The Essential Guide for Patient Safety Officers

Second Edition





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Foreword

In reading this second edition of *The Essential Guide for Patient Safety Officers*, I was struck by the progress that we've made in understanding patient safety since the first edition's publication in 2009. The work described in the book reveals growing insight into the complex task of taking care of patients safely as an intrinsic, inseparable part of quality care. To do this we need to create a systematic, integrated approach, and this book shows us how to do it.

This new approach not only addresses our own desires to do the best we can for our patients but also reflects the influence of external forces such as demands for greater transparency and accountability. The impact of health care reform through the Patient Protection and Affordable Care Act¹ on health care providers is far-reaching, including increasing emphasis on the following:

• Quality metrics—to enable payers (the government, employers, and patients) to identify hospitals and other health care organizations that are providing the best outcomes and safest environments for care.

• The patient's experience—as the government's hospital Value-Based Purchasing program links a portion of the hospitals' CMS (Centers for Medicare & Medicaid Services) payments to performance on the 27-item HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems].^{2,3} Safety certainly influences patients' perceptions.

• Cost control and efficiency—which are critical for the well-being of health care providers, the overall health care system, and, indeed, the entire economy. For example, providers can receive incentives from government programs such as the Medicare EHR (electronic health record) Incentive Program (including the meaningful use criteria),⁴ which motivates medical centers to use EHRs that improve efficiency, accuracy, and safety.

This book outlines several crucial elements of safe care delivery. One is the full engagement of health care leadership in improving patient safety. Organizations emphasize and pursue what leaders, by their example, believe is important. Executive management must lead and be seen to lead improvement work, and this naturally includes patient safety improvement. As a CEO myself, I can attest to the truth of this. And, as Chapter 1 points out, leaders must not only lead the effort, they must "learn that the science of reliability is essential to their role. They must understand and accept the science behind this work and expect others including other leaders, physicians, and staff on the front line—to learn about it."^(p. 3)

Physician leadership is an important part of leadership commitment. An organization that reforms around physicians but does not make them a part of the team will not succeed in the long run. As Chapter 1 reminds us, organizations with stronger physician leadership have been shown to be more successful in delivering change.

This book points out that a culture of safety is not a culture that seeks to blame individuals when things go wrong. Humans are not individually capable of the sustained awareness and attention required for perfect patient safety. On the other hand, as Chapter 10 tells us, the human factor is crucial to a successful system. The human operator is the "one system component that has the capability to resolve the unanticipated forms of failure that emerge in complex systems."^(p. 111)

Technology alone is not the answer but is a crucial part of the systems we need to develop. Achieving the promised benefit, while avoiding the risks inherent in health information technology (HIT), will require us to integrate our use of technology into "human factors, cognitive engineering, and the team-based concept to have maximum effect. Applying HIT to the most complex human endeavor of health care will require the development of new approaches for the design, development, implementation, and optimization of the overall system of care, not just information technology."^(p. 113)

The effective team is a central aspect of safe care, complementing and using technology intelligently. The very diversity of education, outlook, and experience found on teams that communicate effectively (which is so important to collaboration—Chapter 6) is their strength. Each member will see things a bit differently; together they will see the whole.

As discussed in Chapter 9, sometimes overlooked in the movement to create teams are patients and families, who make good partners in the care delivery process. Their insights and experience add invaluable knowledge to our improvement efforts. Patients and families are increasingly well informed and want be involved in care decisions. They also have the right to understandable information, not only about their care and treatment, but also about outcomes and results. We don't yet have a simple way to provide meaningful comparative data, but, as stated, such transparency is part of the reform effort.

When an adverse event occurs or is only narrowly averted, we must be straightforward in disclosing it to all concerned. Disclosure is the right thing to do—and can be viewed as another way to engage patients and their families in care (Chapter 8). It helps begin the coping process, it greatly helps in identifying and repairing systems issues that led to the event, and it may actually improve public perception of the organization.

I am pleased that Chapter 12 covers two improvement approaches, both developed in industry—the Model for Improvement and Lean, which has been gaining ground in health care more recently.⁵ The chapter provides a good overview of how Lean improvement efforts work. We have been taking the Lean approach, based on the Toyota Production System, since 2002; we call it the Virginia Mason Production System.

Now, all our collective efforts to improve patient safety will fail if we don't recognize that this endeavor entails remaking and transforming health care as we know it. That means rethinking our assumptions and accepted truths, attitudes, and practices. Keeping patients safe is a leading indicator of how we are doing in this transformative work.

> —Gary S. Kaplan, MD Chairman and Chief Executive Officer, Virginia Mason Medical Center, Seattle

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Introduction

CREATING A ROAD MAP FOR PATIENT SAFETY

Michael Leonard, MD; Allan Frankel, MD; Frank Federico, RPh; Karen Frush, BSN, MD; Carol Haraden, PhD

Anna Rodriguez—a 27-year-old mother of young twins enters a preeminent teaching hospital for arthroscopic knee surgery on a Tuesday morning after a holiday weekend. The surgery department has a full schedule, with both elective and emergency surgeries scheduled.

Eileen Page, a registered nurse and 20-year veteran of the hospital, preps Ms. Rodriguez in the preoperative area. Per the organization's protocol, Ms. Rodriguez is supposed to receive prophylactic antibiotics one hour before her surgery. Because it is approaching 45 minutes before Ms. Rodriguez's scheduled surgical start time, Ms. Page is in a hurry to give the preoperative antibiotics. Busy with another patient as well, Ms. Page has dozens of procedural steps she must perform to ready both patients for surgery, and she inadvertently overlooks checking the medical record for allergies. Unfortunately, Ms. Rodriguez is allergic to certain antibiotics, including the ones that Ms. Page is about to administer. Buried in the many pages of the medical record is a note about a significant systemic reaction to antibiotics, but no one has noted Ms. Rodriguez's allergies in a prominent place where Ms. Page could easily be reminded.

Because she is in a hurry, Ms. Page tries quickly to explain to Ms. Rodriguez what she is doing. Ms. Rodriguez is from Venezuela and does not speak English well. Ms. Page does not speak Spanish, so communication is sketchy at best. The Spanish-speaking nurse on staff is busy attending to another patient, and Ms. Page is trying to move Ms. Rodriguez quickly into surgery so the surgery schedule will not be delayed. Organization leadership has repeatedly stressed to frontline staff the importance of adhering to the surgery schedule—cases must start on time. In fact, management closely tracks the percentage of cases that start on time and continually pushes to improve it.

As Ms. Page begins to administer the antibiotics, Ms. Rodriguez becomes agitated because of her lack of ability to communicate clearly. Although Ms. Page notices the agitation, she assumes Ms. Rodriguez is just nervous before her surgery.

Approximately 45 minutes after receiving the antibiotics, Ms. Rodriguez is brought into the operating room (OR). The surgeon is anxious to get started and curtly calls the OR team together to begin surgery. As the surgery begins, the OR staff notices that Ms. Rodriguez's vital signs are abnormal, and she appears to be in respiratory distress. The team is unclear as to what is happening. The surgeon and anesthesiologist work to stabilize the patient while one of the circulating nurses checks the medical record. Ms. Rodriguez suffers cardiovascular collapse and is ultimately resuscitated but suffers significant severe neurologic injury.

After reviewing the medical record, the team realizes the nature of the problem. Ms. Page is devastated. The media swarms onto the campus of the medical center, asking difficult questions, but do not receive what they perceive as satisfactory answers from the leaders of the institution. Clinicians and hospital administrators don't interact with Ms. Rodriguez's family in a way that makes them feel that they understand what happened, so they retain an attorney to represent them. The media stir up public outrage about this tragic mistake. Leadership in the organization begins to look for someone to blame for the incident, and Ms. Page seems like a good candidate.

Eventually, hospital leadership goes before the press and public and commit to eliminating medical errors in their facility and improving safety. They hire a consultant, launch some safety initiatives that target medication errors, and feel confident their work is making a difference. However, the root causes of the event that occurred in the OR are still present in the organization: lack of communication, lack of teamwork, lack of patient involvement, lack of reliable processes, lack of organizational emphasis on safety and reliability, and the inability of the organization to continuously learn from its mistakes. Although the implemented safety initiatives may improve medication safety in the organization for a short time, they serve only as a Band-Aid for a deeper, more long-term problem.

What if this operating room scenario or one like it occurred in your organization? Would the response have been the same? Does your organization and its senior leadership value and commit to a culture of safety? reliable systems? teamwork and communication? Is the accountability system in your organization structured to protect the hardworking nurse like Ms. Page, who inadvertently makes a mistake because of a series of system errors? Or is it designed to identify fault and place blame? Does your organization have a systematic approach to responding and learning when errors occur? Does your organization have an open and honest disclosure process? Are patients involved in their care? Do they have a voice within the organization? If your answer to any of these questions is "no," you are not alone. However, you are also nowhere near where you need to be in providing safe and reliable health care.

ALL WORK AND NOT ENOUGH GAIN

In the United States and elsewhere, hospitals and health systems are struggling to improve quality, reduce the current unacceptable levels of harm, engage physicians in improving safety, and deal with regulatory and operational pressures. For many care systems, the current cost structure and dynamic is not sustainable. Quality and safety are increasingly tied to financial incentives and disincentives. The recent Institute of Medicine (IOM) report, *Best Care at Lower Cost*,¹ notes that more than a decade since the IOM's report *To Err Is Human*,² we have "yet to see the broad improvements in safety, accessibility, quality, or efficiency that the American people need and deserve."^{1(p. ix)}

Recent studies assessing harm and adverse events indicate that roughly one in three hospitalized patients in the United States have something happen to them that you or I wouldn't want to happen to us; with 6% of hospitalized patients being harmed seriously enough to increase their length of stay and go home with a permanent or temporary disability.³ A majority of these events are judged to be avoidable or ameliorable—meaning that the outcome could be changed if the care team was aware quickly and took action to resolve the issue.⁴ Yet it has been estimated that only 14% of adverse events are reported into reporting systems,⁵ which reflects the woeful lack of systems designed to proactively seek near misses and adverse events for learning and improvement. We have also come to appreciate that high levels of harm occur in ambulatory care, particularly in diagnostic errors and adverse medication events. More than 50% of medical malpractice claims stem from outpatient care.⁶

The substantial gap between the kind of care that is often provided and safe and reliable care occurs despite the best intentions and unflagging efforts of skilled, dedicated practitioners and administrators. There have been some successful individual efforts to address the issue of safety, although much of the work has been fragmented, focused on specific areas only, and not sustained beyond the short term.

ADDRESSING THE ROOT OF THE PROBLEM

The primary reason for the lack of progress is that organizations are not addressing the root of the safety problem. Yes, decreasing error is important, but it cannot happen without an environment that supports a systematic approach to creating and maintaining reliable processes and continuous learning. In other words, before an organization can realize sustained improvement, it must commit to designing reliable processes that prevent or mitigate the effects of human error, and establish a culture in which teamwork thrives, people talk about mistakes, and everyone is committed to learning and improvement. When an organization achieves an environment of reliability and continuous learning, then patient safety becomes a property or characteristic of the organization and, by definition, the organization starts to reduce errors.

MAKING SAFETY AN ORGANIZATIONWIDE IMPERATIVE

So how do you achieve an environment in which reliable processes exist and continuous learning is an intrinsic value? It doesn't happen by just telling employees to try harder to be safe. It requires a systematic approach that addresses the fundamental ways in which providers interact and provide care. Such a systematic approach involves four critical components⁷:

1. A strategy, which focuses on reliability and continuous learning. This strategy represents an organization's basic values and vision as well as its goals.

2. A structure, which consistently supports the strategy and helps integrate it into the accepted way of doing business. Such a structure builds the appropriate framework, designates the appropriate resources, and defines the reporting relationships that effectively support the strategy.

3. An environment or culture that supports the structure and ensures the proper execution of deliverable outcomes to meet strategic objectives, such as reduced error and enhanced patient safety

4. Clear outcomes and associated metrics that are visible, both internally to the people doing the work and externally to the market and the public. These outcomes and metrics help drive consistent improvement within the organization.

A ROAD MAP FOR SUCCESS

The Essential Guide for Patient Safety Officers provides a road map to enable health care organizations to create the necessary strategy, structure, environment, and metrics to improve the safety and reliability of the care they provide. On the basis of the Institute for Healthcare Improvement's Patient Safety Executive Development Program—a synthesis of patient safety experts' collective experience—and our experience and that of the other contributors, each chapter focuses on a different stop along the map, as follows:

• The Role of Leadership—Effective leadership is critically important at all levels of a health care organization. High-performing organizations teach, embed, and reinforce effective leadership behaviors. It is also essential to have systematic processes that support dialogue, learning, and improvement between frontline providers and senior leadership.

• Assessing and Improving Safety Culture—Safety culture provides valuable insights as to what it feels like to be a unit secretary, nurse, physician, or other caregiver at a clinical unit level. Feeling valued and having the psychological safety to speak up and voice concerns and learn from errors all have a tremendous impact on the quality of care and the social dynamic among caregivers. Safety culture is measurable and can be deployed as a powerful mechanism to engage caregivers in positive behavioral change.

• Accountability and the Reality of the Human Condition—Error and avoidable harm are prevalent in health care today, and fear of blame and punishment is a major obstacle to learning and improvement. High-performance organizations are characterized by fairness and high degrees of accountability. Applying a consistent and fair algorithm to evaluate errors and adverse events that is reinforced by senior leaders is essential for learning and improving care.

• Reliability and Resilience—Consistent, measurable processes of care delivery are foundational to achieving the desired process and outcome measures. Habitually excellent organizations do the basics very well, which provides a foundation for innovation and learning. High degrees of variation, in which clinicians "do it their way" without transparent metrics, leads to inconsistent care and high rates of harm.

• Systemic Flow of Information—Few health care organizations have built process to support robust dialogue between the wisdom of bedside caregivers and senior leaders who are trying to navigate a complex operating environment. Clinicians experience basic system failures every day that are frustrating and wasteful and that get in the way of optimal care. Capturing and acting on these insights drives better care, improves efficiency, and builds organizational trust.

• Effective Teamwork and Communication— Progressively more and more literature is now showing that effective teams deliver better care, to the benefit of not just patients but caregivers. Building teamwork across an organization is intentional work, not just a project, making the difference between sustainable value and "flavor of the month."

• Using Direct Observation and Feedback to Monitor Team Performance—There is a robust science used in numerous industries to observe performance and the associated team behaviors, and provide feedback for learning and improvement. Observation and feedback have been used quite effectively in medical simulation and clinical care environments to provide insights that help drive better care.

• Disclosure—In the aftermath of patient harm or unintended consequences, patients and providers need to be able to talk openly and honestly. This is a learned skill; fear of looking incompetent or getting in trouble often precludes dialogue that is both candid and respectful. Open, honest disclosure needs to be an organizational priority.

• Ensuring Patient Involvement and Family Engagement—We are learning more and more about the benefits of delivering care that is truly centered on the patient and family. Organizations that engage the voice of the patient, listen and learn and incorporate these insights into continually improving the care process will not only deliver better care but are more likely to be successful in a rapidly changing health care environment.

• Using Technology to Enhance Safety—Health care is a sociotechnical process, with skilled humans continually interacting with technology and information systems. Technology can deliver much value if carefully assessed, implemented, and monitored, but if not, technology can negatively affect work flow and increase the risk of patient harm.

• Measurement Strategies—Improvement requires measurement and continuous learning associated with specific skills that are teachable and must be embedded throughout the organization. Measurement strategies are an essential, foundational component for the delivery of safe and reliable care.

• Care Process Improvement—A sample of the many practical methodologies that have been successfully applied within health care to drive improvement and positive change is provided. Key to all are the studying of the process targeted for improvement, the identification of areas of risk and waste, and the determination of opportunities for improvement.

• Building and Sustaining a Learning System—Caring for patients is an extremely complex process, as reflected by the many interrelated topics addressed in this book. A practical framework is essential to support a systematic approach to increasing the quality and safety of patient care. In the absence of such a framework, it is not possible to sustain continual learning and improvement. Successful safety work is not a series of projects but the integration of work so that it is visible, measurable, and sustainable. That is the overall aim of this book.

SUMMARY

This book is designed to help anyone in an organization improve the safety of care provided to patients—from the patient safety officer (or other senior leader) to frontline staff who are charged with improving the provision of care. It details the critical steps involved in enhancing patient safety throughout an organization and ensuring the reliability of care. A full reading gives a clear understanding of what is involved in creating and sustaining a culture of safe and reliable care. You will be armed with tips and tools from other organizations that have engaged in these efforts to apply to your own organization.

Some of the concepts discussed within this book may seem simple in theory, but they can be quite challenging to implement, and dependent on organizational support and a strategic approach to improvement. It takes a commitment from all levels to systematically drive this work and achieve success. By incorporating the different elements discussed in this book into everyday work, organizations can continuously improve, enhance, and achieve patient safety.

The editors acknowledge their colleagues who continue to teach us and advance their understanding of safe care delivery; Richard Bohmer, Donald Kennerly, Gary Kaplan, Aileen Killen, Lucian Leape, Tami Minnier, Paul Preston, Bob Wachter, and Michael Woods deserve special mention. The editors thank Steve Berman, Jane Roessner, and Kathleen B. Vega for their assistance in the development and writing of this book.

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Chapter Ten

Using Technology to Enhance Safety

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istorically, information technology has been used in health care almost exclusively for financial and administrative activities. This is no longer the case. In the United States, the Health Information Technology for Economic and Clinical Health (HITECH) Act-federal legislation that is part of the American Recovery and Reinvestment Act (ARRA) of 2009-offers nearly \$30 billion in financial incentives for hospitals and practitioners to adopt certified electronic health records (EHRs) and use them in meaningful ways.¹⁻³ This legislation has spurred wide adoption of health information technology (HIT) in actual patient care across the continuum,¹⁻³ which has clearly begun to influence patient safety. With respect to the Institute of Medicine (IOM), for virtually all its patient safety reports in the last 15 years, information technology has been viewed as key to safer patient care, and, in its 2011 report Health IT and Patient Safety: Building Safer Systems for Safer Care, is now front and center.1 In this chapter, we review the current state of HIT as it relates to health care delivery and discuss how HIT can and will be used to both measure and improve patient safety.4

CURRENT STATE OF HEALTH CARE INFORMATION TECHNOLOGY Diversity of Definitions of HIT

Traditionally, HIT was viewed as consisting of electronic health records (EHRs; also termed *electronic medical records*) systems in hospitals or clinics, and the increased adoption of HIT during the last five years has been largely in EHRs in those settings and elsewhere across the continuum of care. However, many other aspects of health care have also been the focus of automation, including billing and claim systems; radiology systems; communication systems; and medical devices, such as monitors and remote monitoring sensors. For the purpose of this chapter, HIT is defined broadly, as in the 2011 IOM report,¹ to include any system that facilitates patient care across the continuum—EHR systems; patient engagement tools such as remote monitoring or personal health records (PHRs), which allow patients access to their medical record information; and Health Information Exchange (HIE) systems and their spin-offs but not regulated medical devices, such as intravenous pumps or ventilators.

Health Information Technology Adoption

Adoption of all forms of HIT has grown significantly during the last 10 years in the United States, with the greatest growth in EHRs. Most hospitals now have a basic EHR system, as do more than 50% of physician practices, reflecting the influence of federal incentives.2-3 In addition, HIEs-entities that facilitate the exchange of patient information between health care organizations (and that did not exist 20 years ago)-are now commonplace in many large metropolitan areas. Although the lack of a clear business case has made many HIEs dependent on grants or subsidies,^{2,3} they have become a major presence in health care, allowing for patient information to be widely shared among a panoply of providers and providing the infrastructure needed to support the medical home concept and many functions of accountable care organizations. Both public and private HIEs exist and will be a key part of patient care during the years to come.

PHRs were introduced almost 10 years ago with great fanfare, but many leading PHR vendors have subsequently left the marketplace. Although the future role of stand-alone PHRs remains unclear, PHRs linked to EHRs are commonplace and growing. The use of other patient engagement tools, such as remote patient monitoring systems and patient portals, is also increasing, and such tools may have a far greater impact than stand-alone PHR systems.¹

HIT and Meaningful Use

The HITECH Act's financial incentives have attracted significant interest on the part of hospitals, most of which appear to be planning to meet the relevant criteria for the incentives, which, for a 250-bed hospital, for example, can amount to millions of dollars. The incentives for practitioners, which can total more than \$40,000, have also attracted much interest. Although actual official meaningful use attestment remains low, it is growing rapidly on the part of hospitals and practitioners.¹⁻³ The meaningful use incentives have been broken into three stages over multiple years, with the criteria for the first phase finalized and those for the second stage recently finalized; criteria for the third stage remain to be elucidated.³ Many of the criteria in the first two stages are driven by patient safety improvement goals, such as those related to the use of computerized provider order entry (CPOE), medication reconciliation, decision support, exchange of clinical information, and the tracking of patient safety and quality metrics. EHR vendors have enhanced their products to meet meaningful use criteria and achieve meaningful use certification, which is required for hospitals or practitioners to attest with a vendor product that is officially certified.¹

HIT National Data Standards

One of the challenges in improving safety with EHRs is achieving the interoperability of HIT systems necessary for the free flow of critical patient information. To facilitate this goal, previous IOM reports have called for the national adoption of HIT standards—including those addressing the laboratory, such as Logical Observation Identifiers Names and Codes (LOINC[®]); imaging, such as Digital Imaging and Communications in Medicine (DICOM); vocabulary, such as RX Norm; and disease classifications, such as Systematized Nomenclature of Medicine—Clinical Terms (SNOMED Clinical Terms[®]).⁵ Meaningful use certification requires that vendors adopt these standards or risk being decertified.⁵ In terms of patient safety, a similar movement is forthcoming as part of the Patient Safety Organization legislation allowing for standard patient safety classifications using Agency for Healthcare Research and Quality common formats. These formats have been developed with specific HIT specifications to enable the automation of this content in electronic systems.^{6,7} These patient safety classifications will form the basis for initial patient safety standards within HIT.⁷

LOOKING FORWARD: PATIENT SAFETY AND HIT—THE IOM REPORT

The first part of Health IT and Patient Safety1 outlines the current state of patient safety more than 12 years after the landmark IOM report To Err Is Human, which stated that as many as 98,000 patients may die every year in hospitals in the United States from patient safety problems.⁸ As cited in the 2011 IOM report,1 an Office of the Inspector General study of hospitalized Medicare patients suggests that as many as 180,000 hospitalized Medicare patients may die every year as a result of hospital-acquired adverse events.9 This estimate does not include the non-Medicare hospital populations, so the true number of hospital-related deaths from patient safety problems may be as high as several hundred thousand per year. This sets a new level of harm in the health care system, despite more than a decade of work to improve patient safety. In the setting of this new level of harm in the system, the increased efforts to improve patient safety will increasingly involve technology, with increasingly rapid HIT adoption changing the landscape of health care.1

HIT–Caused Harm

Given these new harm estimates, the need for HIT that actually improves the safety of care is great, but with the greater visibility of HIT associated with large financial incentives, the risk of catastrophic HIT accidents also looms large. The first rule of health care is do no harm. The 2011 IOM report outlines several incidents in which HIT has directly lead to patient injury or death. However, it underlines the reality that most safety tracking systems underreport safety problems in general, and HIT safety problems in particular, so that the true incidence of HIT safety issues is unknown. In addition, many HIT vendors have contractual limitations that prevent users from publicly sharing safety problems, and there is no effective government safety tracking system for this largely unregulated industry.¹

HIT–Reduced Harm

Many of the reports advocating the HITECH Act and the associated meaningful use criteria based their approach on previously published studies outlining the safety benefits of HIT. However, many of those studies come from health care organizations with internally developed ("home-grown") HIT systems rather than the commercial HIT systems that are now in widespread use. On balance, the 2011 IOM report says that the benefits of HIT are best demonstrated in medication safety but poorly demonstrated in other areas of safety, with competing conclusions from various studies. Moreover, HIT can play a key role in improving the detection of all safety problems and not just those safety issues related to HIT.¹

CHALLENGES IN IMPROVING SAFETY WITH HIT

One of the challenges in improving safety with HIT is that the few studies performed that have measured the safety of HIT systems in actual routine operation have found large deficiencies in critical safety checks for medication safety alone, which is usually the most sophisticated patient safety intervention in most EHR systems.¹⁰ As the report explains, this is not unexpected, in that other industries have learned that complex systems continually test and refine operation systems to improve safety performance, as well as build human factors and cognitive engineering concepts into the systems from ground zero. This has not been accomplished in most HIT systems to date but will need to be present in future systems.¹

Patient and Family Utilization of HIT

Patient-/family-centered care, which reflects the belief that health care providers and families are partners, working together to best meet the needs of patients and the patients' families, is heavily emphasized in the IOM report as a critical requirement to improve the safety of care.¹ One goal of the EHR incentive program for meaningful use is the engagement of patients and their families in patients' health care. This policy aims to improve patients' understanding of their health and related conditions so they take a more active role in their health care. It also encourages the involvement of patients' families, on whom many patients depend for support. The use of certified EHR technologies can assist in making health information more readily available to both families and providers. Meaningful use of EHRs will also enable providers to involve patients and their families in more informed decision-making while promoting patients' management of their own health.¹

Excellence in health care happens when providers and patients and their families work together and honor the expertise that everyone brings to every health encounter. Patient-/family-centered care represents a continual effort to be responsive to the needs and choices of each family, and meaningful use criteria are intended to help support the relevant information sharing necessary to make appropriate health care decisions.

How can meaningful use affect patient-centeredness and engagement? A key focus of meaningful use is interoperability. It is believed that its standards and requirements will help ensure a common language to allow for accurate and secure health information exchange among providers and families. Informed and educated patients and their families can take a more active role in health care decision making, especially when having to choose among multiple treatment options. Having access to information, education materials, and other tools can help patients and their families participate in treatment decisions with providers. In addition, having patients more involved can have a substantial impact on their overall health, especially as it relates to chronic diseases such as diabetes and asthma that require self-management.¹

Better use of health care resources is an additional benefit of patient-centered care supported by meaningful use, as represented, for example, by a patient with cancer who needs to see multiple care providers before receiving treatment. Electronic access to medical records, laboratory tests, procedures, and x-rays can reduce the need for redundant testing or procedures and eliminate the need for patients and their families to carry around (and possibly lose) important health records and documentation. Meaningful use, which is intended to help measurably improve quality, safety, and the cost of health care, in the context of patients and families with access to data, knowledge, and tools to make informed decisions and to manage their health.¹

HEALTH CARE IS A SOCIOTECHNICAL ENDEAVOR

On the basis of the concepts presented in the previous section, the 2011 IOM report outlined a series of steps to

increase the transparency of HIT vendor performance and called for HIT vendors to adopt quality management processes. Reporting of safety problems, with a focus on both voluntary reporting and surveillance, was a key part of the report. Drawing from aviation, the report recommended a National Transportation Safety Board–like approach to collect, analyze, and investigate patient safety problems related to HIT, something quite unusual for health care. Finally, it called for Food and Drug Administration (FDA) regulation of HIT if industry selfregulation fails to improve HIT safety.¹

The IOM report also recommended a new conceptual framework for understanding and managing HIT and patient safety—the Sociotechnical System Model. The diversity of roles, tasks, and process interdependencies among people, environments, and technologies mark health care systems as socially and technologically complex; they are complex *sociotechnical systems*. Health care systems may also be characterized as "high-consequence," given that they carry the risk of harm to patients and care providers in event of failure.¹¹ The continuing occurrence of high levels of patient harm, as discussed earlier, suggests that common approaches to the improvement and measurement of patient safety are not yet sufficient to move health care systems from "low reliability" to "high reliability."

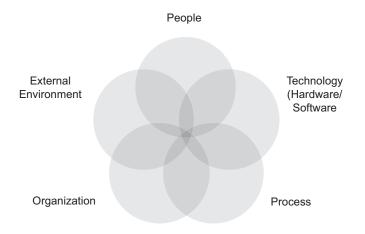
The Sociotechnical System Model is depicted in Figure 10-1 (at right).

As described in the IOM report, the components of the Sociotechnical Model are as follows:

Technology includes the hardware and software of HIT, which are organized and developed under an architecture that specifies and delivers the functionality required from different parts of HIT, as well as how these different parts interact with each other. From the perspective of health professionals, technology can also include more clinically based information (for example, order sets), although technologists regard order sets as the responsibility of clinical experts.

People relates to individuals working within the entire sociotechnical system, including their knowledge and skills regarding both clinical work and technology. It also includes their cognitive capabilities, such as memory, inferential strategies, and knowledge. In addition to these individual aspects, the "people" component encompasses the implementation teams that configure and support the technology and those who train clinical users. Technology has an impact

Figure 10-1. Sociotechnical System Underlying HIT-Related Adverse Events



Source: Committee on Patient Safety and *Health Information Technology, Institute of Medicine. Health IT and Patient Safety: Building Safer Systems for Better Care.* Washington, DC: National Academies Press, 2012. [Adapted from Harrington L, Kennerly D, Johnson C. Safety issues related to the electronic medical record (EMR): Synthesis of the literature from the last decade, 2000–2009. *J Healthc Manag.* 2011;56(1):31–44; Sittig DF, Singh H. Eight rights of safe electronic health record use. *JAMA.* 2009 Sep 9;302(10): 1111–1113; Walker JM, et al. EHR safety: The way forward to safe and effective systems. *J Am Med Inform Assoc.* 2008;15(3):272–277.] Reprinted with permission.

on people; for example, the use of HIT may affect clinician cognition by changing and shaping how clinicians obtain, organize, and analyze information. The way that health care information and data are organized influences the way people solve problems. The scope and nature of clinicians' interactions with technology and with each other in a technology-mediated fashion are very likely to affect clinical outcomes.

Process (sometimes referred to as *work flow*) refers to the normative set of actions and procedures that clinicians are expected to perform during the course of delivering health care. Many of the procedures clinicians use to interact with the technology are prescribed, either formally in documentation (for example, a user's manual, policies and procedures) or informally by the norms and practices of the work environment immediately surrounding the individual. *Process* also includes such tasks as patient scheduling, refilling prescriptions, or ordering diagnostic testing.

Organization refers to organizational decisions relating to technology, including HIT installation, configuration choices, and interfaces with other HIT products. In addition, organizations choose clinical content to be used in HIT. These choices reflect the organization's goals, such as maximizing use of expensive diagnostic equipment, remaining competitive with other health care facilities, and minimizing costs. Of particular relevance is the organization's role in promoting the safety of patient care while maximizing effectiveness and efficiency. Organization also includes the internal rules and regulations set by individual institutions, such as hospital policies and procedures that clinicians must follow. In addition, it encompasses the environment in which clinicians work. In many institutions, the environment of care is chaotic and unpredictable-with clinicians frequently interrupted in the course of their day and subject to multiple distractions from patients, coworkers, and others.

External environment refers to the outside influences that affect the way in which health care organizations operate. Federal, state, and private-sector entities (such as accreditation organizations and third-party payers) establish rules and regulations that dictate how health care organizations and providers operate. For example, health care organizations are required to publicly report on predetermined measures of quality, including errors made in the course of providing care, failure to follow established standards of care, and rates of infections.

COMPONENT-CENTERED VERSUS SYSTEM-BASED SAFETY MANAGEMENT

Findings from research across high-consequence industries suggest that poor progress made in the improvement of patient safety may be due, in substantial part, to the approach to safety management employed by health care organizations.¹² Typically, patient safety improvement strategies focus on enhancing the reliability of components of health care delivery systems. For example, checklists may enhance the reliability of task preparation and performance, wrist bands may remind staff of certain patient conditions/risks, smart infusion pumps may help prevent inappropriate dosing of medication, failure mode and effects analysis may be applied for the improvement of a patient care process, or the layout of a clinical unit may be designed with the intention of enhancing communication and coor-

dination. Although such efforts to create high-reliability organizations that ensure the reliable performance of people, technologies, and processes are necessary, a focus on individual system components does not adequately support the organization in detecting, identifying, and mitigating unanticipated adverse effects stemming from *component interactions*. The case in Sidebar 10-1 (*see* page 108) underscores the IOM's call for an approach to safety assessment and risk mitigation that illuminates the emergent effects of interaction among people, technology, processes, organization, and environment.

As described in Sidebar 10-1, implementation of HIT in an emergency department (ED) altered communication and coordination, undermining the quality and safety of patient care and incurring significant inefficiency. Conducting a study of human, process, technological, environmental, and organizational component interactions in the unit to be served by HIT, which can help identify and mitigate potential adverse HIT implementation effects, is necessary in advance of both selection and implementation.13 Postimplementation surveillance and investigation of unintended effects on system performance are also needed. The problems illustrated by the case in Sidebar 10-1 might not have been addressed as quickly if patient satisfaction scores had not garnered the attention of the CEO. Before the "all hands" meeting, a growing collection of patient complaints and a handful of safety reports caught the attention of the quality, patient safety, and risk management offices (these were considered separate, rather than integrated, functions). The investigation of the patient complaints led to a recommendation for a refresher on a [theme park-based] training program on customer service, and new posters were tacked up in the staff break room promoting "Excellence in Patient Care." Investigation of the safety reports led to the finding that nurses were not responding to physicians' orders on a timely basis-without considering why this might be. This resulted in the requirement that nurses receive reeducation on nursing policy and procedure, and the ED nurse supervisor was also advised to counsel nurses identified in incident reports regarding their performance and to set improvement goals. In effect, this initiated a progressive disciplinary process. None of these actions addressed the underlying conditions for failure that emerged from the interaction of clinical personnel, unitlevel organization, the clinical environment, and extant care

Sidebar 10-1. Case: Communication and Coordination Deficit Introduced with the Implementation of Health Information Technology

We implemented [an information technology system] in our emergency department (ED). Within a few weeks of implementation the climate of our ED had changed; the physicians were complaining that nurses weren't on top of their orders. And nurses and technicians were complaining that doctors weren't communicating their orders and intentions with them anymore. Our patient satisfaction went into the hopper because of delays and suboptimal care. This got the CEO's attention because his pay is linked to patient satisfaction. We had an urgent 'all hands' ED meeting to figure out how we had gotten in such a mess and what we needed to do to get patient satisfaction scores up.

It turns out that we all thought we could see each other's notes in the computer, but we couldn't. Information that

processes with the new HIT system. Rather, the focus was on people; specifically, the ways in which nurses were not complying with policy and procedure. Interaction with the new information technology in the clinical context was not considered.

The foregoing case raises a number of questions, beginning with "How can hospitals better implement and monitor information technology?" Assessment of sociotechnical systems, using, for example, ethnography and cognitive work analysis methods, before selecting and implementing information technology can reveal process constraints, information requirements, and goal conflicts and the tacit strategies employed by clinicians to manage them. Aside from illuminating opportunities for immediate improvement, these insights are useful in considering how a candidate information technology may fit into the work flow and how it may serve the information requirements of clinicians. Moreover, after a technology is selected, a better-informed implementation strategy becomes possible, and the same methods used for the initial assessment may be applied to monitor for the emergence of unintended/unanticipated effects of the information technology implementation.

The case also shows how safety or failure in complex systems may be thought of as an "emergent" system property insofar as it stems from interdependencies, interrelationships, and interactions among the components of the system rather than from the failure of a single element.¹³ These components routinely interact not only across levels and units used to be said out loud was no longer spoken, just entered into the computer. We used to depend on hearing orders and updates—even if we just overheard—to anticipate patients' needs and coordinate our work. It was a big part how each of us knew what was going on and could backup each other and the care processes.

Ironically, [the HIT vendor] marketed the system by asserting that it would improve coordination, efficiency, and patient safety in the ED! We're still trying to figure out how to make the information system work for us. For now, we are making sure to verbally communicate everything we enter into the computer. It's inefficient, but necessary.

Source: Jeffrey P. Brown. Used with permission.

within organizations, but in the external environment, across organizations. From a bird's-eye view, these interactions occur across all levels of the health care system in the United States, which may be viewed as a system of systems. This nationwide macro-level encompasses all the medical facilities, regulatory and accreditation entities, regional environments, and regional populations that provide, oversee, contain, or use health care. At the micro-level, a health care delivery system can be thought of as a grouping of people, processes, and technologies organized within a clinical environment to provide care to a specific patient population.¹⁴ Systems and subsystems, from macro-scale to micro-scale, have the same fundamental components-people, technology, organization, process, and environment. "Cross-scale" interactions among these system components are often asynchronous and their effects insidious, going unnoticed for long periods of time. This makes it impossible for individuals, groups, or organizations to anticipate and identify all ways in which their performance may be compromised by the state of distant or otherwise unobservable roles, functions, technologies, and processes. In work domains where personnel cannot directly observe or monitor the processes on which they depend, decisions are made and actions taken with a high degree of uncertainty.

System designers and frontline personnel respond to the risk and uncertainty that is resident in complex systems by attempting to anticipate potential modes of failure and developing safeguards and countermeasures to combat them, such as checklists or smart infusion pumps, as mentioned earlier or alerts and alarms, redundant operational systems, standard operating procedures, and team/crew training. In addition, frontline operators develop tacit rules and practices to work around problematic features of technology, environment, work processes, and individual, group, and organizational dynamics. For example, regarding a failed medication-dispensing unit on an ICU, a nurse stated the following: "The biometric scanner on our [medication-dispensing] unit is not reliable. When we need medications from the [medicationdispensing unit], we usually need them in a hurry. We reported the problem multiple times, got no action, and then gave up. We just run [literally] to the satellite pharmacy rather than take the chance of wasting time."

Such work-arounds emerge as clinicians strive to avoid the failures and/or inefficiencies based on problematic experience. Frontline work-arounds may be seen as a symptom of deeper problems in the system—commonly involving both local and cross-scale component interaction. In this case, multiple influences were implicated in the "normalization" of the nurses' work-around, including maintenance requests that did not convey urgency; a staffing reduction in the biomedical engineering department, which delayed response to maintenance requests; and an organizational and professional culture that held personnel accountable for getting things done with the resources at hand.

Although work-arounds make it possible to accomplish work in the face of constraints, they may also pose risk. As related by an ICU nurse, the nursing staff stopped reporting the unreliable biometric scanner when they perceived that no corrective response was forthcoming and rapidly normalized their work-around. The risk associated with delay in obtaining critical medications, whether due to malfunction of the medication-dispensing unit or having to run to the satellite pharmacy, remained resident and effectively invisible to the organization. An important insight for patient safety officers, illustrated by the case, is that if there are impediments to the communication of risk by frontline personnel and to obtaining rapid organizational response, work-arounds will become "normalized" quickly, rendering them invisible to risk and safety personnel-they will fly "under the radar." Patient safety officers must remain vigilant for signs of change in frontline practice that may signal the emergence of a work-around and the need for risk assessment.

Although the risk associated with some adaptations and work-arounds may not be immediately obvious, the following case, as reported by a physician patient safety executive (Sidebar 10-2, page 110), illustrates how frontline adaptations/work-arounds may quickly manifest as an unsafe, emergent effect of interaction among system components.¹⁰ This case illustrates how changes that are initiated, and perceived as innocuous, at one system level may significantly and unexpectedly compromise functionality and safety at another. The morphine administration process became unworkable in the context of busy, clinical work as a sideeffect of executive decision making. Executive decision making and governance decision making (the impetus for cost-cutting came from the board of directors in this case), clearly can have a direct impact on the safety and quality of clinical care.

A striking feature of this case is the unintended subversion of the safety purposes of bar coding in medication administration technology as a result of changing a single drug from a bar-coded to a non-bar-coded product. Again, technologies cast as safety "solutions" can quickly be undone by unanticipated, cross-scale interactions among system components. The reliability and safety of technology clearly is not all about the design of software and hardware. In health care and other high-risk, high-consequence domains, accidents may be seen as the end product of a cascade of decision side effects that often have their beginnings at the governance and executive levels. It is important for patient safety officers to promote the participation of board members and senior executives in their organization's patient safety committee. In this way, those with authority to redress a safety issue-that has emerged as a side effect of executive decision making-can be directly involved in both the analysis and development of a corrective response.

CONSIDERATIONS FOR SYSTEM-BASED SAFETY MANAGEMENT

Understanding the effects of implementing or altering technology, whether for improvement in the quality and safety of patient care or for other purposes, requires new, research-based approaches to the design, development, implementation, and optimization of systems of care. Pending these advances, a key challenge for patient safety officers is to promote a systembased perspective on safety in their organizations. We now provide some considerations for this purpose.

Sidebar 10-2. Frontline Adaptations/Work-Arounds Can Undermine Patient Safety

Our risk management office advised me that a nurse educator wanted help. Syringes containing morphine were being found in the clinical areas of the hospital. There are laws, policies, and procedures to prevent this, and the nurse educator's effort to stop the problem through education and admonition had no effect. I was very concerned and curious because this was a previously unheard of problem in our organization.

On exploring the issue with the nurse educator, I learned that nurses had begun keeping syringes with morphine solution in their pockets or were putting the syringes down before wasting the excess and then forgetting to come back and finish the wasting process.

I went to the floor and teamed with a nurse to walk through the medication administration process. We looked at a patient's chart, which had an order to administer 4 mg morphine every two hours. We then went to the medication dispenser, a secure box with narcotics and drugs prescribed for the patient for each day. To access the drugs, the nurse entered her identification and opened the dispenser. Inside was a 10 mg ampoule of morphine. The nurse informed me that this was now the only size carried in our pharmacy. It was also the only non-bar-coded medication in our pharmacy. I learned that a decision had been made by the vice president who oversees pharmacy to stop purchasing barcoded doses of morphine and to purchase the 10 mg, non-bar-coded morphine because it's cheaper. There was a big cost-reduction initiative in the organization-although morphine is relatively cheap, so I don't know why it was specifically selected among all other bar-coded medications. Although this change in purchasing might not seem like a big deal, it had significant impact on nursing work processes.

Because nurses do not use 10 mg of morphine at once, they must go to a separate area, draw the needed amount into a syringe, and dilute it to 1 mg per cc. Then they look for a bar code scanner to "tell" it they are going to dose the patient. However, they can't just scan in the information because these morphine vials have no bar code. Nurses have to override the bar code function and enter that they are administering only 4 mg, not 10 mg. Once that's accomplished, they find a handheld scanner and scan the patient's armband to tell the device they are about to administer the morphine and then that it has been delivered. After that, they must find another nurse to witness them dispose of the excess morphine. Finally, they document the patient's response to the injection.

The morphine administration process had become incredibly time consuming, intruding on other patient care needs and responsibilities. Not surprisingly, if a nurse was unable to find another nurse to witness the disposal of excess morphine and a patient needed attention, the syringe would go into his or her pocket, or get put down for disposal later (if remembered). Then nurses just began saving the syringe for the next shot to avoid the entire rigmarole.

The added steps and delays that were introduced by a switch to non-bar-coded morphine undermined the ability of nurses to meet the needs of their patients, complete other duties, and ultimately provoked a hazardous work-around. By the way, we had a shortage of bar code scanners and were dealing with a nursing shortage when the change in morphine purchasing hit. It was a perfect storm of contributing factors.

Source: Adapted from Brown JP. Achieving high reliability: Other industries can help health care's safety transformation. *Journal of Healthcare Risk Management.* 2004;24(2):15–25. Copyright © 2004 John Wiley & Sons. Reproduced with permission of John Wiley & Sons, Inc.

People Are the Core Source of System Resilience and Safety

If work-arounds are a symptom of systemic problems, as has been argued, experience across multiple high-risk domains has also demonstrated that effective management of uncertainty and risk in complex systems hinges on the ability of people to detect anomalies or problems, to identify and make sense of emergent situations, and adapt activity and action to maintain or restore safety and system functionality.¹⁵⁻¹⁷ Although they are rarely characterized this way, a central purpose of training programs aimed at improving clinical team processes is to enhance the ability of small frontline groups to detect, identify, mitigate, and recover from emergent problems. Interprofessional clinical teams, because of their varied expertise and perspectives, have the potential to become very adept at problem detection, analysis, and resolution.^{18–20} The following statement by Weick can help us to understand why:

When technical systems have more variety than a single individual can comprehend, one of the few ways humans can match this variety is by networks and teams of divergent individuals. . . Whether team members differ in occupational specialties, past experience, gender, conceptual skills, or personality may be less crucial than the fact that they do differ and look for different things when they size up a problem. If people look for different things, when their observations are pooled they collectively see more than any one of them alone would see. $^{21(p.\,33)}$

Historically, system engineering has focused on providing technological controls to protect against system failure and thereby match the potential for component failure with a variety of technological safeguards. The human component was viewed as a source of error and failure that must be countered with technology. The "new view" of the human contribution to system reliability is that the human operator is the one system component that has the capability to resolve the unanticipated forms of failure that emerge in complex systems.^{12,22} Identifying design requirements for HIT that will support the clinician in detection and resolution of problems is one factor in enhancing this capability. Another is to organize clinical work to support effective decision making among members of interprofessional frontline teams. Robust team processes support problem detection and resolution, engaging the social element of the sociotechnical system as an adaptive safety mechanism.^{19,} ²³⁻²⁵ Moreover, insight into the functioning and usability of technology throughout its life cycle can be gathered through routine team debriefing processes. Team debriefing, as a routine practice, remains uncommon in health care. Patient safety officers must continue to lead efforts to develop briefing, debriefing, and other evidence-based team processes in their organizations. Team training, alone, will not ensure development of a high-performing interprofessional team. Observing and characterizing existing team processes in a clinical unit, in advance of team training, enables the patient safety officer to understand how existing technologies, environment, organization, and processes may shape improvement efforts by informing customized requirements for training and implementation design. Working across clinical units permits the patient safety officer to observe and spread useful practices across functional areas of the organization.

HIT Is a Sociotechnical System Component, Prey to the Same Interactive Effects as Other System Components

As we have seen, technology can contribute to emergent safety problems through its interaction with other system components. Yet, the mirror statement is also true—the functionality and safety purposes of technology can be compromised through its interaction with other system components. The sociotechnical perspective views the "system" more broadly than one comprised of software, computer-computer, humancomputer, and human-human interaction. Clinicians do not work alone; they working synchronously and asynchronously with human and machine agents. The provision of patient care is knowledge-intensive, and the information needed to support patient care is voluminous, diverse, and highly distributed. Clinicians continuously "push" and "pull" information, and seek and apply knowledge in support of problem solving, sense making, and decision making. HIT can be a useful adjunct to human-human communication/information exchange, as well as for problem detection, identification, and resolution. However, when design requirements for HIT are predicated on behavioral task analysis, focus groups, preference surveys, and other market research methods, they will reflect an insufficient understanding of both cognitive work and the constraints, goal conflicts, and other behavior-shaping forces that are resident in the system yet largely invisible to its human inhabitants. Even when design requirements for information technologies are reasonably well aligned with the needs of the intended users, changes in the system that alter interaction among its components can undermine functionality, usability, and safety at any time.

HIT implementation should be characterized not as a safety solution but a "safety experiment." Design and implementation hypotheses must be tested in clinical use, for each clinical context of use. Failure Mode and Effects Analysis or other prospective risk identification methods alone are insufficient; implementation of HIT must be accompanied by heightened awareness and monitoring of the potential impact of the technology on overall system functionality, and vice versa. Because the effects of interaction among system components change over time, lasting functionality and system safety can never be assumed. Developing the health care organization's ability to better detect and mitigate emergent risk and safety problems—and to learn from frontline experience—requires significant improvement in system safety surveillance and investigative processes.

Robust Safety Surveillance and Investigation Are the Foundation of Effective Safety Interventions

The challenge of developing effective strategies for assessment of safety in sociotechnical systems is mirrored by the challenge of mitigating risk and improving safety. These challenges exist across high-consequence industries; they are not unique to health care systems. Anticipating all possible forms of failure in complex systems is not possible. The ability to understand failure through postmishap investigation methodologies (root cause analysis, for example) has proven equally problematic; a universal difficulty that derives from efforts to seek an understanding of adverse events or incidents in terms of cause-and-effect relationships.¹¹ As in other domains, the approach and quality of incident- and adverse-event investigation in health care varies widely both within and across organizations. Methods in common use dwell on component failures that are proximal in time and place to the adverse event-most commonly focusing on people. The process of investigation is typically terminated after a plausible/actionable story of causation is "discovered." More accurately, causation is constructed and is influenced by hindsight bias, counterfactual reasoning, fundamental attribution error, and other well-documented analytical vulnerabilities that may impact the integrity of an investigation.²² Postinvestigation corrective measures reflect this focus on broken system components. For example, if a patient falls and the bedside care provider hadn't realized the patient was known (by others) to be at risk of fall, a "fix" may be devised that requires a new color-coded "fall risk" placard be applied to the patient's paperwork-"to ensure that everyone knows." Likewise, if a nurse was found to have been noncompliant with a policy or procedure, say, in operating a pump infusion system, the assumption might be that she or he did not understand the policy and procedure associated with the pump, and the resulting remedy might be reeducation on policy and procedure. These approaches typically pay slight attention to the intersection of system influences that create constraints, drive work-arounds, and create failure-provoking conditions. Issues such as porous information flow across units, cultural barriers to unit-level cooperation, hierarchical barriers to risk communication, maintenance deficiencies, awkward technology, unworkable processes, and imbalance between business goals and risk mitigation may go undetected, remaining resident until their effects combine to "bag" another patient and another provider. Fixes aimed at the people found to be closest in time and space to an incident or adverse event routinely omit attention to the underlying and highly distributed factors and forces that may combine to foil even the most skilled and conscientious personnel.

To develop more effective interventions we need to

better understand the systemic roots of incidents and adverse events. To this end, the 2011 IOM report recommended use of human factors methodologies not only in the design of HIT but in the implementation, and monitoring of the safety status of HIT in clinical use throughout its life cycle.¹

Human Factors/Cognitive Systems Engineering Methods Are Essential to Safety Management in Complex Systems

The term human factors wraps around many disciplines, including sociology, cognitive psychology, engineering, education, and anthropology, among others. Ultimately, the aim of human factors professionals is to aid in designing tools, processes, technologies, organizations, and environments that support safe and effective human performance. A typical understanding of the relevance of human factors to health care is that it is about developing effective team processes to counter the potential for erroneous action or inaction by individuals through more effective decision making, mutual support, and backup among team members. Another view casts human factors as a discipline that supports the development of design requirements to ensure that technologies, such as HIT, are easy to operate, maintain, and train. Both views are reflected in human factors specializations that address components of the system safety puzzle, not the whole. Human factors professionals, and patient safety officers, working on different pieces of the puzzle, require insight into the functioning of the whole to develop appropriate requirements for its components.

A branch of human factors that has arisen specifically to study and support improvement in sociotechnical systems is called cognitive systems engineering (CSE).26 As described earlier, adverse events typically emerge from the unexpected confluence of component interactions, often when people are performing work the way they usually do to achieve their goals safely and reliably. Yet, how people accomplish work is often quite different in practice than as described in policy and procedure manuals. Over time, constraints and goal conflicts arise as changes occur in task design, financial targets, tools, processes, and other performance-shaping features of the organization and clinical environment. The work-arounds that arise as people adapt to these conflicts and constraints are often not known beyond the clinical unit, and an understanding that an action or activity constitutes a work-around is often quickly lost; becoming "how we do things here." As illustrated by the bar-coding case (Sidebar 10-2), work-arounds and deviations from expected practice may be seen as a manifestation of systemic problems emerging from local and/or cross-scale system interactions. As such, they are useful markers—illuminating points of entry for the investigation of actual work culture, structure, and processes, much as medical contrast media make internal structures of the human body visible, enabling and guiding closer examination. CSE professionals look for these markers in assessing the effectiveness and adaptive capacity of sociotechnical systems and in identifying design requirements for system components.

MAXIMIZING THE BENEFITS OF HIT

Given the sociotechnical system perspective, as we have outlined, and the IOM report's recommendations, what can health care organizations do to begin to operationalize this new approach to HIT? Clearly, HIT offers significant potential for improvement in quality, safety, and efficiency. Bates and Kuperman suggest, for example, that EHRs can provide clinicians more timely data access for decision making than paper-based systems and can also organize the data in a way that effectively supports decision making.⁴ Similarly, technology can ensure legibility, completeness, and rapid communication with ancillary departments. EHRs in particular can provide clinical decision support, which paper-based medical record systems cannot. Such support may foster standardization, real-time data checking, flags for critical test results, and links to further information and research.27

Some of the specific technologies that can improve safety include CPOE; bar coding; smart monitoring, which is monitoring that the computer performs with notification to a provider when appropriate; computerized notification about critical test results; computerized monitoring for adverse drug events; and tracking of abnormal test results.⁴ Although the evidence is strongest for improvement of medication safety, HIT can also be helpful for improving handoffs, ensuring that laboratory results receive appropriate follow-up,¹ and, more broadly, for identifying opportunities for improvement in safety and quality.²⁸

Yet realizing the benefits of HIT entails overcoming many challenges. Patient safety officers should be aware of these challenges and work to overcome them as they begin to leverage HIT for patient safety improvement. The IOM sociotechnical system model provides a view of risk and safety that underscores the need to detect and intervene in the unsafe situations that emerge from unanticipated interaction among system components (people, technology, process, environment, and organization). Although there are many tools and tips for patient safety improvement that focus on the *components* of health care systems, there is no research-based "tool box" for identifying and mitigating emergent events. An ongoing and dynamic learning system is essential in devising ways to continually monitor and improve the safety of these systems, and this will necessitate new approaches to safety reporting, investigations, root cause analysis, and conclusions. Koppel et al. have outlined what such an HIT learning system might look like.²⁹

CONCLUSION

Health care has often lagged in adopting best practices from other industries. This has certainly been the case with information technology, which until recently had been mainly adopted for billing and financial areas of health care. However, with the passage of the ARRA, and particularly, the HITECH section, which offers financial incentives to implement EHRs, health care is now rushing to implement HIT in clinical care. Yet, as the 2011 IOM report on HIT states, achieving benefits and avoiding risk will require a paradigm change in thinking about health care and HIT, which will entail the use of a sociotechnical model. This model speaks to not only the safe implementation of HIT but the optimization of HIT to achieve maximum safety benefit. HIT implementations need to evolve as safety experiments, with consideration of human factors, cognitive engineering, and the team-based concept to have maximum effect. Applying HIT to the most complex human endeavor of health care will require the development of new approaches for the design, development, implementation, and optimization of the overall system of care, not just information technology.

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The Essential Guide for Patient Safety Officers Second Edition

Joint Commission Resources and the Institute for Healthcare Improvement (IHI) have developed *The Essential Guide for Patient Safety Officers*, Second Edition. This updated edition offers a road map that enables health care organizations to create the necessary strategy, structure, environment, and metrics to improve the safety and reliability of the care they provide.

This book includes the contributions of faculty for the Institute for Healthcare Improvement (IHI) Patient Safety Executive Development Program and other patient safety leaders.

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