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WHAT DETERMINES
CHAPTER ONE *PATIENT SAFETY?*

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This book is for leaders who believe that patient safety is the right thing to do and who want to know how to make a difference in their health-care organizations. It is for the people who influence not just the safety of patients but also

that of team members providing patient care—imperatives that go hand in hand.

There is reason to be optimistic about one's ability to improve both. This book provides a roadmap to help you, as a leader, improve the level of safety in your organization. In this first chapter we explore what motivates great safety leaders and identify some of the sources of resistance you're likely to encounter.

Understanding the complexity of healthcare safety and the potential resistance to it will forewarn and forearm you and help you prioritize your efforts. Your specific role as a leader in healthcare safety is to discern the safety issues, define the terms of your organization's engagement with them, and use the issues to mobilize the sometimes competing and conflicting constituencies that must cooperate to create a culture that supports safety. Your guiding principle for executing this role is this: All patients have the right to expect not to be injured by the healthcare delivery system. To do no harm¹ is our first duty.

1 "As to diseases[,] make a habit of two things—to help, or at least, to do no harm." Hippocratic Corpus, *Epidemics*, book I, chapter II. From *The Yale Book of Quotations*, ed., Fred R. Shapiro (Yale University Press, New Haven and London, 2006). This injunction, which likely came down to us through Galen, has been espoused in the modern age by prominent medical practitioners such as Florence Nightingale.

We begin with a case history unlike those in most other texts about medical errors. In the case of CH, a person of our acquaintance, everything went well—in large part because she felt empowered to speak up at the right moment.

CH was a 28-year-old, 2-weeks pregnant, white female mother of two who visited her physician and was seen by his nurse practitioner on a Friday in September 1999. She complained of flu-like symptoms and a lump in her neck. Her physical examination was within normal limits except for a swollen, mobile, nontender right cervical lymph node and a rash on her elbows. Blood was drawn and she was sent home. The following Tuesday, the doctor told her that her results did not look quite right and requested that she return for repeat blood work. The repeat test confirmed that she had a very high white count, and the doctor diagnosed leukemia. He sent her to an oncologist, who detected the Philadelphia chromosome and diagnosed chronic myelogenous leukemia.

The patient had a spontaneous miscarriage the Friday after she was first seen and was started on hydroxyurea shortly thereafter. A bone marrow transplant was scheduled for mid-January 2000. However, in November 1999 the patient was found to be pregnant again and elected to carry the baby to term. Since she was unable to take leukemia medications during the first trimester, a right atrial catheter was inserted so that, if necessary, excess white cells could be removed from her blood. After the first trimester the atrial catheter was removed, hydroxyurea was restarted, and she progressed through an uneventful term pregnancy with the birth of a normal, healthy baby.

On January 2, 2001, the patient entered the City of Hope Hospital in Duarte, California, for a bone marrow transplant. There she underwent eight days of treatment with a chemotherapy cocktail to kill her bone marrow. She was transfused with donated marrow on January 11, started on prednisone, and observed for graft versus host disease. She was discharged on February 28 and instructed to live within 15 minutes of the hospital.

Although she had several bouts of fever that required rehospitalization, she never developed graft versus host disease.

Her prednisone was discontinued. She is now checked annually, and as of January 2007 she was leukemia-free for 6 years.

So far, the story of CH's medical care is both miraculous and ordinary. Despite the many danger points in her treatment, mistakes have been avoided and the outcome is happy. The case also reveals the miraculous power of modern medicine: the ability to examine human chromosomes; to place a tube into the heart of a

It is important to maintain a realistic perspective, especially as a patient safety leader. The odds of patients being helped far outweigh their chances of being harmed.

living person; to withdraw her blood, remove excess white cells from it, and return it to her body; to kill a patient's bone marrow and replace it with someone else's, thereby giving her a new immune system; and to cure leukemia. The story is ordinary in that interventions like this happen every day.

Today, while the American healthcare system receives constant criticism, it is important to maintain a realistic perspective, especially as a patient safety leader. With respect to any given patient, there are three strong likelihoods:

- When patients go to their doctors today, their chances of being helped are high—in fact, their chances are better now than at any previous time in human history.
- The chance remains small that a patient will be injured by a physician or by the healthcare system.
- Thus, the odds of patients being helped far exceed their chances of being harmed.

It is important to be clear about these probabilities up front. Patients should not be afraid to go to their doctors or to be treated in a hospital. Healthcare leaders and workers take very seriously their responsibility to help, and the idea of doing harm

is abhorrent to them. On the other hand, patient safety is not a trivial concern. Despite the best of intentions, sometimes patients are indeed injured by those who are trying to help them and by vulnerabilities in the healthcare delivery system itself.

This risk was dramatized and thrust into the public's awareness by the 1999 IOM report, *To Err Is Human: Building a Safer Health System*,² which states that in any year, 44,000 to 98,000 Americans die because of medical errors. As Robert M. Wachter and Kaveh Shojania explain in their excellent book, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes*, more people die each year in the United States as the result of medical errors than from AIDS and breast cancer combined.³ Others have pointed out that this terrible outcome is the equivalent number of lives that would be lost if a Boeing 767 full of passengers crashed every day of the year.

Although these numbers are controversial, the situation clearly warrants action. There is ample room for improvement in patient safety. Medical leaders—among them, physicians, nurses, pharmacists, administrators, regulators, politicians, third-party payers, and concerned organizations and agencies such as the National Patient Safety Foundation, Joint Commission, Agency for Healthcare Research and Quality, and others—have taken the IOM report very seriously and are searching for ways to improve healthcare safety. Everyone is in agreement that:

- Even one unnecessary death within the healthcare delivery system is unacceptable. Yet many such deaths occur each year.
- The problem is urgent; we cannot turn a blind eye to it while conducting business as usual.
- Leadership is needed to change the culture, behaviors, and processes that allow medical errors to happen.

2 Institute of Medicine, Committee on Quality of Health Care in America, *To Err Is Human: Building a Safer Health System*, eds. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson (Washington, DC: National Academy Press, 1999). Viewed at www.nap.edu.

3 Robert M. Wachter and Kaveh Shojania, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes* (New York: Rugged Land, 2005). This book, a must-read for healthcare safety leaders, offers ample facts and ideas and provides an excellent background on the issues involved.

But as we shall see, the challenges faced by any healthcare safety leader are substantial, because the system that delivers healthcare is so highly complex. Moreover, it is more often the human element—leadership, culture, and behavior—rather than the science that proves to be the weak link in the chain of healthcare delivery and patient safety.

Why make safety happen?

Over the past 20 years, the authors and their associates at BST have helped more than 2,000 organizations in 40 countries with many different cultures and languages build strong organizational cultures that support safety and significantly improve

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their safety performance. We find that what motivates healthcare leaders differs little from what motivates the safety leaders in non-healthcare companies.

Ethical considerations

The primary motivation of safety leaders everywhere is ethics. Business leaders don't want to injure their customers or employees; likewise, healthcare leaders don't want to injure their patients or their employees. Fulfilling the moral obligation to ensure a safe setting for both employees and patients builds employee loyalty, reinforces the healthcare organization's reputation, and legitimizes its claim of serving the local community—thereby authenticating its right to a license to operate. Like their industrial counterparts, healthcare leaders also have business reasons for pursuing patient

safety that are less altruistic but no less valid: to address business considerations, to align the organizational culture, because they recognize that safety is good strategy, or all the above.

Business considerations

Modern healthcare is big business. The bottom line counts. The cost of uncompensated services due to adverse events comes right out of the organization's reserves. Although an adverse event may on occasion increase revenue or in some instances decrease short-term costs, it is more likely to increase the organization's legal exposure and damage its reputation in the community, thereby diminishing its ability to compete.

On the upside, a positive bottom line—whether earned by a for-profit owner or by a nonprofit corporation in the public interest—enhances the long-term viability and sustainability of a healthcare organization. The senior leadership, whether clinical or administrative, bears chief responsibility for the sustained capacity of the organization both to deliver care and to ensure the safety of patients and staff. Although financial viability may not come first, more than one nonprofit leader has been heard to say, “If no margin, then no mission.”

Aligning organizational culture

In any industry, healthcare included, directly addressing safety indirectly helps with many other organizational problems. Many healthcare organizations are fragmented along departmental lines; many, if not most, suffer vested interests and fiefdoms. They also tend to suffer from rivalries and conflicting professional agendas. Patient safety is one area in which all parties have a common interest, an area where departments can learn to work together to create a common culture and a strong safety climate.

From working with one organization after another, we now know that both culture and climate can be defined and measured concretely. We also know that although culture (the way we do things around here, rigorously observed) and climate (what gets noticed and recognized most immediately and prominently) are both important to safety, it is leadership that creates them,

and leadership that distinguishes those organizations exhibiting good safety performance from those that excel.

We have also learned that aligning leadership constituencies can pay off in other ways. Alignment consists of getting all the constituencies to see the issue from the same perspective and to think about it in the same ways, thereby creating a common language and a shared way of understanding safety issues. This commonality makes for less conflict, easier and more successful communication, and smoother operations. These factors all facilitate both safety and productivity.

Finally, building a strong safety climate makes meeting healthcare safety regulations much easier. We place regulatory compliance last because we regard it as necessary but woefully insufficient to the avoidance of hazards for patients and employees.

Safety is good strategy

Recognizing the many advantages of successfully attending to this issue, some forward-looking healthcare organizations already regard healthcare safety and the idea of being recognized as a world-class healthcare provider as a strategic issue: it pays off in reputation, referrals, and reimbursement schedules, while enhancing the organization's ability to attract and keep the best talent in healthcare delivery and leadership.

While these business advantages are strong, the most common and fundamental motive of great safety leaders is that they see clearly that improving safety is the right thing to do. They hold fast to the principle that we have an obligation to ensure that first, we do no harm.

What stands in the way of improved healthcare safety?

The complexity of modern medicine is both miraculous and a source of many of its errors. This complexity makes it difficult for a leader to have a clear grasp of where to begin. It also engenders a resistance to change that those aspiring to higher levels of healthcare safety may encounter as they work to improve the safety of their organizations. You may encounter

these resistances not only in others but in yourself. The patient safety problem can seem overwhelming, that is just too daunting, so perhaps you should just focus on issues that will yield more easily to your efforts.

This conclusion would be mistaken. There is great variability among organizations in healthcare safety performance. For example, when HealthGrades, Inc., analyzed publicly reported information on Medicare patients in all U.S. hospitals annually during 2003 through 2005, it found the following:⁴

- There were wide, highly significant gaps in individual PSIs [Patient Safety Indicators] and overall performance between the Distinguished Hospitals for Patient Safety and the bottom-ranked hospitals.
- Medicare patients in the Distinguished Hospitals for Patient Safety had, on average, approximately a 40% lower occurrence of experiencing one or more PSIs compared with patients at the bottom-ranked hospitals. [That is, these patients were 40% less likely to suffer the occurrence of one or more PSIs compared with patients in the bottom-ranked hospitals.] This finding was consistent across all 13 PSIs studied.
- If all hospitals performed at the level of Distinguished Hospitals for Patient Safety, approximately 206,286 patient safety incidents and 34,393 deaths of Medicare patients could have been avoided while saving the United States approximately \$1.74 billion during the period 2003 to 2005.

So there are definitely ways to do things better. Furthermore, leaders who have tackled this issue have been able to show results rapidly, and they have found that even small improvements have substantial short-term payoffs. Table 1-1 summarizes some of the efforts described in the Commonwealth Fund's 2006 report, *Committed to Safety: Ten Case Studies on Reducing Harm to Patients*.⁵

4 HealthGrades Fourth Annual Patient Safety in American Hospitals Study (Golden, CO: Health Grades, Inc., 2007), pp. 2, 3, 5, and appendix.

5 Adapted from Douglas McCarthy and David Blumenthal, *Committed to Safety: Ten Case Studies on Reducing Harm to Patients* (New York: Commonwealth Fund, April 2006). Viewed at www.commonwealthfund.org. Used with permission.

TABLE 1-1. TEN PATIENT SAFETY INTERVENTIONS AND RESULTS.

INTERVENTION	OBSERVED IMPROVEMENT
Accelerate patient safety in a 569-bed, level I trauma center through a multifaceted culture change program involving setting and monitoring behavioral expectations, enhancing analytic capabilities, and streamlining and focusing on critical policies.	<ul style="list-style-type: none"> • 42% increase in expected communications behaviors. • 50% reduction in events of harm per 10,000 adjusted patient days when culture change strategies were applied system-wide.
Lead organizational cultural change in Veterans Administration hospitals by empowering local facilities and front-line staff with proven tools, methods, and initiatives for patient safety improvement.	<ul style="list-style-type: none"> • 30-fold increase in internal safety incident reporting. • 100% increase in perceived preventability of safety events studied by root cause analysis teams.
Initiate a preoperative safety briefing and perinatal patient safety project as part of a program of organizational learning to promote effective teamwork and communication in high-risk areas in an integrated group-model health maintenance organization with 8.2 million people enrolled nationally.	<ul style="list-style-type: none"> • A near doubling in the proportion of operating room staff reporting a positive teamwork climate. • Two-thirds reduction in the turnover rate among operating room nursing staff.
In a 295-bed community hospital that annually treats 250 patients in its cardiac surgery program, use collaborative rounds involving all members of the care team with the patient and patient's family to proactively identify and prevent potential errors and safety threats.	<ul style="list-style-type: none"> • 56% lower than expected risk-adjusted mortality among cardiac surgery patients. • 15% to 32% higher staff ratings of teamwork and work satisfaction compared with traditional rounds.
In a 489-bed acute care hospital, establish rapid response team to intervene early with patients showing signs of medical deterioration before they suffer acute crises.	<ul style="list-style-type: none"> • 60% decrease in emergency calls for respiratory arrest. • 15% decline in cardiac arrests. • 3.95% reduction in hospital mortality rate.
In a 14-bed oncology surgical intensive care unit (ICU) and a 15-bed surgical ICU within a 900-bed academic medical center, implement a comprehensive unit-based safety program that empowers staff to identify and eliminate patient safety hazards following eight action steps.	<ul style="list-style-type: none"> • 49% to 91% increase in the proportion of ICU staff reporting a positive safety climate. • Elimination of 43 observed catheter-related bloodstream infections, saving eight lives. • One-day reduction in average ICU length of stay, saving an estimated \$2 million annually.
In more than 40 ICUs in diverse community hospitals nationwide, focus all members of the care team on adhering to a "bundle" of evidence-based care practices associated with improved patient outcomes.	<ul style="list-style-type: none"> • 29% to 41% reduction in combined rates of ventilator-associated pneumonias. • 11% to 15% decrease in average lengths of stay across participating ICUs. • 18% lower mortality.

INTERVENTION	OBSERVED IMPROVEMENT
Specify best practices, eliminate variation from standards, and work toward ideal performance in a medical ICU and a cardiac care ICU in an 829-bed academic health center.	<ul style="list-style-type: none"> • 76% reduction rate of central-line-associated bloodstream infections, saving 18 lives per year. • \$2 million savings by reducing unreimbursed costs of care.
For an alliance of more than 200 not-for-profit hospitals and health systems, develop a trigger tool to measure the incidence and kinds of adverse events, so as to prioritize areas for improvement, design appropriate interventions, and track the effect of changes over time.	<ul style="list-style-type: none"> • 50-fold increase in detection of adverse drug events as compared with other common methodologies such as incident reporting, pharmacy interventions, or billing codes.
Reduce adverse drug events by improving the process of medication reconciliation, the safe use of high-risk medications, and the reliability of medication dispensing in a 165-bed acute care hospital.	<ul style="list-style-type: none"> • 10-fold reduction in detected adverse drug events. • 8% improvement in perceived safety culture among hospital staff.
Source: Commonwealth Fund.	

The interventions highlighted by the Commonwealth Fund report are sometimes isolated, sometimes funded demonstration projects, and often not integrated solutions that form an overarching organizational strategy. The use of one-off approaches, while informative, often threatens the achievement of sustainable results. Still, if the efforts are sustained, the financial benefits implied in Table 1-1 are clear: reductions in unreimbursed costs of care, improved patient progress, enhanced bed utilization, and more efficient and effective treatment team involvement.

So the situation is not hopeless. Far from it! But it is complex. To begin to understand this complexity, let's take a look at the safety dilemma as seen through the eyes of some of healthcare's key constituencies.

Safety roadblocks from the patients' point of view

Patients complain that they can't afford the escalating costs of healthcare or medical insurance. Many people lack medical insurance and must seek treatment in busy emergency rooms

where they are triaged under pressure and may or may not receive timely treatment. But even for patients with insurance, the system does not always provide a smooth ride. Patients complain that when their previously approved provider is dropped from the insurance company's authorized provider list (because, for example, the provider's group was unable to negotiate a satisfactory contract), the patient must either pay more out of pocket or find a new provider.

Finding a new provider can be overwhelming, especially for the elderly and infirm. Self-employed patients and young patients can have a similarly difficult time. Patients complain that they have no reliable way to determine who is a good doctor. When diagnosed with a serious illness, they find it difficult to assess the quality of the hospital where they will be treated.

Even when their treatments are successful, patients sometimes experience mistakes in their medical care. Let us continue with CH's story:

CH received frequent chest x-rays to make sure she was not developing pneumonia during the period in which she lacked a functioning immune system. On one such x-ray visit, she was not offered a protective apron for her abdomen until she spoke up and requested one. The radiology technician explained that he had thought she didn't need one because the radiation dose she was about to receive from a chest x-ray was slight compared with the much higher dose he (incorrectly) assumed she would soon be receiving in the radiation treatment for her leukemia. She told him that there was no such plan to give her radiation treatment.

This interaction between CH and the radiology tech was an example of not only a breakdown of communication between departments but also an incorrect supposition on the part of the technician.

Why did CH speak up? In part, it could be her personality. Perhaps CH is naturally assertive and does not hesitate to ask that her needs be met. It could have been the personality of the radiology tech, who communicated through his words and demeanor a willingness to respond. In telling us her story, CH said she spoke

up because the culture of the City of Hope hospital where she was being treated had been so clearly and consistently on her side in her fight against leukemia. The people at City of Hope obviously wanted to do everything they could to ensure her survival and support her well-being. Without such a culture, this woman of childbearing age might have said nothing—and might have received unnecessary radiation to her reproductive organs.

A strong, healthy culture is an essential ingredient in health-care safety. One indicator of a strong, healthy culture is that everyone—whatever their position in or relationship to the organization, whether patient, vendor, nurse, CFO, janitor, or visitor—feels empowered to step outside the usual reporting hierarchy to raise a safety concern or call a halt to an unsafe activity before an error occurs.

In addition to communication problems, relationship problems can also cause safety issues. Patients complain that doctors are impersonal, arrogant, or brusque; that doctors don't give patients enough time to unburden themselves of their concerns; that doctors don't really listen. Patients complain that their doctors say things the patients don't understand and give instructions that are impractical to follow or hard to remember. These communication and relationship issues create the climate for a malpractice perfect storm—a storm that can brew even in the absence of medical errors, because of an undesirable patient outcome.

Safety roadblocks from the physicians' point of view

Hospitals, physicians, and other clinicians deal in matters of disease, disability, and death. Many of the patients are frail; some are only a step away from the grave. At the next unfortunate turn of events, some will suffer even greater disability; others will not survive.

Are all adverse events preventable? The answer depends on the definition of "adverse event." Some patients will die in the natural course of events, irrespective of the quality of treatment provided. But this by itself does not mean that some number of medical errors are inevitable.

One of the criticisms of the IOM report is that it does not do a good job distinguishing between adverse events and deaths that were not preventable. This ambiguity is important because it can

leave the treating staff feeling guilty, undermine their professional confidence, and provide a loophole for their conscience, leading to the unfortunate attitude that some number of untoward events is inevitable. The important issue is not blame but how to design systems and human factors so that they mitigate the hazard to the patient. Improving these factors is a continuous process.

This case, originally reported in *Hospital Pharmacy*,⁶ was part of a course presented to pathologists by a medical malpractice insurance company.

A patient underwent a surgical procedure to remove a cancerous eye. A nurse set everything up for the case. To prepare a container for the surgical specimen, she poured glutaraldehyde (preservative) into a medicine glass and placed it on the sterile field. Excess spinal fluid had been removed from the patient to reduce cerebral pressure because the malignancy had spread to his brain. The spinal fluid was in another unlabeled, identical, medicine glass also on the sterile field.

Decreased spinal fluid can cause severe headaches. So near the end of the procedure, the anesthesiologist filled his syringe with what he thought was the patient's spinal fluid and injected it into the spinal canal. Unfortunately, the clear fluid he injected was not spinal fluid but glutaraldehyde. Glutaraldehyde is extremely toxic. The patient's nervous system was irreparably poisoned and he died.

A patient is dead. Whose fault is it? The aftermath among the team members from this tragic accident is unknown, but we can imagine the devastation and guilt. The anesthesiologist may have wondered why in the world the nurse didn't explain what was in each medicine glass; the nurse, paying attention to her own tasks, may have wondered why he didn't ask. Both were working in good faith, trying to do their jobs. One may have blamed the other, or so we speculate. The accident may have had career implications for those involved.

Whatever the ethical and psychological outcomes for the team, from a legal standpoint, under the "captain of the ship" doctrine,

6 *Hospital Pharmacy*, Medication Error Reports column, July 1989. Note: The details of this presented case were recalled from memory and may differ from actual events.

the anesthesiologist was considered to be in charge of everything that went on in the operating room.

The anesthesiologist may have concluded that despite medicine's marvelous technological advances, human errors like this one are not always preventable. From the point of view of the individual provider working in isolation, this perspective is understandable. From a systems and cultural perspective, it is a different matter altogether (more on this in chapters 2 and 9). While it is obviously our responsibility to prevent adverse events, it is also our duty to learn how to prevent adverse events that are not currently perceived to be preventable. The latter may be the harder challenge.

Adverse drug events⁷ and mistakes that occur due to communication⁸ problems and handoffs are among the most frequent types of medical errors. To the doctor these often appear to be inexcusable errors that have occurred because somebody else wasn't paying attention or failed to speak up. But there is always more than enough blame to go around, and a doctor may have blinders on about his or her role in the event. Perhaps it was her poor handwriting or his terse verbal style that created the occasion for error. When asked what she thought was the solution to such errors, one surgeon replied, "A new generation of docs. I'm not going to change. I'm the captain of the ship, not a team cheerleader, and I certainly don't want someone looking over my shoulder in the OR."

Physicians deplore mistakes and inefficient organizational systems that let them down and injure their patients. But few doctors are trained in systems thinking, culture development, or process control methods, and they often feel that these problems are beyond their control, i.e., the responsibility of other people. The attitude is, "My job is to practice good medicine. Nurses should accurately carry out my orders. Administrators should see to it that hospital systems function properly."

The doctor who doesn't think that his or her professional identity encompasses a leadership role in patient safety is a part of the problem. Whether or not a doctor acknowledges

7 Institute of Medicine, *To Err Is Human*, pp. 32–35. Viewed at www.nap.edu. See also Jane E. Brody, "To Protect Against Drug Errors, Ask Questions," *New York Times*, January 2, 2007, p. D7.

8 See The Joint Commission's "Root Causes of Sentinel Events" report at www.jointcommission.org.

it, every physician is a leader in setting the tone of the culture of the organizations within which he or she functions. For better or worse, the doctor's impact extends deeply into the organization. As clinicians, we should acknowledge our impact and join others in learning how to improve the organization and its culture.

Doctors often cite unreasonable production pressure as leading to medical errors, as well as the necessity to practice wasteful, defensive medicine in order to avoid malpractice exposure. Doctors often think that they don't have time to relate to their patients on anything but a technical level.

The explosive growth of medical knowledge further complicates the professional lives of clinicians and puts additional strains on their time. Some doctors complain that they don't even have time to do a thorough job of sustaining technical mastery. An internal medicine colleague recently confided that she struggles just to stay current on the cardiovascular literature and does not have time to read other journals. Much of her practice does consist of patients with cardiovascular disease, but what about those who have other problems?

Excessive demands on their time and an unjust malpractice system damage physician morale. Some doctors have even stopped practicing medicine over these issues; others refuse to perform certain procedures. There are communities, for example, where none of the obstetricians will deliver babies and no psychiatrist will perform electroconvulsive therapy. If you have a complicated pregnancy or suffer an intractable depression, good luck!

Another major consequence of defensive practice is maintaining the public appearance of perfection. One of the many possible repercussions of this façade is the failure to learn from errors, and certainly the failure to share learnings with others.

But, as often happens in healthcare, the situation is even more complex than it at first appears. A doctor's knowledge of the latest procedure or new medication does not always benefit the patient. Take, for example, a new, scientifically validated clinical best practice protocol. Should the physician adopt it? Not necessarily. It may contain procedures or call for the use of medications with which the physician has little familiarity and no experience. It is

the patient who pays the price of the physician's learning and incurs the cost of mistakes while the doctor gains the experience necessary to use the new protocol proficiently. Sometimes it serves the patient far better for the doctor to stick with his familiar methods. Using them, the doctor can draw on an extensive body of experience to recognize when the patient is vulnerable to complications, failing to respond as expected, developing a significant side effect, or in need of a different approach or a referral.

This recitation is just to underscore that the situation is complex. It is not to say that best practice protocols have no place in clinical practice. We have heard protocols rejected by colleagues who thought they were defending good practice against "cookbook medicine." The issue is not cookbook medicine versus good medicine. Rather, it is the difficulty of the decisions facing physicians. Some decisions are easy because the right way to proceed is uncontroversial and clearly known: e.g., routinely examining the feet of patients with severe diabetes, using aspirin in cardiovascular disease, or administering tissue plasminogen activator to dissolve blood clots within three hours of the onset of ischemic stroke symptoms. These simple best practices should be a standard for all physicians.

The ease or difficulty of a decision is a function of how much is known about the specific patient and how far the relevant science has advanced. There are decisions for which many variables are involved and a lot is not known. These cases draw heavily on the clinician's experience, and in these cases the value of clinical protocols is less clear-cut.

Much criticism has been leveled against doctors for relying too heavily on their individual experience when they make critical medical decisions. Important studies of cognitive bias show the dangers inherent in this kind of decision making, and we will discuss these vulnerabilities at some length in chapter 7. Nevertheless, cognitive science has shown that experience-based decision making is what distinguishes experts from amateurs and adult decision processes from those of teenagers. Experience is also what distinguishes all human thought from computerized imitations, and it is why clinicians generally perform better than software algorithms. Computerized decision aids based on good science are undoubtedly part of a solution for decreasing medical

errors, but we should not be too eager to replace the practitioner's experience with an algorithm.

The professional lives of physicians are complicated by regulatory intrusion and third-party payer interference with medical decision making, by the concomitant growing paperwork burden, and by the resultant impact on the physician's time, autonomy, and bottom line. A pediatric patient who had been physically abused was refused treatment by a third-party payer. When one of the authors appealed the decision on the child's behalf, the reviewer for the third-party payer, a retired nephrologist, told the author that in his opinion, the child just needed a good spanking! The patient was again refused authorization. Was this poor decision making on the part of the nephrologist a medical error? It was certainly a problem in the healthcare delivery system, one that further damaged the patient.

Safety roadblocks from the nurses' point of view

Nurses generally spend more time with patients than any other professionals in the healthcare system. Because of their proximity to patients they often possess detailed knowledge of medical errors and their causes. Again, because of frequent interaction with patients, nurses are also the last line of defense against medical errors and are in a position to catch errors before any damage is done. What do nurses say about medical errors and patient safety?

The first thing they usually mention is time pressure. Nurses complain that they have more patients than they can manage, that teamwork is poor, morale low, and burnout high. They feel their availability for bedside patient care is compromised by a growing body of administrative tasks.

Confusion is another issue. It can stem from any of several sources:

- Similar names and packaging for different drugs
- Storing different but similar-looking drugs in the same place
- Frequent changes in drug suppliers, which results in a drug's being packaged in a different container with every new supplier

- Equipment from different manufacturers that does the same job, but operates differently and has different readouts
- Different ways of doing things at different hospitals (many nurses are temps)
- Every doctor having his or her own preferred way of dealing with specific medical issues

When asked what stands in the way of improved patient safety, nurses often point to administrative and physician indifference or complacency, to arrogant and disruptive physician behavior, to physicians who are unwilling to make themselves available when needed, to a punitive response to the voicing of errors, and to the lack of cooperation between departments. They sit at the patients' sides more often than other practitioners and often find themselves at the eye of a confusing and daunting storm.

Safety roadblocks from the administrators' point of view

Administrators cope with increasing regulatory demands, exposure to unreasonable legal liability, and being squeezed in their contracts with large third-party payers. They often face inadequate resources, stiff competition from the hospital across town, and hard-won profits. They are concerned about the nursing shortage, poor morale, and high turnover, particularly among critical care nurses. They may have to contend with multiple ethnicities, cultures, values, and even languages among their staff and patient populations. They may be frustrated by conflicts between key groups or with entrenched, independent departments or functions, such as their contract pathology and laboratory group or their emergency room group. Administrators may find it difficult to elicit cooperation from constituencies that all seem to have competing financial interests, conflicting agendas, and differing professional loyalties.

The administrative leadership, again whether medically certified or not, faces the chief responsibility of directing, coordinating, monitoring, and reporting on the professional efficacy of teams of free agents, i.e., professionals often not beholden to the delivery institution for their license to serve and at times not accountable to

the leadership for the responsibility to serve safely. Administrative leaders thus bear the dual charge of managing independent providers—with their concomitant flows of service, information, and cash—and reporting the net clinical and financial results to their trustees, whether the latter are owners' representatives or agents of the community at large.

When patient safety fails, the trustees turn first to the administrative leadership for insights and remedies: "What happened, and why?" Even when safety hazards recur in the form of hospital-acquired infections in the operating suite, the trustees turn first to the administrator for accurate information and proposed solutions. The inability to provide either may stifle or shorten a promising administrative career.

Competing professional agendas

Several of the key groups upon which patient safety depends often have different expectations. For example:

- Some patients think that a hospital stay should be like a visit to a hotel or spa, not realizing that money spent on fancier rooms or meals could have been spent on making their visits safer.
- Physicians sometimes think that the hospital exists at their pleasure and should cater to their individual ways of doing things, without considering the complexity and increased opportunity for error that this customization creates.
- Administrators, nurses, and physicians often individually think, "*We are the hospital*"—meaning that the essence of the institution is contained in their perspective and presence. Attitudes and behaviors follow that take into account only a limited perspective of the institution.

Professionals are accountable to their profession, and some regard that accountability to be more important than their responsibility to the organization in which they practice. This outlook means that physicians are accountable to their peers. But systems of peer accountability are notoriously ineffective. Doctors policing other doctors does not work very well, not

only because it is emotionally difficult to confront a peer but also because physicians can incur legal liability by doing so.⁹ Yet administrators and managers may have limited willingness and little power with which to confront and hold physicians and other clinical staff accountable, especially physicians who are on staff but are not employed by the hospital.

Administrators sometimes are faced with midlevel managers (upon whom they must rely) who may have high-level technical skills but few management skills. Too often no one in the organization has the knowledge, skills, and abilities needed to address comprehensively and successfully the organizational issues required to build a strong safety climate. And few come by the required leadership strength naturally.

Many think that the CEO is responsible for fixing the system. Others say there simply *is* no healthcare system. If you consider the extended environment that healthcare encompasses, this claim may be true: healthcare includes hospitals and physician offices, drug and medical equipment manufacturers, community pharmacies, patient homes, emergency transport vehicles, nursing homes, and hospice. Interactions and handoffs among these environments present communication challenges and great opportunities for error, as do the handoffs within the office, hospital, or nursing home. No single person holds a position from which to command and coordinate all these different pieces. It takes leadership and many people—whether clinician or administrator—working together.

Whose job is it to take the lead?

Healthcare safety, as we've said, is complex. The complexity arises from the many constituencies involved and their sometimes competing and conflicting agendas, as well as system and cultural fragmentation, the difficulties of standardizing procedures and practices, inherent professionalism and the lack of hierarchical authority, highly complex technical and technological issues with life-and-death decisions made in crisis situations, plus a litigious atmosphere bearing on people who are often overworked and fatigued.

9 Wachter and Shojania, *Internal Bleeding*, pp. 321–326.

The leader's role is to define the healthcare safety issue for the organization and the terms of the organization's engagement with it. The leader marshals the constituencies that must cooperate to create a strong safety climate and an organizational culture that supports safety. In subsequent chapters we address how this is done well, what it is made up of, and how such efforts are measured.

Throughout this book we refer to the leader of healthcare safety without giving this leader a functional title. This ambiguity stems from our conviction that, when successful, leadership in the matter of patient safety occurs simultaneously at many different levels of the delivery system and within several distinct professional disciplines. One of your challenges in applying these insights will be to discover who else in your organization and on staff needs to join you in taking the lead.

In the next chapter we present a model for understanding healthcare safety that untangles the complexity and arms you with a useful way to think about the issues. It lays the groundwork for understanding exactly what you need to do to lead healthcare safety improvement and build a strong safety climate in your organization.