Electronic Health Records

Challenges in Design and Implementation

Dean F. Sittig, PhD
Editor

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TORONTO NEW JERSEY

CRC Press
Taylor & Francis Group
6000 Broken Sound Parkway NW, Suite 300
Boca Raton, FL 33487-2742

Apple Academic Press, Inc
3333 Mistwell Crescent
Oakville, ON L6L 0A2
Canada

Version Date: 20131115

International Standard Book Number-13: 978-1-4822-3155-7 (eBook - PDF)

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Dean F. Sittig, PhD, is a Professor at the School of Biomedical Informatics at The University of Texas Health Science Center at Houston and a member of the UT Houston-Memorial Hermann Center for Healthcare Quality and Safety. Dr. Sittig's research interests center on the design, development, implementation, and evaluation of all aspects of clinical information systems. In addition to Dr. Sittig's work on measuring the impact of clinical information systems on a large scale, he is working to improve our understanding of both the factors that lead to success, as well as the unintended consequences associated with computer-based clinical decision support and provider order entry systems.

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ACKNOWLEDGMENT AND HOW TO CITE

The chapters in this book were previously published in various places and in various formats. By bringing them together here in one place, we offer the reader a comprehensive perspective on recent investigations of electronic health records. Each chapter is added to and enriched by being placed within the context of the larger investigative landscape.

We wish to thank the authors who made their research available for this book, whether by granting their permission individually or by releasing their research as Open Source articles. When citing information contained within this book, please do the authors the courtesy of attributing them by name, referring back to their original articles, using the credits provided at the end of each chapter.

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INTRODUCTION

Establishing a safe and effective electronic health record (EHR)-enabled health care delivery system is one of the most important and complex challenges facing clinicians and the healthcare organizations they work for today. Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, a portion of the American Recovery and Reinvestment Act of 2009, the proportion of clinicians using EHRs on a routine basis has increased from less than 20% to over 60%. Concomitantly, the number of certified EHR vendors in the United States has increased from 60 to more than 1700. When coupled together, this influx of healthcare organizations and clinicians that are new to the uses of health information technology, along with a myriad of new EHR vendors, stands to create significant new and often unanticipated challenges. The goal of this book is to provide an overview of the challenges in EHR design and implementation along with an introduction to the "best practices" that have been identified over the past several years. The book is divided into and introduction and eight subsections. Each subsection focuses on a key implementation issue or a specific component of an EHR.

The first section provides an overview of the issues at hand. In the first chapter, Sittig and Singh looks at some of the concerns surrounding EHR use and proposes eight rights of safe EHR use. These rights are grounded in Carayon's Systems Engineering Initiative for Patient Safety, a human factors engineering model that addresses work-system design for patient safety.

In Chapter 2, Cresswell and colleagues argue that the implementation of health information technology interventions is at the forefront of most policy agendas internationally. However, such undertakings are often far from straightforward as they require complex strategic planning accompanying the systemic organizational changes associated with such programs. Building on experiences of designing and evaluating the implementation of large-scale health information technology interventions in the USA and

the UK, the authors highlight key lessons learned in the hope of informing the ongoing international efforts of policymakers, health directorates, healthcare management, and senior clinicians.

Part II, titled "Identifying and Preventing EHR Safety Concerns," examines the many organizations in the midst of implementing Electronic Health Records (EHRs). Research and experience gained over the past 20 years has shown that implementing EHRs is difficult, time-consuming, and expensive. In addition, recent reports indicate that many organizations continue to experience various types of unintended adverse consequences. The goal of this section is to illustrate how an organization can identify specific EHR-related safety concerns as well as begin their understanding of what they should do to remedy these situations before tragedy strikes.

In Chapter 3, Sittig and Singh find that despite the promise of health information technology (HIT), recent literature has revealed possible safety hazards associated with its use. The Office of the National Coordinator for HIT recently sponsored an Institute of Medicine committee to synthesize evidence and experience from the field on how HIT affects patient safety. To lay the groundwork for defining, measuring, and analyzing HIT-related safety hazards, they propose that HIT-related error occurs any time HIT is unavailable for use, malfunctions during use, is used incorrectly by someone, or when HIT interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted. These errors, or the decisions that result from them, significantly increase the risk of adverse events and patient harm. They describe how a sociotechnical approach can be used to understand the complex origins of HIT errors, which may have roots in rapidly evolving technological, professional, organizational, and policy initiatives.

The next chapter details how although electronic health records (EHRs) have a significant potential to improve patient safety, EHR-related safety concerns have begun to emerge. Sittig and Singh analyzed 369 responses to a survey sent to the memberships of the American Society for Healthcare Risk Management and the American Health Lawyers Association and supplemented by their previous work in EHR-related patient safety, the authors identified 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; 4) System-to-system interface errors; 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. In this paper, the authors present a "red flag"-based approach that can be used by risk managers to identify potential EHR safety concerns in their institutions. An organization that routinely conducts EHR-related surveillance activities, such as the ones proposed here, can significantly reduce risks associated with EHR implementation and use.

Chapter 5, by McCoy et al., seeks to quantify the percentage of records with matching identifiers as an indicator for duplicate or potentially duplicate patient records in electronic health records in five different healthcare organizations, describe the patient safety issues that may arise, and present solutions for managing duplicate records or records with matching identifiers. For each institution, they retrieved de-identified counts of records with an exact match of patient first and last names and dates of birth and determined the number of patient records existing for the top 250 most frequently occurring first and last name pairs. They also identified methods for managing duplicate records or records with matching identifiers, reporting the adoption rate of each across institutions. They found that the occurrence of matching first and last name in two or more individuals ranged from 16.49% to 40.66% of records; inclusion of date of birth reduced the rates to range from 0.16% to 15.47%. The number of records existing for the most frequently occurring name at each site ranged from 41 to 2552. Institutions varied widely in the methods they implemented for preventing, detecting and removing duplicate records, and mitigating resulting errors. The percentage of records having matching patient identifiers is high in several organizations, indicating that the rate of duplicate records or records may also be high. Further efforts are necessary to improve management of duplicate records or records with matching identifiers and minimize the risk for patient harm.

Part III is titled "EHR Users and Usability"; the rapid increase in the rate of EHR adoption following the HITECH Act of 2009 has highlighted many shortcomings of existing EHR technology. Many of these shortcomings revolve around the concept of EHR usability as exemplified by the need for users to engage in data entry, communication, and review. A major confounder in the usability debate revolves around the multiple

users of the EHR; each with a distinct and often conflicting set of requirements. A major challenge is to identify the myriad EHR users and the key tasks they need to accomplish, for example, clinicians need to record their thoughts and actions regarding patients past medical history, current presenting complaints, and future plans including ordering diagnostic tests and therapy. The EHR is also used as a front-end to the billing process that requires documentation using a distinct set of billing codes that record exactly what the clinician did (i.e., physiologic systems examined, procedures performed, tests and therapies ordered) during the encounter. The same data are also used by the organization's administration to measure and monitor the quality of care provided across the organization. Attempts to improve EHR usability must take a comprehensive view of this problem considering the viewpoints of all potential users.

In Chapter 6, Sittig and Singh argue that despite the potential benefits of electronic health records, clinicians have experienced several challenges in their adoption and use. To encourage debate on strategies to overcome these challenges, they developed a set of 10 "rights" of clinicians that represent important features, functions and user privileges of electronic health records that clinicians need to provide safe, high·quality care. Each right is accompanied by a corresponding responsibility of clinicians, without which the ultimate goal of improving quality of health care might not be achieved.

Lowry and colleagues examine the practice of EHR in pediatric medicine in Chapter 7. Adoption of electronic health record (EHR) systems in hospitals and physician practices is accelerating. Usability of EHRs has been identified as an important factor impacting patient safety, and recommendations for improvement have been provided. Pediatric patients have unique characteristics that translate into unique EHR usability challenges. It is not surprising, then, that the adoption of EHRs by pediatric care providers has lagged behind adoption for adult care providers. In this document, we highlight important user interactions that are especially salient for pediatric care and hence to the EHR user-centered design process. These interactions and associated usability recommendations were identified by consensus during a series of teleconferences with experts representing the disciplines of human factors engineering, usability, informatics, and pediatrics in ambulatory care and pediatric intensive care.

In addition, extensive peer review was provided by experts in pediatric informatics, emergency medicine, neonatology, pediatrics, human factors engineering, usability engineering, and software development and implementation. This report details recommendations to enhance EHR usability when supporting pediatric patient care and also identifies promising areas for EHR innovation. Finally, the authors illustrate unique pediatric considerations in the context of representative clinical scenarios that may be helpful for formative user-centered design approaches and summative usability evaluations.

Chapter 8 examines a different challenge of adopting EHR practices, this time in developing countries. Sittig, Kahol, and Singh examine the potential for health information technology (IT) to enhance quality of care is limited by unanticipated problems following adoption of new systems and technologies. Proactive assessment of system vulnerabilities can help improve existing systems and ease implementation of new innovations. The authors applied a comprehensive socio-technical model of safe and effective health IT use to the formative evaluation of a novel tablet-based device designed to support primary care practice in rural India. Based on their conceptual model, they developed an assessment guide for the tablet system that was informed by literature review, interviews, and observations of health workers and supervisors. The assessment revealed and addressed both technical (functionality, content, usability, user interface) and non-technical (workflow, processes, and policies etc.) areas of improvement.

Part IV, titled "Clinical Decision Support" (CDS) interventions as integrated within an EHR, are designed to aid the clinician's decision-making process at the point of care. The current scope of CDS focuses primarily on medications, laboratory testing, radiology procedures, and providing access to clinical reference literature. There is substantial evidence to suggest that well-designed clinical decision support not only enhances the quality of care provided but directly impacts patient safety by decreasing common errors and reducing missed opportunities or omissions that result in patient harm. In spite of this, many electronic health records (EHRs) do not have robust or reliable decision support features, and poorly implemented HIT systems have been shown to adversely affect care by introducing errors. This section outlines overarching guidelines for effective,

efficient, and reliable CDS systems and provides specific suggestions to improve the design, implementation, and use of these systems.

In Chapter 9, Bates and colleagues argue that while evidence-based medicine has increasingly broad-based support in health care, it remains difficult to get physicians to actually practice it. Across most domains in medicine, practice has lagged behind knowledge by at least several years. The authors believe that the key tools for closing this gap will be information systems that provide decision support to users at the time they make decisions, which should result in improved quality of care. Furthermore, providers make many errors, and clinical decision support can be useful for finding and preventing such errors. Over the last eight years the authors have implemented and studied the impact of decision support across a broad array of domains and have found a number of common elements important to success. The goal of this report is to discuss these lessons learned in the interest of informing the efforts of others working to make the practice of evidence-based medicine a reality.

Sittig and colleageus argue that a simple reminder is not always sufficient when it comes to encouraging various health reminders in Chapter 10. State-of-the-art electronic health record systems with advanced clinical decision support (CDS) capabilities can fundamentally improve quality and reduce costs of health care. However, these outcomes have not been universally achieved. They also argue that maximizing the potential of CDS for improving quality and safety of care requires attention to several factors, not all of which are related to the computer system.

Chapter 11, by Ash and colleagues, seeks to identify recommended practices for computerized clinical decision support (CDS) development and implementation and for knowledge management (KM) processes in ambulatory clinics and community hospitals using commercial or locally developed systems in the U.S. Guided by the Multiple Perspectives Framework, the authors conducted ethnographic field studies at two community hospitals and five ambulatory clinic organizations across the U.S. Using a Rapid Assessment Process, a multidisciplinary research team gathered preliminary assessment data; conducted on-site interviews, observations, and field surveys; analyzed data using both template and grounded methods; and developed universal themes. A panel of experts produced recommended practices. The team then identified ten themes related to CDS and

KM. These include: 1) workflow; 2) knowledge management; 3) data as a foundation for CDS; 4) user computer interaction; 5) measurement and metrics; 6) governance; 7) translation for collaboration; 8) the meaning of CDS; 9) roles of special, essential people; and 10) communication, training, and support. Experts developed recommendations about each theme. The original Multiple Perspectives Framework was modified to make explicit a new theoretical construct, that of Translational Interaction. These ten themes represent areas that need attention if a clinic or community hospital plans to implement and successfully utilize CDS. In addition, they have implications for workforce education, research, and national-level policy development. The Translational Interaction construct could guide future applied informatics research endeavors.

Chapter 12 seeks to detail what structures need to be put in place for EHS to be successful. Wright and colleagues describe clinical decision support (CDS) as a powerful tool for improving healthcare quality and ensuring patient safety. However, effective implementation of CDS requires effective clinical and technical governance structures. The authors sought to determine the range and variety of these governance structures and identify a set of recommended practices through observational study. Three site visits were conducted at institutions across the USA to learn about CDS capabilities and processes from clinical, technical, and organizational perspectives. Based on the results of these visits, written questionnaires were sent to the three institutions visited and two additional sites. Together, these five organizations encompass a variety of academic and community hospitals as well as small and large ambulatory practices. These organizations use both commercially available and internally developed clinical information systems. Characteristics of clinical information systems and CDS systems used at each site as well as governance structures and content management approaches were identified through extensive field interviews and follow-up surveys. Six recommended practices were identified in the area of governance, and four were identified in the area of content management. Key similarities and differences between the organizations studied were also highlighted. Each of the five sites studied contributed to the recommended practices presented in this paper for CDS governance. Since these strategies appear to be useful at a diverse range of institutions, they should be considered by any future implementers of decision support.

In Chapter 13, Wright and colleagues show that many computerized provider order entry (CPOE) systems include the ability to create electronic order sets, collections of clinically related orders grouped by purpose. Order sets, promise to make CPOE systems more efficient, improve care quality, and increase adherence to evidence-based guidelines. However, the development and implementation of order sets can be expensive and time-consuming, and limited literature exists about their utilization. Based on analysis of order set usage logs from a diverse purposive sample of seven sites with commercially and internally developed inpatient CPOE systems, the authors developed an original order set classification system. Order sets were categorized across seven non-mutually exclusive axes: admission/discharge/transfer (ADT), perioperative, condition-specific, task-specific, service-specific, convenience, and personal. In addition, 731 unique subtypes were identified within five axes: four in ADT (S = 4), three in perioperative, 144 in condition-specific, 513 in task-specific, and 67 in service-specific. Order sets (n = 1914) were used a total of 676,142 times at the participating sites during a one-year period. ADT and perioperative order sets accounted for 27.6% and 24.2% of usage respectively. Peripartum/labor, chest pain/acute coronary syndrome/myocardial infarction and diabetes order sets accounted for 51.6% of condition-specific usage. Insulin, angiography/angioplasty, and arthroplasty order sets accounted for 19.4% of task-specific usage. Emergency/trauma, obstetrics/gynecology/labor delivery, and anesthesia accounted for 32.4% of service-specific usage. Overall, the top 20% of order sets accounted for 90.1% of all usage. Additional salient patterns are identified and described.

Part V details the role of EHR in the referral process. Electronic health records are increasingly being used to facilitate referral communication in the outpatient setting. Outpatient referrals involve processes that include a transfer of responsibility for some aspect of patient's care from a referring provider to a secondary service or provider. They are an important but challenging aspect of primary care practice.

In Chapter 14, Esquivel and colleagues show that electronic health records are increasingly being used to facilitate referral communication in the outpatient setting. However, despite support by technology, referral communication between primary care providers and specialists is often unsatisfactory and is unable to eliminate care delays. This may be in part

due to lack of attention to how information and communication technology fits within the social environment of health care. Making electronic referral communication effective requires a multifaceted "socio-technical" approach. Using an 8-dimensional socio-technical model for health information technology as a framework, the authors describe ten recommendations that represent good clinical practices to design, develop, implement, improve, and monitor electronic referral communication in the outpatient setting. These recommendations were developed on the basis of the authors' previous work, current literature, sound clinical practice, and a systems-based approach to understanding and implementing health information technology solutions. Recommendations are relevant to system designers, practicing clinicians, and other stakeholders considering use of electronic health records to support referral communication.

Section VI is about laboratory test result management and reporting practices, which include communication of test results from diagnostic services (e.g. radiology and laboratory) to the ordering 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 automated features to improve the safety and effectiveness of how laboratory test result information is communicated.

Singh and Vij look at the reporting of abnormal test results in Chapter 15. Healthcare organizations continue to struggle to ensure that critical findings are communicated and acted on in a timely and appropriate manner. Recent research highlights the risks of communication breakdowns along the entire spectrum of test-result abnormality, including significantly abnormal but nonemergent findings. Evidence-based and practical institutional policies must uphold effective processes to guide communication of abnormal test results. Eight recommendations for effective policies on communication of abnormal diagnostic test results were developed based on policy refinement at the Michael E. DeBakey Veterans Affairs Medical Center (Houston), institutional experience with test result management, and findings from research performed locally and elsewhere. Research findings on vulnerabilities in existing policies and procedures were taken into consideration. The eight recommendations are based on important refinements to the policy, which clarified staff roles and responsibilities for

test ordering, follow-up, and communication; defined categories of abnormal test results to guide appropriate follow-up action; and elaborated procedures for monitoring the effectiveness of test result communication and follow-up. Participation of key stakeholders is recommended to enhance buy-in from personnel and to help ensure the policies feasibility and sustainability. The proposed recommendations for ensuring safe test-result communication may be potentially useful to a wide variety of institutions and health care settings. These practical suggestions, based on research findings and experiences with a previous policy, may be a useful guide for designing or amending policies for safe test-result communication in both inpatient and outpatient settings.

Chapter 16, by Singh and colleagues, argues that early detection of colorectal cancer through timely follow-up of positive Fecal Occult Blood Tests (FOBTs) remains a challenge. In the authors' previous work, they found 40% of positive FOBT results eligible for colonoscopy had no documented response by a treating clinician at two weeks despite procedures for electronic result notification. They determined if technical and/or workflow-related aspects of automated communication in the electronic health record could lead to the lack of response. Using both qualitative and quantitative methods, they evaluated positive FOBT communication in the electronic health record of a large, urban facility between May 2008 and March 2009. They identified the source of test result communication breakdown and developed an intervention to fix the problem. Explicit medical record reviews measured timely follow-up (defined as response within 30 days of positive FOBT) pre- and post-intervention. Data from 11 interviews and tracking information from 490 FOBT alerts revealed that the software intended to alert primary care practitioners (PCPs) of positive FOBT results was not configured correctly and over a third of positive FOBTs were not transmitted to PCPs. Upon correction of the technical problem, lack of timely follow-up decreased immediately from 29.9% to 5.4% ($p < 0.01$) and was sustained at month 4 following the intervention. Electronic communication of positive FOBT results should be monitored to avoid limiting colorectal cancer screening benefits. Robust quality assurance and oversight systems are needed to achieve this. The authors' methods may be useful for others seeking to improve follow-up of FOBTs in their systems.

Part VII is titled “Bar Coded Medication Administration”. Bar-Coded Medication Administration (BCMA) is a key component of a healthcare organization’s inventory control system. A BCMA system consists of a barcode printer that adds a barcode label to each medication to be administered, a barcode reader used to scan the barcoded patient identification wristband attached to each patient, a mobile computer (with WiFi) that collects the information and transmits it to a central computer server that matches the patient identification information to the medication that was prescribed. These systems have the potential to improve medication safety by verifying that the right drug at the right dose via the right route is being administered to the right patient at the right time.

Chapter 17 gives some best practice recommendations. Patterson and colleagues show that since 2000, the Veterans Health Administration (VHA) has pioneered the development and deployment of a BCMA system. Based on VHA experience, 15 “best practices” for BCMA implementation, integration, and maintenance are recommended. Data were collected on potential barriers to the effectiveness of BCMA to improve patient safety by direct observation of medication administration, simulated BCMA use in a laboratory setting, a survey of nursing informatics specialists regarding policies and procedures, and 30 unstructured interviews with diverse stakeholders. Fifteen practices were proposed, categorized by implementation and continuous improvement, training, troubleshooting, contingency planning, equipment maintenance, medication administration, and maintenance of paper patient wristbands. For example, Recommendation 15 (“Periodic replacement of wristbands”) advises weekly bar-coded wristband replacement in long-term care settings to improve the scanning reliability. Lessons learned about best practices to address challenges may offer insight to others considering implementation of bar-code technology.

The final section, Part VII, describes computer-based provider order entry; a module within an electronic health record system that allows the patient’s healthcare provider (most often a physician, but a nurse practitioner or physician’s assistant could also perform these tasks) to enter an order for a diagnostic procedure or therapeutic treatment. This order can then be sent electronically to the appropriate person or ancillary department (computer-based order communication) where it is carried out. In

addition to eliminating the legibility problems that surround many handwritten orders and the need for repeated transcriptions and movement of the paper medical record, the system can also check for duplicate orders, potential drug-drug or drug-laboratory interactions, perform dosage checks, and ensure that all orders are complete. Computer-based provider order entry (CPOE) is the single most important clinical computing application that has been developed in terms of its ability to influence clinical decision-making and provider behavior at the point of care. While many informaticians, clinicians, and organizational leaders have recognized this and attempted to develop the clinical computing infrastructure and organizational culture that would allow such an application to be implemented over the past 30 years, to date, very few healthcare organizations have been successful.

Chapter 18, by Campbell and colleagues, attempts to identify and describe unintended adverse consequences related to clinical workflow when implementing or using computerized provider order entry (CPOE) systems. They analyzed qualitative data from field observations and formal interviews gathered over a three-year period at five hospitals in three organizations. Five multidisciplinary researchers worked together to identify themes related to the impacts of CPOE systems on clinical workflow. CPOE systems can affect clinical work by 1) introducing or exposing human/computer interaction problems, 2) altering the pace, sequencing, and dynamics of clinical activities, 3) providing only partial support for the work activities of all types of clinical personnel, 4) reducing clinical situation awareness, and 5) poorly reflecting organizational policy and procedure. As CPOE systems evolve, those involved must take care to mitigate the many unintended adverse effects these systems have on clinical workflow. Workflow issues resulting from CPOE can be mitigated by iteratively altering both clinical workflow and the CPOE system until a satisfactory fit is achieved.

The final chapter, Chapter 19, by Sittig and colleagues, is written in response to another article, "Unexpected Increased Mortality After Implementation of a Commercially Sold Computerized Physician Order Entry System" by Han et al. The authors are to be congratulated for their courage in bringing their compelling account of computerized physician order entry (CPOE) implementation problems to the medical literature as they

tried to interpret their results concerning mortality. Their article is as much a search for answers as it is a recitation of the shortfalls in their implementation process and computer systems. It is critically important to understand that the types of problems described by Han et al. are not limited to their institution. In fact, setbacks and failures in the implementation of clinical information systems (CISs) and CPOE systems are all too common. Although it is tempting to focus solely on the role of new technology in the problems highlighted by this example, there are also important lessons to be learned about related organizational and workflow factors that affect the potential for danger associated with CPOE implementation.

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PART I

INTRODUCTION

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CHAPTER 1

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. However, concerns have been raised about the safety of EHRs in light of the limitations of currently available software, the inexperience of clinicians and information technologists in implementation and use, and potential adverse outcomes associated with clinician order entry and other clinical applications.[2-4]

President Obama has referred to EHRs as a solution to reduce medical errors. To avoid medical errors resulting from EHR use and to achieve the promise of EHRs, this Commentary proposes 8 rights of safe EHR use. These rights are grounded in Carayon's Systems Engineering Initiative for Patient Safety, [5] a human factors engineering model that addresses work-system design for patient safety.

1.1 RIGHT HARDWARE OR SOFTWARE

An EHR system must be capable of supporting required clinical activities. If hardware or software is inadequately sized, configured, or maintained, the EHR will function poorly. Anything that slows or disrupts the clinician's workflow could negatively affect patient safety. [6] For example, an EHR should be able to calculate a medication dose, transmit the order to

the appropriate department, and notify the nurse of a placed order. A medication error could easily follow a breakdown in any of these functions.

Local software oversight committees are a way to help ensure proper and safe functioning. [7] Another solution may be cloud computing, reliablecomputingservices that are accessible from remote locations via the Internet. Although the cloud may reduce hardware procurement, configuration, and maintenance burdens for health care organizations, its benefits hinge on the improvement of Internet speed, reliability, and access.

1.2 RIGHT CONTENT

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

The federal government has taken a significant step toward advancing a controlled vocabulary with its support of Systematized Nomenclature of Medicine—Clinical Terms, the most comprehensive, multilingual clinical health care terminology in the world. The National Library of Medicine distributes it for free through an agreement with the International Health Terminology Standards Development Organization.Adoption of a standard vocabulary is prerequisite to implementing advanced clinical decision support (CDS).To increase access to a standards-based set of validated, evidence-based CDS, an open access clinical knowledge base of interventions should be developed, focusing on helping clinicians achieve the quality and safety targets for meaningful EHR use.

1.3 RIGHT USER INTERFACE

The right user interface allows clinicians to quickly grasp a complex system safely and efficiently. The interface should present all the relevant pa-

tient 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 1 screen and limited screen space. Errors may follow when clinicians miss crucial information in applications that include too much information on 1 screen. Yet, systems with too many nested menu options or redundant pathways can be difficult to learn and time consuming to use. The physical aspects of the interface (eg, keyboard, mouse, or touch screen) may also contribute to error in the input or selection of information.

Another difficult problem facing clinicians is the requirement to navigate different interfaces safely and efficiently at different practice sites. Although remedying this problem is a complex undertaking, the federal government and EHR vendors should develop common user interface standards for health care applications.

1.4 RIGHT PERSONNEL

Trained and knowledgeable personnel are essential for safe use as are software designers, developers, trainers, and implementation and maintenance staff. System developers should have software engineering skills, be able to design effective user interfaces, use existing standardized clinical vocabularies, and have a sound understanding of clinical medicine. Trainers, implementers, and maintenance staff should have clinical experience, understanding of system capabilities and limitations, and excellent project management skills. [6] Clinicians should understand how to integrate the system into their workflows and how to function when it is unavailable. 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 individuals, the American Medical Informatics Association has created the "1010 Training Programs" and has identified the knowledge and skills necessary for clinical informatics subspecialty fellowship programs. Such programs need to be implemented nationwide.

1.5 RIGHT WORKFLOW AND 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, and communication tasks deemed critical could be required to have a traceable electronic receipt acknowledgment.

Errors may result from CDS interventions (ie, alerts and reminders) that are not well focused or not judiciously delivered at the point in the workflow that best supports the clinician's decision making or data entry. [8] Clinical decision support interventions should be streamlined with clinicians' electronically enabled workflow through a standard set of functions (eg, pop-up alerts, pick lists, or order sets).

1.6 RIGHT ORGANIZATIONAL CHARACTERISTICS

As with other safety models, a culture of innovation, exploration, and continual improvement are key organizational factors for safe EHR use. Organizations should actively facilitate reporting of errors or barriers to care resulting from EHR use, even if the findings are used only locally. Organizations must also carefully review their existing policies and procedures before implementation. For instance, although EHR systems can improve transmission of critical information through electronic notifications, this may do more harm than good if there are no policies for appropriate follow-up. [9] 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 end users.

1.7 RIGHT STATE AND FEDERAL RULES AND REGULATIONS

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

The American Recovery and Reinvestment Act stipulates that clinicians and health care 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 suboptimal systems. Furthermore, the legislation includes patient privacy provisions, such as access to lists of all third-party data disclosures that will require significant modifications to existing systems. Regulations to safeguard patient privacy are clearly important but may also have the greatest unintended consequence on national EHR implementation. Policies must address the safety and effectiveness of health information exchange across organizational boundaries, which may reopen the debate about unique national patient identifiers. Currently used probabilistic patient matching algorithms, used to link patient information from disparate health care organizations, are prone to error, and many matches are never made. We recommend that state and federal governments should create a regulatory environment compatible with widespread use and interoperability, thereby enabling systems to continue evolving while maintaining appropriate safety and privacy oversight.

1.8 RIGHT MONITORING

The creation of the Certification Commission for Health Information Technology is a significant step toward accelerating adoption, but an equally detailed postimplementation usability inspection process is also needed. Several 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. [10] Organizations must continually evaluate the usability and performance of their systems after implementation, reliably measure benefits, and assess potential iatrogenic effects. Furthermore, the federal government should mandate use of a vendor-independent hazard reporting database and a national implementation accreditation test to help ensure that the systems are functioning as designed and are safe to use. The LeapFrog clinical decision support functionality test is an example of how such a test could be constructed.

EHR developers have encountered many roadblocks to achieving safe and effective EHRs for all. Success in the next 10 years will require a coordinated multidisciplinary research and development effort, much like the formation of National Aeronautics and Space Administration following President Kennedy's promise of a moon landing, to bring the best scientists, engineers, and clinicians together to address the problems and challenges in ensuring safe and effective use of EHRs. Efforts must move beyond the lone informatics researcher in an isolated laboratory if the complex interaction of organizational, technical, and cognitive factors that affect the safety of EHRs are to be understood and addressed and without this understanding, any solutions are certain to be far from optimal. Without high-quality, welldesigned, and carefully implemented EHRs, highly reliable, safe health care may never be achieved.

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