapses in communication. • Nurses are notified via the EHR when new results or orders are entered into the system for one of their patients (e.g., when they login to the system an alert tells them that new orders are available, or they are sent an informative page or text message). [69] • Orders that are not acknowledged by

the individual responsible for carrying out the orders within 4 hours are automatically sent to a appropriate supervisor. [70] • Workflow is evaluated to ensure that all electronic orders go to the intended recipient and that person documents their actions in the EHR.

12. Interruptive alerts,

such as pop-ups at the

time of ordering, are used

with discretion and only

for high-risk, high-priority

conditions. [44-49,60]

EV, IT Excessive use of interruptive alerts creates clinician dissatisfaction and reduces their effectiveness, causing clinicians to miss important alerts.29 • For low priority conditions, passive alerts that do not force an interruption of the workflow are available. [47] • High risk, high priority conditions that justify interruptive alerts are identified by clinicians and are subject to review. • Interruptive alerts at the pointof-care are used only after considering other available options. [71]
Addressed Practices/Scenarios

13. Drug-allergy interac

tion checking occurs

during the entry of new

medication orders and new

allergies. [50,67] (MU)

C, Ev Interaction checking minimizes the risk of adverse drug events related to allergies. • Checking occurs when an ACE inhibitor is prescribed to ensure that a patient with a history of ACE inhibitor-induced angioedema is protected. • Allergy checking also occurs whenever a new allergy is entered into the system.

14. Duplicate check

ing occurs for high-risk

medication, diagnostic

test, or procedure orders

(excluding as needed

“PRN” medications).

[50,67] C, Ev Duplicate order checking reduces the risk of inadvertent drug overdoses and unnecessary tests and procedures. [50,67] • Therapeutic duplication checking occurs before new high-risk medication orders are submitted (e.g., two orders for the same or different beta-blockers are ordered). • Duplicate checking occurs before high-risk diagnostic tests or procedures are ordered. [72] • Duplicate checking does not include PRN (i.e., As needed) medication orders. • PRN orders should not include “overlapping” criteria (e.g., for pain 1-3 – give aspirin AND for pain 2-4 give vicodin).

15. Drug-condition check

ing occurs for important

interactions between drugs

and selected conditions.

[50] C, Ev Electronic drug-condition checking reduces the risk of preventable adverse drug events related to specific conditions. • Drug-condition interaction checking occurs when new medications are ordered or new conditions are identified (e.g., Accutane or tetracycline prescribed for a pregnant woman).

16. Drug-patient age

checking occurs for impor

tant age-related interac

tions. [13] C, Ev Drug-patient age checking reduces the risk of preventable age-related adverse drug events. • Drug-patient age interaction checking occurs when new medication orders are submitted for dispensing (e.g., medications contraindicated in the elderly). • Changes in frequency, dose, or substitutions are suggested for more age-appropriate strategies.

17. Dose range checking

(such as maximum single

dose or daily dose) occurs

before medication orders

are submitted for dispens

ing. [50,73] C, Ev Dose range checking reduces the risk of medication overdose. • Renal dose adjustment suggestions along with information on the patient's renal status are clearly displayed prospectively for relevant medications. Addressed Practices/Scenarios • Patient context (age, renal function) dynamically changes the defaults prospectively. • Maximum single dose and maximum daily dose are independently checked. • Dose limits are age and body size appropriate.

18. A process is in place to

review interactions so that

only the most significant

interaction-related alerts,

as determined by the

organization, are presented

to clinicians. [46,47] (MU)

C, Ev Tiered alerting by severity (significance) is associated with higher compliance rates of Drug-drug interaction alerts. • Less significant alerts are presented as information only, rather than interruptive alerts. [46] • Alerts are modified in a dynamic fashion based on feedback from the users and monitoring of user behavior.

19. Clinicians are required

to re-enter their password,

or a unique PIN, to "sign"

or authenticate an order.

C, Ev Explicit order authentication reduces the risk of inadvertently entering orders under the wrong identity

when someone else is logged in. It gives users an additional opportunity to confirm that the orders they entered are correct, and prevents them from inadvertently signing orders they did not intend to sign. • An explicit authentication process occurs in addition to their original login for access to the EHR

20. Corollary (or

consequent) orders are

automatically suggested

when appropriate and

are linked together, so

that changes are reflected

when the original order is

rescheduled, renewed, or

discontinued. [74] Ev Automatically suggested linked orders reduce order inconsistencies by managing closely associated orders in tandem. • Examples include: Prothrombin time monitoring when Warfarin is prescribed, or drug level measurement with Vancomycin or aminoglycoside orders. [74] • Corollary orders are deleted whenever the main order is deleted (e.g., if colonoscopy is cancelled, bowel prep is also cancelled).

21. Users can access

clinical reference materi

als, directly from the

EHR, including organi

zation-specific informa

tion when available.

[42,53,59,60,62,75] Ev, IT Ready access to information can reduce the risk of errors. CDS to improve diagnostic or therapeutic decision-making should be accessible in real time at the point of care; otherwise, the advice generated may be useless or underutilized. [50] • Medication monographs (such as Micromedex), dosing

calculators, diagnostic guides, laboratory reference materials, image atlases, anatomical diagrams, patient education materials, and diseasespecific treatment guidelines are directly accessible from the order entry screen or module. [76] Addressed Practices/Scenarios

22. CPOE and CDS

functionality are tested to

ensure proper operation

before go-live and with

test patients in the produc

tion system before clinical

use. C, Ev, IT Appropriate testing reduces the risk of errors associated with inappropriate CDS or CPOE system behavior. • Leap Frog Test is taken to ensure safety of CDS. [77-79] • CDS interventions are evaluated to ensure correct firing of alerts and reminders. [80]

Phase 2 – Safer Application and Use of IT

Principle: System Usability (All EHR features and functions required to manage the treatment,

payment, and operations of the healthcare system are designed, developed, and implemented in

such a way to minimize the potential for errors. In addition, pertinent information should be easily

accessible by authorized users, visible, understandable, prioritized and organized by relevance to

the specific user.)

23. Questions presented

to the user by CPOE and

CDS are unambiguous.

[50,81] Ev, IT Misunderstanding queries posed by the system can lead to risks of errors and adverse events. [82] • There are policies and procedures to evaluate the clarity of questions posed to users. • Questions should be

kept simple and focused. For example, “Is IV contrast contraindicated?” may be confusing. It might be better to ask: Is IV contrast safe to administer? Yes, safe. No, not safe. • Avoid negatively and poorly worded questions such as “Do you want to cancel this alert? Yes, No, Cancel.”

24. CPOE and CDS

implementation and use

are supported by usability

testing based on best prac

tices from human factors

engineering. [83] C, Dx,

Ev, IT, Rx Risks of untested usability include decreased clinician efficiency and clinician dissatisfaction, as well as errors and adverse events due to unintended consequences of CDS use. • Major CDS and CPOE changes/ interventions are tested with representative end users.83 • Clinician-reported hazards associated with CPOE and CDS due to poor usability are regularly communicated to someone in a position to make improvements. Follow-up is monitored

25. Critical patient infor

mation is visible during

the order entry process.

[84] Ev Ensuring that critical data is visible in the EHR minimizes errors related to misidentification or failing to account for common clinical issues • Pertinent clinical information (age, weight, allergies, pregnancy status, creatinine clearance/GFR) as well as identifying patient information is displayed on or behind the ordering screen with no scrolling required to view all the pertinent clinical data. [84] Addressed Practices/Scenarios

26. The clinician is

informed during the

ordering process when ad

ditional steps are needed to

complete the order being

requested. Dx, Ev, Rx Clinicians may not be aware that an order will not be completed without additional steps, leading to delays in performing the order.

27. Use of abbreviations

and acronyms is mini

mized and standardized.

[85-87] C, Ev Acronyms and abbreviations are a source of errors in both paper and electronic records. Minimizing and standardizing use of acronyms and abbreviations reduces the risk of errors related to misunderstanding. • Organizational policies on the use of abbreviations and acronyms incorporate and are consistent with their use in EHRS. • Use of abbreviations and acronyms is consistent with industry best practices. • Abbreviations such as qd or qid are avoided

28. Additional safeguards,

such as double check by

a second specialist, are

implemented in the EHR

before high-risk medica

tions are prescribed. Ev,

Rx Medication errors are the most common type of error that reach patients and cause harm. For high-risk medications, additional safeguards are justified to reduce the likelihood of harm • A clinician- or specialist-driven process is in place to identify high risk medications that justify additional safeguards and to integrate those safeguards into the EHR. • Chemotherapy agents require special authorization and are displayed in a visually distinct way (e.g., different color, italics, etc.). • TALLman lettering is used to reduce CPOE errors from orthographically similar medication names (i.e., look-alike or sound-alike medication names; acetaZOLAMIDE and acetoHEXAMIDE). [88-90]

Phase 3 – Leverage IT to Facilitate Oversight and

Improvement of Patient Safety

Principle: Safety Surveillance and Optimization (Monitor, detect and report on safety-critical

clinical and administrative aspects of EHRs and healthcare processes and make iterative refine

ments to optimize safety.)

29. Key metrics related

to order entry and clinical

decision support (e.g.,

override rates) are defined,

measured, reported and

acted upon. [38,91] C,

Ev, IT Well-designed and correctly used CPOE and CDS can reduce the most common errors that harm patients. Monitoring and oversight of the performanceand clinician use of CPOE and CDS functionality allows optimization of a powerful driver of improved patient safety in an EHRenabled health care system. Key CPOE safety indicators, such as the following, are monitored and reported to leadership on a periodic basis: • Rates of preventable ADEs • CPOE use rate • Frequency (volume) of orders that generate an alert Addressed Practices/Scenarios • Override rate (% of alerts that are overridden) in comparison to alert volume • Median turn-around time for STAT laboratory or radiology results. • Percent of all orders requiring modification by someone other than the ordering provider • Alerts with the highest percentage of overrides are evaluated on at least a quarterly basis for effectiveness and turned off if deemed unacceptable. • Usage of evidence-based order sets is monitored • Clinician satisfaction with CDS alert functionality.

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11 Chapter 11: ASSESSMENT OF DIAGNOSTIC TEST RESULT REPORTING AND FOLLOW-UP

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IMPROVING TEST RESULT FOLLOW-UP THROUGH ELECTRONIC

HEALTH RECORDS REQUIRES MORE THAN JUST AN ALERT

Dean F. Sittig and Hardeep Singh

A recent American Medical Association report highlighted failures in com

munication of abnormal test results as an important but understudied facet

of improving safety in ambulatory care. [1] Because many outpatient test

results are not life-threatening and don’t require verbal communication,

health information technology (IT) has potential to reliably transmit result

information in the fragmented outpatient setting. Thus, few will disagree

Springer and the Journal of General Internal Medicine, 27,10, 2012, pp 1235-1237, Improving Test

Result Follow-up through Electronic Health Records Requires More than Just an Alert, Sittig DF and

and Business Media.

advantages of health IT will be observed. In this issue of JGIM, Callen et al. report the results of a timely sys

tematic review of 19 studies that documented quantitative evidence of test

results not followed up in ambulatory settings. [2] They found wide varia

tion in abnormal results lacking follow-up: 7 % to 62 % for laboratory, and

1 % to 36 % for imaging tests. Although evidence of the effectiveness of

electronic test management systems was limited, there was a general trend

towards improved follow-up in electronic systems. In another article in this issue, El-Kareh et al. discuss the results of a

randomized controlled trial that put electronic communication to the test.

The authors studied the effectiveness of sending microbiology test result

alerts via a secure, internal e-mail system to clinicians when results were

fi nalized post-discharge. [3] They found better documented evidence of

appropriate follow-up within 3 days in the intervention group (28 % vs. 13

% in controls). Neither group’s laboratory follow-up rate

was particularly

encouraging. On the bright side, both studies used distinctly different research ap

proaches to reach similar conclusions, i.e., application of information and

communication technologies, such as electronic health records (EHRs)

with alerting capability, can increase the likelihood of appropriate test re

sult follow-up. In paper-based systems, evaluating evidence of follow-up

is itself challenging. On the other hand, both articles remind us that using

EHR-based technology by itself does not entirely solve the problem of

failure to follow up test results. Callen et al., as well as others, have made

a strong case for addressing these failures based on safety implications.

Additionally, Stage 2 meaningful EHR use (slated for implementation in

2014) includes laboratory test result reporting criteria. Time is now ripe

for novel approaches to understand and improve this complex problem. The use of technology in the complex healthcare system must take

into context the social environment where technology is embedded. For

example, Callen et al. found lack of clear policies and procedures in rela

tion to test result follow-up. We previously identifi ed ambiguity of respon

sibility for test result follow-up to be a key factor in failure to follow up

abnormal results. [4] Several EHRs now use asynchronous alert notifi ca

tions to transmit results, but providers often receive many other types of

viders (PCPs) receive a mean of 57 alerts a day in an integrated delivery

system's EHR, all with new information they need to process and/or act

upon. [5] Important information about abnormal results might get buried

among other alerts. To help understand the complexities involved with electronic commu

nication of test results and facilitate progress in developing multifaceted

solutions, a "sociotechnical" approach is needed. In our work, we use an

eight-dimension sociotechnical model to study both problems and solu

tions related to safe and effective EHR implementation and use. [6] In the

sections below, we illustrate the usefulness of this model by discussing

each of its eight dimensions, as applied to issues raised by the two studies.

We also take the liberty of making several recommendations that might be

useful to reduce failures in test result follow-up in EHR-based systems. 1. Hardware/Software: To maintain superiority over paper, EHRs must be configured to ensure that results are reported to the correct provider in a timely fashion. Thus, all test orders should be placed via a Computer-based Provider Order Entry (CPOE) system. Orders should be transmitted in a coded format to the entity performing the test, and the transmission should occur via a twoway system-to-system interface that can send orders and receive results. Otherwise, results might not make it

back into the EHR in a form that allows clinical decision support interventions (e.g., alert for abnormal creatinine will not fire while entering an order for metformin). 2. Clinical Content: Results should be stored as structured/coded data to facilitate reporting and tracking of results. This feature enabled El-Kareh and colleagues to extract results from the EHR, and can facilitate result-tracking functions. Institutions must also define standardized result categories and definitions (e.g., critical, normal, etc.) to facilitate prioritization and reporting. For instance, certain levels of abnormalities can be flagged in the EHR for more immediate action based on urgency. Care should be taken to avoid flagging borderline or clinically insignificant results as urgent. cal information. EHRs should have result review screens that ensure that all critical information is displayed on one screen (i.e., no scrolling is required) and all columns are sufficiently wide to allow users to see all pertinent information. In addition, users should be able to sort, or filter, results by date, type, patient, or urgency. [7] 4. Personnel: Providers should be trained to process their alerts in a timely manner and document follow-up and communication of results to patients in the EHR. Poor documentation is widely prevalent and might be one reason to explain the low follow-up rates reported in El-Kareh et al.'s study. 5. Workflow/Communication: Institutions must avoid partial use of EHRs for test result management (i.e., results or notes, but not both, available electronically [8]), because this leads to a higher risk of test result follow-up failures. Workflows related to certain high-risk areas (tests ordered by residents, part-time physicians, emergency deparment physicians; send-out tests; and post-discharge results) must be well-defined. This process should include creation of back-up procedures (including use of surrogates) and fail-safe escalation systems to safeguard against results "falling through the cracks". To what extent this was done, if at all, in the El-Kareh study is unclear, and thus a seemingly straightforward technological intervention might not have reached its full potential. Additionally, practices must create robust processes to send both normal and abnormal test results to patients. In the Veterans' Health Administration (VA), providers can generate letters though EHR templates, which are then sent to patients through centralized mailing facilities. Many institutions use web-based portals to make results accessible to patients, and some directly notify patients bypassing provider review. Whether the latter approach reduces follow-up failures is unclear. [9] 6. Internal Organizational Policies, Procedures, Culture and

Environment: Responsibility for test result follow-up is an under-recognized and underemphasized contributory factor in follow-up failures. Responsibility should always be clear, and can be delegated to someone as long as that procedure is clear to both parties. It test result follow-up responsibilities; many that did not answer the survey or follow up appropriately might have attributed this responsibility to someone else (e.g., inpatient physician thought that the PCP was responsible post-discharge). We also recommend that all institutions/clinics should have an annually updated, written policy on all aspects of test result management (e.g., provider notification, patient notification, follow-up responsibilities). [10] This document should define processes and procedures for test result communication, including which results are critical and need verbal communication. Institutions should also maintain updated contact information for all providers and patients. Some of the email alerts sent by the investigators might not have reached the study physicians. 7. External Rules and Regulations: In 2009, the VA released a policy directive requiring communication of all test results to patients within 14 calendar days after the test result is available to the ordering practitioner. To the best of our knowledge, there are no other federal or state policies giving guidance on definitions and measurement of timeliness of test result follow-up. 8. Measurement and Monitoring: The VA is now instituting a measurement system for test results follow-up, and we encourage other institutions to do the same. Logs of test result values, alerts, and provider acknowledgment of alert receipt (results review) could be used for this purpose. However, acknowledgment of a test result receipt does not guarantee that the follow-up action has taken place;4 alternative measurement systems should be in place to monitor test result follow-up.

11.2.1 CONCLUSIONS

Timely follow-up of test results remains a problem even in institutions that

use state-of-the-art EHR systems to alert providers about abnormalities.

We believe that solutions to these problems will require a comprehensive

sociotechnical approach beyond just implementing alerts and other tech

sue of the journal convincingly illustrate this point.

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TEST RESULT ALERTS IN THE ELECTRONIC HEALTH RECORD

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Missed abnormal test results are a significant patient safety problem, es

pecially in the outpatient setting. Failure to communicate and follow up

on abnormal diagnostic test results can lead to diagnostic errors, adverse

events, and liability claims. [1-4] Automated alert notification systems

integrated within electronic health records (EHRs) offer a potential solu

tion. [5,6] For instance, communication of abnormal clinical information

through “alerts” (computerized notifications of significantly abnormal or

critical test results) can potentially facilitate rapid review of patient infor

mation. [7] The Computerized Patient Record System (CPRS), an inte

grated EHR used at all Veterans Affairs (VA) facilities, uses an automated

notification system (the View Alert system) to communicate abnormal

diagnostic test results (Figure 11.3.1). Despite this automated notifica

tion system, we recently found that 7% of abnormal outpatient laboratory

results and 8% of abnormal imaging results lacked follow-up within 30

days. [8, 9] Therefore, electronic alerts do not eliminate the problem of

missed results. We also found that clinicians did not acknowledge 18% of

diagnostic imaging alerts and 10% of diagnostic lab alerts. Some clinicians

received an overwhelming number of alerts (e.g., > 50 per day), some of

which they never reviewed. Many clinicians had inconsistent knowledge

of specific features in the EHR to help manage alerts. Improving critical test result reporting is a national patient safety goal

of the Joint Commission. [10] Additionally, the VA recently released a

directive emphasizing timeliness of test result communication to practitio

ners and patients and further recommended that each VA facility address

Ten Strategies to Improve Management of Abnormal Test Result Alerts in the Electronic Health Re

cord. Singh H, Wilson L, Reis B, Sawhney MK, Espadas D, and Sittig DF. Journal of Patient Safety 6,2

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and qualitative evaluation work, we have identifi ed ten strategies that cli

nicians can use immediately to improve their management of automated

notifi cations related to abnormal test results. We identifi ed these strategies

on the basis of two chart review studies, [9,12] a focus

group study, [13]

and in-depth task analysis sessions [14] that we conducted over the course

of a 2-year project funded by the VA National Center for Patient Safety.

Subsequently, we obtained informal feedback from numerous primary care

physicians who agreed that adoption of these strategies could help them

manage alerts more reliably and effectively. Consistent with our recently

proposed model for safe EHR use, [15] the strategies are divided into three

groups: clinician (user) centered, human-computer interface centered and

communication and workfl ow centered.

11.3.1 CLINICIAN (USER) CENTERED

Clinician centered strategies generally require additional user training.

They include the following.

11.3.1.1 ADJUSTING VOLUME OF NOTIFICATIONS

Clinicians receive several types of notifications, not just abnormal test re

sults. Many clinicians do not realize that certain non-mandatory notifica

tions can be turned on or off. For instance, if they don’t believe particular

types of notifications are useful in their practice, they may decide to turn

them off to reduce information overload and alert fatigue. Similarly, new

users may expect to receive certain types of notifications,

but these may

have been turned off in the EHR by default. Therefore, clinicians must

use the notification menu in the EHR to customize their notifications ac

administrators to identify some alerts as “mandatory” so that they cannot

be turned off.

FIGURE 11.3.1: The View Alert Notification window of the VA’s electronic health record

11.3.1.2 PREVENT LOSING TRACK OF NOTIFICATIONS

Once acknowledged, notifications may not always stay in the clinician’s

inbox. Thus, if the clinician is interrupted while processing an alert, the in

formation may be lost. CPRS offers a “Renew Alert” feature to prevent the

alert from disappearing (if, for instance, the clinician is called out of the

office while processing an alert). Even though this feature currently ex

ists in the software, and clinicians would like to have the ability to “save”

alerts, we found most clinicians had no knowledge of this feature.

11.3.1.3 MAKE THE PROCESSING SOFTWARE (“PROCESS

ALL”) FEATURE WORK

In CPRS, the “Process All” feature allows clinicians to process alerts one

after the other without returning to the View Alert window. This may in

nicians have to process all alerts at once; it may still be

done piecemeal.

11.3.1.4 CREATE A STRATEGY TO PRIORITIZE

Clinicians who are short on time should prioritize alerts based on urgency

level. For instance, we recommend processing high priority and critical (ab

normal imaging and laboratory) alerts first. We also recommend that clini

cians avoid processing alerts altogether when they are particularly rushed.

Setting aside a specific time of day best suited to the clinician’s workflow

may be required to manage the increasing number of alerts being generated.

11.3.2 HUMAN-COMPUTER INTERFACE CENTERED

The human-computer interface centered strategies require optimal use of

the existing display features of the EHR screen. They include the following.

11.3.2.1 SORTING ALERT NOTIFICATIONS

FOR EASIER PROCESSING

in the View Alert window (Figure 11.3.1). They may use the sorting feature

to view higher priority alerts at the top of the list or to process similar kinds

of alerts at the same time. For instance, sorting by location would generate a

view of all inpatient alerts categorized by ward location, followed by all out

patient alerts. This technique can improve the efficiency of alert processing.

11.3.2.2 RESIZE THE NOTIFICATION WINDOW

TO SEE MORE ALERTS

The size of the notification window can be adjusted to see more alerts on

the screen. This may help to decrease the risk of missing an important

size does not force users to use a horizontal scroll bar to see all alert

details. Horizontal scrolling could be a difficult skill for some users

to master.

11.3.2.3 DON’T MISS CRITICAL INFORMATION IN THE EHR

DUE TO SMALL COLUMN SIZE

When viewing information about patient diagnostic tests or labs in the

EHR, clinicians may miss supplemental information due to narrow col

umn width. For instance, in the CPRS imaging reports menu, abnormal

reports are often hidden with only the “A” visible after the report. Resizing

data columns will show the entire word “Abnormal.” As described above

in (6), default column widths should be set wide enough to see all text in

the longest string.

11.3.3 COMMUNICATION AND WORKFLOW CENTERED

Patients are often seen by multiple providers, and test results must con

tinue to be monitored and acted upon when the primary or ordering clini

cian is unavailable. Strategies that focus on communication

and workflow

aspects include:

11.3.3.1 USING THE “SURROGATE CLINICIAN” FEATURE

IN THE EHR

While clinicians are away from their offices, especially
for extended pe

riods, they must identify another clinician to receive
their alert notifica

tions. Before designating surrogates, we recommend that
clinicians mini

mize the volume of alerts that will be transmitted to their
covering partner

by temporarily customizing their notifications (e.g.,
turning off non

urgent alerts).

NOTIFICATION ABOUT A PARTICULAR TEST

A CPRS feature “Alert When Results” allows clinicians to
notify an addi

tional clinician when the results of an order are
available. This is most use

ful when a specific clinician needs to be notified of a
particular test on a

one-time basis, or when residents want to hand off a
potentially important

test to their supervisors or alternates. When clinicians
need to track a par

ticular test order to ensure proper follow-up action
(regardless of result),

this is the most appropriate feature to use. This feature
is of special signifi

cance because the Joint Commission has recently recommended
that or

ganizations distinguish “critical tests” and “critical results.” [16] “Critical

tests” always require rapid communication of the results, even if normal.

11.3.3.3 REMAIN “ALERT” ABOUT RESPONSIBILITY

When multiple clinicians receive notification of the same test, responsibil

ity for follow-up may be ambiguous. For instance, a sub-specialist and a

primary care provider who receive the same alert may both assume that

the other will provide follow-up. While there is a need for other reliable

procedures to assign message responsibility in the EHR, currently it is best

to communicate verbally and clarify responsibility with the other clinician

in cases where no follow-up actions have been documented. Although our strategies have face validity, we recommend them with

the caveat that we have no systematic evidence linking these strategies

to improved outcomes. We plan to conduct such validation studies in the

future. Another potential limitation is that we identifi ed these strategies

through research on the particular EHR used in VA health care facilities.

However, because other EHR systems have similar notifi cation capabili

ties and features, we believe that many of these strategies can be utilized

by providers outside the VA. For example, some of the

interface sugges

tions would be applicable to any EHR that uses basic Microsoft Windows

user interface features (e.g., sorting a column by clicking on the head

ing; resizing a column or a window by moving the pointer to the border

and dragging the column border to the desired width). Other strategies

another. Finally, several strategies describe key features or functions that

have proven useful to healthcare providers. Users should work with their

EHR training and support personnel or EHR vendors to propose additional

desired functions in future versions of their applications. In conclusion, we propose ten strategies to help providers better man

age alert notifi cations related to abnormal test results in the EHR. Once

these strategies have been implemented, health care organizations using

automated EHR-based notifi cation systems could potentially see fewer

communication failures and improvements in test result follow-up.

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SAFER SELF-ASSESSMENT GUIDE: TEST RESULT REPORTING AND

FOLLOW-UP

SAFER Guides

OVERVIEW

Test results reporting practices, which include communication of test re

sults from diagnostic services (e.g. radiology and laboratory) to referring

clinical practitioners, are complex and vulnerable to breakdown. In the

EHR-enabled healthcare environment, we rely upon technology to support

and manage these processes. EHRs can incorporate standardized and auto

mated features to improve the safety and effectiveness of how test results

information is communicated. However, best practices for EHR-based

results reporting are not well defined yet. This self-assessment guide is

intended to increase awareness of practices to improve the safety of EHR

based results reporting and support proactive evaluation of selected high

risk areas. It helps you identify and evaluate where test result reporting

and follow-up breakdowns may occur in your healthcare delivery system.

providers, i.e., when providers are notified electronically

of the results and

are then responsible for reviewing the results and follow-up with patients.

Use of this assessment guide is intended to stimulate implementation of

the recommended practices, as well as sustain those already present. When

assessing EHRs at repeated intervals (e.g., initially, annually, and when

changes are made), the guide can be used to establish a baseline for mea

suring the effect of interventions designed to improve the safety of test

result communication. The guide is applicable to ambulatory physician

practices and other outpatient settings as well as hospitals.

EXPECTATIONS

Healthcare professionals should use this assessment to identify and pri

oritize patient safety issues related to EHR-based test results reporting

and appropriate patient follow-up. Prioritization could consider both the

frequency and severity of a safety event that might result in absence of a

specific practice. We anticipate this to be a useful tool in ongoing safety

and risk management programs, allowing you to address new risks that

arise in EHR-enabled healthcare settings and helping you take advantage

of the safety benefits of EHRs. Please refer to the guide

for additional

information, including the specific risks and rationale addressed by the

recommended practices, and examples of potential strategies to support

the recommended practices.

INSTRUCTIONS

A multidisciplinary team should work together to complete this assess

ment and evaluate patient safety risks addressed by the recommended

practices within the context of your healthcare delivery system. Differ

ent team members will be needed for input depending on what aspect of

test results reporting is being assessed (see Practice Table). Input will be

needed from a number of individuals, which could include IT managers

(e.g., IT service provider, EHR vendor, CIO, or CMIO), risk managers,

clinical stakeholders that are involved in ensuring the safety of diagnostic

service reporting practices and patient follow-up (nurses, laboratorians,

pathologists, radiologists, etc.). The following table can be used as a guide

to facilitate multidisciplinary input and collaboration to achieve practice

implementation:

Legend Key Multidisciplinary Facilitators of Practice Implementation

C Clinicians, support staff, and/or clinical administration (e.g., Medical Records and Risk Managers)

Dx Diagnostic services, such as laboratory or radiology—could be local or remote

Ev EHR vendor

IT IT support staff, could be local or contracted. Responsible for maintaining the EHR and infrastructure

Rx Pharmacy – could be local or remote

TEST RESULTS REPORTING AND FOLLOW-UP

Recommended Practices Rationale for Practice or Risk Addressed Examples of Potentially Useful Practices/Scenarios

Phase 1 – Make Health IT Safer

Principle: Data Availability (EHRs and the data contained within them are available to authorized

individuals where and when required to support healthcare delivery and business operations.)

1.Test names, values, and

interpretations for labo

ratory results are stored

in the EHR as structured

data using standardized

nomenclature. [6,11,13

17] Dx, Ev, IT Structured laboratory results facilitate EHR-based result reporting and tracking functions. [4] Structured data enable use of clinical decision support (CDS) that can avoid errors and optimize patient safety. • Test result IDs (e.g., sodium, potassium) that are sent with LOINC codes are stored as coded data. [18] • Abnormal test result values and interpretations are defined and stored in a standardized, coded format (e.g., high/low sodium; critical potassium; positive/negative fecal occult blood test, etc.). [9] dressed ful Practices/Scenarios • There is a process to handle

paper-based test results that includes, at a minimum, the entry of a coded value into the EHR to indicate whether the result was normal or abnormal along with a scanned copy of the report in the EHR.

2. Predominantly text

based test reports (e.g.,

radiology or pathology

reports) have a coded

(e.g., abnormal/normal at

a minimum) interpreta

tion associated with

them. Dx, Ev, IT Coded results in structured fields facilitate EHR-based result reporting and tracking functions. [4] • Imaging results are coded as abnormal using a structured code if there is a new or unexpected abnormality that requires follow-up. [19,20] • Mammography results are stored according to BIRADS® criteria

Phase 1 – Make Health IT Safer

Principle: Data Integrity (Data are accurate, consistent and not lost, altered or created inappropri

ately.)

3. Functionality for

ordering and reporting

results is tested pre-and

post-go live. C, Dx,

Ev, IT Problems related to system configuration errors leading to results routing logic errors are inevitable. With testing, many such unforeseen problems can be identified and addressed before they result in patient harm. Errors related to closed loop test order entry and results delivery are difficult to detect and can lead to delays in care. • Efforts are made to proactively identify failure points related to EHR-enabled test results delivery. • Specifically designed testing scripts are

used to identify points remediable points of vulnerability [21] in order to build systems that are more fault-tolerant. • Specific testing of routing logic, provider recipients, and configuration is performed to ensure accurate results delivery.

4. After system changes

in components or appli

cations related to CPOE

and diagnostic services,

the data and data pre

sentation are reviewed

to ensure accuracy and

completeness. Dx, Ev, IT System changes can unexpectedly affect the integrity of the data as it moves through organizations in ways that may not be recognized without proactive review. • Organizations identify specific types of EHR system changes that impact CPOE and diagnostic services, such as application upgrades or changes to interfaces, and carefully review data integrity at all points where data is used. dressed ful
Practices/Scenarios • Problems related to tables out of sync are identified with thorough testing • Error queues are used to monitor for proper system performance; results that cannot be automatically delivered are manually delivered. • Order entry and result reporting interfaces are tested after every change to the laboratory/ imaging ordering catalog.

Phase 2 – Safer Application and Use of IT

Principle: Complete/Correct EHR Use (Correct system usage [i.e., features and functions used

as designed, implemented, and tested] is required for mission-critical clinical and administrative

processes throughout the organization.)

5. Orders for diagnostic

tests are placed using

CPOE and electroni cally transmitted to the diagnostic service provider (e.g., laboratory or radiology). [6,22,23]	(MU) Dx, Ev, IT	A hybrid paper and electronic environment for test ordering is hazardous. CPOE can facilitate closed loop communication and results accessibility via the EHR, but only if the results are available in the system. Test results can be lost or missed if on paper, when clinicians have come to rely on the EHR. • For common tests, there is a two-way system-to-system interface (i.e., for ordering, resulting, acknowledging, and cancelling orders) between the clinic/institution and the testing facility. [24] • Diagnostic tests that are not orderable through CPOE for any reason are promptly added to the system.	
6. EHR is able to track the status of all orders and related procedures (e.g., specimen received and collected; test completed, reported, and acknowledged). [4]	Dx, Ev, IT	• Tracking orders facilitates closed loop communication. This enables detection of problems regarding processing and delivery of test results. • EHR can track whether the specimen was received, collected, test completed, results reported, and acknowledged. • Clinical practices where test result information is not yet fully integrated into the EHR use additional tracking strategies to enable follow-up. [25]	
7. The ordering clinician is identifiable on all ordered tests and test			

reports, and, if another

clinician is responsible

for follow-up, that clini

cian is also identified in

the EHR. [8] C, Ev, IT • Clear identification of the ordering clinician facilitates closed loop communication. • Ambiguous responsibility increases the risk of follow-up failure.[4] • Result routing systems supports delivery of results to the ordering provider. [5,9,11] • EHR supports assignment/ transfer of responsibility for test order follow-up. dressed ful Practices/Scenarios

8. When test results are

amended, the change

is clearly visible in the

EHR and printed reports.

[9] Dx, Ev, IT Results that are subsequently changed carry a significant potential for delayed or wrong treatment based on outdated, incorrect results. ▪ Changed results are clearly flagged as such in the EHR (such as marked as “amended”).

9. When test results are

changed or amended, the

ordering clinician and

other clinicians respon

sible for follow-up are

notified electronically.

For clinically significant

changes, the clinicians

are also contacted

directly. [26] C, Dx,

Ev, IT Results that are subsequently changed carry a significant potential for delayed or wrong treatment based on old (incorrect) result/interpretation. The individual changing the results is responsible for notifying appropriate clinicians of those changes. Since electronic systems do not always ensure that a critical communication will be received and reviewed promptly, for clinically important changes to results appropriate clinicians are also contacted directly. • Policies and procedures ensure that changes in test results (and accompanying documentation) are effectively communicated to the appropriate clinicians responsible for patient care, including after the patient has transitioned to another setting of care

10. Send-out (or refer

ence lab) tests are elec

tronically tracked, and

their results are incorpo

rated into the EHR, with

a coded test name, result

value and interpretation.

C, Dx, Ev, IT Send-out tests are vulnerable to loss of follow-up. ▪ The EHR facilitates the tracking of "send-out" tests and provides a mechanism to allow clinicians or organizations to incorporate these results into the EHR and assign them to the correct patient. ▪ Procedures exist to ensure that all test results, including those received from outside the institution through fax or mail, are properly incorporated into the EHR.

11. Written policies

specify unambiguous

responsibility for test

result follow-up with a

shared understanding

among all involved in

providing follow-up

care [4,6,9,13,14,27,28]

C, Dx New workflows resulting from the introduction of EHRs can introduce new hazards related to miscommunication of responsibility for follow-up. Ambiguous responsibility increases the risk of follow-up failure. • In the outpatient setting, ordering provider is responsible for follow-up unless he or she delegates this (e.g., covering provider). Delegation should be documented and accepted by the delegate. dressed ful Practices/Scenarios • Ordering clinicians in any setting assume responsibility for follow-up care, unless that responsibility is unambiguously transferred to another clinician, who accepts responsibility.

12. Workflows that are

particularly vulnerable

to mishandling of test

results, especially critical

ones, are identified, [29]

and back-up procedures

ensure test results are

received by someone re

sponsible for the affected

patient's care. [6,26] C,

Dx, Ev, IT Lost or mishandled test results, especially critical ones, are a significant risk to patients, especially in situations with workflows particularly vulnerable to such failures, such as shift changes or transitions of care. [30] • Situations that are vulnerable to test results follow-up failures are identified. These include handoffs between clinicians (such as between residents, part-time physicians, ER physicians, and hospitalists), and care transitions between clinical settings (such as between different units of a hospital, and between the hospital and home or a post- acute

facility). In these situations, processes should be in place to ensure that test results are communicated to a clinician responsible for follow-up care • Life threatening results are notified through verbal means to ensure positive confirmation of receipt. [9] • Notifications that remain unacknowledged after a prespecified number of days are forwarded (or escalated) to an alternate responsible provider. [31] • Diagnostic services should ensure that test results are communicated to a back-up provider in a timely fashion in the event that the primary provider is not available. The necessary timeliness is dependent on the significance of the test result. [32] • Institution maintains an updated contact list of all providers that practice in it and this list includes their coverage schedules. [8] dressed ful Practices/Scenarios • Institution maintains a patient-provider link (e.g., patient's PCP is identified).

Phase 2 – Safer Application and Use of IT

Principle: System Usability (All EHR features and functions required to manage the treatment,

payment, and operations of the healthcare system are designed, developed, and implemented in

such a way to minimize the potential for errors. In addition all information in the system must be

clearly visible, understandable, and actionable to authorized users.)

13. Results outside

normal reference ranges

(or determined to be

abnormal) are flagged

(presented in a visually

distinct way). [6,9] Dx,

Ev, IT Although absence of flags does not necessarily mean the result is normal, flagging can reduce likelihood of missing abnormal or critical results. ▪ Abnormal results are flagged (e.g., bolded font, asterisk beside values, use of "H" or "L," different colors, etc.) or marked for better visualization in the EHR. ▪ Color is not used as

the only visual indicator of clinical significance. • Critical values are flagged in a distinct way from simply abnormal values

14. Display of results

(e.g., numeric, text,

graphic, image) should

be easily accessible,

clearly visible (and not

easily overlooked), and

understandable. Dx,

Ev, IT Missed or misunderstood test results as the result of a poorly designed human-computer interface are as dangerous to patients as lost or wrong results. Results visualization and display should maximize safety in order to ensure critical information isn't missed. • Displays of test results undergo usability testing for the intended clinical users. • Information is displayed in columns that are sufficiently wide to allow review of all pertinent information (i.e., providers do not need to drag columns on the user interface to detect abnormalities). [1]1 • Multicomponent results are reported in one place (e.g., lupus anticoagulant has 2-3 subcomponents that may be individually positive or negative but should be reported together). • Result details are reported on one screen, eliminating the need for horizontal scrolling. For example, providers should not have to use additional scrolling (e.g., on to the "next page"), [6,11] to access critical information. dressed ful Practices/Scenarios • If the screen is not displaying the full message, there are salient indicators directing the user to the non-displayed remainder of the message (e.g., obvious scroll bars). • Most recent test results should be displayed first (e.g., either at the top of a row-based display or at the left-side on a columnar display) to ensure that clinicians are always aware of current data. [33]

15. Automated non

interruptive results

notifications (also called

“in-basket alerts” or

flags) are limited to

those that are clini

cally relevant in order to

minimize “alert fatigue.”

[4,11,14,27,28,34,35]

Dx, Ev, IT • Information overload from too many alerts is associated with more missed test results. [36] • Results that are poorly displayed increase risk of misinterpretation or being overlooked completely. • A multidisciplinary committee that includes frontline clinician decides which abnormal result alerts the providers are required (i.e., mandated) to receive and which ones clinicians can choose to suppress. • Outpatient clinicians have the option to receive results from their patients in the their electronic inboxes. • Notifications of a patient’s results are batched (aggregated) by type and/or date to minimize the number of notifications. • Institution/clinic monitors providers’ inbox, i.e., the total number of alert notifications sent to providers. • The institution/clinic provides workflow support to help a provider when the number of unread notifications in his or her inbox grows large.

16. Results notifications

remain in the clinician

inbox until a clinician

action occurs to address

them. [4,11,37] C, Ev, IT If notifications drop off, providers can miss results. Notifications remain in the inbox until a clinician signs them. dressed ful Practices/Scenarios

17. There is an EHR

based process for

clinicians to either assign

surrogates [6,8,38] for

reviewing notifications

or to enable surrogates

to look at the principal

clinicians' inboxes. C,

Ev, IT Not using surrogate features and functions appropriately increases risk of loss of test result follow-up. • If providers plan to be away, they assign a covering provider to whom the system can automatically forward test results. • Organizations have policies and procedures that establish expectations for timely review of test results and specifically address planned and unplanned absences

18. There are mecha

nisms to forward results

and results notifications

from one clinician to an

other. [11,27] C, Ev, IT Notifications sometimes are sent to incorrect providers, and in this situation, this functionality allows providers to forward alerts to the correct person. • In addition to automatic forwarding, such as when a clinician is on vacation, forwarding can be done under clinician control (e.g., when the notification is transmitted to the incorrect clinician). • Mechanisms are in place for tracking acknowledgment and acceptance of forwarded notifications

19. Summarization tools

to trend and graph labo

ratory data are available

in the EHR. Ev, IT Displaying certain laboratory test results over time helps identify clinically relevant anomalies or trends. Summarization tools in the EHR improve visualization, interpretation, and accessibility of results. ▪ The EHR incorporates automated tools and reports that enable selected lab results to be easily graphed and displayed over time to view trends.

20. Test results can be

sorted in the clinician’s

EHR inbox according

to clinically relevant

criteria (e.g., date/

time, severity, hospital

location, or patient).

[6,11,26,28] Ev, IT Clinicians need ways to prioritize results review so they can address the most pressing issues first and cope with information overload.39 Sorting also improves visualization and accessibility of results. Results can be sorted according to important parameters such as date, type, urgency, patient, and location.

21. The EHR has the

capability for the clini

cian to set reminders for

future tasks to facilitate

test result follow-up.

[28,40] Ev, IT The EHR can help clinicians’ follow-up with patients regarding test results. Unless they set reminders for themselves, clinicians may forget about follow-up tasks they need to do. Functionality to record a follow-up action due at a future date exists in the EHR.
dressed ful Practices/Scenarios

Phase 3 – Leverage IT to Facilitate Oversight and Improvement of Patient Safety

Principle: Safety Surveillance and Optimization (Monitor, detect and report on safety-critical

clinical and administrative aspects of EHRs and healthcare processes and make iterative refine

ments to optimize safety.)

22. As part of qual

ity assurance activities,

organizations monitor

selected practices related

to test result reporting

and follow-up. Moni

tored practices include

clinician use of the EHR

for test results review

and clinician follow-up

on abnormal test results.

[4-6,13,26,41-44] C,

Ev, IT Effective quality assurance patient safety programs include monitoring of core clinical metrics. Errors related to missed or delayed follow-up of test results are a significant cause of adverse events that harm patients. • The organization has in place processes to monitor and report alert responses (e.g., acknowledged or not; time to acknowledgement)8 and test result follow-up with patients. [5] • Clinicians document communication of test results to patients in their EHR. [45] • Organizational QA activities select and measure test resultsrelated benchmarks for ongoing monitoring, starting in areas of identified concern and high risk. A measurement system for test results reporting exists with the following potential measures: 1. Percentage of all active clinicians who have reviewed at least one laboratory test result within the last month. If greater than 95%, this measure could indicate if the EHR is the “source of truth” for laboratory test results (vs. dependence on paper-based communication). 2. Test results with the lowest follow-up rate are investigated to understand root causes of the problem. [6,43] 3. Percentage of all test results reviewed by the ordering provider within 4 days. This should be greater than 90%. 4. Results not reviewed for more than a week. This should be minimal. dressed ful Practices/Scenarios

23. There is a process to monitor results related to certain high-risk areas: patients undergoing transitions (e.g., pending test results of discharged patients) or providers undergoing transitions (e.g., tests ordered by residents that routinely rotate to new services, clinics, or locations). [6,26,29,44] C, Dx, Ev, IT Test results are missed in EHR systems despite advanced systems for notification. Test results with the lowest follow-up rate are investigated to understand root causes of the problem. [6,43]

24. As part of quality assurance, the organi zation monitors and addresses test results sent to the wrong clinician or never transmitted to any clinician (e.g., due to an interface problem or patient/provider

misidentification). [21]

C, Dx, Ev, IT When test results are “lost in the system,” there is a danger that there will be no follow-up, posing a significant risk of patient harm. • Error logs are used to detect results such as those that were never delivered, results without any ordering providers, results with unidentifiable providers, etc. • National Provider ID (NPI) is used for provider attribution of orders. • Monitor provider master files to ensure that they are synchronized to avoid scenarios in which the ordering provider’s contact information is outdated or unknown.

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12 Chapter 12: ASSESSMENT OF CLINICIAN-TOCLINICIAN E-COMMUNICATION

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SAFER Guides

OVERVIEW

Processes relating to clinician communication are complex and vulnerable

to breakdown. In the EHR-enabled healthcare environment, we rely upon

technology to support and manage these complex communication process

es. If implemented and used correctly, EHRs have potential to improve

the safety and effectiveness of how information is communicated between

clinicians. This self-assessment guide is intended to increase awareness

of practices to improve the safety of EHR-based communication and sup

port the proactive evaluation of select risk areas. It helps you identify and

evaluate where communication breakdowns may occur in your healthcare

delivery system and focuses on processes relating to electronic commu

nication between clinicians. While the guide is broadly applicable, it is

focused on three high-risk processes: consultations or referrals, discharge

related communication messages and patient-related messaging between

clinicians. Thoughtful use of this assessment guide by EHR users is in

tended to stimulate implementation of the recommended practices, as well

as sustain those that are already present. When assessing EHRs at repeated

intervals, (such as initially, annually and when changes are made), the

guide can be used to establish a baseline for measuring the effect of inter

ventions designed to improve the safety of clinician communication. The

guide works for ambulatory physician practices and other outpatient set

tings as well as for hospitals.

EXPECTATIONS

Healthcare professionals should use this assessment to aid in identifying

and prioritizing patient safety issues related to EHR-enabled clinician

communication. For example, you could consider both the frequency and

anticipate this to be a useful tool in ongoing safety and risk management

programs, allowing you to address new risks that arise in EHR-enabled

healthcare settings and helping you take advantage of the safety benefits

of EHR-enabled healthcare settings. Please refer to the guide for addi

tional information, including the specific risks and rationales addressed by

the recommended practices and example strategies implemented in other

clinical settings to support the recommended practices.

Legend Key Facilitators of Practice Implementation

C Clinicians, support staff, and/or clinical administration (e.g., Medical Records and Risk Managers)

Dx Diagnostic services, such as laboratory or radiology—could be local or remote

Ev EHR vendor

IT IT support staff, could be local or contracted. Responsible for maintaining the EHR and infrastructure

Rx Pharmacy – could be local or remote

CLINICIAN COMMUNICATION

Communication is a key aspect of nearly all processes of patient care and

has an enormous potential to impact patient safety. [1-6] Communication

breakdowns between clinicians are one of the most common

causes of

medical errors and patient harm. Several attributes of electronic health re

cord-based communication can result in a disconnect between the sender

and the receiver of clinical information, including: • It is generally asynchronous, and often the sender cannot be sure when or if the message has been received. • It is structured mostly around a single patient record, whereas work and relationships happen across patients. Communication processes have increasingly become integrated into

the electronic health record. [7,8] These include sending and receiving

referral and consult communication, transitioning the patient from the in

patient to outpatient setting (peri-discharge period), and communicating

communication in these processes can fail: • Failure to include all the necessary information within the message • Failure of the information to reach the correct person at the correct time (e.g., to an alternate clinician when primary clinician is unavailable) • Failure to support situational awareness by overloading the user by presenting too much unstructured or irrelevant information (e.g., too many messages or alerts) [5,9] Throughout this guide, the term “electronic communication” will pri

marily refer to electronic communication related to three broad activities:

(1) Referral and consultation-related communication (2) Clinician-to-cli

nician messages, and (3) Communication during the peri-discharge pe

riod; although many of the recommended practices apply to other forms of

electronic communication.

Recommended

Practices Rationale for Practice or Risk Addressed
Examples of Potentially Useful Practices/Scenarios

Phase 1 – Make Health IT Safer

Principle: Data Availability (EHRs and the data contained within them are available to authorized

individuals where and when required to support healthcare delivery and business operations.)

1. Urgent clinical

information is

delivered to clini

cians in a timely

manner, and de

livery is recorded

in the EHR. C,

Ev, IT • If active efforts are not taken to inform clinicians of the presence of critical information, this information may be missed by clinicians resulting in delays in care. [11,12] • If primary care physicians (PCPs) do not receive a timely discharge summary, they may incorrectly restart or change medications for which contraindications have been identified during hospitalization. • The organization has a policy for verbal delivery of critical information that supplements use of the EHR. • Hospitals have policies and procedures to address timely electronic delivery of important clinical information. For example, hospital discharge summaries are delivered to clinicians responsible for followup within two business days. • Messages are automatically forwarded to an alternate clinician if not responded to within certain time period appropriate to the timeurgency of the message. • The EHR allows automatic forwarding of messages to a surrogate clinician during a specific time period or circumstance, such as when the clinician is absent.

Practices dressed Practices/Scenarios • Messages are delivered to a “pool” that several clinicians are held accountable for and the responsibility of which clinician has to follow-up and when is clear. • When a patient

transitions to another setting, a clinician provides a summary of care record to the receiving hospital or clinician in a timely manner. The summary record should include at a minimum, the Common Meaningful Use Data Set. [13]

2. Policies and

training facilitate

appropriate use

of messaging

systems and limit

unnecessary mes

saging. C Information overload is a significant problem in EHR systems. When a large amount of information that is not clinically relevant is transmitted through the same channels as information with high urgency, the latter may be missed leading to potential patient harm. [5,9] • The organization has a policy on secure messaging that specifies what should and should not be transmitted, and users are trained on it • Messages are sent only to persons who may need to act upon them. 'Reply to all' is used only when necessary. • Mechanisms are in place to allow communication of non-clinical information (e.g., appointment request) in a way that does not impact communication of clinical information (e.g., abnormal laboratory results).

3. The EHR in

cludes the capabil

ity for clinicians

to look up the

status of their

electronic com

munications (e.g.,

delivered, opened,

acknowledged).1

Ev, IT Delays in care may result from referrals, consults, and clinician-toclinician messages that do not receive timely action. [1,14,15] • A real-time tracking system allows referring clinicians to determine the status of all their referrals and consults transmitted and allows specialists to identify all referrals and consults that are pending. • Clinicians and specialists are able to print a report of all their referrals and consults with the respective status of each. • Clinicians are able to identify whether their messages have been opened (read receipt). • The EHR automatically notifies the ordering clinician or team when referrals or consults are canceled or completed.

Practices dressed Practices/Scenarios • Clinicians are notified if a message they sent has not been opened within a pre-specified number of days. • The EHR can track whether a message was received or not. • Outpatient practices where messaging systems are not yet fully integrated into the EHR use additional tracking strategies to enable follow-up.

Phase 1 – Make Health IT Safer

Principle: Data Integrity (Data are accurate, consistent and not lost, altered or created inappropri

ately.)

4. Messages

clearly display the

individual who

initiated the mes

sage and the time

and date it was

sent. Ev In order to make informed and appropriate decisions, clinicians need to know the source and timing of a message. • The EHR message interface prominently shows the date, time, and sender

Phase 2 – Safer Application and Use of IT

Principle: Complete/Correct EHR Use (Correct system usage

[i.e., features and functions used

as designed, implemented, and tested] is required for mission-critical clinical and administrative

processes throughout the organization.)

5. The EHR fa

cilitates provision

of all necessary

information for re

ferral and consult

request orders

prior to transmis

sion. [1,16] C,

Ev, IT • Referral and consult processing and routing may be delayed if information provided with the request is inadequate, resulting in care delays. • Referral and consultation request without certain fields filled, such as “Specialty” or “reason for referral” might be delayed • Templates are used to facilitate completion of electronic referrals and consults to meet the specialist’s requirements. • Clinicians are prompted when certain key fields, such as the “reason for referral” or “specialty” field, are left blank. • Referral requests should include, at a minimum, the Common MU Data Set. [13]

6. The EHR

facilitates ac

curate routing of

clinician-to-clini

cian messages and

enables forward

ing of messages

to other clinicians.

Ev, IT Delays in patient care may results when important information is inadvertently transmitted to an incorrect recipient and cannot be redirected to the correct one. • In the EHR, “To:” and “From:” fields are visible on message inbox and at the top of message content. • The EHR supports forwarding of incorrectly routed messages to other clinicians.

Practices dressed Practices/Scenarios • Clinicians can forward messages they received incorrectly to the correct recipients • Additional mechanisms exist for tracking acknowledgment and acceptance of forwarded notifications

7. Clinicians are

able to electroni

cally access up to

date patient and

clinician contact

information (e.g.,

email address,

telephone and fax

numbers, etc.) and

identify clinicians

currently involved

in a patient’s care.

[17] C, Ev Patient care delays result from time spent searching for correct clinician contact information, a patient’s treating clinician, or provider’s care team members. Care delays may also result from incorrect message routing based on inaccurate contact information. • The EHR system is updated at least monthly with a contact list of all practicing clinicians, and, for hospitals, includes clinician coverage schedules • The EHR automatically addresses internal messages between clinicians, so that email address or fax numbers need not be typed

8. Electronic

message systems

include the capa

bility to indicate

the urgency of

messages. Ev Communicating the urgency of a message, such as a referral or consult, is necessary to facilitate triaging, and to ensure timely follow-up • The EHR has functionality to allow clinicians to flag referrals or consults as urgent when needed. • Specialists are given immediate access to all referral and consult requests, and can triage patients and schedule appointments based on urgency. • Messages that are administrative in nature are clearly differentiated from clinical alerts.

9. The EHR

contains a copy of

clinician-to-clini

cian communica

tions. Ev • Clinicians may miss important information related to a particular patient because it is “hidden” in secondary data repositories or in paper-based record storage. • Delays in care may result when specialist recommendations (such as to order further testing) are not received by the ordering clinician. • Written clinician-to-clinician communication is documented into or scanned into the EHR. • The EHR includes a secure messaging module with external access (i.e., to facilitate electronic communication with patients or providers not using the EHR) that does not require separate, external software. • If clinical messaging systems external to the EHR are used, a copy of every message is stored in the EHR.

Practices dressed Practices/Scenarios

Phase 2 – Safer Application and Use of IT

Principle: System Usability (All EHR features and functions required to manage the treatment,

payment, and operations of the healthcare system are designed, developed, and implemented in

such a way to minimize the potential for errors. In addition all information in the system must be

clearly visible, understandable, and actionable to authorized users.)

10. The EHR

displays time

sensitive and

time-critical

information more

prominently than

less urgent infor

mation. Ev • Clinicians may miss urgent information when commingled with other less urgent messages, resulting in delayed care. • A clinician may miss a small section of relevant and important information within several pages of a referral or consults note sent to him or her. • Messages with critical or urgent information are made visually distinct (e.g., visually highlighted). • The EHR allows sorting of clinician-to-clinician messages by urgency. • When sending notes/documentation to other clinicians (such as for co-signing), the EHR allows the sender to add recipient-specific explanatory messages, highlighting, or markups.

11. Both EHR

design and orga

nizational policy

facilitate clear

identification of

clinicians who are

responsible for

action or follow

up in response

to a message. [1]

C, Ev On messages addressed to multiple recipients, each recipient may incorrectly assume that the other recipient(s) will take follow-up action, leading to no action being taken at all. • Message screens display a “responsible clinician” indicator. • The system supports forwarding and accepting responsibility for follow-up. • The EHR is able to display when responsibility for follow-up action is accepted by a clinician. • A comprehensive policy exists outlining responsibility for follow up action for certain situations (e.g., no-shows).

Phase 3 – Leverage IT to Facilitate Oversight and Improvement of Patient Safety

Principle: Safety Surveillance and Optimization (Monitor, detect and report on safety-critical

clinical and administrative aspects of EHRs and healthcare processes and make iterative refine

ments to optimize safety.)

12. Mechanisms

exist to monitor

the timeliness of

acknowledgment

and response to

messages. [1,18]

C, Ev, IT System problems related to delayed acknowledgment of clinician-toclinician messages may go unnoticed if monitoring systems are not in place and checked regularly. • Referring clinicians, specialists, and/or leadership receive an alert when no action is taken on a referral or consult request or a clinician-to-clinician message within 14 days. • Referrals and consult response times are tracked by organization leadership.

Practices dressed Practices/Scenarios • Messaging is periodically monitored to understand and improve quality of communication. • Policies and procedures are in place to prevent messages “lost” in the system, such as messages sent to clinicians no longer employed by the organization

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SAFER SELF-ASSESSMENT GUIDE: ORGANIZATIONAL ACTIVITIES

AND RESPONSIBILITIES FOR ELECTRONIC HEALTH RECORD

(EHR) SAFETY

SAFER Guides

Legend Sources of Input

C Clinicians, support staff, and/or clinical administration (e.g., medical records and risk managers)

Dx Diagnostic services, such as laboratory or radiology—could be local or remote

Ev EHR vendor and/or other IT or HIT vendors

IT IT support staff, could be local or contracted. Responsible for maintaining the infrastructure

Rx Pharmacy – could be local or remote

L Leadership Team – (e.g. Board of Directors, executive team, clinical leadership, operational leadership)

M Multi-professional Team – (e.g. clinicians, IT, patient safety/quality, informatics)

HI Health Informatics Team (e.g. content specialists, clinical analysts, nursing/medical informatics, informatics consultants)

ORGANIZATIONAL ACTIVITIES AND EHR SAFETY

Recommended Practices

and Responsibilities* Rationale for Practice or Risk Addressed Examples of Potentially Useful Practices/Scenarios

Principle 1: Defined decision making activities assure EHR safety.

and Responsibilities* Addressed Practices/Scenarios

1.The highest-level deci

sion makers (e.g., boards

of directors or owners of

physician practices) are

committed to promoting

a culture of safety that

incorporates the safety

and safe use of EHRs. • Leadership can provide motivation for all staff to pay attention to EHR safety. • Those in authority can provide resources for ensuring EHR safety. • Without leadership involvement, EHR safety efforts will likely fail. • Highest-level decision makers recognize that EHR safety is integral to patient safety. They ensure that EHR safety is integrated into organizational policies and procedures and risk management practices. • Highest-level decision makers ensure that adequate staffing and resources exist so that safety issues associated with adoption and use of EHRs can be addressed. • Highest-level decision makers review the results of assessments of EHR safety, such as those from SAFER Guide use. • Highest-level decision makers identify EHR-related patient safety goals, assess whether those goals are being reached, and address any shortcomings.

2.An effective decision

making structure

exists for managing and

optimizing the safety and

safe use of the EHR.

Responsibility Large

organization: Board

Responsibility Small

organization: Owners

Input Source: L,M • Clarifies responsibility • Maximizes involvement of disciplines • Ensures that important EHR safety issues are addressed • For larger organizations, all of the following are represented in decision making about EHR safety: clinicians, administrators, patients, Health IT/informatics, board of directors and CEOs, and quality and legal staff. • For smaller ambulatory practices and small hospitals, both clinical and administrative staff members are represented in decision making about EHR safety, with assistance from outside experts. • An EHR safety officer or someone assigned that responsibility part time in a small organization plays a key role in assuring safety. • EHR safety is appropriately included in job performance appraisals. • For a larger organization, an EHR safety oversight committee is in place [1, 2[or these functions are assumed by an EHR or Safety and Quality oversight committee.

and Responsibilities* Addressed Practices/Scenarios

3. Staff members are

assigned responsibility

for the management of

clinical decision support

(CDS) content.

Responsibility (L): Infor

matics type department

Responsibility (S):

Providers

Input Source: HI, C, M,

EV, Rx • Facilitates decision making about clinical decision support and other content • Provides accountability for decisions • Avoids hazardous wrong or outdated content in EHR • A decision-making structure exists for making decisions about clinical content.3-6 • Responsibility for management of content, from selection to maintenance, is clear. • Committees or other collaboration mechanisms are in place to approve order sets and documentation templates. • There is clear responsibility for the review of a new decision support that becomes available from developers and other sources (e.g., professional organizations). • Developers provide clear documentation of decision support content and the evidence-base to support that content. • Developers routinely review and update decision support content they provide. • Personnel are available either internally or externally to ensure that decision support is tailored to the workflows of professional roles and specialties.7-1

4. Practicing clinicians

are involved in all levels

of EHR safety-related

decision making that

impact clinical use.

Responsibility (L):

Administration

Responsibility (S):

Providers

Input Source: C, M • Facilitates wise decision making about clinically relevant issues • Assures focus on patient care • Increases acceptance of decisions • Clinicians, including physicians, nurses, pharmacists, and others, are included on the EHR safety oversight committee of a large organization. • Clinicians are involved in decision making about all proposed changes to the EHR.

and Responsibilities* Addressed Practices/Scenarios

5. Clear clinician

oversight is maintained

when clinicians delegate

aspects of order entry,

medication reconcilia

tion, or documentation

tasks.

Responsibility (L): Hos

pital departments

Responsibility (S):

providers

Input Source: C, M • Assures that the safety risks of assigning these tasks to medical assistants or scribes are carefully weighed • Assures that responsible providers take the time to review delegated work • For teaching hospitals and clinics, attending physicians are diligent about reviewing the work of trainees. (Koshy; Santell) • In community non-teaching settings, responsible providers oversee and are diligent about reviewing the delegated work.

Principle 2: Activities to maximize EHR quality and data quality assure EHR safety

6. Staff members are

assigned to regularly

monitor EHR hardware,

software, and network/

Internet service provider

(ISP) performance and

safety.

Responsibility (L):

Safety officer, infor

matics-type department,

IT Responsibility (S):

Office management,

IT staff or contractor,

providers

Input Source: L, HI, C,

M, IT • Problems can be caught before harm is done • Providers and others can learn from their mistakes • The impact of changes to the EHR or CDS is transparent • A plan outlining responsibility for EHR safety monitoring is in place. (Singh; Sittig and Classen; Strom) • Errors involving system-to-system interfaces are routinely monitored. • Providers and others including leadership in large organizations are encouraged to use tools to monitor EHR safety and care quality. • A plan exists for learning from incidents to improve EHR safety. • The review and communication of lab results are monitored. • The test results reporting loop is closed. • Selected post-implementation care outcomes are monitored. • Alert and reminder responses are monitored. • Alert and reminder specificity and sensitivity are appropriately adjusted.

and Responsibilities* Addressed Practices/Scenarios

7. Staff members are

assigned to regularly test

for and promptly correct

problems with EHR

hardware, software, and

network/ISP performance

and safety.

Responsibility (L):

Safety officer, infor

matics-type department,

IT Responsibility (S):

Office management, IT

staff/contractor, provid

ers

Input Source: L, HI, C,

IT, Ev • Customization of either the EHR or content must be skillfully done or upgrades to the EHR can produce unique hazards • Inadequate or unprepared staff members can cause problems to go unaddressed • The organization has adequate numbers of trained staff members available either on site or elsewhere to modify software. • Adequate technical staff members are available to fix hardware problems during operating hours. • Staff members are available to catch and correct errors such as registration, order entry, or test results communication errors in a timely manner. • When errors occur, a multidisciplinary review and discussion takes place. • The organization has a rigorous process in place for testing new software. (Walker) • The organization has a rigorous process in place for testing new hardware. • Workflow analysis to map the way work is actually done is conducted prior to any system upgrade. • Risk assessments are conducted prior to go live. • The potential impact of any EHR upgrade is carefully assessed.

8. Staff members are as

signed responsibility for

selecting, testing, moni

toring, and maintaining

CDS for performance

and safety.

Responsibility (L):

Safety officer, informat

ics-type department,

IT Responsibility (S):

Office management, IT

staff/contractor, providers

Input Source: L, HI, C,

IT, Ev • Untested CDS can lead to patient care errors • Lessons from testing can prevent implementation of error prone CDS • The organization has a rigorous process in place for testing new CDS. (Walker) • Risk assessments are conducted prior to go live with new CDS. • Clinical content is developed or modified by a multidisciplinary group including clinical specialists when appropriate.

and Responsibilities* Addressed Practices/Scenarios

Principle 3: Activities to assure safe use of the EHR can prevent EHR safety hazards

9. EHR training and sup

port are sufficient for the

needs of EHR users and

readily available.

Responsibility (L):

Informatics-type depart

ment, IT, vendor

Responsibility (S): Of

fice management, vendor

Input Source: L, HI, C,

IT, Ev • If the EHR is not used or is poorly used, patient harm can result • Training and support staff must be well trained to maximize effectiveness • All users are trained prior to their using the system, supported while they are first using the system, and trained again before each change to the system. (Singh) • Different modalities for training are offered to accommodate user schedules and learning styles. • EHR safety is covered in EHR training. • Users are trained on how to proceed during system unavailability (downtimes). • Providers must demonstrate

competency via testing in using the system before using order entry. • In larger organizations, IT and informatics staff take vendor training and are certified as appropriate. • A process is in place so users can get help immediately whenever and wherever they need it. (Ash b)

10. EHR training and

support are of high qual

ity provided by qualified

trainers, and appropri

ately tailored to specific

types of users' needs.

Responsibility (L):

Informatics-type organi

zation, IT, vendor

Responsibility (S): Of

fice management, vendor

Input Source: L, HI, C,

IT, Ev • Suboptimal training and support lead to wasted time for users • Lack of diligence can cause EHR safety hazards • Whether done by dedicated internal trainers or those hired from outside, pre-implementation training prepares users for go-live. • Training and support are provided by individuals who can fill the gap between the clinical and IT languages and understand clinical workflow. (Ash a) • Support is available on site at least during the first week after go-live of the EHR. • A protocol exists so that all users know where to go for technical, software, and connectivity support. • Initial training includes running through scenarios that mirror the tasks users will need to accomplish. • Training stresses that users must be diligent about entering accurate data. (Singh; Thompson; Hogan; Chuo; Magrabi)

and Responsibilities* Addressed Practices/Scenarios • User skills are monitored and upgraded when needed.

11.EHR training and

support are assessed

regularly to optimize

complete and safe use of

the EHR.

Responsibility (L):

Informatics-type organi

zation, IT, vendor

Responsibility (S): Of

fice management, vendor

Input Source: L, HI, C,

IT, Ev • Since training and support are ongoing and expensive, feedback for continuous improvement is important • A training plan outlines regular ongoing training opportunities so that users can optimize their use of the EHR. • Training and support must be tailored to the needs of EHR users. • A plan exists for ongoing assessment of training and support. • Feedback about training and support is responded to effectively.

12. Workflow analysis to

map how work is actu

ally done is conducted

regularly. Responsibility

(L): Informatics-type

department

Responsibility (S): Of

fice management and

vendor or consultant

Input Source: L, HI,

Ev, M • Inattention to how the EHR fits workflow can result in wasted time and money. • Workarounds that result from workflow-related problems can lead to errors that affect patients. • Workflow analysis is conducted prior to implementation of the EHR. (Campbell) • Workflow analysis is conducted prior to any major change to the EHR system. • An effective change management approach guides needed workflow changes based on the workflow analysis.

13. Clinical staff is as

signed responsibility for

ensuring that CDS con

tent, such as alerts and

protocols, supports effec

tive clinical workflow in

all practice settings.

Responsibility (L):

Informatics-type depart

ment

Responsibility (S):

Providers

Input Source: C, HI,

M, Rx • Without customization, generic CDS that is not useful to the recipient's role or specialty may create hazards. • A process exists for the review and modification of any locally-developed, commercial, or freely available CDS so that it is appropriate for a particular setting. (Bates) • A clinical rules committee has a defined process for evaluating and overseeing the testing and monitoring of the CDS. • The unique needs of the pediatric population are taken into account when reviewing and modifying CDS. (Walsh)

and Responsibilities* Addressed Practices/Scenarios

14. Organizational policy

facilitates reporting of

EHR-related hazards and

errors and ensures that

reports are promptly in

vestigated and addressed.

Responsibility (L):

Safety officer and all

those involved in safety

initiatives, informatics

type department

Responsibility (S):

Office management,

providers

Input Source: L, HI, C • A culture of safety relies upon reporting and follow up. If hazards exist but remain unreported they could cause harm. • The mechanism for reporting EHR-related safety hazards internally is clear to all users. • Those who manage EHR and patient safety initiatives for the organization have a clear protocol for addressing reported problems and for reporting problems externally to the vendor and/or a patient safety organization when appropriate. (Walker; Chuo)

15. Records of reported

and addressed EHR-re

lated hazards and errors

are maintained.

Responsibility (L):

Safety officer, informat

ics-type department

Responsibility (S):

Office management,

providers

Input Source: L, HI, C • If records of these hazards are not maintained, the same problems might arise at a future time without access to prior solutions and mitigation strategies. • There could be some liability risk if the history is undocumented • If users cannot learn the disposition of their reports, they may not bother submitting future reports • Larger organizations often use help desk software to keep track of internal reports and disposition. The user who reported the issue is notified of the outcome when appropriate. • Smaller organizations develop databases of reports and assign responsibility for maintenance of the database, usually to the health IT person.

Principle 4: Activities to assure the availability of information in the EHR can prevent EHR safety

hazards

16. Staff members are as

signed responsibility for

the maintenance of the

EHR-related hardware,

software, CDS, and net

work/ISP performance.

Responsibility (L): IT HI

(for CDS)

Responsibility (S): IT

contractoror internal IT

oriented person

Input Source: IT • Without maintenance, components of the EHR may impede use • Inadequate maintenance could cause

the EHR to be unavailable, creating safety risks • Regular maintenance of hardware, software, network/ISP/CDS is organized and funded.

and Responsibilities* Addressed Practices/Scenarios

17. Staff members

regularly monitor main

tenance of the EHR-re

lated hardware, software,

CDS, and network/ISP

performance and safety.

Responsibility (L): IT,

informatics-type depart

ment

Responsibility (S): Of

fice management

Input Source: L, C, IT,

HI • Inadequate maintenance may result in unplanned downtime • Inadequate maintenance may cause the EHR to be unavailable, causing safety risks • When maintenance for these components is provided from outside the organization, oversight is provided by an internal staff member to assure the competence and performance of the contractors. • When maintenance is provided internally, regular schedules exist for it. • Assessments are conducted on a regular basis to assure adequate maintenance.

18. Organizational

procedures ensure that

EHR users are able to get

timely help when there

are EHR-related hard

ware, software, CDS, or

network/ISP problems .

Responsibility (L): IT,

informatics-type depart

ment

Responsibility (S): Of

fice management

Input Source: L, C, IT,

HI • Without knowing where to go for help, users will develop workarounds, which can be dangerous • Time can be wasted when users and staff members have difficulty finding help • In small practices, guidelines exist for figuring out whom to seek help outside the organization. • In larger organizations, guidelines exist for users to know how to get help, and for Health IT staff members to know when and how to get outside assistance.

Principle 5: Activities to help the organization learn from EHR safety efforts can prevent EHR

safety hazards

19. Communication

mechanisms ensure that

EHR users learn of EHR

changes promptly, and

users are able to give

feedback on related

safety concerns.

Responsibility (L):

Vendor, Informatics-type

department, IT

Responsibility (S): Of

fice management (S)

Input Source: L, C, IT,

HI, Ev • If observed errors are not Reported, they will generallynot be fixed • If the developer does not receive feedback, he or she will generally not address the issues. • Patient harm can result if hazards are not addressed • Responsibility is clear for reporting EHR safety errors and getting feedback. • Someone is responsible for being the liaison to the vendor for reporting problems and getting feedback. • Communication channels are in place for including health information management staff in patient registration error correction and feedback. • Software errors or desired changes for safety reasons are routinely reported to the vendor.

and Responsibilities* Addressed Practices/Scenarios • Reports about EHR safety reach the highest level in the organization on a routine basis and feedback is given. • Users know who the go-to person is for reporting EHR safety problems.

20. Staff members with

job responsibilities for

EHR safety are encour

aged to participate in

relevant professional ac

tivities and communicate

with others in similar

positions.

Responsibility (L):

Vendor, Informatics-type

department, IT

Responsibility (S): Of

fice management

Input Source: L, C, IT,

HI, Ev • If key internal people do not network with outsiders, up to date knowledge may not reach them • Organizations support professional development of staff assigned responsibility for any aspect of EHR safety, by budgeting for and encouraging training. • Staff members with responsibility for EHR safety establish routine mechanisms for discussing problems they encounter as they optimize the safety and safe use of EHRs. This may include participation in specific EHR computer user groups or in professional association activity. • Professional organizations, including those for clinicians and office administration, often provide information about issues that might affect EHR safety.

21. Self-assessments,

including use of the

SAFER guides, are

conducted routinely by

ateam, and the risks of

foregoing or delaying

any recommended prac

tices are assessed.

Responsibility (L):

Safety officer and those

involved in safety initia

tives, informatics-type

department

Responsibility (S):

Office management,

providers

Input Source: L, HI, C • Without learning through use of available self-assessment tools,organizations risk overlooking critical hazards • Self-assessments related to EHRs and patient safety are done routinely. • The self-assessment process includes setting targets for addressing items the organizational team identifies.

even when they are of the same type and size. The responsible parties listed here are

ideal examples and possibilities. We denote large organizations with an L and small

organizations such as independent ambulatory clinics with an S. Groups of clinics or

hospitals with centralized IT and informatics services are considered large. The EHR

safety activities in these large organizations are often included in more general safety and

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INFORMATION TECHNOLOGY SAFETY CENTER

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The Institute of Medicine's 2012 report on Health IT and Patient Safety

called for the establishment of an independent federal entity for monitor

ing and analyzing patient safety data and investigating serious incidents

related to health IT. [1] In an attempt to address this recommendation,

President Obama requested $5 million in his 2015 Federal budget for the

Office of the National Coordinator for Health Information Technology

(ONC) to create a roadmap for a Health Information Technology Safety

Center (HIT Safety Center) [2]. This was followed a week later by an

influential and much awaited report that responded to the U.S. Food and

Drug Administration Safety and Innovation Act (FDASIA) [3]. Briefly,

this Act required ONC, Food and Drug Administration (FDA), and Fed

eral Communication Commission (FCC) to describe "strategy and recom

mendations on an appropriate, risk-based regulatory framework pertaining

to health information technology, including mobile medical applications,

that promotes innovation, protects patient safety, and

avoids regulatory

duplication." This report, a culmination of deliberations of the FDASIA

workgroup chartered by the FDA, ONC, and FCC [4], reinforced the call

for an ONC-based HIT Safety Center [5]. The HIT Safety Center is envi

sioned as a public-private entity that will serve as "a trusted convener of

health IT stakeholders in order to focus on activities that promote health

IT as an integral part of patient safety with the ultimate goal of assisting

in the creation of a sustainable, integrated health IT learning system that

avoids regulatory duplication and leverages and complements existing and

ongoing efforts." [5]

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of what will be required to put its infrastructure in place and to maintain its

functionality. Assuming that the US Congress provides the necessary fund

ing and oversight authority, the HIT Safety Center has the potential to play a

key operational role for major national initiatives related to health informa

tion technology and patient safety [6]. This also assumes that recent ques

tions regarding the authority of ONC to even create it are

answered satisfac

torily [7]. More recently, ONC issued a 2-year, task order entitled, “Health

IT Safety Center Road Map” that asks contractors to develop a diversifi ed

plan including federal funding options, public-private collaboration and po

tential private sector funding of activities. In this paper, we assume the best

case scenario and propose several specifi c patient safety goals that the HIT

Safety Center could adopt to deliver on the promise of creating safe and ef

fective HIT-enabled healthcare systems [8]. As noted in a recent endorsement by the HIT Policy committee [6],

the time is ripe for the Health IT Safety Center. The FDASIA report’s

high-level vision created momentum for its development given the in

creasing recognition by both frontline clinicians and health care organi

zations (HCOs) of both the benefi ts and unintended consequences of the

rapidly increasing use of health information technology (HIT), includ

ing electronic health records (EHRs). For example, safety concerns have

arisen from the design and functioning of HIT and from the disruptions

in clinicians’ workfl ow in settings where EHRs have been implemented

[9]. Emerging evidence from the scientifi c literature [10,11,12] as well as

anecdotal reports [13] suggest that “HIT-related safety events” (i.e., events

arising from unsafe technology or unsafe use of technology) are occurring.

Given that neither the FDA nor any other agency will be regulating most

forms of HIT, the HIT Safety Center could be instrumental in uniting key

“frontline” stakeholders (i.e., clinicians, HCOs, quality and safety person

nel, and HIT vendors) with key administrative and policy stakeholders

to develop the necessary methods and infrastructure to ensure a cohesive

national approach to HIT safety. To facilitate rapid cycle improvements related to patient safety and to

benefi t the maximum number of patients, we posit that the HIT Safety

Center must lead the coordination of activities to achieve four goals: tem to monitor HIT-related patient safety events, including events that lead to patient harm and “near misses” [14]; • Develop the methods and governance structure to support the investigation of major HIT-related safety events; • Create the infrastructure and methods needed to carry out random assessments of large, complex, HIT-enabled healthcare organizations; and • Advocate for HIT safety with various government (e.g., U.S. Congress, Centers for Medicare and Medicaid Services (CMS), Office of Civil Rights, Department of Defense, or state departments of health) and private entities (e.g., EHR vendors, healthcare provider organizations). The following sections provide a brief description of the rationale for

these goals and specifi c actions that could be undertaken.

15.2.1 FACILITATE CREATION OF A NATIONWIDE HIT-RELATED

PATIENT SAFETY SURVEILLANCE SYSTEM

Currently, we are unable to quantify the rate of

HIT-related patient safety

events with any precision using the existing patient safety reporting and

analysis infrastructure, [13] which consists of a small number of reports

within very large public databases that are not specific to HIT (e.g., FDA_

MAUDE [15], Pennsylvania Patient Safety Authority [16], MEDMARX

[17]). Moreover, there is still no clear consensus on taxonomy and measure

ment methods for HIT-related safety events. Thus, the HIT Safety Center

could create a robust foundation for improving future measurement and sur

veillance of patient safety at a national level. For example, ONC could part

ner with not-for-profit entities (e.g., ECRI's recently formed "Partnership

for Promoting Health IT Patient Safety" [18]) to create a federally-funded

research and development center for event reporting, analysis, and informa

tion sharing, similar in concept to the Veterans Affairs' Informatics Patient

Safety office's case tracking database [12]. These centers, in conjunction

with local and national PSOs, could play pivotal roles in establishing key

safety benchmarks EHR developers and HCOs could use to assess safety

performance. This surveillance system should gather data to help HIT de

velopers and clinicians better understand and mitigate risks associated with

HIT implementation and use.

tems is that most clinicians either do not understand what should be re

ported or cannot recognize that near misses or events have occurred. To

facilitate measurement and monitoring of HIT safety, we propose the term

“health information technology (HIT) related safety concern” to broad

ly describe patient safety events that reached the patient (regardless of

whether harm occurred), near misses, and unsafe conditions. Although

this terminology of “safety concern” is consistent with AHRQ common

format reporting standards [19], these standards do not adequately capture

the breadth of health IT-related safety concerns defi ned below and thus

need to be broadened. We propose that the AHRQ common format should

address fi ve major types of HIT-related safety concerns (Table 15.2.1),

including instances in which: • HIT fails during use or is otherwise not working as designed [20]. The safety concern is directly attributable to the HIT. • HIT is working as designed, but the design does not meet the user’s needs or expectations (i.e., bad design) [21]. HIT is a contributing factor to the safety concern. • 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 [22]. These events are related to use of HIT (i.e., rather than HIT itself) and may be referred to as configuration errors, “work-arounds” or incorrect usage. • 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 [23]. These events are inevitable due to the interactive complexity of tightly coupled systems. They are often referred to as HIT system interface safety concerns [24].
• Specific HIT safety features or functions were not implemented or not available [25]. At a minimum, event types 1-4 should be subjected to reporting and

surveillance. To standardize this process, we propose development of a

small set of safety concerns that HCOs and EHR vendors should be re

quired to report at regular intervals to the HIT Safety Center via a Pa

tient Safety Organization (PSO) [26]. Voluntary event reporting by clini

cians should be incentivized by providing Continuing Medical Education

or Maintenance of Certifi cation credits. In addition, automated reporting

mechanisms could greatly advance these surveillance efforts. For in

standardized performance measures in an electronic format) directly from

EHRs could be added to future EHR certifi cation requirements [27]. These

eMeasures could be modeled after the “near misses” within the airline

safety reporting system [28], the types of events and threats reported to

the United States Department of Homeland Security’s Computer Emer

gency Readiness Team (US-CERT) [29], or events tracked in mandatory

public health reporting systems maintained by the FDA and

CDC. Some

examples of potential HIT safety eMeasures, which would be a good place

to start, are listed in Table 15.2.2.

TABLE 15.2.1: Definitions and Examples of Different 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 de

signed, 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

4. Instances in which HIT is working as de

signed, 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 avail

able (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

15.2.2 DEVELOP A FRAMEWORK TO SUPPORT INVESTIGATION OF MAJOR HIT-RELATED SAFETY EVENTS

The HIT Safety Center can also address the problem of slow progress

in learning from HIT-related safety events by creating criteria and meth

defined as those causing severe patient harm or placing more than 100

patients at risk for harm or an HIT-related “sentinel event” reported to the

Joint Commission [30]. As more organizations rush to implement compre

hensive EHRs, we expect more serious EHR-related safety events. These

events would need to be investigated under the auspices of PSOs to iden

tify causes and prevention strategies; most likely similar events will occur

at other institutions. Alternatively, Congress could create a new indepen

dent agency within the ONC, similar to the National Transportation Safety

Board within the Department of Transportation that is authorized to con

duct investigations and make recommendations [31]. While the creation

of such a new agency may currently appear doubtful given the current

socio-political climate, the increasing reliance on the use of HIT within all

aspects of healthcare may justify the cause. For example, over the last several years, several reports have document

ed long-term (>4 hours) or widespread (i.e., affecting multiple organizations

or sites of care) periods of EHR unavailability [32,33]. As the consolida

tion of HCOs continues, coupled with increasing numbers of large-scale,

remotely hosted EHR implementations, similar events are certain to occur.

An example of a major HIT-related safety event, that might warrant further

investigation to identify generalizable lessons, is a widespread HIT down

time that lasts for more than 24 hours, is unrelated to a natural disaster, and

affects at least two of the following EHR functions simultaneously: admis

sion/discharge/transfer; clinical results review; provider order entry, com

munication, verifi cation; barcode medication verifi cation; picture archiving

and communication; clinical documentation; alert notifi cation; or participa

tion in local health information exchange [34]. The types of safety events that need investigation could be further re

fi ned by the HIT Safety Center. The investigation format and approach

will also depend on the type and severity of the event but in general, anal

ysis should be conducted by independent investigators with deep tech

nical knowledge of the underlying hardware and software systems and

extensive clinical knowledge of various healthcare work processes, in

conjunction with patient safety experts from PSOs. Investigations should

produce comprehensive, publically available reports that outline how sim

ilar events can be prevented at other institutions. This HIT Safety Center

a “learning” HIT-enabled health care system as the IOM suggests [35].

TABLE 15.2.2: Candidate HIT Safety eMeasures that could be Reported to the HIT Safety

Center on a Quarterly Basis.

Proposed HIT Safety EMeasures or Events	Rationale
Unexpected EHR-related downtimes lasting	more than 8 hours After 8 hours it is likely that the downtime event will increase the risk of “change-of-shift”.
Mean EHR response time as measured from	the end-users viewpoint As response time increases (e.g., past 10 seconds) the likelihood of “functional downtime” increases.
Interruptive alerts that have fired more than	100 times with 100% override rate Frequent, synchronous alerts that are repeatedly overridden increase the risk of alert fatigue and clinicians missing potentially life-threatening events.
Erroneous displays of laboratory test results	or medications Incorrect result or medication displays increase the risk of erroneous diagnosis or treatment.
Percent of EHR users trained and passing a	

competency test before getting a login [35] Allowing untrained users to login to the EHR can lead to missing key data, erroneous data entry, or failed communication and affect patient care.

Rate of Computer-based provider order entry

use Incomplete CPOE usage, results in duplicative order entry systems which greatly increases risk of errors

Percentage of “order-retract-reorder” events

recorded Order-retract-reorder events are correlated with orders entered on the wrong patient.

Percentage of potential duplicate patients

in the live clinical database (i.e., same First

name, Last name, and date of birth) Duplicate patients increase the risk of clinicians missing key information.

Software bugs reported to the EHR vendor A large quantity of serious software errors increases the risk that data is incorrectly entered, transmitted, stored, or lost.

15.2.3 FACILITATE SAFETY ASSESSMENTS OF LARGE, COMPLEX,

HIT-ENABLED HEALTHCARE ORGANIZATIONS

We recently developed self-assessment tools, referred to as Safety Assur

ance Factors for EHR Resilience (SAFER) guides [36] to help clinicians

and HCOs proactively assess the safety and effectiveness of their EHRs

[37]. These, freely-available guides help identify areas of vulnerability and

cerns [38]. During their development, we learned that even the most highly

regarded HIT-enabled healthcare organizations often had significant gaps in

their EHR features, functions, or usage [39]. For example,

one organization

noted for its longstanding, highly successful computer-based provider order

entry (CPOE) system did not have an interface between the EHR system

used by physicians to enter orders and the laboratory system used to gener

ate and report results. Similarly, another organization noted for its effective

use of advanced clinical decision support never implemented CPOE. Over the last 15 years, education and outreach alone have been insuf

fi cient to improve the safety of the healthcare system [40]. Therefore, we

believe that more rigorous assessments are needed to improve the safety of

EHR-enabled health care. We propose that the HIT Safety Center should

work with an independent entity to refi ne the SAFER methodology and be

come a coordinating hub (i.e., establish the assessment criteria and aggre

gate the results) for random, preferably unannounced, on-site assessments of

large, complex organizations that have received meaningful use incentives.

These assessments could be carried out as part of current CMS site visits or

by independent entities such as existing CMS deeming authorities (e.g., The

Joint Commission) as a part of their accreditation process site visits. Assess

ment activities could include interviews with stakeholders, live EHR dem

onstrations, observations of clinicians as they interact with the EHR, tours

of key clinical and technical sites, and reviews of EHR-related policies and

procedures [41]. Reports of these visits could be submitted to regulatory or

ganizations such as FDA, U.S. Inspector General, Offi ce of Civil Rights, or

CMS for their review and follow-up and made available on public websites

[42]. While this might require additional resources, we believe some form

of an EHR assessment strategy is key for organizations to reduce health IT

safety issues [43].

15.2.4 ADVOCACY FOR HIT SAFETY, EVIDENCE GENERATION AND KNOWLEDGE DISSEMINATION

The HIT Safety Center must work with leading organizations that represent

the broad range of “users” of HIT systems and the resulting data including

for example, to inform policy decisions and regulation related to HIT-related

safety issues. This will ensure that future mandates take into account com

plex socio-technical and clinical implications of these decisions [44]. In ad

dition, it must work with private entities involved in design, development,

and use of these systems to help them understand why certain, safety-critical

mandates were enacted and perhaps suggest potential

technical solutions to

address them. For example, EHR vendors may be reluctant to implement the

eMeasures previously described [45]. The HIT Safety Center should coordi

nate, along with AHRQ, research required to generate and disseminate best

evidence regarding the intricacies of designing, developing, implementing,

and overseeing HIT within complex adaptive healthcare organizations [46].

Initially, the focus could be key research topics that need to be quickly re

solved, such as development and validation of methods to measure, moni

tor, and improve EHR usability [47,48] and methods to achieve widespread

interoperability [49]. Immediate deliverables could include acceleration of

the long-standing work by the National Library of Medicine and the ONC

on the standardization of clinical vocabularies [50] and technical data inter

change standards [51]. For instance, to resolve the persistent and widespread

problem of patient identification across healthcare organizations [52,53,54],

the HIT Safety Center could encourage research, development, and imple

mentation of innovative approaches to patient identification and matching

[55]. Such solutions may not only reduce the burden of incorrect diagnosis

and treatment but also improve the efficiency of healthcare processes by

reducing duplicate testing and manpower required to merge and validate

duplicate patient records.

15.2.5 CONCLUSIONS

We applaud FDASIA's recommendation to create a federally-supported

HIT Safety Center. Although the initial funding request is insufficient to

establish and maintain such a Center, we are optimistic about its develop

ment and future funding decisions. The convening ability of such a center

could be critically important to our transformation to safe and effective

HIT-enabled healthcare systems. To ensure progress and to avoid failure of

ity, in keeping with the rapid pace of HIT implementation. A HIT Safety

Center focused on the exemplary goals and activities we outline will more

likely realize the transformative benefits of state-of-the-art health infor

mation technology and enable patients to receive HIT-facilitated, safe, and

high value healthcare that they deserve.

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