Patient Safety

Abha Agrawal • Jay Bhatt
Editors

Patient Safety

A Case-based Innovative Playbook for Safer Care

Second Edititon

Springer

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To patients: who teach us everything.
To Mummy and Papa: who made it possible to learn.

Dr. Abha Agrawal

In honor of my mom and dad as well as my patients, teachers, colleagues who have taught me so much so that I could help advance high quality care.

Dr. Jay Bhatt

Dr. Patricia O'Neill, MD
March 5, 1956–February 18, 2023
In loving memory of Dr. Patricia O'Neill, a renowned trauma surgeon in New York whose brilliance and unwavering dedication to her patients was an inspiration to all who knew her. Dr. O'Neill was a trailblazer in her field, known for her exceptional surgical skills and her tireless efforts to save lives in some of the most challenging and high-pressure situations.
Her loss is deeply felt by the medical community, and her legacy as a pioneer in trauma surgery will continue to inspire and guide us in our work.
May this book serve as a tribute to Dr. O'Neill's exceptional life and career, and may her memory continue to inspire us to strive for excellence in all that we do.

Foreword

Almost three million people die across the world each year as a result of medical harm, much of which is preventable. According to the World Health Organization, the occurrence of adverse events due to unsafe care is likely to be one of the ten leading causes of death and disability in the world. While we often focus on hospital-related harm due to the acuity of illness, the problem of harm is even worse in primary and outpatient care. Up to 80% of this harm may be preventable, with the most detrimental errors related to diagnosis, prescription, and the use of medications.

Based on the work of experts over the last two decades, we know that the problem of medical errors does not stem from incompetent, uncaring, or negligent professionals. On the contrary, the knee-jerk reaction of blaming and punishing healthcare professionals, especially doctors, nurses, and pharmacists, is one of the biggest impediments to improving the safety of care. The root cause of iatrogenic harm lies in the complexity and fragmentation of systems and processes of the modern healthcare system. Modern drugs, while far more potent than those available at the start of the twentieth century, are also far more capable of causing harm if not prescribed or administered with the utmost care.

My role as the Patient Safety Commissioner for England is to promote patient safety and to promote the value of listening to patients and thereby reduce incidents of avoidable harm when it comes to medicines and medical devices. This was a recommendation from the Independent Medicines and Medical Devices Safety Review published in 2020. The review heard from patients, primarily women, who had been harmed from the use of medicines or medical devices. Patients had not received the right information to consent to treatment and when they raised concerns, they were ignored or dismissed, meaning avoidable harm continued. The health system in England was described as slow, disjointed, dismissive, and lacking in compassion. My role is to bring the system together, promote the safety of patients in relation to medicines and medical devices, and to prevent similar scandals from recurring.

But it is cultural change that will lead to the major improvements in patient safety that are needed. To do this requires a mindset change so that patients are truly listened to, and what they say is acted upon. Patients need to be seen as partners in

their care and involved at every stage of the design and delivery of healthcare. Without patients' views, treatment plans will continue to be designed to benefit the system, not those receiving care, and harm will persist.

This is not unique to England. All health systems need to listen to patients including the many voices that are seldom heard and are easily ignored: people who are disadvantaged, who are vulnerable, who face language barriers, and who are fearful of bureaucracy. They must be supported to access the full range of services and to avoid worsening health inequalities, those services need to be shaped to meet patients' needs.

Leaders play a vital role in creating the right cultures by setting a leadership intent to listen. Leaders must develop psychological safety in their organizations so everyone, patients, carers, and workers, feel able to raise concerns without fearing that nothing will be done or that they might be disadvantaged as a result. Patients and families need to know that their views matter and that feedback and concerns are welcomed as a means of making continuous improvements.

Leaders need to put safety first so that it is seen as everyone's business. Safety cannot be left to the patient safety specialists alone—it needs to be embedded into the system, from the initial development of devices to the pharmacist dispensing a medicine with the appropriate warning. Leaders who put safety first consider the catastrophic outcomes that we are trying to avoid, then put the controls and barriers in place to prevent harm. This is known as process safety management, seen in high safety industries, and links to a just culture where errors lead to learning, not blame.

Once these changes are made, patient safety will improve and with that comes added benefits: health outcomes improve, less harm occurs, patient satisfaction rates rise, staff are better motivated, retention increases, and less time and money is wasted on fixing problems. Listening to patients and acting on their views is the route map to success.

This book is for leaders in healthcare at all levels. It aims to enhance the engagement and understanding of the concepts of patient safety, types of medical errors, and practical solutions to improve the safety of care. It uses a case-based learning approach where sample cases are discussed in each chapter to highlight the type of safety problem, followed by a comprehensive analysis and practical solutions.

We know that improvements to patient safety are taking place in countries across the world. Looking outwards nationally and internationally, and learning from new initiatives, will help make patients safer, everywhere.

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Preface

The first edition of this book, published in 2013, was driven by the compelling evidence of substantial harm to patients from medical errors [1]. Its goal was to engage caregivers—physicians, nurses, administrators, leaders, quality and safety professionals, and trainees such as medical and nursing students—in learning about medical errors and more importantly, in devising systems improvement strategies that will improve the safety of patient care in hospitals.

We continue to drive forward the vital importance of learning about patient safety for all stakeholders in healthcare with this second edition of the book, as the work on patient safety is far from over. Patient safety remains literally a matter of life and death as almost 3 million people die across the world of medical harm, much of which is preventable [2].

The Continued Challenge of Medical Errors

While a lot of progress has been made globally in advocacy for patient safety, and we have seen some reduction in specific types of medical errors (such as healthcare acquired infections) as a result of concerted actions by patient safety programs [3], the scourge of medical errors continues. "To Err is Human," published in 1999 by the Institute of Medicine (presently called the National Academy of Medicine), was the first major report to acknowledge that up to 98,000 patients die in US hospitals every year from medical harm [4]. In 2010, the Office of the Inspector General (OIG) conducted an analysis of 780 Medicare beneficiaries over a period of 1 month and found that 27% of hospitalized patients suffered medical errors that led to either permanent harm, required serious life-sustaining intervention, or contributed to their deaths [5]. What was even more remarkable is that almost half of this harm was found to be preventable. The analysis concluded that projected to the entire Medicare population, about 15,000 patients (from the Medicare population alone) die in US hospitals every month as a result of potentially preventable adverse events.

Subsequent reports do not paint a safer picture. A controversial report by Makary and Daniel, published in the British Medical Journal in 2016, asserted that over 250,000 patients die from medical errors in US hospitals, and based on these numbers, medical error is the third leading cause of death after heart disease [6]. An updated report by the OIG, published in May 2022, reported that 25% of patients still experienced harm during the hospital stay, and yet again, 43% of the harm was preventable—virtually no change compared to a decade ago [7]. And, most recently, a January 2023 article by Bates and colleagues in the New England Journal of Medicine concluded that "adverse events were identified in nearly one in four admissions, and approximately one fourth of the events were preventable" [8].

Globally, according to the World Health Organization, the occurrence of adverse events due to unsafe care is likely one of the ten leading causes of death and disability in the world [2]. In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care [9]. The harm can be caused by a range of adverse events, with nearly 50% of them being preventable. Each year, 134 million adverse events occur in hospitals in low- and middle-income countries (LMICs) due to unsafe care, resulting in 2.6 million deaths [10]. While we often focus on hospital-related harm due to the acuity of illness, the problem of harm is even worse in primary and outpatient care, with an estimated 4 out of 10 patients harmed in ambulatory settings. Up to 80% of this harm may be preventable, with the most detrimental errors related to diagnosis, prescription, and the use of medications [11].

Making Healthcare Safer

Based on the work of many experts over the last two decades, we know that the problem of medical errors does not stem from incompetent, uncaring, or negligent professionals. On the contrary, the knee-jerk reaction of blaming and punishing healthcare professionals, especially doctors, nurses, and pharmacists, is one of the biggest impediments to improving the safety of care. In his testimony to the U.S. Congress in 1997, Dr. Lucian Leape, a renowned patient safety expert, stated, "The single greatest impediment to error prevention is that we punish people for making mistakes" [12]. David Marx, a noted author and expert in human error, explained in a 2001 report, "Few people are willing to come forward and admit to an error when they face the full force of their corporate disciplinary policy, a regulatory enforcement scheme, or our onerous tort liability system" [13].

The root cause of medical errors lies in the complexity and fragmentation of systems and processes of the modern healthcare system. On the one hand, advances in healthcare, including smart devices, complex surgeries, and modern information technology, have contributed much to improving patient care outcomes. On the other hand, increasing specialization of care has introduced fragmentation of the healthcare team leading to communication failures and a lack of coordination of care among various teams. As a matter of fact, communication failures among

healthcare teams remain one of the foremost causes of medical errors [14]. Modern drugs, while far more potent than what was available at the beginning of the twentieth century, are also far more capable of causing harm if not prescribed or administered with utmost care. Anticoagulants, pain medications, and insulin remain some of the main culprits of medication-related harm [7]. Advances in information technology (IT) such as electronic health records (EHRs) and computerized physician order entry (CPOE) have virtually eliminated errors of the past due to illegible prescriptions and lack of access to previous clinical notes. However, health IT has introduced new types of errors due to inherent flaws of technology such as cloned notes caused by reckless usage of copy-paste feature of EHR that are useless at best and dangerous at worst [15].

Our hope to prevent medical harm and save lives depends on improving systems and processes of care. While, without a doubt, healthcare is a unique enterprise, we must be open to learning from other industries, such as the aviation industry and nuclear plants, that have successfully introduced principles of "high reliability" in their operations to achieve extreme safety and high quality as evidenced by almost zero recent fatalities. We must continue to inculcate a culture of safety that is based on an acknowledgment of medical errors accompanied by transparent reporting and thorough analysis to arrive at potential root causes that lead to effective improvement of systems and processes.

We must continue to advance the judicious use of information technology and systems that enable us to do the "right things" (such as a point-of-care alert to order a mammogram for breast cancer screening) and prevent us from doing the "wrong things" (such as prescribing two medications with potentially fatal drug-drug interaction).

A significant gap in patient safety improvement efforts over the years has been the lack of engaging patients and families as true partners in improving the safety of care. While patient-centricity has been recognized as one of the six dimensions of quality of care, the work on patient engagement has been rather superficial and more around the onerous process of filling out HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey forms and scores and not a true bedside partnership. Further meaningful work on this front should yield substantial gains.

What's New in the Second Edition?

Similar to the first edition, the purpose of this book is to bring the conversation about quality and patient safety from academic discussions in patient safety journals and conferences to "front line" clinicians who provide day-to-day clinical care. The book aims to enhance the engagement and understanding of the concepts of patient safety, types of medical errors, and practical solutions to improve the safety of care.

There are a number of new chapters in this edition. The COVID-19 pandemic brought the issue of health disparities and inequities in access to care to the forefront of national dialogue because of a substantially higher burden of COVID-19 illness

and death on racial and ethnic minorities [16]. To be sure, health disparities in access to care, quality of care, and health outcomes have existed in the US health system for decades; the pandemic jolted the system and illuminated the disparities for all to view. As a matter of fact, "equity" was considered one of the six goals of the quality of care in the Institute of Medicine model that has been foundational to our understanding of healthcare quality since 2001 [17]. While the other five goals—safety, timeliness, effectiveness, efficiency, and patient-centeredness received attention, equity had not received the focus and attention it needed. Therefore, we have updated the book with one chapter on the overall discussion of health equity (Chap. 2) and another one focusing on the issues of equity relative to COVID-19 (Chap. 5).

Another unacceptable tragedy of the pandemic was the high case and death toll among the residents of nursing homes, which spurred the dialogue on the safety of nursing home residents. The number of deaths and inadequate care provided at nursing homes was explored in a National Academy of Medicine Report in 2022 [18]. We include a chapter on the safety of nursing home residents in this new edition (Chap. 22).

The opioid epidemic continues to ravage the fabric of many families and communities. According to provisional data by the Centers for Disease Control and Prevention, more than 109,000 people died of a drug overdose in the 12-month period ending March 2022 [19]. Annual overdose deaths reached record levels during the pandemic. A new chapter on opioid safety is included in this edition (Chap. 16).

Patient safety and quality know no boundaries. The toll of medical errors is global, and the value of human life is universal. Further, based on our conversations with colleagues in India, Saudi Arabia, Uganda, Ghana, and Mexico, it is clear to us that the systems issues around the world are quite common in scope. We have included a chapter to bring an international perspective to patient safety in this edition (Chap. 24).

By looking at other high-risk industries, such as aviation and nuclear plants, we have gained new insights and lessons that can be applied to healthcare to mitigate patient harm. These include the concepts of a high-reliability organization and the importance of human factors engineering; we include chapters on both of these topics (Chaps. 1 and 4, respectively).

Diagnostic errors have received much greater attention since the publication of the Institute of Medicine report, "Improving Diagnosis in Healthcare" in 2015 [20]. The diagnostic error chapter has been updated to incorporate newer insights and research (Chap. 15).

While emergency medicine issues, especially the patient safety risks imposed by boarding in the ED, have been known for a long time, the COVID-19 pandemic substantially exacerbated this problem. A notable addition to the book is the chapter on safety in the emergency department (Chap. 23).

Most clinical professionals enjoy learning around clinical cases rather than the abstract concepts of safety. Similar to the first edition, we utilize the case-based learning approach where sample illustrative cases are discussed in each chapter to highlight the type of safety problem, followed by a comprehensive analysis and

practical solutions. In addition, the solutions-based approach should be helpful for quality and safety professionals, students, and instructors in patient safety, as well as healthcare administrators and leaders.

Our hope is that you will find the case studies helpful in advancing your understanding of patient safety and that you will use some of the solutions in your practice or healthcare organization. Ultimately, even if one life, anywhere in the world, is saved as a result of this book, we would consider this a worthy endeavor.

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