The Patient Safety Challenge and Setting the Zero Patient Harm Goal

WHY ZERO?

This book brings together for the first time the essential safe care practices learned from highly successful, highly reliable healthcare organizations as a comprehensive strategy to achieve the high-reliability goal of zero preventable patient harm. If you have ever witnessed a loved one or acquaintance suffer from a medical mistake made during their stay in a hospital, you know why zero is the right goal. If you are an executive or senior leader in a hospital who has experienced a serious safety event, you know why zero is the right goal. If you are a physician, nurse, or some other caregiver who has been involved in or witnessed an error that caused harm, you know why zero is the right goal.

Zero preventable patient harm should be the norm, not the stretch goal, in US hospitals. Experts agree that most of the errors that result in pain, injury, or even death during patient care are preventable. For simplicity's sake, in this book zero preventable patient harm is referred to as *zero patient harm*, with the acknowledgment that it always means *preventable* harm.

During my 20-year career as an executive with The Joint Commission, thousands of cases of preventable harm that occurred in US hospitals were reported to The Joint Commission through its Sentinel Event Database. By mid-2017, more than 13,300 serious safety events had been reported to The Joint Commission since

it established its mandatory and voluntary event reporting system in 1995. The sentinel event reports and the attendant root cause analyses were very disturbing: patients severely or permanently injured or killed as the result of an error, a series of errors, or latent systems failures. Most of these adverse events were preventable.

As the father of three boys, I remember a sentinel event that occurred in the late 1990s that was particularly upsetting (*Arizona Republic* 1998). An eight-year-old boy weighing 56 pounds (we'll call him Sam) was taken into the operating room (OR) for a procedure to remove a small mass from his neck. The surgeon the family had selected to perform the surgery was still performing brain surgery in another surgical suite, so a substitute surgeon performed Sam's procedure. Another boy, a five-year-old weighing 20 pounds, was also scheduled for an operation that morning to have a cyst removed from his gallbladder. Sam was taken to the OR that was expecting the five-year-old. A half hour into performing the wrong procedure on the wrong site of the wrong patient, the surgeon could not find the cyst on the gallbladder and suggested they check the patient's identity. Now believing that the patients must have been switched, the surgeon sent a nurse to check on the patient in the other OR.

Sam was under anesthesia for more than two hours instead of the expected 30 minutes. After waiting for nearly two hours with no word about how the surgery had gone, Sam's parents were finally informed of the mistake. Although obviously stunned, they agreed to allow the original surgeon, when he became available, to perform the correct operation. It took Sam hours to wake up from the effects of the anesthesia. In addition to the small scar on his neck, he had a five-inch scar on his stomach from the incorrect surgery. When Sam woke up, he wanted to know why his side hurt so bad. He was angry at his parents, refused to talk to them, and demanded to know why they had let this happen to him. Sam's mother wanted to know, "How does this happen?" The surgeon who performed the wrong surgery on the wrong patient said he had done nothing wrong and that surgeons often do not check the patient's identity before incision. The hospital must have agreed, because its action was to simply fire the nurse who had brought Sam to the OR. (A side note: In the 1990s, before the patient safety conscience of US hospitals and healthcare systems was stoked into action, firing the nurse—any nurse—was the typical knee-jerk reaction to fixing flawed patient care processes after a sentinel event. Fire the nurse, problem solved. Of course, red-rule violations and culpable acts also occurred that made dismissing a team member the right decision. However, notwithstanding the violation of safe care practices, the singular action of firing the nurse was and is not an effective way of addressing the underlying weaknesses or correcting the design of healthcare

processes and systems. Ignoring these system failures can potentially lead to serious safety events.)

Over the years, Sam's story has served as my constant reminder that the occurrence of preventable harm is unacceptable and the goal of zero patient harm is achievable only in a culture and climate that support *harm-free healthcare*.

THE ANTAGONISTS

Some people just do not believe in setting a goal of zero patient harm, even if it is clarified to mean *preventable* harm. YouTube presentations have been posted that rail against the zero harm concept—and, dare I say, the zero harm movement. The opposition argues that the goal of eliminating all patient harm is unrealistic and unachievable and will leave healthcare staff frustrated with their inability to accomplish the objective. These antagonists suggest that the goal implies the need for perfection, which is difficult or impossible to deliver in a healthcare system that is filled with uncertainty, complex, and in an evolving state of safety science. They also say the goal puts too much pressure on surgeons, other clinicians, and the patient care team, and pressure itself is a known cause of error and its negative consequences.

Moreover, the antagonists argue that an overemphasis on eliminating all patient harm could suppress the provision of treatments or services that could *potentially* be harmful but are otherwise proven or intended to be beneficial to the patient, thus engendering the *do nothing and no harm will occur* mind-set. Last is the concern that encouraging healthcare staff to achieve the zero goal will result in the underreporting of errors and safety events.

The concerns of these opponents are real. However, I don't agree with their rationale. As one high-reliability expert has said, "If you don't pursue perfection and event-free performance, you will never achieve it."

Why must zero patient harm be the goal of every hospital and healthcare system and the objective to which every individual working in these organizations is committed? The answer is that patient injury and death related to hospital-acquired conditions such as medication errors; falls; central line–associated bloodstream infections; ventilator-associated pneumonia; pressure ulcers; inpatient suicide; catheter-associated urinary tract infections; retained surgical items; and wrong-site, wrong-person, or wrong-procedure surgery are largely preventable and grossly unacceptable occurrences.

EXPERT SUPPORT FOR ZERO PATIENT HARM

For decades, one of the many criticisms of the US healthcare system was that it never had an articulated vision and strategic plan for how the system should work and what its quality and cost-control objectives should be. This changed with the 2010 enactment of the Affordable Care Act. The act required the secretary of the US Department of Health and Human Services to establish the nation's first healthcare quality improvement plan—the National Strategy for Quality Improvement in Health Care (the National Quality Strategy, for short). The first National Quality Strategy was issued in March 2011 as one of the three broad national aims to "improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe" (AHRQ 2011). Citing the unacceptably high numbers of healthcare-associated infections (1.7 million), resulting deaths (99,000), and adverse medication-related events (770,000) each year, the National Quality Strategy stated that "health care-related errors harm millions of American patients each year and needlessly add billions of dollars to health care costs." The first strategy was the Making Care Safer initiative, which formally established the national goal of zero patient harm (AHRQ 2011):

> Health care providers should be relentless in their efforts to reduce the risk for injury from care, aiming for zero harm whenever possible and striving to create a system that reliably provides high-quality health care for everyone.

In addition, many healthcare leaders, leading healthcare systems, and national organizations, including the following, are proponents of the zero patient harm goal:

- *National Patient Safety Foundation (NPSF)*. In 2017, the NPSF issued a call to action for healthcare leaders to "initiate a coordinated public health response to improve patient safety and drive the collective work needed to ensure that patients and those who care for them are free from preventable harm." The NPSF's 2015 report *Free from Harm* urged the adoption of a total systems approach to achieve meaningful improvement in patient safety (IHI 2015). The NPSF hoped its report would "prompt substantial movement toward a safer health care system" (NPSF 2017). In May 2017, the NPSF merged with the Institute for Healthcare Improvement (IHI) to "reset and reenergize the patient safety agenda," according to IHI president and CEO Derek Feeley (IHI 2017). Under the banner "Together for Safer Care," IHI/NPSF intend to build on

their mutual experience in helping healthcare organizations implement harm-reduction strategies (IHI 2017). Also in 2017, IHI/NPSF and the American College of Healthcare Executives (ACHE) collaborated with some of the most progressive healthcare organizations and globally renowned experts in leadership, safety, and culture to develop *Leading a Culture of Safety: A Blueprint for Success*—an evidence-based, practical resource with tools and proven strategies to help create a culture of safety and achieve zero harm (ACHE 2017).

- *Institute for Healthcare Improvement.* IHI's mission is to improve health and healthcare worldwide. The organization created the *care bundle approach* to preventing harm, and its patient safety initiatives are focused on building safety into every system of care, ensuring that patients receive the safest, most reliable care possible. One of IHI's founding principles was to redesign healthcare into a system without errors or waste. To this end, IHI is involved in developing new measures to move organizations toward harm-free healthcare (IHI 2018).

- *Nationwide Children's Hospital.* This hospital's "Zero Hero" program focuses all staff—from the board and senior leaders to frontline employees—on the fundamental patient expectation of "Do Not Harm Me." Nationwide Children's claims to be the first children's hospital to describe and publicly aspire to a goal of zero patient harm: "Nationwide Children's Hospital is committed to the safety and care of its patients. The idea of zero harm has led to our nationally recognized 'Zero Hero' program. 'Zero' is the only acceptable goal, and one that we all strive for" (Nationwide Children's Hospital 2019).

- *Vidant Health.* With a nine-hospital system serving eastern North Carolina, this system's commitment is "simple. We want zero events of preventable harm and 100 percent exceptional experiences for every person we serve" (Vidant Health 2018).

- *University of Pittsburgh Medical Center (UPMC).* UPMC comprises 30 academic, community, and specialty hospitals serving the greater Pittsburgh, Pennsylvania, area. Patient safety is at the heart of its ability to provide reliable and consistently high-quality patient care. According to UPMC (2018), "The best results occur when everyone is involved in patient safety—from each member of the UPMC health care team to you, our patient. Working together, we are making steady progress toward our goal of zero errors."

- *Memorial Hermann Health System.* This system of 15 hospitals in southeast Texas strives to serve people who "expect hospitals to be

high-reliability organizations (HROs) where zero error is the norm. The reality, however, is far different. When we embarked on our journey to become a high reliability organization, we didn't do it to win awards. We did it in the best interest of our patients and their families. We recognize that becoming an HRO is a never-ending quest toward the achievable goal of zero harm to patients under our care" (Memorial Hermann Health System 2013).

- *Solutions for Patient Safety.* This collaborative of more than 100 children's hospitals is driven by the shared goal to "Do No Harm" and to urgently reduce and then eliminate serious harm for all of the children under the care of its facilities. In describing its mission, Solutions for Patient Safety (2018) states, "We are 100+ Children's Hospitals working together to help each individual hospital make progress on a journey to zero harm: so that every child receives safe care every time they enter our hospitals."

- *MedStar Health.* A 10-hospital system serving Maryland and the Washington, DC, area, MedStar Health (2018) puts patient safety as a number-one priority by committing to delivering patient care with zero patient harm.

- *Mark Chassin, MD, president, The Joint Commission.* In an article in the *Milbank Quarterly*, Dr. Chassin posited that "All the constituencies of leadership, both formal and informal, must share the same singular vision of eventually eliminating harms to patients." Citing the exemplary safety improvement record of the US commercial aviation industry for many decades, Dr. Chassin stated that the "lesson for health care is not to be satisfied with modest improvements. Aiming for zero is the first step toward achieving it" (Chassin and Loeb 2013, 468).

- *US Department of Energy (DOE).* The DOE is one of the world's largest high-reliability organizations responsible for the nation's fossil and nuclear power generation, nuclear waste disposal and storage, and maintenance of a safe and secure nuclear weapons deterrent. The DOE's primary objective is the continuous safe, reliable, and efficient production of its operating facilities. DOE training focuses on improving human and facility performance through a dual emphasis on reducing errors and maximizing the controls or defenses that are intended to stop errors from causing a safety event. "Only controls can be effective at reducing the severity of the outcome of error" (DOE 2009, 1-16). Therefore, the DOE's successful strategy for experiencing zero significant events has been to concentrate on reducing errors and managing the controls or defenses.

- *The DuPont Company.* DuPont has been a world leader in safety since its founding along the Brandywine River in Wilmington, Delaware, in

1802. Like most highly reliable organizations, DuPont learned how to be a safe company the hard way. An explosion at its powder mill in 1818 led the way for the creation of a shared owner, leadership, and employee commitment to safe operations every day. In the early 1800s, DuPont implemented safety rules and an expectation for personal accountability for safe operations for every employee. Owner E. I. DuPont "kept safety foremost among his concerns" and, in 1911, created the first safety office and safety officer. For more than 100 years, the company has had an employee recognition and safety incentive program, which rewards employees who have stellar safety records and actively report hazards. Being "Committed to Zero Injuries, Illnesses, and Incidents," DuPont abides by this safety commitment: "We believe that all injuries . . . and environmental incidents, are preventable, and are committed to a goal of zero for all of them" (DuPont 2016).

AND THEN THERE WAS HIPPOCRATES

Evidently, the admonition of and pledge to "first, do no harm" is not specifically in the Hippocratic Oath but was contained in another of Hippocrates' works titled *Epidemics*. But even in this work, the oath is quoted indirectly: "As to diseases, make a habit of two things—to help, or at least to do no harm" (Strauss 1968, 625). No matter; it is a wonderful patient safety mnemonic. Similar to the Hippocratic Oath taken by some medical school graduates, nursing school graduates promise to "abstain from whatever is deleterious and mischievous," which is found in the Florence Nightingale Pledge for nursing graduates (Vanderbilt University 2010).

THE FIVE DISCIPLINES OF PERFORMANCE EXCELLENCE

Organizations that achieve and sustain excellent individual, team, and organizational performance over long periods—from high-risk industries such as commercial airlines to Super Bowl–winning football teams—do the following five things extremely and consistently well:

1.   Prepare—through simulation, deliberate practice, and training—for excellent performance.
2.   Apply proven offensive strategies that exhibit consistent, excellent individual and team performance.

3. Minimize both individual and team (system) errors through immediate feedback, video playback, and coach interventions.
4. Employ strong defensive strategies that effectively block the potential negative effects of errors, latent hazards, and emerging threats.
5. Coach individuals and teams to achieve consistent, excellent performance in all four areas: preparation, offense, error minimization, and defense.

Examples of safe care practices associated with each of the five disciplines are shown in exhibit A. The fifth discipline, coaching excellence, spans and plays a role in optimizing each of the other four disciplines.

Healthcare professionals—caregivers and executives alike—who implement these five safe practices all the time can accomplish the elusive goal of eliminating adverse events and the preventable injury or death from these events. In other words, these strategies enable the achievement of the desired future state of harm-free healthcare and the safety goal of zero patient harm. I refer to these as the *Five Disciplines of Performance Excellence*.

Exhibit A: The Determinants of a Safe Patient Care Experience: The Five Disciplines of Performance Excellence

Preparation
– Deliberate Practice
– Simulation

Safe Care Practices
– Mindfulness
– Resilience
– Catch and Correct

Minimize Errors
– Error Modes
– Error Precursors
– Error-Likely Situations

Maximize Defenses
– Functional Hazard Analysis
– Defenses-in-Depth
– Physical
– Administrative
– Human

Coaching Excellence

Healthcare is disappointingly far behind in consistently adopting and applying these winning strategies, which have been used effectively in sports and in other successful industries. As listed earlier, an expanding cohort of exemplary hospitals and healthcare systems is, however, leading the zero harm movement in creating the patient care culture and practices needed to ensure every inpatient receives safe, harm-free healthcare. In addition, the emergence of simulation centers; evolution of patient care bundles; and adoption of safe practices, error-reduction strategies, and methods to strengthen the controls or defenses learned from high-reliability organizations are encouraging signals of the advances in patient care safety. However, complacency and acceptance of the status quo are prevalent. They are reflected in the slow progress toward accurately identifying, measuring, reporting, and eliminating serious safety events that occur in US hospitals. This tolerance of harm is rampant but is anathema to everything that every healthcare executive, doctor, nurse, allied health professional, and other direct providers of care stand for and are committed to: helping patients get better.

EXCUSES, EXCUSES, EXCUSES

Healthcare leaders, providers, and policymakers have based their tolerance of unacceptable levels of preventable patient harm on a bevy of excuses, such as the following:

- Healthcare is constantly changing, the current healthcare delivery model is complicated, or the healthcare system is too poorly organized for providing standardized, consistent care to patients with chronic conditions.
- Healthcare is highly fragmented and lacks basic clinical information capabilities (IOM 2001).
- Practitioners (doctors and nurses) are frequently interrupted with a continuous flow of information, stressing the limits of human memory and making the system prone to failure (Leonard et al. 2010).
- Harm is an inevitable, small, and acceptable price to pay for the technological and clinical advances of an evolving healthcare system (Leonard et al. 2010).
- Patients are far more complicated and idiosyncratic than airplanes, and the field of medicine is more complex than just about any other field of human endeavor (Gawande 2002).
- Staff are insufficient in number and training. Frontline clinical staff are often fatigued and feel grossly overworked (Dhand 2016).

These excuses somehow give us the peace of mind that, despite the best efforts of healthcare professionals, some unintended patient harm can be expected and is just an unfortunate consequence of a highly stressful, technically complex, and ever-changing environment in hospitals. "The problem of medical errors," says Robert Wachter (2012, xiii), "is not fundamentally one of 'bad apples' . . . but rather one of competent providers working in a chaotic system that has not prioritized safety. Most errors are made by good but fallible people working in dysfunctional systems."

CURRENT STATE OF PATIENT SAFETY

The current state of patient safety in US hospitals is, quite frankly, scary. Just read the headlines within the past decade alone:

- "What Surgeons Leave Behind Cost Some Patients Dearly—Doctors Sew Up Patients with Sponges and Other Supplies Mistakenly Left Inside— Costing Some Victims Their Lives" (Eisler 2013)
- "Pharmacy Error Led to Patient Death, Hospital Confirms" (Associated Press 2014)
- "Diagnostic Errors More Common, Costly and Harmful Than Treatment Mistakes" (Johns Hopkins Medicine 2013)
- "Researchers: Medical Errors Now Third Leading Cause of Death in United States" (Cha 2016)
- "Medical Errors May Cause Over 250,000 Deaths a Year" (Bakalar 2016)
- "Medication Errors Found in 1 out of 2 Surgeries" (McGreevey 2015)
- "Study: Medical Errors Cost U.S. Almost $20 Billion in '08" (Ledue 2010)
- "Hospitals Can Kill You" (Makary 2012)

The current state of delivering harm-free healthcare is unreliable, inconsistent, and porous. This means the negative effects of performance errors often penetrate the gaps in weak defenses. Such errors result in patient harm, and both occur at an alarming rate. But you would have to be a healthcare insider to know the current rate of preventable harm, or know how to find and interpret the academic literature regarding patient safety in hospitals. In most states, hospitals are not required to accurately measure or report their actual patient safety data, whether they are infection rates, medication errors, or any other adverse events. No one—not the state regulators, hospital administration, healthcare providers, patients, or the public—really knows the exact type, frequency, or level of harm that results from the occurrence

of serious safety events in hospitals. Therefore, we are left with estimates obtained from published studies or from limited, unaudited reporting systems such as the Hospital-Acquired Conditions (HAC) Initiative. The HAC Initiative was implemented in 2008, mandated by a provision of the Deficit Reduction Act of 2005. With an increased emphasis on value-based purchasing, the HAC Initiative focuses on several *never events* that are reasonably preventable through the application of evidence-based guidelines (Waters et al. 2015).

The 2015 *National Healthcare Quality and Disparities Report* published by the Agency for Healthcare Research and Quality (AHRQ 2017) stated that patient safety in hospitals improved substantially between 2010 and 2014. During this period, hospitals reported a 17 percent reduction in HACs, from 145 per 1,000 discharges to 121 per 1,000 discharges. The leading types of HACs were adverse drug events, pressure ulcers, patient falls, and catheter-associated urinary tract infections. According to the American Hospital Association (2017), there were 33.1 million hospital admissions in 2014, an equivalent measure of the number of hospital discharges. An extrapolation of the 121 HACs per 1,000 discharges for 33.1 million discharges means that an estimated 3.9 million HACs occurred in 2014, for a hospital defect rate of 12.1 percent. In Six Sigma terms, hospitals were operating at a poor safety rate of 2.67 Sigma, with 121,000 defects per million opportunities (DPMO), whereas best-in-class high-reliability industries were operating at better than 6 Sigma, or less than 3.4 DPMO.

"On any given day, about one in 25 hospital patients has at least one healthcare-associated infection." This was the conclusion reached by the US Centers for Disease Control and Prevention (CDC) in its 2016 *National and State Healthcare-Associated Infections Progress Report*. This report was based on the CDC's 2014 Healthcare-Associated Infection (HAI) Prevalence Survey, which estimated that 722,000 HAIs occurred in acute care hospitals and that approximately 75,000 patients with an HAI died during their hospital stay (CDC 2016). Surgical-site infections, bloodstream infections, urinary tract infections, and pneumonia were included in the estimates. As a *Modern Healthcare* article title proclaimed in 2014, "Despite Progress on Patient Safety, Still a Long Way Across the Chasm" (Rice 2014, 8). The chasm referenced here is the *quality chasm* described by the Institute of Medicine (IOM) in its 2001 report *Crossing the Quality Chasm: A New Health System for the 21st Century*. *Crossing the Quality Chasm* identified the existing, but surmountable, gap between the current state and the desired future state of healthcare quality in the United States. The report stated that "health care today harms too frequently and routinely fails to deliver its potential benefits" (IOM 2001, 1). Moreover, it found that safety flaws were unacceptably common and that safety problems were the result of poorly designed care processes and systems that set the healthcare staff up for failure (IOM 2001). It concluded that the US healthcare system "often lacks

the environment, the processes, and the capabilities needed to ensure that services are safe" (IOM 2001, 26).

Collectively, HAC data from AHRQ and the CDC (2018) as well as the 2001 report by the IOM suggest an "epidemic of patient harm in hospitals," which is exactly what John James (2013, 122) concluded in his study of adverse events in US hospitals. James based his conclusion on the review of four studies that used the Global Trigger Tool to identify safety events. He found that a low estimate of preventable harm in hospitals was 210,000 deaths per year, but "the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year" (James 2013, 122). He observed that the "action and progress on patient safety [were] frustratingly slow" and hoped for an "outcry for overdue changes and increased vigilance in medical care to address the problem of harm to patients who come to a hospital seeking only to be healed" (James 2013, 127). As Dr. Tejal Gandhi (2016), president of the NPSF, has said, "We have a long way to go yet on patient safety."

Desired Future State of Patient Safety

The Five Disciplines for Zero Patient Harm is intended to bring together, as an organized framework, the proven and effective offensive and defensive patient care practices to achieve the National Quality Strategy, Centers for Medicare & Medicaid Services (CMS), and IOM goals of safe care for every patient in every setting every time.

Seeking to improve the health and healthcare of all US residents, the National Quality Strategy involves federal agencies, purchasers, providers, payers, and the public in implementing changes to achieve six priorities. These priorities include promoting effective prevention and treatment practices, better coordination of care, engaging patients and families as partners in their care, and increasing the use of best practices. The number-one priority, however, is "making care safer by reducing harm caused in the delivery of care" (AHRQ 2011, 3). As an example of these "Priorities in Action," the current initiatives that are successful in achieving the priorities are listed and updated monthly on AHRQ's website (see www.ahrq.gov/workingforquality/priorities-in-action/index.html). Following the directive that "no patients should be harmed by the health care they receive," AHRQ's 2014 progress report to Congress, *Working for Quality: Achieving Better Health and Health Care for All Americans* (AHQR 2014, 7), cites the significant progress that Connecticut hospitals have made in reducing the rate of bloodstream infections. Using the Comprehensive Unit-based Safety Program (CUSP), these hospitals were able to reduce central line–associated bloodstream infection rates by nearly 50 percent—from 1.99

infections to 1.05 infections per 1,000 central line days. The CUSP method involves the coordinated use of safety checklists, standardized processes, the identification and mitigation of defects, communication training, and improvements in the safety culture (AHRQ 2011).

CMS designed the CMS Quality Strategy to align with the National Quality Strategy and to encompass and implement several CMS priorities. The Partnership for Patients, Hospital Value-Based Purchasing, and patient-centered medical homes are examples of CMS programs that "reward providers for adopting best practices that can decrease harm" (AHRQ 2011, 19). The strategic vision of the CMS Quality Strategy "is to optimize health outcomes by improving quality and transforming the health care system" (CMS 2017). To accelerate progress toward the number-one priority of Making Care Safer, CMS provides financial incentives to providers that develop and implement best practices designed to reduce patient harm. Moreover, CMS payment incentive programs support the cultivation of cultures of safety, elimination of inappropriate and unnecessary care that may contribute to patient harm, and reduction of HAC rates (CMS 2016). In addition, the Making Care Safer initiative focuses on preventing or minimizing harm in all settings of care delivery by improving medication error rates, decreasing patient falls, and reducing HAIs (CMS 2016).

The IOM created the strategic quality framework and priorities that influenced both the National Quality Strategy and CMS Quality Strategy. The IOM was created in 1970 by the National Academy of Sciences, a private, not-for-profit society focused on scientific and engineering research. Under a congressional mandate, the academy is required to provide advice to various federal agencies. In 2001, the IOM's Committee on Quality of Health Care in America, comprising 19 well-respected national healthcare quality experts, issued its comprehensive assessment of the state of healthcare in the United States, titled *Crossing the Quality Chasm: A New Health System for the 21st Century* (discussed earlier), and detailed solutions for making healthcare better. To improve the twenty-first-century healthcare system, the IOM (2001, 41–42) proposed six specific aims:

1. *Safe*—avoiding injuries from care that is intended to help
2. *Effective*—providing services based on scientific knowledge to patients who can benefit from the service and not to those who are unlikely to benefit
3. *Patient-centered*—ensuring that patient values guide all clinical decisions and that care is respectful and responsive to patient preferences and needs
4. *Timely*—reducing waits and sometimes harmful delays in treatment
5. *Efficient*—avoiding waste, particularly the waste of equipment, supplies, ideas, and energy

6.   *Equitable*—providing care that is consistent in quality to patients regardless of their gender, race/ethnicity, geographic location, or socioeconomic status

The IOM's vision for the future state of patient safety is that the "health care environment should be safe for all patients, in all of its processes, all the time" (IOM 2001, 47). In other words, this environment is a culture of harm-free healthcare with the goal of zero patient harm.

The Big Y Formula: Y = f (X$_1$, X$_2$, . . . X$_x$)

This formula means the *Big Y* is a function of, and depends on, the critical input variables X_1, X_2, and X_3. In Six Sigma speak, the Big Y is the most important result that is linked to the critical customer requirements and expectations. Six Sigma is a management methodology developed in 1986 by Motorola as a statistically based process for reducing variation and product defects. The formula $Y = f (X_1, X_2, . . . X_x)$ provides an analytic structure to define and measure the functional relationships between input and output variables (BusinessBalls 2017).

Applying the formula to the challenge of improving the safety of care provided in hospital settings and achieving the Big Y of zero patient harm yields the following formulaic representation of the essential concepts of the Five Disciplines of Performance Excellence:

Big Y = ZPH, or zero patient harm
X_1—*P*, or prepare to deliver safe care
X_2—C_s, or apply proven safe care or offensive strategies
X_3—E_{min}, or minimize errors and mistakes
X_4—D_{max}, or maximize controls or defenses
X_5—*CE*, or coach individuals and teams for excellent performance
$ZPH = f\ CE\ [P + C_s + E_{min} + D_{max}]$

Hospitals and healthcare systems can achieve the desired future state of zero patient harm by implementing the five disciplines, distilled into the formula $ZPH = f\ CE$ $[P + C_s + E_{min} + D_{max})$.

We—the leaders, caregivers, and others invested in improving patient safety—know what processes or care practices can reduce surgical-site infections or patient falls, for example. We know that to become as highly reliable as a nuclear power plant, a commercial airline, or a theme park, we need to deliver excellent service consistently over a long period to every patient, every time. We must not allow the

LESSONS FROM HIGH-RELIABILITY ORGANIZATIONS

The US Department of Energy

High-reliability organizations operate safely for many years, not just for days or months, and deal with many of the same challenges that hospitals face. They often make decisions under pressure, operate in high-risk situations, work with inadequate information, and are subject to catastrophic consequences if their system controls or defenses fail to prevent a hazard from occurring.

The US Department of Energy (DOE) is widely regarded as an HRO. It has more than 14,000 employees and is responsible for protecting the safety of the nuclear weapons stockpile, energy security, 24 research laboratories, 2 million acres of nuclear waste, and all nuclear and fossil fuel energy delivery in the United States. It is an expert in human factors and human performance as they relate to maintaining consistently safe operations. Through its Human Performance Center, the DOE has developed extensive training materials to train its staff and contractors; these materials are also available to the public. The DOE's *Human Performance Improvement Handbook* states that "the primary objective of our operating facilities is the continuous safe, reliable, and efficient production of mission-specific products" and that "the strategic approach for improving performance is to reduce human error and manage controls [defenses, safeguards, or barriers] so as to reduce unwanted events and/or mitigate their impact" (DOE 2009, v, 1-1).

The DOE uses the formula $R_e + M_{c/d} = 0E_s$ to provide a strategic reminder to all DOE staff and contractors of the critical disciplines necessary to consistently perform with zero significant events ($0E_s$). Reducing errors (R_e) and effectively managing the controls, barriers, or defenses ($M_{c/d}$) have proven, over decades of experience, to be an effective management and operational model for securing a hazard-free, adverse event–free performance record. The Big Y formula for achieving zero patient harm ($ZPH = f\,CE\,[P + C_s + E_{min} + D_{max}]$) draws heavily from the DOE's $R_e + M_{c/d} = 0E_s$ and the *Human Performance Improvement Handbook*.

normalization of deviance to create a culture in which adverse events are accepted as a by-product of a complex, dynamic, and pressure-oriented healthcare environment. We must not allow complacency to diminish our commitment to creating a

zero harm environment in which patients never experience an iatrogenic injury or death as a result of failures in the healthcare system itself.

ORGANIZATION AND CONTENTS OF THIS BOOK

The Five Disciplines for Zero Patient Harm is a guide for leaders of hospitals and healthcare systems, but it is also useful for frontline clinical staff who provide patient care at the "sharp end."

The Five Disciplines of Performance Excellence—preparing to deliver safe care, applying proven safe care or offensive strategies, minimizing errors and mistakes, maximizing the controls or defenses, and coaching individuals and teams—are fully developed in parts II through VI of the book. Part I highlights the importance of mastering the skills necessary to effectively bring about the behavioral changes that lead to harm-free healthcare and prepare both individuals and teams to deliver safe care. Part VI focuses on coaching to facilitate safe care. Exemplary hospitals and healthcare systems have implemented peer-to-peer patient safety coaching programs with impressive results. Organizational culture is the result, not the cause. Changes in individual attitudes, beliefs, values, actions, and behaviors result in changes in the culture of the organization and the achievement of a desired safety culture. Therefore, part VII describes leadership's role in guiding the cultural transformation into a safe care culture and climate. Each chapter includes specific, implementable safe care practices, which are recommended action steps to achieve a harm-free healthcare culture and the goal of zero patient harm.

Part I (Mastering Change to Enable Safe Care) is the first section of the book for a good reason. It would be very difficult, if not impossible, for a hospital or healthcare system to install any of the high-reliability safe care practices described in the book and sustain them over time without first mastering the disciplines of change facilitation, change management, or change acceleration. Change occurs through people. Meaningful change will not happen unless the hospital staff *want* that change to happen. Therefore, the healthcare leader must become a master change agent with the ability to engage, enlist, encourage, educate, and empower staff to see and feel the need for change, embrace it, and commit to changing their own behavior in the service of the change initiative.

Part II (Preparing to Deliver Safe Care) explores how HROs, much like winning sports teams and record-holding athletes, prepare for excellent performance through deliberate practice and simulation, which are fundamental contributors to success. These chapters show how successful organizations and emerging leaders in healthcare have worked to enhance the technical and nontechnical skills of their team members and to set behavioral expectations for individual performance that

counter complacency and establish an urgency for safe, harm-free healthcare. Training individuals to actively participate on teams and using safety communication tools are fundamental to enhancing team performance and results. Communication among caregivers and care teams is a major factor in the delivery of safe patient care; thus, the safety communication tools and methods used by HROs are presented and discussed. Although physicians, nurses, and other healthcare professionals may have strong clinical or technical skills, they may lack the social and cognitive skills to complement their clinical or technical knowledge and capabilities. Included in part II (chapter 2) is Rhona Flin, Paul O'Connor, and Margaret Crichton's research into enhancing nontechnical skills in healthcare.

Part III (Performing Safe Care Practices: The "Offensive" Strategy) focuses on the proven safe care bundles and other clinical guidelines published and recommended by AHRQ and other authoritative sources. Ten of the top high-risk threats to patient safety and harm-free healthcare are described, and the attendant guidelines or care bundles are presented as safe care practices (e.g., steps to prevent ventilator-associated pneumonia, infections, medication errors, and patient falls). This part also emphasizes the need for resilient adaptability in the field of care delivery, the role of technology in patient safety, and the conduct of after-action reviews to facilitate team learning about what went right and what could be improved in care, treatment, or service delivery.

Part IV (Minimizing Errors and Event Precursors) recognizes that the prevailing construct in healthcare safety science is that errors will always occur in a complex, dynamic system. The current approach to patient safety seems to be to accept as an intractable problem the errors that result from the extensive human-to-human and human-to-machine interfaces in healthcare delivery. HROs do not accept this premise and work hard to reduce the occurrence of error. They work diligently to minimize active and latent errors and to strengthen the controls (defenses, safeguards, and barriers) that protect against and prevent harm. This part describes classification and reporting systems for near misses and serious safety events, management of human factors, system improvements to reduce latent organizational weaknesses, and early intervention and harm prevention strategies. The process of catching and correcting errors before they can cause harm is a central practice of HROs and is described in the chapters in part IV.

Part V (Maximizing Defenses and Barriers: The "Defensive" Strategy) discusses one of the most important disciplines of HROs—understanding the complexities of the system they work in and then anticipating, with great accuracy, where failures will occur in the system. These organizations use causal analysis, failure mode and effects analysis, and barrier effectiveness analysis to trace past failure causes, proactively predict future risks, and critique the effectiveness of existing defenses and barriers. To counter the inevitable errors in the care delivery process, they develop

controls and defenses to protect the patient from potential harm. This part demonstrates how HROs have successfully maintained and sustained a safe or winning performance. They routinely conduct various analyses to learn how existing controls or defenses are performing, whether the defensive strategy is effective in blocking potentially harmful errors, whether the defensive strategy was worked around, and whether defenses are in place.

Part VI (Coaching to Facilitate Safe Care) describes the desirable characteristics and performance traits in an individual interested in becoming a patient safety coach. The chapters in this part present the major roles and responsibilities of such a coach and how to effectively coach a care team. Teaching individuals and teams to adopt and consistently apply safe care practices, avoid complacency, and catch and correct errors before they can cause harm is central to this role. The safe care practices in this part include how team members should engage in respectful communications with one another and adhere to the controls, defenses, and safeguards against potential harmful error. The coaching skills useful in this regard are described, and examples are provided to demonstrate how performance data can be used to improve a team's safety performance. Moreover, advice is offered to prospective patient safety coaches on how to deal with staff complacency and resistance as well as what approaches are helpful in changing behaviors to keep patients safe. These recommendations guide coaches in answering the most challenging questions they will encounter and in convincing a disparate group of physicians, nurses, and other providers to listen and change their behaviors. Even talented players need a great coach to elevate their individual and team performance. This is as true in healthcare as it is in competitive sports or in high-reliability industries in which error-causing accidents can have catastrophic consequences.

Part VII (Creating a Safety Culture and Climate) discusses creating the organizational culture and climate that encourage and facilitate safe care. Eight specific behaviors and practices based largely on James Reason's work are presented, and leadership's role in promoting a culture of safety is explored.

The Golden Circle Approach: Start with the Why

The material in each chapter is presented according to Simon Sinek's golden circle principle. By first asking and then answering the why (rather than the what or the how) of safe care practice, readers will want to learn more about it and how it is pursued or implemented. In his book *Start with Why: How Great Leaders Inspire Everyone to Take Action*, Sinek (2011, 1) says that "if we're starting with the wrong questions, if we don't understand the cause, then even the right answers will always steer us wrong." By first communicating the reason for achieving the goal of zero

Exhibit B: The Why, How, and What of Achieving Zero Patient Harm

Why—Zero Patient Harm

How—Promote Proven Safe Care Practices

What—Five Disciplines of Performance Excellence
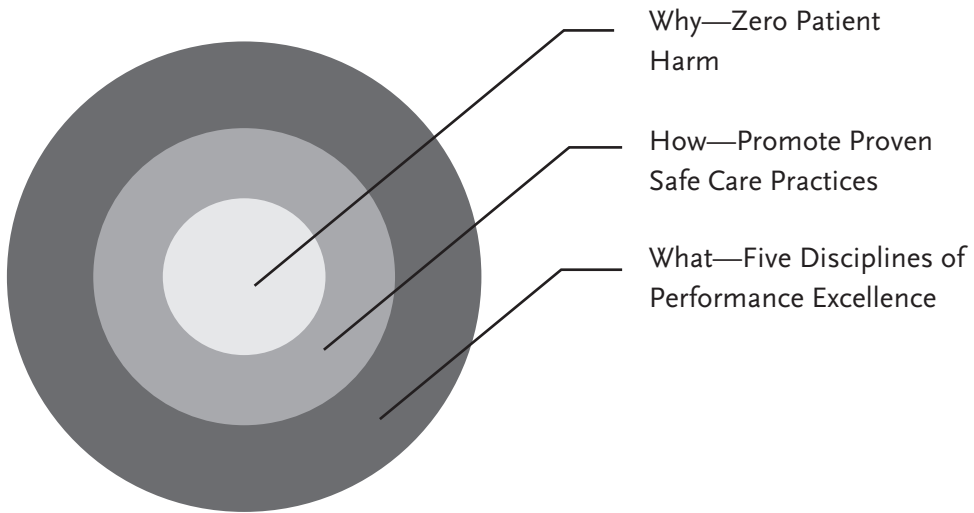
harm—so that healthcare is safe for every patient, every time—I invite (and hopefully inspire) others to learn about it, to believe in it, and to take action by changing their behaviors and practices (exhibit B). The recommended practices and tools throughout the book are well defined, tested, and proven to be effective.

Note About Clinical References

To be clear, *The Five Disciplines for Zero Patient Harm* does not suggest changes in medical practice or procedures. Medical protocols, procedures, and practices are the purview of the medical community. Any clinical practices cited in this book are derived from the existing literature, mostly the patient safety practices described in *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices* (AHRQ 2013). Many other credible clinical guidelines and sources are cited as well.

CONCLUSION

The disciplined actions that enable a football team to win a Super Bowl or a nuclear power plant to operate safely year after year can also be applied to healthcare to protect patients from harmful errors in care delivery. Thousands of preventable adverse events occur in US hospitals each year that permanently injure or kill patients. If

hospitals and healthcare systems applied the successful strategies of HROs, patients would be a lot safer during their hospital stay. The Five Disciplines of Performance Excellence presented in this book are modeled after the exemplary practices of successful healthcare organizations, HROs, and sports teams. These "Disciplines" have been proven over decades of use to help high-risk industries and high-performing organizations achieve consistent, highly reliable performance excellence. Hospitals and healthcare organizations can apply these five disciplines with equal success.

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