INTRODUCTION

One need only turn on the news to see that health care is still at the forefront of national consciousness. Twelve years after the release of the landmark Institute of Medicine (IOM) report, To Err is Human: Building a Safer Health System, preventable errors continue to occur, systemic frailties in every aspect of the health care delivery system exist, and seemingly simple solutions gain limited traction. It is difficult to determine whether media coverage has caused or increased consumer concern or whether the public’s desire for information prompts the media to scrutinize events more closely. What is certain is that keeping patients safe is now an expectation in health care.

Accountability to ensure safety of all patients is expected at all levels of leadership, from individual clinicians to national legislators who oversee healthcare regulations. Recent events have ensured that patient safety is never far from the minds of caregivers, patients, payers, and regulators. Although advances in patient safety have been made, countless numbers of patients continue to suffer preventable medical errors. More and more attention is being paid to system issues. Wachter graded the progress from a C+ in 2004 to a B– in 2010, noting advancement in many areas such as error reporting and involvement by leaders. However, he also noted a lack of progress in areas such as health information technology and malpractice system reform. Efforts to improve patient safety are not limited to hospitals and healthcare institutions. Healthcare institutions are not the only ones coming under scrutiny; the public is growing wary of medical device manufacturers and the pharmaceutical industry. The existence of several device recall registries, the fact that often the labeling practices of drugs have been shown to be one of the root causes of many medical errors, and the fact that product recalls make the news on a regular basis attest to the fact that device malfunctions and drug safety are not isolated incidents.

Much progress has been made in patient safety over the past decade. Yet, as an industry, health care has only scratched the sur-
face. In this chapter, the authors will review the foundation of patient safety by exploring the historical events that have shaped patient safety as it is known today. We will discuss critical issues that continue to gain attention. By examining the issues health care faces and the history of patient safety in America, we will show that a more cohesive and united effort is needed to have a meaningful effect on both quality of care and patient safety.

**A HISTORY OF PATIENT SAFETY**

The frequency and magnitude of avoidable adverse patient events was not well known until the 1990s, when multiple countries reported staggering numbers of patients harmed or killed by medical errors. Recognizing that healthcare errors affect 1 in every 10 patients around the world, the World Health Organization called patient safety an endemic concern.  

The first big step toward improving patient safety was the formation of the Institute of Medicine (IOM). Established in 1970, the IOM is the health arm of the National Academy of Sciences, chartered under President Abraham Lincoln in 1863. The IOM asks and answers the nation’s most pressing questions about health and health care. The Institute’s goal is to provide unbiased, reliable information about health care, especially as it pertains to public health and policy. Information is furnished primarily by committees in the form of formal reports. The IOM arranges forums for sharing information and conducts its own research. Information and research provided by the IOM has been invaluable for advancing the cause of patient safety. As a nonprofit, nonpartisan organization, policy makers highly regard and give considerable weight to findings from the IOM. *To Err Is Human* is one of the recognized contributions from the IOM. Additionally, because the IOM has completed numerous studies and reports on issues pertaining to patient safety, it is an excellent source of information for those advocating for safer care both at the patient and the provider levels. Many of the studies that the IOM undertakes begin as specific mandates from Congress, whereas others are requested by federal agencies and independent organizations.

The IOM tackles questions about general patient safety and quality, whereas the newer FDA MedWatch (developed in 1993) focuses more on medical products, such as medications and devices. MedWatch provides medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans via its Web site and the MedWatch E-list. MedWatch allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. It also has played a pivotal role in incorporating consumers into improving patient safety.

The catalyst for addressing patient safety concerns was initiated by three major publications put out by IOM: *To Err Is Human* (1999), *Crossing the Quality Chasm* (2001), and *Preventing Medication Errors* (2006). The first report sent shock waves through the industry and the nation by awakening everyone to the level of preventable medical errors occurring in the United States. *To Err Is Human* was the inspiration for the Institute for Healthcare Improvement’s 100,000 Lives Campaign, which in 2006 claimed to have prevented an estimated 124,000 deaths in a period of 18 months through patient safety initiatives in more than 3,000 hospitals. *Crossing the Quality Chasm* urgently called for changes to healthcare system processes to improve patient care. It analyzed this dilemma and explored potential ways in which change could be implemented in the healthcare delivery system at all levels. These two documents were instrumental in raising patient safety awareness in health care and among policy makers. Most recent, the report *Preventing Medication Errors* put forth a national agenda for reducing medication errors predicated on estimates.
of the incidence and cost of such errors and presented evidence on the efficacy of various prevention strategies. This report proved to be more of a call to action than were the other two, providing specific strategies for medication safety improvement rather than more general information detailing the errors in health care and specific patient safety concerns.

Efforts to improve patient safety have been made in the past, and the report built on this earlier work. In the early part of the century, two important pieces of legislation were passed: the Biologics Control Act and the Food, Drug and Cosmetics Act. The former, passed in 1902, was spurred by the deaths of 13 children who had received a diphtheria vaccine. It regulated the production of biological products to ensure the safety of consumers. The latter, passed in 1938, required that drugs be proven safe before advertised to the public, set quality standards for packaged products, and authorized inspections of production facilities. The importance of this legislation cannot be overstated. Medications and vaccines are indispensable for consumer health but can do more harm than good if not properly regulated. The legislation of 1902 and 1938 set precedents for product regulation and demonstrated the willingness of the government to step in on behalf of consumers. The next landmark event in patient safety occurred in 1951 with the founding of The Joint Commission (TJC). At its inception, the TJC provided accreditation to hospitals based on adherence to its published standards. In 1965, adherence to TJC standards became mandatory for hospitals that wished to participate in Medicare or Medicaid, ensuring compliance by even more institutions. Over time, standards became more complex, and councils were formed to oversee accreditation for mental health facilities, facilities for persons with disabilities, hospice facilities, and long-term care facilities, among others. Although accreditation is an important part of its mission, the TJC also conducts research on patient safety and healthcare quality, provides tools to help hospitals measure performance, and periodically issues reports on the state of patient safety.

Two decades after the founding of the IOM, another critical piece of legislation was passed. The Safe Medical Devices Act was passed in 1996 and gave the FDA power to regulate the medical device industry. The law stipulates that hospitals and other healthcare providers must report and track undesirable events related to medical devices. Additionally, manufacturers must create tracking methods for each device they produce, such as a unique serial number or bar code. This legislation greatly expanded the regulatory capabilities of the FDA and officially brought medical devices into the realm of patient safety concerns. In 1994, Error in Medicine was published, drawing attention to the need for human factors research in the prevention of medical errors. In 1997, the National Patient Safety Foundation was created with a singular mission of ensuring safe care of patients. Several other organizations, such as the Agency for Healthcare Research and Quality, the Institute for Healthcare Improvement (IHI), and the Leapfrog Group, have as central to their missions the improvement of quality and patient safety.

Although much was accomplished before To Err Is Human was published, the report spurred a wave of interest and action in the realm of patient safety and established it firmly as a movement rather than a collection of isolated efforts. In 2002, the TJC created the National Patient Safety Goals program to help organizations target areas most in need of improvement. The following year, in 2003, the National Quality Forum (NQF) published a set of guidelines called Safe Practices for Better Healthcare, an evidence-based list of 30 practices to be employed by all healthcare facilities to increase safety and quality. The guidelines address topics such as safety culture, transfer of information, and medication safety, and suggest ways to improve them.
Two years later, another important piece of legislation was passed, the Patient Safety and Quality Improvement Act (PSQIA) of 2005. This law led to the creation of the patient safety organizations with the goal of learning from collated event data to improve patient safety. This law laid a framework in which providers and organizations could collect patient safety data without fear of legal retribution. Malpractice suits are a serious concern for healthcare organizations and providers; for them to be forthcoming about errors, a certain level of protection needed to be ensured. The PSQIA also emphasized the need for a comprehensive database of adverse safety events. It is hoped that ultimately this reporting initiative will collect information in a standardized way and will be useful to compare geographic regions and track national trends.

The latest development in patient safety is the creation of the Partnership for Patients program. Launched in 2011, the Partnership has two main goals: to reduce patient harm in healthcare environments and improve transitions from hospitals to less-acute care settings to lessen the rate of readmission. To accomplish these goals, the Partnership for Patients has identified nine areas of concentration: adverse drug events, catheter-associated urinary tract infections, central line-associated bloodstream infections, inpatient falls, adverse obstetrical events, pressure ulcers, surgical-site infection, venous thromboembolism, ventilator-associated pneumonia, and other unspecified hospital-acquired conditions. If the goals of this program are met, the federal government estimates that $35 billion and 60,000 lives could be saved over the next three years.

The above-mentioned organizations and legislation are testimony to the leadership and movement in patient safety. Despite the consistent efforts of many in health care, this industry continues to be faced with critical issues that have a profound effect on patient outcomes. We will discuss some of these critical issues and their prevalence later in this chapter in more detail. Creating a culture of safety is considered to be the foundation for all patient safety activities and perhaps, given the tradition and hierarchy in our healthcare delivery system, has proven to be one of the most challenging issues.

**CREATING A CULTURE OF SAFETY**

According to the Institute of Medicine, changing patient safety culture is the biggest impediment to improving outcomes. Workplace culture makes a difference in clinical outcomes. All healthcare organizations must recognize that patient safety is a top priority and make decisions based on that priority. Several omnipresent elements that support a culture of safety include a blame-free work environment, transparency, and a process designed to prevent errors. A just and fair culture of transparency is essential to empowering employees to create safe processes and improve the safety of the care they deliver. In organizations committed to patient safety, leadership must recognize patient safety as its top priority and describe the factors that must be present in an organization to support a culture of safety. Among these factors are a pervasive commitment to patient safety, which is evident in all decisions made by leadership; open communication, where everyone in the organization feels free to report potential safety concerns; a blame-free environment, where such reporting is rewarded rather than ignored; and the use of tools, techniques, and processes that have been proven to prevent future errors.

Safety culture can be defined as the set of values, beliefs, and norms about what is important, and how to behave and what attitudes are appropriate when it comes to patient safety in a work group. Many organizations measure patient safety culture through the use of the Safety Attitude Questionnaire, developed by the Agency for Healthcare Research and Quality (AHRQ).

The dimensions measured by the AHRQ patient safety culture tool are as follows:
Most Common Patient Safety Concerns

Over the past 12 years, research specific to patient safety has accelerated, and though clearly we have yet to fully operationalize the solutions, we have a much clearer understanding of the problems. Analysis of specific event types is bringing us closer to the development of specific strategies for reducing or eliminating these patient safety risks.

Medication Errors

One of the most common preventable medical errors relates to the ordering, dispensing, preparing, and administering of medication. Medication errors injure 1.5 million people per year and amass an additional $3.5 billion in additional healthcare costs. According to National Coordination Council for Medication Error Reporting, a medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including: prescribing, order communication, product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. An adverse medication event denotes some type of harm, from unexpected side effects to serious injury and death. Some medication errors result from patients taking their medications incorrectly, but others result from errors by healthcare providers. Examples of these errors include errors in transcription, errors in dispensing, errors in prescribing, and errors in administering drugs. Together, errors by clinicians and patients send more than 282,500 people to the emergency department each year. Of those, 98,000 are children, 177,000 are elderly, and 7,500 are middle aged. Clearly, the elderly are at the most risk, but this may also be because they take the most medications and fill the most prescriptions of any age group.

Research has identified many of the reasons for medication errors, which include hard-to-read paper prescriptions, confusing labeling or packaging, unclear directions, low health literacy, and an unwillingness of patients to ask questions about their medications. Means of prevention include bar-coded medications,
electronic medical records, rewriting medication directions so they are easier to understand, higher health literacy in general, and closer monitoring of at-risk groups, such as infants and the elderly. Establishing standards by which to identify and assess gaps in the medication management process is a first step to prevention of medication errors.

### Hospital-Acquired Infections

Hospital-acquired infection (HAI), also referred to as a nosocomial infection, is an infection acquired during the course of treatment at a healthcare facility that was not present prior to the visit. The infection often occurs within 48 hours of admission, but infections that occur after discharge are also considered HAIs if the pathogen was acquired during the patient’s stay.

The World Health Organization estimates that around 8.7% of hospital patients worldwide have an HAI at any given time. In the United States, one out of 20 hospitalized patients contracts an HAI and 100,000 die each year, but as of 2010 only 27 states had laws requiring hospitals to report their rates of infection. For patients, the cost of an HAI is high: the length of the hospital stay increases by seven to nine days and they pay $40,000 more on average. For the healthcare system as a whole, HAIs add between $4.5 and $5.7 billion each year to medical costs. There are many types of HAIs, but the most common are central line-associated bloodstream infections, catheter-associated urinary tract infections, and ventilator-associated pneumonia. Although surgical-site infections and MRSA (methicillin-resistant *Staphylococcus aureus*) are also grave concerns, the aforementioned infections account for more than two-thirds of all HAIs.

Fortunately, HAIs are preventable. The World Health Organization (WHO) and the Centers for Disease Control (CDC) recommend several steps to reduce infection: hand washing of the proper length and frequency, proper cleaning and sterilization of the patient’s environment, proper staff attire, and reduction of unnecessary injections and surgical procedures. It has been demonstrated through clinical research that strict adherence to these recommendations has the potential to prevent infections or reduce infection rates to extremely low levels. Ensuring that the recommendations are followed correctly and uniformly, however, has proved difficult.

### Surgical-Site Errors

Surgical-site errors result in procedures being performed on the wrong site, correct procedures performed on the wrong person, incorrect procedures being performed at a site, and procedures that are more invasive than intended or necessary. Causes vary, but some are cited by The Joint Commission (TJC) as risk factors because of their prevalence in cases where wrong-site surgeries have occurred. These include time constraints (caused by emergency surgery or a full schedule), room or staffing changes, multiple procedures being performed, and patient characteristics, such as obesity or physical deformities, that prompted a change in operating room setup.

Wrong-site surgeries, though uncommon, are preventable. Between 1995 and 2010, 956 wrong-site incidents were reported to The Joint Commission. However, these numbers are believed to represent only 10% of actual occurrences because reporting to the TJC is voluntary. One study surveyed surgical procedures from 28 hospitals and found the incidence of wrong-site surgeries to be approximately one in 112,994 procedures. For the average hospital, this means one error every five to 10 years. This study also surveyed the costs of these incidents to the hospitals. The median payment to the patient was $12,000, and the cost of defense was $1,500, for a total of $13,500 per case on average.

To address the problem of surgical-site errors, The Joint Commission chaired a summit that produced the “Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.” The Protocol makes...
The Impact of Literacy on Patient Safety

Care physicians because they are often the first healthcare providers patients present to deal with a problem. The primary care physician is often responsible for the patient’s course of care.

The effects on patients are even more sobering because early detection and a proper course of treatment are crucial for fighting chronic conditions such as cancer, diabetes, asthma, and other autoimmune disorders. Meta-analyses have shown the diagnostic error rate to be between 4.1% and 49.8%, with 4% of cases displaying preventable, lethal errors. Diagnostic error is difficult to study, however, because it often goes undetected or unreported.

Present studies rely heavily on autopsy findings and malpractice suits for data, which is problematic because such methods preferentially select for a population that has already been seriously harmed by errors. Nonetheless, the effects of diagnostic error—poor prognoses, lost productivity, increase in costs for patients and healthcare systems—are known, but the scope and prevalence are yet to be determined.

THE IMPACT OF LITERACY ON PATIENT SAFETY

It is well acknowledged that informed patients make better decisions. The ability to obtain and analyze information pertaining to health and wellness is called health literacy. Health literacy is necessary to navigate the healthcare system and to make decisions about one’s health care; unfortunately, many Americans have low health literacy. This has negative consequences for patient safety for several reasons. First, patients with low health literacy are more likely to misunderstand medical instructions or ignore advice from their doctors. This can lead to adverse medication events, a worsening of medical conditions, and repeat visits to the hospital for the same problem. Second, patients with low health literacy are less likely to speak up or ask a question when something is amiss, which removes a source of protection against clinician errors. Finally,
patients with low health literacy incur more costs than those with high literacy. This places an additional strain on already strapped health systems and diverts money from improvement initiatives.  

Health literacy is recognized as an important facet of patient safety, and improvements are already under way. Centers for health literacy have been created as a part of existing organizations and as free-standing groups. With these centers has come the position of consumer health librarian, an individual who creates community partnerships and teaches people to access and understand health information. Another point of focus is on making healthcare materials—prescription information, device recalls, and Web pages—simpler and easier to understand. Most sources of healthcare information are written at a college level, and many Americans’ reading comprehension is below this. Advocates hope that by conducting outreach and making materials more accessible, the public can make better healthcare decisions.  

**EMERGING TRENDS**

As an industry, health care is testing new tools to help improve patient safety. Risk management has historically focused on ameliorating damage once it occurs and minimizing legal retributions. Safety officers and risk management experts are focusing more on prevention as a result of the new emphasis on patient safety, being proactive and learning from close calls and near misses. Sharing these outcomes is imperative to improving the safe care of patients.

Many industries have identified teamwork as a critical factor in developing a culture of safety. Rather than praising clinicians exclusively for their individual skills and encouraging them to solve problems on their own, healthcare systems are emphasizing teamwork skills as important for clinical outcomes and preventing medical errors. Utilizing skills from other industries, team building has become an important tool in healthcare facilities. Working in teams puts an emphasis on an interdisciplinary approach to providing care to patients. Instead of working in silos, the emphasis is on collaborative care among physicians, patients, and the entire healthcare team.

Before the patient safety movement, responsibility for medical errors was considered to be solely that of the clinician. Slowly, this mindset is changing and there is a realization that breakdowns in the system are to be blamed for most medical errors.

**TECHNOLOGY**

From electronic health records to palm-scanning devices, many believe that new technology can help prevent medical errors. The Obama administration passed the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the recently enacted stimulus bill, demonstrating its support of health information technology (HIT) as a means of addressing quality and cost issues. $19.2 billion allocated to motivate
increased use of electronic health records, which in turn shall improve the processes of healthcare delivery documentation and record keeping for safer care. However, there is skepticism too that the lack of a completely integrated health information technology system is a risk to patient safety. The infrastructure does not allow for the plethora of systems to seamlessly integrate data, hence creating a gap in the patient record. An infrastructure to enable multiple care settings and systems to integrate data is the key to safer care.

**CONCLUSIONS: WHERE WE STAND TODAY**

Improving patient safety is a daunting task, not least of all because the well-being of millions is at stake. Most can agree on the importance of keeping patients safe, but the agreement often ends there. There is a plethora of proposed solutions, and we continue to search for solutions that will be accepted by all stakeholders. Compounding the problem is the fact that the body of knowledge gleaned from research is not always consistent. It varies tremendously in source, scope, and reliability. This is in part due to the nature of what we are trying to study—behavior is intensely subjective both for the performer and the observer—and in part because different research groups are seeking different results. It is commonly understood that being observed changes the nature of an action and that the way in which a question is phrased determines the nature of the answer received. Therefore, the different interests of stakeholder groups create different understandings of patient safety and different ideas about what action is necessary. The problem of patient safety can be stated thus: the pursuit for an understanding of the full scope of the problem and exact solutions remains a work in progress.

Despite these hurdles, the patient safety movement has made great strides. The central issues have been identified, which means that the healthcare industry now has a direction in which to focus in terms of research and policy developments. The system level weaknesses are evident, now the industry must agree on concrete solutions for conditions to change considerably. Additionally, there is a growing realization across different sectors that everyone has a stake in and responsibility for patient safety. There is an increasing emphasis on patient safety in areas such as patient engagement, health literacy, medication management, safer devices, prevention of healthcare acquired infections, and hospital acquired conditions. This development shows that different sectors of the healthcare industry are beginning to consider their roles in improving safety and understand how critical it is at each system juncture.

Creating change is always difficult. For all striving to create sustainable culture of safety, the below provides a solid foundation. The inaugural meeting of the LLI at NPSF, cast the vision for the transformation of the healthcare delivery system by proposing five key areas: transparency, care integration, consumer engagement, restoration of joy and meaning in work, and medical education reform. Stakeholders must be honest with themselves about shortcomings and willing to compromise with one another to make the necessary changes. It won’t be easy, but with acceptance of the problem, transparency, cultural evolution, and a blame-free environment, patient safety will improve drastically.

**References**


5. “World Alliance for Patient Safety.” Available at: www.who.org


References


