Chapter 1
First Do No Harm: An Overview of HIT and Patient Safety

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A 44-year-old patient with pneumonia is ordered an antibiotic at 9 AM to be administered twice a day using the hospital's newly implemented computerized physician order entry system. The software automatically calculates the antibiotic administration time to 8 AM and 8 PM. The patient doesn't receive the first dose till 8 PM–11 h later—because the order was written after 8 AM and computer system knows to trigger only default administration times on the nursing medication administration screen. Neither the physicians nor the nurses had a clear mechanism of knowing this gap in the technology system.

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A nurse is using the bar-coded medication administration system, touted as a safety technology, with a modern wireless scanner and medication cart. While administering and documenting medications on a complex patient who is on nine medications, she hits a "cold spot" in the hospital's wireless network. She has to spend over 15 min to redo the entire work delaying medication administration for other patients and causing her anxiety and frustration.

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Due to high noise levels and "noise fatigue" among staff and patients, an ICU nurse silences the alarm system on a cardiac monitor on an ICU patient. She thought this was a temporary change but the system took it to be a permanent change. Later in the evening, the patient is found deceased in his room. The monitor tracings show that he had a fatal arrhythmia that would have normally alerted the staff for prompt life-saving measures had the alarm not been "silenced."

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A 66-year-old woman, mother of three and grandmother of five, visits her primary care physician with chest symptoms. The physician orders a chest X-ray and CT scan; both reveal a small lung nodule. However, due to integration issues between the radiology system and the electronic health record, the report does not get "filed" into the patient's chart. She is finally diagnosed with advanced untreatable lung cancer 1 year later. The radiologist who interpreted the initial studies said he tried to call the ordering physician but the contact information in the system was not up-to-date and therefore he couldn't reach the referring physician.

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During a busy holiday weekend, with several physicians covering on a medical floor, a patient with low potassium was given potassium both intravenously (IV) and orally (PO) resulting in an overdose. The patient suffered cardiac arrhythmia and expired. The analysis identified that IV and PO orders are available on separate ordering screens, neither of which displays the total potassium dose being administered. Despite months of negotiations, the software vendor hasn't been able to fix the system. In the absence of a technology fix, training has been instituted to alert users to double-check both the IV and PO orders and add up the total dose themselves. This adds to yet another source of frustration and time-crunch for medical staff and residents.

Introduction

Growing concerns about the cost, efficiency, and safety of our health care system [1, 2] have turned national attention on health care information technologies (HIT) such as electronic health records (EHRs) as important foundational solutions to enable the transformation of health care delivery [3]. Over the last several years, a number of countries have made multibillion dollar investments in EHRs to improve quality, safety and efficiency and reduce costs. In the USA, the 2009 American Recovery and Reinvestment bill (ARRA), popularly known as the "stimulus plan" provided for approximately $36 billion in incentive payments to hospitals and office practices for demonstrating "meaningful use" of certified EHRs [4].

As a result, there has been an accelerated adoption of EHRs around the world. In the USA, over 90 % of office practices and hospitals currently use certified EHRs [5]. As of August 2015, almost 545,000 physician practices and hospitals have received approximately $31 billion in incentive payments [6]. In the UK, Australia, the Netherlands, and Germany, close to 90 % of physician practices are reported using EHR technology [7]. As the eminent researcher and policy expert, David Blumenthal, noted, "Information is the lifeblood of modern medicine. Health information technology (HIT) is destined to be its circulatory system [4]."

The EHR can play a transformative role in health care by improving medication safety, making patient health information available at the point of care, facilitating care coordination, optimizing efficiency, and engaging patients and caregivers. A review of the recent literature concluded that 92 % of the published articles on HIT demonstrated net benefit in improving quality and outcomes [8]. HIT demonstrated positive results for efficiency of care, effectiveness of care, patient and provider satisfaction, care process, preventive care, and access to care.

Unintended Consequences and Safety Risks of Health Information Technology

As Everett Rogers might have predicted, this transformative technology also has unintended consequences:

> *No innovation comes without strings attached. The more technologically advanced an innovation, the more likely its introduction will produce many consequences, both anticipated and latent* [9].

In fact, a growing number of research and review articles are raising concerns that poor implementation, workflow integration or design of EHR systems can paradoxically facilitate medication errors [10], increase mortality [11], lead to physician dissatisfaction [12], and adversely impact physician–patient relationship [13]. A number of news stories in print and online media have also reported incidents of HIT leading to serious injuries and death [14].

In 2007, noted informatics researcher Weiner coined the term "e-iatrogenesis" to denote patient harm resulting at least in part from HIT [15]. In his 2010 testimony to Institute of Medicine Committee on Patient Safety and Health Information Technology Public Meeting, Jeffrey Shuren, the Director of Food and Drug Administration (FDA)'s Center for Devices and Radiological Health noted, *"In the past 2 years, we have received 260 reports of HIT-related malfunctions with the potential for patient harm—including 44 reported injuries and 6 reported deaths. Because these reports are purely voluntary, they may represent only the tip of the iceberg in terms of the HIT-related problems that exist."* [16] Further, the ECRI Institute, a widely recognized nonprofit organization has been listing various HIT products among their top 10 technology hazards annually since 2011 [17].

Recognizing the mounting risks of HIT and EHR systems, in 2008, The Joint Commission released a sentinel events alert #42 titled "Safely Implementing Health Information and Converging Technologies" focusing on technology-related adverse events and encouraging health care providers to be alert to the associated safety risks [18]. Of note, a new sentinel events alert #54 was issued in March 2015 which yet again highlights that the HIT-associated risks require our ongoing attention for ensuring patient safety [19].

Besides potential direct safety risks to patients, a number of reports are citing EHRs as contributing to the growing problem of professional dissatisfaction and burnout among physicians. In a joint 2013 report by the American Medical Association and RAND Corporation [12], physicians approved of EHRs in concept and appreciated having better ability to remotely access patient information and improvements in quality of care. However, for many physicians, the current state of EHR technology significantly worsened professional satisfaction in multiple ways. Aspects of current EHRs that were particularly common sources of dissatisfaction included poor usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information, and degradation of clinical documentation. In a more recent 2015 Medscape Physician Lifestyle report, 46 % of all physicians said that they are burned out [20]. The "increased computerization of the practice" was cited as the fourth most significant contributor to physician burnout in the 2015 report, moving up from the ninth place in the 2013 study. Seventy percent of physicians said that EHR technology decreased their face-to-face time with patients, and 57 % noted that it detracted from their ability to see patients. Furthermore, according to a 2014 Physicians Foundation survey, although 85 % of physicians have now implemented an EHR, only 32 % say the technology has improved the practice, and 46 % say the software has detracted from efficiency [21]. It is not only the physicians; patients are also reporting the negative consequences of the intrusion of the computer and EHRs in the exam rooms on physician–patient relationship. In a 2012 article in the Journal of the American Medical Association titled, "Cost of Technology," the physician author shared a story and a drawing by his 7-year-old patient depicting her view of the exam room. The artist, the young patient, is sitting on the exam table with her family around her. The doctor is sitting staring at the computer, his back to the patient— and everyone else [22].

In addition to the unintended consequences in regards to safety risks, questions are also being raised about the promised value of HIT in curbing the cost of health care. A 2005 report by RAND Corporation had projected that the rapid adoption of HIT could save the US health care system $81 billion annually [23]. However, a new analysis 7 years later demonstrated that the conversion to EHRs has failed so far to produce the hoped-for savings in health care costs and has had mixed results, at best, in improving efficiency and patient care. The study found that the results are primarily attributable to the lack of integration between various systems and the poor usability of EHRs [24].

Because of the central role of HIT in the reengineering of the health care delivery system and because so many hospitals and physician offices are rapidly adopting EHRs, it is essential and urgent that we understand HIT's unintended and adverse consequences and their root causes, and implement risk mitigation strategies to ensure that this largely beneficial technology can continue to improve the health of our patients.

The Sociotechnical Context of Health Information Technology

The foundational insight from recent literature is that the EHR is not a technology but rather a system that operates in a larger sociotechnical context [25]. Therefore, the benefits and risks are dependent not only on the software but on the other elements of the sociotechnical system such as clinical workflow and processes, users, hardware, and organizational policies. We can apply the model of sharp-end errors and latent errors to HIT as well [26]. For HIT-related events, let us consider EHR to be at the sharp end of the error; for HIT-related safety risks to take place, there are a host of "latent" sociotechnical factors that are aligned in a Swiss Cheese model [27] to cause an adverse event. We must address the entire system for us to mitigate HIT-related safety risks and to realize the promised benefits of HIT.

Additionally, how users interact with the technology and the usability of the technology itself is a major determinant of the willingness/satisfaction of the users of technology as well as the outcomes. The diametrically opposite worlds of technology and humanity come together every day in countless hospitals and practices: technology—rigid, certain, inflexible, preprogrammed, without emotions or fatigue, oblivious to environment; humanity—emotional, variable, compassionate, subjected to conditions around us. In the words of the New York Times columnist, David Brooks, this is "the bloody cross-roads where technology meets humanity" [28]. This bloody cross-roads is where patients get harmed. The safety of our patients depends on how well we manage this cross-roads and what kind of traffic signals we put there. Unfortunately, much of the current design, development and implementation of HIT have taken place with little regard to these complex human factors.

It is also important to understand that the safety risks posed by HIT are unique as compared to the other types of errors in health care. First, they are opaque to users; it can be very challenging to understand how a particular failure occurred and could potentially be forestalled. Second, HIT systems tend to have a "magnifying" property, wherein, one exchanges a large number of small failures in a paper-based system for a small number of large, potentially catastrophic failures in an electronic system. For example, in a non-electronic system, one pharmacist can make a single transcription error that affects one patient, where a medication dispensing robot with a software glitch can produce hundreds of errors in an hour. Moreover, as different HIT systems get coupled (e.g., when a CPOE system is directly linked to a pharmacy information system and an electronic medication administration record), errors early in the medication process can quickly pass unscrutinized to the patient. Hence, for HIT implementations to be successful, it is essential that we understand not only the technology but also the workflow and the health care workers.

Another important consideration is that currently there is a lack of clarity regarding shared accountability between the vendors (developers of HIT) and users (hospitals, physicians, other clinicians etc.). The users are quick to blame EHRs for inefficient practices and workflows that existed long before the introduction of EHRs. The vendors are reticent to take responsibility for the product due to contractual languages and fear of bad press and litigation; they often point the blame at how

EHRs are implemented or customized by the user or integrated into workflow. To improve safety of EHRs, we need to ensure that there is shared responsibility and transparency in accountability between the developers, implementers and uses of EHRs [29].

Why This Book?

Even though there is incontrovertible evidence of unintended consequences of HIT, many HIT vendors, hospital leaders and IT departments underestimate the potential safety risks of HIT. Worse, when clinicians bring them to the attention of IT department or administrators, they are often disparagingly labeled as "neo-Luddites" or "not with the program" and are admonished to "try harder."

Much of the conversation around unintended consequences of HIT and the need to ensure its safety has been taking place in academic, policy or technology circles. In spite of emerging literature, most front-line clinicians remain unaware of these risks and specific strategies to ensure patient safety in the world of technology-enabled health care. Since the realm of HIT has moved from the world of technology to the world of clinicians, this book is written from the clinical viewpoint. Through the lens of a variety of case studies, this reference book illustrates that HIT/EHR usage is not without risks and provides practical clinically acceptable risk mitigation strategies. The book aims to take the discourse about HIT and patient safety from the policy/research or technology-centric discussion to patient-centric discussion. The unique strength of the book is that these are clinical case scenarios of post-implementation HIT-in-use (in vivo) from the field as opposed to hypothetical "use cases" designed by the developers of systems in early stages of technology development (in vitro).

One of the key recommendations in the Institute of Medicine's landmark report titled *Health IT and Patient Safety: Building Safer Systems for Better Care* is that mechanisms for reporting HIT deaths, serious injuries or unsafe conditions must be established and efforts should be developed to remove barriers to reporting [14]. It is widely acknowledged that adverse event reporting for all patient safety concerns (not just HIT-related) is critical to promoting safer systems. Still studies find that the reporting of events remains low [30]. This is even more applicable to HIT-related events due to a lack of regulatory requirements and reporting mechanisms for such events. By increasing awareness through case studies, and by fostering a dialog among users, this book should facilitate reporting of HIT-related events as reporting mechanisms get clarified.

The book builds the case that these safety risks from HIT are often as a result of usability, work flow integration, information exchange issue and other variables and that it is unproductive to blame the technology itself or the users (mostly clinicians) for those risks or unintended consequences. Since little is available in the literature regarding what actions institutions can take when they encounter HIT-related

adverse events (or adverse events in which HIT plays an important contributory role), the book aims to provide examples of practical solutions that have been used by other organization as risk reduction strategies. A greater understanding of EHR-induced risks and vulnerabilities will help address and mitigate potential safety risks before patient harm occurs. The ultimate goal of the book is to save patients' lives through safer use of health IT.

The Road Ahead

It is worth reiterating that HIT is an essential technology for modern health care; no one can or should argue going back to the world of paper. A recent joint report from the Canadian Patient Safety Institute and Canada Health Infoway "Electronic Health Records and Patient Safety: Future Directions for Canada," expresses this well [31]:

> *"I think if you went back to the early nineteen hundreds and did a controlled clinical trial—or, not clinical but a controlled trial—on the horse versus the car, in the very early days of the car, the horse probably would have won. And if you took a snapshot of those early days and based your future projections on it, you'd say, "Well, let's throw out the car and go with the horse. They're obviously much more reliable." And so on and so forth. But cars got better and people had the vision to realize that and stay with them and improve them to the point where they soon outdistanced the horse."*

The health care reform law of 2010 holds the potential to "bend the cost curve" by implementing innovative programs such as the value-based purchasing, accountable care organizations and patient-centered medical homes. None of these can be accomplished without HIT providing the necessary enabling infrastructure. Given billions of dollars of investments and rapidly accelerating adoption of HIT, there is a tremendous interest among clinicians, policy makers, EHR vendors, researchers, and hospital administrators alike in the evaluation and understanding of its potential benefits and risks. It is my sincere hope and belief that this book will add to the dialog by providing a clinical and patient-centric viewpoint.

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