

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 reli-

ability 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 to 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
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Introduction

CREATING A ROAD MAP FOR PATIENT SAFETY

*Michael Leonard, MD; Allan Frankel, MD; Frank Federico, RPh;
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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 rein-

forced 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.

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