Patient Safety

A Case-based Innovative Playbook for Safer Care

Abha Agrawal
Jay Bhatt
Editors

Second Edition

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.

Dr. Henrietta Hughes OBE FRCGP SFFMLM
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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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Part I
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Chapter 1
High Reliability in Healthcare

Molly Dwyer-White, Adam Novak, Gary L. Roth, and Sam R. Watson

> Healthcare is the most difficult, chaotic, and complex industry to manage today. (Peter Drucker)

Introduction

When one considers the multiplicity of variables during the care of a given patient, Peter Drucker's statement rings true. In addition to the complexity of healthcare, it is also a high-risk endeavor. For the most part, patients receive care that results in an improvement in their condition. That said, when failures do occur, they can be catastrophic and result in serious harm or even death.

Healthcare is not alone in the realm of complex and high-risk undertakings. Other industries such as nuclear power, aircraft carrier flight operations, and amusement parks have complex activities and operate in an environment with

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inherent hazards. In the case of these operations, failures are substantially lower as compared to what has historically been experienced in healthcare [1].

The organizations that operate in these complex, high-risk environments have common behaviors. Weick and Sutcliffe identified the following five characteristics of what they termed **High Reliability Organizations (HRO)** [2]:

1. *Preoccupation with failure*—being aware of vulnerabilities that could lead to a failure.
2. *Sensitivity to operations*—being aware of the day-to-day activities and how they may influence outcomes.
3. *Reluctance to simplify*—not looking at processes or systems in a way that over-simplifies and obscures more detail on what may result in an unexpected event.
4. *Commitment to resilience*—when an event of failure occurs, an organization must be able to continue through its operations.
5. *Deference to expertise*—regardless of hierarchy, allowing those with the greatest understanding of, and proximity to, the process or system to make decisions to address an event.

These characteristics require a commitment from leadership that is embedded in the culture of the organization. An example of this leadership behavior is seen in aircraft carrier flight operations. Prior to commencing any flights, individuals of all ranks walk the deck to look for loose objects that may cause damage to an aircraft resulting in catastrophe. This is called a Foreign Object on Deck, or FOD, walk. Likewise, in healthcare, a similar exercise is conducted daily. Meetings led by leadership where issues from the previous day, or expected challenges for the day ahead, are shared across all disciplines of the healthcare team in what is often termed a Daily Check-In (DCI). Both are examples of two high reliability characteristics: preoccupation with failure and sensitivity to operations.

It is critical that leadership demonstrates the behaviors through participation and encourages the identification of issues or potential problems. Once problems are identified, leadership must look to those most capable of addressing them. An example of the practice of deference to expertise may be found in the Learning from Defects approach [3]. In this case, using a tool to guide their work, staff are given the support to address defects in processes within their patient care unit or department. Similarly, if adverse events occur, the organization must have enough dexterity to continue normal operations and initiate processes to learn from them, as is outlined in the commitment to resilience principle of high reliability. One study examined 34 publications on healthcare organizations' capacity to withstand shocks to its system and adapt and evolve in the face of challenges [4]. The authors found several major influencers of resiliency, including leadership practices, organizational culture, material resources, preparedness, human capital, social networks, and collaboration. Collectively, embracing characteristics like these can help organizations effectively manage and excel through adversity.

While not called out by Weick and Sutcliffe, transparency is an important element of high reliability. Access to information throughout the organization gives staff a greater window into operations and allows for a closed-circuit communication loop.

In addition to sharing qualitative data through the activities such as the DCI, sharing quantitative measures across the organization is important to inform staff and leadership on the status of reliability. The Donabedian model is an effective approach to measure reliability.

Avedis Donabedian described the use of structure, process, and outcome as a framework for the evaluation of medical care [5]. He states that the ease of collection and validity are important characteristics of measures used in determining the quality of care. As an organization monitors its systems, measures must not be burdensome to collect. Further, if clinicians do not find them valid, they may be disinclined to heed the results.

In some instances, a given aspect of care may be measured using all three categories. Taking hand hygiene as an example, the number and placement of hand washing stations serves as a structural measure. The frequency at which staff wash their hands at the appropriate time is a process measure. Finally, infection rates, such as *Clostridium difficile*, may serve as an outcome measure.

In other cases, it may not be practical to capture all three categories. When considering central line associated bloodstream infections (CLABSI), a line cart is a demonstrable intervention to support improvement. While this may be captured as a structural measure and could be considered a correlate, it is not causal and may be viewed as invalid by clinicians. Adhering to line insertion practices may prove to be difficult or burdensome to accurately collect during all instances of placement, whereas CLABSI rates using a standardized approach may be captured as a valid outcome measure. The use of feasible and valid measures plays an important role in identifying system failures and determining the efficacy of mitigation strategies.

High Reliability Learning Network: A Statewide Experience

The Michigan Health & Hospital Association (MHA) Keystone Center has a long-standing history of leading statewide efforts where hospitals throughout Michigan collaborate, utilize evidence-based best practices, and advance safe patient care. At its start, the MHA Keystone Center facilitated hospital-based patient safety initiatives at the individual patient care unit level by engaging multidisciplinary teams. As the efforts progressed, processes evolved that created collaboration between patient care units and then toward hospital-wide projects. Keystone's successes in Michigan were emulated nationally, as well as globally.

With stagnation of the successes and in some instances regression of what had been achieved, a new approach was necessary. The adoption of the principles of HRO with the expectation of transforming these concepts into the healthcare space was a natural fit. Therefore, in partnership with the Joint Commission Center for Transforming Healthcare (CTH), all hospitals in Michigan were invited to join a quest toward zero preventable harm. A two-tiered approach was adopted, and 90 of Michigan's community hospitals volunteered to join a Tier-1, 3-year program, while nine hospitals also committed to a deeper dive into high reliability as the Tier-2

cohort. Both tiers were provided monthly educational webinars, annual face-to-face workshops, and access to extensive resources to expand their knowledge of HROs. Participants had access to the Joint Commission's Oro 2.0 leadership assessment, including facilitated debriefing [6].

The Tier-2 cohort commitment began with a written pledge from the hospital's Chief Executive Officer (CEO) and the expectation of engagement and involvement of the full senior leadership team. Staff from Keystone and CTH conducted semiannual onsite visits. These visits always included educational sessions, one-on-one mentoring with the senior leadership team, and visits to the frontline staff. Twice during the 3-year partnership, the Oro 2.0 leadership assessment was completed with a two to three-hour in-depth facilitation, analysis, and review of the results for each Tier-2 hospital.

Every Tier-2 team was expected to select areas of opportunity for improvement, develop and implement an appropriate action plan, and follow it to fruition. The cohort also met as a group annually for interactive workshops with presentations, group brainstorming, and experience-sharing.

As the partnership evolved, it became evident that the Tier-1 and Tier-2 hospitals varied in commitment and participation. Highly engaged hospitals were consistently associated with top leadership investment and willingness to be transparent. The few hospitals that seemed to reap the least benefit were disengaged at the top.

The commitment to transparency seemed to be the greatest hurdle for the Tier-2 hospitals. Those who were not transparent only shared outcomes with their senior team whereas those who started down the road of greater transparency began to share outcome reports with middle managers and then frontline staff. Hospitals that were most confident and willing to share outcomes posted their quality metrics in public locations including on video monitors in their lobbies. One organization's CEO went to the airwaves and shared their metrics, whether good or bad, via radio commentary.

As the 3-year partnership progressed, the question of "how do we know this work is making a difference?" came up frequently. Although there was not a defined measure that could directly answer their question, there appeared to be many that did so, indirectly. The least objective and certainly the most impressive, was what was observed. Staff identifying with and entering into conversations with leadership, during structured executive rounding or a simple acknowledgment in the cafeteria, was a powerful recognition of success. This change in culture was readily observed in many of the Tier-2 hospitals during the MHA-CTH onsite visits.

Several hospitals recognized objective measures such as reductions in hospital acquired conditions (HAC). Reduction in falls, CLABSI, and Catheter Associated Urinary Tract Infections (CAUTI) were noted in many of the Tier-2 hospitals. More than 2 years after sunsetting the partnership, organizations that were fully engaged and had started hardwiring the processes continued their quest and commitment toward high reliability. Many of these hospitals observed ongoing reductions in HACs 2 years later.

There were a number of lessons learned from this 3-year partnership:

- Leadership commitment is imperative to a successful high reliability undertaking and appeared to be a primary indicator of outcomes and sustainability.
- The most important lesson learned was the value of transparency. This was also the most difficult leap of faith. Not only did it require senior leadership's commitment and action, but it also necessitated frontline leadership's willingness to share, and bedside staff's acceptance of internal truths.
- Internal, system-wide, and external partnerships create success. Through the partnership, an environment of accountability was created, and this was further supported through mentorship and onsite coaching by the Keystone and CTH team.
- Avoiding the perception that high reliability is a project, initiative or the "flavor of the week" is important to foster a mindset of high reliability by doing it every day, with every patient, throughout the organization. Since journeys have endpoints and quests do not have defined ends, establishing the latter as the accepted nomenclature and as a concrete mindset ensures longevity and sustainable outcomes.
- Terminology is important—avoid calling the work "HRO," such as we are "doing HRO." Healthcare has a long way toward becoming highly reliable, and referring to high reliability as a noun suggests it is a project or initiative. Instead, organizations should reinforce that becoming highly reliable is a process and not a time-specific program.
- High reliability requires a change in mindset. To attain zero preventable harm requires becoming reliable, followed by highly reliable, with the aim of becoming a highly reliable organization.

The MHA high reliability quest with its member hospitals provides an example of how leadership support, or lack thereof, is of paramount importance. Hospitals that possessed active and engaged leadership, supporting the work toward high reliability, more often excelled, and those who lacked enthusiasm and commitment struggled. So far, this chapter has emphasized the need for staunch leadership support and provided examples of preoccupation with failure and sensitivity to operations, citing other highly complex industries as exemplars. However, in the field of healthcare, which by its very nature is person-centric, informing processes with the patient experience can have a tremendous effect on the reliability with which a healthcare organization operates. This will now be discussed by detailing the experience of a renowned academic medical center.

Patient Experience and the Pursuit of High Reliability Organization

Becoming an HRO in healthcare is impossible without acknowledging the reason health systems exist in the first place—the patient. These individuals, members of our families and communities, become patients when they engage in healthcare.

Their needs are what convene healthcare employees in a united purpose to determine the best way to care for them. Yet, healthcare has evolved to be increasingly complex, with systems that can span many locations for exams, lab testing, specialty care, and therapies which can be difficult to navigate. The multiple entry points into healthcare can also lead to a vastly different experience for the patients that can impact their level of trust or awareness of what might be pertinent to disclose at each point of care. Because the care continuum is rarely linear, it has become increasingly pertinent to fully engage the patient and their family as the key stakeholders. Sharing information and considering patients' needs, values, preferences, and previous experiences can decrease the risk of error to cure, treat, palliate, or prevent illness or injury [7].

Patient and family-centered care (PFCC) has been defined by the Institute of Patient and Family Centered Care as an "approach to the planning, delivery, and evaluation of healthcare that is grounded in mutually beneficial partnerships among patients, their families, and healthcare professionals. It redefines the relationships in healthcare by placing an emphasis on collaborating with patients of all ages, and their families, at all levels of care, in all healthcare settings, and in organizational change and improvement." [8] Because healthcare operations balance firmly upon cultural underpinnings, PFCC must be comprehensively integrated into organizational culture to ensure that these key stakeholders of healthcare are included as essential allies in quality and safety initiatives.

Better care and outcomes have been associated with measures of patient experience [9] and there is well-documented evidence supporting that PFCC methodology drives improvements in patient satisfaction and perceptions of their care [10, 11]. Additionally, the PFCC approach is shown to improve staff engagement and job satisfaction [12], and higher staff engagement is associated with better patient ratings of their care [13]. This level of staff engagement and job satisfaction can reduce burnout and improve well-being which translates to safer patient care [14]. For this reason, it is important to ensure that patient and family engagement is embraced at the point of care where they can participate in bidirectional communication.

At one large academic medical center, the approach to ensure patient perspectives was included in the design of the high reliability strategic planning process, and patients and their family members were consulted as experts in their care. This included open discussions about what safety meant to them in the healthcare setting, which is an important exercise in active listening. This occurred on several fronts and tapped into the expertise of the Patient and Family Advisory Councils (PFACs). The PFACs consisted of a dedicated team of individuals, predominantly represented by patients and family members, who come together regularly to work on opportunities to improve the health system. This valuable resource was accessible to the high reliability teams and was able to provide crucial input to narrow the gap between the needs and preferences of patients. One theme emerged repeatedly: patients want to be believed, to be treated with empathy, and to know what to expect.

Because patient and family stories about their care highlighted areas of opportunity to improve and how much "small moments mattered," the institutional Office

of Patient Experience launched a patient story library. The library included stories from a diverse group of patients who shared their healthcare journey and highlighted areas of importance, many of which revolved around safety. These stories were used to educate healthcare team members across the health system on the importance of becoming highly reliable. The videos were shared broadly, with organizational meetings featuring patient stories from the library and from staff's own experience. A fantastic example arose from these efforts, where an environmental services team member, who had been cleaning beds for many years, declared that in his mind he always considered how he would make sure each bed was clean so that no one would get an infection on his watch. Because of the sharing and learning network, this was validated and recognized by all.

Listening to Patients, and Encouraging Them to Speak-Up

PFCC includes respect for patients' values, preferences, and expressed needs; the coordination and integration of care; information, communication, and education; physical comfort; emotional support; and the involvement of family and friends [15, 16]. Greater patient engagement in healthcare is known to contribute to improved health outcomes [17]. It is, therefore, essential to know what practices generate positive patient feedback and desirable clinical results. PFCC practices, such as physician and leadership rounding, bedside nursing shift change reports, and the use of individualized white dry-erase boards are examples of initiatives that engage patients in being active in their care, and critical team members on the road to higher reliability.

A growing body of literature indicates that patients and their family members can provide key insights for their care, which symbolizes deference to the expert [18–21]. This contributes to the greater understanding of near misses and may serve to alert staff of concerns leading to more significant issues. Approaches such as initiating Rapid Response Teams [22] for patient-driven second opinions in hospital settings can make a profound difference. This directly influences the reluctance to simplify principle of high reliability, as well. By assuming a patient and family-inclusive model, seemingly minor concerns or requests for clarification from patients can unearth potentially catastrophic issues at the point of care. Culturally, this bespeaks a commitment to critically assessing process failures and setting a standard of excellence when it comes to safety.

Using Reason's Swiss cheese model of patient safety [23, 24], we can apply patient engagement as one of the systems in place to eliminate errors, or the metaphorical holes in the Swiss cheese. As was noted with PFCC, it is pertinent to employ best practices that can be reliably performed in the same way no matter which shift, unit, or care team member is interacting with the patient. Furthermore, the use of white dry-erase boards in patient rooms is prevalent in most hospitals and serves as a low-tech, cost-effective tool, and structural measure that may improve communication to patients and families. Information such as the plan of care,

projected discharge dates and preferred name are crucial, and even smaller things such as daily goals, the time for physical therapy, or team members' names can have a major impact [25, 26]. These tools are not only critical for engaging patients and families, but also help every team member know what is important for the patient; a major benefit of a shared tool that is easy to see and update.

Effective patient communication with clinicians can also aid in successful care planning and decisions about most clinical interventions, as well as in understanding safety and confidentiality information. Staff and faculty prioritize providing the safest, highest quality care, but increasingly recognize the need to also improve the patient and family experience without necessary resources. Furthermore, patients often do not feel informed about the details of their hospital stay, including surgical procedures and expected outcomes, and care teams report that patients arrive unprepared for what to expect. Thus, further integration of tools that help eliminate the holes in the Swiss cheese through patient and family engagement across the patient's stay and into care management planning is needed.

According to research, nearly 20% of hospitalized patients experience adverse events after discharge, of which 75% may have been preventable [27]. Involving patients and families in the discharge planning can improve the outcomes and reduce readmissions as well [28]. The IDEAL Discharge Planning Checklist [29] created by the Agency for Healthcare Research and Quality incorporates PFCC principles in full and emphasizes the following elements:

- *Include* the patient and family as full partners in the discharge planning process.
- *Discuss* with the patient and family five areas to prevent problems at home:
  - Describe what life at home will be like
  - Review medications
  - Highlight warning signs and problems
  - Explain test results
  - Make follow-up appointments
- *Educate* the patient and family in plain language about the patient's condition, the discharge process, and next steps throughout the hospital stay.
- *Assess* how well doctors and nurses explain the diagnosis, condition, and next steps in the patient's care to the patient and family and use teach back.
- *Listen* to and honor the patient's and family's goals, preferences, observations, and concerns.

Barriers to shared decision-making include overworked providers, insufficient training, and a lack of understanding about what ensures a quality patient experience. Yet, it is known that shared decision-making is not only a key tenet to the PFCC principles, but it also results in improved outcomes [30].

PFCC can help spread good practices and guide leadership and staff on engagement approaches, ultimately helping to provide strategic oversight to the efforts. This also underscores the HRO principle of sensitivity to operations described above, when considering the role of family presence at the bedside of the patient.

Throughout the course of the Covid-19 pandemic, hospitals across the United States enacted restricted visitor policies to minimize the risk of infection to patients and staff. However, evidence also showed that safety events such as falls, pressure ulcers, and delirium increased. Multiple studies suggest that attendant family members significantly reduced delirium by providing comfort and tethering the patient to reality [31, 32]. Given the plethora of data supporting better outcomes for patients who have a visitor, hospitals will continue to consider how one operational change for safety may unintentionally impact another [33–39].

However, as emphasized by the Institute for Healthcare Improvement (IHI), "genuine and effective partnerships with patients at the clinical and organizational level are slow to develop, despite exemplars with proven results" [40]. Patience and consistency are critical in order to make an impact that affects patient satisfaction scores. Due to the hierarchical nature of healthcare organizations, it is vital that leaders are visible at recognizing and promoting a patient-centered culture as a critical aspect of becoming an HRO.

Conclusion and Lessons Learned

- High reliability, as indicated in this chapter, is a multidimensional concept requiring strong leadership commitment and the full engagement of healthcare staff, patients and their family members or caregivers, when appropriate.
- Preoccupation with failure and sensitivity to operations, as evidenced by DCI in healthcare allows team members to identify and prepare for potential complications.
- Leaders who foster a culture of safety, ensure transparent use of information, adequate material resources and organizational collaboration, are shown to have higher resilience and are better able to weather inevitable challenges that occur.
- Adopting a PFCC model of care helps organizations establish elements of high reliability, as well.
- Healthcare organizations that look at critical components affecting safety and quality outcomes through a patient and family-centric lens demonstrate a clear reluctance to simplify their processes.
- Finally, by deferring to the expert, or the patient and their family, healthcare teams are provided with rich information regarding the patient's clinical history before entering the health system, and subtle changes in their disposition afterward. This can serve to fill another proverbial hole in the slice of Swiss cheese in the safety nets established by healthcare organizations.

Ultimately, healthcare has ground to cover in its quest for high reliability, though it is shown to be achievable if systemic and thoughtful approaches to safety and quality of care are assumed. However, this can only be done through robust leadership support and a culture of inclusivity, transparency, and continuous learning.

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Chapter 2
Health Equity: A Key Aspect of Patient Safety

Derek J. Robinson

Introduction

In its sentinel 2001 report Crossing the Quality Chasm: A New Health System for the 21st Century, the Institute of Medicine (today known as the National Academy of Medicine) established six primary aims for improving the U.S. healthcare system. These aims are a foundational framework for defining quality health care, where such care should be safe, timely, effective, efficient, equitable, and patient centered [1]. Across initiatives and quality measures implemented by health care stakeholders in the public and private sectors, significant progress has been made in advancing most of these aims. For example, more than two-thirds of patient safety measures analyzed in a 2017 report demonstrated overall improvement [2]. However, in the more than two decades since this report was released the opportunity to ensure the delivery of equitable care has largely been ignored by key stakeholders in health care.

Beyond the physical walls of health care delivery settings are substantial factors which influence the health status of individuals and communities, which are commonly known as the social determinants of health (SDOH). Major categories of SDOH in Fig. 2.1 include health behaviors, social and economic factors, physical environment, and clinical care; non-clinical factors are estimated to drive 80% of an individual's overall health status [3]. By their nature, these SDOH permeate the daily lives of individuals and can positively or negatively shape their lived experiences, creating material differences in physical and emotional health. An understanding of how SDOH factors affect the downstream demand for health care services and shape unique risk factors for patient populations is an important consideration in improving patient safety.

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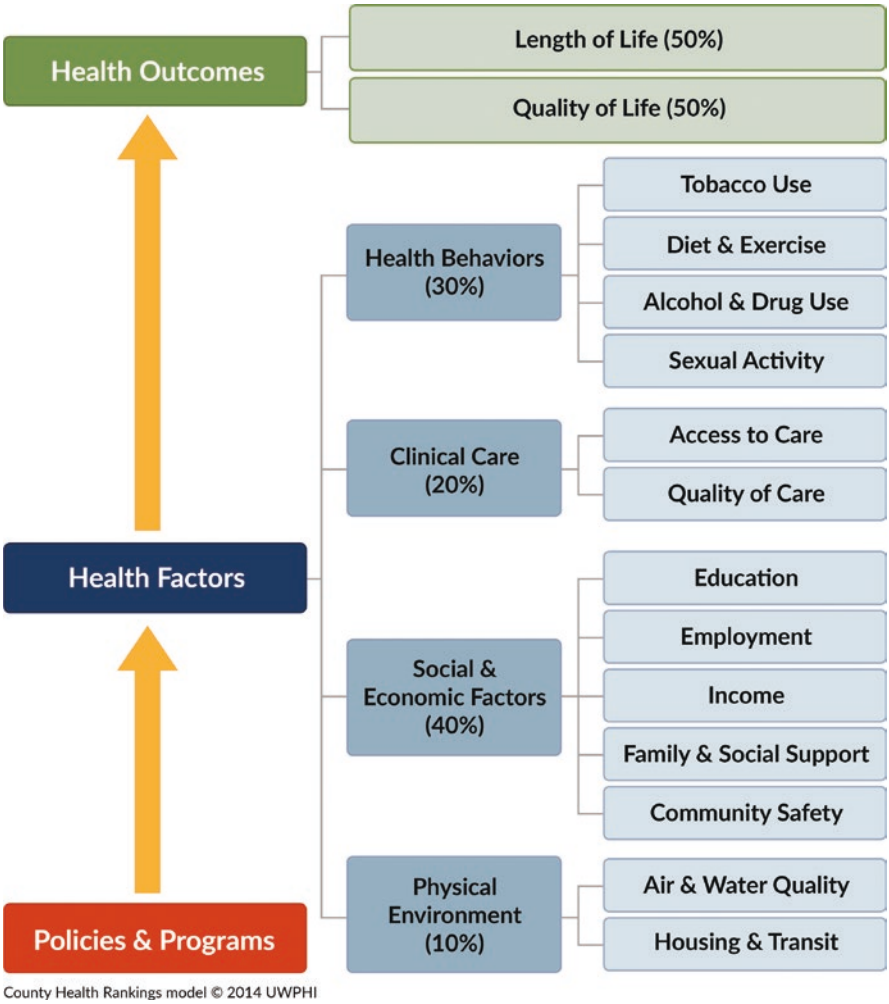

Fig. 2.1 The University of Wisconsin Population Health Institute. County Health Rankings & Roadmaps, 2022. www.countyhealthrankings.org

Patients have some visible or observable characteristics that may distinguish them from others, such as sex, age, weight, and primary language. Evidence has shown that these characteristics and others ascribed by society, such as race and social class, can impact the quality of care received. Equitable care ensures that every patient receives the care necessary to achieve the best possible health outcome, without disadvantage on the basis of race, ethnicity, primary language, sexual orientation, gender identity, weight, class, or other individual or social characteristics. When health care leads to differences in health outcomes observed across patient subpopulations or demographics, these differences can be described as health care disparities. The identification of these disparities alone is insufficient in

the pursuit of equitable care. Understanding why health care disparities occur is important in determining where avoidable and unfair practices, like sexism, ableism, and racism, for example, are at the root cause of the observed differences. Racial misconceptions regarding biologic variation are deeply rooted in the American society and western medicine and have contributed to health care disparities based upon race, a social construct [4]. Likewise, health care has not been immune to disparate experiences and outcomes for individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGTBQ). In a national survey of LGTBQ adults, 34% either experienced discrimination in health care or avoided seeking health care for themselves or a family member due to anticipated discrimination [5]. When historically marginalized populations avoid or delay seeking preventative or urgent clinical care as a result of negative experiences, this contributes to poorer health and health care outcomes, which the health care system must address. Health care inequities are avoidable and unjust health care disparities.

Not dissimilar to other parts of society in the U.S., the health care system has a well-documented legacy of disparate treatment of patients, contributing to glaring disparities in health outcomes. Although heart disease is a leading cause of death among women, following a heart attack, women are less likely to receive aggressive care. In the Health of America report, the Blue Cross and Blue Shield Association reported an analysis of a claims data set with 43 million members and found that when compared to men, women with heart attacks were 5% less likely to received angiography of the coronary vessels, 27% less likely to receive angioplasty, and 38% less likely to receive coronary bypass surgery [6]. Perhaps most pernicious has been the role of race and racism. The 2003 landmark report Unequal Treatment documented that after controlling for social factors, racial and ethnic minoritized patients were more likely to receive inferior care than their white counterparts [7]. It is now well accepted that quality care must inherently be safe. Quality care, including efforts to advance patient safety must also be rooted in the important aim of equity.

Historical Perspective

Case Studies

Case 1

J.M. was a 27-year-old G3P2 EGA 38 weeks who presented to L&D in active labor. After evaluation by the physician, it was determined that she would be taken to the OR for cesarean section where a healthy, full-term baby boy was delivered. During

her post-operative recovery on L&D, she was accompanied by her partner. After approximately 4 h, J.M. began to feel fatigued and experienced mild abdominal pain which was reported to her nurse through the bedside call system. Her nurse shared with her that pain after surgery was normal and that she should continue to rest. As her pain increased over the next 2 h, she reported feeling lightheaded, which prompted her partner to speak with the nurse at the nurse's station. Her vitals were taken which showed a heart rate of 115 bpm and blood pressure of 100/64. She had experienced minimal vaginal bleeding based upon evaluation of her pad. At the insistence of the patient's partner, the nurse paged the physician from home to discuss her clinical status; as a result, a hemoglobin and hematocrit were ordered and subsequently sent to the lab following the blood draw by the phlebotomist. The results demonstrated a 5 g/dL drop following surgery and were phoned by the lab to the nurse, who then notified the physician. The nurse noted that due to the darkness of the patient's skin, the patient did not reflect the usual sign of pallor associated with blood loss.

As he returned to the hospital from home, an emergency transfusion was ordered by the physician and three units of packed red blood cells were ordered from the blood bank. While consenting the patient for the blood transfusion as instructed by the physician, the nurse prepared to place a second IV that was large bore in size. He explained to the patient that although it might be difficult to place the IV successfully on the first attempt due to the thickness of the patient's skin, it was a necessary step to assist with her resuscitation. Approximately 12 h following the C-section, J.M. was taken back to the OR where 2 L of blood was evacuated from her abdomen. She suffered an intraoperative cardiac arrest due to hemorrhagic shock and despite resuscitative efforts, died in the OR.

Analysis and Discussion

During the course of post-partum care, the initial complaints of pain and fatigue by the patient to her nurse appear to have not been taken seriously by her nurse. There was no documented evaluation by the nurse at this time, and the treating physician was not contacted. While the indications for her C-section are unclear, the risk of occult hemorrhage should have been high on the list of potential causes of the patient's complaints and given that the treating physician was not in-house, early consultation was particularly important. The nurse's comments reflect an implicit bias against the patient based upon her skin color. This is demonstrated in part by the false belief that the skin of patients with darker pigment is thicker than the skin of patients with lighter pigment. His competency in recognizing pallor is also called into the question. Pallor can not only be observed on the skin but on the oral mucosa, palpebral conjunctiva, and nailbeds.

While both pain and hemorrhage can cause tachycardia independently, the physician had a duty to re-examine this postoperative patient urgently and should not have waited for the results of blood work to initiate the resuscitation process. More

importantly, overall slow recognition of the patient's progression through stages of shock and non-adherence to established patient safety bundles were key failures with interpersonal racial bias at the root cause.

The risk of death from pregnancy related complications have remained 3–4 times higher in Black women compared to white women for many years [8]; in fact, this racial disparity in death is widest between Black and white women with the lowest pregnancy risks (normal birth weight, low-to-moderate parity) [9]. Pregnancy complications not resulting in death, which could be considered as near misses, are 50–100 times more common than maternal deaths. Severe Maternal Morbidity (SMM) is a composite measure of such complications, and Black women have twice the risk of SMM than that of white women. Hemorrhage is the leading major complication of childbirth, the leading cause of SMM, and the most preventable cause of maternal death [10].

While the history of the United States is replete with examples of laws and practices that unfairly treated individuals on the basis of race, it may be commonly assumed that attitudes and practices in health care and medicine have been immune to such influence. A study [11] published in 2016 evaluated the presence of false beliefs regarding biological differences between Blacks and whites among medical students and resident physicians and had the following findings:

- Among first year medical students, 29% believed that the blood of Black people coagulates more quickly than whites;
- 42% of second year medical students believed that Black skin was thicker than white skin and 25% of resident physicians had the same belief;
- 28% of second year students believed that Blacks age more slowly than whites;

14% of second year students believed that Black nerve endings are less sensitive than whites.

The assessment of and response to patient pain is an important measure of quality. Pain is a qualitative experience, and its assessment can be subjective, despite modern patient reported tools that attempt to quantify pain. Dr. Marion Simms who is often revered as the "father of American gynecology" taught his students in the mid nineteenth century that Black women did not need anesthesia as he demonstrated experimental vaginal surgeries on enslaved Black women [12]. Contemporary studies have shown that Black patients are less likely to receive pain medication in the clinical setting than whites and when treated for pain, receive lower quantities of medication [13].

Black and Hispanic women, after adjusting for clinical risk factors, are more likely to have cesarean sections than white women in the United States [14]. For some context, nineteenth century anatomical descriptions of the female pelvis like the Caldwell-Moloy classification, which persist in modern medicine, describe the pelvis of Black women as "anthropoid" or animal like and described them as less prepared for childbirth when compared to white women, where the "gynecoid" description is applied [15]. This may be one of several factors that influence the clinical decision-making of a physician to perform a cesarean section on a Black

woman, especially when the clinical circumstances are discretionary [14]. Moreover, this health care inequity is amplified by the modern use of race in predicting the potential success of a woman having a successful vaginal delivery for a subsequent pregnancy after a prior cesarean section. The commonly used clinical algorithm for vaginal birth after cesarean (VBAC) assigns a higher risk of failure for Black and Hispanic women [15]. The increased incidence of primary cesarean sections, which may be related to physician bias and miseducation, coupled with the secondary structural racism in the VBAC calculator driving subsequent surgeries, places Black women at greater risk for SMM.

Systemic bias also potentiates with the interpersonal bias that occurs in obstetrical care. In alignment with a 2008 ACOG Practice Bulletin No. 95: Anemia in Pregnancy, many obstetrical providers and hospitals have used a lower threshold for diagnosing anemia in pregnant Black women than for other pregnant women. As a consequence, Black women may be more likely to present with anemia at delivery and experience greater clinical risk in the setting of post-partum hemorrhage compared to other women [16]. In recognition of this systemic inequity in using a different standard for Black populations, ACOG revised its Anemia in Pregnancy: ACOG Practice Bulletin, Number 233 and removed the race-based threshold for treatment of anemia during pregnancy [17].

Summary

Early recognition and treatment of postpartum hemorrhage is a patient safety imperative. There are many evidence-based processes and recommendations that improve patient safety and outcomes in the setting of post-partum hemorrhage. When the clinical environment accepts failure and does not guard against individual provider variation, by both policy and transparent measurement, disparate care and poor outcomes may occur. Improvement is possible. In a California-based study across 99 hospitals, researchers determined that the baseline SMM among women with hemorrhage was 22% overall but when stratified by race, 28.6% among Black women and 19.8% among white women [18]. They implemented a multi-year quality improvement initiative which implemented and measured 17 evidence-based recommendations. Adherence led to a decline in overall SMM with hemorrhage to 18.5%, including a disparity narrowing 9% absolute reduction for Black women. The study also found that the single most important driver of SMM disparity for Black women was cesarean section.

The persistent of differences in health care outcomes by race are not surprising but also should not be accepted as the inevitable future. Within health care, medical education must take the lead in unlearning and discontinuing the teaching of racial myths which have contributed to inequities in clinical care. Clinical quality and patient safety systems must ensure that patients receive necessary care that is free of negative racial bias.

Case 2: The Role of Race in Access to Safe Care

Clinical Summary

S.P. is 78-year-old physically active female with early-stage dementia and hypertension who lived independently in a suburban community, several blocks from her home. She was admitted to the hospital through the emergency department following a ground level fall in her home where she tripped over her dog and sustained a right femoral neck fracture and multiple contusions. On hospital day 2, she underwent hip replacement surgery without notable intraoperative complications. On hospital day 5, she is noted to have swelling in the right calf and her work up revealed the presence of a right femoral vein deep venous thrombosis along with multiple bilateral subsegmental pulmonary embolisms. Daily nursing notes reflect that the patient has been turned at regular intervals and seen by physical therapy daily to promote ambulation. S.P. complains of back pain on hospital day 10 while her family is visiting. When the patient is rolled over by the nurse, she is noted to have a stage 3 decubitus pressure ulcer. S.P.'s family members have a health care background and launch a complaint with the hospital and health system regarding substandard care and perceived racial bias.

The hospital system has a patient safety program and it described as "robust," which monitors general and surgery-related patient safety indicators across the four hospitals in its system. In addition to adhering to relevant patient safety bundles, it routinely publishes internal provider specific performance data. During a meeting with the family, it shared that system wide and hospital specific performance on these indicators were above the 85th percentile for the region, reflecting high quality care. When asked by the family about disparities in care delivered, health system leadership noted a high level of compliance with cultural competency and implicit bias training by its staff and the absence of analysis reflecting disparities in patient care.

Analysis and Discussion

In this clinical case, the patient experienced at least two adverse clinical outcomes that are well studied and preventable. The first was the development of a post-operative deep venous thrombosis (DVT) and associated pulmonary emboli (PE). Standard of care calls for the use of anticoagulant medication for hospitalized patients during the post-operative period to prevent the development of DVTs and life-threatening PEs. Sequential compression devices have also been routinely used in hospitalized patients to reduce the incidence of PEs. The case does not speak to the use of these preventable measures in the patient's care. The second-adverse clinical outcome is the occurrence of a stage 3 decubitus pressure ulcer. The prevention of pressure ulcers requires ongoing interdisciplinary actions, reflecting prioritization and expertise by both the health care team and individual providers.

The clinical outcome conflicts with the quality of pressure ulcer prevention care documented, introducing the possibility that adherence to best practices in care did not occur.

In this case, the patient's family identifies as Afro-Latino and raises a concern that the care received was inferior due to negative racial bias, challenging the assumption that all patients are equal beneficiaries of patient safety efforts. A 2021 report by the Urban Institute and Robert Wood Johnson Foundation entitled "Do Black and White Patients Experience Similar Rates of Adverse Events at the Same Hospital" evaluates an important question in patient safety, where the underlying framework did not have an intentional focus on equity. Researchers analyzed 2017 data from more than 2340 hospitals across 26 states with a focus on four (4) general patient safety indicators and seven (7) surgical adverse events. After controlling for age and gender, they determined that on three (3) measures, there were no significant difference in care but on two measures, whites had worse outcomes. On six (6) measures, including four surgical adverse events along with pressure ulcers and central line associated blood stream infections, Blacks had clinically large and statistically significant worse outcomes than whites [19].

Experts have noted that Black and white patients consume health care services at different facilities, consistent with the local nature of health care and endemic racial segregation in residential housing. Researchers in this study evaluated a subset of hospitals where at least 25% of patients were Black, testing the hypothesis that hospitals with greater experience in caring for diverse populations may more fairly apply best practice guidelines and demonstrate results that differ from hospitals where less than 25% of patients treated were Black. Their analysis of four general patient safety measures demonstrated statistical similarity, reflecting that the proportion of Black patients served was largely unrelated to the disparity in the quality of care between Black and white patients in the same hospital. There is room for improvement in the collection of patient sociodemographic data and health care disparities research of subpopulations beyond Blacks and whites; however, there remain key patient safety lessons.

Beyond the differences in care that result from discrimination, emerging research has illuminated biological pathways through which the stress induced by discrimination may negatively affect the health of individuals. The coordinated physiologic response to discrimination may include the neuroendocrine system, autonomic system, immune and inflammatory processes, and metabolism [20]. The resulting elevation in biomarkers may not only have an impact in long-term health but during acute care inpatient stays, where patients may be especially vulnerable and stressed. Further study in this area is needed.

Summary

Equitable care must be at the core of a hospital and health system's patient safety program. Failure to look for and identify disparities in patient safety does not mean that they do not exist. In fact, failing to ensure that all patient subpopulations receive

safe care will sustain and perhaps widen pernicious health care disparities. In the Urban Institute study and clinical case alike, the phenotypical difference in skin color alone does not explain the higher incidence of pressure ulcers and other adverse outcomes in Black patients. While it is possible that pressure ulcers (PU) may occur rapidly over a matter of hours, it is more likely that in this case that the PU developed over a period of time and this care outcome was the result of an interdisciplinary, systemic failure of clinicians at the bedside and a lack of transparency and accountability. Understanding and addressing how racism, explicit bias, and implicit bias operate at a system level, impacting the care of patients is a patient safety imperative.

Conclusion

Patient safety has achieved significant and yet necessary advancements in the quality of clinical care. These strides have been sustained, in part, by research, measurement, transparency, analysis, and accountability. Yet there remains a need for more research to understand how discrimination and racism manifest as patient safety issues and to design appropriate interventions and solutions. These efforts should be prioritized and include attention to how the intersectionality of several social factors may significantly increase patient safety risks for historically marginalized groups [21]. The case studies and discussion content in this chapter serve as a clarion call for patient safety experts to integrate health equity into the core of their work, ensuring that all patients can benefit from access to high quality care.

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Chapter 3
Leading Change in the Culture of Patient Safety

Dennis Wagner and Tom Evans

National Call to Action to Improve Care and Save Lives

The landmark Institute of Medicine (IOM) report, To Err Is Human, identified serious problems with medical errors in hospitals. When it was issued in 1999, it was estimated there were between 44,000 and 98,000 deaths annually in US hospitals due to medical errors [1]. The report precipitated a national call to action to increase awareness and improve patient safety.

Early efforts to improve hospital safety included work in the Veterans Hospital Administration, the Institute for Healthcare Improvement (IHI) 100,000 Lives Campaign, and other initiatives. Each initiative contributed to the knowledge and evidence base that provided a framework for future work. In 2010, the federally sponsored Partnership for Patients (PfP) initiative was introduced. The program used clear goals, an organized program of work, national investments in quality improvement, and a focus on leadership practices to achieve dramatic reductions in hospital harm. Care in US hospitals became consistently safer, year after year for the period 2010 through 2017.

This chapter describes progress on national hospital patient safety in the last two decades in the United States and focuses on key leadership actions used to advance the culture of safety. It includes a case study of the Iowa Healthcare Collaborative's (IHC) experiences and results as an example of a leading contributor's work in state

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and regional work to improve hospital safety. Also included is a specific example of how the leadership methods and principles were applied by one of IHC's supported hospitals, the Mary Greely Medical Center in Ames, Iowa.

Bold Aims Drive Change: The Partnership for Patients

In 2010, the Centers for Medicare and Medicaid Services (CMS) launched the PfP initiative. The program featured the bold national aim to reduce preventable harm in all US hospitals by 40% by 2014 [2]. Independent reviews by the Agency for Healthcare Research on Quality (AHRQ) reported that safety improved in US hospitals from the 2010 baseline year through 2014. AHRQ's National Scorecard documented 2.1 million fewer harms, an estimated 87,000 deaths prevented, and $19.8 billion in cost savings [3]. By the end of 2014, US hospitals had achieved a 17% reduction in overall harm from the 2010 baseline, which equated to a 39% reduction in preventable harm.

Based on the success of the initial 4-year PfP initiative, CMS established a new aim to achieve a further 20% reduction in overall harm from the new 2014 baseline of 121 harms per thousand discharges. New harm areas were added like sepsis and C. difficile. Other harm areas like central line associated blood-stream infections came under control. AHRQ estimates of sustained national reductions in hospital harm rates through 2017 are summarized in Fig. 3.1 [4]. The harm rate was lowered from 145 harms per thousand discharges in the 2010 baseline year to 86 harms per thousand discharges in 2017. Two values are reported for 2014 to permit comparisons of rates that reflect an adjustment in AHRQ's standardized methodology for tracking hospital harm. Additional in-depth analyses of these datasets and methodology by CMS, AHRQ, and others documented further national improvements in hospital patient safety through the end of 2019 [5].

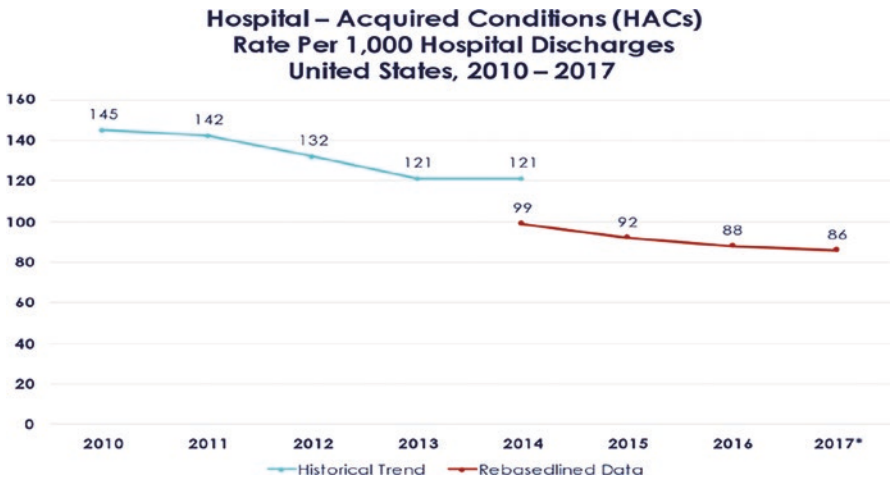


Fig. 3.1 National reductions in hospital harm, 2010–2017

The clear, bold aim of the PfP was accompanied by a coordinated strategy and program of work, as summarized below.

Key Elements
Partnership for Patients Initiative

Create Will
- Recognized that hospitals want to do this work based on science, medicine, and good care
- Partnered with organizations trusted by hospitals as change agents to create engagement, alignment, and support
- Led with a clear bold aim that was quantifiable and time limited: 40% reduction in preventable harm by end of 2014

Focused Ideas
- Narrowed focus to the ten biggest harms
- Spread best practices to address selected harm areas

Systematic Execution
- Standardized national measurement to track progress
- Focused on building leadership capabilities of change agents
- Fostered alignment through engagement of provider associations and other impactful private parties
- Stimulated and aligned related work across federal agencies
- Invested $500 million through CMS Innovation Center to support hospital improvement

This performance proved sustainable during the life of the campaign. The healthcare system was severely stressed during the COVID 19 pandemic, and there is recent evidence to suggest this contributed to backsliding on some measures of patient safety [6].

Achieving Cultural Transformation in Hospital Safety

The PfP initiative was based on the extensive knowledge and experiences accumulated in the prior decade of quality improvement work in hospital safety. Standardized measurement, application of known science on the diffusion of innovations, and a sustained focus on will, ideas, and execution were key elements. Systematic spread of known leadership principles and methods of choice, bold aims, synergy, abundance, net forward energy, and pacing events were a powerful complement to the discipline of quality improvement.

Each of these key elements drove the PfP and participating Hospital Engagement Networks (HENs) like the Iowa Healthcare Collaborative (IHC) to dramatic improvement in performance across thousands of US hospitals.

Standardized Measurement

The PfP used a standardized, comprehensive, measurement system to assess the overall impact of its work [7]. It focused on both measurement for purposes of improvement by the participants, and an external assessment of impact by AHRQ.

Participants tracked improvement monthly. Hospitals reported data on each of the top ten harm areas to their HENs, who used this data to track and guide improvement in their partnering hospitals. The HENs shared the monthly data with CMS and with each other. This evaluation was used to track and guide improvement work across the larger network of federal agencies, national partners, and HENs.

External assessment was achieved using the AHRQ National scorecard. The scorecard used in the campaign incorporated three different measurement systems from large AHRQ, Centers for Disease Control (CDC), and CMS datasets. It was based primarily on an annual randomized sample of up to 30,000 chart reviews originating with the Medicare Patient Safety Monitoring System (MPSMS). Chart abstracters counted every hospital harm in these charts for use in constructing the annual estimates of the numbers of harms per thousand patient discharges. This methodology was repeated annually and summarized with a single, comparable assessment of the number of harms per thousand discharges as outlined in Fig. 3.1.

Diffusion of Innovation Science

The PfP initiative recognized the importance of tailoring improvement to different stages of hospital readiness. Everett Rogers' seminal work on the diffusion of innovations, as shown in Fig. 3.2, provided leaders in the federal government and public and private partners with a powerful roadmap for leading change among participating hospitals and providers [8].

This helps quality improvement leaders organize their efforts to appropriately target interventions to each segment of their populations. For example, personnel from among the Innovator and the Early Adopter hospitals served as faculty to support improvement efforts by hospitals in the Early Majority category. The Late Majority, in turn, are influenced by evidence and progress in the Early Majority. To avoid the common mistake of trying to convince Laggards, PfP improvers limited efforts with this category. The Laggard category will often actively challenge change efforts until they have proof that an innovation cannot fail [9].

Based on this receptivity to change, innovations that confer competitive advantage move through the provider community. As a 'new way' becomes imbedded

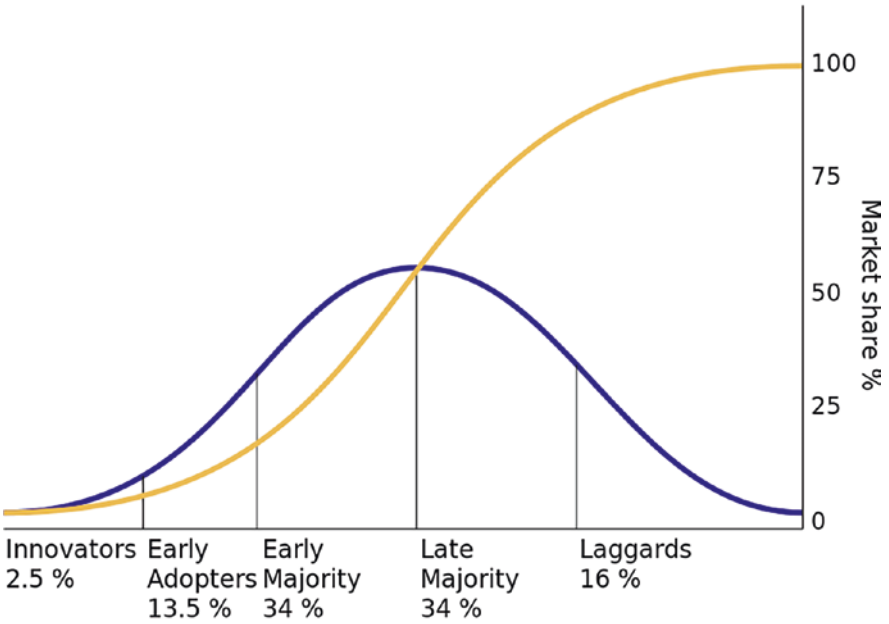


Fig. 3.2 Adopter categorization on the basis of innovativeness

into their work processes, the share of the market delivering these innovations increases. The result is a new, safer standard of care.

Competent and experienced faculty were key to the results of the Partnership. These leaders created trust, spread known best practices, and invested in sustainable culture change. Organizations that served as campaign "nodes" in the 100,000 Lives and the 5 Million Lives Campaigns, like the IHC, provided an abundance of hospital clinicians and leaders to serve as faculty. These C-suite leaders, physicians, and nurses were powerful assets for leading change.

Focus on Will, Ideas, and Execution

The Partnership conducted its work with a clear understanding that ***will***, ***ideas,*** and ***execution*** are at the heart of creating systematic change.

Will

Creating the will to change is the first step in transformation. Bold aims are a powerful asset in building the will necessary to lead and manage large-scale change. The use of bold aims confers many benefits:

- Shift the mindset: focus moves from barriers to change to an exciting, better future.
- Mobilize new thinking: makes clear that "business as usual" approaches will not be sufficient and that breakthrough thinking, and actions are required. Bold aims disrupt the natural inertia that pervades large organizations like hospitals, state and national associations, and federal agencies.
- Are attractive: bold aims signal to the world there is an opportunity to be part of something significant that could potentially change the world.
- Engender accountability: measuring progress becomes more essential when bold aims are used as key drivers.

For the PfP, committing to the bold aim of achieving a 40% reduction in preventable harm was a key step. It fostered the necessary Will to actively adapt, test and spread the changes necessary to achieve improvement across all US hospitals. The increased Will helped competitors to align and engage with one another as partners in transformation.

Ideas

Ideas for change were plentiful. By the time, the PfP was launched in 2011, there was a solid base of evidence-based practices that had been used by many higher-performing hospitals to reduce hospital harm. The 10 largest sources of hospital harm with evidence-based best practices in 2010 were selected as the focus of the overall national improvement initiative.

Ten Priority Harm Areas

1. Adverse drug events
2. Catheter-associated urinary tract infections
3. Central line associated blood stream infections
4. Injuries from falls and immobility
5. Obstetrical adverse events
6. Pressure ulcers
7. Surgical site infections
8. Venous thromboembolism
9. Ventilator-associated pneumonia
10. Reducing readmissions

The PfP later added an "11th harm" of early elective deliveries based on leadership guidance from HHS Secretary Sebelius.

As the initiative progressed, participants evolved new and better practices for achieving progress on the aim. In some situations, like Adverse Drug Event prevention, new and emerging practices were developed when the initial interventions

were more limited. In other situations, innovative approaches evolved—like the implementation of cross-cutting practices on Patient and Family Engagement (PFE) to help create a culture of safety. New PFE learning included the systematic use of patient and family advisory councils (PFACs), direct engagement by providers with patients and family members at bedside at shift changes, and more. Lessons were shared across the network to drive further improvement.

Execution

Systematic execution was at the heart of the initiative. CMS teamed with public and private partners, Hospital Engagement Networks, and other federal agencies to bring system and method to the daily, monthly, and annual work of execution. A series of constant, regular pacing events helped to ensure both coordination and mutual accountability.

Systematic Accountability to Drive Execution

- Weekly webinars on best practices for hospital engagement networks.
- Weekly working sessions with Federal Agencies and StaffDivs.
- Weekly briefings for HHS secretary, deputy secretary, and agency heads.
- Quarterly accountability sessions with hospital engagement networks.
- Quarterly working sessions with 50+ national partners.
- Organized program of work to spread leadership mindsets and methods.
- Annual outcome milestones to sustain HEN contract funding.
- Annual CMS quality net conference to highlight successes, best practices, and areas for needed improvements.

These recurring pacing events instilled a cadence of accountability across the entire national network for action, adaptability, and progress. This accountability was key to the execution strategy.

Systematic Use of Leadership Principles

The PfP leadership team used a powerful series of cross-cutting leadership principles to help build and sustain a culture of constant, effective execution. Some of these were adapted from prior change management initiatives. Others were adapted from the work of thought leaders such as Stephen Covey, author of the seven Habits of Highly Effective People, and Doug Krug, co-author of Enlightened Leadership [10, 11]. The CMS leadership team worked to systematically spread the use of these principles throughout the network of participants. Six leadership principles were especially important to the work of the larger initiative and the IHC.

Choice

How we choose to respond to a stimulus is the first step in constructive action. A particular stimulus does not always have to lead to a "standard" response when leaders get conscious about their choices [12]. This is especially true with negative stimuli. For example, when someone insults us, we can choose not to respond in kind. World-renowned psychiatrist and Nazi concentration camp survivor, Viktor Frankl, addressed this in his seminal work, *Man's Search for Meaning*. We can cultivate greater awareness, confidence, and proficiency at responding to "bad" stimuli with "good" responses [13]. Turning negative stimuli into positive action is a powerful and effective way to lead quality improvement work. For patient safety leaders, it is important to learn to choose consciously and intentionally to turn a "bad" event like a hospital harm into learning and impetus for "good" improvements in safety. Learning to consciously make these choices was a powerful asset in building a culture of safety.

Bold Aims

Participants in the PfP initiative were focused on a 40 percent reduction in preventable harm. Bold, time-limited, quantitative aims help to engender the urgency and intensity needed to propel constant action and progress. They are effective in creating the kind of thinking and action needed to achieve breakthrough results. One powerful feature of the PfP bold aim was that it worked at every level. For example, a hospital could adopt the aim and work to achieve a 40% reduction in preventable harm in their hospital. Similarly, a hospital system or a statewide organization like the IHC could adopt the aim and seek to generate a 40% reduction in preventable harm in hospitals throughout their service area. Progress at each of these levels rolled up to overall results at the national level.

Synergy

Focusing on this principle expands our resources by tapping into the unknown potential of ourselves and our stakeholders. Synergy is achieved through the strategic use of the two key behaviors of *asking* and *disclosing.* Seeking feedback and input from colleagues and partners by *asking* for it, and *disclosing* information, motivations, history, and other information from our private domains is at the heart of increasing synergy [14]. The systematic use of these two behaviors increases shared knowledge to fuel greater teamwork, new insights, and possible actions that were previously unknown to either us or our partners [14]. The process of consistently sharing emerging best practices and associated results on safety among hospital competitors is a powerful example of synergy in action.

Abundance

The principle of abundance means believing that we can gain access to all that we need to achieve our shared aims. Two leadership speech acts of offers and requests are key to unlocking the natural abundance of the world. Offers involve voluntarily offering what you have that others don't. Requests solicit information or resources from others. When offers or requests are acted on, they result in commitments. When many partners worked together and consistently made requests and offers to each other, the resulting expanded commitments helped to generate the actions and resources needed to achieve shared aims. Offers and requests generate the expected commitments and actions when people say "yes." They also generate unexpected and unpredictable future positive actions that lead to abundance. Learning to anticipate and "look for" these positive additional consequences can help us to become natural generators of abundance.

For example, shortly after the Partnership for Patients was launched, HHS Secretary Sebelius requested that CMS add an 11th harm area of Early Elective Deliveries (EEDs) to the work of the PfP. This generated both the expected results on reduced EEDs, as well as unexpected abundance. Not only were the desired major national reductions in early elective deliveries achieved, but adapting to the unexpected new challenge allowed participants in the initiative to prove themselves nimble and adaptive. We learned, together, that our network was capable of rapid, dramatic, measurable progress, and results. The straightforward challenge posed by EEDs produced greater confidence and esprit de corps across the entire network.

Net Forward Energy

Leaders often embrace accountability for catalyzing action or showing the way forward. Less commonly, leaders assume accountability for cultivating positive energy. Nurturing positive energy can have a tremendous impact. This involves modeling it ourselves, and then actively calling for this attitude and approach as part of our shared work. In the PfP, managing our own leadership mindsets, and helping others to consciously do the same, created positive momentum.

Not all the energy that we generate in our quality improvement work is positive. It is also helpful for leaders to learn the art of flipping negative energy. When colleagues articulate complaints, rants, challenges, and issues as part of shared work, leaders should recognize this seemingly unproductive act as an opportunity. Negative energy is still energy. These seemingly negative behaviors indicate a high degree of caring by those who express them. Many participants in the PfP initiative learned to see negative energy as an asset, and regularly shared methods and insights for flipping the negative energy into action and forward motion.

Pacing Events

PfP participants were frequently convened in Pacing Events aimed at generating action. These events could be national, statewide, or local. Participants came together in these events to learn, share best practices, and encourage one another. The result was a new awareness of the standard of care, and alignment of both vision and effort.

An especially important feature of pacing events was that participants were challenged to go beyond learning, and to make commitments. Pacing events challenged participants to put new learning into action by adapting, testing, and taking action. Don Berwick MD, one of the world's foremost leaders of healthcare quality improvement, is well-known for asking "*What is your team going to do by next Tuesday?*" Meetings and events became engines for action and results through the deliberate and intentional use of commitment and execution. For example, when 500 quality improvers attended a meeting/conference and each of these participants left with 10 new commitments for action to improve patient safety in their organizations, the conference essentially generated 5000 actions. This approach created community, accountability, and momentum. Pacing events were an incredible aid to effective execution.

Hospital Engagement Networks like the IHC learned to use standing meetings and conferences as Pacing Events to help their participating hospitals and others to engage in requests, offers, and "dealmaking sessions." The systematic encouragement at all levels to engage in requests, offers and deal-making resulted in a constant stream of commitments for the testing, adaptation, and changes necessary for successful campaign execution.

Case Study: Iowa Healthcare Collaborative

Establishing the Iowa Healthcare Collaborative

In 2003, the three largest healthcare systems in Iowa gathered to compare efforts to improve quality, safety, and value. Each organization shared their best practices and results where they believed their performance was exceptional. In the end, each realized their competitors were performing some aspect of care much better than they were. The meeting illustrated the abundance of local expertise and a real opportunity for synergy. With startup dollars pledged by the Iowa Hospital Association and the Iowa Medical Society in 2005, the Iowa Healthcare Collaborative (IHC) was launched as a provider-led performance improvement initiative. This not-for-profit foundation now facilitates sustainable healthcare transformation in Iowa and in other states across the nation.

Iowa's population of 3.15 million is served by 118 hospitals. In this primarily rural state, 82 of those hospitals are small critical access hospitals that are particularly challenged. The IHC was one of the original 26 HENs (Hospital Engagement Networks) and successfully engaged all Iowa hospitals in the PfP. The statewide

commitment to performance improvement and raising the standard of care drives execution, creates new systems, and produces results.

Like the national PfP initiative, quality improvement work in Iowa used the leadership principles in parallel with the focus on will, ideas, and execution. The concepts of *Choice* and *Bold Aims* were critical to engaging and aligning hospitals and physicians for action. *Abundance* and *Synergy* were important to overcome the local clinical cultural barriers and inertia by surfacing, sharing, and adapting the work of Iowa high performers and their best practices. A commitment to *Net Forward Energy* and the employment of *Pacing Events* created accountability, generated energy and momentum, and encouraged *Resilience*.

Building Will in Iowa

IHC focused on the key leadership principles of choice and bold aims to build will. *Choice* embraces accountability and the power to react and adapt differently. IHC brought together all 118 Iowa hospitals and charged them with ownership of the new, higher standards of care embodied in the patient safety goals of 100,000 Lives and the PfP. After creating awareness of the current standard of care in Iowa through measurement of specific harm areas, IHC challenged hospitals to come together to eliminate the documented harm. They asked the question, "If not us, who will do this?"

Bold Aims were used to push the limits of what hospitals thought they *could do*. Vision is often limited by the current resources at hand. It is common to take our known systems and set aims for them to achieve. Aspirational leadership looks beyond our current resources and limitations and asks what we *should do*? This kind of leadership sets Bold Aims beyond current levels of resources and knowledge. Bold aims created an inspirational vision and strong motivation to do what had not been done before. No hospital wanted to be outside the vision of a new standard of care. Bold Aims moved the hospital community mindset from asking "why?" to "why not?" and helped IHC develop the new and improved systems necessary to both measure and reduce these known harms.

Ideas and Practices for Reducing Hospital Harm in Iowa

Too often innovation is limited by the idea that progress will not occur without another investment of additional resources. In reality, we have an *abundance* of knowledge and known best practices that can be used to generate improvement in healthcare quality, safety, and cost. Improvement isn't about additional resources, but execution. Deployment of known best practices, however, often runs into barriers of provider culture. Traditional roles and processes can hinder both innovation and cooperation. Navigating these waters can be complex and sometimes dangerous.

IHC uses the concept of *synergy* to overcome resistance to change. Like-minded competing organizations can teach each other a lot through a commitment to *synergy.* This involves organized efforts to routinely disclose and share emerging local best practices and associated results. Presenting organizations ask for feedback from our competing peers on their experiences and how to improve this work. The IHC provided the convening, coaching, and support to catalyze this synergy with system and method.

Participation in organized national initiatives like the 100,000 Lives Campaign and the PfP drive commitment and action with our hospital partners. Using the principles and methods of abundance and synergy, Iowa hospitals and health systems have made remarkable strides in reducing hospital harm. One powerful example of lasting progress in safety are reductions in early elective deliveries of babies.

Reducing Early Elective Deliveries Nationally and in Iowa

As noted previously, HHS Secretary Kathleen Sebelius made a leadership decision to add an "11th harm" of early elective deliveries to the work of the PFP. Data showed that induction of labor or cesarean section before 39 completed weeks of pregnancy poses serious risks compared to babies born at 39 and 40 weeks [15].

In 2012, in response to the Secretary's leadership direction, the IHC implemented a rapid improvement campaign in collaboration with project partners: Iowa Department of Public Health, Iowa Hospital Association, March of Dimes, and the University of Iowa. Hospitals that delivered babies were challenged to institute a "Hard Stop" Policy within 1 year. This policy stated that unless medically indicated, early elective deliveries prior to 39 weeks would not be performed in the hospital.

The IHC and statewide partners helped Iowa hospitals to design their Hard Stop policies, to engage physicians in this process, and to measure results. The 84 hospitals in Iowa that provided obstetrical services were tracked regarding commitment and progress in deployment of the Hard Stop Policy and procedures. All Iowa hospitals responded to the challenge to raise the standard of care. Figure 3.3 details the rapid progress in implementing Hard Stop Policies across Iowa hospitals.

A clear bold leadership aim to implement Hard Stop Policies in all Iowa hospitals that delivered babies had a dramatic effect on clinical performance. As detailed in Fig. 3.4, the rate of early elective deliveries (EEDs) dropped from an initial measure of 7.55% in Iowa hospitals to less than 1% over a period of only 13 months. The standard of care had clearly risen.

Another important benefit of this work was the promotion of "coopetition" between local hospitals. While the Hard Stop Policy was good medicine and reduced preventable harm, there was a financial risk that patients and their doctors would choose another hospital in town to enable an early elective delivery. It was much easier for hospitals to deploy the Hard Stop Policy when it was the recognized community standard of care, in place with all hospitals. Using the leadership speech acts of Requests and Offers, the Iowa Healthcare Collaborative effectively secured

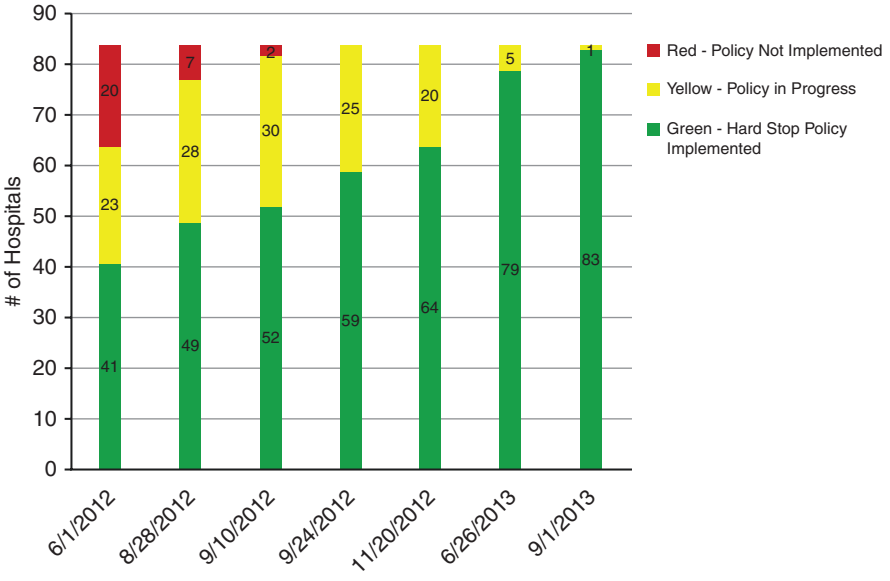
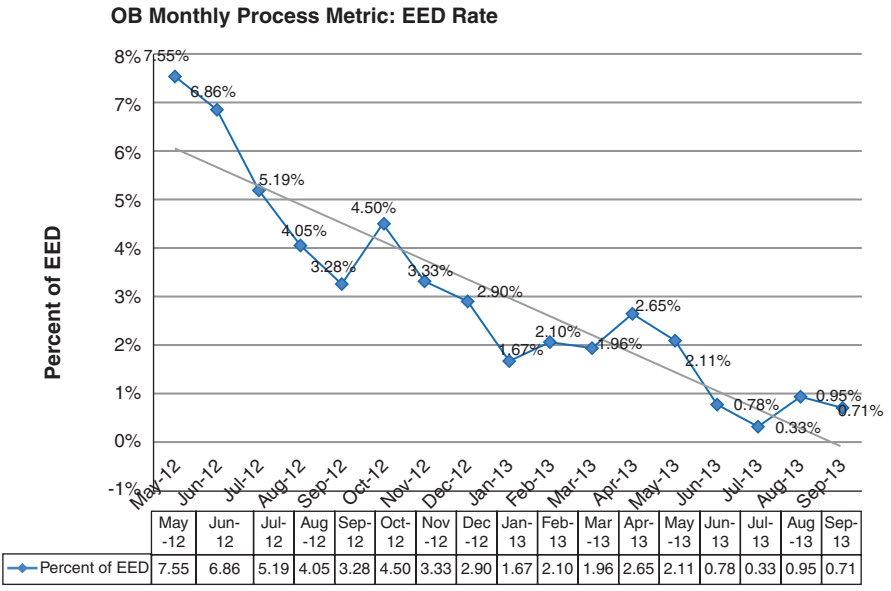


Fig. 3.3 Implementation of EED Hard Stop Policy in Iowa hospitals



	May -12	Jun-12	Jul-12	Aug -12	Sep-12	Oct-12	Nov -12	Dec -12	Jan-13	Feb-13	Mar -13	Apr-13	May -13	Jun-13	Jul-13	Aug -13	Sep-13
Percent of EED	7.55	6.86	5.19	4.05	3.28	4.50	3.33	2.90	1.67	2.10	1.96	2.65	2.11	0.78	0.33	0.95	0.71

Fig. 3.4 Aggregate EED rate declined in Iowa hospitals

commitments from all hospitals in Des Moines to implement the new Hard Stop Policy at the same time. This mitigated financial risks for each hospital, raised the local standard of care, and established an example for the rest of the state to follow.

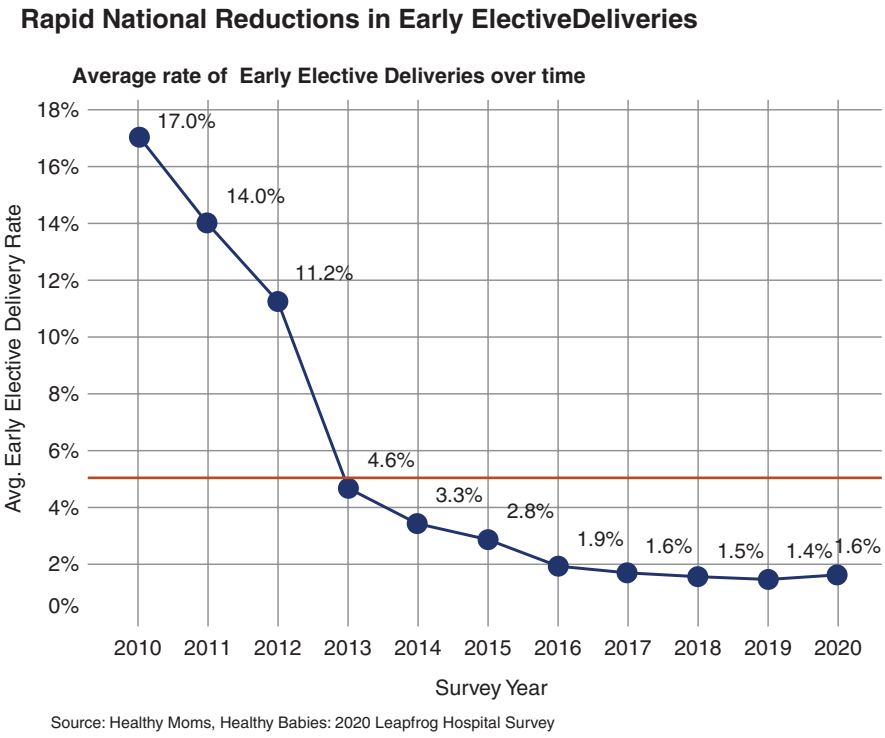


Fig. 3.5 Aggregate EED rate declined nationally

Reductions in early elective deliveries in Iowa contributed to a comparable pattern of dramatic reductions across the nation, as detailed in Fig. 3.5 [16].

It is encouraging to note that there has been no backsliding on the dramatic reductions in early elective deliveries that were achieved during the PfP initiative. Progress on this harm area may have proven more resilient than other areas because of the implementation of hard-wired hospital policies like the hard stop. These lasting results could inform future approaches to building greater resilience into other patient safety improvements.

Constant Execution in Iowa

Healthcare is an amalgam of different provider cultures, each with their own standards of professionalism. Issues of culture, authority, and resources often erode efforts to deploy best practices. We have learned that simply educating providers about best practices alone will not generate sustainable change. A strong focus on strategies to promote execution is key to changing and improving practice and the quality of care.

The key leadership mindset IHC used to advance execution was *Net Forward Energy*. Creating a culture of "net forward energy" involves managing your own mindset and that of others to create positive energy and forward momentum in teams, organizations, families, and life. This is achieved when the number of positive statements, actions, and behaviors consistently outweighs the negative statements, actions, and behaviors. To generate momentum, IHC used both data and Pacing Events to consciously model and call for Net Forward Energy and encourage execution. We learned that deliberately bringing attention to the kinds of behaviors, actions, attitude, and energy we sought, and then calling for "net forward energy" among our partners and participating providers was a powerful way to spread this practice. People naturally want to be part of a positive, aspiring, uplifting work environment.

IHC used *Pacing Events* to fuel Net Forward Energy and promote execution. In these events, participants came together to share progress and new learning. IHC discovered that these events generated both the readiness and actions necessary to achieve the goals of large-scale performance improvement.

Transformation and Sustainability in Iowa

The bold aim of the national PfP campaign to reduce preventable harm in all US hospitals by 40% by 2014 provided an inspiring vision for transforming care [2]. It was simple, and clearly aligned with the standard mantra of medicine to "first do no harm." Health care is local, and each of the 4000+ participating hospitals had the freedom to devise and deploy their own strategies and drive their own progress.

As one of the HENs, the IHC was vibrantly connected to and trusted by the hospitals that we supported. This enabled us to tailor our improvement support to the appropriate stage of hospital readiness on Everett Roger's Diffusion of Innovation distribution. We intentionally and appropriately deployed the educated self-starters and innovators in our hospital population to help localize the spread of best practice, often through coopetition in local markets.

IHC estimated that Iowa hospitals eliminated 6023 harm events over the period from the 2010 baseline through 2016. IHC applied the AHRQ algorithms to estimate the cost savings and lives saved associated with the reductions in these harms. The estimated cost savings associated with the reduced harm were $80,100,461. Most important, IHC estimated that 43 lives were saved through elimination of these unintended hospital harms. The estimated results were reported to CMS and used to substantiate decisions associated with contract renewals [17].

Iowa hospitals, together with IHC and other statewide partners, continue this work today—long after the original Partnership for Patients campaign. One strong example is Mary Greeley Medical Center in Ames, Iowa. Committed to the systemic use of the leadership principles described in this chapter, MGMC has achieved breakthrough results and has demonstrated sustainability and resilience, even in the face of the COVID pandemic.

Choice: The hospital CEO, Brian Dieter, was an experienced Chief Financial Officer (CFO) at two facilities prior to joining MGMC. Early in his MGMC tenure, he recognized the impact of strong clinical leadership and an innovative clinical environment on the organizational bottom line. CEO Dieter chose to focus both board attention and organizational resources on clinical innovation and improvement. He became a visible champion for quality, safety, and value and dedicated organizational resources to this vision.

Bold aims: To back up this vision, the organization committed to a systematic stepwise approach to achieving the Malcom Baldrige National Quality Award. The rigorous multi-year application of the Baldrige Excellence Framework has proven to be a valuable tool for measuring performance and leading organizations of all sizes and levels of complexity in uncertain environments. MGMC achieved the Baldrige National Quality Award in 2019.

Synergy and abundance: MGMC has been a strong supporter and contributor to the work of the Iowa Healthcare Collaborative and the spread of best practices throughout Iowa hospitals. This was best demonstrated in their response to the COVID 19 pandemic of 2020. While all of healthcare was derailed in that experience, MGMC was resilient in their use of measurement and systems to monitor and address the safety of care for their patients. When MGMC dashboards showed increases in patient harm over the course of the pandemic, the organization went to work to address the backsliding. In a June 2022 IHC learning session, CEO Dieter described how the organization implemented practices to refocus on patient safety and quality, and "snapped back" to new, even higher levels of patient safety in the post-pandemic period. MGMC has led discussion across the state about new applications for remote care with a challenged workforce. Their experience, offers, and assistance to others have helped to model and generate synergy and abundance among hospitals across the state.

Net forward energy: MGMC works hard to maintain momentum and a steady drum beat of improvement. An entire conference room has been dedicated as a "command center" for performance improvement. The walls of this room are covered with run charts that detail clinical performance, hospital operations, the state of its workforce, financial performance, and more. This is not a museum, however. The charts are live with the latest data and often covered with sticky notes from performance improvement discussions and next steps to be tested. As an example, consider MGMC's current performance on Early Elective Deliveries. When CMS, IHC, and hospitals in Iowa went to work on the systematic reduction of EEDs in 2012, MGMC was in the middle of the pack among Iowa hospitals. Figure 3.6 documents more recent MGMC performance on EED through the pandemic and through May of 2022. For the entire period from January, 2019 through May, 2022 there has been only a single EED in the Mary Greely Medical Center.

Pacing events: Pacing events aimed at generating action are common at MGMC. As one example, there is a vibrant weekly meeting focused on tracking and improving clinical performance across all departments in the hospital. Mary Greely has also been a pace-setter in using statewide pacing events to generate

Month	2019	2020	2021	2022
January	0	0	0	0
February	0	0	0	0
March	0	0	0	0
April	0	0	0	0
May	0	0	0	0
June	0	0	0	0
July	0	0	1	0
August	0	0	0	0
September	0	0	0	0
October	0	0	0	0
November	0	0	0	0
December	0	0	0	0

Fig. 3.6 Number of EEDs per month at Mary Greely Medical Center

action and results among their own staff. One year, CEO Dieter called to negotiate a bulk attendance rate for the IHC annual conference. He then rented a bus and brought 75 employees and Board members to the conference for joint learning, engagement, and further commitments for action and improvement.

Expansion of IHC's Work Beyond Iowa

Iowa hospitals are fully committed to patient safety improvement, and the Iowa Healthcare Collaborative is now advancing hospital safety in three other states. IHC has also successfully used many of the principles and methods outlined here in projects with local communities in Iowa to drive alignment and execution and is now in action with over 12,000 physicians across 15 states to advance patient safety and performance improvement in clinical practices.

Call to Action: Sustain and Expand National and Local Progress on Patient Safety

Hospitals in the United States achieved remarkable progress in patient safety during the 2010 to 2019 timeframe. Hospitals got safer every year. Disciplined use of leadership principles and methods, paired with quality improvement techniques of Will, Ideas, and Execution, were essential elements of national, state, and local progress.

CMS continued to provide financial support for quality improvement technical assistance through a series of follow-on contracts for Hospital Improvement and Innovation Networks (2016–2019) and Hospital Quality Improvement Contracts (2020 through present) for sustained improvement in hospital patient safety. CMS quality improvement technical assistance for patient safety was substantially reduced in 2020, to focus mainly on supporting rural hospitals. This reduction in funding and emphasis on hospital safety, coupled with the impact that the COVID pandemic has had on healthcare providers and hospitals, appears to have at least temporarily eroded the substantial progress achieved during the 2010 to 2019 time period. A New England Journal of Medicine article by CMS and CDC officials documents some of the erosion [6].

It is vitally important to patients that we restore sustained national progress in hospital patient safety. The key elements of national strategy, evidence-based practices for addressing known harms, quality improvement science, and the leadership principles and methods necessary to guide this restoration are all known and available.

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Chapter 4
Human Factors to Improve Patient Safety

Thomas Purchase, Paul Bowie, Peter Hibbert, Rajesh G. Krishnan, and Andrew Carson-Stevens

> *…the patient safety movement itself has gotten things wrong. Its understandings … of concepts such as safety, harm, risks and hazards are incomplete and simplistic and, as a result, its work has been grounded in assumptions and generalisations that are either wrong or lacking in context* (Wears and Sutcliffe 2020)

Introduction

Since the 1940s, the scientific discipline of Human Factors and Ergonomics (HFE) has evolved and become embedded into a wide range of so-called safety-critical industries. These industries, including nuclear, maritime, military operations, civil

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aviation, rail and others involve systems where failure might endanger human life, lead to substantial economic loss, or cause extensive environmental damage [1].

The terms 'human factors' and 'ergonomics' are considered synonymous and can be used interchangeably or together (e.g. HFE, EHF). HFE focuses on the interplay between humans and the other various elements of a system. Through applying theory, principles, standards and methods to the design/redesign of a work system, improvements in human wellbeing and system performance are jointly sought [2]. In the context of HFE, a 'work system' is considered a set of inter-related or coupled activities or entities (person, tasks, environment, organisations, technology, see Fig. 4.1), with a joint purpose to produce an outcome such as a product or service [4]. In health care, for example, this may be a primary care sexual health clinic, a colonoscopy service, or emergency ambulance service.

The application of HFE ensures that these systems, products, and services are designed to make them easier, safer and more effective for people to use via a human-centred approach. When designing any system to be safe and sustainable, the principles of HFE can be considered by asking the question, 'how do we design this in order to make it easy for people to do the right thing?' There are three fundamental principles which distinguish and shape such a system design approach [5]:

1. *It must always have a systems approach*. This reflects a holistic perspective where the system is viewed as a whole and is fundamental to seeking a better understanding of the dynamic and interactive nature of multiple entities (e.g. person, tasks, environment) within a sociotechnical system. No one component in a work system should be viewed in isolation, for example, wrongly focussing just on individuals at the 'sharp-end' of patient care without consideration of the environment in which they are working.

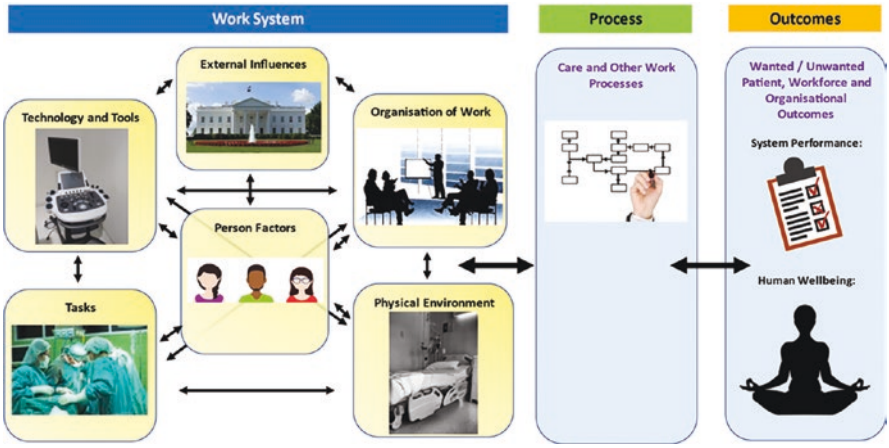

Fig. 4.1 Systems Engineering Initiative for Patient Safety (SEIPS) model. (Adapted from Holden et al. 2013 [3])

2. *It must always be design-driven*, taking into account the stakeholders (for example, patients, clinicians and managers) and human characteristics (such as needs, capabilities, limitations and preferences). Optimum system performance is not possible if the tools, technologies and workspaces are not designed to support usability and accessibility, to help improve all aspects of human work.
3. *It must always focus on two closely-related outcomes*, jointly optimising **human wellbeing** (such as staff welfare, job satisfaction) and **system performance** (such as effectiveness, efficiency, safety) [6].

Multiple safety-critical industries, such as nuclear [7] and aviation maintenance [8], have successfully integrated the HFE concepts and approaches into their work systems to better understand how problems develop and apply this knowledge to mitigate risks and create more resilient systems when adverse events arise. The healthcare industry, in this regard, is lagging behind [9].

Why Integrate HFE into Healthcare?

The primary aims of HFE in healthcare are to support healthcare professionals with the cognitive, physical, socio-cultural and organisational aspects of their work and to promote safe, high-quality care for patients. This is because the principles of HFE recognise that the wellbeing, safety and performance of staff are intrinsically linked to the efficiency of a healthcare organisation and the safety of patient care. For example, not printing the distance lengths on surgical drains can contribute to their retention in patients' bodies as manual measurement or clinician memory must be relied upon to monitor them over time [10]. HFE is therefore critical to the design and redesign of healthcare and patient safety systems and as a result the integration of HFE principles is strongly recommended by the World Health Organization (WHO) as part of a fundamental strategy to tackle avoidable harm in healthcare (described in the WHO Global Patient Safety Action Plan (2021–2030)) [11].

Dispelling the Myths of HFE

The real-world application of HFE in healthcare is currently limited and this is partly due to a lack of understanding about what HFE entails. There are a number of 'myths and misunderstandings' amongst healthcare communities and institutions regarding the purpose, benefits and approach of HFE and addressing these may improve their implementation [9].

A common misconception is that 'human factors' equates to 'human error'. HFE is not about eliminating 'error' but focuses on designing care systems that are resilient to unanticipated events, meaning the impact on the people and organisations when things invariably go wrong is minimised. It is more prudent to consider

'human error' as a symptom of a wider system problem and if you arrive at this conclusion then this should be considered as the starting point and not the end of a safety investigation.

HFE does not address issues by teaching people to modify their behaviour but rather attempts to redesign the work system to better support the performance and wellbeing of people. HFE is often wrongly considered to be equated with 'factors of the human' with a focus on individual behaviours, attitudes and characteristics. The focus of HFE ranges from understanding and optimising interactions involving people at the micro, meso and macro levels of the organisation and beyond, such as regulation. As HFE is a wide-ranging, scientific and professional discipline, it is a fallacy to believe the principles can be learned during a short training program. Indeed, HFE specialists require years of training and supervised practice and hold relevant undergraduate and/or postgraduate degrees, as well as being members of professionally appropriate bodies in the same way as clinicians. However, there are a number of accessible and intuitive HFE concepts, tools and methods that can be understood and used with minimal training, such as the Systems Engineering Initiative for Patient Safety (SEIPS) framework, which will be discussed in detail later.

In the following cases studies, we will describe how a structured HFE approach to thinking about a clinical problem can help to identify where and how the system can be optimised in order to improve future outcomes for patients and staff.

Case Studies

Case 1: A Patient Collapse in a Primary Care Provider Waiting Room

A 70-year-old male patient attended a family practice with his wife for an appointment with his primary care physician. He became increasingly sweaty and short of breath whilst sat in the busy waiting area late in the afternoon and collapsed onto the floor. The fall was witnessed by the receptionist who triggered the emergency alarm on their computer. The practice team responded promptly and found the patient unconscious but breathing. A new student nurse was sent to collect the emergency trolley and oxygen cylinder but took a long time to find them. The practice nurse reported the oxygen cylinder was almost empty. The ambulance didn't arrive for over an hour. The patient was transferred to hospital, successfully treated for sepsis and survived. The family later made a formal complaint, with a threat to take legal action against the practice.

Case 1 Study Analysis

Understanding Complex Systems

Following the complaint lodged by the family, the practice launched an investigation of the patient safety incident to prevent similar incidents occurring in future. Traditional approaches to patient safety management or investigating a patient safety incident focus on identifying errors that have resulted to an unwanted event, such as the sequential accident model or the epidemiological model [12]. This approach to 'investigating what went wrong' adopts a reactive method to retrospectively identify the cause of harm after a patient safety incident, assuming the relationship between cause and effect is linear and that any problem has a root cause. An example of a commonly utilised investigative method following a patient safety incident is a Root Cause Analysis (RCA). A high proportion of recommendations generated from RCAs have been found to be unlikely to either be sustainable or inform practice [13–15], thereby not achieving their intention of reducing healthcare-associated harms. A lack of HFE thinking when conducting such an analysis is believed to be, in part, contributing to this outcome.

Healthcare delivery systems are complex adaptive systems involving multiple components where a structured approach is needed to gain a holistic understanding underpinning the incident to avoid an oversimplistic analysis [16]. By adopting HFE methods, a more proactive stance to understanding patient safety would assume that everyday adjustments to working environments and human performance are normal within a complex adaptive system to manage uncertainty and change in demand. There is an aim to prevent harm by maximising the number of events with a successful outcome by learning how things go right within a system, for example, safe episodes of care, rather than solely focussing on mistakes.

Visualising Complexity

A number of tools are available to help apply a complex system lens to better understand a multi-faceted healthcare system. One such tool which demonstrates how components within a complex process interact is the Functional Resonance Analysis Method (FRAM) [17]. FRAM maps the inter-relationships between the 'functions' or 'activities' being performed to explore 'work-as-done', giving insight into how healthcare professionals actually work together and adapt to changing circumstances. It can be used to help understand how performance of key activities leads to unwanted outcomes. This is different from 'work-as-imagined', which is typically enshrined in established processes, guidelines and protocols, and often reflects what is imagined by workers in other parts of the system, such as senior managers, clinical guideline developers and policy makers.

For example, a study in a Scottish regional health authority utilised a FRAM model of a complex system to improve the identification and management of sepsis within primary care [18]. They collected data from the records of patients admitted

to hospital from primary care with suspected sepsis and interviewed multiple stakeholders to establish the key work functions required to manage these patients successfully. The data were used to define each 'function', represented as a single hexagon (Fig. 4.2). The FRAM model was then built using a FRAM model visualiser software [19]. The connections between the functions are made using six functional aspects (see example in Table 4.1).

The FRAM model explores the influence of system conditions, such as resource availability, and the subsequent variability of the function output. By providing an aid to understand the complexity of the function interactions within a system, the model helped to direct an expert group to reconcile suggested improvement interventions in the management of patients with sepsis with how the system was estimated to be currently working. They were then able to design a potentially more meaningful multi-component intervention to improve the management of sepsis. Figure 4.2 illustrates the multiple functions identified as part of this complex process and the interactions and feedback loops connecting them. This is a clear visualisation of the non-linear nature of a complex adaptive system.

In order to account for this complexity, the family practice decided to conduct their investigation utilising a HFE framework. This is outlined in Table 4.2 and demonstrates how an event as common as a patient collapsing incorporates these multi-faceted components and illustrates how this makes delivering safe and effective patient care inherently complex and uncertain.

Case 2: Rising Levels of 'Burnout' in Hospital Clinicians

Clinicians working in busy, demanding and dynamic acute hospital settings are at risk of experiencing burnout over time. When healthcare systems are placed under significant pressures and constraints, such as during the COVID-19 pandemic, the risk of staff burnout is likely to increase. Following a cross-sectional survey of internal medicine physicians across two tertiary hospitals in Vancouver, the prevalence of burnout was as high as 68%, higher than the prevalence reported prior to the pandemic [20]. *Those who reported that COVID-19 had affected their burnout were also more likely to report signs of burnout and consider quitting their position.*

Case 2 Study Analysis

'Burnout' is a condition brought about by chronic exposure to work-related stress. In healthcare, it is estimated that around one in three physicians experience symptoms of burnout at any one time [21]. Symptoms include depersonalisation and disinterest in the workplace, reduced performance and cynicism. Impacts of burnout include high staff turnover, an association with greater levels of safety incidents and quality of care issues, reduced patient satisfaction, a breakdown in

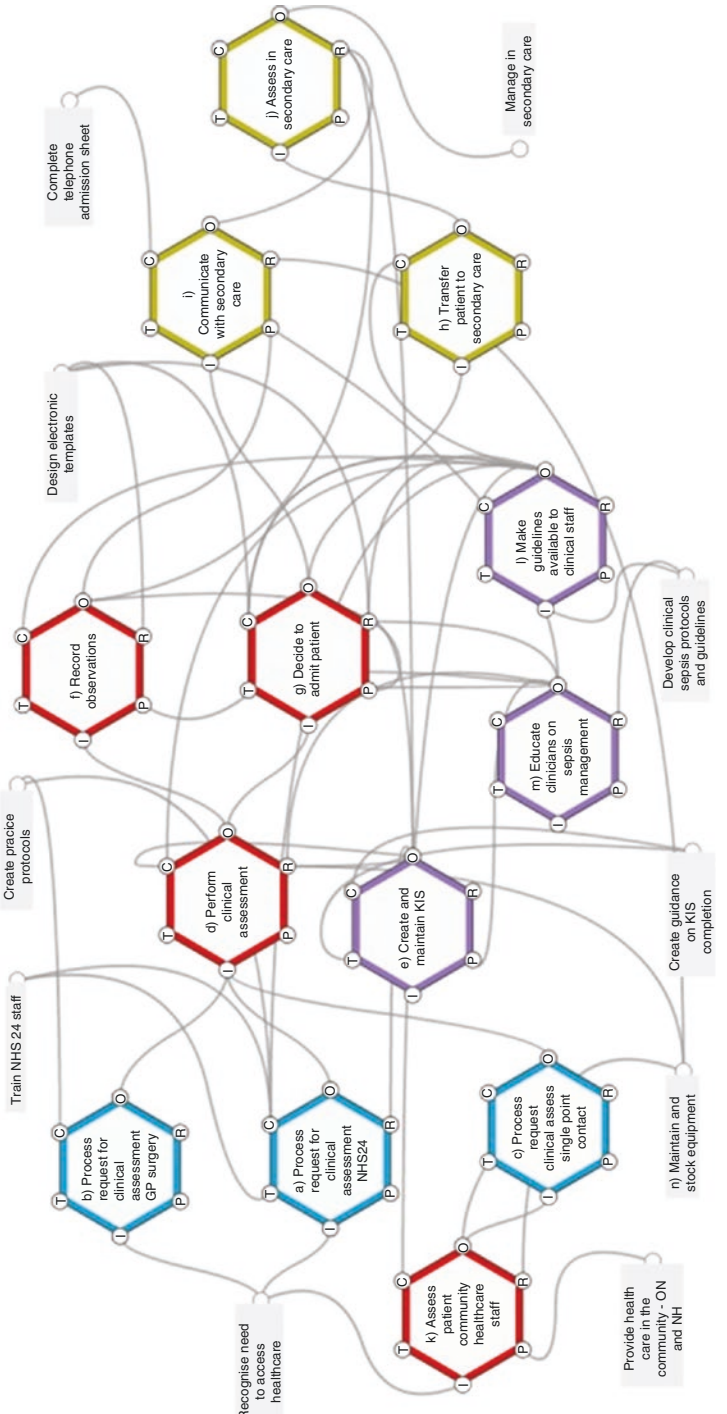

Fig. 4.2 FRAM model of system to identify and clinically manage sepsis in primary care in NHS Ayrshire and Arran Health Board [18]

Table 4.1 Aspects for the function 'perform clinical assessment' [18]

Aspect	Description	Example
Input (I)	What the function acts on or changes and starts the function	Patient arriving at the consultation room
Output (O)	What emerges from the function—this can be an outcome or a state change	Clinical assessment complete
Precondition (P)	Some condition that must be met before the function can start	Appointment booked
Resources (R)	Anything (people, information, materials) needed to carry out the function or anything that is used up by the function	Thermometer, stethoscope
Control (C)	Anything that controls or monitors the function	Protocol or guidelines
Time (T)	Time constraint that may influence the function	Ten minute consultation

working relationships as well as negative personal consequences away from the workplace. From a HFE perspective, it is an organisational rather than solely an individual issue, as the occupational stressors that contribute to the syndrome are multi-faceted and system-wide. However, this is not well understood in healthcare, where efforts to reduce burnout levels tend to focus narrowly at the individual level (such as personal behavioural interventions), rather than more holistically at the organisational and wider system level. As outlined in Table 4.2, employing a HFE framework allows us to consider a broader range of attributable factors leading to clinician burnout which in turn may contribute to establishing strategies to tackle such an important issue.

Human Factors Frameworks

Implementing HFE in System Design and Patient Safety

In practice, how can healthcare teams and organisations apply the principles of HFE to evaluate systemic problems and improve patient safety?

One of the most prevalent systems-based human factors frameworks is the Systems Engineering Initiative for Patient Safety (SEIPS) [22]. The model is rooted in human-centred systems engineering and incorporates Donabedian's well-established Structure-Process-Outcome model of healthcare quality. The major components of SEIPS include the interactions of work system elements (which can apply to any setting where care is provided), the care processes resulting from the work system, the subsequent system outcomes and feedback loops between the process and outcomes to the work system (Fig. 4.1). The six related components of the work system are *people* (this is placed in the middle as the person is central to a healthcare system), *tasks, technology and tools, physical environment, organisational conditions and external influences*. Lists of examples to consider for each work system component are given in Fig. 4.3.

Table 4.2 A SEIPS approach to an incident investigation for Case 1 (patient collapse in the waiting room) and to gaining a deeper understanding of the interacting system factors in Case 2 (rising levels of burnout during the COVID-19 pandemic)

Work system component	Case 1 examples (patient fall, incident investigation)	Case 2 examples (burnout, systems understanding)
People	– Elderly, male patient collapsed in the waiting room – Patient's wife anxious and concerned – Clinicians and nurses attended with varying levels of experience, training and knowledge – Staff fatigue following a long day of working – Multiple other patients in the waiting room	– Rising patient demand with greater levels of clinical complexity – Reduced staffing levels due to infectious illness/shielding – Staff fatigue, work hassles and frustration – Inadequate psychological safety – Redeployed staff with limited experience of new job roles
Task(s)	– Emergency alarm raised by receptionist and timely call made to the emergency services – Prompt response from other team members – Student nurse had difficulty locating emergency equipment – Uncommon and stressful task in this setting – Practice nurse cared for patient's wife	– Demanding clinical tasks in PPE – Unfamiliar tasks (e.g. proning) – Physical and emotional tasks in responding to treating infected patients
Technology and tools	– Functional computer alarm system and telephone used to contact the emergency services – Oxygen cylinder nearly empty as it had been used recently	– Limited supplies of quality PPE and related equipment – Sub-optimal interface designs on medical devices, e.g. newly purchased ventilators – Sub-optimal design of electronic health records systems – Design of new work procedures and redesign of existing work procedures did not reflect the reality of 'work-as-done' at the sharp-end of clinical practice – Limited supplies of oxygen
Physical environment	– Team interaction with patient and equipment negatively impacted by the small waiting area – Difficult to ensure privacy due to design of the waiting area – Staff distracted by comments made by other patients in the waiting area – Emergency trolley not easily accessible	– Mismatch in clinical workspace designs and redesign to treat excess patients – Excessive noise from sounds of medical devices and staff communication – Excessive heat exacerbated by wearing of PPE – Lack of staff car-parking and need to pay impacting on morale

(continued)

Table 4.2 (continued)

Work system component	Case 1 examples (patient fall, incident investigation)	Case 2 examples (burnout, systems understanding)
Organisation	– No formal process for checking and replacing emergency equipment – Safety climate did not prioritise formal checking processes – Student nurse not given a full practice orientation and induction – Limited reflective learning by practice team from previous significant event analyses	– Prevailing safety culture across some departments was immature and unsupportive – Shift-work and rota patterns impacting on performance and wellbeing of staff – Lack of visible leadership – Tensions with management over resource availability – Effective team working difficult due to new teams rapidly forming – Conflicting guidance on PPE requirements and local infection control policies – Dispute over financial payments for overtime
External influences	– Increasing pressures on ambulance services leading to long waiting times – Practice primarily focussed on the contractual demands and improving patient access to services	– Inappropriate external policy targets still in place, e.g. 4-hour waiting time target in emergency room – Political interference in running of health services – Failure of public health policy leading to national lockdowns
Outcomes		
People	*Patient* – Clinically managed until paramedics arrived to stabilise and transfer the patient to hospital – Treated in hospital for sepsis and discharged *Team members* – Feelings of guilt and embarrassment – Attributing blame to individuals – Work relationships affected	*Patients and families* – Increased mortality and morbidity – Increased safety incidents – Families unable to visit patients – Dissatisfaction *Team members* – Works stress and burnout – Musculoskeletal issues – General anxiety – Work dissatisfaction and disillusionment – Staff considering quitting their position
Organisation	*Practice* – Formal complaint written by patient's family and threat of legal action – Impact on patient relationships with the family practice	*Hospital* – Severe mismatch in demand and capacity – Limited resources – Performance and productivity struggles – Negative media publicity

Any changes to these components can have a positive or negative impact on work or clinical processes, such as the care given, maintenance and cleaning. Crucially, the model integrates patient, employee and organisational outcomes, as these outcomes all relate to the joint improvement of system performance and human

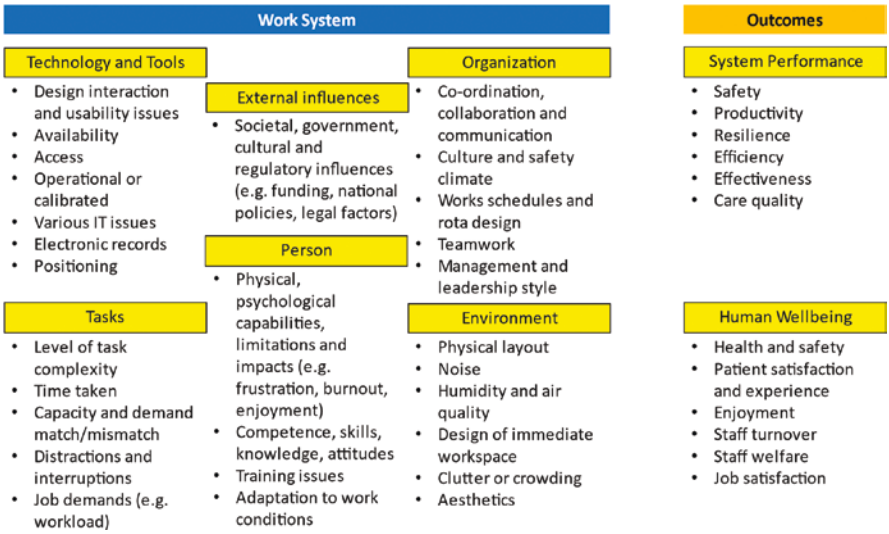

Fig. 4.3 A non-exhaustive list of examples for the SEIPS 2.0 model of work system and patient safety

wellbeing. The SEIPS models thereby adopts a 'whole system' approach to evaluating work system design.

Since the first version of the SEIPS model in 2006, it has evolved and undergone a number of iterations. These include SEIPS 2.0 [3], which highlights the importance of the work done by patients, families and other non-professionals, and SEIPS 3.0 [23], which expands on the process component via the patient journey. To help simplify these models for broader use by researchers, practitioners and others, a practice-orientated SEIPS 101 model has been proposed, with the aim of being more streamlined, memorable and easier to use [24].

Application of the SEIPS Model

The SEIPS model as a multi-factorial tool can be considered the 'Swiss Army Knife' of entry-level HFE approaches. This is thanks to its wide-ranging applicability and potential to add value to a number of healthcare-related activities, projects and training. These can include incident reporting and data collection, process mapping, care system designs, designing simulation scenarios, proactive hazard analysis, team-based learning from incidents/complaints/everyday work, workforce wellbeing, problem solving everyday hassles and teaching the fundamentals of the HFE systems approach. As shown in Fig. 4.1, the SEIPS models elegantly depict system complexity, making it simpler for those unfamiliar with HFE or SEIPS to follow and digest. The model can be readily customised for the purposes outlined

above, for instance, through using a blank worksheet tailored to the SEIPS work descriptors and outcomes (Fig. 4.4) [25].

It is recognised that patient safety investigative teams would benefit from skills in HFE [15, 26]. The SEIPS model can be applied to incident analysis, such as the incident investigation conducted in Case 1. The SEIPS models enhance the investigation by helping the team to gain a deeper understanding of how the interactions between contributing factors lead to the safety incident. By thoroughly exploring these interdependent factors, more data is collected than may have been considered if following a traditional linear approach, such as a RCA. Table 4.2 demonstrates how each SEIPS work system component and outcome (for examples see Fig. 4.3) specifically applies to both Cases 1 and 2.

Human Factors Intervention: Developing a Checklist

Bowie et al. present an example of how applying the principles of HFE in research helps to make sense of the multiple challenges faced within a system. The team employed the SEIPS work system model to a primary care setting to identify and prioritise workplace hazards that are known to impact on the safety, health and well-being of patients, visitors and primary care team members and organisational

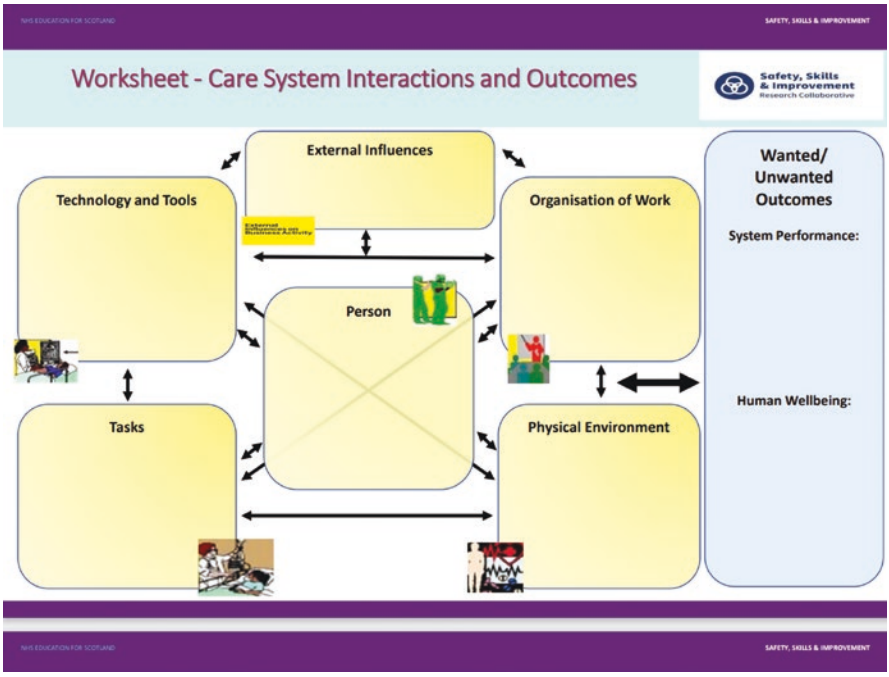

Fig. 4.4 Worksheet of SEIPS 2.0 work system interactions and outcomes [25]

performance [27]. These were then used to codesign and validate a solution, in the form of a standardised checklist for their primary care practice, that reflected system-wide patient safety-related uncertainties, hazards and risks. The checklist formed a list of the key tasks with explicit statements regarding the frequency of when those tasks should be completed, by whom, and how. They actively involved frontline workers (an 'expert group', primary care physicians, nurses and practice managers) with expertise of the subject matter in the process, alongside a patient and public forum coordinated on a quarterly basis by the practice, that way ensuring that the patient and public needs were met and allowed them to iteratively address usability concerns prior to implementing the checklist. Staff having to rely on memory in high-risk industries is a known issue [28]. Human factors interventions such as user-designed checklists can support workforce safety performance and offer an additional defence against incidents and patient harm.

The use of the SEIPS model in this study aided them in conducting a user-centred, systems-based methodological approach in developing a safety checklist. Had such a checklist been applied within the family practice in Case 1, a number of areas identified as contributing to the outcome (as seen in Table 4.2) could have been mitigated.

Discussion

Successfully integrating a HFE approach in healthcare is a fundamental strategy to jointly improve system performance and human wellbeing and produce sustainable solutions to many of the complex problems faced.

In the UK, a recent National Health Service (NHS) safety strategy commented:

> *The NHS does not yet know enough about how the interplay of normal human behaviour and systems determines patient safety. The mistaken belief persists that patient safety is about individual effort. People too often fear blame and close ranks, losing sight of the need to improve. More can be done to share safety insight and empower people – patients and staff – with the skills, confidence and mechanisms to improve safety* [29].

This sends a powerful message that although organisations worldwide are aware of the need to adopt a systems-thinking approach, there is still some way to go for this to be fully realised and a need to unlearn historical practices.

There are multiple barriers contributing to the underutilisation of HFE within healthcare systems due to a poor understanding of the full benefits of the discipline and a lack of engagement with qualified and experienced HFE professionals. Across healthcare systems, the number of employed HFE professionals is far behind what is common practice in other safety-critical industries, indicating a strong need to build related capacity and capability [30].

Healthcare systems continue to capture the bulk of their learning by investigating harms and mistakes [31], frequently through processes such as RCA. This linear, reductionist and deterministic view of healthcare systems often oversimplifies the

work done and commonly yields the same person-level recommendations, for example ‘more education and training’ is needed [15]. Whilst education and training can be an effective and needed intervention, often other solutions are necessary in parallel to this, such as leadership support, involving staff in implementing changes or focussing on the processes within a system [32]. To achieve a more sustainable, long-term change, more emphasis should be placed on learning from everyday work. By narrowly focussing on investigating patient safety incidents, organisations risk continuing to foster a culture of person-level blame [33]. Instead, a broader reach through multiple methods, inclusive of analysing safety incident reports, should be sought to learn directly from what happened and perceived reasons why in the moment, from staff witness to or involved in the incident, and wider inquiry about what works well the rest of the time in a system [34].

Safe healthcare design and delivery requires a more rigorous and science-based HFE contribution [35]. The key enablers for this include commissioning bodies, regulators and organisations, alongside strong leadership to urgently upskill healthcare professionals with a role in quality improvement and embed qualified HFE professionals to support the workforce. The proactive design of any healthcare system should consistently incorporate HFE to maximise patient safety, system performance and wellbeing.

Conclusion and Lessons Learned

- HFE is critical to the design of safe healthcare systems.
- HFE is a system- and design-based practice and science, with a focus on the influence of interacting systemic factors in healthcare and how they give rise to both wanted and unwanted outcomes.
- Safety incidents are caused by multiple, interacting contributory factors from across the care system.
- Recognise that there is no ‘root cause’ of a safety incident in highly complex systems, such as in healthcare.
- Adopt a recognised systems approach, such as using the SEIPS model, to structure and achieve a holistic approach to the investigation, learning and improvement from patient safety incidents.

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Chapter 5
COVID-19, Health Inequities, and Patient Safety

Dana E. Loke and Garth Walker

Introduction

In December 2019, a worldwide pandemic began after the emergence of a novel coronavirus in Wuhan, China. Known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV2), the virus caused an infection with a variety of symptoms and presentations known as COVID-19 [1]. Cases quickly spread to other countries, including to the United States (U.S.). By January 2020, nearly 10,000 cases had been diagnosed worldwide [2].

The first U.S. case was diagnosed on January 20, 2020 at Providence Regional Medical Center, after which case numbers quickly rose [2]. Soon after, person-to-person transmission was confirmed [2]. By March 11, 2020, the World Health Organization declared COVID-19 as a worldwide pandemic [3]. On March 13, 2020, the COVID-19 pandemic was declared a national emergency in the U.S. The pandemic and its national response resulted in far-reaching consequences on national and local healthcare systems, the economy, and the social well-being of U.S. citizens. Many hospitals operated at or above maximum capacity with limited resources despite delaying elective surgeries and canceling non-emergent outpatient appointments [4]. Many states enacted "stay-at-home" orders that closed schools [4]. Many workplaces also closed to in-person activity, resulting in nearly $138 billion in lost work hours in the first year of the pandemic alone [5].

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Despite implementing these measures in an attempt to mitigate virus spread, the U.S. was particularly devastated by the COVID-19 pandemic. In 2020 alone, the U.S. experienced three pandemic waves and ultimately had the highest case numbers and deaths of any country [6]. Early data had predicted increased risk of serious illness and death in patients with hypertension, diabetes, obesity, and older age [7, 8]. While trends in U.S. cases and deaths did reflect this early data, another alarming trend was identified. As case numbers and deaths rose, striking racial and ethnic disparities in COVID-19 infection, morbidity, and mortality were identified [7, 9–13].

Next, we consider several of the factors presented above in a case study involving an African-American patient in a resource-limited setting during the COVID-19 pandemic.

Case: ED Boarding, Structural Racism, and Healthcare Disparities in a Public Health Crisis

Clinical Summary

A 65-year-old African-American woman with a history of diabetes, hypertension, and coronary artery disease presents to the ED with shortness of breath during the COVID-19 pandemic. On arrival she is febrile and hypoxic. She is quickly intubated for acute hypoxemic respiratory failure. She is found to be COVID-19 positive. An ICU bed is ordered however no beds are available. The patient waits in the ED for 2 days before an ICU bed becomes available. Shortly after arriving in the ICU, she decompensates. She suffers a cardiac arrest and dies.

Analysis

The above case demonstrates several pervasive patient safety issues. ED boarding and overcrowding, a public health crisis, structural racism, and healthcare disparities all contributed to this patient's unfortunate clinical course. The issues of ED boarding and overcrowding, as discussed in Chap. 23, are more complex and pronounced during a public health crisis, as in this case. Next, we discuss the COVID-19 pandemic, healthcare disparities, and structural racism in depth.

COVID-19: A Public Health Crisis

Public health crises present additional patient safety challenges as evidenced in the COVID-19 pandemic. Within only a few months of the first U.S. case in January 2020, supply issues abounded. The demand for personal protective equipment (PPE), ventilators, tests, and beds quickly overwhelmed supply [7]. The significant PPE shortage during the COVID-19 pandemic resulted from problems from a dysfunctional costing model in hospital operating systems. This was magnified by a very large demand shock triggered by acute need in healthcare and panicked marketplace behavior. The U.S. is the world's largest importer of face masks, eye protection, and medical gloves, which makes it especially vulnerable to disruptions in exports of medical supplies and prone to supply issues. All of these factors, plus those in Fig. 5.1, led to depletion of domestic PPE inventories [14]. Lack of effective action on the part of federal government agencies to maintain and distribute domestic inventories, as well as severe disruptions to the PPE global supply chain, further amplified the problem [14]. Shortages in testing capabilities were also an issue during the COVID-19 pandemic. These shortages led to inequities, as shown in the higher prevalence of testing sites within white neighborhoods in Dallas, among other cities (Fig. 5.2) [15].

Ventilator shortages were also a grave and highly publicized problem during the COVID-19 pandemic. Estimates of the number of ventilators needed for care for patients in the U.S. ranged from several hundred thousand to 1 million, depending on the number, spread, and severity of infections and even the availability of testing sites [16]. Some other estimates were more modest, suggesting 60,000–160,000 ventilators would be needed, depending on whether ventilators with partial functionality could be used. The CDC Strategic National Stockpile (SNS) serves to stock and maintain ventilators to be deployed in times of need, such as the COVID-19 pandemic, and to help mitigate ventilator shortages. However, in March 2020, the

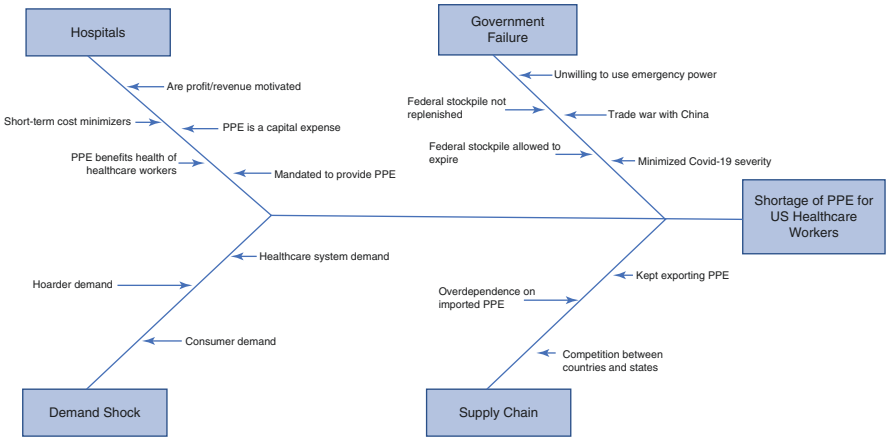

Fig. 5.1 Fishbone diagram showing contributors to PPE shortage [14]

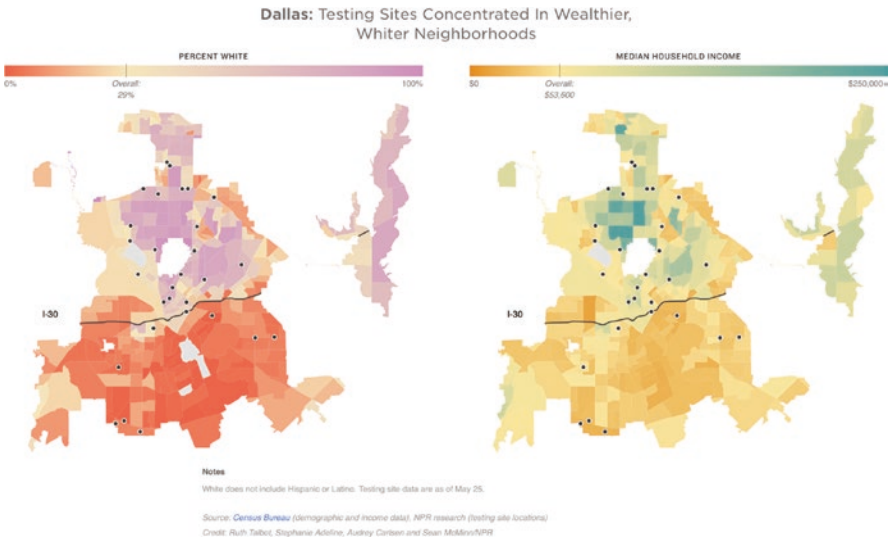

Fig. 5.2 Heat map of COVID testing sites in Dallas, Texas shows concentration of sites in wealthy and white neighborhoods [15]

SNS reported having only 12,000–13,000 ventilators stored for on-call deployment. Regardless of the estimate used, the U.S. had far fewer ventilators than was estimated to be needed during the pandemic [17].

Availability of hospital beds, too, was a major patient safety issue during the COVID-10 pandemic. Early predictions suggested that hospitalization and ICU needs from COVID-19 patients alone could exceed current capacity [18]. This prediction became a reality, with rapid surges of critically ill patients presenting to EDs and requiring ICU admissions quickly overwhelming bed supply [19]. A significant association was found between the availability of hospital resources (particularly ICU beds) and patient mortality during those early weeks of the COVID-19 pandemic [20]. Similarly, at the state level, COVID-19 mortality rates increased with COVID-19 admission rates [21]. This created a vicious cycle for many hospitals. Those hospitals at maximum capacity, already overwhelmed with high volumes of patients, suffered decompensating patients and higher mortality rates, in turn led to higher patient volumes and supply shortages as patients became sicker.

Many of the hospitals that suffered most through the COVID-19 pandemic were safety net hospitals. Safety net hospitals disproportionately care for those with low incomes and communities of color, the very groups hit hardest by the pandemic. Those hospitals typically treat a larger share of Medicaid and uninsured patients than other hospitals and thus often operate on thinner financial margins, making them especially vulnerable to pandemic stresses [22]. Often already resource-limited and financially insecure, safety net hospitals became particularly

overwhelmed during the COVID-19 pandemic in caring for the most marginalized and vulnerable communities [23].

COVID-19 and Healthcare Disparities

The COVID-19 pandemic has also shed light on the persistent and pervasive issue of equity and healthcare disparities. Significant variations across hospitals, including case burden, bed occupancies, ventilator usage, healthcare personnel, and supply status, are a potential source of inequitable outcomes and an indication that more equitable distribution of patients and PPE is needed [24]. Hospitals with fewer beds saw higher mortality rates in ICU patients [21]. Dilemmas around rationing and equity became an unfortunate reality during the pandemic, with those populations facing structural barriers disproportionately affected. The need for clear ethics around rationing became quickly apparent. Emanual et al. describe a number of recommendations to maximize benefits with rationing, including prioritizing health workers, allocating based on need rather than on a first-come, first-served basis, being responsive to evidence, recognizing research participation, and applying the same principles to all COVID-19 and non-COVID-19 patients [25].

The most striking inequities of the COVID-19 pandemic have been the disparate outcomes of underrepresented minority patients, who developed and died from COVID-19 at disproportionately higher rates than non-minorities [9]. Black patients have been found to contract COVID-19 at higher rates and are more likely to die from the disease [9]. In Chicago, about 50% of COVID-19 cases and 70% of COVID-19 deaths occurred in black individuals, although they only make up 30% of the population. Those deaths have been shown to be concentrated in mainly five neighborhoods on Chicago's South Side [9–11]. This inequitable pattern of COVID-19 cases and deaths was found across the nation. A study at Johns Hopkins University found that the infection rate in the 131 predominantly black counties in the U.S. is more than three-fold higher than that in predominantly white counties. Astoundingly, the death rate in the predominantly black counties was found to be six-folder higher than in predominantly white counties [9]. Hispanic patients, too, have been found to have a significantly higher death rate after contracting COVID-19 compared to non-Hispanic individuals [12].

COVID-19: The Role of Social Determinants of Health

When analyzing the source of inequitable outcomes faced by underrepresented minorities during the COVID-19 pandemic, one must consider the role of social determinants of health. A study by Baptist et al. confirmed that socioeconomic status and the effects of institutional racism played a role in disparities seen in asthmatics during COVID-19 [13]. Equally important to note is that health behaviors,

Fig. 5.3 The social determinants of health [26]

sources of information, and attitudes did not play significant roles in those disparities [13]. Each of the social determinants of health in Fig. 5.3, including economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context, may partially explain health disparities [26]. For instance, minority individuals reported having been more likely to have had COVID-19, more likely to have lost their jobs because of COVID-19, more likely to have difficulties obtaining their medications during the pandemic, and more likely to live in a neighborhood with higher prevalence of COVID-19 cases [13]. Additionally, higher case reports have been reported in people with lower annual income levels, greater household sizes, and inability to work from home [7].

COVID-19 and Structural Racism

Although social determinants of health have a crucial role in influencing health disparities, **structural racism** has been recognized as another factor that promotes health disparities and therefore must also be considered as a cause of COVID-19 health disparities [27]. Structural racism refers to "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems of housing, education, employment, earnings, benefits, credit, media, health care, and criminal justice." [27] All of these systems in turn reinforce discriminatory beliefs, values, and resource distribution. Structural racism does not require individual intent or actions. Rather, structural racism occurs as a result of an establishment of patterns, procedures, practices, and policies that penalize or exploit minorities [28, 29]. This results in socioeconomic inequality, such as limited access to housing,

food insecurity, and poor access to health insurance and healthcare facilities [7]. Existing inequity is often highlighted in emergency conditions. The disproportionate effects of COVID-19 on minority communities reflect the racial inequality and social exclusion that existed far before the COVID-19 pandemic [30]. In fact, the overall impact of COVID-19 is likely underestimated in minority communities due to particularly poor access to testing for these populations [7].

Solutions

Despite the substantial obstacles to providing safe and equitable care to all patients during a pandemic, many potential solutions have been proposed.

To mitigate supply issues around hospital bed availability, transparency throughout the emergency response and hospital systems is needed. Emergency Medical Services (EMS) must think critically so that the most at-risk have equitable access to care. This may involve diverting from full community hospitals to less full academic hospitals. Early in the COVID-19 outbreak, there was a significant decrease in the number of EMS responses across the U.S., which may have represented an opportunity to think wisely about and develop equitable emergency services [31]. Others have proposed directing crucial resources, such as intensive care beds and ventilators, to patients predicted to benefit most [25]. Although there are significant structural and bureaucratic challenges for safety net and other small community hospitals to transfer patients to academic institutions, it is certainly possible. In a study by Uppal et al., patients from the most affected hospitals in New York were transferred to other hospitals that had more capacity to ensure bulk redistribution so that each community had access to critical care [32].

The Social Vulnerability Index (SVI) and Community Vulnerability Index (CVI) are two measures that can also help identify the most vulnerable communities in a public health crisis or disaster scenario [33, 34]. The SVI identifies the most socially vulnerable communities by considering the effects of socioeconomic status, household composition and disability, minority status and language, and housing and transportation on social vulnerability [33]. The CVI considers healthcare, affordable housing, transportation, childcare, and safe and secure employment [34]. Both the SVI and CVI can be used to help state and local officials target efforts to ensure the safety and well-being of their most vulnerable residents.

Regarding supply of PPE, tests, ventilators, and other equipment, there have been many attempts at solving the supply issue. Novel solutions such as 3D printing have been used but have significant cost implications and are more difficult to implement in low resource settings already overwhelmed with care delivery. Market prices have been shown to not be an appropriate method for rationing. Instead, removing the profit motive for purchasing PPE in hospital costing models, strengthening the government's capacity to maintain and distribute PPE stockpiles, developing and enforcing regulations, and pursuing strategic industrial policy to reduce the U.S.'s continued dependence on imported PPE are all necessary to ensure

healthcare workers have adequate access to PPE supplies [14]. Specifically, Cohen et al. recommend that the U.S.:

- Prepare hospitals to better protect workers by removing the profit motive in the purchasing and maintenance of PPE inventories;
- Strengthen the capacity of local, state, and federal government to maintain and distribute PPE stockpiles;
- Improve enforcement of OSHA's current regulations around PPE, including requirements to source the proper size for each employee;
- Develop new regulations to reduce practitioner stress and fatigue;
- Improve the federal government's ability to coordinate supply and distribution across hospitals and local and state governments;
- Consider strategic industrial policy to increase U.S. production of medical supplies and to reduce the dependence on the global supply chain for PPE;
- Consider industrial policy to incentivize PPE production using existing technology while encouraging development, testing, and production of higher-quality, reusable PPE.

Overall, a coordinated response is needed in order to combat the supply issues the U.S. will inevitably face in its next public health crisis. This would ideally include coordination between state and federal entities around common goals, such as equitable distribution of supplies. In order to accomplish this, flexibility, traceability, transparency, persistence, responsiveness, global independence, and equitable access are needed. System and supply chain thinking, in addition to strong governance, minimal bureaucracy, and use of technology, are necessary to address supply gaps and eliminate inefficiencies and supply inequities [35, 36]. Oversight and stewardship from the government are crucial in order to engage and orchestrate different partners to achieve common goals, for example, ensuring that private-sector supply chains achieve desired results [35]. An important part of this government stewardship involves ensuring that the areas hit hardest at any given time receive necessary equipment on the basis of need. Since COVID-19 cases are unlikely to surge in different regions of the nation all at once, there is an immense opportunity to fill gaps of need [16].

While the COVID-19 pandemic has magnified pre-existing inequities and health disparities, there has been a renewed focus on equitable access and delivery of care to mitigate such disparities. But before all else, structural racism must be named as a cause of such disparities and its health implications and connection to health disparities must be understood in order to advance health equity and public health [27]. It must also be understood who is disproportionately affected by structural racism, and how. For instance, studies show that black and Hispanic individuals are more likely to be affected by factors associated with structural racism, such as residing in larger households, working in person, and using public transportation, which significantly increase the likelihood of COVID-19 exposure [37]. It is also

important to understand and learn from the history of structural racism in order to understand the present climate. Acknowledging that long-standing systemic inequalities, and the effects of racism on mental and physical health, have fueled the impact of the COVID-19 pandemic disproportionately on minority communities is an important first step [38, 39].

Next, the structural factors that have perpetuated racial inequities during the COVID-19 pandemic must be understood and acted upon. Factors such as housing, education, healthcare, employment, and the justice system, among others, affect health in a myriad of ways that encourage unequal distribution of resources leading to social deprivation from reduced access to employment and housing, higher rates of environmental exposures and marketing of unhealthy substances and foods, limited healthcare access, trauma from police brutality and chronic exposure to discrimination, and reduction in healthy behaviors or higher participation in unhealthy behaviors as mechanisms to cope [40]. The factors that do not contribute to racial inequities in health outcomes must also be understood. Those factors that do not contribute include age, sex, and birthplace [40].

There are a number of suggested strategies to mitigate structural racism and its effect on health equity [40]. First, policies that keep structural racism in place must be changed. Data on "ambulatory care sensitive conditions," or preventable emergency department visits and admissions related to diagnoses for which timely and effective outpatient care can help prevent or treat, for example, can be used as a proxy for disparities and structural racism and how to address associated inequities. Hospitals and regions with high rates of ambulatory care sensitive conditions can shed light on where marginalized groups are most affected and how well inequities and inadequate access to care are addressed. Second, silos must be broken in order to make way for cross-sector partnerships to be formed. Third, policies to increase economic empowerment must be instituted and community programs that enhance neighborhood stability must be funded. Fourth, health systems must engage in consistent efforts to build trust in vulnerable communities. Lastly, targeted interventions that address social risk factors must be tested and deployed.

To improve upon disparate outcomes in a public health crisis, efforts must also focus on addressing social risk factors and unmet social needs. The social determinants of health seen in Fig. 5.3 link to both adverse social conditions associated with increased risk of exposure to COVID-19 and immediate social conditions that individuals identify as most pressing to maintain their health [40]. Better access to equitable housing can mitigate the role of crowded households and inability of patients to isolate away from other family members. Less expensive and more robust transportation can help mitigate the role of packed public transit on increased risk of COVID-19 exposure. Equitable access to all job types can reduce the effect that greater representation in service occupations has on the health of minorities [40]. Better access to healthier food options and green space could have immediate effects on health and reduce obesity, diabetes, heart disease, and other comorbidities linked to poorer outcomes in COVID-19.

Conclusion

The COVID-19 pandemic had striking and far-reaching consequences on national and local health systems, the economy, and the social well-being of U.S. citizens. The devastating effects of the COVID-19 pandemic led to high case numbers and deaths in the U.S., disproportionally so for minority populations. Healthcare inequities related to supply and bed availability issues, the social determinants of health, and systemic racism all contributed to the disproportionate effects of the COVID-19 pandemic on minority case numbers and deaths. Many solutions have been proposed in order to prevent recurrence of these inequities in future public health crises, including coordinating state and federal responses, addressing unmet social factors and needs, and studying and acting upon the structural factors and policies that have perpetuated racial inequities.

Key Lessons Learned

- The COVID-19 pandemic had far-reaching consequences on national and local healthcare systems as well as significant social and economic consequences.
- Public health crises present unique safety issues and exacerbate pre-existing disparities as a result of supply and bed availability issues, especially in safety net hospitals.
- A coordinated response including state and federal assistance is necessary to combat the associated safety issues and inequities.
- Social determinants of health and systemic racism must be considered and mitigated to improve the health and outcomes of minority populations.

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Part II
Concepts

Chapter 6
Patient Identification

Christopher Montgomery and Eric Wei

Every system is perfectly designed to get the results it gets. (Paul Batalden)

Introduction

Safe care begins with proper identification. Since the first set of National Patient Safety Goals (NPSG) was established by The Joint Commission in 2003, accurate patient identification has remained a high priority on this list [1]. Patient identification refers to the process of "correctly matching a patient to appropriately intended interventions and communicating about the patient's identity accurately and reliably throughout the continuum of care" [2]. In 2016, the ECRI Institute Patient Safety Organization developed a care process map (Fig. 6.1), illustrating the extent of patient identification throughout a patient's encounter with a health care system [2]. In all three phases—intake (i.e., triage, registration, scheduling), encounter (e.g., diagnosis, treatment, monitoring, discharge/visit completion), and post-encounter/follow-up care (e.g., referrals, electronic prescribing, health information exchanges), patient identification is pervasive [3]. The consistency of patient identification occurring throughout the entire continuum of care underscores the necessity for accuracy and prevention of patient misidentification.

As broad and unique the circumstances, situations, or risk factors leading to a patient being misidentified could be, so too are the possible consequences of that error. The potential for inaccurate or incomplete information being used in clinical decision-making, treatment choices, or monitoring could have a strong negative impact on patient morbidity and mortality [4]. Similarly, from an administrative

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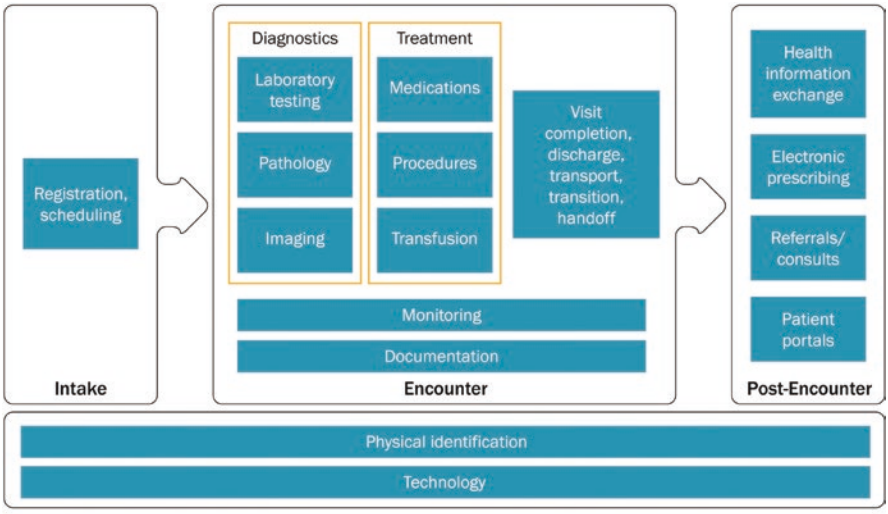

Fig. 6.1 Patient identification care process map. (Reprinted with permission, Copyright 2021, Emergency Care Research Institute d/b/a ECRI. www.ecri.org. 5200 Butler Pike, Plymouth Meeting, PA 19462. This material is protected by copyright laws and may not in whole, in part, or by reference be used in any advertising or promotional material, or to compete with ECRI)

perspective, the existence of multiple records for a single patient, duplicative testing, and issues related to patient privacy could lead to the utilization of costly internal/external assessment services, denied reimbursement, and liability concerns resulting in increased costs and diminished returns impacting the functionality and structure of a hospital/health care system [5].

While the frequency of patient misidentification remains elusive and difficult to accurately calculate due to the inconsistency in reporting and variability in resulting outcomes, attempts to quantify the incidence and elevate concern have occurred. A qualitative analysis performed on 227 root cause analyses (RCA) reports from the Veterans Health Administration found that 182 of 253 identified errors in the test cycle were attributable to patient misidentification [4]. The State of New York recorded 27 incidents of invasive procedures performed on incorrect patients between April 1998 and December 2001 [6]. Finally, in the 2016 National Patient Misidentification Report published by the Ponemon Institute, it was identified that on average, a hospital loses $17.4 million per year in denied insurance claims associated with misidentification [5].

Preventing the Recurrence of Patient Misidentification

Human error is inevitable, and the very occurrence of human error implies that it can happen again. In order to address an event and prevent its recurrence, it is critical to always remember that while a person may have carried out the error, there are numerous system factors that facilitated/enabled the error to occur. Root causes refer to the most fundamental reason a problem has occurred; a contributing factor that when acted upon by a solution prevents the problem from reoccurring [7]. While any form of patient misidentification is in it of itself problematic, it presents an opportunity for thorough assessment and identification of root causes leading to the improvement of a system and an opportunity for prevention of future events. For our cases below, we will focus on better understanding and preventing patient misidentification through root cause analysis (RCA), a comprehensive, system-based review process used to identify any root causes/contributing factors resulting in adverse events, create action plans and strategies to prevent recurrence, and develop a plan to monitor/measure the effectiveness of these action plans and strategies. With numerous tools and methods available to health care facilities and systems related to RCAs, it is critical to identify or develop a specific RCA process and/or structure in order to consistently and effectively prevent and address identified root causes.

The Importance of a Culture of Safety

RCA methodology brings consistency to the process of identifying, mediating, and monitoring root causes and is critical for effective prevention and improvement. Just as important and often forgotten, is the environment or culture surrounding this process. The Joint Commission defines a safety culture as the "product of individual and group beliefs, values, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety" [8]. The safety culture present at any institution determines the comfortability of staff/employees in reporting and participating in the process of RCA and systems improvement. The development of a culture of safety refers to the creation of an environment where employees at all levels are comfortable in their commitment to safety. They are not merely encouraged to work toward change but feel secure in acting when needed [9]. Whether it be the collection of data pertinent to an event, participation or buy-in to implemented action plans/strategies, or even just the reporting of events, the safety culture of any health care organization or facility plays an enormous role in the care/safety of patients and employees.

Identifying and Implementing Effective Actions/Strategies

The most important step in the RCA process is the identification and implementation of actions and/or strategies to address, eliminate, or prevent any identified root causes. In Table 6.1, we see a corrective action hierarchy, adapted from the US Department of Veteran Affairs National Center for Patient Safety [7]. The goal of any RCA is to increase safety in the long term and not allow a similar event to occur, so the actions taken to address root causes need to be carefully considered. As previously discussed, the occurrence of human error is ever present, therefore it can be understood that solutions oriented toward addressing human behavior directly, such as training, policies, or warnings, are considered weaker solutions. Whereas solutions oriented toward addressing/changing the system, while often more cumbersome and expensive, are much more effective [10]. Keeping this framework in mind, we want to clarify that "weaker' actions are often temporarily necessary, but efforts oriented toward identifying and implementing at least one stronger or intermediate strength action should always take place.

Table 6.1 A corrective action hierarchy (adapted from the VA National Center for Patient Safety)

	Action category	Example
Stronger actions	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA2 process; purchase needed equipment; ensure staffing and workload arebalanced.

Table 6.1 (continued)

	Action category	Example
Intermediate actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug–drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
Weaker actions	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/memorandum/policy	Remember to check IV sites every 2 h.
	Training	Demonstrate the hard-to-use defibrillator with hidden door during an in-service training.

Source: National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm. Figure 3. Based on Root Cause Analysis Tools, VA National Center for Patient Safety. Boston, MA. 2015. And include the following link: http://secure-web.cisco.com/1P7wVyTKwwbyBA8wjmpCiuT4x4JdnsEyzEDUGvK_5fo7upAojvVJkxTvw2BDCtI6gmkU0VIaX9ZbRIChXTAOg9jLdWYUmY256cRodNO0jEAqhVOH5JmemlTopX1xfdeo-JGdpMwZkbVrFNWSYXsz8vd18VZRT18U-XEA7j_4w8au5_2IOhJ8dW0lICnWXxE8dg30uwM9EgIuqxzShH16_oNlKf4uazX8kKBc78ZpTI03_7oToSo4qiKfL7cD8g0qIc6CyXgIBQfo7nwVPaMIcRZnrVQqcmFIqB4yDwUZIzZOg/http%3A%2F%2Fwww.patientsafety.va.gov%2Fdocs%2Fjoe%2Frca_tools_2_15.pdf

Case Studies

To better understand the importance of patient identification, in this next section, we will present two cases of patient misidentification, discuss various concepts, and use different tools commonly utilized in RCA methodology. Thereafter we will discuss different strategies and action plans to address the identified issues.

Case 1: Let's Wake Him up to Double Check

Early Saturday morning, a 30-year-old primarily Spanish-speaking male arrives to the Emergency Department (ED) with severe right ankle pain and swelling. Two days ago, he sustained an injury falling while working at his construction job. At registration, the patient presents the clerk with a Driver's License as his form of identification, Hector Ruiz. Not able to find a chart for this patient, the clerk opens a new medical record. Shortly thereafter, X-rays identify a fracture of the right distal tibia and orthopedics is called. As the orthopedic resident arrives to the room, she reads off the patient's first name from her notes, but the patient, still awake, does not respond. The second time she calls his name, getting his attention, she informs the patient that surgery is needed and that it can be completed on an outpatient basis to allow some of the swelling to decrease. Working with interpreter phone services, she is able to obtain informed consent. The patient is then discharged with a pre-anesthesia appointment.

Arriving at his pre-anesthesia appointment, the patient presents a passport as his form of identification. Looking at the passport, the registration clerk notices two last names, Ramon Ruiz Ramirez. The clerk, unable to identify the patients' medical record, decides to open a new medical record and check the patient in with the provided passport. The patient's evaluation was unremarkable, and informed consent for anesthesia was obtained with interpreter phone services.

On the day of his surgery, the patient arrives to the pre-operative area and informs the registration clerk that he forgot his wallet and gives them his work ID, Ramon Ramirez. As the clerk begins to check the patient in, they begin having difficulty identifying the patient's chart, a new medical record is opened for Ramon Ramirez. While waiting in the pre-op holding area the nursing, anesthesia, and orthopedic teams all check in on the patient. Soon thereafter, the patient is wheeled back to the operating room and placed under general anesthesia. As the OR circulating nurse calls for the team to go through the standardized OR time-out, the team reviews the completed consent forms and realize that they do not match. In fact, upon checking the patient's wrist ID band they are shocked to find that it also does not match either consent form. Unsure of who the patient laying on the operating table is, the team decides to abort the operation, wake the patient up, and double check who they were about to operate on.

After confirming the patient's identity and ensuring their safety, the risk manager was contacted and an occurrence report was completed and filed. It was thereafter

Table 6.2 Case study flow chart—let's wake him up to double check

Timeline	Identified problem points
• ED: Visit: 30-year-old primarily Spanish-speaking male arrives to ED with leg injury. – Presents registration clerk with driver's license as form of identification (Hector Ruiz). – A new medical chart is opened.	• Interpreter services not used. • Patient used brother's driver's license in order to use his insurance. • No biometric identification available.
• Fracture of right distal tibia identified. Orthopedics is consulted. Surgery recommended on outpatient basis; informed consent obtained through phone interpreter. Patient discharged with pre-anesthesia appointment.	• Two identifiers not used.
• Ambulatory visit: – Patient presents registration with passport as form of identification (Ramon Ruiz Ramirez). – Registration clerk cannot find a medical chart in the system for the name on the passport. – A new patient chart is opened.	• Interpreter services not used. • Patient now using his own identity once he realized he needs surgery. • Quick to default to opening new chart. • No standard algorithm for patient ID at registration. • No biometric identification available.
• Anesthesia evaluation was unremarkable, and informed consent for anesthesia was obtained with interpreter phone services.	
• Day of surgery: patient presents to pre-op. – He forgot his wallet and provided the registration clerk his work ID (Ramon Ramirez). – Registration clerk could not find a medical chart in the system linked to the work ID. – A new patient chart is opened.	• Active identification not used. • Different ID's with different number of last names. • Quick to default to opening new chart. • No standard algorithm for patient ID at registration. • No biometric identification available.
Patient placed under general anesthesia.	
OR time-out: surgery team recognizes that names and dates of birth on both consents do not match, as well as the ID band on patient's wrist.	• No two patient identifier by multiple team members. • OR time-out too late for proper identification.
Decision made to abort the operation and wake patient up	

determined that an RCA is necessary for the event. After briefly reviewing the information collected related to the adverse event, the Chief Quality Officer (CQO), who is leading this root cause analysis, proposed the completion of a flow chart to identify the facts of the case (Table 6.2). Next, the RCA team went through the process map to identify system issues (Table 6.2), and performed 5 Why's to hone in on root causes.

Regardless of any policies, protocols, or tools that are created and implemented to prevent patient misidentification, ultimately, the information provided by the patient plays a major role in the capability of being able to properly identify who we are taking care of. The first NPSG from TJC recommends that clinical staff use at least two patient-provided identifiers when providing any form of care, treatment, or

services [11]. Three different forms of identification each with a different name were provided by the patient. When discussing this with the patient, the risk management team learned that he used his brother's ID on the initial visit due to his immigration and insurance status. The RCA team also identified that something as simple as a second last name seen on the passport, but not on the work ID made it difficult to identify the patients' medical record and led to the creation of a third medical record. The limitations of common methods like wrist bands and patient identifiers used to prevent patient misidentification have led to the exploration of other add-on technologies including biometric identification technologies. Biometrics refers to the recognition of individuals based on their anatomical, physiological, and/or behavioral characteristics, which permits identification without physical objects. These technologies are advantageous because biometrics data is more difficult to "steal, exchange or forget." Across the United States, various forms are being used to identify patients. Such approaches include fingerprints, palm vein scanning, iris scanning, and facial recognition [3].

The team identified that language barriers played a major role in the occurrence of this event. A language barrier, which is a communication barrier resulting from the parties concerned speaking different languages, has been shown to be a threat to the quality of hospital care. Several studies described the link between a language barrier and patient safety. Divi et al. showed that US patients with low English proficiency experienced more adverse events than patients with adequate English proficiency [12]. The RCA team found that during every interaction with clerical staff, interpreter services were not utilized. Also, the phone interpreter was only utilized for consents but not the entire orthopedic and anesthesia evaluations. Studies have also shown improved communication with live interpreters followed by video interpretation services than audio only interpretation [13]. As healthcare organizations strive for greater efficiency throughout all services, especially the ED, high expectations are imposed on staff commonly leading to strategies individual to the health care workers (providers, clerical staff, etc.) leading to deviation away from standardized methods resulting in unpredictable consistency in the delivery of safe care to patients. Reviewing this information, the RCA team recognized the important balance between system efficiency and patient safety.

Lastly, it was not recognized that the patient's wristband did not match either of the informed consents until after the patient was under anesthesia. A patient's wristband is an identification tool consistently placed on patients prior to any form of admission in order to prevent misidentification. While it was a good catch by the OR circulating nurse to identify the discrepancy, it would be much more appropriate for this to have occurred prior to any form of services/treatment having occurred.

Root Causes

1. No standard patient identification process/algorithm in registration led to three separate medical records being created for the same patient.

2. Not utilizing effective interpreter services through all communication touchpoints prevented the patient from playing an active role in patient identification.
3. Having the OR time-out after the patient was already under general anesthesia led to delay in identifying errors in patient identification with consents and ID band.

Corrective Actions

The RCA team began to identify actions/strategies/solutions to address these identified root causes and prevent future harm events. Recognizing the importance of addressing this event, the team referred to the Corrective Action Hierarchy (Table 6.1), to identify effective solutions.

1. With the consistent risk of incorrect information being provided by patients, the team decided it would be important to focus on the development of procedures oriented toward patient empowerment through understanding. The goal being to develop a policy/procedure for clerical staff related to patient identification in which patient language preferences are confirmed and clearly documented in the electronic medical record (EMR) and a script is developed oriented toward informing and educating patients on the importance of correct identification.
2. The team knew that all staff were already aware of the importance of patient identification and the standard around two patient identifiers. They realized that another memo, reminder, or lecture would not create lasting change. Therefore, the team engaged frontline staff and managers to co-develop a campaign using visual nudges to remind staff at the doorway and other key locations to use two patient identifiers. The campaign also empowered patients to ask about patient identification with each care interaction.
3. The RCA team also decided to develop a proposal to pilot a new biometric facial recognition software. The limitations of common methods like wrist bands and patient identifiers used to prevent patient misidentification and have led to the exploration of other add-on technologies including biometric identification technologies. Biometrics refers to the recognition of individuals based on their anatomical, physiological, and/or behavioral characteristics, which permits identification without physical objects. These technologies are advantageous because biometrics data is more difficult to "steal, exchange or forget." Across the United States, various forms are being used to identify patients. Such approaches include fingerprints, palm vein scanning, iris scanning, and facial recognition [3]. Facial recognition does not require any physical contact with a device for recognition, and patients can be recognized even when they are unconscious. The comparison of facial characteristics obtained from a patient with stored or preregistered facial records in a database allows the recognition process to verify the patient [14].
4. To address the recognition of an inconsistency between the wrist band and both informed consents, the RCA team recommended the review and subsequent

development of a pre-operation huddle that occurs prior to patient moving to the operating room. A pre-op huddle is the team's short pause to confirm patient identity matches consents and ID band with active involvement of the patient. The team also looked at other situations where a multi-disciplinary huddle prior to high-risk procedures or interventions could be deployed to ensure proper patient identification.

Case 2: The Curious Case of Pneumonia-Phylaxis

A 50-Year-old female, Jane Smith, presents to the Emergency Department with 5 days of fever, cough, and generalized weakness. Patient was registered, triaged, and placed into the main ED for provider evaluation. The ED physician took a full history and noticed rales on lung auscultation. She then ordered basic labs and a chest X-ray. Jane was diagnosed with community-acquired pneumonia and the physician ordered Ceftriaxone and Azithromycin with plan to place Jane in ED Observation for 24 h to ensure she was appropriately responding to the treatment. The ED nurse obtained the medications from the Pyxis machine and used the barcode scanner to scan the bag of Ceftriaxone and one of the barcodes on a sheet of patient stickers sitting at bedside. Shortly after the Ceftriaxone infusion began, the patient complained of chest and throat tightness and difficulty breathing. Soon Jane was unresponsive, and an airway emergency code was called. The ED physician quickly determined the patient was having an anaphylactic reaction with associated respiratory failure. Oxygen, Epinephrine, and Benadryl administered while the team set up for rapid sequence intubation. Jane was successfully intubated and admitted to the ICU where she was quickly weaned off the ventilator and observed for rebound anaphylaxis. The rest of her hospital course was unremarkable and she was discharged home with oral antibiotics.

After ensuring the patient was appropriately stabilized and handed off to the ICU team, the ED provider contacted risk management and the second victim peer support team. Referring back to a culture of safety, it is important to not only frame mistakes as potential opportunities for improvement, but to also take care of your employees and ensure that they are physically, emotionally, and psychologically supported. While the patient is typically the primary or direct victim of an adverse event, staff are often secondary victims. Staff live with feelings of guilt, incompetence, or inadequacy following medical errors [15]. Ensuring both the patients and staffs well-being is critical to the process of addressing adverse events and creating a culture of safety.

After the information related to the case was collected, it was determined that the case qualified for an RCA, which was led this time by the Chief Nursing Officer (CNO). An effective alternative to the flow chart with 5 Why's, a fish bone diagram, was completed to thoroughly analyze the event (Fig. 6.2).

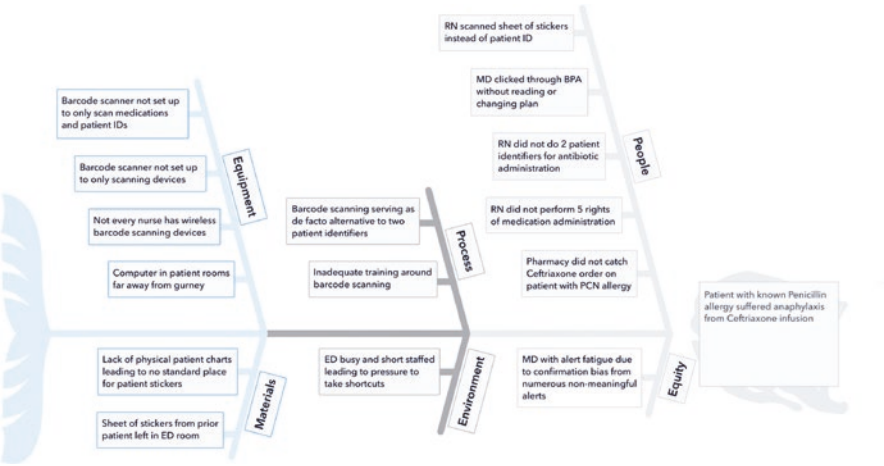

Fig. 6.2 Case study fish bone diagram—the curious case of pneumonia-phylaxis

Root Causes

1. High demand on ED nursing staff and inadequate barcode scanning training led to ED nurse scanning barcode on sheet of patient stickers instead of the ID band on the patient's wrist.
2. Over reliance on technology (barcode scanning) led to ED nurse not using two patient identifiers and 5 rights of medication administration.
3. Alert fatigue due to high number of best-practice alerts (BPAs) led to the ED provider clicking acknowledge for the Ceftriaxone-Penicillin allergy alert without fully reading or changing treatment course.

Corrective Actions

1. The RCA team learned through a walkthrough of the ED that utilizing the sheet of patient stickers as a proxy for the patient ID band was a common practice. Using the substitution rule, they clearly had a system issue rather than an individual issue. Working with the informatics team, the barcode was removed from patient stickers so it could no longer be scanned. All nursing staff were re-trained in barcode scanning to utilize the barcodes on the medication and patient ID bands only. It was also reinforced that barcode scanning supplements but does not supplant need for two patient identifiers and 5 rights of medication administration.
2. The CNO and ED nursing director did a full review of ED nursing staffing model to ensure safe nurse staffing that matched patient demand patterns. Ensuring there is safe staffing is key to avoiding unreasonable demands on staff who are

forced to balance patient safety precautions (i.e., two patient identifiers) with keeping up with patient care.
3. The CMO and CMIO led a workgroup of frontline providers to review all EMR alerts to remove any non-meaningful alerts to reduce interruptions and alert fatigue. The workgroup also reviewed the design of EMR alerts to draw provider attention to key information.

Discussion

Patient misidentification has remained on the NPSG list for almost 20 years and continues to be a significant contributor to patient harm [16]. The potential factors and causes contributing to the propensity for patient misidentification to occur are present across all aspects of the care continuum. Through the RCAs completed in response to both of the cases, we were able to identify common and complex issues impacting patient identification and present current best practices as well as those oriented toward ever improving technology. While nothing replaces the importance of performing patient identification through two identifiers while involving the patient, there have been technological advances with biometric identification, barcode scanning, and photographs in the EMR that can make systems safer to mitigate inevitable human errors. However, patient safety experts must beware of unintended consequences and workarounds when implementing technology solutions.

Key Lessons Learned

- Use at least two patient identifiers when providing care, treatment, and services.
- Regardless of policies, interventions, or tools available, the validity of the information provided by the patient plays an enormous role in correct identification.
- With the advent of new technology such as biometric imaging, alternative tools such as facial recognition provide effective consistency in the identification of persons seeking care.
- Beware unintended consequences of implementing technology patient identification solutions.

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Chapter 7
Teamwork and Trust for Patient Safety

Connor Lusk and Ken Catchpole

Introduction

Healthcare delivery is complex, uncertain, and dynamic, with demands that can vary widely from patient-to-patient, unit-to-unit, or moment-to-moment. Healthcare team members must collaborate across a diverse range of different providers to deliver care to a wide array of patients within an ever-changing organization. No clinician works or acts alone. For inpatients, the entire care team can change every 8–12 hours. Consequently, efficiency, safety, quality of care, and good patient outcomes are all dependent upon the successful collaboration and communication of multiple care team members.

Communication and teamwork are essential to all parts of care delivery, yet are often cited as a common cause of patient safety incidents. Headline studies suggest that lack of effective teamwork in organizations contributes to ineffective communication and 68.3% of accidental patient harm [1, 2]; 60% of surgical incidents are attributable to communication failures [3]. Failing to "speak up" about a problem due to hierarchical tensions or information being lost ("falling between the cracks") during handovers is also often cited, which prevent team members from speaking up or even communicating at all. Effective teamwork is a persistent challenge, requiring a range of experience and skills that are not necessarily formally taught or considered important clinical skills. However, effective teamwork and communication are what allows us to be successful in the first place, without which it would be impossible to deliver patient care.

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Clinical Teams

Teams that possess one or more common goals are brought together to perform organizationally relevant tasks**,** exhibit interdependencies, have different roles and responsibilities, and are embedded in an encompassing organizational system [4–11]. Effective teamwork is demonstrated by shared understanding, clearly designated roles, challenging other members respectfully, sharing expertise, and psychological safety [12, 13]. High performing team members are not scared to speak up when a conflict arises, make the best use of individuals, **c**apture errors that might occur by mutually supporting one another, resolve hazardous situations before they perpetuate and multiply, mitigate the effects of existing hazards, and create and maintain a culture of safety [14].

Team activities are required for diagnosis and treatment, planning and ongoing evaluation, instructive, informative and discursive training (e.g., teaching, learning about and discussing evidence), organizational strategies (e.g., assigning more experienced staff to challenging patients), and social components. These tasks, interactions, and exchanges can be conducted synchronously (face to face, over the phone, video conferencing/telehealth), and asynchronously (text messages, email, pagers, chart records, notes, stickers, annotations) over long (years) and short (seconds) time periods. There is no "one" healthcare team; everyone is a member of multiple teams that form and interact around patient needs.

Clinical teams require various members with diverse skills and backgrounds from very different training, creating a diversity of opinions, care options, languages, motivations, and worldviews that are both strengths and potential weaknesses. This brings many different perspectives on potential treatment but can also create disagreements and conflicts. While safe effective patient care is always a shared goal, how to go about this, and the tradeoffs required, may differ. So, naturally team members will come into conflict, which is not a bad thing, but a reflection of multiple potential treatments. It is important for team members to be able work together effectively and speak the same "language" when it comes to teamwork.

The "Systems" Approach to Teamwork

Adopting a "systems approach" to healthcare delivery has helped us understand how people, tasks, technology, workspace, and organization all interact to deliver low risk, effective, efficient care [15]. Teamwork is enacted by skilled individuals performing tasks with tools within a work setting, supported and influenced by administrative and regulatory structures within organizations. To understand and address teamwork, it is helpful to adopt a systems view that not only sees teamwork as individual and collective skills to be trained and maintained, but also considers the wider technological, environmental, and organizational context in which teamwork occurs.

Different professionals see patient needs differently and act independently despite inter-dependencies, through different language, education, and communication styles. Clinicians are not trained in teamwork and communication, rarely train as a team, and have few opportunities to practice as a team outside of everyday operational demands. Work is complex and unpredictable, asynchronous, requires multiple disciplines, and is geographically distributed and time pressured. Effective teamwork varies for clinical contexts; a surgical team has very different teamwork features in comparison to an intensive care unit (ICU) team. Even within surgery, the necessary teamwork for success in cardiac surgery is very different to that in orthopedic surgery. Technologies are constantly evolving, increasing teamwork demands, with few opportunities to compromise, as it is often high risk.

By recognizing the context in which any healthcare team is situated, we can develop the adaptive capacity necessary to deal with the everyday challenges of care delivery.

Teamwork Improvement Interventions

The dominant approach to teamwork improvement is through training with the aim of changing behaviors directly. Training as a team is sensitive to individual backgrounds, strengths, preferences, and can be empowering. Team-based learning conducted within simulation allows the practice of specific scenarios with protected debriefing time to understand experiences and reinforce the learning, with the understanding that simulation can never truly represent real working conditions. As teams are constantly changing, it may also be valuable to train individuals in a common set of team skills. This provides a standard basis for all members to understand and utilize, making it easier to work with new members. Breath, depth, and specificity all need to be considered in training design. However, caution is also advised. It is expensive to conduct, with the cost-benefit equation unclear [16] and does not address the systemic contextual factors that influence teamwork. If delivered as a once-only event, it is likely to degrade over time as the skills become forgotten, and new staff without the training join. Furthermore, if delivered remedially, following adverse events, it implies blame, and can ignore underlying and complex team or organizational issues. Even if not intentional, it implies a deficiency that may not be recognized by the team, who may not be receptive to training.

There are also many other ways in which teamwork can be influenced indirectly. Checklists, structured briefings, huddles, debriefings, and formal communication protocols (e.g., callouts, read-backs) aid team processes and decision-making, ensuring all members are acting in unison, reducing the chances of specific adverse events [17, 18]. Role and process visibility allow team members, who may not know each other, to understand what they need to do and where in the process they are, facilitating coordination and mutual support. Debriefings or team performance reviews may be one of the most effective teamwork activities; but, in an environment

where there is constant pressure to move on to the next patient, it is one of the most challenging to implement and sustain [19]. These structural approaches compliment behavioral training and may offer greater contextual-sensitivity and clearer behavioral standards.

Combining both skills training with deeper systemic support in the form of checklists, debriefings, and a range of other organizational practices and tools is more likely to be effective than either on their own.

Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS®)

TeamSTEPPS® is a comprehensive and thorough approach to individual team skills and some deeper systemic components. It was specifically developed to address the many patient safety teamwork challenges, constructed around team structure, leadership, communication, situational monitoring, and mutual support, acknowledging multiple teams and the importance of team context, rather than just behavior. It has modules related to critical communications protocols, readbacks and checkbacks, handovers and handoffs, briefs, debriefs and huddles, checklists, situation awareness and cross-monitoring, feedback, and approaches for speaking up (Table 7.1).

There are several significant barriers to wider use. First, the comprehensive nature of the approach means that the quantity of materials is cumbersome to deploy, leaving many with feelings of information overload [20]. The critical aspects of performance can substantially differ between teams, and how the specific themes manifest within a given context, for example: when a readback or a briefing would be appropriate, will also differ. The generic nature of the curriculum also does not necessarily reflect the specific needs of any one team. Unless substantial effort is given to understand the needs of each team trained, it will be up to the learners to interpret the TeamSTEPPS® curriculum in their own way. This is inefficient, can leave effectiveness to chance, and may disengage learners from relevance of their learning. Other barriers to preventing TeamSTEPPS® from reaching its full potential include a lack of administrative support and resources, lack of training focus to address hierarchal differences and incivility at all levels of health care practice and administration, inadequate instruction and simulation practices, and educators' resistance to change are all barriers [20]. To be effective, it needs to be carefully configured for purpose, and supported long term by departmental and organizational leadership.

Context and team-specific TeamSTEPPS® interventions should be implemented through a saturation-in-training model, which aims to train the greatest number of people in the shortest amount of time to achieve the greatest effect [20–22]. Team performance should be assessed pre-intervention, which should be comprised of classical lectures and videos, simulations, debriefing, and an immediate

Table 7.1 Essential teamwork for work system components

TeamSTEPPS tool	Leadership	Situation monitoring	Mutual support	Communication
Work system factor	Resource management, delegation, brief and debrief, group huddle	Situation awareness, cross monitoring	Task assistance feedback, advocacy and assertion, CUS, 2 challenge rule	SBAR, handoff, callout
People	Team consistency, familiarity with roles and responsibilities	Active information sharing across team	Constructive performance feedback, speaking up (ex: CUS), combat fatigue, team alertness members	Brief, clear, and specific information shared among team
Task	Clear team goals and objectives, facilitating problem solving with clear team structure	Communication to ensure shared mental models of work, cross monitor others, regular huddles/ briefs/debriefs for coordination	Appropriate task support for members, even workload distribution	Verification that correct information was communicated and received
Tools and technologies	Clear consistent communication between leader and team members	Utilize communication tools that permit others to be aware of team individual and whole roles and responsibilities (e.g., electronic white board), shared visual displays, equipment availability and function checks	Shared visible displays that integrate information across workspace	All available information sources visible and accessible to team throughout workspace
Environment	Organized physical environment that allows team leaders to locate and gather staff easily	Interactive workspace that facilitates visibility between team members	Becoming familiar with different work environments to plan processes as a team, necessary equipment accessible	Necessary equipment accessible for information gathering

(continued)

Table 7.1 (continued)

TeamSTEPPS tool	Leadership	Situation monitoring	Mutual support	Communication
Organization	Supportive and communicative organization, open top to bottom and bottom to top lines of communication	Supportive teamwork culture, leadership involvement, ongoing constructive feedback mechanisms, teamwork training, informal communications	Ability to speak up, safety voice	Ability to speak up, safety voice

post-intervention assessment. A follow-up intervention to assess post-intervention team performance, retention, and sustainability should be conducted at least 2 months after initial training.

Crew Resource Management

Crew Resource Management (CRM), built on post-hoc analysis of aviation accidents and based on simplified cognitive and behavioral principles with an emphasis on procedural checklists, has proven popular in healthcare. CRM key competencies include managing fatigue and workload, stress management, creating and managing teams, recognizing adverse situations, cross checking, communicating, assertiveness, developing and applying shared mental models for decision-making, situational awareness, and giving and receiving performance feedback [23]. CRM structured briefing tools include: SBAR (situation, background, assessment, recommendation) [24–26], FOR-DEC (facts, opinions, risks and benefits, decision, execution, check) [27], and SNAPPI (stop, notify, assessment, plan, priorities, invite ideas) [28]. These formal communication protocols support communication for frequent crises experienced by heterogeneous teams but may be disregarded for time required or task irrelevance [27].

Effective CRM interventions must be practical, relevant, and realistic to actual clinical work and introduce teamwork principles, communication, checklists, and cognitive skills for clinicians who may have never encountered these concepts before. It helps if trainers first understand the complexity of the system and develop strategies which provide hands on practice, relevancy, debriefing, on the job learning, reinforcement, and sustainability [11, 29]. Training must consume minimal time and expenses to be feasibly delivered during regular work, so a microlearning approach may reduce training times into smaller "chunks" (down from several hours to 15-min intervals) for the "time-poor clinician" [30–32]. Evidence-based CRM interventions should be comprised of traditional lectures and videos, observed and evaluated simulations, debriefings, and pre- and post-intervention knowledge/skill assessments and surveys, all aimed to reinforce behaviors and increase

retention. CRM interventions should be developed with minimum requirements for implementation: design (aims, methods for workshops and organizational change management, repeatable contents), training conditions (duration, target group, sample size, trainer qualification), and evaluation (methods, surveys, databases, sample size, statistical data, effect size, outcomes observed at environmental and organizational levels) [33].

Aviation has many similarities with healthcare, but also has critical and fundamental differences. Translation from other industries needs to be considered carefully, as healthcare systems lack many of the features that makes CRM valuable. CRM was built on top of an already very carefully controlled, regulated, and engineered system, which may not require as broad adaptation to working conditions, the extraordinarily large and diverse teams communicating sync- and asynchronously, or the wide variation in work contexts or tasks [34]. Thus, considerable care must be taken to ensure the specific clinical contexts, knowledge, skills, background, or needs, of different roles are understood through the context of CRM, not superimposed in a "one size fits all" onto the trainees.

Safety Voice

Safety voice training, or "speaking up," is derived from an understanding of the importance of teams to look out for each other and spot when things are about to go wrong. Frequently in accidents across many safety-critical systems, someone on the team knows that a wrong choice has been made, but feels unable to inform the rest of the team. Junior members feel they cannot tell senior colleagues that they have made a mistake. The structured approach to "speaking up" usually emphasizes escalation of concerns through key trigger words, often in mnemonics. More challenging is that it requires a psychologically safe work environment and will not help an organization where employees are afraid to speak up, where speaking up is not actively encouraged, or where hierarchy is reinforced [20].

TeamSTEPPS® approach uses CUS: "I'm concerned"; "this is unsafe"; and "stop, this is a safety issue" [35]. Another model uses PACE: probe ("Is this right?"), assert ("This seems wrong"), challenge ("This is wrong"), and emergency ("This is an emergency") [36]. Training teams to recognize the appropriate escalation stages and trigger words require relatively few resources, though ongoing reinforcement is necessary. Communication must go upward as it does downward to create a psychologically safe environment where people will safety voice is ineffective without "safety listening" [37], and explicitly demonstrates that without other active methods to reduce power-distances, that this type of safety intervention will not be especially effective. Where nurses are commonly trained to "speak up" and physicians are not trained to "listen down"; hierarchy and power-distances are maintained; and where there is a lack of psychological safety, this sort of intervention is unlikely to be effective. As the opportunities to use "safety voice" are relatively

infrequent, evaluation is challenging, and evidence of effectiveness is largely anecdotal.

Case Study

A ventriculoperitoneal (V-P) shunt was being given to a pediatric patient. The scrub nurse was new to the operation, but was being supported by an experienced nurse, and the consultant surgeon was joined by a semi-retired colleague and mentor. The operation did not immediately proceed smoothly, with several problems and stoppages due to equipment problems; the diathermy did not immediately function effectively; the pneumatic hose on the cranial drill was occluded when it was secured to the drapes and took several minutes to rectify (with the nursing staff first changing several parts of the drill before another nurse solved the problem). The surgeons were also struggling with the equipment, some of which was an inappropriate size for the patient, and since this operation was being performed in another part of the hospital from usual, no alternatives were available. To rinse the incision site for passing the V-P shunt under the skin, the semi-retired surgeon requested saline, but the inexperienced and overloaded scrub nurse, also attending to the needs of the attending surgeon, accidentally gave the previously used syringe of local anesthetic (Chirocaine). As the surgeon was about to deliver the contents of the syringe to the incision site, the second (experienced) scrub nurse realized the error and very loudly shouted "No don't do that," and the error was captured.

This study demonstrates how team configurations can both create and reduce risks. In this case, there were four people at the operating table—a scrub tech, a trainee scrub tech, an attending surgeon, and a senior surgeon—when usually there would be two. This created an unusual dynamic, in terms of experience, hierarchy, leadership, and task distribution. No briefing had been conducted before and that might have resolved this, and it later led to ambiguities and interaction problems.

The team had to deal with a range of intraoperative issues, none of which are uncommon, but which also stretched the process, the team, and their awareness. In fact, an essential part of successful surgery is the ability of the team to overcome equipment, coordination, supply, and other problems on top of the technical requirements of the surgery and patient challenges. This takes experience, communication, and situational awareness. Later in the case, the inexperienced scrub tech was trying to address the needs of both surgeons, which can be challenging for even experienced scrub techs. In doing so, they were predisposed to make a mistake, in this case mistaking one syringe for another. However, the awareness of the more experienced scrub tech, and her ability and confidence to speak up immediately and assertively, meant that this syringe swap was identified and prevented.

Conclusion and Key Lessons Learned

- Effective teamwork is necessary to a high functioning, interprofessional healthcare environment.
- Practicing new skills promotes cohesion within teams, builds trust, strengthens the bond between team members, and ultimately increases patient safety.
- Behavior is dynamic, difficult to study and generalize, is not easy to change, prohibitive to ongoing operations, and unsustainable to many healthcare facilities.
- Training should be built around the specific needs of teams within their specialty or clinical system.
- Trainers should be fluent in the theory of how teams work together successfully, but also how teamwork changes in different contexts.
- Including high fidelity simulation teamwork training allows teams to operationalize the knowledge and skills taught in realistic scenarios.
- Administration should ensure transfer of effective teamwork by creating an environment that enables the knowledge and skills learned to be practiced.
- Too much focus on studying and directly modifying behavior neglects other important components in the system.
- Rather than a "once only" deluge of slides, teamwork improvement needs to be seen as something to develop specifically, carefully, and continually, with collaboration and knowledge from each unique care context, across multiple topics and training modalities, adapting both the context of work, the work itself, as well as the people who deliver it, with explicit and clear organizational commitment.

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Chapter 8
Handoff and Care Transitions

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Introduction

With the increasing complexity of medical care and medical specialization, care delivery has shifted from being the responsibility of one or two healthcare providers to being distributed across a complex system of providers. A patient will typically encounter multiple health care providers even when receiving care for the same issue, potentially leaving them without an integrated understanding of their problem or a systemic solution that addresses their needs. In this landscape of decentralized care, effective communication and teamwork among health care providers are critical, particularly during transitions of care. Indeed, poor communication is the most common cause of medical error [1], accounting for at least 30% of all medical malpractice claims in the US [2]. Teamwork failures in the US contributed to 70% of medical malpractice claims among medical trainees [3].

In this chapter, we present two case studies of patient harm events caused by ineffective handoff communication and teamwork during transitions of care. Our goal is to examine some of the common challenges faced by clinicians and to provide insights into how these obstacles can be overcome.

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Clinical Case Studies

Case 1: Ineffective Communication upon Discharge

Lynda was a young woman with a dual diagnosis of a mental health condition and substance use disorder. She was admitted to a psychiatric hospital for the treatment of severe depression. Under the care of the hospital treating psychiatrist (Dr. T), Lynda's condition improved and she was subsequently discharged. During her two-week inpatient stay, she was prescribed clozapine and fluoxetine, and adjustments were made to her existing medications. At the time of discharge, she was taking a total of seven medications (clozapine, diazepam, fluoxetine, methadone, clopixol, quetiapine, temazepam).

Dr. T intended to cease clopixol and progressively lower the dose of quetiapine. However, this treatment plan was not communicated to the resident assuming her care on the day of discharge. Prior to the inpatient admission, Lynda was receiving care from three separate health care providers: a primary care physician (PCP; Dr. F), a private practice psychiatrist (Dr. H), and a methadone clinic. Because Dr. H was on leave, upon discharge, Dr. T referred Lynda to Dr. E at a clozapine clinic to manage her clozapine treatment. A written discharge summary was prepared by the resident and faxed to Dr. F and Dr. H, but not to Dr. E. However, the discharge summary did not reach Dr. F and Dr. H. At the time of discharge, Lynda and her family did not receive a discharge summary.

There was also no discussion of her care plan. Lynda's family was simply told that she would be a "different person" with the new medications. Following discharge, Lynda continued to receive methadone at the methadone clinic, clozapine at the clozapine clinic, and the remaining medications and clopixol injections administered by Dr. F. At home, Lynda's mother managed her prescription medications and would make them available to her each day to prevent overdose. She observed a significant deterioration in her daughter's health in the weeks after discharge, with Lynda heavily sedated and unable to carry out daily activities. Two months following discharge, Lynda died at home in her sleep. The medical cause of death was respiratory depression as a result of the interaction of a number of prescribed medications that had a central nervous system depressant effect.

What Happened?

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants is a well-established risk factor for life-threatening respiratory depression. Managing potential interactions of these medications becomes increasingly difficult as the number of medications prescribed increase. Following discharge from the hospital, Lynda was simultaneously taking seven CNS active drugs without being closely monitored. The combination of these medications

exerted an additive effect, leading to oversedation, respiratory depression, and ultimately death.

Why Did It Happen?

Ineffective Clinical Handoff During Transitions of Care

Poor clinical handoff during transitions of care was a primary contributing factor to Lynda's death. Effective clinical handoff requires the transfer of information pertinent to the care of a patient, as well as the transfer of professional accountability and responsibility, neither of which occurred at Lynda's discharge from the hospital. The intended treatment plan of the hospital psychiatrist was not communicated to any of the providers taking over Lynda's care at the time of discharge. Furthermore, there was no direct handoff communication between the transferring and receiving providers. Although a written discharge summary was sent to Lynda's PCP and private psychiatrist, there was no process in place to verify that the information was received, or to provide an opportunity to discuss and clarify the patient's care plan.

Lynda's tragic death was precipitated not only by a failure in information transfer. A diffusion of responsibility across the many health care providers led to further missed opportunities to rationalize and optimize her treatment. Following discharge from the hospital, Lynda was seen by her PCP (Dr. F) on several occasions. Despite not having received discharge instructions from the hospital, Dr. F did not attempt to contact the hospital. He continued to issue prescriptions for benzodiazepines and administer clopixol injections. When interviewed by investigators regarding this incident, Dr. F expressed his view that as a PCP, he did not have the authority to advise Lynda on mental health treatment and would therefore "leave the mental health issues for the experts." Lynda was also seen by Dr. E at the clozapine clinic. Beyond providing clozapine treatment, Dr. E did not consider he had any broader responsibility to monitor Lynda's other medications. There was no communication among Dr. F, Dr. E, and the methadone clinic. Furthermore, no attempts were made by any of these providers to discuss Lynda's care plan with Dr. H, Lynda's private psychiatrist. Thus, the lack of clarity about who is responsible for Lynda's overall care and communication failures among these providers contributed to this incident.

Fragmented Care Environment

The disturbing lack of communication among Lynda's health care providers is symptomatic of a compartmentalized approach to medical care. Patients with multiple conditions often interact with multiple health care providers from different specialties. Because clinical care guidelines typically focus on patients with only one disease, providers from one specialty may not focus on how the treatment that they administer interacts with other concurrent treatments for other conditions. Poor coordination of care in this fragmented care environment frequently results in

overall poor health outcomes, especially when treatment options for one condition can potentially affect the outcomes of another. The risk of adverse drug reactions, for example, is particularly high among patients with multiple chronic conditions such as Lynda [4, 5]. The complex medical needs of these patients further compound the risk and impact of poorly coordinated care.

Ineffective Communication of Discharge Care Plan with Patient and Her Family

Inadequate post-discharge planning was also a contributing factor to the incident. Ensuring a safe transition from hospital to home requires effective communication of the post-discharge care management plan to patients and their families. This did not occur at Lynda's hospital discharge. There was no discussion of the treatment plan with the patient or her family, or advice as to the potential symptoms and warning signs to be aware of. Consequently, despite recognizing changes in Lynda's behavior in the weeks after discharge, her family was unaware of the potential significance of these changes. Thus, the opportunity to intervene was missed.

What Can Be Done to Prevent It from Happening Again?

Effective Clinical Handoff

Transitions of care are a period of heightened error vulnerability [6]. Effective clinical handoff during these critical times can prevent inevitable mistakes from harming patients. To improve the safety and quality of clinical handoff, in the US the Joint Commission mandates that all hospitals implement a standardized approach to handoff communication, including an opportunity to ask and respond to questions [7]. A range of communication strategies and tools such as mnemonics, checklists, and templates have been recommended to support these efforts [8]. SBAR (Situation, Background, Assessment, and Recommendation) is the most commonly used standardized framework for conveying essential information in patient handoffs [9] (Table 8.1). I PASS the BATON [10] is another mnemonic technique that standardizes the flow of information critical for patient care (Table 8.2).

Table 8.1 SBAR framework for standardizing clinical handoff

S	Situation	What is the situation?
B	Background	What is the background information?
A	Assessment	What is your assessment of the problem?
R	Recommendation	How should the problem be corrected?

Table 8.2 "I PASS the BATON" strategy for enhancing information exchange during care transitions [10]

I	Introduce	Introduce yourself and your role
P	Patient	Name, identifiers, age, sex, location
A	Assessment	Present chief complaint, vital signs, symptoms, and diagnosis
S	Situation	Current status/circumstances, including code status, level of uncertainty, recent changes, and response to treatment
S	Safety	Critical laboratory results, socioeconomic factors, allergies, and alerts (e.g., falls, isolation)
The		
B	Background	Comorbidities, previous episodes, current medications, and family history
A	Actions	Explain what actions were taken or are required
T	Timing	Level of urgency, timing, and prioritization of actions
O	Ownership	Identify who is responsible (person/team), including patient and family members
N	Next	What will happen next? Anticipated changes? What is the plan? Are there contingency plans?

While standardization of handoff communication has the potential to improve the accuracy and consistency of information transfer, it does not address problems that can arise due to poor teamwork, such as those caused by the diffusion of responsibility seen in Lynda's case. Recognizing the importance of teamwork in ensuring patient safety, the US Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense jointly developed TeamSTEPPS (Tools to Enhance Performance and Patient Safety) [11] to serve as a national standard for team training in health care. TeamSTEPPS includes evidence-based guidelines for clinical handoff that can be tailored to any medical setting, as summarized in Box 8.1. These guidelines emphasize the dual function of handoff—that of information transfer, as well as the transfer of responsibility and accountability—and clarify the respective roles of the transferring and receiving providers. To prevent diffusion of responsibility at care transitions, communication at the time of the handoff should result in a clear understanding by each provider about who is responsible for which aspects of the patient's care. The transferring provider cannot relinquish responsibility of patient care before: (a) the receiving provider understands and accepts the transfer of responsibility and (b) an interactive handoff communication has taken place between the transferring and receiving providers, allowing the receiving providers to clarify the information being transferred so that the handoff is understood and accepted.

Box 8.1 TeamSTEPPS Guidelines for Conducting an Effective Clinical Handoff

Effective handoff includes the following [12]:

- **Transfer of responsibility and accountability**: When handing off, it is the transferring provider's responsibility to know that the receiving provider is aware of the transfer of responsibility.
- **Clarity of information**: When uncertainty exists, it is the transferring provider's responsibility to clear up any ambiguity of responsibility before the transfer is completed.
- **Verbal communication of information**: Handoff communication should be interactive and provide opportunity to ask questions, clarify, and confirm the information being transmitted. The transferring provider cannot assume that the receiving provider will read or understand written or nonverbal communications.
- **Acknowledgment by receiver**: Handoff communication requires a process for verification of the received information. Until it is acknowledged that the handoff is understood and accepted, the transferring provider cannot relinquish responsibility of patient care.
- **Opportunity to review**: In addition to facilitating transitions of care, handoffs present an opportunity to review and evaluate care management plans to ensure that a patient is receiving optimal care.

In addition, handoffs include the transfer of knowledge and information about:

- The degree of certainty and uncertainty regarding a patient, such as whether a diagnosis has been confirmed.
- The patient's response to treatment.
- Recent changes in condition and circumstances.
- The plan of care, including contingencies.

Care Coordination in a Fragmented Care Environment

Care coordination involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care [13]. Coordination of care during care transitions is especially important in a fragmented care environment. The level of care coordination needed also increases with greater clinical complexity and decreased patient capacity for participating effectively in coordinating one's own care [14]. A range of care coordination models have been proposed and evaluated, with varying

success [13, 15–18]. While effective strategies for coordinating care likely vary by patient population and clinical settings, successful models typically incorporate the following elements [19]: (a) an individualized care plan based on assessment of a patient's needs; (b) effective and continuous information sharing among providers, as well as between providers and patients; and (c) a lead point of contact (e.g., PCP, care coordinator) who serves as the primary liaison between providers and patients and is responsible for ensuring that the care plan is implemented. Having a lead point of contact who "owns" the care coordination process prevents role ambiguity during transitions of care. Importantly, throughout the continuum of care, it should always be clear which provider fulfills this role, and the provider must be accessible to all other providers or carers involved in the care of a patient.

Patient-Centered Discharge Planning

As illustrated in Lynda's case, the discharge of patients from a hospital is a challenging process as patients transition from professional care to self-management. Effective discharge planning is needed to ensure safe transition of care. Discharge planning is the process of identifying and preparing patients for their anticipated health care needs after they leave the hospital [20]. This involves development of a post-discharge care plan tailored to a patient's health and social care needs and ensuring that patients and their families understand and are capable of carrying out the care plan. Participation of family members in the discharge process is particularly important when patients have limited capacity for self-management. Published studies showed that improving provider-patient communication and patient education at discharge led to fewer hospital readmission, improvement of treatment adherence, and patient satisfaction [21, 22]. The Joint Commission recommends following the "5 D's of discharge" for communicating the intended care plan to the patients and their families [21] (Box 8.2). To reinforce verbal instructions, the patient should also be provided with a written discharge summary that includes language and literacy-appropriate instructions and patient education materials. In its published handbook, "Care Transitions from Hospital to Home: IDEAL Discharge Planning" [20], the AHRQ highlights key elements of engaging patients and their families in the discharge planning process. The IDEAL Discharge Planning strategy emphasizes a patient-centered approach to discharge planning that engages a patient and their family as full partners to more effectively tailor the treatment plan to the patient's needs and treatment preferences, and to better deliver patient-centered education and self-care skills (Box 8.3). Discharge planning that is tailored to an individual has the potential to improve the quality of health care delivered by reducing delayed discharge from hospital and hospital readmissions [22].

Box 8.2 The 5 D's of Discharge

- **Diagnosis**: Does the patient understand his/her diagnosis and why he/she was in the hospital or receiving care from the physician?
- **Drugs**: Does the patient know each medication he/she must take, the reason for the medication, when to take the medication, and how to administer? Does the patient have the resources to obtain the medications?
- **Diet**: Does the patient know and understand any dietary restrictions? Does the patient need a nutrition consult?
- **Doctor follow-up**: When should the patient see the doctor next? Can the patient make the necessary appointment and get appropriate transportation? Include the name and location of sites for continuing care.
- **Directions**: Are there any other directions necessary to increase the patient's ability to achieve optimal health, e.g., does the patient understand when urgent care should be obtained?

Box 8.3 The IDEAL Discharge Planning Strategy

- **Include** the patient and family as full partners in the discharge planning process.
- **Discuss** with the patient and family five key areas to prevent problems at home:
  - Describe what life at home will be like
  - Review medications (including the purpose of each medicine, how much to take, how to take it, and potential side effects)
  - Highlight warning signs and problems (including contact information if there is a problem)
  - Explain test results
  - Make follow-up appointments
- **Educate** the patient and family in plain language about the patient's condition, the discharge process, and next steps at every opportunity throughout the hospital stay.
- **Assess** how well doctors and nurses explain the diagnosis, condition, and next steps in the patient's care to the patient and family and use teach back.
- **Listen** to and honor the patient and family's goals, preferences, observations, and concerns.

Case 2: Cognitive Bias

Shona was a young woman with severe intellectual disability. On the day of the event, she was being cared for at a disability care center at which she had been a patient for more than 15 years. During a routine medical appointment at the center with a neurologist (Dr. G), she became highly distressed. Dr. G was unable to identify any physical or psychological trauma that might have caused her distress and advised her carer to take her to the hospital if her behavior did not improve within the next hour, to exclude any physical cause of her agitation. Shona appeared to calm down for several hours, before becoming highly agitated again in the late afternoon, moaning and banging her head on the ground. The disability service worker (Mr. P) responsible for her care on that day had recently joined the center and failed to recognize that Shona's behavior was "unusual for her." During the night shift change, another disability service worker who had been caring for Shona for many years recognized that Shona was in pain and immediately sent for paramedics to take her to the emergency department (ED). Upon arrival at the ED, Shona was initially assessed by a nurse. The triage notes recorded that the patient was "severely developmentally delayed," had a "history of ingestion of foreign bodies/substances," and appeared to be "in distress, with distended abdomen." Because of the difficulties in examining Shona, important vital signs including blood pressure and pulse were not assessed. Shona was subsequently seen by an ED physician (Dr. M). Although the paramedics informed Dr. M that her carers believed she was in physical pain, Dr. M had taken Shona's past history of ingesting foreign objects and past "behavioral issues" as his working diagnosis. He ordered an X-ray and blood tests, but did not commence any treatments or pain management to relieve Shona's distress or to improve the capacity to obtain vital signs. By then, Shona was likely exhibiting signs and symptoms of sepsis. On the night of the event, the ED was overcrowded. Shona was then left waiting at the ED, during which her condition declined. She died at the ED while still awaiting treatment.

What Happened?

Shona died of peritonitis-induced sepsis secondary to gastrointestinal torsion. Her condition was left undiagnosed and untreated. She was therefore slowly deteriorating throughout the day before her death.

Why Did It Happen?

Cognitive Bias Affecting Safety of Care Transitions

Misinterpretation of the seriousness of Shona's condition at two critical points of care transition contributed to her death. First, the disability service worker (Mr. P) did not act on Dr. G's instruction to take her to the hospital if her condition did not improve. Second, upon arrival at the ED, the ED physician (Dr. M) mistook Shona's symptoms as behavioral issues, despite being informed by the paramedics that Shona was in physical pain. Cognitive biases affected how these providers interpreted and processed the information communicated to them. Mr. P, though an experienced disability service worker, did not recognize Shona's signs of distress as unusual. After years of exposure to behavioral problems in individuals with intellectual disability, he may have become desensitized to the potential significance of such behaviors. Similarly, despite being an experienced physician, Dr. M failed to recognize that Shona was presenting with signs and symptoms of septic shock. Instead, he assumed Shona's past history of ingesting foreign objects and behavioral problems as his working diagnosis.

Shona's case highlights an under-recognized challenge in clinical communication—providers often fail to correctly interpret or perceive the importance of the messages communicated to them due to cognitive biases. Humans do not perceive information in a neutral way. We have an inherent set of biases that cause us to draw conclusions not necessarily supported by the immediate evidence. Indeed, cognitive biases have been identified as contributors to a number of sentinel events reported to The Joint Commission [23]. Notably, up to 75% of errors in internal medicine practice are potentially caused by cognitive error [24, 25]. Specific to Shona's case, the following types of cognitive bias may have contributed to lapses in clinical judgment: (a) confirmation bias—the tendency to process information by looking for, or interpreting, information that is consistent with one's existing beliefs; (b) anchoring bias—giving weight and reliance on initial information/impressions, despite availability of new information; and (c) diagnostic overshadowing—once a diagnosis is made of a major condition, there is a tendency to attribute all other problems to that diagnosis, thereby leaving other coexisting conditions undiagnosed.

What Can Be Done to Prevent It from Happening Again?

Addressing Cognitive Biases During Transitions of Care

While it appears impossible to eliminate cognitive biases in clinical decision-making, being cognizant of predisposing factors can help improve handoff communication to mitigate cognitive biases. This case study highlights the unique challenges faced by individuals with intellectual disability, who are particularly

vulnerable to preventable adverse events. Among these patients, diagnostic overshadowing often occurs when symptoms of physical illness are mistakenly attributed to behavioral problems or as being related to intellectual disability [26]. This leads to delay in diagnosis and treatment, and suboptimal outcomes for patients. Diagnostic overshadowing also occurs frequently among patients with multiple coexisting chronic diseases; clinicians often assume that clinical findings are related to a single cause [27].

To ameliorate this tendency, handoff communication should directly address any uncertainties relating to the patients' condition, including any recent changes in behaviors, conditions, or circumstances, and coexisting conditions. Applying the handoff principles described in TeamSTEPPS (Box 8.1), the transferring provider is responsible for ensuring that the individuals taking over care have not made any incorrect assumptions about a patient's condition before relinquishing the responsibility of care. Communication of patient information should clearly distinguish patient data from its clinical interpretation. This can be facilitated by standardized communication frameworks such as SBAR (Table 8.1), whereby a patient's **S**ituation and **B**ackground should be described using only objective clinical information, and interpretive information can be provided as **A**ssessment and **R**ecommendation. Handoff communication should also allow for opportunities to verify assumptions, interpretations, and conclusions. Situations of stress, fatigue, and cognitive overload may predispose to error and predispose providers to cognitive bias [28]. In such situations, checklists and standardized clinical guidelines can be used during handoff as a debiasing strategy that forces providers to consider diagnoses that they may not otherwise consider [25].

Key Lessons Learned

- Effective clinical handoff requires the transfer of information pertinent to the care of a patient, as well as the transfer of patient care accountability and responsibility.
- To ensure safe transition of care, communication at the time of the handoff should result in a clear understanding by each provider about who is responsible for which aspects of the patient's care.
- Before relinquishing the responsibility of care, it is the responsibility of the transferring providers to ensure that the individuals taking over care: (a) acknowledge and understand the information being transferred and (b) understand and accept the responsibility of care.
- To ensure a safe transition from hospital to home, it is the responsibility of the discharging providers to develop a post-discharge care plan that is tailored to the patient's health and social care needs, and to ensure that the patient and his/her family understand the care plan.
- Cognitive biases, such as confirmation bias and diagnostic overshadowing, can influence how clinical information is interpreted. To prevent cognitive biases during care transitions, handoff communication should directly address any uncertainties relating to a patient's condition and allow for opportunities to verify assumptions, interpretations, and conclusions.

Acknowledgments The case studies presented in this chapter were obtained from the Coroner's Court of New South Wales, Australia. We thank Dr. Jeff Brady for his valuable feedback on the chapter.

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Chapter 9
Electronic Health Record and Patient Safety

Jitendra Barmecha and Zane Last

Introduction

Over two decades ago, the Institute of Medicine (IOM) released two reports that laid the foundation of the patient safety movement in the US. The reports identified the Electronic Health Record (EHR) as an important tool for improving patient safety in the care continuum. The first report in 1999 "To Err Is Human—Building a Safer Health System [1]" concluded that preventable medical errors were one of the leading causes of death. In 2001, in a subsequent report "Crossing the Quality Chasm," the use of information technology was recommended as playing a central role in the redesign of the entire healthcare system preventing errors, improving healthcare quality, efficiency, and enhancing the overall care experience [2].

In spite of the publication of these reports, EHR adoption in both hospitals and ambulatory care settings remained very low. This lag in the healthcare industry's EHR adoption was significantly remediated by the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act under the American Recovery and Reinvestment Act of 2009 [3]. As illustrated in Fig. 9.1, only 9% of the hospitals and 17% of the office-based physicians had adopted even a basic EHR in 2008 but as of 2019, this number increased to 96% and 72%, respectively (https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records).

The HITECH Act authorized nearly $30 billion toward Medicare and Medicaid incentive programs to encourage the adoption, implementation, upgrade, and

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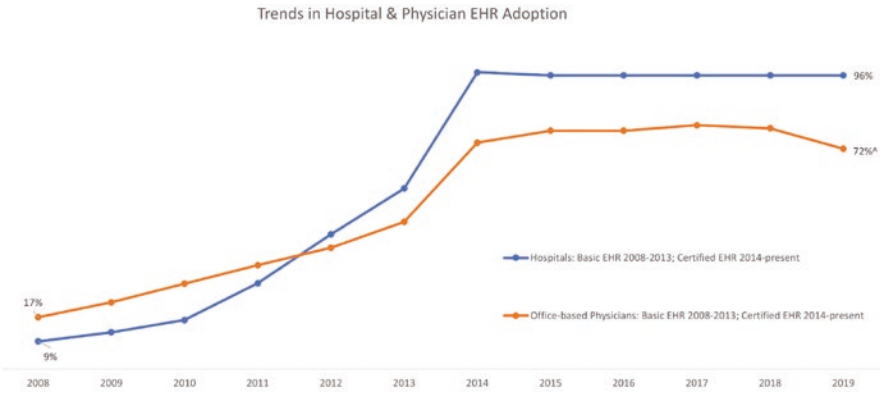

Fig. 9.1 Percentages of hospitals that adopted at least a basic electronic health record system. (Source: HealthIT.gov at https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records. Last accessed September 3, 2022)

demonstration of meaningful use of certified EHRs by hospitals and eligible medical professionals. The HITECH Act also created support programs to provide technical assistance and help build the enterprise-wide systems to enable the full use and potential of EHRs. The HITECH Act further required that meaningful use of EHRs include electronic reporting of data on the quality of care. Hence, the EHR meaningful use rule struck a balance between acknowledging the urgency of adopting EHRs to improve healthcare quality and recognizing the challenges that adoption posed to health care providers.

The EHR Meaningful Use or Incentive Programs were envisioned as a three-stage process that would encourage EHR adoption, promote interoperability, and ultimately the quality of care:

- **Stage 1** set the foundation by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.
- **Stage 2** expanded upon the Stage 1 requirements with a focus on advancing clinical processes, the use of EHRs for continuous quality improvement at the point of care, and the exchange of information in the most structured format possible.
- **Stage 3** focused on using EHRs to improve health outcomes.

To continue the commitment toward promoting and prioritizing interoperability and exchange of health care data, the Centers for Medicare and Medicaid Services (CMS) renamed the EHR incentive programs to Promoting Interoperability Programs in April 2018 [4]. This change moved the programs beyond the existing

requirements of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.

The EHR plays a transformative role in healthcare by improving medication safety, making patient health information available at the point of care, facilitating care coordination, optimizing efficiency, and engaging both patients and caregivers [5]. A 2011 literature review by Buntin et al. (2011) concluded that 92% of the studies on health information technology (HIT) demonstrated net benefit [6]. Outcome measures were positive for efficiency of care, effectiveness of care, patient and provider satisfaction, care process, preventive care, and access to care (Fig. 9.2) [6]. Similarly, a recent systematic review by Kruse et al. (2018) also concluded that HIT continues to show positive effect on efficiency of care and medical outcomes [7].

As the adoption rates for HIT in clinical settings increased, the potential for unintended consequences increased alongside. While consequences can be positive or negative, we will focus on the unanticipated negative consequences that can arise and provide insights into how they can occur and how to avoid adverse impact on patient outcomes.

In this chapter, we present two case studies that illustrate some unintended adverse consequences of EHRs and what can be done to prevent them. These case studies identify the flawed workflow, processes, or systems leading to an EHR-related adverse event and recommends strategies to mitigate potential safety hazards.

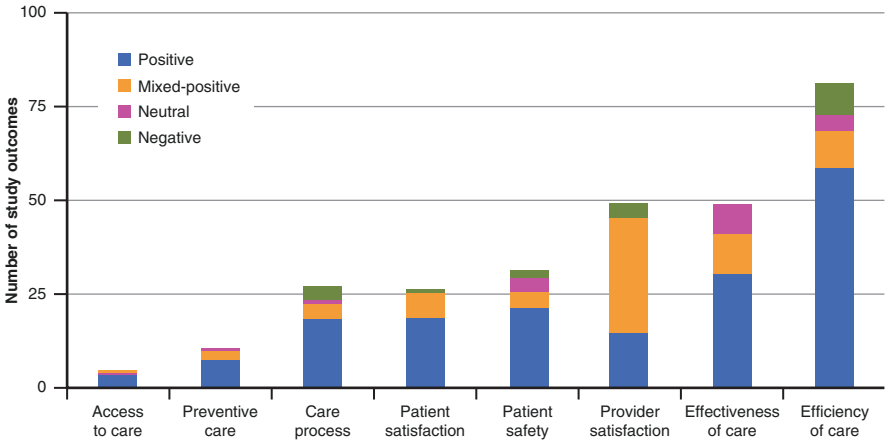

Fig. 9.2 Evaluations of outcome measures of health information technology. (Adapted with permission from Buntin MB et al (2011) (6))

Case Studies

Case Study 1: Medication Error Related to Pediatric Weight Entry Issues

Clinical Summary

A 2-year-old patient was admitted to the hospital's pediatric ward with fever. The admitting physician ordered acetaminophen in the hospital's CPOE (computerized physician order entry system) which provides a field for weight-based dosing (expected to be expressed in mg/kg). The child's weight was 27.5 pounds (lbs). Prior to the medication order, the nurse inadvertently entered the patient's weight as 27.5 kg (in the kilogram field as opposed to in the pounds field of the EHR). The ordering physician, unaware of this problem, assumed the entered weight was accurate and ordered about 2.5 times the recommended dose of the medication. The built in CPOE decision support did not provide any alert that this dose is excessive for a child of this age because the systems decision support computed the dose based on the incorrectly entered weight. The patient received one incorrect dose before the nurse realized the documented weight error, corrected it, and alerted the physician to discontinue and reorder the acetaminophen with the correct dose.

Analysis

The unique characteristics of the pediatric patient population inherently add significant variability and complexity to medication prescribing due to the need for weight-based dosing [8, 9]. A 2006–2007 analysis of the United States Pharmacopeia's MEDMARX database illustrated the risk inherent in weight-based dosing by revealing that one-third of pediatric medication errors were the result of "improper dose/quantity" and 2.5% of those pediatric dosing errors ultimately led to patient harm [10].

The adoption and implementation of EHRs with CPOE have drastically enhanced pediatric medication safety [11] but careful consideration must still be given to workflow. CPOE tools help providers determine the proper dose by pre-populating the patient's weight and performing the pre-determined calculations helping to alleviate the need to perform extensive manual calculations that are often complicated and error prone. The use of these tools eliminated guesswork, sped up the process, and assisted clinicians in prescribing the proper dose. However, as identified in the clinical summary above, a simple data entry error can lead to perpetuation of the error in the downstream workflow as automation provides a false sense of security among users that since the system is calculating the dose, it must be correct.

Corrective Actions

A collaborative team of pediatricians, nurses, and pharmacists was formed and based on an extensive review of the hardware, software, and workflow configurations, the following changes were made to the system:

(a) Implementation of a pediatric weight alert system: an extensive system of alerts to identify and alert multiple professionals in the medication management workflow if an abnormally high or low weight is encountered in a pediatric patient as detailed below.
(b) Modification and replacement of all scales in the institution to weigh only in kilograms.
(c) Additional staff training and reporting of any future errors.

Pediatric Weight Alert System (Figs. 9.3, 9.4, and 9.5) [12]

The trigger for the alert is based on the patient's age-based weight being outside the standard deviation (3% and 97%) of the growth chart. In this situation, if a potentially inappropriate weight is entered by a nurse, the system will trigger a "soft stop" requiring a reason to be acknowledged. If the nurse proceeds with the entered weight, the physician on any subsequent order entry or the pharmacist during any subsequent medication verification for this patient will be presented with an alert to review all active orders for accuracy. This closed loop system of prompts ensures

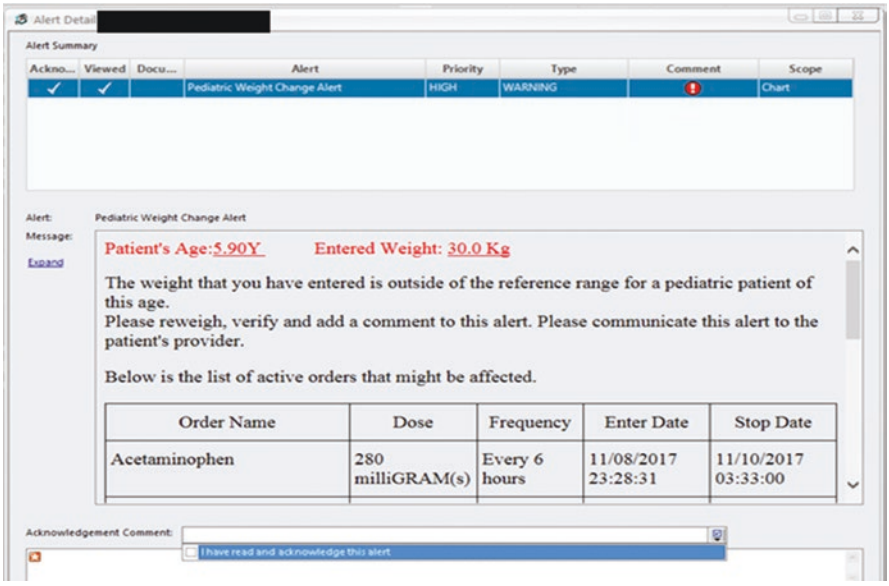

Fig. 9.3 "Soft stop" requiring a reason to be acknowledged

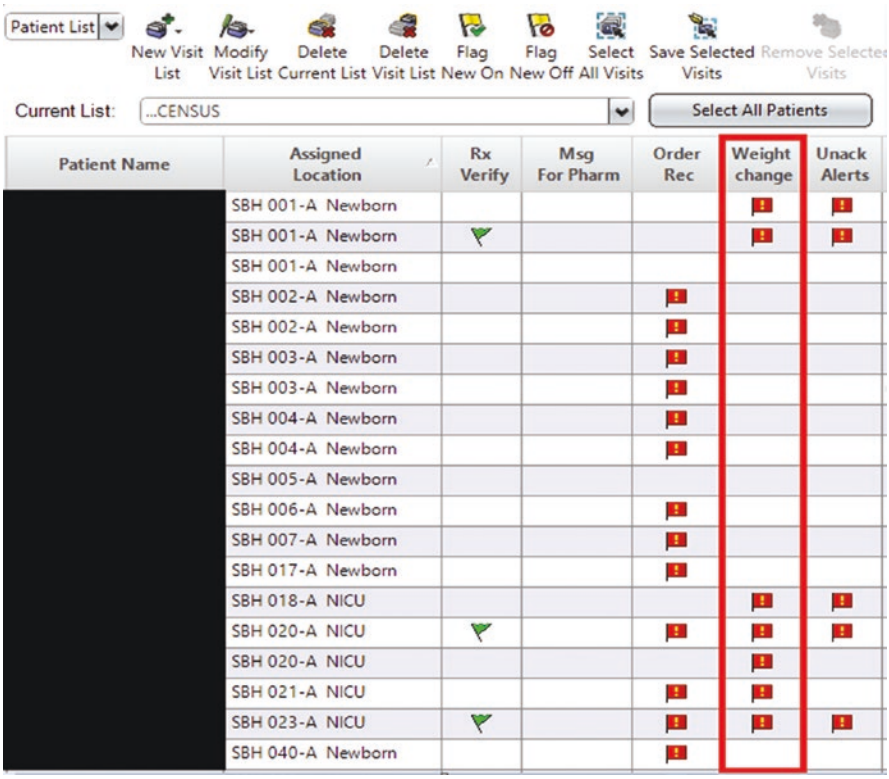

Fig. 9.4 Alerts for any weight changes outside the reference range to the physician

that alerts are reviewed and acted upon by nurses, physicians, and pharmacists collaboratively as redundant safety checks.

In addition to the medication process, these weight-based alerts are also displayed in the other areas of the EHR generating an audit trail each time an alert is triggered:

- Structured notes (admission pediatric profile, ED triage note, newborn/NICU admission profile)
- Flow sheets for pediatric patients

This abnormal pediatric weight alert is fired when all of the following is true:

- Patient is located on one of the neonatal or pediatric floors
- Patient's age is less than or equal to 15 years
- Patient's weight falls outside the standard pediatric weight based on the CDC weight-for-age chart for pediatric patients aged 0–15 years old

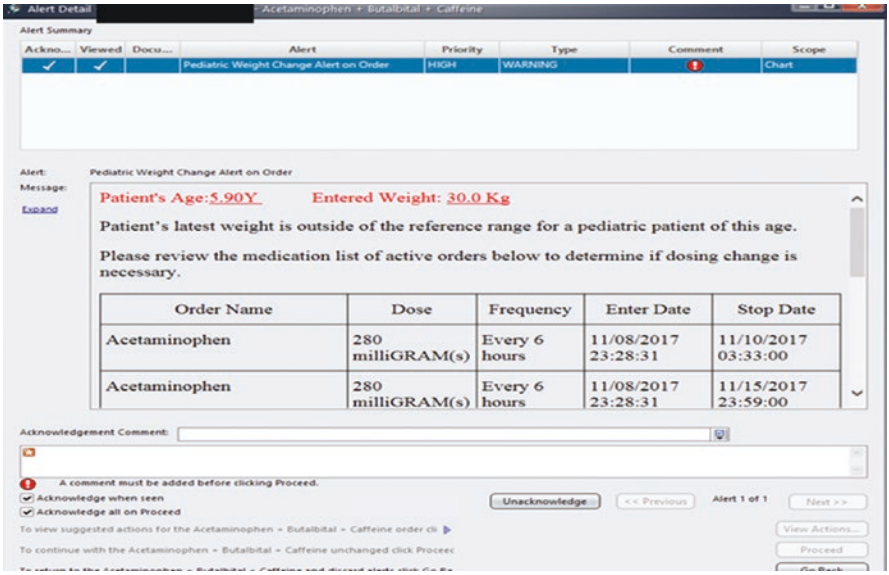

Fig. 9.5 Alert to physician or pharmacist on any subsequent order entry or medication verification

Case Study 2: Incorrect Medication Administration

Clinical Summary

A patient admitted to an inpatient floor of the hospital, with an extensive medication profile documented on their EHR, was scheduled to receive her next round of medications during regular nursing rounds. Unfortunately, she suffered a medication error as she was administered the wrong medication. Ropinirole (used to treat symptoms of Parkinson's disease), intended for a different patient on the floor, was incorrectly administered to this patient instead of the properly prescribed risperidone (used to treat the symptoms of schizophrenia). This administration error occurred during a busy lunch time shift where the administering nurse had pulled multiple medications for multiple patients on the floor, thereby allowing for the incorrect medication to be picked up from the medication tray. Most critically, the nurse did not follow the hospital's standard safety system, called bar-coded medication administration (BCMA), of scanning the patient's wrist band as well as the medication to ensure both the patient's identity and the medication match the order placed by the physician.

Analysis

Medication administration is a busy and complicated time for nursing staff who are often responsible for multiple patients, many of which are prescribed multiple medications to be administered over a narrow timeframe. Additionally, obstacles such as staffing shortages, technology, and poorly designed or implemented workflow can make the process even more prone to errors. When utilized correctly, HIT systems such as BCMA are critical to ensuring the five rights of medication administration—the right patient, right medication, right does, right route, and right time and at the same time provide a proper documentation of the administration process [13]. With scannable barcodes ubiquitous to the pharmaceutical industry, placed on most medication packaging, electronic systems can readily identify an individual, patient-specific drug, its dosage form and the strength to be administered. Closing the medication administration loop with processes and workflows incorporating barcodes printed on patient wristbands, EHRs can quickly and accurately validate the right patient. Matching the ordered medication's frequency in the EHR with previous administrations of the drug or with future scheduled administrations with the time of day the last "right" of time for administration can be assured. In this case, the nurse bypassed protocol by not scanning the barcode on the medication or the patient's wrist band and manually administered the incorrect medication outside of identified best practices leading to a medication error.

Corrective Actions

Implementation of a BCMA system, process, and workflow is not the end of the story but a beginning to the journey. Medication errors can occur across multiple pathways beginning with a medication order through to its administration to the patient. A culture of safety must be pervasive, encouraging participation at all levels and be grounded within training and continued monitoring of the entire system including a robust culture of compliance reporting, review, and action. A multidisciplinary team of physicians, nurses, pharmacists, and information technology professionals must convene regularly to monitor processes and adverse event reporting providing feedback to end users, clinical stakeholders, and leadership in a continued effort to drive toward patient safety. In this case, the BCMA workgroup identified the following issues that potentially prevent users from adhering to safety practices:

- Batteries powering computers and or scanning devices run out of charge
- Computers locked out due to password issues preventing users accessing software
- Scanners not working properly requiring reprogramming or replacement

Another source of medication errors that cannot be corrected with BCMA is the issue of providers entering orders, medication or otherwise, on the wrong patient. To detect and correct this type of error, the team undertook an assessment of current "near miss" error rates using a "retract and reorder" tool [14]. This tool identified

and reported on orders first placed on one patient then canceled with the identical order added to another patient's chart by the same clinician within a 10-min time frame. This assessment was taken as a proxy for those incorrect orders with a high likelihood of ultimately reaching the patient. Data review identified approximately 1 near miss per day [14]. A solution to this problem was identified requiring configuration changes to the EHR to produce a series of provider-based alerts at the beginning of order entry. Providers were required to enter the patient's initials and year of birth at the start of the order entry session (Fig. 9.6) [12] which are then validated against the patient's chart before being allowed to proceed. This not only aligns with the Joint Commission's national patient safety goal of using at least two patient identifiers when providing care, treatment, and services but also proved to reduce the prevalence of this type of error. If the prescriber enters the wrong patient identifier when starting order entry, a second alert is presented allowing for a correction to be made (Fig. 9.7) [12]. A subsequent third error (Fig. 9.8) [12] prevents the provider from proceeding with order entry requiring a new order entry session be initiated to proceed. An analysis comparing near misses before and after the alert configuration showed approximately a 35% decrease in near miss events in the emergency department of the hospital [12].

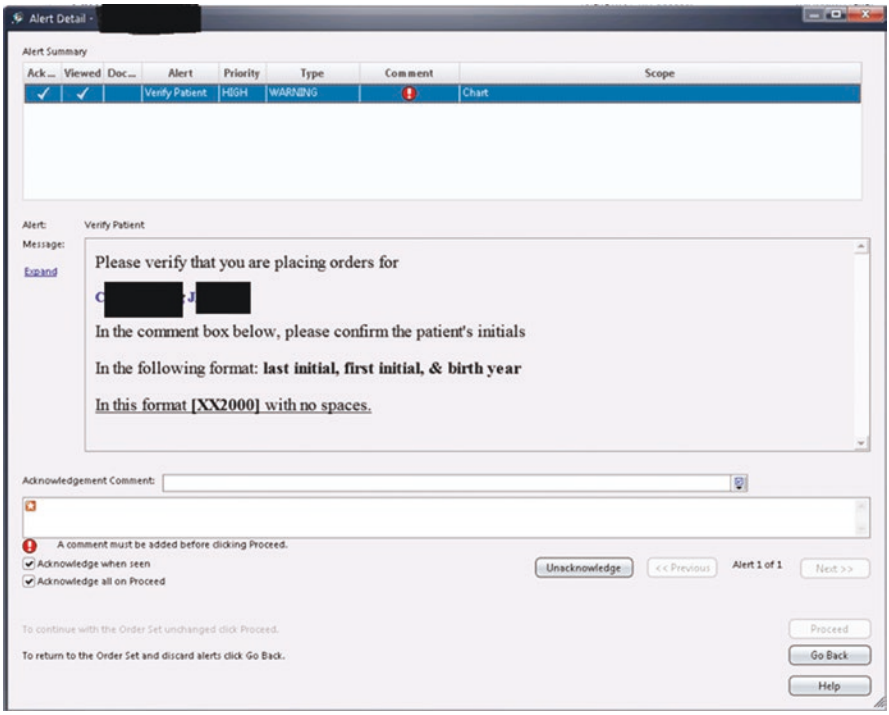

Fig. 9.6 Alert to the prescriber to input patient initials and year of birth. If the prescriber correctly inputs this data, then the ordering process can proceed. If the data is incorrect, then a second alert is activated

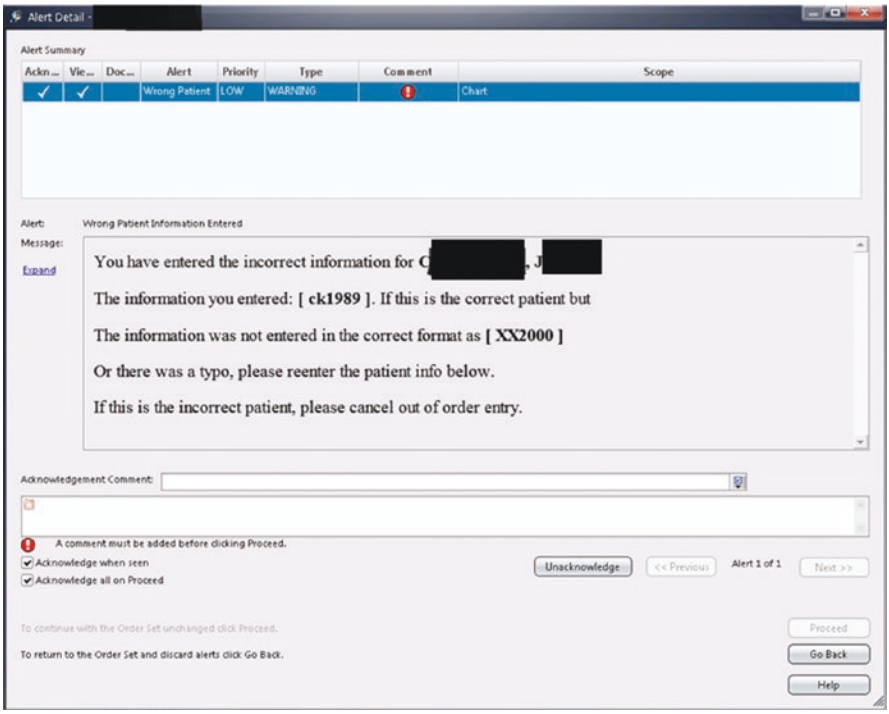

Fig. 9.7 This allows for typographical errors that may not be related to a patient ID error. If the prescriber enters the correct patient identifiers, then he or she can proceed normally with the order. However, if the prescriber again enters the wrong patient identifier, a third and final alert is generated

Discussion

Potential Benefits and Safety Concerns for Health IT

Health information technologies (HIT), such as EHR, CPOE, and clinical decision support system (CDSS), may enhance the safety, quality, patient-centered care, and increase efficiency. However, a growing body of research and user reports reveal many unintended adverse consequences of implementation that often undermine patient safety practices and occasionally harm patients [15]. Figure 9.9 [16] describe the potential benefits and safety concerns for CPOE, clinical decision support system (CDSS), BCMA, and patient engagement tools as reported in the book titled *Health IT and Patient Safety* published by the Institute of Medicine [16].

Ash et al. (2004) have described two major kinds of implicit EHR-related errors: those related to entering and retrieving information and those related to

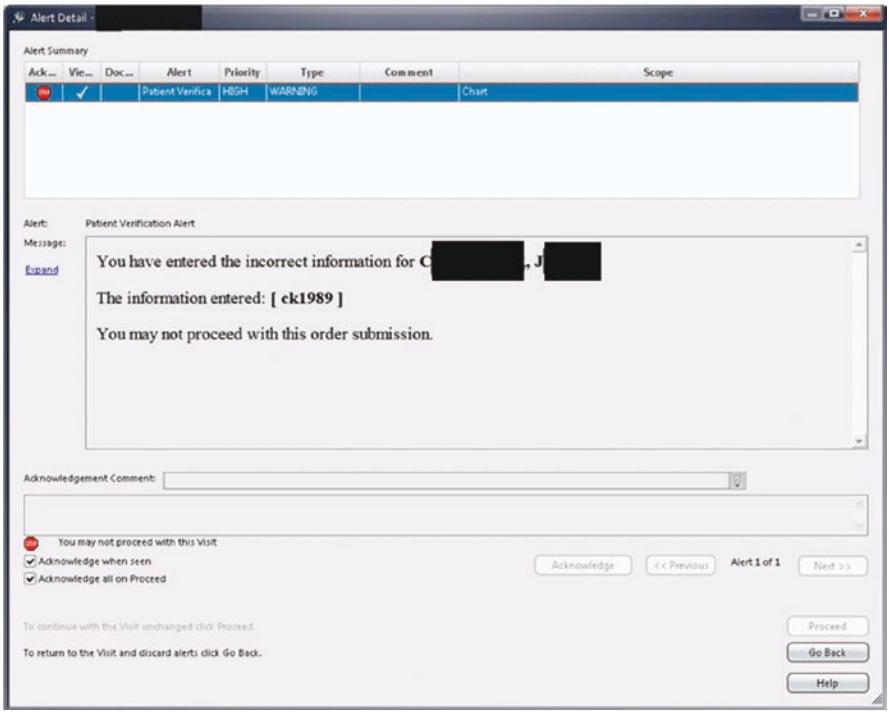

Fig. 9.8 The EHR system will see this second, failed, attempt as a true error in patient ID and will not allow the prescriber to proceed with the order

communication and coordination. As the potential causes of these errors are subtle but insidious, the problems need to be addressed in a variety of ways through improvements in training, education, systems design, implementation, and research [17].

The Sociotechnical Model

Although technical flaws often cause problems, many harmful or otherwise undesirable outcomes of HIT implementation arise from sociotechnical interactions—the interplay between new HIT and the provider organization's existing social and technical systems—including their workflows, culture, social interactions, and technologies. The "Sociotechnical" model is also an instrument for root cause analysis (RCA) that describes various factors and processes that can cause adverse events and a systems approach is necessary to reduce or eliminate future adverse events. As described by Meeks et al. (2014) [18], the sociotechnical model has the following

eight dimensions: clinical content, human–computer interface, people, workflow & communication, internal organizational features, external rules & regulations, measurement & monitoring, and hardware & software. These eight dimensions are processed through a three-phase patient safety model (safe technology, safe use of technology, and use of technology to improve safety) to help various stakeholders understand anticipated risks about patient safety and HIT.

The sociotechnical model of identifying unintended adverse consequences of HIT can assist software developers and end users become more aware of the flawed workflows and processes, which in turn will help deployment of HIT more effectively to improve overall healthcare safety and quality.

EHR-based interventions to improve patient safety are complex and sensitive to who, what, why, when, and how they are delivered. Current reporting guidelines do

Computerized Provider Order Entry (CPOE)

An electronic system that allows providers to record, store, retrieve, and modify orders (e.g., prescriptions, diagnostic testing, treatment, and/or radiology/imaging orders).

Potential Benefits

Large increases in legible orders
Shorter order turnaround times
Lower relative risk of medication errors
Higher percentage of patients who attain their treatment goals

Safety Concerns

Increases relative risk of medication errors
Increased ordering time
New opportunities for erros, such as:
- Fragmented displays preventing a coherent view of patients' medications
- Inflexible ordering formats generating wrong orders
- Separations in functions that facilitate double dosing

Disruptions in workflow

Clinical Descislon Support (CDS)

Monitors and alerts clinicians of patient conditions, prescriptions, and treatment to provide evidence-based clinical suggestions to health professionals at the point of care

Potential Benefits

Reduction in:
- Relative risk of medication errors
- Risk of toxic drug levels
- Time to therapeutic stabilization
- Management errors of resuscitating patients in adult trauma centers
- Prescriptions of nonpreferred medications

Can effectively monitor and alert clinicians of adverse conditions
Improve long-term treatment and increase the likeihood of achieving treatment goals

Safety Concerns

Rate of detecting drug-drug interactions varies widely among different vendors
Increases in mortality rate
High override rate of computer generated alerts (alert fatigue)

Fig. 9.9 Potential benefits and safety concerns of Health IT

Bar-Coding

Bar-coding can be used to track medications, orders, and other health care products. It can also be used to verify patient identification and dosage.

Potential Benefits

Significant reductions in relative risk of medication errors associated with:

- Transcription
- Dispensing
- Administration errors

Safety Concerns

Introduction of wortkarounds for example, clinicians can:

- Scan medications and patient identification without visually checking to see if the medication dosing and patient identification are correct
- Attach patient identification bar-codes to another object instead of the patient
- Scan orders and medications of multiple patients at once instead of doing it each time the medication is dispensed

Patient Engagement Tools

Tools such as patient portals, smartphone applications, email, and interactive kiosks, which enable patient to participate in their health care treatment

Potential Benefits

Reduction in hospitalization rates in children
Increases in patients' knowledge in treatment and illnesses

Safety Concerns

Reliability of data entered by:

- Patients
- Families
- Friends or

Fig. 9.9 Continued

not capture the complexity of sociotechnical factors that control or confound or influence interventions. Singh et al. propose a methodical framework for EHR interventions targeting patient safety building on an eight-dimension sociotechnical model for design, development, implementation, use, and evaluation of HIT [19]. This Safety-related EHR-based Research (SAFER) reporting framework enables reporting for patient safety focused EHR-based interventions needed to reduce or eliminate preventable harm, while accounting for the multifaceted sociotechnical context affecting intervention implementation, effectiveness, and generalizability.

Although, the sociotechnical model is a valuable tool for RCA after an error has occurred, there are two additional tools that can be used prospectively: Failure Modes and Effects Analysis (FMEA) [20] and EHR usage metrics. A comprehensive reference guide on FMEA is available online at the website of the Veterans Administration's National Center for Patient Safety (http://www.patientsafety.gov/SafetyTopics/HFMEA/HFMEA_JQI.html). EHR usage metrics can be monitored using "run charts" to find problems and track their resolution [21]. These metrics can include percent system uptime, mean response time (measured in tenths of a second), percentage of orders entered electronically, percentage of order sets used, percentage of alerts that fire, percentage of alerts overridden, system interface efficiency, and miscellaneous or free-text orders (which bypass clinical decision

support).The "Issues Log" is another tool to collect and manage unintended consequences of Health IT. A good sample issues log [22] can be downloaded from the www.HealthIT.gov.

Clinical Decision Support System (CDSS)

The Office of the National Coordinator for Health Information Technology (ONC) defines Clinical Decision Support as follows [23]: "*CDSS provides clinicians, staff, patients or other individuals with knowledge and person specific information, intelligently filtered or presented at appropriate times, to enhance health and healthcare.*"

CDSS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information. The ONC also asserts that CDSS "promotes patient safety", contributing to "increased quality of care and enhanced health outcomes" and "avoidance of errors and adverse events".

To achieve these patient safety goals across the clinical care continuum, it is essential CDSS tools succeed in getting the right information to the right people in the right intervention formats through the right channels at the right times in workflows [24].

An effective CDSS involves six levels of decision-making: alerting, interpreting, critiquing, assisting, diagnosing, and managing. Alerts are a vital component of a CDSS, and automated clinical alerts remain an important part of current error reduction strategies that seek to affect the cost, quality, and safety of health care delivery.

Systematic reviews of the impact of CPOE and CDSS across inpatient settings have reported significant reductions in medication errors, with modest reductions in length of stay and overall mortality [25].

Alert Fatigue

An important unintended adverse consequence of CDSSs is the overabundance of warnings and reminders which can result in alert desensitization and fatigue for clinicians. While notifications are meant to help clinicians by pointing out important information, EHR systems often produce excessive and unnecessary alerts that can lead to negative treatment outcomes, compromise patient safety, and even lead to clinician burn-out. To overcome this problem, software developers must design solutions using machine learning tools [26] that can aid clinicians' workflows without causing alert fatigue.

EHR Downtime and Patient Safety

Healthcare providers experience EHR downtime periods, when partial or all functions within the EHR are not available. Downtimes can be planned, when software upgrades to the EHR are performed, or unplanned, due to IT infrastructure or network outages. The unplanned ones have the potential to result in serious patient safety risks since critical information needed to provide effective care is not readily available [27]. Further, CDSS and safety alerts of EHRs that clinicians are dependent on are not available during downtimes. The Safety Assurance Factors for EHR Resilience (SAFER) guides [28] released by ONC—Health IT provides high level guidance and recommends that appropriate downtime procedures be put in place and practiced routinely to reduce patient harm.

Usability

Usability is a critically important consideration from the technology category that deserves elaboration. Simply put, usability is how easy a technology is to learn and use. Other related terms include human factors and user-centered design. Shneiderman promotes eight rules for human–computer interface design (Fig. 9.10) [29]. Ultimately, we believe that a more usable EHR is a safer EHR. While providers can change processes, training, and organization, rarely can they improve the usability of their EHRs. Complaints abound from clinicians about the poor usability of many EHRs. The concerns expressed include the excessive number of clicks to find information, non-intuitive graphic user interfaces, and lack of integration or interoperability between clinical systems. With the sheer volume and complexity of information in patient care today, poor usability can compromise decision-making and patient safety.

In order to minimize potential adverse impacts of EHRs on patient safety, the IOM report on patient safety and health IT made a number of significant recommendations [16] including:

- Specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety, culture, and usability.
- Establish a mechanism for both vendors and users to report health IT-related deaths, serious injuries, or unsafe conditions.

Additionally, the Office of the National Coordinator—Health IT (ONC) has proposed new EHR certification rules that would promote safety-enhanced design that mandate developers to adopt user-centered design, document software quality management [30], and in 2022 become certified with Real World Testing [31]. These rules are important steps in building more usable and safer EHRs.

Principles	Characteristics
Strive for Consistency	Samilar tasks ought to have similar sequences of action to perform, for example: • Identical terminology in prompts and menus • Consistent screen appearance Any exceptions should be understandable and few
Cater to universal usability	Users span a wide range of expertise and have different desires, for example: • Expert users may want shortcuts • Novices may want explanations
Offer informative feedback	Systems should provide feedback for every user action to: • Reassure the user that the appropriate action has been or is being done • Instruct the user about the nature of an error if one has been made Infrequent or maijor actions call for substant ial responses, while frequent or minor actions require less feedback.
Design dialogs to yield closure	Have a beginning, middle, and end to action sequences: Provide informative feedback when a group of actions has been completed
Prevent errors	Systems should be designed so that users cannot make serious errors, for example: • Do not display menu items that are not apprropriate in a given context • Do not allow alphabetic characters in numeric entry fields User errors should be detected and instructions for recovery offered Errors should not change the system state
Permit easy reversal of actions	When possible, actions (and sequences of actions) should be reversible
Support internal locus of control	Surprises or changes should be avoided in familiar behaviors and complex data-entry sequences
Reduce short-term memory load	Interfaces should be avoided if they require users to remember information from one screen for use in connection with another screen

Fig. 9.10 Eight golden rules for interface design. (Adapted from Shneiderman B, Plaisant C, Cohen M, Jacobs S. Designing the user interface: Strategies for effective human-computer interaction. Boston, MA: Addison-Wesley; 2009 (reprinted with permission))

This newest ONC requirement for 2022 of Real-World Testing, as outlined in the 21st Century Cures Act Final Rule, requires Certified Health IT Developers to document and publicly report out results of interoperability and functionality (Fig. 9.11) [32]. Functionality must now be tested in "real world settings" outside of traditional, in house, controlled test environments. This new requirement is designed

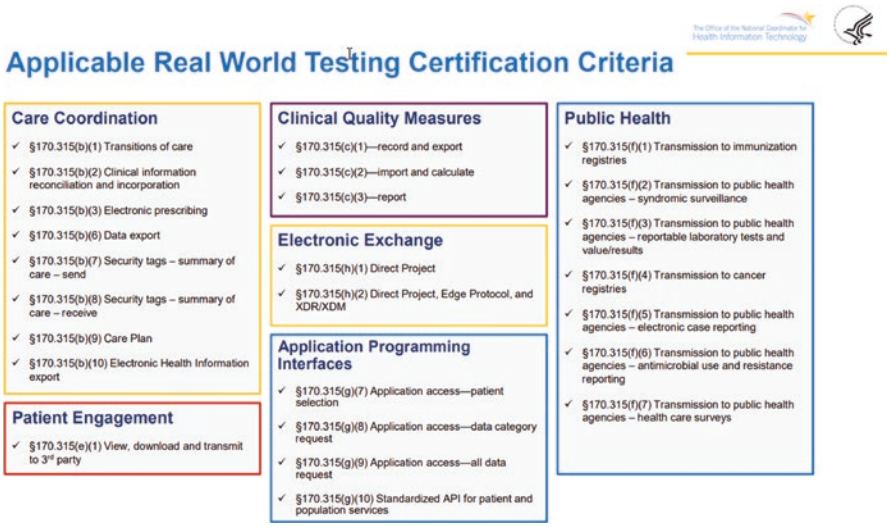

Fig. 9.11 Applicable real-world testing certification criteria

to force developers to demonstrate their software's ability to perform as intended in a transparent way to both the ONC and the public community.

Conclusions and Lessons Learned

- Healthcare is becoming a high-reliability industry with a mission of having zero harm during the care processes and continuum [33].
- Two decades ago, health IT was identified as an integral solution to improve clinical quality and patient safety. During this period, various legislative, incentive, and regulatory requirements have accelerated health IT implementation. However, adoption of these systems has burdened clinician users due to design, configuration, and implementation issues resulting in poor usability, challenges to workflow integration, and sub-optimal clinical documentation requirements. These must be addressed to ensure health IT provides maximum benefits for the healthcare professionals and their patients.
- There is mounting evidence of the role of EHRs in improving safety and quality of care. However, like any innovation, use of EHRs in clinical practice can lead to unanticipated and potentially adverse consequences on patient safety. These must be recognized and addressed.
- With the 21st Century Cures Act, there are opportunities for all stakeholders to work collaboratively in building various health IT solutions resulting in safer healthcare with improved health outcomes.

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Chapter 10
Clinical Ethics and Patient Safety

Erin A. Egan

Introduction

Patient safety and ethics are both fields that seek to operationalize fundamental values in health care. In both areas, broad values drive practical responses in clinical settings. There are two common sites of overlap. First is to ensure safety practices in areas where clinical ethics concerns arise frequently. Clinical ethics is an everyday practice in all settings but ethical conflicts are most common in hospitals. Areas like end-of-life care have a strong component of clinical ethics as well as being a high-risk area for errors and compromise of patient safety. The other area of overlap is professional ethics and the commitment to patient safety. Given that patient safety is grounded in ethical principles and the resultant ethical responsibility of healthcare to serve and protect patients, provider commitment to patient safety is a professionalism and professional ethics responsibility.

Principles of Medical Ethics

The fundamental principles of clinical ethics in the context of care provided in the US are beneficence, non-maleficence, autonomy, and justice (Table 10.1) [1]. Beneficence is the principle of providing benefit. Non-maleficence is the principle of doing no harm. In ethics, these principles are applied to sort out the implications of different courses of action by weighing the values at stake. Both are applicable to patient safety efforts.

This conceptual structure is valuable as a means to categorize and target patient safety efforts along ethical principles. Ultimately, the basis of formally addressing

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Table 10.1 Principles of ethics and applications in patient safety

Autonomy—respect for a person's right to control their own body • A central principle of quality care, central to ensuring patient-centered care • Examples: Adequate informed consent to prevent errors in procedures (wrong site procedures), preventing unwanted care (improper DNR orders)	**Beneficence—the duty to provide benefit** • Establishing standard practices that promote benefit • Examples: Standardizing pre-op antibiotic procedures to maximize efficacy, pharmacy assisted medication dosing to ensure maximum benefit
Non-maleficence • Establishing practices to prevent harm Examples: Infection control/hand washing, procedure "time outs" • Ethical concept: Failure to use these practices compromises safety	**Justice** • Standardization of practices and procedures ensures equitable treatment across social and societal strata

patient safety deficits is to provide benefit and prevent harm. Using ethical analysis to make that concrete helps focus on the goals and methods. It facilitates the process of understanding the goals of patient safety improvement in a tangible and concrete sense.

Clinical ethics is a practice or a skill set, meaning that it is a clinical process utilized in the context of patient care. As with any clinical practice, there are standards for best practices, and variable levels of adherence to those best practice standards. Instead of viewing ethics as a nebulous intellectual endeavor, clinical ethics should assist in solving problems and effectuating desirable outcomes.

Case Study 1

Clinical Summary

Mary is a 93-year-old woman presenting to the emergency department (ED). A family member went to check on her at home, where she has lived independently since the death of her husband 5 years prior, and found her agitated and confused. Mary has had decreasing mental status in the ED and appears to be septic. She is intubated and transferred to the ICU. She has several complications including a heart attack, and she shows no signs after 5 days of being ready to come off the ventilator. The medical team consults family members regarding her "code status." One son thinks she has a living will asking to be "Do not resuscitate (DNR)," but isn't sure where it might be. A daughter says she had spoken with her mother after her husband's death and her mother said she "wouldn't want to be kept alive on machines." The third son says that his conversations with mom about religion have focused on the inherent value of life and he believes she would "want everything done." Two of the children want to withdraw ventilation, while the third wants to proceed to placement of a tracheostomy and PEG tube.

This scenario is unfortunately all too commonly encountered by almost all physicians with an increasing frequency in hospitals across the country. The case demonstrates that the nexus between ethics and safety occurs at two points: the role of clinical ethics practice to promote safety and quality and ensuring that safety mechanisms need to be in place to prepare for and prevent injury related to foreseeable ethical conflicts [2]. Many commonly encountered clinical ethics conflicts follow a similar pattern, and it is important to recognize that patient safety concerns with an ethical component are common, can be predicted, and should be addressed by the same strategies as any other clinical patient safety issue.

Case Analysis

Ethics and Law

The law often plays a role in the analysis of ethical issues in healthcare. An essential step in clinical ethics, particularly at the end of life, is to determine what is permissible. The law itself is not the fundamental basis of either quality or ethics. The law sets rough boundaries within which many practices may be "legal," but says little about what is ethical. Safety failures may result in legal consequences, but a guiding principle of safety promotion is identifying problems and correcting them before a patient is actually injured. Therefore, effective patient safety practices should prevent legal involvement. That being said, the law does have a practical impact in setting standards and influencing change; therefore, knowing the guidelines of the law is essential.

In many areas of healthcare legislation where ethical issues are addressed, the law tries to put into place a process that will ideally yield an ethical outcome. While the process in the legislation may or may not promote an ethical outcome, the legislative process may create a framework for the healthcare institutions to use to solve conflicts. Legal solutions tend to be rigid, while clinical solutions need to be flexible. Knowledge of the law is a necessary ingredient for effective ethical decision-making, but it is not sufficient in and of itself.

Autonomy, beneficence, and non-maleficence all have legal relevance. Autonomy translates into informed consent. In malpractice cases, beneficence and non-maleficence are relevant to establishing the presence of a duty, the standard of care for the elements of the duty, and whether the duty was met. Table 10.2 demonstrates the parallels between ethics, safety practices, and examples of potential legal causes of action.

Specific to this case, the law clearly recognizes the authority of a person to refuse all unwanted health care, even when it would be life-prolonging or life-saving [3]. The United States Supreme Court has established that life-saving or life-sustaining treatment can be withheld or withdrawn from incompetent (including unconscious) patients, and that States may define the necessary authority required for this decision to be made for an incompetent/unconscious patient [4]. The law has several ways of

Table 10.2 Practical comparison of principles in patient safety, ethics, and law

Principle	Ethics	Patient safety	Law
Autonomy	– Respect for a person physically as well as emotionally – Respect for a person's values	– Injury caused by providing care that a patient didn't want – Injury caused by failing to provide desired care	– Assault and battery for unwanted physical interference – Negligence[a] claim based on failure to obtain proper consent – Negligence for failing to provide necessary care
Beneficence	The intent to provide benefit	– Failing to ensure practices that promote benefit – A safety promotion plan in fact causes harm – Causing injury by improperly implementing a beneficial plan	– Negligence in providing the standard of care – Negligence in creating a hazard despite benevolent intent – Negligence for failing to implement a hospital policy or practice that would have prevented harm
Non-maleficence	The duty to prevent harm—"first do no harm"	– Inadequate safeguards to prevent foreseeable harm – Failure of safeguards to prevent harm—existing safeguards are inadequate or are improperly implemented – Harm from the intended safeguard itself (i.e.. delay in provision of a medication because the medication is not available immediately on the floor—no override or not stocked on floor)	– Negligence based on failing to protect a patient (the claim is more severe as the foreseeability of the harms increases) – Negligence in failing to uphold hospital policies, negligence/ incompetence in execution – Negligence in failing to provide competent care, negligence in creating a hazard

[a] Negligence is a general term for failing to meet the standard of care. The basic elements of any negligence claim is the presence of a duty, a breach of the duty (the failure to meet the standard of care in meeting the duty), harm caused by the breach, and the determination of the type and value of the injury caused. In this table, the negligence refers to the nature of the failure to meet the standard of care that would arise in safety failures

approaching decision-making for an incompetent patient. Often these laws are state-specific and healthcare providers need to be familiar with the laws in their own state [5].

The first step in this case, before invoking the relevant law for the incompetent patient, would be to understand the nuances of determining a patient's decision-making capacity. Medical decision-making capacity is a fundamental requirement for informed consent to be valid and in most US jurisdictions and is based on four abilities: (a) ability to understand the relevant information about the proposed test or treatment, (b) ability to appreciate the nature of one's situation and the consequences of one's choices, (c) ability to reason about the risks and benefits of

potential options, and (d) ability to communicate a choice [6]. Only when these abilities are absent can be patient be deemed incompetent to make a clinical decision.

Ethics and Patient Safety

Within the framework defined by the legal parameters, basic quality and safety principles can be applied to the clinical scenario. As defined by the Institute of Medicine, care needs to be safe, effective, patient-centered, timely, efficient, and equitable [7]. Defining what these mean in the clinical context operationalizes the principles.

Safety in this scenario is the importance of not making the wrong decision: premature termination of support would be unsafe, but continuing unwanted care is also unsafe. The injury from withdrawing support prematurely is obvious. The injury from continuing unwanted support is also substantial. Freedom for unwanted invasion of one's body is a fundamental societal value as well as a fundamental healthcare value [7].

Patient-centered decision-making at the end of life or at any time is critical. Ethics exists only within a clinical context, and that context is unique to the patient. It is easy to get distracted by what is safe for the providers or the institution. Withdrawal of support over the objection of a family member has potential consequences for the providers and institution. The perception may develop that the "safest" course is to maintain the status quo (continue the current level of support), or to err on the side of continued medical care in the face of a dispute. However, patient-centered care emphasizes that safety in this situation is compromised as much by providing unwanted medical intervention as it is by withdrawing support prematurely.

Improved end-of-life care is often discussed as an issue of wasted money and wasted resources [8]. These are substantial societal as well as individual concerns. Failure to resuscitate has obvious consequences. However, unwanted resuscitation has immense consequences as well and is an increasingly common issue [9]. The idea that unwanted resuscitation may have legal consequences is developing [10].

Solutions

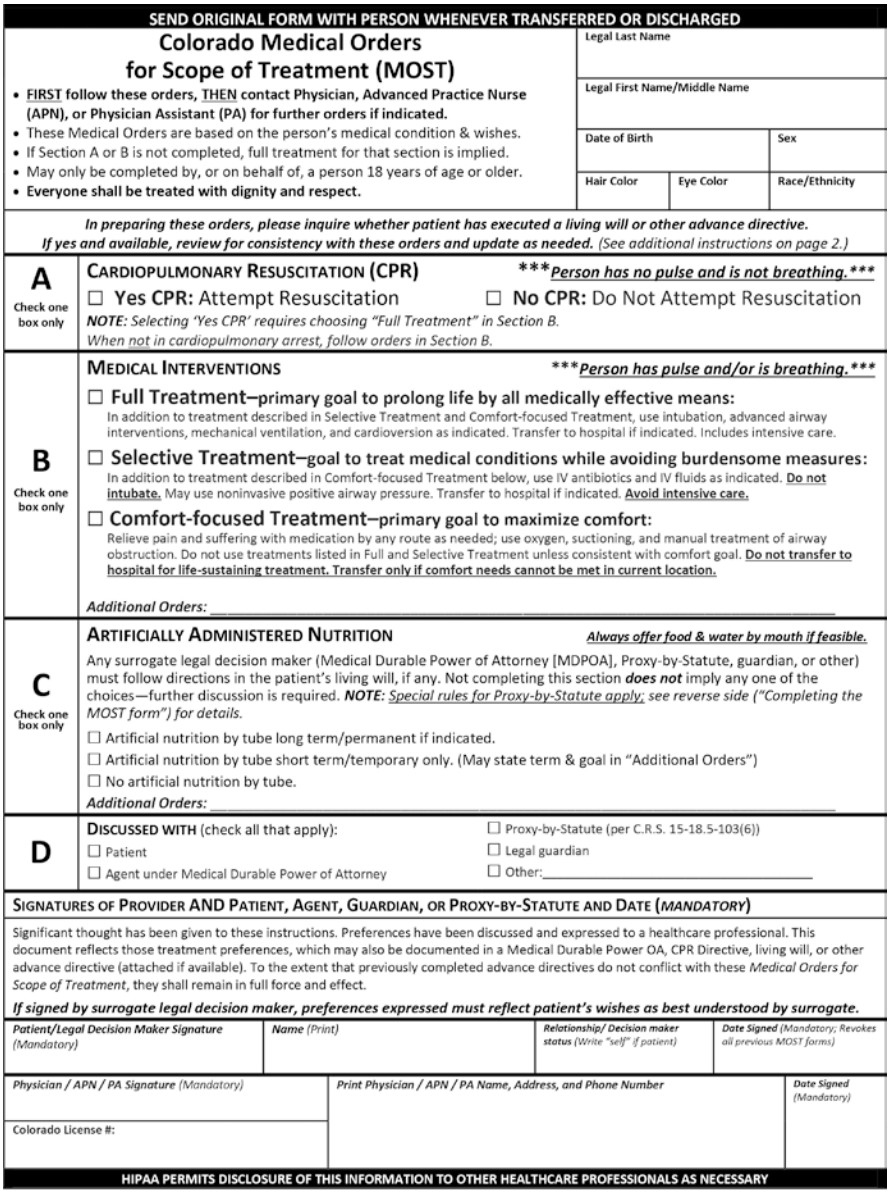
Health care providers and institutions may use several strategies to prevent conflict such as presented in this case. First, discussing a patient's wishes regarding their treatment preferences is a standard part of medical care that should be addressed with every patient before an end-of-life situation arises or the patient loses decision-making capacity. This patient was unable to express her wishes on admission, but there is ample opportunity in most patients' care to determine a patient's wishes. Second, adequate documentation of a discussion and patient's decision is critical.

In this case, a discussion may have been had at some point, but none of the family members is clear what the content of that discussion might have been. Many of the prominent, high profile media cases have revolved around what a patient said and to

whom. Nancy Cruzan and Teresa Schiavo both made statements about how they saw medically dependent life support, but the statements were sporadic, varied in different conversations, and had ambiguous meaning when applied to their actual conditions at the end of their lives [4, 11]. Open conversation within families and among loved ones makes a person's wishes clear, and hopefully prevents conflict. A clearly documented statement prevents misunderstanding of a patient's wishes and helps ensure safe end-of-life care. Palliative care is a fundamental issue in end-of-life care, and mismanaged palliative care has numerous safety implications. Clear, adequately documented end-of-life care wishes make palliative care safer, and in being safer it can be administered more effectively.

Traditionally, patients' preferences for life-sustaining treatments are documented and communicated using patient-generated advance directives or medical orders such as "DNR (Do Not Resuscitate)" regarding cardiopulmonary resuscitation. Unfortunately, these practices have been found to be largely ineffective at altering end-of-life treatments [12]. Advanced directives, such as living wills, are generally unhelpful in clinical settings because of vague instructions and the lack of certainty as to when to act on them. While medical orders, such as DNR, may appear more helpful due to their specificity, they address a narrow decision regarding resuscitation and do not provide guidance regarding other issues around end-of-life care such as use of intravenous nutrition, and antibiotics. Another barrier to effective DNR orders has been that they need to be rewritten in each setting and at each transition of care. Only a credentialed physician can write an order at a given hospital, so the same physician may not be able to write a valid order at another facility. A new set of orders has to be written with each transition: outpatient to inpatient, nursing home to hospital, hospital to hospice. Each set of orders should be complete and should replace all prior orders. Often, if the end-of-life care discussion isn't well documented and/or a conversation about end-of-life care preferences can't be discussed immediately, the patient may be made "full code" until such a discussion can be had. Further, because of the need to renew the DNR order at each visit, often the conflict between loved ones including the patient may need to be revisited and re-inflamed with each transition.

To address the limitations of the traditional practices for communicating patient treatment preferences, there have been attempts to create a set of orders that travels with the patient, is valid in every setting, and can be relied upon by providers in every setting. These are commonly called Physician Orders for Life Sustaining Treatment (POLST] [13]. A fundamental benefit of the POLST approach is that the POLST form translates a patient's treatment preferences into medical orders. It is designed for patients of any age with advanced illnesses or frailty. The POLST form expands upon CPR status to include orders based on preferences about a range of life-sustaining treatments, e.g., antibiotics, artificially administered nutrition like tube feeding. Some states have variant names, for example, Colorado uses the term Medical Orders for Scope of Treatment or MOST (Fig. 10.1). The mechanisms by which these are valid are dependent on the State, but typically the State legislature enacts the use of the form, often as part of the medical decision-making act that describes medical durable powers of attorney and living wills. The dominant



SEND ORIGINAL FORM WITH PERSON WHENEVER TRANSFERRED OR DISCHARGED

Colorado Medical Orders for Scope of Treatment (MOST)

- FIRST follow these orders, THEN contact Physician, Advanced Practice Nurse (APN), or Physician Assistant (PA) for further orders if indicated.
- These Medical Orders are based on the person's medical condition & wishes.
- If Section A or B is not completed, full treatment for that section is implied.
- May only be completed by, or on behalf of, a person 18 years of age or older.
- Everyone shall be treated with dignity and respect.

Legal Last Name | Legal First Name/Middle Name | Date of Birth | Sex | Hair Color | Eye Color | Race/Ethnicity

In preparing these orders, please inquire whether patient has executed a living will or other advance directive. If yes and available, review for consistency with these orders and update as needed. (See additional instructions on page 2.)

A — Check one box only

CARDIOPULMONARY RESUSCITATION (CPR) ***Person has no pulse and is not breathing.***

☐ **Yes CPR:** Attempt Resuscitation ☐ **No CPR:** Do Not Attempt Resuscitation

NOTE: Selecting 'Yes CPR' requires choosing "Full Treatment" in Section B.
When not in cardiopulmonary arrest, follow orders in Section B.

B — Check one box only

MEDICAL INTERVENTIONS ***Person has pulse and/or is breathing.***

☐ **Full Treatment**–primary goal to prolong life by all medically effective means:
In addition to treatment described in Selective Treatment and Comfort-focused Treatment, use intubation, advanced airway interventions, mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Includes intensive care.

☐ **Selective Treatment**–goal to treat medical conditions while avoiding burdensome measures:
In addition to treatment described in Comfort-focused Treatment below, use IV antibiotics and IV fluids as indicated. Do not intubate. May use noninvasive positive airway pressure. Transfer to hospital if indicated. Avoid intensive care.

☐ **Comfort-focused Treatment**–primary goal to maximize comfort:
Relieve pain and suffering with medication by any route as needed; use oxygen, suctioning, and manual treatment of airway obstruction. Do not use treatments listed in Full and Selective Treatment unless consistent with comfort goal. Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location.

Additional Orders: _____

C — Check one box only

ARTIFICIALLY ADMINISTERED NUTRITION *Always offer food & water by mouth if feasible.*

Any surrogate legal decision maker (Medical Durable Power of Attorney [MDPOA], Proxy-by-Statute, guardian, or other) must follow directions in the patient's living will, if any. Not completing this section ***does not*** imply any one of the choices—further discussion is required. ***NOTE:*** *Special rules for Proxy-by-Statute apply; see reverse side ("Completing the MOST form") for details.*

☐ Artificial nutrition by tube long term/permanent if indicated.
☐ Artificial nutrition by tube short term/temporary only. (May state term & goal in "Additional Orders")
☐ No artificial nutrition by tube.

Additional Orders: _____

D

DISCUSSED WITH (check all that apply):
☐ Patient
☐ Agent under Medical Durable Power of Attorney
☐ Proxy-by-Statute (per C.R.S. 15-18.5-103(6))
☐ Legal guardian
☐ Other:_____

SIGNATURES OF PROVIDER AND PATIENT, AGENT, GUARDIAN, OR PROXY-BY-STATUTE AND DATE (*MANDATORY*)

Significant thought has been given to these instructions. Preferences have been discussed and expressed to a healthcare professional. This document reflects those treatment preferences, which may also be documented in a Medical Durable Power OA, CPR Directive, living will, or other advance directive (attached if available). To the extent that previously completed advance directives do not conflict with these *Medical Orders for Scope of Treatment*, they shall remain in full force and effect.

If signed by surrogate legal decision maker, preferences expressed must reflect patient's wishes as best understood by surrogate.

Patient/Legal Decision Maker Signature (Mandatory) | *Name* (Print) | *Relationship/ Decision maker status* (Write "self" if patient) | *Date Signed* (Mandatory; Revokes all previous MOST forms)

Physician / APN / PA Signature (Mandatory) | *Print Physician / APN / PA Name, Address, and Phone Number* | *Date Signed* (Mandatory)

Colorado License #:

HIPAA PERMITS DISCLOSURE OF THIS INFORMATION TO OTHER HEALTHCARE PROFESSIONALS AS NECESSARY

Authority for this form and process is granted by C.R.S. 15-18.7: Directives Concerning Medical Orders for Scope of Treatment, enacted 2010.

Fig. 10.1 Sample Colorado MOST form

advantage of POLST, namely a single discussion and resulting document can result in an order that clearly indicates the patient's preferences, is obvious. Further, POLST can be relied on safely by anyone, including EMS personnel. Providers'

concerns for their own legal safety in failing to resuscitate someone are negated by a POLST document in a State that recognizes it.

Ultimately, for a patient without decision-making capacity with end-of-life issues, a plan of care needs to be decided upon. If there is an advance directive, it needs to be found. A patient's own wishes, expressed by them in writing, are invaluable. Under Federal law, a patient must be asked on admission whether they have an advance directive and must be given information about it [14]. If there is no advance directive and no durable power of attorney for healthcare, a decision maker must be chosen. In this scenario, in most states the three children would have equal authority. Some states would treat the situation differently if the patient had a living spouse. If the children have equal authority, then a facilitated family meeting is the main tool for resolution. Most often these are effective, especially if all the interested parties are available, in person, and appropriate support is provided. In this case, the presence of a religious advisor may be beneficial since one child's concerns are based on religion. Usually there is an informal "majority rules" approach, but if there is one outspoken member of the minority position, the hospital counsel and administration should be involved. However, the guiding principles of the discussion and the plan of care should be the basic quality improvement principles with a focus on safety, efficacy, and patient-centeredness.

Discussion

There are core competencies in end-of-life care as well as in most ethical aspects of medical practice. The American Council for Graduate Medical Education (ACGME)'s Residency Review Committee prescribes areas of expected competence in ethical practice in several contexts [15]. A minimal level of ethical knowledge and clinical skill is part of professional practice. Analogous expectations exist for most clinical practitioners in their respective codes of ethics and clinical competencies.

After evaluating the role of patient safety and the relationship to ethical practice, the case scenario may be simplified. Like most situations where clinical ethics is involved, this will be an intense and painful discussion for this family no matter how well it is handled, and it may be that consensus is not possible. The value of a clinical ethics approach, especially if a clinical ethicist is involved, is to make the discussion productive and effective. Ultimately, whenever there is an ethical conflict, there is a potential injury resulting from a "wrong" decision. There is no single ethically right decision for every situation, but in any situation there is a need to reach a resolution.

Case Study 2

Clinical Summary

A large tertiary care medical center has been able to recruit a well-known cardiologist who has several large grants. The presence of this physician at this institution is important to the mission of the institution, and the grants are important to the department and the institution. The physician is well liked by patients, colleagues, and other health care team members. It has been brought to the physician's attention several times that she forgets to wash her hands or use sanitizer, but she indicates that "washing her hands isn't her priority, taking care of patients is." There is an outbreak of Clostridium difficile in the hospital, affecting cardiology patients disproportionately. A number of clinicians have raised concerns that the hand washing practice of this physician is contributing to the outbreak, and a data review indicates a much higher rate of infection among her patients.

Disruptive physician behavior is a problem across all provider levels and care settings. The term "disruptive physician" usually applies to physicians who are impaired at work, abusive, or sexually and personally inappropriate. However, the American Medical Association Code of Medical Ethics defines disruptive behavior as "personal conduct, whether verbal or physical, that negatively effects or may potentially negatively affect patient care [16]." Failure to adhere to clearly beneficial patient safety practices, such as hand washing, negatively affects patient care and should be addressed as a disruptive behavior. It is noteworthy that while often disruptive behavior points toward physicians, this behavior is found in all levels of clinicians across all care settings.

Case Analysis

Approaching quality improvement and patient safety issues in this case from an ethical perspective, the principles of beneficence and non-maleficence describe the underlying philosophy. The healthcare system as a whole, and all of the members within it have a duty to promote welfare and avoid harm. In a very real sense quality improvement is inherently an ethical issue. Failing at any opportunity to confer benefit or prevent harm affects quality adversely, but it also compromises the ethical obligations inherent to providing health care.

There are many professional codes of ethics, specific to various professions within health care. Despite the variation of skills and practices, most professional codes of ethics are similar in regard to basic ethical principles. The physician code of ethics will be used for the purposes of discussion, but most professional codes of ethics could be used with similar conclusions.

Competence is a universal ethical obligation [16, 17]. While this seems too self-evident to warrant discussion, clearly established safety practices take a notoriously

long time to implement uniformly. For example, despite the clear benefits of prescribing aspirin after a myocardial infarction, removing Foley catheters as early as possible to prevent UTIs, or ensuring that advance directives are known and available these practices have been adopted slowly by providers and have only taken uniform hold with targeted hospital initiatives and Medicare or Joint Commission Core Measures [18, 19]. The need for strong incentives and disincentives to ensure uniform practice indicates that knowledge alone doesn't ensure competent practice.

Similarly, the ascendance of the best interest of the patient and protecting the patient from harm is ubiquitous. It would hold that a practice that has been shown to have overwhelming benefit and has essentially no risks would be adhered to without reservation. Failure to do so would seem to be a breach of the central ethical foundations of health care. Despite this, physicians (and other healthcare providers) routinely deviate from known safety practices, but many of these physicians would be indignant to be labeled "unprofessional" or "disruptive."

Hand washing is one such practice with immense positive clinical impact. Improved hand washing consistently lowers morbidity and mortality from infectious disease in the hospital [20]. Still, failure to adhere to this unequivocal best practice is common, and hand washing/hand-sanitizing rates are embarrassingly as low as 50% [21].

In this scenario, there is a prominent provider clearly ignoring safety practices. In clinical situations where quality and safety practices are of more ambiguous benefit, it is easy to see why they would be even more difficult to enforce. However, in the case of hand washing, there is no potential argument that the practice in question has adverse effects or the evidence of benefit is equivocal. Otherwise, she is a good doctor in terms of patient care, patient satisfaction, peer interactions, and contribution to the field.

This scenario may appear implausible to lay people as no provider should refuse to wash her hands despite prompting, and no institutional culture should permit it. However, we know that providers do refuse to wash their hands, and institutions tolerate it. The literature on how and why is addressed elsewhere, while this discussion focuses on the responsibility issue [22].

If a physician is presented with the evidence that she is doing harm and refuses to change her practice, she should be removed from patient interaction. This requires integrity from an institution, but is a position that institutions are increasingly willing to take. The response to disruptive physician behavior is discussed extensively in medical codes of ethics [16], and among executive and healthcare administrators [23]. The most hopeful outcome is that, when presented with direct evidence of harm and a conversation in the context of ethical and professional responsibilities, the physician will change. Changing her habit may take time, but most providers would respond to evidence that they are injuring patients. When behavior is tied to principles of conferring benefit and preventing harm, professionals tend to be very committed to trying to improve. However, if the provider remains defiant and uncooperative, the institution is obligated to prevent contact between this physician and patients, and the provider's clinical privileges should be suspended or terminated.

Discussion

A central implication of the duty to protect patients is to advocate for safety and to inculcate a culture of safety. "Culture change" is a catchphrase in quality improvement because it is a critical element of change. A culture that insists on safety practices creates that reality, and a system that refuses to create that reality will not develop a true culture of safety. Failure to participate in such a culture fails ethical duties, and participation in this culture needs to empower people in any setting to expect safe practices from people regardless of the setting.

Creating a culture of safety, empowering everyone in a system to ensure quality and safety, enforcing best practices, and seeking systematic improvement are patient safety goals, but also ethical professional practice goals. What may not be recognized by the providers is the relationship between ethics, duty, quality, and safety.

The seminal IOM report, To Err is Human [24], had widespread impact with the assertion that thousands of people die from healthcare errors, more than from breast cancer, or motor vehicle accidents or AIDS. However, these conclusions were not based on new data, but instead re-framed existing data. The data had been available for some time but had never been concretely translated by providers into the idea that preventable mistakes kill patients. The re-framing of the existing data had an overwhelming impact. The information wasn't new, but the paradigm for understanding it was redefined. The IOM report made it clear that healthcare institutions *cause* death. People who are in the hospital die for no other reason than that they are in the hospital.

Addressing the issue of death caused by preventable errors directly and explicitly made the issue of patient safety central to ethical and professional behavior. The connection between beneficence, non-maleficence, quality, and safety was made very clear. Once providers and institutions saw errors in tangible terms as preventable harm, the perception shifted and quality became an ethical issue. Healthcare providers want to be altruistic. They want to help people. They want to prevent harm. As soon as quality and safety were understood in these terms, providers and institutions became committed to quality and safety. Enlightenment wasn't the trigger, responsibility was.

Conclusion

Ethics, quality, and safety are interrelated concepts. There are issues of quality improvement in clinical ethics and developing strategies in clinical ethics practice that parallel quality improvement initiatives in other areas. There is also the inherent ethical obligation to be committed to quality improvement and improving patient safety. The strongest motivators in quality and safety have recognized the fundamental ethical responsibility and underlying motivation of providers to take care of patients.

Key Lessons Learned

- The role of quality measures to improve patient safety is as relevant in ethics practice as it is to any clinical practice. Standards for best practices in ethics are available, and adherence to them promotes the safe and effective care of patients.
- Providers need to be knowledgeable and committed to safety in areas of clinical ethics practice.
- Promoting and participating in patient safety measures are an ethical obligation. Failure to adhere to known safety practices is a failure to meet the professional standards of ethics.
- Repeated failure to follow patient safety guidelines is inherently disruptive behavior and should be treated as such when considering consequences for failure to protect the safety of patients.

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Part III
Clinical Scenarios

Chapter 11
Medication Error

Abdul Mondul and Mei Kong

Introduction

Medications are the most common source of medical errors in all levels of care, from hospitals, ambulatory care, to long-term care settings [1]. Medications account for approximately "one out of every 131 outpatient deaths, and one out of 854 inpatient deaths" [2], a total of 7000–9000 estimated potentially preventable deaths per year in the United States alone. With over 7 million patients experiencing medication-associated errors, and causing harm to at least 1.5 million people per year, the additional cost of care exceeds $40 billion annually. Furthermore, patients are exposed to physical and mental harm, which leads to dissatisfaction and decreased trust in the healthcare system that supposed to heal, and not to harm [1, 3].

Adverse drug events (ADEs), particularly those related to ineffective patient education about medications and monitoring of drug therapies account for up to 66% of the adverse events after patients are discharged from the hospital [4]. Adults 65 years or older are seven times more likely (approximately 450,000 times each year) to visit emergency departments than younger adults [5]. According to Agency for Healthcare Research and Quality (AHRQ), *ADEs account for nearly 700,000*

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emergency visits and 100,000 hospitalizations annually [6]. Furthermore, the use of high-risk medications such as opiates, warfarin, insulin, phenytoin, carbamazepine, and digoxin especially in elderly patients accounts for 33% of the ADEs treated in emergency departments (EDs) and 41% of ADEs leading to hospitalizations [7].

A medication error is defined as "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 event may be related to professional practice, health care products, procedures, and systems [8]." An adverse drug event (ADE) is defined as an injury or harm to the patient that is caused by medication usage [9]. It is important to note that not all medication errors lead to ADEs and not all ADEs are medication errors.

According to the National Coordinating Council for Medication Error Reporting Program (NCC-MERP), medication errors are categorized into the following nine categories depending on the level of patient harm (Fig. 11.1) [10].

Medication errors may occur at any of the five stages of the medication management process, namely (1) ordering/prescribing, (2) transcribing and verifying, (3) dispensing, preparing and delivering, (4) administering, and (5) monitoring and reporting. It is estimated that 39% of the errors occur during prescribing, 12% during transcribing, 11% during dispensing at the pharmacy, and 38% during administering [11]. As illustrated in Fig. 11.2, most medication errors occur as a result of multiple vulnerabilities and failures in the continuum of the medication management process (the Swiss Cheese concept) [12, 13].

Similar to other patient safety adverse events, medication errors can arise from human errors and/or systems failures. Human errors include problems in practice (e.g., taking short cuts), training deficiencies, undue time pressure, distractions, and poor perception of risk. Systems failures can be related to products, procedures or processes (e.g., unclear or cumbersome policies) [2]. The most common medications associated with severe ADEs and mortality include central nervous system agents, anti-neoplastics, and cardiovascular drugs. The types of errors that contribute to patient death involve the wrong dose (40.9%), the wrong drug (16%), and the wrong route of administration (9.5%) [14]. In addition, prescription opioids were involved in nearly 24% of all opioid overdose deaths in 2020, a 16% increase when compared to 2019 [15].

The American Hospital Association lists the following as the common types of medication errors [16]:

- Incomplete patient information such as allergies, other medications that have been taken, medical history and lab results
- Unavailable drug information such as knowledge of up-to-date warnings from the Food and Drug Administration (FDA)
- Miscommunication of drug orders which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes or decimal points, confusion of metric and other dosing units, and inappropriate abbreviations
- Incorrect labeling as a drug is prepared and repackaged into smaller units
- Environmental factors such as heat, adequate lighting, noise, and interruptions
- Failure to follow established facility policies and procedures

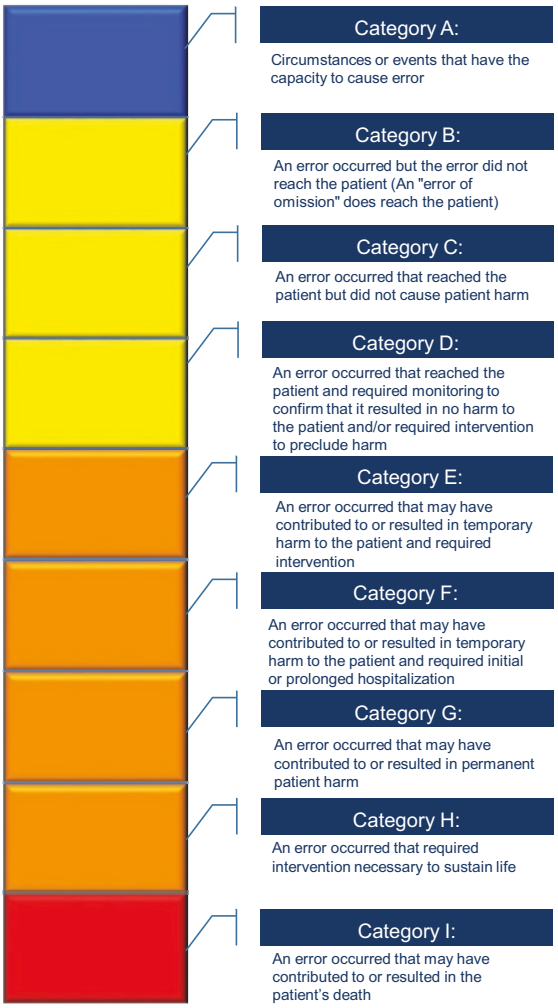

Fig. 11.1 NCC-MERP index for categorizing medication errors

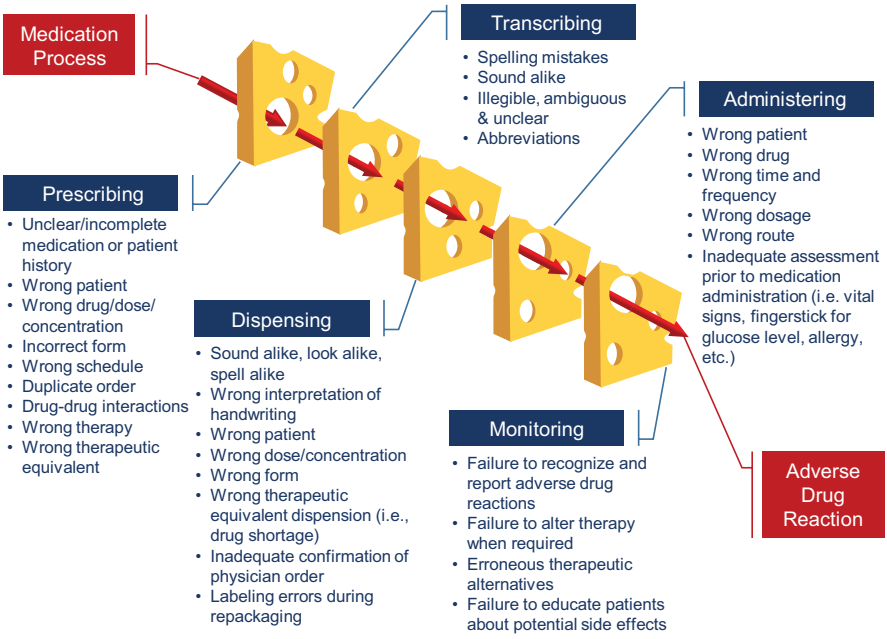

Fig. 11.2 Medication points of failure

Case Studies

Case Study 1: Respiratory Depression Caused by Opioid Overdose

Clinical Summary

A 56-year-old patient with a history of metastatic esophageal cancer was admitted for progressive enlargement of a left neck mass leading to dysphagia and severe pain related to bone metastasis. He had been taking non-steroidal anti-inflammatory drugs (NSAIDs) at home with partial pain relief. In the ED, he was treated with intravenous (IV) Ketorolac and was admitted for pain management and hypercalcemia. Upon admission to the floor, the on-call resident ordered Fentanyl 50 mcg transdermal patch every 72 h because the patient had difficulty swallowing oral pain medications. The patient continued to complain of severe pain, and additional morphine was administered intravenously (IV) on as needed basis. Forty-eight hours after the admission, the patient was found to be comatose with pin-point

pupils and slow, shallow breathing. Naloxone hydrochloride 0.4 mg/mL intravenous push (IVP) was administered to reverse the opioid effect and the patient subsequently developed generalized tonic-clonic seizures. The patient required intubation and mechanical ventilation and was observed in intensive care unit for 7 days. He was successfully extubated, transferred back to regular floor, and eventually discharged home. For the rest of the hospital stay, his pain was managed with short-acting morphine elixir 10 milligrams (mg) by mouth (PO) every 4 h with breakthrough coverage.

Analysis and Discussion

This case study illustrates a number of errors related to opioid prescribing for pain management. First, Fentanyl patch is a long-acting agent (the onset of action is up to 48 h); therefore, it should not be used to treat acute pain especially in opioid-naïve patients. Second, the patient received a combination of IV morphine along with Fentanyl leading to opioid overdose. Fifty mcg of Fentanyl is equivalent to 135–224 mg of daily oral morphine equivalency. The prescribing physician should have been more aware and careful about the potential risks of prescribing opioids in high doses. At the same time, neither the pharmacist nor the nurses raised an alarm about the dose of pain medications being received by this patient. Finally, the rapid reversal of opioids may lead to seizures and other withdrawal symptoms. Hence, naloxone should have been diluted and given in 0.04 mg/mL boluses, one tenth of the IVP dose given to the patient.

Literature shows that opioid analgesics rank among the drugs most frequently associated with ADEs [17]. The most serious and sometimes fatal side effect is respiratory depression which is generally preceded by sedation. The reported incidence of respiratory depression in post-operative patients is about 0.5% [17]. All patients receiving opioids must adequately assessed and reassessed for pain and for previous history of opioid use/abuse to identify potential opioid tolerance or intolerance. There is commonly a lack of knowledge about potency differences among opioids, especially equivalence between short-acting and long-acting/sustained release opioid; therefore, sufficient time should be allowed to assess the patient's response to an initial dose before increasing the dosage or prescribing long-acting opioids. When converting from one opioid to another, or changing the route of administration from oral, IV or transdermal, a pharmacist or pain management expert should be consulted if available or a conversion support system should be used to calculate correct doses [18]. When opioids are administered, the potential for opioid-induced respiratory depression should always be considered, especially in opioid naive patients.

Case Study 2: Wrong Drug Dispensing and Administration Due to Similar Sounding Names ("Look-a-Like" "Sound-a-Like")

Clinical Summary

On the oncology unit, Dr. Sure ordered Taxol (paclitaxel) 260 mg IV (175 mg/m^2 × 1.5 m^2 body surface area = 262.50 mg) for Ms. Jones for her advanced stage breast cancer. After a review of the order, the pharmacist mistakenly dispensed 260 mg of Taxotere (docetaxel). The nurse reviewed the order and thought what was sent up by pharmacy was the correct medication and administered Taxotere 260 mg. The usual adult dose for Taxotere is 60–100 mg/m^2 IV [19]. Due to this error, the patient received the wrong medication at three times the usual dose and died 4 weeks later from neutropenic sepsis and hepatic failure.

Analysis and Discussion

Both Taxol and Taxotere are used for breast cancer, are from the same family of medications, the taxanes, but have different pharmacokinetics and side effect profiles. There is an increased risk of serious (possibly fatal) reactions when receiving higher doses of Taxotere, such as severe neutropenia, neurosensory symptoms, asthenia, fluid retention, trouble breathing, chest pain or tightness, fast or irregular heartbeat, or abdominal swelling [19].

Since Taxol and Taxotere are indication-alike, look-alike, sound-alike, and spell-alike drugs, they need additional safeguards for differentiation. A simple and frequently used solution to improve safe use of such medications is to use Tall Man Lettering (Fig. 11.3) [20] to highlight the dissimilar letters in two names.

The Institute for Safe Medication Practices (ISMP), FDA, the Joint Commission, and other safety organizations have promoted the use of tall man letters as a means of reducing confusion between similar drug names [21]. This methodology can be used throughout the medication process including on CPOE ordering screens, computer-generated pharmacy labels, pharmacy computer drug selection screens, shelf labels, automated dispensing cabinet screens, computer-generated medication administration records, and even preprinted order sheets.

On the pharmacy dispensing side, the use of separate storage areas and different color containers could have helped to distinguish these two otherwise similar

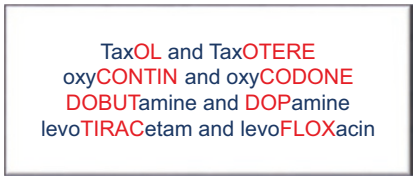

Fig. 11.3 Tall man lettering

sounding medications. The nurse unfortunately also missed the opportunity to avert the error from reaching the patient. Had a bar-coded medication administration (BCMA) system to ensure the "five rights" of medication administration (right drug, dose, route, patient, and time) been in place at the bedside, the system would have detected that the medication being administered does not match the medication ordered, thus averting this high-risk error [22]. Additionally, most institutions mandate verification by two nurses prior to administration of a high-alert medication such as a chemotherapeutic agent which had not been implemented here due to staffing constraints.

Medication Safety Strategies

There are five essential strategies in improving medication safety. These include:

Use of Information Technology (IT)

IT applications such as electronic health records (EHRs) and computerized physician order entry (CPOE), especially when augmented by a point-of-care clinical decision support (CDS) system have been demonstrated to reduce medication errors and improve patient safety [23–25]. Advantages of CPOE include legibility, prompt pharmacy review, links to drug–drug interactions, decision algorithms, easier ADE identification, less risk for look-alike/sound-alike medication errors, and improved medication reconciliation. Another advantage of CPOE is the capacity to embed CDS tools in the form of order sets, guidelines, or protocols [23, 24]. In addition to the safety of medication ordering, IT tools also improve efficiency of the process through the automation of medication preparation and packaging via the use of robotic dispensers.

Another technology that has been demonstrated to improve medication safety is the bedside bar-coded medication administration (BCMA) system. In this system, the nurse scans the bar-coded bracelet on the patient's wrist band to ensure that the medication(s) will be administered to the right patient. The nurse also scans the unit dose of the medications. The system compares each medication with the physician's orders and alerts the nurse to any mismatch of patient identity or of the name, dose, or route of administration of the medication. BCMA systems have been shown to lead to a 54–87% reductions in medication errors during the administration step [26, 27].

It is important to note that technology is not a panacea and can have unintended and potentially adverse consequences on safety. A widely quoted 2005 study found that CPOE implementation in an academic tertiary care children's hospital during an 18-month period actually resulted in an unexpected *increase* in mortality rate [28]. A commercial CPOE program that was designed for adult general

medical-surgical usage was quickly implemented across this pediatric facility without appropriate customization, workflow configuration, and testing/user training. The study found an unexpected increase in mortality coincident with CPOE implementation and concluded that technology must not replace the critical thinking process necessary to make appropriate treatment choices. Other reports have also demonstrated that safe implementation of CPOE requires ongoing assessment of the system, integration processes with the human interface, as well as constant monitoring and evaluation of medication error rates and mortality [29].

Other risks of CPOE include "alert fatigue" and an overreliance on the automated decision process sometimes substituting critical clinical thinking. "Alert fatigue" occurs when physicians receive too many alerts of questionable perceived value leading them to override the alerts. Therefore, the CPOE implementation should carefully consider the number and types of alerts that are turned on in a system [30, 31].

Another important IT tool is an efficient medication error reporting system, to enhance a more reliable practice and to measure progress toward achieving safety. Improvement efforts and system changes require an organizational culture of "good catch" and error reporting, simple reporting methods, analysis of medication error reports, and finally, constructive and proactive recommendations that will effect changes toward reductions of injury to future patients [32].

Addressing Health Literacy and Engaging Patients and Families

Medication error prevention requires collaboration among different members of the healthcare team as well as with the patients and their families. It is important for clinicians to communicate clearly using plain language with visual cues, such as models, pictures, or videos and by focusing on the key points [32]. The team should recognize the higher risk of medication error in patients with lower literacy levels as they may not have the skills necessary to effectively navigate the medication use process and are more likely to misinterpret the prescription label information and auxiliary labels [33–35].

High-Alert Medications

High-alert medications, such as anticoagulants, opioids, sedatives, insulin, chemotherapy, and electrolytes, can cause an immediate and life-threatening condition for the patient even when administered in usual doses. Due to high risk for patient harm, institutions should take additional steps to identify and mitigate risks to patient safety from such medications.

Some steps include: (1) standardize protocols and dosing; (2) establish order sets for the physicians with automated alerts; (3) dispense medications from pharmacy

only and utilize auxiliary color-coded labels indicating high-alert medications; (4) establish monitoring parameters on assessing, reassessing, and documentation of patient responses to the medications; (5) train staff on early recognition of potential adverse events and how to rescue patients, including antidotes that are available; (6) employ redundancies such as automated or independent double checks, a procedure in which two clinicians separately check each component of prescribing, dispensing, and verifying the high-alert medication before administering it to the patient [36, 37].

Medication Reconciliation

Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. It should be done at the points of transition in care where new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner or level of care. The medication reconciliation process comprised of the five steps below:

1. Develop a list of current medications, e.g., home medications
2. Develop a list of medications to be prescribed
3. Compare the medications on the two lists
4. Make clinical decisions based on the comparison
5. Communicate the new list to appropriate caregivers and to the patient

Studies have shown that more than half the patients experience one or more unintended medication discrepancy at the time of a hospital admission and nearly 40% of these have the potential for moderate to severe harm [37]. It is easy to overlook medications that may cause an adverse event, especially when combined with new medications or different dosages. An effective medication reconciliation process across care setting can help prevent errors of omission, drug–drug interactions, drug–disease interactions, and other discrepancies [38, 39].

Foster Pharmacy Collaboration

Pharmacists can advise physicians in prescribing medications and enhance both physicians' and patients' understanding of medications [40]. Pharmacist participation during rounds with the medical teams on a general medicine unit contributed to a 78% reduction in preventable ADEs (from 26.5 to 5.6 per 1000 hospital days) by providing support at the time when decisions about therapy are made [41]. In addition, increased collaboration with the team resulted in enhanced interventions during rounding, such as dosing-related changes and recommendations to add or modify a drug therapy [41].

An Interdisciplinary Approach to Medication Error Prevention

In this section, we describe the role of various health team members in preventing medication errors and improving safety.

The Prescribers' Role

Prescribing is an early point at which medication errors can arise. For safer prescribing, ordering physicians should stay knowledgeable with current literature review, consult with pharmacists and other physicians, as well as participate in continuing professional education. It is critical that prescribers evaluate the patient's overall status and review all existing therapies before prescribing new or additional medications to ascertain possible antagonistic or complementary drug reaction(s). Medication orders should be complete, clear, unambiguous and should include patient name, generic drug name, brand name (if a specific product is required), route and site of administration, dosage form, dose, strength, quantity, frequency of administration, prescriber's name and indication. In some cases, a dilution rate and time of administration should be specified. The desired therapeutic outcome for each medication should be expressed when prescribed. It is important not to use inappropriate abbreviations such as "QD," "BID," etc. The prescriber should educate the patient/caregivers about the medication prescribed, special precautions or observations and potential anticipated side effects. The teach-back method, simply asking the patient/caregivers to repeat back information that was taught, should be used to determine information retention such as understanding of medication usage, indication(s), and side effects. Finally, the prescriber should follow up and evaluate the need for continued therapy for individual patients on a regular basis [42].

The Pharmacists' Role

The pharmacist, in collaboration with other team members, should be involved in assessing therapeutic appropriateness, medication interactions, discrepancies, and pertinent clinical and laboratory data for all orders. Pharmacists need to be familiar with drug distribution policies and procedures to ensure safe distribution of all medications and related supplies. They also maintain orderliness and cleanliness in the work area where medications are prepared and should perform one procedure at a time with as few interruptions as possible. They should observe how medications are actually being used in patient care areas to ensure that dispensing and storage procedures are followed as recommended. A review of medications that are returned to pharmacy is important as such review processes may reveal system breakdowns

or problems that resulted in medication errors (e.g., omitted doses and unauthorized drugs). Pharmacists also play in key role in counseling patients/caregivers and verifying that they understand why a medication was prescribed, its intended use, any special precautions that might be observed, and other needed information [42].

It is of great importance that organizations support flattening of hierarchies leading to facilitation of escalation processes and open communication between the interdisciplinary team in a fair and just culture environment.

The Nurses' Role

Nurses play a key role in medication safety and prevention of errors because they are the final check point in the medication process before the medication is actually administered to the patient [42]. Also, by virtue of their direct involvement in patient care activities, nurses are in the best position to detect, deter, and report medication errors. Nurses need to review medications with respect to desired outcomes, therapeutic duplications, and possible drug interactions. They must review and verify all orders before medication administration and ensure that the drug dispensed matches the order in all respects, and know if the patient is allergic to any medications. It is standard practice for a nurse to verify the "5 rights"—the right patient, drug, time, dose, and route—at the bedside prior to administration. It is essential for a nurse to observe patients for medication responses and reactions by m*onitoring and documenting the patient's vital signs, symptoms, and changes in condition* in the patient care record, especially after the first dose. It is important for the nurse to t*imely report all significant findings to the patient's physician as well as report good catches or events through a structured reporting system in a transparent learning environment.* Nurses also play a key role in the education of patients and family to ascertain that they understand the use of their medications and any special precautions or observations that might be indicated [42]. Engaging the patient in his/her care may improve information retention, adherence, outcome and reduce the opportunities for errors [43].

The Patients' and Caregivers' Role

The most important role for the patient and the family is to keep an up-to-date list of all medications. They should learn to recognize their pills—what they look like in size, shape, and color, and the indication and potential side effects. Teaching patients is not simply preparing a list of pills with days and times attached; it should also include information about their diseases and the indication for medications. Patients should be asked to repeat or demonstrate back to ensure they understood what was taught. It is important that patients keep a medication tracker log for both

scheduled and as needed prescribed medications as well as over the counter medications. This provides a comprehensive understanding of adherence and guide therapeutic modifications.

Conclusion

Medication errors are frequent, often harmful but with good systems and processes largely preventable. Many of the high-alert medications are associated with severe errors. Therefore, we must adopt effective, evidence-based error safeguarding interventions at all stages of the medication use process [44]. Equally important in medication safety is the role of organizational culture that promotes transparency in reporting and a non-punitive response to human errors. Only through an open and honest discussion of errors and systems failures changes can be made to improve performance and prevent harm [45].

Key Lessons Learned

- Medication errors may occur at all phases of the medication process.
- Even seemingly simple medication errors are multifactorial, frequently involving more than one process and more than one line of responsibility.
- Many medication errors occur due to poor communication. A collaborative approach and better communication and interaction among members of the healthcare team and the patient are essential.
- Information technology solutions such as CPOE and BCMA are critical elements of an overall organizational strategy to prevent errors.
- Developing an organizational culture of safety, so that leaders and staff are committed to safety and are preoccupied with potential errors, is a vitally important piece in improving medication safety. A safety culture embraces open communication and empowers staff to report concerns.
- Finally, we must always respect the power of medication and never underestimate its potential to cure but also to harm patients.

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Chapter 12
Wrong-Site Surgery

Patricia O'Neill and Charles S. La Punzina

Case Studies

Case 1

Clinical Summary

Mr. Jones is a 51-year-old diabetic male with a history of chronic ulcerations involving both lower extremities. After 2 days of increasing fatigue, fever, and foul-smelling drainage from his right foot, he presented to Dr. Michaels' surgery office for evaluation.

Dr. Michaels diagnosed wet gangrene of the right foot extending above the ankle. The left foot had a deep, chronic ulcer on the lateral plantar aspect but was pink with minimal exudate and felt to be viable. Dr. Michaels had an extensive discussion with the patient regarding the need for amputation to control his infection. Mr. Jones reluctantly agreed to the procedure and signed consent for a below knee

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amputation of the right lower extremity. The surgeon's office assistant booked the operative procedure as an emergency in the local hospital.

Six hours later, Mr. Jones arrived in the holding area of the operating suite while the nursing team set up the room and equipment for the amputation. The surgeon arrived shortly after and, while he was changing into his scrubs, the anesthesiologist and circulating nurse brought the patient into the operating room, induced anesthesia, and proceeded to prep and drape the patient.

Dr. Michaels entered the operating room, thanked his colleagues for their efficiency and proceeded with the amputation. After Dr. Michaels cut through all the soft tissues and ligated the major blood vessels, the circulating nurse became anxious and called out to the team. While organizing her paperwork she noted that the surgical consent was for a right below knee amputation but the team was operating on the left leg. There was immediate silence followed by a prolonged period of distress by the members of the operating team. Unfortunately, the procedure had progressed to a point where they were committed to amputation and Dr. Michaels had no choice but to complete the amputation of the left leg. The following morning Mr. Jones underwent a right below knee amputation to treat his gangrenous extremity by another surgeon.

Analysis of Errors Leading to the Wrong Limb Amputation

Analysis of this case reveals a series of errors and system failures leading to the wrong limb amputation and subsequent bilateral leg amputations despite the fact that the surgeon had obtained the correct consent (see Table 12.1).

The first error was performed by Dr. Michael's office assistant who inadvertently booked the case as a "left" below knee amputation rather than a "right" amputation. The office assistant routinely booked the surgeon's cases via phone. This error could have been prevented if she had been required to review the consent form at the time of the booking. Similarly, if the individual who received the call and put the case on the OR schedule had a faxed copy of the signed consent form to review at the time the case was entered, the discrepancy could have been identified and rectified at the time of booking.

Once the patient arrived in the holding area of the operating suite, there was no attempt made to confirm the correct procedure by any member of the OR team. At that time, there was no requirement in place for the team to confirm the planned procedure with the patient and the consent form.

In an effort to be efficient, the anesthesiologist and scrub team brought the patient into the operating room while the surgeon was still changing into scrubs. This was a common practice in that OR to minimize turnover time. In addition, there were several other emergency cases still waiting to be done and the team was pressured

Table 12.1 Case 1: Timeline of events/risks and solutions

Risks and failures during the process	Solutions
The surgeon determines the need for right below knee amputation and obtains appropriate informed consent. Office assistant books the case as "left" below knee amputation instead of "right." Wrong procedure placed on OR schedule.	Standardize booking process for all operative procedures. Require that provider /clerk cross check procedure against a written consent or medical record at time of booking. Have electronic booking form or, fax the consent or a written booking form to the OR if off-site booking.
The OR team failed to verify the planned procedure with the patient and medical record prior to the patient entering the OR. The operative site was not marked by the surgeon and confirmed prior to entering the OR. The opportunity to identify the booking error before entering the OR was missed.	Block entry into the OR unless a verification process has been performed with both the patient and consent form by all members of the surgical team. Assure that the surgeon physically marks the intended operative site and have it confirmed by other members of the team before entering the OR.
The left leg was already prepped and draped at the time of the surgeon's arrival increasing the chances of a perception error or confirmation bias on the part of the surgeon. Another opportunity to identify the error in laterality was missed.	Assure that the correct operative site is marked and visible before the patient is prepped and draped.
There was no team discussion performed prior to the start of the operation to re-confirm the planned procedure with the patient and the consent form. The team proceeded to amputate the wrong leg.	Do not allow any incision until a "time-out" process is performed by all members of the operative team. The process must re-confirm the correct patient, the correct procedure, and the correct side/site and agreed on by all.

to move the case along. Once in the room, the team proceeded to prep and drape the wrong extremity according to the OR schedule.

When Dr. Michaels arrived in the OR, he proceeded with the left leg amputation without taking the time to review the consent, confirm the surgical site, or discuss the planned procedure with the other members of the team. The fact that the left leg was already prepped and draped introduced the risk of a perception error and/or confirmation bias, increasing the chances that he would not recognize that the wrong leg was prepped. The fact that Mr. Jones had skin ulcerations involving both lower extremities was another factor that contributed to the sequence of events. Since both legs were already bandaged upon arrival to the holding area, there was less of an opportunity for a member of the team to identify the discrepancy between the diseased limb and the one booked for amputation.

Case 2

Clinical Summary

Mrs. Smith was a 68-year -old female with a history of prior left pneumonectomy for lung cancer. She was admitted to the MICU for COPD exacerbation and required endotracheal intubation for respiratory failure. Mr. Wong was the patient in the bed adjacent to Mrs. Smith and was also in respiratory failure requiring mechanical ventilation. During afternoon rounds, the medical team decided to place a central venous catheter in Mr. Wong.

The team had difficulty reaching Mr. Wong's wife for consent. Due to the delay, the day resident signed out the procedure to the night-float resident. Shortly thereafter, the night resident gathered the required supplies and began placing a central line via *Mrs. Smith's right subclavian vein. During the procedure, the nurse came to the bedside to inquire what the night resident was doing as she was not aware of any planned procedure for her patient. The resident replied that an informed consent for central venous catheter insertion was in the patient's chart and proceeded with the insertion. While the nurse was confirming the consent, the resident called frantically for her to come back because the patient was arresting. A code was called but resuscitation efforts were unsuccessful. The resident realized that she had placed the central line in the wrong patient. A post-mortem examination determined that the cause of death was a right sided tension pneumothorax.*

The resident was suspended for the remainder of her second year because she failed to adhere to the "Universal Protocol" policy. The nurse was reprimanded for not being more observant and ensuring the safety of her patient. While the resident had excellent medical knowledge and clinical skills, she decided that the stress caused by her mistake was too overwhelming and she decided to pursue a career in the pharmaceutical industry.

Analysis of Errors Leading to Death from Wrong-Patient Procedure

Similar to Case 1, a series of errors and contributing factors led to the death of Mrs. Smith. These errors could have been interrupted at several points during the process had appropriate policy and procedure been followed (see Table 12.2). As in Case 1, an informed consent was properly obtained for the correct procedure on the correct patient. Unlike in Case 1, the institution did have a policy in place (the "Universal Protocol") that mandated a "verification" and "time-out" process to identify the correct patient, the correct procedure, and the correct side/site prior to initiating any invasive procedure. However, the policy was not followed.

In her haste to get started, the resident failed to notify the nurse that the procedure was being performed. She failed to verify the patient's identity against the consent obtained earlier by the prior team. Had this been done the resident would have immediately recognized that the procedure was planned for Mr. Wong.

Table 12.2 Case 2: Timeline of events/risks and solutions

Risks and failures during the process	Solutions
Patient Wong was unable to sign own consent leading to delay in procedure. Delay required procedure to be "signed-out" to the night-float resident. Combination of "hand off" and a sedated patient imposed increased risks for patient misidentification.	Standardize the process for handoffs. Assure accurate transfer of information with special attention to follow up procedures and tasks. Need increased provider vigilance when performing high-risk procedures in high-risk environments.
Resident initiated the procedure without confirming the correct patient and consent. Resident failed to involve the patient's nurse in the process. Procedure initiated on the wrong patient.	Implement the universal protocol for all bedside procedures. Protocol requires a verification and time-out process be performed with a second team member prior to the initiation of any invasive procedure in order to assure the correct procedure is performed on the correct patient.
Patient's nurse raised concern at the initiation of the procedure but failed to insist the procedure be stopped until the plan was confirmed. Opportunity to halt procedure before patient harm missed.	Foster an environment where open communication is respected and valued among all members of the healthcare team. Empower any member of the team to stop a procedure immediately if there are any patient safety concerns.
Resident proceeded with the procedure on the wrong patient despite nurse's concern causing pneumothorax in a patient with a prior pneumonectomy causing the patient's death.	Promote individual accountability for patient safety. Educate providers to stop all procedures immediately if any team member raises a safety concern until the issue is resolved or corrected.

When Mrs. Smith's nurse was puzzled at seeing a procedure being performed without having prior knowledge, she should have immediately voiced her concern and insisted that the resident stop the procedure until she could verify the correct patient and procedure in concordance with the consent. Once the nurse questioned the procedure, the resident should have been cued into recognizing that this was a potential safety issue and subsequently stopped on her own accord until these issues were clarified. Had this been done the procedure would have been aborted before causing harm to Mrs. Smith.

Other factors that increased the risk for error in this case include the fact that the procedure was planned by the day team but executed by the night team. Shift work and hand offs are occurring with increasing frequency in medicine today. All practitioners need to recognize the increased risk for miscommunication and misinterpretation of information transmitted during hand-off procedures. The transfer of information during handoffs must be structured and complete and all parties must be extra diligent during the process. Time pressures and increased workloads often lead to employees "cutting corners" and by-passing policies to get the work done.

Discussion

Case 1 has many similarities to the real-life case of Mr. Willie King that occurred at University Community Hospital in Tampa Florida on February 20, 1995. Like the patient in the scenario, Mr. King was left with unnecessary bilateral below knee amputations because the planned surgical procedure was erroneously booked as a left below knee amputation rather than a right below knee amputation. Policies and procedures were not in place to pick up the error before the wrong amputation was performed [1]. The case of Willie King was heavily publicized at the time and although the circumstances of his case are not unique, it is historic in that the notoriety from the King case brought wrong-site surgery (WSS) to the forefront of patient safety initiatives. As a result of its publicity, the Joint Commission initiated its Sentinel Event policy in 1995 as a method to identify and track the leading causes of medical errors within the United States. This initiative mandated that accredited hospitals analyze and report any unexpected occurrence that resulted in death or serious physical or psychological injury to a patient [2]. In 2002, the National Quality Forum (NQF) followed the Joint Commission's lead and developed its own list of 27 Serious Reportable Events [3].

Definition

"Wrong-site surgery (WSS)" is most often associated with surgical procedures performed on the wrong side (laterality) of the correct patient. However, the term WSS actually encompasses a broader definition of surgical errors and includes any procedure that is performed on a wrong patient, a wrong procedure performed on the correct patient, and all procedures performed on the correct patient but at the wrong level or the wrong site such as the wrong vertebral level or the wrong finger. The definition of WSS also includes the placement of incorrect implants and prostheses such as when prosthesis for a left hip is inserted into the right hip or a left corneal implant is placed into the right eye.

Incidence

The true incidence of WSS is difficult to determine. It depends on how one defines WSS, how the data is collected, and whether or not mandatory reporting by institutions is required. For instance, Kwann and co-authors evaluated all wrong-site surgeries reported to a single, large, medical malpractice insurer in Massachusetts between 1985 and 2004. Among the 2,826,367 operations performed at the hospitals within that system, there were only 25 wrong-site operations identified from the malpractice claims. This produced an incidence of 1 in 112,994 operations [4].

Based on these results, the authors concluded that WSS is an exceedingly rare event. However, using single payer malpractice claims to determine the rate of wrong-site procedures underestimates its true incidence. For one thing it fails to identify cases in which malpractice claims were never filed. It should be pointed out that Kwann's analysis excluded spine related procedures. Since spine surgery is one of the specialties at highest risk for WSS, one has to interpret Kwann's results cautiously.

In contrast to Kwann's study, the Physician's Insurance Association of America (PIAA) evaluated claims from 22 malpractice carriers insuring 110,000 physicians from 1985 to 1995. The PIAA study revealed 331 WSS cases and 1000 closed malpractice claims involving WSS. Their study identified a significantly higher number of cases occurring over a shorter period of time when compared to Kwann's analysis [5].

After the Joint Commission initiated its mandatory reporting in 1995, there were 531 sentinel events involving wrong-site surgeries reported between 1995 and 2006. Similar results were seen in several states that also require mandatory reporting of these events. The State of Minnesota reported 26 wrong-site surgeries during their first year of public reporting and another 31 during their second year [6]. In Virginia, a WSS was reported in 1 of every 30,000 surgeries equating to about 1 case per month and in New York, a WSS was reported in 1 out of every 15,000 surgeries [7]. Thus, wrong-site surgeries are not rare events. Wrong-site surgical procedures ranked the highest among all 4074 sentinel events reported to the Joint Commission between January 1995 and December 2006 [8].

WSS affects all surgical specialties. Of 126 Joint Commission sentinel cases of WSS reported between 1998 and 2001, 41% involved orthopedic or podiatric surgery, 20% general surgery, 14% neurosurgery, 11% urologic surgery. The remaining cases included cardio-thoracic, ear-nose-throat, and ophthalmologic surgeries [9]. Wrong-site surgical and invasive procedures occur throughout all surgical and non-surgical settings. Of the 126 cases of WSS reported to the Joint Commission, 50% of the WSS cases occurred in either a hospital based ambulatory surgery unit or freestanding ambulatory setting. Twenty-nine percent (29%) occurred in the in-patient operating room and 13% in other in-patient areas such as the Emergency Department or the ICU [8, 10]. Similar results were found by Neily and colleagues in a review of the Veterans Health Administration (VHA) National Center for Patient Safety database. Of 342 reports of surgical events in Neily's study, there were 212 actual adverse events (62%) and 130 close calls (38%). One hundred and eight (50.9%) of the adverse events occurred in the operating room (OR) and 104 (49.1%) occurred elsewhere [11]. Similar results were reported by the same group in a 2011 follow-up study (see Fig. 12.1) [12]. As with the Joint Commission data, wrong-side surgery procedures in Neily's study were the most common errors performed within the OR while wrong-patient procedures were the most frequent in the non-OR setting. Although intraoperative errors tend to get more publicity, errors performed outside the OR are no less harmful.

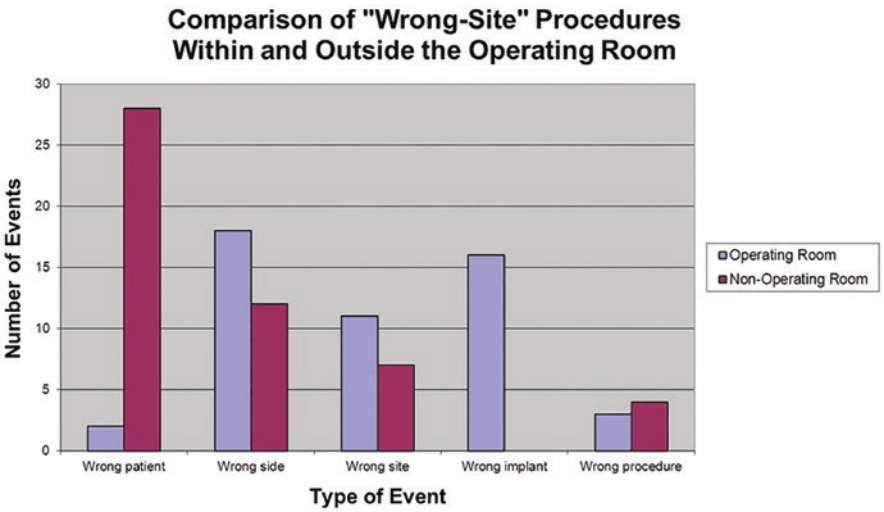

Fig. 12.1 Comparison of Wrong-site procedures performed inside and outside of the operating room based on the Veterans Health Administration patient safety database between July 2006 and December 2009. Of note, wrong-patient procedures outside the operating room outnumbered all other events in either location

Impact

Cases of WSS that result in significant harm are not only devastating to the patient, but also to the families, the caregivers, and the institutions involved. Intense media attention often leads to a loss of public trust in the healthcare system and its providers. Defending these types of errors is nearly impossible and those involved usually pay a significant emotional, professional, and financial price for the event. In Case 2, the young resident had such difficulty dealing with the consequences of her error that she gave up a promising career in medicine (see Chap. 27 on "Second Victim" phenomenon). In the case of Willie King, the Florida authorities suspended the surgeon's license for 6 months and fined him $10,000. The Tampa hospital paid Mr. King $900,000 and the surgeon paid an additional $250,000 directly to Mr. King [13].

The Universal Protocol

Due to the high incidence of WSS identified as a result of its mandatory reporting, the Joint Commission implemented the Universal Protocol (UP) on July 1, 2004 and applied it to all Joint Commission accredited organizations including ambulatory care facilities and office-based surgery programs [2, 7]. The protocol was also to include special procedure units such as Endoscopy and Interventional Radiology. In

Table 12.3 The three steps of the universal protocol for preventing wrong-site surgery [29]

Conduct a pre-procedure verification process Address missing information or discrepancies before starting the procedure. • Verify the procedure, the patient, and the site. • Involve the patient in the verification process. • Identify the items that must be available for the procedure.
Mark the procedure site At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient. • Mark the site before the procedure is performed. • Involve the patient in the site-marking process. • The site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.
Perform a time-out The procedure is not started until all questions or concerns are resolved. • Conduct a time-out immediately before starting the procedure or making the incision. • All relevant members of the procedure team actively communicate during the time-out. • The team members must agree, at a minimum, on the correct patient identity, the correct site, and the correct procedure to be done.

2009, the WHO extended this mandate to require that the "Universal Protocol" be performed for all procedures done outside of the operating room as well [14].

The Universal Protocol consists of three steps: verification, site marking, and "time out." It requires multiple people to confirm that the correct procedure is being performed on the correct location of the correct patient. Table 12.3 describes the intended process for each of these three steps. If there is a discrepancy in the information provided or a team member has concerns regarding the elements of the case at any point during these three processes, the procedure should not proceed until the discrepancy is reconciled [15]. It was hoped that performing the Universal Protocol would eliminate the rates of WSS.

Unfortunately, even after implementation of the Universal Protocol, the problem of WSS still exists. A review of the top 10 sentinel events reported to the Joint commission in 2021 revealed WSS as the fourth most frequent adverse event [16]. Figure 12.2 shows the sentinel event volume reported to the Joint commission by year since the initiation of the UP in 2004 [16]. As shown, despite some variation in numbers from year to year, the overall volume of reported WSS events has not significantly changed. Similarly, a review of the Pennsylvania Patient Safety Reporting System (PA-PSRS) by Yonash and Taylor identified 368 WSS reported events among 368 healthcare facilities in Pennsylvania between 2005 and 2019 [17]. This calculated to an average of 1.42 WSS events per week during the five-year period of which 76% of cases resulted in temporary or permanent harm to the patient. When the data was analyzed by body region, it showed that 24% of the WSS procedures were related to spinal surgery. These findings were not unique to Pennsylvania. The Minnesota Department of Health showed similar findings in its annual adverse event report released in February 2018. Minnesota also showed an overall increase in wrong-site surgical events of which spine surgery was the most reported type [18].

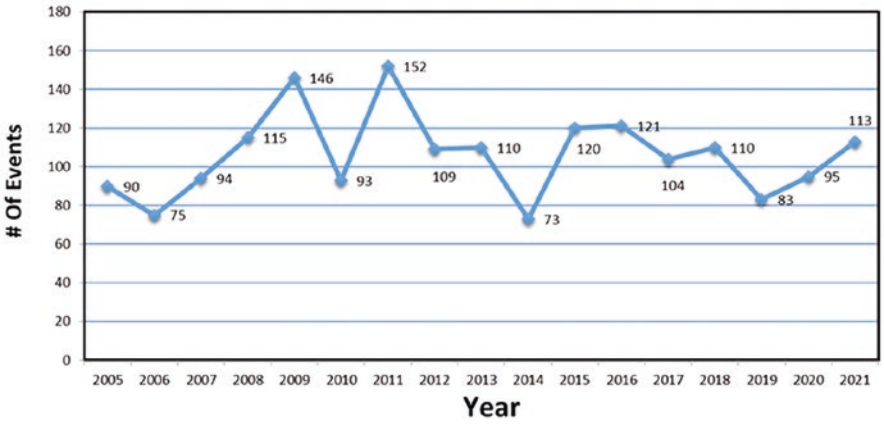

Fig. 12.2 The graph displays the number of wrong-site surgery events reported to the Joint Commission between 2005 and 2021 after the initiation of the Universal Protocol. Although there has been variation form year to year the overall number of events has not significantly changed. (*Printed with permission from Joint Commission* [16])

Based on these results, one might surmise that the initiation of the Universal Protocol has had no impact on preventing WSS events. However, data show that with correct use of the Universal Protocol, wrong-site surgery can be prevented but it appears to be more effective in some procedures compared to others. James and co-authors queried the American Board of Orthopedic Surgery database from 1999 to 2010 in a study to compare the incidence of WSS before and after the initiation of the UP [19]. There were 44 WSS events reported in 609,715 (0.0072%) orthopedic procedures performed between 1999 and 2005 and 27 WSS events reported out of 435,382 (0.0062%) procedures between 2006 and 2010. This difference was not significant. However, when spine related procedures were excluded from analysis, the rate among non-spine surgeries fell by 35% [19]. Neily et al. demonstrated a decrease in the number of incorrect procedures from 3.21 to 2.4 per month in the Veterans Health Administration following the introduction of the protocol [12] while Blanco and colleagues demonstrated a higher compliance rate with site marking in "near miss" cases compared to cases of actual WSS events suggesting that the process of site marking prevented the errors [20].

Root Causes and Potential Solutions

Thus, the UP does have value in reducing WSS procedures. But since its inception we have learned that the prevention of WSS is a complex problem and evidence shows that the UP itself cannot prevent all cases of wrong-site surgery. For instance, a review of the Veterans Health Administration database showed that of 308 wrong-site surgery procedures, 48 (16%) were deemed not preventable through the

checklist process [21]. Thirty-two (67%) of these events were due to "upstream errors" (occurring before the day of surgery) and 16 (33%) occurred "downstream" (after completion of the time-out processes). Examples of upstream events include the mislabeling radiographs, patient reports, and specimens such as biopsies pre-procedure. Surgical booking errors are one of the more common "upstream" errors relating to WSS events [21–23]. In a review of "near miss" and actual wrong-site surgery events, incorrect scheduling was the most commonly cited contributing factor [6]. In a review of 13 cases of WSS from a liability insurance company database, 9 of the errors originated prior to the patient arriving in the perioperative area. These sources of error included an incorrectly printed MRI (11%), a referral to a surgeon that specified the incorrect laterality of pathology (11%), multiple pathologies that were not identified, clarified, or documented during the clinic visit (33%), and incorrect OR scheduling (44%). A tenth error originated in the holding area where the surgeon discussed a change in the laterality of a procedure for a patient with bilateral pathology. The patient did not recall consenting to the contralateral procedure because the patient did so after receiving sedation [24]. Wrong implants for cataract surgery are another example of "upstream errors." Preoperative calculations for intraocular lenses may be mislabeled or erroneously calculated prior to the time of operative procedure [25].

One of the most common "downstream" errors that occur after the initiation of surgery and hence after the completion of the Universal Protocol is the inaccurate localization of the correct vertebral level during spinal surgery. Wrong spine level events account for the high rate of WSS procedures reported in spinal surgery [18, 26–29]. Some of the unique factors contributing to incorrect spine procedures include patient positioning, use of fluoroscopic images, higher mass body index, and anatomic variations [26].

At first glance it's hard to understand why these events occur with such frequency and why they have been so hard to eliminate. It is not a surprise that wrong-site and wrong-side surgeries occur more commonly in the orthopedic, podiatric, neurosurgical, and urological specialties since most of the procedures performed by these specialties involve laterality. However, if laterality was the only risk factor for WSS, then the initiation of "site-marking" would essentially eliminate the problem. Like many other errors in medicine today, the causes of WWS are complex and many factors contribute to their occurrence. The most common of these are listed in Table 12.4 [9, 24]. Awareness of these root causes allows institutions and practitioners to become more vigilant during high-risk situations and may even prompt the institution or practitioner to create additional preventive measures.

For example, it has been shown that wrong-patient procedures are more prone to occur in fast-moving environments. Eye operations are particularly vulnerable to wrong-patient, wrong-site, and wrong-implant errors because they are short procedures with rapid turnover times. There are usually several patients waiting simultaneously at the center for similar procedures involving one or the other eye. The knowledge that such situations increase the risk for error should prompt the team to be more vigilant during their verification and time-out process [7, 9]. Such

Table 12.4 Common risk factors for wrong-site surgery [9, 17]

Patient -related factors
• Morbid obesity
• Physical deformity
• Comorbid conditions
• Presence of bilateral disease
Procedure-related factors
• Emergency case or procedure
• Need for unusual equipment or set-up
• Multiple procedures performed
• Multiple surgeons/physicians involved
• Change in personnel
• Room changes
Environmental factors
• Incomplete or inaccurate communication
• Poor booking practices
• Failure to engage patient or family in the processes
• Unusual time pressures

knowledge may also prompt prevention measures such as scheduling only right- or left-sided procedures on a particular day.

Poor communication and incomplete patient assessment are the two factors that have been shown to contribute most to inadequate patient or site verification. Of 455 wrong-site surgeries reviewed, inadequate communication was deemed to be the root cause in almost 80% of the cases [7]. Types of communication errors include miscommunication, misinformation, information not shared, and information not understood. These communication errors are often perpetuated by incomplete or inadequate preoperative assessments, such as what occurred in Case 1. However, having a process in place by itself will not be effective if the involved individuals do not complete the process appropriately and diligently every time.

Good communication is an active process. It must engage the patient and/or family members in the informed consent and again during the surgical site verification process. A collaborative team approach, with each team member taking individual responsibility to assure the correct patient and site, is the best way to prevent an error due to inaccurate or incomplete information and will serve to catch a "miss" by other members of the team.

Another overlooked cause of WSS includes perception errors due to a person's inability to discriminate right from left. A study of Irish medical students in 2008 showed significant variability in the students' ability to distinguish the right hand from the left hand using stick figure illustrations. The errors in discrimination occurred most frequently when the figures were varied between views of the front and back. This emulates the situation in the operating room where patients are often positioned in different orientations. The study also showed that the ability to perform right-left discrimination was significantly worse when figures were viewed from the front than when they were viewed from the back. This is an important finding since

most patients are supine on the operating table and thus viewed from the front by the surgeon [30].

There are also risk factors unique to certain subspecialties. Wrong-site procedures have been reported by anesthesiologists in association with increased use of regional anesthesia. Reasons include the fact that nerve blocks are performed prior to the surgical time-out. Since the site for the nerve block is usually away from the operative site, marking of the operative site may not be enough to assure that the anesthesiologist injects the correct site. Edmonds reported two cases of wrong-site peripheral nerve blocks and suggested the creation of a policy that mandates that the anesthetic consent specifies the laterality of the surgery and that a separate anesthetic time-out be performed to include participation of the nurse and patient prior to the start of regional anesthesia. Of note, marking of the injection site for regional anesthesia by the anesthesiologist was not advised because a second marking could be a source of later confusion at the time of incision [31].

Dental procedures pose several risks for wrong-site (tooth) surgery. There are currently three major systems that can be used for numbering teeth for identification; (1) the Universal/National System, (2) the Federation Dentaire International System, and (3) the Palmer Notation Method. Each of these systems number teeth differently. Thus, a written notation identifying a specific tooth using one system by one practitioner will refer to a different tooth if a different system is used to interpret that notation by another practitioner. Misidentification also occurs in patients in whom teeth are already missing. Correct identification of the remaining teeth is more difficult because the roots or sockets of the missing teeth are often obscured leading to a miscount of the remaining teeth. To avoid these errors, Lee recommends a standardized referral form for oral procedures that includes a diagram of the mouth for marking the desired pathologic tooth. Since there is no practical way to mark teeth at the time of surgery, it is essential that the correct site be marked on a dental diagram or X-ray [32].

Foot surgery is prone to a similar set of errors because patients use a variety of terms to refer to their toes. One study asked 100 patients to label the toes on each foot choosing to use either name or number according to their preference. The patients had an overall error rate of 11.6%. Other factors that increase the risk for errors in foot surgery include the fact that patients frequently have disease that affects multiple toes, such as gangrene or rheumatoid arthritis, and the fact that foot pathology is common among diabetics who may not be able to see or feel their feet due to retinopathy and neuropathy [33].

Good teamwork, communication, and redundant systems are the only way to reduce these types of errors. However, as more WSS cases are analyzed, it is increasingly clear that "good teamwork" may need to be fostered [34–37]. Institutions that have promoted medical team training programs and the use of checklists, briefings, and debriefings have not only reduced the incidence of surgical errors such as WSS but have shown a significant reduction in overall surgical mortality as well. Haynes et al. reported a decrease in mortality after initiating a

surgery safety checklist involving eight hospitals [38]. Neily and her colleagues demonstrated a dose-response relationship between OR team training and surgical mortality within the Veterans Healthcare Administration System. For each quarter period of team training at a single institution, the risk adjusted mortality rate within that institution decreased 0.5 per 1000 procedures. Data analysis also showed an almost 50% greater reduction in mortality rates in the trained VHA institutions when compared to those that had not yet received training [37].

Preventive Strategies

In order to reduce the incidence of wrong-site surgical events, current preventive strategies must go beyond the use of the Universal Protocol and also focus on eliminating upstream and downstream errors. The Joint Commission Center for Transforming Healthcare identified four main causes for booking errors and recommends a corresponding solution for each. These include (1) verification of booking documents by office schedulers; (2) requiring written requests for surgical bookings and avoiding verbal requests; (3) eliminating abbreviations, cross-outs, and illegible handwriting on booking forms; (4) having consent and history and physical forms available at the time of booking [39]. The Minnesota Alliance for Patient Safety addressed their potential booking errors by creating a booking form that requires the physician performing the surgery to fill out key sections of the form, such as the procedure and laterality [40]. Enforcing simple policies such as removing prior patients' labels and paperwork from the area will help prevent mislabeling of specimens or mixing of reports between consecutive patients [21].

Other efforts at preventing errors have had to focus on the unique challenges within certain surgical subspecialties such as the intraoperative identification of the correct spinal level during spine surgery or assuring the correct lens is implanted during eye surgery. Several reports have been published describing techniques used to assure the correct localization of spine levels [21, 26, 41]. Although there are some small variations in the actual technique described, each of these techniques involve, at a minimum, the use of a metallic marker on a fixed anatomical landmark such as a facet joint followed by radiographic confirmation of the level of the marker to direct the correct exposure of the spine [21, 26, 41]. In order to minimize wrong-implant eye procedures, the VHA standardized its preoperative processes for the calibration of equipment, the performance of axial length and keratotomy measurements, as well as the preparation and transmittal of implant lens calculations across their entire network [21].

Until recently most preventive strategies for WSS have been human-focused interventions such as education, training, policies, and use of checklists. Although still important and useful, time has shown that these strategies alone are not enough to eliminate surgical errors. Given the complexities of the root causes of the various wrong-site error events, there is growing interest in current safety efforts to strike a balance between the traditional approaches of safety management which focus on

reducing and eliminating the number of things that go wrong (termed Safety-I) while optimizing the number of things that go right (termed Safety-II) [42].

Given that for any one healthcare institution, the incidence of WSS events are rare as it makes sense for institutions to also explore and learn from processes that help things to go right. With this concept in mind, the Joint Commission Center for Transforming Healthcare developed the "Targeted Solutions Tool" (TST®) for safe surgery [39]. The TST® is an on-line application that guides health care organization through a step-by-step process to accurately measure their organization's true performance level, identify the causes of performance failures, and direct them to already proven solutions that are customized to address their particular needs. The TST® for safe surgery looks at the entire surgical care system from the time of procedure scheduling through the completion of the operation. It provides the institution with a proactive way to identify risk points in its key processes along with effective strategies to reduce these risks throughout the perioperative period [39].

Moving forward, ideal prevention strategies need to bypass the human factors associated with WSS and utilize innovative technologies and forcing functions to prevent surgical errors. Converting to electronic booking practices with predefined "hard stops" built into the program or requiring two-person confirmation systems to accept critical data entry are simple examples. The "StartBox Patient Safety System" is a novel use of technology currently under investigation to prevent WSS procedures [43]. The StartBox System uses a mobile software application and includes a blade delivery kit that can only be accessed if all safety information has been provided. To date, the system has been tested by 11 orthopedic surgeons doing 487 cases. There were no WSS events reported among the 487 cases, and the system was successful at preventing 17 WSS events (near misses) [43].

Conclusion

Despite focus on the problem of WSS for more than two decades by organizations such as the Joint Commission and the World Health Organization, the incidence of WSS remains above that for a never event. Wrong-patient, wrong-side, and wrong-site procedures occur with equal frequency within and outside of the operating room and with the same risk of harm. The Joint Commission created the Universal Protocol as a mandatory safety standard in 2004 in order to eliminate wrong procedures through the implementation of a pre-procedure verification, site marking, and "time-out' process in order to confirm the correct patient, the correct procedure, and the correct side/site prior to the start of any invasive procedure. Up to 70% of wrong-site procedures can be prevented if the verification and time-out process are performed correctly. The remaining 30% of wrong procedure errors are more difficult to address. Avoidance of these errors requires redundant systems, teamwork, and equal accountability between all members of the operating team and constant

vigilance by all practitioners who participate in invasive procedures both inside and outside the operating room.

Aggressive education of all employees, both clinical and non-clinical, in the prevention of WSS is essential for a successful prevention program. It must include the education of staff in the risk factors and common errors known to occur at each step along the process. But even with the actions mentioned, there is need for additional considerations. Experience shows that to achieve zero wrong-site procedures, preventive strategies must go beyond addressing the human factors. Increased standardization and computerization with the use of forcing functions along with the use of innovative technology may be the only way for WSS to become never events.

Key Lessons Learned

- There must be a policy and procedure in place at every institution to assure the correct patient, correct procedure, and correct site prior to performing any surgery or invasive procedures.
- Errors in information and communication can occur at multiple steps along the process.
- There must be a verification checklist that ensures that all sources of information have been checked before starting any procedure.
- Ensure that all pertinent radiologic studies and pathology specimens have been reviewed and are consistent with the planned procedure, the medical record, and the patient diagnosis.
- Assure effective communication between all members of the operative or clinical team. Special care should be given when information is transferred during handoff procedures.
- Include the patient and/or family member in the process at every feasible point.
- Ensure accurate site markings to include right versus left, multiple structures (finger/toes), or levels of the spine. Use the assistance of radiographs, photographs, diagrams, and forms when marking the actual operative site is not feasible.
- Do not allow time pressures to short-cut completion of the verification and time-out process.
- Train the team so that each member feels empowered to raise concerns. Other members must never belittle or dismiss another's inquiry and should halt all procedures until concerns are reconciled.
- System focused interventions utilizing standardization, computerization, forcing functions, and innovative technology may be the solution to attaining zero wrong-site surgeries.

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Chapter 13
Hospital-Acquired Infections

Ethan D. Fried

Introduction

Hospital-Acquired Infections (HAIs) are infectious complications of care in health-related settings. Common elements involved are a disruption in a patient's normal barriers to infection such as surgical interventions, intravenous lines, and other devices, in concert with the presence of resistant bacterial organisms resulting from the use of antibiotic agents. Strict adherence to sterile techniques and infection control protocols can prevent some HAIs, but antibiotic stewardship and policies that limit the utilization of devices are key. Since the establishment of many HAIs as "never events" by the Center for Medicare and Medicaid Services (CMS) in 2008, the rate of HAIs has been reduced. From 2011 to 2015, the total percentage of in-patients with HAIs is estimated to have gone from 4 to 3.2%. The most significant reductions were seen in surgical site infections (SSI) (0.97–0.56%) and catheter-associated urinary tract infections (CAUTI) (0.58–0.32%). Ventilator-Associated Pneumonia (VAP), C. difficile, and Central Line-Associated Bloodstream Infections (CLABSI) remained essentially unchanged [1]. It is notable that operating room checklists help to reduce post-op wound infections. Also, widely adopted hospital policies allowing nurses to remove bladder catheters at their discretion have clearly been successful in reducing CAUTIs. However, in 2020 a worldwide pandemic of the SARS-CoV-2 virus stretched hospital resources to the breaking point leading to sharp increases in HAIs of all kinds [2]. These increases were

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attributed to the use of traveling agency nurses, a general reluctance to enter patients' rooms to limit exposure, and a depletion of Personal Protective Equipment (PPE) [3].

In 2014, a team from the Centers for Disease Control and Prevention and Emory University School of Medicine released a multistate point-prevalence survey of HAIs which concluded that 4.0% of inpatients at 183 hospitals suffered an HAI. Nearly 22% of these were Healthcare-Associated Pneumonias (HAP), 22% were SSIs, 17% were gastrointestinal infections such as C. difficile, and 26% were related to devices like central venous lines and urinary catheters. The estimated prevalence of HAI was 721,000 infections in the US [4]. The cost of these infections is significant. In 2013, a group at the Medical Education Research Alliance in New Jersey estimated that direct costs of HAIs could be between $34.3 and $74 billion and that indirect costs could be from $61.6 to $72.6 billion for a total societal cost of $96–$147 billion annually [5].

Today, HAIs are included by CMS in determining the "Star Rating" of hospitals so that potential patients can compare the quality of care they might receive [6].

Case Studies

Case 1

Clinical Summary

Ms. Jillian Bass, a 59-year-old woman was admitted to the hospital through the emergency department with neutropenic fever 7 days after an infusion of folinic acid, fluorouracil and oxaliplatin (FOLFOX) for metastatic carcinoma of the colon. Although she was instructed to contact the treating oncologist for any complication, she chose instead to go to the emergency department. She experienced fever to 102.6 °F (39.2 °C) with rigors and general malaise. White blood cell count at the time of admission was 1.7 × 10^9/L. Neutrophils made up 35% of WBCs. Absolute neutrophil count (ANC) was 595.

She was started on intravenous piperacillin/tazobactam (Zosyn) via *her subcutaneous port and IV fluids* via *a peripheral line. She was also given filgrastim to stimulate the recovery of her white blood cells. Routine daily care of the infusion was occasionally performed without gloves due to shortages incurred due to an ongoing COVID-19 pandemic. Over the next week, her fever subsided, and white blood cell count began to recover. On Hospital Day #5, however, the white count was 15 × 10^9. The high white blood cell count was attributed to the filgrastim and her intravenous antibiotics continued. On hospital day #6, she again developed fever to 101.8 °F (38.8 °C). Antibiotics were stopped, all intravenous lines were removed, and the subcutaneous port was de-accessed. Blood cultures were drawn peripherally and* via *the port. Within 24 h, a vancomycin-resistant enterococcus (VRE) was identified in all culture bottles. She was started on intravenous linezolid*

and vascular surgery was consulted for the possible removal of her subcutaneous chemotherapy port.

Root Cause Analysis (Fig. 13.1)

While neutropenic fever is a cause for alarm, guidelines help to manage this complication of cancer chemotherapy. This patient's ANC was less than 1000 but not less than 500. Still the presence of fever makes her a high-risk patient and inpatient therapy with piperacillin/tazobactam was a reasonable choice [7]. The Multinational Association for Supportive Care in Cancer (MASCC) score in this patient is well above the cutoff of 21 points which would identify her as low risk implying that antibiotics could be switched to oral agents if the patient becomes stable [8].

When intravenous antibiotics are used, it is important that neutropenic precautions be taken. These include hand hygiene, standard barrier precautions including infection-specific isolation if needed, patients receiving hematopoietic stem cells or bone marrow transplants being placed in rooms with >12 air exchanges/hour, and high-efficiency particulate air (HEPA) filtration. Plants and dried or fresh flowers should not be allowed in the rooms of these patients. Furthermore, healthcare workers must report any illnesses or exposures as a condition of working with these

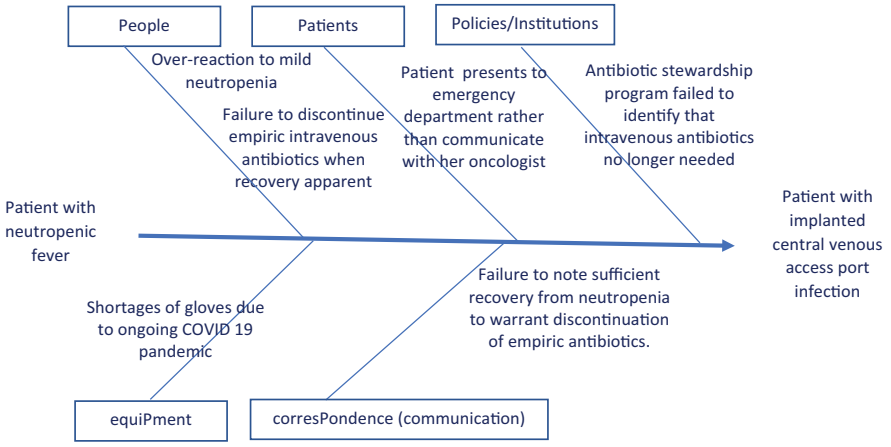

Fig. 13.1 Cause-and-effect diagram for Case 1 using the "5 Ps". The 5 Ps are a useful pneumonic for the branches of the cause-and-effect diagram which can be used to elucidate the potential causative factors of an adverse medical outcome. "People" includes all health care professionals. "Patients" is meant to include unique aspects of the patient involved. "Policies/Institutions" include hospital policies and procedures, outside agency regulations and any other statutory issues that could be related to the outcome. "Equipment" (note the "p" in the middle of the word) includes any equipment used including intravenous lines, pumps, air filters, gloves, antiseptic solutions, etc. "Correspondence" (communications) includes how information is passed from one professional to another through notes, sign-outs, nurses reports, queries from other departments and other instances of information transfer

patients. Procedures for protecting an implanted central venous access port are also important to keep in mind. Avoiding the use of the port except for chemotherapy, intravenous nutrition, and blood transfusions may prolong the life of the port. Of course, strict adherence to central line infection precautions (see the CLABSI bundle in Table 13.1) must be used [9]. In any event, the most effective way to avoid a CLABSI is to carefully monitor the patient's condition and withdraw the central infusion as soon as possible. Despite clear signs of improvement, this patient continued to receive empiric antibiotics via the port for nearly a week. Even when there were already signs of a hospital-acquired infection such as a rising WBC after an initial response to empiric antibiotics, this was incorrectly attributed to the use of filgrastim rather than a new infection. In the end, continued unnecessary antibiotic administration through an intravenous device port in concert with the improper handling of the port due to a shortage of clean gloves during the COVID-19 surge were found to be the primary causes of this CLABSI.

Case 2

Clinical Summary

Four days ago, an 84-year-old man named Charles Frost was sent from the Blessed Virgin nursing home to the Central Valley Hospital (CVH) for fever and severe diarrhea. Before the transfer, he was treated for fever related to a deep sacral decubitus with oral sulfamethoxazole/trimethoprim for 10 days at the nursing home. His white blood cell count went from 10 × 10^9 per L, declining to 2 × 10^9 per L within 5 days on oral antibiotics. Four days ago, he was noted to have voluminous diarrhea which prompted the transfer. On the day that the diarrhea was noted, his white blood cell count was 22 × 10^9 per L.

At the hospital, the patient was diagnosed with presumed Clostridioides difficile colitis. He was placed on contact isolation and was admitted to an isolation room at the far end of the corridor. Stool samples were collected and sent to the lab facility for C. difficile antigen testing, and oral fidaxomicin was prescribed. After 4 days of unremitting diarrhea and attempted fluid resuscitation even with the addition of oral vancomycin, Mr. Frost died in his bed.

Table 13.1 CLABSI bundle to prevent central line infections

1. Hand hygiene
2. Maximal barrier precautions upon insertion
3. Chlorhexidine skin antisepsis
4. Optimal catheter site selection, with avoidance of the femoral vein for central venous access in adult patients
5. Daily review of line necessity with prompt removal of unnecessary lines

That very same day, two other elderly patients on the same floor began to have diarrhea. A root cause analysis (RCA) was requested by the hospital's infection control director.

Root Cause Analysis (Fig. 13.2)

Hospital procedures for cases of *C. difficile* colitis were to place the patient on contact isolation in a private room with a vestibule that had its own sink and antimicrobial soap dispenser. There were only four such rooms at each end of the corridors on the third and the fourth floors. A supply of yellow impermeable gowns and gloves in three sizes were to be placed on a rolling table outside the door of the room. The isolation rooms were to be stocked with their own disposable stethoscopes, blood pressure cuffs, and electronic thermometers with supplies of probe covers so that this equipment would not be carried from one room to another. Brown placards would be placed on the hallway side of the door indicating that the patient within was on contact isolation and warning visitors to see the charge nurse before entering the room.

In the RCA, it was noted that the population of patients admitted with COVID-19 related infections had depleted the supplies of isolation gowns, gloves, and disposable diagnostic equipment. Often personnel would enter the room briefly without isolation equipment or personal protective equipment (PPE). Each staff member developed differently their own protocols for using diagnostic equipment that was later used for other patients (wiping it down with alcohol, placing the chest piece of a stethoscope inside a glove, etc.). These improvised techniques were not considered standard practice. In fact, they revealed a misunderstanding about the

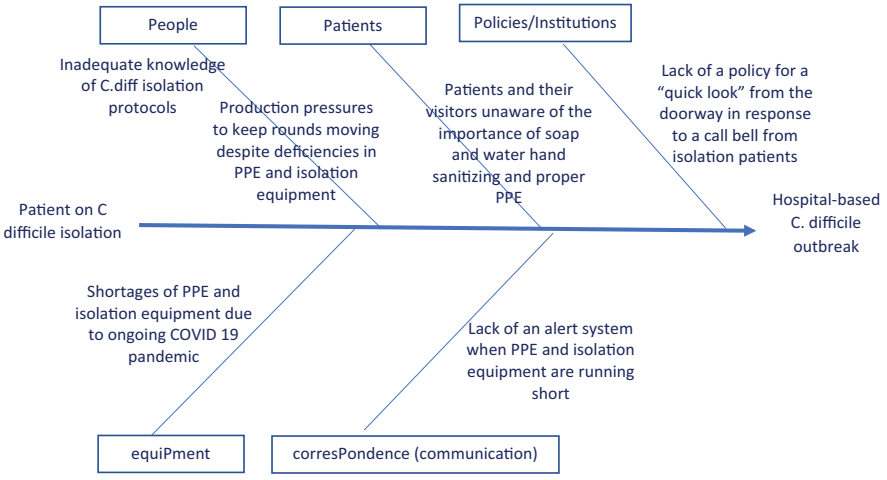

Fig. 13.2 Cause-and-effect diagram for Case 2

ability of alcohol and alcohol-based hand sanitizer to eliminate the spores of *C. difficile* which are more reliably destroyed by washing with soap and water.

In many cases when Mr. Frost pushed his call bell, the nearest nurse would pop in the room without donning PPE to ask what the problem was. If the patient needed hands-on assistance, the nurse would then step out and don PPE but it was known that some simply put on gloves alone and went in to assist him.

The Internal Medicine Resident who sat on the RCA stated that often there was no PPE available near the room so they would enter and examine the patient without PPE. The resident was also unaware of the insufficiency of alcohol-based sanitizer for eliminating *C. difficile* spores.

The RCA committee concluded that *C. difficile* had been spread from Mr. Frost to at least two other patients because of multiple failures of the infection control procedure. They recommended that contact isolation patients be cohorted in the unit adjacent to the one with COVID-19 patients in order to consolidate the supply of PPE to a single location. All personnel were required to review infection control procedures through an online staff education portal.

Standard procedures for cleaning *C. difficile* isolation rooms with bleach solutions and monitoring terminally cleaned *C. difficile* isolation rooms with the use of a handheld meter that tests surfaces for adenosine triphosphate (ATP) were to continue.

In addition, contact isolation would include the marking of a square with red masking tape extending 2 feet from the door into the room. Personnel were instructed that they could stand in this square and speak to the patient from the doorway without donning PPE. However, if they had to enter the room beyond the square, PPE would be required. Finally, red signs were to be placed next to alcohol-based hand sanitizer dispensers near *C. difficile* isolation rooms to inform all that soap and water hand washing was required before and after gloving when working with these patients.

Discussion

Background

Before there was a patient safety movement, there was infection control. In the 1840s, Oliver Wendell Holmes and Ignaz Semmelweis, before the discovery of germ theory itself, independently recognized that the hands of physicians could transmit some agents from the autopsy table to the womb of expectant mothers that resulted in puerperal sepsis and maternal death. Semmelweis demonstrated that rinsing the hands in a mixture of chlorinated lime dramatically reduced maternal deaths [10].

In 1965, E.A. Mortimer and his colleagues demonstrated that the hands of medical personnel transmitted *S. aureus* in a neonatal unit and that hand hygiene with

hexachlorophene prevented such transmission [11]. Modest measures in infection control followed in the 1970s but interestingly it was the concern for healthcare workers in the 1980s and the risk of transmission of HIV virus and viral hepatitis from patients to healthcare workers that really got infection control going [12]. In 1991, the Occupational Safety and Health Administration (OSHA) required hospitals to protect workers from these pathogens. By 2003, the Joint Commission (TJC) launched an infection control-related sentinel event alert and put institutions on notice that deaths and major morbidity related to nosocomial infections were to be treated as sentinel events and investigated by a team of healthcare professionals and that systemic steps be taken to prevent such events [13].

Infection Control as a Multidisciplinary Team-Based Enterprise

Thus, it can be said that infection control was the first aspect of patient safety that utilized the modern quality improvement team-based approach. Recommendations made by Haley and Quadeet et al. published in 1980 described the components of the modern infection control program. They said that an effective team must (1) monitor HAIs and give feedback to workers, (2) institute best practices with regard to sterilization, disinfection, asepsis, and the handling of medical devices, (3) include an infection control nurse and a physician epidemiologist or microbiologist with special skills in infection prevention [14].

As with any quality improvement process, systematic solutions are more effective than staff education. The most effective solutions work behind the scenes and are so integral to a process as to be harder to perform incorrectly than correctly or they are forced functions that do not allow step “B” to be performed until step “A” is completed. These solutions, sometimes called “change concepts” can be as simple as removing a wasteful test from a preprinted laboratory order form. By making physicians write in the name of the test rather than just checking a box, the frequency of ordering this wasteful test is reduced [15]. Antibiotic stewardship is a form of forced function in that one cannot obtain an overused or otherwise risky antibiotic without specifically consulting with an expert who makes sure that the criteria for using it are met [16].

Comprehensive Unit-Based Safety Program (CUSP)

In 2003, researchers from Johns Hopkins University led by Peter Pronovost implemented a system in the intensive care units in 127 hospitals in Michigan in what came to be known as the Michigan ICU project. The system was comprised of a Comprehensive Unit-based Safety Program (CUSP) and the CLABSI bundle effectively reducing CLABSI rates to zero. In 2008, the Agency for Healthcare Research and Quality began to fund a nationwide expansion of CUSP. Today over 750

hospitals across 44 states and territories utilize the "CUSP: Stop BSI" program and the percentage of participating institutions with zero CLABSI over a three-month period is now 69%.

The CUSP system is comprised of five steps [17]:

1. Education of the staff in the science of patient safety as a team function including open discussions of mistakes.
2. Identification of defects in the patient safety system including near misses (good catches).
3. Improving the lines of communication between frontline staff and senior hospital leadership.
4. Implementation of rapid cycle projects to reduce risks triggered by actual events.
5. Broaden lessons learned from the rapid cycle pilot projects into hospital-wide protocols.

Hand Washing Video Surveillance

Although hand washing was historically the first measure proven to fight HAIs, it remains to this day one of the hardest safeguards to use clinically. Healthcare workers' average adherence to hand washing is approximately 40% based on an oft-cited systematic review [18]. Although biologically inferior to thorough soap and water hand washing, hand disinfection with alcohol-based, self-drying hand rubs, gels and foams is thought to improve the adherence to any sort of disinfection routine as to make it a superior strategy to reduce the transmission of infection [18]. Even with the ubiquitous placement of alcohol-based hand rub dispensers, the best-proven measurement of hand hygiene practices and enforcement is direct and video surveillance [19, 20]. Other surrogate metrics include the consumption of hand hygiene materials and dispensers that count the number of actuations. Studies have shown that role modeling by senior clinicians is the strongest motivator of hand hygiene adherence [21, 22].

Standardized Utilization Ratio

In 2022, the National Healthcare Safety Network (NHSN) updated the Standardized Utilization Ratio (SUR) to adjust for facility location level factors. The SUR is simply the "observed device days" divided by the "predicted device days." SUR greater than 1.0 is considered to be an additional risk for HAI. By monitoring their risk according to their local conditions and predicted device use rates, facilities can lower infection rates by reducing SUR to levels less than 1.0 [23].

Central Line-Associated Bloodstream Infection

In the first scenario, a failure to properly monitor the progress of the patient and discontinue intravenous antibiotics (antibiotic stewardship) in combination with nonadherence with sterile technique and PPE policies led to the development of a CLABSI. The prevention of such adverse events depends on strictly monitoring the patient's progress and discontinuing the use of these lines as soon as possible.

In addition to using the CLABSI bundle, the training of residents using simulation with close direct observation and feedback to ensure proper sterile precautions has been shown to help standardize the insertion of these lines which led to an impressive reduction of CLABSI [24].

While the use of the CLABSI bundle and central line insertion checklists clearly reduces infections in short-term catheters, many medically necessary catheters are designed for long-term use defined as longer than 10 days. To prevent infections associated with these catheters, as in the first case discussed, a strategy to reduce the formation of intraluminal biofilm must be used. Factors that have been proven to reduce the growth of intraluminal biofilms include hand hygiene when accessing ports, adequate disinfection of ports, use of split septum rather than mechanical valve needleless connectors, and the replacement of administration sets and add-on devices no more frequently than the manufacturer's recommended rate unless contamination occurs [25] (Fig. 13.3).

C. difficile *Antibiotic-Associated Diarrhea*

In the second scenario, it was determined that isolation room supplies and PPE needed to be available at the point of care. In this case, by cohorting *C. difficile* patients in a location near the isolation units for COVID 19 patients, the important supplies and equipment were more likely to be easily available. This would be considered an example of a "Change Concept" [26].

Antibiotic Stewardship

We have mentioned several times that Antimicrobial Stewardship is one of the key ingredients to the reduction of HAIs. Indeed, in a recent study conducted at four hospitals in Saudi Arabia, HAIs in a population of 79,369 inpatients before the implementation of an antimicrobial stewardship program were compared to 330,034 inpatients after the implementation of the program. Not only did antibiotic expenditures decrease by 28% but rates of HAIs decreased significantly from 2015 to 2019 including an 86% decrease in *C. difficile* infections, a 75% decrease in VAP, and a 94% reduction in CLABSI [27].

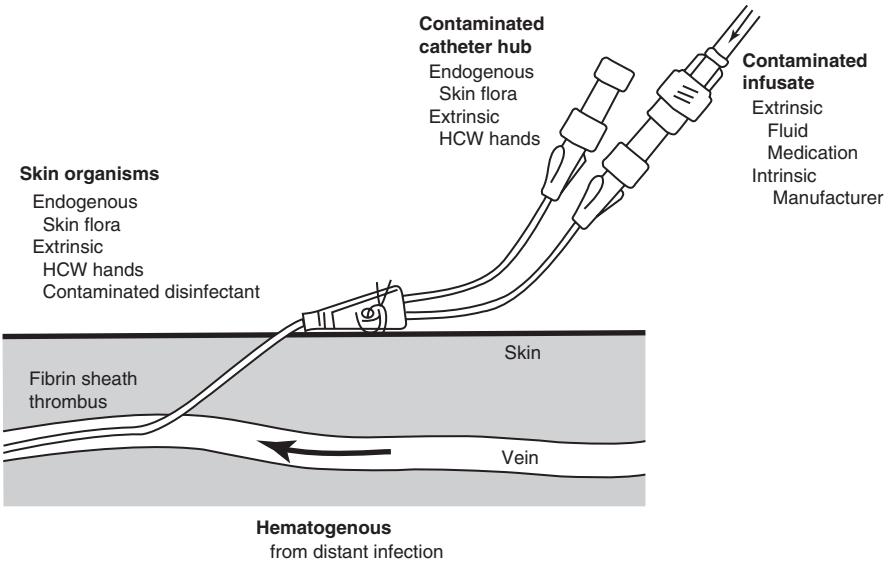

Fig. 13.3 Routes for central venous catheter contamination with microorganisms. Potential sources of infection of a percutaneous intravascular device (IVD): the contiguous skin flora, contamination of the catheter hub and lumen, contamination of infusate, and hematogenous colonization of the IVD from distant, unrelated sites of infection. HCW: health care worker. (Source: Crnich CJ, Maki DG. The promise of novel technology for the prevention of intravascular device-related bloodstream infection. I. Pathogenesis and short-term devices. Clin Infect Dis. 2002 May 1;34(9):1232–1242)

Elements of an antimicrobial stewardship program for clinicians include institutional commitment and accountability for optimizing antibiotic prescribing, an action plan for using evidence-based diagnostic criteria and treatment recommendations and a delayed prescribing practice or watchful waiting when appropriate, a system for monitoring and tracking of antibiotic prescribing with feedback to improve prescribing patterns, and a system of education to practitioners and patients about when antibiotics are not useful, and the potential harms of antibiotics. Elements for facilities include the identification of a single leader of antimicrobial stewardship with the duties of this position written into their job description and communication with all staff about the expectations of this leader, a program of clinical support for clinicians, a call center or pharmacy hotline to triage antibiotic requests, the requirement of explicit justification for unrecommended prescribing, and tracking and reporting of antibiotic usage with transparent data on quality measures associated with the program [28].

Catheter Associated Urinary Tract Infections (CAUTI)

The primary way to prevent CAUTIs seems to be to avoid or limit the use of indwelling urinary catheters. CAUTIs represent up to 40% of HAIs but their consequences vary greatly. Asymptomatic CAUTIs are rarely associated with adverse outcomes and generally do not require treatment. Bacteriuria and pyuria associated with fever or other urinary tract symptoms, however, can lead to renal failure and sepsis and must be treated accordingly. Strategies for the avoidance of CAUTI include alternatives to indwelling urinary catheters like intermittent catheterization and others as well as nursing discontinuation of catheters after measuring bladder volume with ultrasound. It is recommended that when catheters must be used as in patients with obstructive or functional urinary retention, urinary incontinence in the setting of sacral decubiti or other perineal skin wounds or when urine output must be monitored continuously that the catheters be placed under sterile conditions and removed as soon as possible. As with central intravenous lines, a bladder bundle can reduce the number of CAUTI [29] (Table 13.2).

Ventilator-Associated Pneumonia (VAP)

Health Care-Associated Pneumonia (HAP) and Ventilator-Associated Pneumonia (VAP) account for up to 15% of HAIs and are associated with as many as 36,000 hospital deaths. Although there is no gold standard for establishing a diagnosis of HAP, it is generally thought that any pneumonia that develops more than 72 h into a hospitalization falls into this category. Small amounts of gram-negative and resistant oropharyngeal flora are thought to be aspirated causing HAP and VAP. It is important for health care providers to recognize that intubation with an endotracheal tube and feeding with a nasogastric tube do not prevent these microaspirations and may even promote them.

Table 13.2 The bladder bundle: The ABCDE for preventing CAUTI

Adherence to general infection control principles like hand hygiene and sterile insertion
Bladder ultrasound to monitor for the need for catheterization
Condom catheters and other alternatives to indwelling catheters like intermittent catheterization
Do not use indwelling catheters unless absolutely necessary
Early removal of catheters using a reminder or other nurse-initiated removal protocols

Table 13.3 The ventilator bundle to prevent VAPs

1. Head of the bed raised to 30°
2. Daily sedative interruption and assessment of readiness to extubate
3. Peptic ulcer disease prophylaxis
4. Deep venous thrombosis prophylaxis
5. Daily oral decontamination with chlorhexidine

Other factors that may promote HAP and VAP include supine positioning in patients who have altered mental status or who are intubated and the use of proton pump inhibitors for acid suppression which may promote colonization of stomach contents. A ventilator bundle or checklist has been shown to reduce morbidity and mortality associated with VAP [30].

The ventilator bundle is designed as much to reduce some of the complications associated with VAP as it is to prevent the aspiration of infectious material (Table 13.3). Included in the bundle is the peptic ulcer disease prophylaxis, usually with a long-acting proton pump inhibitor (PPI) despite the risk of gastric bacterial overgrowth. The incidence of stress-related ulcers in ventilated patients who develop pneumonia contributes to so much morbidity and mortality that it is safer to use PPI routinely in ventilated patients. Similarly, deep venous thrombosis (DVT) prophylaxis is recommended in the absence of contraindications.

Of all the measures that have been attempted to remove infected material from the oropharynx, oropharyngeal decontamination with chlorhexidine seems to be the most powerful.

A chapter on hospital-acquired respiratory infections would not be complete without mentioning hospital-acquired tuberculosis, legionella, and aspergillus pneumonia. Each of these pathogens can be controlled with the disciplined use of isolation, surveillance, and containment of the offending agents. All suspected tuberculosis patients must be isolated, ideally in rooms equipped with negative pressure and there must be periodic surveillance of the infectious status of health care workers with PPD skin tests. Alert institutions will maintain surveillance of the water and air conditioning systems of a hospital to prevent outbreaks of Legionella. Finally, hospitals that undertake renovation projects must use precautions to avoid the airborne spread of aspergillus, which tends to colonize older construction.

Surgical Site Infections (SSIs)

Surgical site infections (SSIs) occur in 2–5% of surgical procedures which amounts to 300,000 to 500,000 infections each year in the US. With over 230 million operations occurring annually worldwide even a 3% infection rate yields almost seven million preventable infections [31] each adding more than a week of hospitalization, costing up to $29,000 per patient [32] and increasing surgical mortality by 2–11 fold [33].

Many risk factors have been identified that may contribute to SSIs. Recommendations that mitigate these risks can reduce SSI greatly (Table 13.4). Of these, the following four recommendations stand out: appropriate use of prophylactic antibiotics, appropriate hair removal, controlled postoperative glucose control (especially in cardiac surgery), and prevention of postoperative hypothermia (especially in colorectal surgery) [34].

Table 13.4 Risk factors and recommendations to mitigate the surgical site infections (SSIs)

Risk factor	Recommendation
Patient related	
Glucose control	Control serum levels to below 200 mg/dL
Obesity	Adjust dose of prophylactic antimicrobials according to body weight
Smoking	Encourage smoking cessation within 30 days of the procedure
Immunosuppressive medications	Avoid if possible
Nutrition	Do not delay surgery to enhance nutritional support
Remote sites of infection	Identify and treat before elective procedures
Preoperative hospitalization	Keep as short as possible
Procedure related	
Hair removal	Do not remove unless presence interferes with operation. If necessary remove by clipping and not shaving immediately before surgery
Skin preparation	Wash and clean area around surgical site with approved solutions
Chlorhexidine nasal and oropharyngeal rinse	No recommendation. Some evidence that nosocomial infections reduced in cardiac surgery
Surgical scrub (surgeons hands and forearms)	2–5 min preoperative scrub with appropriate antiseptic agent is needed
Incision site	Appropriate antiseptic agent
Antimicrobial prophylaxis	Administer when indicated
Timing of prophylaxis	Within 1 h prior to first incision
Choice of prophylaxis	Appropriate to surgical procedure
Duration of prophylaxis	Stop within 24 h of procedure
Surgeon technique	Eradicate dead space
Incision time	Minimize
Maintaining oxygenation with supplemental O_2	May be important in colorectal procedures
Maintain normothermia	Actively warm patient to >36°. Particularly in colorectal surgery
Operating room characteristics	
Ventilation	Follow American Institute of Architects' recommendation
Traffic	Minimize
Environmental surfaces	Use approved hospital disinfectant to clean visibly soiled or contaminated surfaces and equipment

Mangram AJ, Horan TC, Pearson ML, et al. Guidance for prevention of surgical site infection, 1999. Center for Disease Control Hospital Infection Control Practices Advisory Committee. American Journal of Infection Control 1999, 27(2):97–132

Impact of COVID-19 on HAI Incidence

Throughout 2020 to 2022, an unprecedented worldwide pandemic challenged hospitals in many ways. Hospitals in every state and in every country were inundated with patients and the need for intensive care beds and ventilation equipment outstripped capacity. Before long a combination of infected healthcare workers having to stay away and overutilization of those remaining becoming burned out and leaving healthcare, there were not enough personnel or equipment to continue surveillance and reporting of HAI. As a result, CMS implemented the extraordinary circumstance exception (ECE) policy excusing health care facilities from HAI surveillance and reporting during the first half of 2020. In the second half of 2020 reporting levels returned to pre-pandemic levels. Some institutions continuously reported HAIs throughout 2020. The data that could be collected found significant increases in CLABSI, CAUTI, VAE (Ventilator-Associated Events), and Methicillin-Resistant Staph Aureus (MRSA) bacteremia in 2020 compared to 2019 with the largest increases in the fourth quarter and particularly in the ICU setting where CLABSI increased by 65%, CAUTI increased by 30%, and VAE increased by 44%. At the same time, there were significant decrease for C. difficile, and SSIs remained unchanged (despite the suspension of non-elective surgery in many hospitals).

Decreased adherence to central line insertion and maintenance procedures, longer lengths of stay, increased rates of co-morbidities, increased use of ventilators, and reluctance to enter patients' rooms unless necessary were postulated to account for some of the increases. A decrease in patients receiving intravenous antibacterial may have accounted for the decline in *C. difficile* infections [35].

Conclusions

The preceding cases and concepts in preventing HAIs clearly show that HAIs are amongst the most wasteful and destructive error-related adverse events. In each instance, there are bundled evidence-based processes that offer systematic ways to avoid these complications. These take teamwork and discipline to ensure compliance. Strong leadership that emphasizes the use of bundles and checklists makes safe processes more reliable. Facilities should work to make it easier to do things the right way than to subvert safe practices with "workarounds" [36].

Key Lessons Learned

- HAIs are no longer considered acceptable at any level. They are felt to be a failure of infection control practices, and they erode the trust that patients place in institutions and violate the fundamental principle of "First, do no harm."
- Many HAIs can be avoided through the use of bundled checklists that usually start with hand hygiene and include meticulous sterile techniques when placing, accessing, and maintaining medical devices.

- The most effective way to prevent device-associated HAIs is to carefully consider when they can be removed and then remove them as soon as possible. Nursing professionals can often make this determination such as discontinuing urinary catheters after ultrasonic bladder scans.
- The COVID-19 worldwide pandemic stretched many healthcare facilities' resources to the brink of collapse and during that time, HAIs increased dramatically.
- The simple removal of payment to hospitals when infectious complications prolong hospitalizations alone was not enough to eliminate HAIs but did seem to reduce some forms of HAIs.
- As with almost all patient safety initiatives, a systematic and multidisciplinary approach is needed to successfully prevent HAIs which includes administration and frontline healthcare providers.

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Chapter 14
Hospital Falls

Elizabeth M. Byrd, Cynthia J. Brown, and Rebecca S. (Suzie) Miltner

Introduction

Fall prevention has been the subject of significant research particularly among community-dwelling older adults. Numerous risk factors for falls have been identified, and national guidelines recommend single and multifactorial interventions that are specific to an individual's diagnosis, physical disability, or need [1]. In the past decade, numerous studies have also examined fall prevention practices in the hospital setting. Although progress has been made, there are no universal guidelines for fall prevention in the hospital setting. Indeed, the definition of a fall has yet to be standardized across all hospitals; however, the definition adopted by the American Nurses Association (ANA)'s National Database of Nursing Quality Indicators (NDNQI), which defines a fall as "an unplanned descent to the floor," is frequently cited [2].

Among all hospitalized patients, inpatient falls have been estimated to range between 2.2 and 12 [3] to 20 [4] falls per 1000 patient days. Rates vary depending on the hospital service and the characteristics of the patient. For example, in one academic center, rates for surgical patients were significantly lower at 2.2 falls/1000 patient days when compared to medical patients with a rate of 6.8 falls/1000 patient days. There is also significant evidence that suggests inpatient nursing units that

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treat patients with cognitive deficits have a higher incidence of patient fall events [5]. In another prospective study, 53% of patients who fell were over the age of 65 years [6]. Unfortunately, falls in the hospital are often associated with injury. Approximately 30% of hospital falls result in minor injuries with up to 15% leading to serious injuries such as head trauma, fractures, and death. Patients who suffer an injurious fall are more likely to have longer lengths of stay and are at higher risk of admission to a long-term care facility [3, 7]. Also noteworthy is the psychological effect a fall can have on an individual patient. It is common for a fall to cause significant distress and suffering, which can lead to a fear of falling and co-morbid immobility that negatively affects quality of life and longevity post-discharge [8]. It is estimated that costs are approximately $13,000 higher for patients who sustain a hospital fall [9, 10].

Falls as a Patient Safety Issue

In 2005, the Joint Commission included falls as a National Patient Safety Goal for the first time [11]. Specifically, hospitals were expected to reduce the risk of patient harm resulting from falls. Initially, the focus was identification of those at risk, specifically through medication review and nursing interventions. However, the stakes were raised for hospitals in 2008 when falls with injury were declared by the Center for Medicare and Medicaid Services (CMS) to be a "never event." As a hospital-acquired condition, falls with injury during hospitalization were no longer reimbursed at the higher payment for secondary diagnosis [12]. As hospitals grappled with how to reduce their fall and injury rates, researchers were also trying to provide evidence for best practices. There were also some who raised concerns about the unintended consequences of potential fall reduction strategies, specifically those interventions that reduced mobility and independence [13]. Still others have suggested that a culture of patient safety may hold the key to reducing hospital falls and injuries [14].

Case Studies

Case #1

Mr. Owen is a 78-year-old male with a history of hypertension admitted with an exacerbation of his heart failure. He is evaluated by the attending physician and nursing staff who find he has significant shortness of breath with ambulation, and 3+ pitting edema to the knees. He is unable to lay flat in the bed and is begun on oxygen. He is encouraged by the physician and nursing staff to remain in bed, and a urinary catheter is placed. Within 24 h his fall risk is assessed per protocol using

the Morse Falls Scale [15]. He is found to be at low risk, scoring: 35/125 points for having a secondary diagnosis and heparin lock. His medications include furosemide, metoprolol, acetylsalicylic acid (ASA), and he is started on alprazolam for sleep. On day 3 of the hospital stay, he is found on the floor by the nursing staff. When asked what happened, he reports he wanted to get the water pitcher on the bedside table, but that it had been pushed out of his reach. When he tried to get up to get it, his legs gave away. He complains of right leg pain, and a radiograph reveals a right intertrochanteric fracture.

Case #2

Mrs. McDonald is an 86-year-old woman with early Alzheimer's disease who is admitted with increased agitation and confusion. Per her daughter, Mrs. McDonald lives alone and is able to perform all her own activities of daily living (ADLs) and most instrumental activities of daily living (IADLs). However, she stopped driving a year ago, and the patient's daughter does the checkbook and bill paying. Mrs. McDonald's past medical history is significant for atrial fibrillation, hypertension, and osteoarthritis. Her medications include warfarin, lisinopril, and acetaminophen as needed for pain. Her Morse Fall Scale score is 50/125 with 15 points each for secondary diagnosis and "forgets" limitations, and 20 points for heparin lock. Lab work reveals a urinary tract infection as the probable cause of her delirium and the patient is begun on antibiotics. She is encouraged by the physician and nursing staff to stay in bed. The patient's daughter spends the night with her and Mrs. McDonald does well overnight. On day #2 of the hospital stay, just after lunch, Mrs. McDonald gets out of bed without assistance and has a fall without injury. She is helped back to bed and examined by the physician. There are no new orders, and she is not reassessed for her fall risk. Mrs. McDonald is encouraged by the nursing staff to use the call button, and she nods her head in agreement. However, just before dinner, Mrs. McDonald is again found on the floor, only this time she is noted to have a significant bruise on her left temple area. A CT scan is obtained that reveals a subdural hematoma with some shift. She is begun on q2 hour neurological checks. Approximately 7 h after her fall, Mrs. McDonald is noted to be unresponsive with shallow respirations. A repeat CT shows significant worsening of her subdural hematoma, she is transferred to the ICU, and intubated. She dies the following morning.

In this large, urban medical center, a lot of work had been done to reduce falls including policies for risk assessment, and the implementation of technologies suggested to reduce falls such as bed alarms, low beds, and hourly rounding. A root cause analysis (RCA) was completed for each of these individual events, and each of these two events signaled that there were underlying problems that had not been addressed through the current efforts. Several contributing factors were noted to be systemic issues. For example, Mrs. McDonald's first fall was not directly communicated to the oncoming shift or between resident teams suggesting poor

information exchange between nursing staff members, and between medical staff members. The organization made the decision to complete an **aggregate RCA** due to the recurrent problem with over 80 falls per month (3/1000 patient days).

While RCA is a common tool used to understand the underlying causes of adverse events in healthcare organizations, an expansion of this tool, an aggregate RCA, can help identify trends and systems issues across similar events [16]. The aggregate RCA can be used in lieu of individual case analysis of adverse events or as a method to analyze high-risk processes. Step by step instructions to conduct an aggregate RCA are available [16, 17].

Aggregate Root Cause Analysis

Step One: Charter a Team

The first step in an aggregate root cause analysis is to charter a team to gather and analyze all information about all falls that have occurred for a given period of time. An interprofessional team including hospitalists, geriatric specialists, nurses, nursing assistants, physical therapists, risk management, and service line administrators was formed to review the data about all falls from the previous 12-month period obtained from the adverse occurrence reporting system and additional information from the organization's risk management database. Over 900 falls were reported in this large medical center. Ninety percent of falls occurred on inpatient nursing units, so the team focused on this group of patients for further analysis.

Step Two: Map the Process

In the second step, the team drew a high level process map of the hospital experience related to falls and falls prevention measures (Fig. 14.1). When the patient was admitted, a falls risk assessment was completed by the admitting RN. Physicians may do an informal assessment of falls risks during the admission process. A nursing plan of care is developed to address patient nursing needs. A medical plan of care is developed to address the problems that led to the current admission. Theoretically, the nursing and medical plans of care become the largest component of the interdisciplinary plan of care. This plan of care should focus on desired outcomes of care and should be implemented, evaluated, and modified as needed throughout the hospitalization. The plan of care should also include interventions to address falls prevention. The team found that the development of nursing and medical plans of care is generally parallel processes with little direct integration of each discipline's assessed patient needs and plans to address these needs.

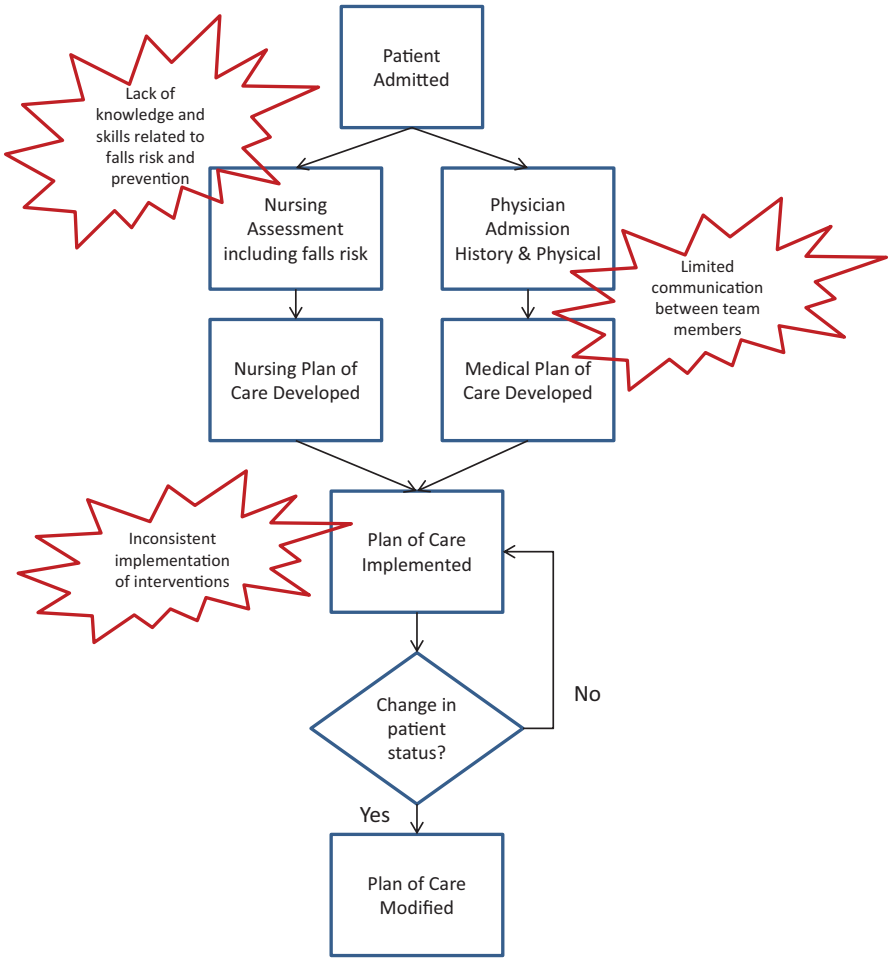

Fig. 14.1 Process map of assessment and prevention of falls

Step Three: Review the General Processes in the System

Next, the team used the high-level process map to review the data available on the 900 reported falls based on each step in the process. Analysis of the data showed several areas for further exploration including assessment of risk, planned interventions, and ongoing communication of patient risk.

Risk Assessment Tools

Best practice suggests hospitals should identify those patients at highest risk and target interventions to those patients. Review of the literature will show there are numerous fall risk assessment tools available [18]. Risk assessment tools are often categorized into two types, tools that assess the factors that contribute to the patient's risk of falling and tools that predict the probability of the patient falling [19]. Multiple risk factors identified across various studies include advanced age, weakness, unstable gait, and the use of certain medications. Environmental factors include the presence or absence of bed rails, the height of the toilet seat, and obstacles in the form of furniture or equipment [18]. Ideally any assessment tool used would accurately identify patients at highest risk; thereby, allowing interventions to be targeted to those in greatest need and resource utilization to be minimized for those not identified as being at risk. Unfortunately, these scales have several limitations including the fact that few of the scales have been validated in more than one cohort of patients. One meta-analysis examined the predictive accuracy of fall risk assessment tools and found that the St. Thomas's Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY) instrument provided greater diagnostic validity when compared to the Morse Fall Risk Scale, and the Hendrich II Fall Risk Model [19]. A former meta-analysis found that the STRATIFY instrument, the Morse Fall Risk Scale score, and nursing clinical judgment all provided similar levels of accuracy [20]. Nonetheless, it remains standard of care to assess patients within 24 h of admission for the risk of falls and periodically thereafter especially if there is a change in their medical status. For Mr. Owen, the addition of the benzodiazepine on day #2 would have triggered a repeat assessment of his fall risk. Mrs. McDonald having been found on the floor on hospital day #2 would also have triggered repeat assessment.

There is a paucity of data regarding risk factors for injurious falls, which may differ from known risk factors for falling. In a single center study that examined variables contributing to falls with injury over a 7 year period, the discharge diagnosis code "symptoms, signs, and ill-defined conditions" was identified as the single significant predictor of injurious falls. Future research should focus on understanding the difference between fall risk and injurious fall risk [21], but at this time, fall risk assessment should be used as a surrogate for injury risk until better instrumentation is available.

Targeted Interventions to Prevent Hospital Falls

Bed and Chair Alarms

Bed and chair alarms are often employed in an attempt to reduce falls. These devices come in a variety of styles including those that are attached to the patient as well as those that are incorporated into the bed or chair. The devices do not prevent a fall. Instead they alert the healthcare providers when a patient is trying to stand or get out of the bed unassisted. To date, the evidence regarding the effectiveness of bed alarms

is conflicted. One uncontrolled 12-month before and after study among patients recovering from hip fracture used bed sensors that were linked to a central pager for all patients on the ward to assess the impact on falls. They showed reduced odds of being a faller (Average Odds Ratio (OR) 0.55, 95% CI 0.32–0.94) but no significant reduction in the fall rate [22]. A cluster randomized trial using bed and chair alarms showed no difference in fall rates, or the relative risk of being a faller despite good use of the devices on the intervention wards [23].

Bed and chair alarms, though they are intended to alert the provider of impending danger, can be triggered by small movements, like reaching for a bedside item, or shifting one's weight in the bed [24]. In this circumstance, bed and chair alarms can contribute to the cacophony of sounds that lead to alarm fatigue, which is desensitization that can occur when clinicians are exposed to an excessive number of false alarms [25]. Bed and chair alarms can also affect patients. In 2017, CMS began discouraging their widespread use in long-term nursing facilities citing the audible noise as a restraint if the patient restricts movement as not to set off the alarm [24].

Low Beds

Beds that are capable of being lowered to within inches of the floor have also been proposed as both a fall and an injury prevention measure. It has been postulated that if a patient falls from the "low bed" they will be less likely to injure themselves due to the relatively short distance they fall before impacting the ground. In addition, it is harder to get up from the low position, making it more likely staff will have time to intervene when a patient is trying to get out of bed unassisted. There has been a single cluster randomized trial of low height beds that included 22,036 participants and found no significant reduction in frequency of patient injuries due to the beds. However, this study also reported no injuries among either the control or the intervention groups [20, 26]. A more recent study argues that low beds may prevent injuries if a patient rolls out of bed and onto the floor but presents challenges for patients who want to ambulate unassisted. Because the low beds were closer to the floor, patients had a more difficult time rising from a seated position to a standing position, and vice versa. This study concluded that low beds should only be used when there is consistent observation of the patient entering and exiting the bed. Otherwise, the low bed could potentially cause patient harm [27]. Further work is needed in this area to determine the impact of low height beds to reduce falls and injuries.

Patient Rounding

Frequent rounding has been proposed as another intervention to reduce falls. Nursing rounds done every 1–2 h have been recommended. In one study of 27 units in 14 hospitals, nurses rounded at 1–2 h intervals with specific actions recommended. They found decreased call bell light use and increased patient satisfaction. There was a significant reduction in falls with 1 h, but not 2 h rounding [28]. An additional

study found that incorporating hourly rounding improved pain management and staff responsiveness scores, while reducing patient fall events by 50% during the project period [29]. Case reports of quality improvement projects implemented on individual units report varying degrees of success. One report cites a 52% reduction in fall events [30] while others report no significant impact in fall prevention [31]. Subsequent studies about rounding have either not used patient falls as an outcome measure or have not found a significant reduction in patient falls associated with rounding [32]. Tucker, et al. found that reduction in the number of falls over time was not sustained with rounding with 4.5, 1.5, and 3.2 falls per 1000 hospital days in three periods over time [2]. Inconsistent results may be related to weak study designs and the fidelity of the implementation of nursing rounds. For example, Deitrick, et al. used ethnographic techniques to examine problems with implementation of hourly rounding. They report that most staff members were unable to verbalize the purpose for hourly rounding [33]. Again, as with the previous interventions, further work is needed to understand the effect of structured nursing rounds and falls reduction.

Increased Ambulation

Often patients are encouraged to remain in bed unless assisted to walk for fear of falls. However, there is growing evidence that limiting patient's mobility in an effort to reduce falls may be the wrong approach. There are significant consequences associated with bed rest and low mobility, especially for the older adult, including functional decline and need for new nursing home admission [34]. Thus, a careful weighing of the risks and benefits of increasing patient mobility is warranted. The Hospital Elder Life Program, which includes scheduled toileting, provision of physical therapy, and early mobilization has been shown to not only reduce the incidence of hospital delirium, but to also reduce fall rates [35]. Studies like this demonstrate that the prevention of hospital falls need not come at the expense of promoting mobility. Rather, the promotion of early ambulation and mobility decreases functional decline and may decrease hospital falls as well [36]. Lastly, von Renteln-Kruse and colleagues tested a structured fall prevention program that included fall risk assessment, assistance with transfers and use of the toilet, provision of ambulatory devices as needed and early mobilization strategies. There was an 18% reduction in falls in the intervention group using this protocol [37] further demonstrating that the promotion of safe and early mobility may actually help to prevent injurious falls.

Multifactorial Interventions

Among community-dwelling older adults, multifactorial interventions which target a variety of risk factors have been very successful in reducing falls among community-dwelling older adults [38, 39]. This method has also been utilized in the hospital setting. In a cluster-randomized study at four hospitals, researchers

examined the effect of a computerized fall prevention tool kit (FPTK) to reduce falls. Patients were screened using the Morse Fall Scale on admission, and specific interventions were identified based on the patient-specific risk factors identified. Dykes et al. found a reduction in the fall rate (3.15 vs. 4.18 per 1000 bed-days) with a rate difference of 1.03/1000 bed-days. In a subgroup analysis, patients who were ≥65 years benefitted the most from the intervention with an adjusted rate difference of 2.08 (95% CI 0.61–356/1000 bed-days). The authors noted the number needed to treat to reduce one fall during a typical 3-day hospital stay was 287 [40]. Three additional systematic reviews have consistently suggested that the incorporation of multifactorial assessments coupled with patient-specific interventions reduce falls in the hospital by 20–30% [26, 41, 42]. Although the tested multifactorial interventions varied widely, several commonly included components included engagement of patient and hospital staff, appropriate fall risk assessment, medication review, and scheduled toileting [43]. To note, one systematic review and meta-analysis that included only prospective controlled-design trials found no conclusive evidence that acute care hospital fall prevention programs were able to reduce falls [44].

Step Four: Identify Resources

This facility dedicated significant personnel and other financial resources for falls prevention over the last 5 years as part of improving overall quality, work toward Nursing Magnet Recognition for excellence in professional nursing practice, and to address pay for performance penalties. The current falls prevention policy included risk assessment, identification of patients at risk, and use of technology and patient rounding to prevent falls. Falls prevention was incorporated in hospital orientation and ongoing competency assessment programs. Data about falls were reported on quality report cards within the organization. And, most importantly, organizational leaders including the Chief Nursing Officer, Chief Executive Officer, and the Hospital Board were keenly interested and engaged in reducing adverse patient events including patient falls.

Step Five: Determine Focus of this Aggregate Review

A review of the aggregate data on falls showed that 60% of the inpatient falls occurred during the evening or night and the majority were related to toileting. Significant interest has focused on the timing and circumstances of falls and the impact of nurse staffing level. In one study, more patients fell in the evening or night and almost 80% had an unassisted fall. Among patients of all ages, at least 50% of falls were elimination-related. However, for patients who are 65 years of age or older this proportion increased to 83% [6].

The organization had structural elements in place to support fall prevention including evidence-based policies and procedures, adequate staffing and staff mix as well as use of technology and other evidence-based interventions. Review of

analyses of previous falls showed that staffing was not identified as a contributing factor in the fall.

As the medical center data was similar to other reported data, the team focused on the actual processes of care on the unit level. The team collected additional data from nursing units including interviewing hospitalists, unit managers, staff members, charge nurses, and unit clerks. Some team members completed observations of several nursing units at change of shift and during physician rounds. Examining the processes of care more closely revealed gaps between the structural elements and the actual processes implemented at the unit and shift level. Falls risk assessment, especially changes in status, were inconsistently reported during nursing handoffs and even more rarely between nursing staff and physician staff. Considerable variation was noted in interpretation of the organizational policies between nursing units and between individual nurses. The team focused on this variation in implementation of falls prevention measures.

Step Six: Determine Root Cause/Contributing Factors

Analysis of the aggregate falls data as well as other data suggested three root causes or contributing factors that affected the inconsistency in policy implementation (Fig. 14.2). First, there was inconsistent communication about patients at risk for falls between nursing staff on the units. Worse, there was virtually no

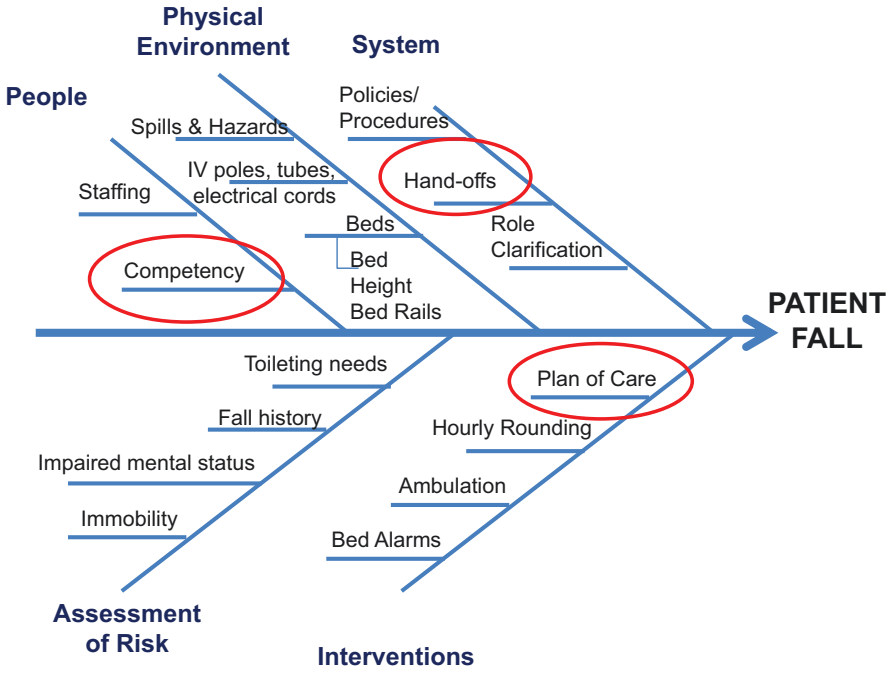

Fig. 14.2 Fishbone diagram of root causes/contributing factors

communication about patients at risk for falls between nursing staff, physicians, or other members of the healthcare team. No formal document or process was consistently used during nursing change of shift reports to ensure consistency of report or to make sure risk information was communicated every time. There was more inconsistency on medical surgical units than there was on critical care units that may be related to the number of patients assigned per nurse. In addition, except in most critical care units, nurses did not consistently round with physicians daily. Falls risk was not generally discussed in medical rounds except as follow-up after an adverse event occurred.

Second, several training and competency issues were identified. Medicine and nursing recognize the importance of practitioners who offer care that is supported by evidence, provided in a technically accurate manner and with the humanistic approach that reflects community expectations [45]. Ongoing professional development as well as competence validation should occur in the practice setting. While this organization had annual education related to falls prevention, this education was delivered in a discipline specific, online format with 5–10 test questions at the end to demonstrate content mastery. Staff frequently bypassed the content and went straight to the test to complete the task. No point of care assessment of content mastery was completed.

Third, there was inconsistent application of the evidence-based policies and procedures in place. Staff attitudes toward certain falls prevention interventions such as hourly rounding were mixed, which is consistent with other studies that suggest that many staff members do not understand the rationale for rounding [46]. In another study, nurses rated rounding benefits for patients, but not for themselves (36.54 vs. 27.83, $p < 0.001$) [32]. In addition, because of the high number of patients identified at falls risk, staff may become inured to the interventions and they become background noise to the numerous other things that must be paid attention to in the shift.

These contributing factors were derived from the aggregate data and team observations of the over 900 falls in this organization. But these were also contributing factors to the two serious events described above. Contrary to evidence, Mr. Owen was instructed by physicians and nursing staff to remain in bed which contributes to debilitation. The structured elements of hourly rounding including placing personal items within reach of the patient were not consistently implemented. And, as previously mentioned, there was no verbal communication of Mrs. McDonald's first fall to oncoming nursing and medical staff which may have heightened awareness of her risk for subsequent fall.

The remaining steps in the aggregate RCA process are to further develop the root causes/contributing factors determined in step six, determine actions to address the root causes, write outcome measures, propose changes to organization leaders for concurrence, and implement the actions [17]. As part of Step Eight, this team determined three actions to address the root causes:

- Units will develop formal processes to communicate falls risk and adverse events to the interprofessional healthcare team. This includes, but is not limited to, nursing change of shift reports and nurse and physician communication about the plan of care.

- The organization will develop an interdisciplinary team training program focused on developing staff competencies that will reduce the risk of hospital induced adverse events.
- The organization will develop accountability measures to reduce variation in patient assessment of risk and implementation of interventions designed to reduce risk.

The team developed outcome measures related to each action and communicated their recommendations to hospital leadership. Hospital leaders recognized that these findings could be applied not only to falls, but to multiple issues including hospital-acquired pressure ulcers and infections.

Fall reduction is an ongoing problem in healthcare organizations because of the complexity of the problem. Even with the ideal implementation of evidence-based policies and procedures, it is not possible to eliminate all falls in hospitals. Worse, the evidence for the best risk assessment measures and preventive interventions is inconsistent and/or weak. In the absence of strong evidence for interventions, organizations have to look at system/contextual solutions to improve patient safety. Success in reducing falls is dependent on developing unit cultures that exhibit characteristics of High Reliability Organizations [47]. These include creating a state of mindfulness for reliability including sensitivity to operations, reluctance to simplify, preoccupation with failure, deference to expertise (not authority), and staff resilience. There is evidence that programmatic team training as recommended by this team can support positive changes in unit culture [48]. Building this reliable culture within an organization requires committed leadership, shared values among team members and attentiveness to the patient safety risks for hospitalized patients.

Key Lessons Learned

- Falls are common during hospitalization and associated with adverse outcomes including fractures, head injury, and even death.
- Evidence for the best fall risk assessment measures and preventive interventions is lacking. The most commonly used interventions include bed alarms, low beds, frequent patient rounding by nursing, and increased ambulation. Multifactorial interventions may be more effective than a single intervention.
- Improving communication and teamwork (for example, among nursing staff during shift change and among nursing and physician staff) regarding falls risk assessments and targeted interventions is the key to reducing the risk of falls related adverse events. Tested interventions may not be enough to reduce falls in hospital systems that do not provide a culture of patient safety.
- The aggregate RCA tool supports process and systems improvement by identifying trends and system issues across groupings of similar events and may be an appropriate tool for patient safety problems like falls, that are high-volume and high-risk.

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Chapter 15
Diagnostic Error

Adam Cohen, Satid Thammasitboon, Geeta Singhal, and Paul Epner

Introduction

Diagnostic errors are common and have potentially catastrophic consequences for patient care. Inaccurate or delayed diagnosis has been described by the Society to Improve Diagnosis in Medicine as, "the most common, most catastrophic and most costly of all medical errors" [1]. This statement is based on several key statistics, including that 12 million adults in outpatient settings experience a diagnostic error annually [2]. Furthermore, it is estimated that more than 100,000 patients die prematurely in hospitals each year due to diagnostic error [3]. In a survey of patients who had experienced a medical error, the most frequently mentioned error was misdiagnosis and nearly six in ten reported it [4]. A 25-year review of malpractice claims found that diagnostic error is the most common complaint [5]. Ultimately, the annual financial impact to the US economy from diagnostic errors was estimated to be in excess of $100 billion per year from 2012 to 2014 [6]. Unfortunately, studies show that these errors are not uniformly distributed across the population, but rather disproportionately affect vulnerable groups associated with gender, race, ethnicity, age, and socioeconomic factors [7]. However, the most impactful comment about the burden of diagnostic error might also be the most intuitive: an accurate and

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timely diagnosis is fundamental to the right care plan for the patient's complaint. Without understanding the patient's illness, the treatment plan might be suboptimal or even harmful.

Case Summaries

Case 1

A 70-year-old male presented to emergency department with severe abdominal pain and shock. After a comprehensive investigation, he was diagnosed with a ruptured abdominal aortic aneurysm (AAA). After an emergent repair of the AAA, the patient developed paraplegia.

Upon review of his medical records, 5 years ago, the patient was found to have a "very small AAA" on routine screening due to heavy cigarette use. Three years ago, he was diagnosed with nasopharyngeal carcinoma, underwent chemotherapy, and is now in remission. Two years ago, he had a planned cancer follow-up of his CT chest and abdomen which showed no evidence of any metastases. However, among other detailed findings, the report noted a 4.6 cm AAA, "a slight increase" in size compared with the previous CT. Of note, the patient did not recall if he had been informed of this finding or if he needed to be seen for follow-up.

Case 2

A 15-year-old male underwent a laparoscopic paraesophageal hernia repair and was admitted to the oncology ward for postoperative care due to the surgical ward being full. The patient's mother was alarmed to see that her son appeared pale and restless, "dripping with cold sweat," as they had been informed this was "a minimally invasive procedure." While the procedure took longer than usual, the anesthesia team's handoff to the first- year resident noted that the "patient did well and that the surgery was uneventful."

Despite the mother's repeated requests for doctors to see her son, she was reassured by the nurses that the patient probably had some abdominal pain from intestinal ileus. All of the front-line residents were busy all night, but briefly assessed the patient a couple times and prescribed analgesics and a suppository. The mother was frustrated and could not communicate fluently as English was not her first language. Given his unremitting "pain," the mother then requested "upper level" physicians be consulted. The nurse informed the mother that the surgical team was dealing with emergencies in the OR. The chief resident prescribed morphine and fluid bolus over the phone to address his pain and persistent tachycardia. The patient and the mother then stopped asking for help and slept through the night. In the morning, the nurse was unable to obtain his blood pressure after multiple attempts. A code was called

for cardiopulmonary arrest. The patient was taken to the OR for emergent exploratory laparotomy and found to have intra-abdominal bleed from the gastric vessels. After repair of the vessels, he recovered and was discharged home in good health.

Case Analysis

The diagnostic error has continually gained attention in the past decade. This type of error is now recognized by the ECRI Institute as the foremost patient safety problem in healthcare today [8]. While there have been multiple iterations of what constitutes a diagnostic error, the landmark report from the National Academies of Sciences, Engineering and Medicine (NASEM) from 2015 on Improving Diagnosis in Health Care [9] brought a unifying definition to the field. This report conceptualizes the definition through a sociotechnical model [10], illustrating the diagnostic process and its outcomes that serve as a framework for a dual focus on error reduction and improving care quality (Fig. 15.1). The NASEM model describes a complex, collaborative and iterative process that evolves over time and is situated within a system context, with acknowledgment of outside factors that inevitably influence the process. Opportunities to improve the diagnostic process and outcomes always exist through an adaptive learning process of the system to "reduce diagnostic uncertainty, narrow down the diagnostic possibilities, and develop a more precise and complete understanding of a patient's health problem" [9].

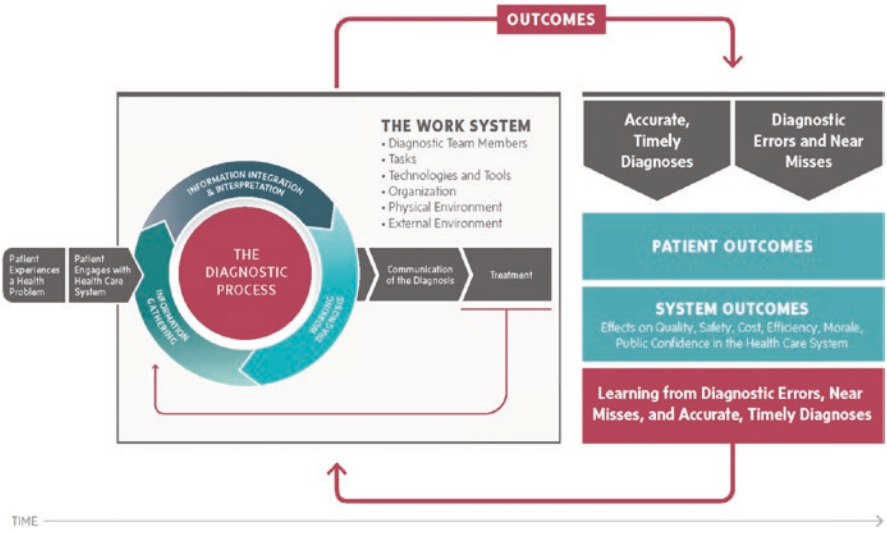

Fig. 15.1 The diagnostic process and its outcomes, according to the National Academies of Sciences, Engineering and Medicine [9]

The report defines a diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient." An inaccurate diagnosis can be defined as differing from the true diagnosis due to imprecision, incorrectness, or incompleteness [9]. However, defining a "timely" diagnosis is challenging to determine as it is situation-dependent. Experts have defined "significant delay" as patient care cases in which there were apparent missed opportunities to establish a diagnosis earlier and which could have led to a change in management that improves patient outcomes [11, 12]. Many cognitive factors can contribute to making an inaccurate and/or delayed diagnosis, including a number of cognitive biases and heuristics, as well as inadequate data collection and inadequate knowledge [9, 13].

Both cases above illustrate a diagnostic error according to the NASEM definition. Case 1 illustrates a missed diagnosis: the opportunity to detect and intervene on a clinically significant AAA was missed according to existing guidelines which recommend more frequent surveillance when the AAA is greater than 4 cm in size. Studies have shown that patients with small aneurysms who do not undergo the recommended surveillance or who are lost to follow-up are more likely to present with rupture [14]. The patient in this case also suffers from a misdiagnosis-related harm, with subsequent paraplegia after his ruptured aneurysm. While Case 2 represents a failure to make a timely diagnosis, even this case is debatable. An "experienced" clinician might have suspected an intrabdominal bleed, but the optimal timing of making a diagnosis can be challenging to determine, and ultimately, the patient recovered.

As illustrated by Case 1, where there was a failure to communicate the radiologic findings and trigger the appropriate action, ineffective communication within the diagnostic team can lead to error. However, communication of diagnostic findings to the patient cannot reliably guarantee that an appropriate action will be taken. Unfortunately, patient harm due to communication breakdowns is a major factor relating to diagnostic error. An accurate and timely explanation of the health problem can only be accomplished when the information is conveyed and clarified to the extent that both the patient and the health care team can implement the appropriate action(s). Communication mishaps related to diagnostic testing may account for nearly half of all errors made by typical primary care physicians in their practices. In a study that examined patient stories with communication errors, communication-related breakdowns were found to be in two distinct themes: (1) provider-focused communication and (2) patient/family communication. Strategies for clinicians include taking patients/family members' questions and concerns seriously and providing timely and meaningful information. Patients are encouraged to be assertive and proactive, which can be done by asking questions, reporting concerns, following up, and getting second opinions [15].

Some failures in the diagnostic process, however, will not automatically lead to a diagnostic error as subsequent steps in the process may compensate for the initial failure—also known as near misses. Though the patient in Case 2 had a full recovery after an emergent exploratory laparotomy and suffered no harm, a formal root cause analysis is warranted. Even though timely diagnosis of the abdominal bleeding may have prevented hypovolemic shock, system failures also contributed to the near

miss and should be addressed. System issues may include a lack of standardization in care, errors with the electronic health record (EHR) system, a lack of availability for communication tools including language interpreters, and many more. A robust work and safety system should learn from these failures and design strategies to improve diagnosis and prevent errors.

Discussion

Diagnosis might just be the most complex process in medicine. A specific problem can present quite differently from patient to patient, and even within a single patient as the illness evolves over time. Patients and clinicians alike will describe the complaint at each encounter quite variably [16]. Those descriptions can be further nuanced by multiple modifiers, such as time of day, and/or exacerbating or alleviating behaviors. In seeking evidence to prove or disprove a working diagnosis, the clinician can choose from several thousand standard clinical pathology tests, genetic tests, imaging modalities, and other testing methods. Based on symptoms, relevant history that includes comorbidities, medications, social determinants of health, and test results, the clinician must then choose the correct diagnosis from a list of approximately 70,000 ICD-10-CM diagnostic codes [17]. Despite this complexity, research findings estimate that clinician accuracy ranges from 85 to 90% [18]. However, given the residual burden, attention must be paid to diagnostic errors. In fact, the NASEM report concludes that "Improving the diagnostic process is not only possible, but it also represents a moral, professional, and public health imperative." [9].

As illustrated by the NASEM framework, diagnosis is iterative with multiple working diagnoses considered before a final diagnosis is made. The urgency with which a diagnosis is pursued, i.e., the diagnostic pace, is influenced by schedules, consideration of cost, assessment of risk and other factors often decided without consideration for patient preferences, especially in ambulatory settings. The role of clinical judgment plays a significant role in diagnosis, posing both a challenge for measurement and for improvement. Malpractice literature found that when examining claims leading to death or permanent disability, clinician judgment was a contributing factor in 85% of cases. Since such claims averaged more than three contributing factors, judgment was not the only problem, but it was the most frequent problem [19].

Judgment is also influenced by cognitive biases, both explicit and implicit, adding another layer of difficulty in both measurement and improvement [20]. Table 15.1 describes some of the common cognitive biases that can influence diagnostic decision-making.

While improvements can be made, challenges remain. The uncertainty surrounding diagnosis leads to measurement problems when tracking diagnostic error. In fact, we lack generally accepted standards for measuring accuracy or timeliness [22]. Without certainty, the ability to assess accuracy will always be imprecise.

The risk of such failures can be mitigated by ensuring that robust well-designed systems are in place, by having a safety-first organizational culture, with

Table 15.1 Common cognitive biases [21]

Availability heuristic	Tendency to accept a diagnosis due to ease in recalling a past similar event or case, rather than based upon statistical prevalence or probability
Representativeness heuristic	Improper use of pattern recognition to detect representative characteristics (prototype) to diagnose a condition, which can predispose physicians not to consider differential diagnoses
Anchoring	Tendency to stay with an original diagnosis despite evidence to the contrary
Diagnosis momentum	The tendency for an opinion or working diagnosis to become almost certain when it is passed from person to person and suppresses further evaluation
Omission	The tendency toward watchful waiting and reluctance to treat for fear of being held responsible for adverse outcomes, preferring that an event be seen to happen naturally rather than as a result of action taken by a physician
Confirmation	The tendency to seek out data to confirm one's original idea rather than to seek out or validate disconfirming data
Premature closure	The tendency to apply closure to the diagnostic process too early on the basis of vivid presenting features that may be convincing for a particular diagnosis, such that the correct diagnosis is not considered

practitioners skilled in physical exam, patient history taking, and with clinical reasoning capabilities. It is this last category, as much as any other, that makes the improvement task so daunting and often leads to organizational and clinician inertia. The frequency of a specific error type in a specific setting for a specific condition can often be low. It is only in the aggregate that the burden demands attention. Challenges additionally arise as the diagnostic process occurs over time, complicating error recognition by those engaged in the process. Yet these are precisely the opportunities for meaningful improvement that can reduce harm.

Approaches to Reducing Diagnostic Errors

Establishing how to identify, measure, analyze, learn, and intervene on practice will mitigate diagnostic error occurrence. While some organizations will address a specific diagnostic problem driven by leadership priorities, complaints, or other external realities, many will benefit from first establishing a culture of awareness, active learning, and infrastructure building. Only then can they prioritize and pursue specific improvement opportunities.

Step 1: Identification of Diagnostic Error

Whether designed to engage in broad learning or to embark on a specific improvement effort, strategies to address these important errors begin with identifying diagnostic error cases. Common data sources are patient complaints, autopsy reports,

malpractice claims, and incident reports. However, many reporting systems lack a category for diagnostic errors, which complicates their utility. Local attempts to remediate that gap successfully led to increased discovery of diagnostic errors [23]. Investigators have also used EHR surveillance algorithms to design a simple mechanism for identifying diagnostic errors [24]. While the surveillance method works, the sensitivity was found to be relatively low. Attempts to refine the algorithms led to somewhat improved results [25, 26]. Other health systems have sought to have their clinicians voluntarily report diagnostic errors for the purpose of learning with some notable successes [27–29].

Once potential diagnostic errors have been identified, the next step is to determine whether the incident truly reflects a diagnostic error. Many organizations have used the Revised SaferDx tool to make that determination [30]. For an error to be classified as a diagnostic error, a missed opportunity must exist. The intent is that the understanding of missed opportunities will allow for focus of improvement efforts on failures with an identified mechanism for improvement. This approach, however, may inadvertently lead to the elimination of important diagnostic errors from consideration in which there is no missed opportunity that can be identified within the system's current capabilities while another organization with different capabilities might recognize it as a missed opportunity.

Step 2: Classification of Diagnostic Error

After identifying diagnostic errors for study, they can then be classified by the process step where the error occurred or by the contributing factor(s) that were involved. The NASEM process (Fig. 15.1) can be the basis for defining the process step and classify the contributing factor (Fig. 15.2). A common alternative approach is the

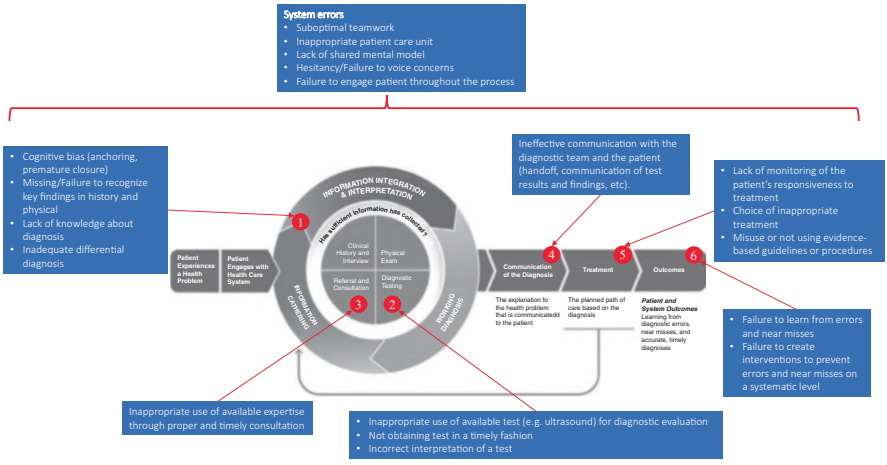

Fig. 15.2 Error analysis overlayed on NASEM's diagnostic process framework [9]

Diagnostic Error Evaluation and Research (DEER) Taxonomy, which offers a more granular analysis of process steps than NASEM, and Reliable Diagnostic Challenges (RDC) to determine contributing factors derived from a published pitfall approach [31]. The DEER Taxonomy can be found in Table 15.2.

Table 15.2 Diagnostic Error Evaluation and Research (DEER) taxonomy

Diagnostic process	Failures
1. Access/presentation	A. Failure/delay in presentation B. Failure/denied care access
2. History	A. Failure/delay in eliciting a critical piece in history B. Inaccurate/misinterpreted critical piece in history C. Suboptimal weighing of a critical piece of history D. Failure/delay to follow up on a critical piece of history
3. Physical examination	A. Failure/delay in eliciting a critical physical exam finding B. Inaccurate/misinterpreted critical physical exam finding C. Suboptimal weighing a critical physical exam finding D. Failure/delay to follow up on a critical physical exam finding
4. Tests	**Ordering** A. Failure/delay in ordering needed test(s) B. Failure/delay in performing ordered test(s) C. Suboptimal test sequencing D. Ordering of wrong test(s) E. Test(s) ordered wrong way **Performance** F. Sample mix-up/mislabel G. Technical errors/poor processing of specimen/test H. Erroneous laboratory/radiology reading of test I. Failed/delay transmission of result to physician **Clinical processing** J. Failed/delayed follow-up action in test result K. Erroneous physician interpretation of test
5. Assessment	**Hypothesis generation** A. Failure/delay in considering correct diagnosis B. Suboptimal weighing/prioritizing C. Too much weight to lower probability/priority diagnosis **Recognizing urgency/complications** D. Failure/delay to recognize/weigh urgency E. Failure/delay to recognize/weigh complications
6. Referral/consultation	A. Failure in ordering referral B. Failure/delay obtaining/scheduling ordered referral C. Error in diagnostic consultation D. Failure/delay communication/follow-up consultation
7. Follow-up	A. Failure to refer patient to close/safe setting/monitoring B. Failure in timely follow-up/rechecking of patient

Step 3: Analysis of Diagnostic Error

To learn from cases, a systematic analysis is required to identify areas for improvement. Historically, system-oriented failures and failures in cognition were handled separately. However, to bifurcate analysis into the two traditional paths ignores the interplay between the contributing factors. Tools, such as a modified RCA approach, have been developed that incorporate the dual nature of these errors, [32] but adoption of this combined approach has been limited. Summaries of separate approaches are published and should be reviewed for applicability in any new improvement efforts [33–35]. Case reports of system-wide approaches to organizational learning and change are available and instructive to organizations wishing to embark on a campaign to build awareness, secure engagement, and identify opportunities for improvement [36, 37].

Step 4: Interventions to Reduce Diagnostic Error

Reports of interventions directed to team-based diagnosis are found less frequently, an area that NASEM reported was needed [9]. Effective teams would include new roles for nursing, laboratory and radiology professionals, and others [38, 39]. Studies that have examined this focused largely on the in-patient population, [40] including TeamSTEPPS, which was developed by that Agency for Healthcare Research and Quality and available at their website [41]. Additionally, interventions designed to engage and empower patients, either as a member of the clinical team or as an individual, are rare but have the potential to mitigate error. Research has demonstrated that patient engagement is useful in reducing safety issues generally [42]. Patient care engagement is key, as patients have the most complete knowledge of their experience and are the common denominator in a diagnostic journey that often includes changing practitioners and settings. Another promising area for intervention involves expanding the patient's interaction with online test results and clinical encounter notes, now available to them by federal regulations [43]. Efforts to engage patients through this capability have proven to reduce diagnostic delays through more timely follow-up, reduce diagnostic inaccuracy through identification of documentation errors, and increase patient engagement in their care, especially those who are underserved [44, 45]. Patients and their families can be educated about what symptoms to look for, the expected time course of their illness, and how to seek help if their condition does not improve or new symptoms emerge. Patients can be also encouraged to ensure that their test results are reviewed.

Cognitive errors are one of the most common causes of diagnostic errors [9]. As Fig. 15.2 shows, failure to establish a differential diagnosis is a major issue. While

clinicians who limit their consideration to the most likely diagnosis will still perform well in that the most likely is often the appropriate explanation for the patient's complaint, they will do little to reduce avoidable harm. Improving diagnostic quality necessitates a more robust differential to avoid a "failure to consider" error. This error is often associated with limited experience or knowledge. Several quality improvement approaches have sought to support clinicians in this endeavor. Organizations have used checklists tied to chief complaints to ensure that a more robust differential of likely and "can't miss" diagnoses are developed [46]. Differential diagnosis generators are a software tool that serves the same purpose as checklists. While research into their efficacy has shown mixed results, their potential holds promise [47]. Also known as clinical decision systems (CDS) or computerized diagnostic decision support systems (CDDSS), a large meta-analysis conducted in 2015 found that these tools are scattered and suggests that a more standardized, computable approach is needed to support the integration of new knowledge and integration into the electronic health record [48].

Another strategy that shows promise are audit systems, but they have not been studied in great detail. An audit system is defined as a system that provides an individual or an organization a performance measure against professional standards or provides feedback to the individual or organization [49]. Examples of this range from interventions such as processes, systems, models, programs, and procedures designed to ensure that certain activities are carried out effectively and consistently. In this meta-analysis, results showed that trigger algorithms, including computer based and alert systems, may reduce delayed diagnosis and improve diagnostic accuracy.

Finally, the use of simulation software to expand the clinician's exposure to situations that their own personal experience might not have encountered may be useful [50]. Reduction in availability bias through simulations have been shown to be especially helpful in atypical presentations that are relatively high in frequency, e.g., stroke presenting with dizziness, but are expected to be less useful for uncommon events, e.g., a young women presenting with dysphagia who ends up having esophageal cancer.

A frequent system issue that causes harm is a failure or delay in obtaining consultation or referral. Several systems have used algorithms applied to their clinical database to look for omissions of care when compared to locally defined guidelines [51, 52]. For example, the database is periodically queried for patients who had an elevated PSA, but for whom there is no record of a follow-up appointment with urology or oncology within a specified time. If the logic finds such a patient, it is able to address the missed action. This approach does not prevent non-compliance with the guideline, but does ensure that it is recognized quickly before any harm occurs. A secondary benefit of this approach is that the rate at which various algorithms are triggered can serve as a measure of diagnostic near misses. This approach is especially well suited for ambulatory care where diagnoses occur over longer periods, but for which there is little current attention to improvement.

Step 5: Measurement of Improvement

When embarking on a specific improvement effort, measures are needed to determine if these improvements help the patient. The National Quality Forum (NQF) has undertaken efforts to catalyze measure development and produced lists of measure concepts suitable for consideration during improvement efforts [53]. The Gordon and Betty Moore Foundation is also supporting the development of measures through the Diagnostic Excellence Initiative [54]. An update on the state of measurement in diagnostic safety was recently published [22] and highlighted numerous strategies to consider when utilizing different data sources and measurement techniques.

The Road Forward

Studying and improving diagnosis is a complex undertaking and much remains to be done toward identifying effective and efficient interventions. Every year more attention is being paid to the importance of improving diagnosis. The U.S. government is now funding research efforts specifically targeted to diagnostic quality. Inclusion of patients in measurement and improvement activities is becoming more common and there is an ever-expanding inventory of clinical decision support tools and machine-learning applications.

Technology innovations are also expanding quickly, however, with limited understanding of the unintended consequences of their use on diagnostic quality. The advent of telemedicine, and specifically telediagnosis, has increased access and timeliness for many patients, but little is understood of what is lost when the clinician and patient are not physically in the same place [55]. While machine-learning and CDS show real promise in reducing cognitive burden and increasing diagnostic quality especially in the area of perceptual analysis, i.e., anatomic pathology and radiology, machine-learning, rules derived from a non-representative sample of patients also run the risk of hard-wiring diagnostic bias [56].

While substantial progress has been made in recognizing and understanding the causes of diagnostic error, measuring the frequency of the problem and of identifying interventions to mitigate it are still being developed. Given the burden of diagnostic error, solutions will come from patients, clinicians, healthcare leadership, and policy makers who prioritize and collaborate to achieve improvement in diagnosis through increased attention to data collection, quality improvement, and shared learning.

Key Lessons Learned

- Diagnostic error is defined as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient." While seemingly simple, diagnostic error can be tied to multiple different systematic and cognitive errors.

- While much work has been done in defining and improving the burden of diagnostic errors, there are still many areas that need further investigation, including identifying and measuring diagnostic errors, and finding consistent safety interventions to prevent them.
- Mitigation strategies are continuing to evolve and include the use of artificial intelligence, software tools, and computer algorithms to identify diagnoses and appropriate consultation, increasing patient engagement in the diagnostic process, bias mitigation protocols, and teamwork improvement interventions.

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Chapter 16
Opioid Safety

Sarah Pressman Lovinger and Elise Wessol

Introduction

The overuse and inappropriate prescribing of opioids have contributed to a deadly public health crisis in the United States. From 1999 to 2017, more than 700,000 residents have died from a drug overdose, the majority of which involve an opioid [1]. Clinicians use opioids to treat chronic non-cancer pain (CNCP) despite a lack of evidence that opioids treat chronic pain more effectively than non-opioid pain relievers [2]. Three to 4% of the adult US population receives long-term opioid therapy [3]. Patients taking chronic opioids experience numerous poor outcomes, including a greater likelihood of hospitalization and death from overdose [4]. Patients prescribed chronic opioids also face the risk of developing an opioid use disorder (OUD), with features of OUD present in more than 25% of patients receiving opioids for chronic pain [5]. Table 16.1 describes the DSM-5 (The Diagnostic and Statistical Manual of Mental Disorders, 5th edition) criteria for OUD. Untreated OUD strains the healthcare system and puts patients' lives at risk [5].

The millions of Americans taking daily opioids for CNCP face additional health burdens. Patients with coronary artery disease, chronic kidney disease, and obstructive sleep apnea incur a higher risk of hospitalization and death when taking opioids for chronic pain. Polypharmacy with CNS depressants for the treatment of pain and anxiety and insomnia also increases the overdose risk. The addition of benzodiazepines prescribed to people on opioid pain medications significantly heightens overdose risk to the additive effects [6]. Despite these risks, the proportion of US adults prescribed chronic opioids who were co-prescribed benzodiazepines increased from 9 to 17% between 2001 and 2013. Gabapentin, a neuroleptic

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Table 16.1 DSM-5 criteria for diagnosing a substance use disorder

Substance Use Disorder DSM-5 Criteria
A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within the past 12 months:
Impaired control
Opioids are often taken in larger amounts or over a longer period than was intended
There is a persistent desire or unsuccessful efforts to cut down or control opioid use
A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects
Craving, or a strong desire or urge to use opioids
Social impairment
Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home
Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioid use
Important social, occupational, or recreational activities are given up or reduced because of opioid use
Risky use
Recurrent opioid use in situations in which it is physically hazardous
Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
Pharmacological (only if not due to prescription medications taken as prescribed)
Tolerance
Withdrawal (if applicable)

Ref: The Diagnostic and Statistical Manual of Mental Disorders (5th ed.; **DSM–5**; American Psychiatric Association, 2013)

commonly prescribed off-label for the treatment of pain, can also potentiate the risk for opioid overdose when combined with opioids [7].

US adults developing OUD following prescribed opioid use represent a further challenge to our healthcare system due to lack of standardized education and treatment efforts by clinicians. A recent study found that people who were prescribed opioids for CNCP were eight times more likely to initiate injection drug use than opioid-naive individuals to avoid withdrawal symptoms [4].

The US overdose epidemic transpired in three waves. It started in the 1990s when drug-makers pushed patient-reported pain as the fifth vital sign, and claimed oxycodone was not addictive [8]. The next wave occurred around 2010 with the rise of heroin use. Less expensive than prescription opioids on the black market, people prescribed opioids turned to heroin after being "cut off" their prescriptions by their prescribers [5]. The rise of opioid overdoses primarily due to synthetic opioids, such as fentanyl, has marked the third wave starting in 2013 with historic levels of overdose occurring in 2021.

As we write this chapter, the proverbial genie is out of the bottle. Physicians and other clinicians have been overprescribing readily available opioids to treat chronic pain for decades; and now the US is facing a grave opioid crisis that harms and kills patients and burdens the health care system. At least 2.5 million adults had been

diagnosed with opioid use disorder in 2014 [9]. To improve treatment outcomes for the millions of Americans now dependent on chronic opioid therapy, the US healthcare system needs to make a renewed commitment to nearly eliminating new chronic opioid prescriptions and decrease polypharmacy when treating patients reliant on chronic opioids in addition to providing medications for addiction treatment (MAT), such as buprenorphine to those who meet DSM-5 criteria for OUD [5]. This will require a commitment at all levels of medical practice, including physicians and other medical providers, hospital systems, local and national medical societies and government agencies. We present two cases here to show the pitfalls of common opioid-prescribing practices and help guide clinicians to make safer decisions. We also suggest ways for hospitals and public health systems to support clinicians [10].

Case Studies

Case 1

The patient is a 64-year-old male with a history of hypertension, obesity, coronary artery disease (CAD), obstructive sleep apnea (OSA), chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), right hip replacement, and depression. He has been taking chronic opioids for 3 years to treat right hip pain that developed after a total hip replacement to treat severe osteoarthritis. He currently takes 10 mg of oxycodone three times daily. The patient declined a repeat total hip replacement and requested pain medicine instead. He received a short course of outpatient physical therapy for hip pain and cited no change in pain status. He is retired from an office job, lives alone, and leads a sedentary lifestyle. He is a former smoker. One year ago, his right hip pain was worsening, so his primary care physician added gabapentin to treat his pain, an off-label but common approach to chronic musculoskeletal pain. The patient started taking gabapentin 300 mg three times daily. His primary care physician (PCP) increased his gabapentin to 600 mg three times daily, providing some pain relief. The patient had been experiencing trouble sleeping for a few months that he attributed to his hip pain. He made an appointment with his PCP, who was on vacation. He saw a covering clinician who prescribed lorazepam 1–2 mg/night for sleep without checking the Prescription Drug Monitoring Program (PDMP), an electronic database that tracks controlled substances filled by pharmacies in each US state. The patient took lorazepam 1 mg when he was experiencing insomnia. He was still unable to sleep, so he took a second lorazepam 1 mg tablet. A neighbor knocked on his door the next morning and the patient did not respond. The neighbor called 911, and first responders found the patient in bed, unresponsive and breathing shallow breaths. They administered two doses of naloxone and the patient became more responsive, but still groggy and unable to answer questions. He was intubated in the ER and after 5 days in the ICU, he was weaned from the ventilator, transferred to the medical floor, and discharged home after 5 more days.

Analysis

This patient scenario underscores the risks of chronic opioid use, even when prescribed in a legal manner by licensed health care professionals. Additionally, this patient's underlying medical conditions, including his age, his history of OSA, CAD, COPD, and CKD put him at risk for a poor outcome when combined with chronic opioid use.

When taken alone, both opioid medications and benzodiazepines can suppress breathing, leading to overdose and death. Taken together, the combination of opioids with benzodiazepines increases the risk of overdose and death [11]. Cotreatment with opioids and benzodiazepines is increasing [6]. In the period from 1993 to 2014, the co-prescription of opioids is more than doubled [12]. Additionally, the risk for a poor outcome increases with increasing opioid dose [13]. To help monitor controlled substance prescriptions, the US developed Prescription Drug Monitoring Program (PDMP) database, available in all 50 states. This information can help clinicians monitor controlled substance use and help avoid overprescribing and co-prescribing. The PDMP has its limitations, as patients may obtain opioids and benzodiazepines outside of the medical system from other contacts [14].

In addition to the risk of opioid and benzodiazepine co-prescribing, opioid and gabapentin co-prescribing also present significant risk of overdose and death. Gabapentin is widely used off-label for the treatment of pain. Despite research indicating the increasing misuse potential of gabapentin, it is not categorized as a controlled substance [15]. Researchers found a dose-dependent mortality risk among patients co-prescribed gabapentin and opioids. Furthermore, advancing age, CKD, and chronic lung disease may increase the risk of gabapentin-related respiratory depression [16].

This case illustrates many of the pitfalls clinicians face when prescribing chronic opioids to treat non-cancer pain in patients with comorbidities. With the high prevalence of chronic opioid prescriptions in the US and the overwhelming evidence of poor health outcomes particularly when co-prescribed with benzodiazepines and/or gabapentin, clinicians need guidance on how to manage chronic pain to avoid prescribing opioids initially and how to care for patients currently taking chronic opioids in the safest way. Hospitals and health care systems need to develop methods to improve safe prescribing. This can include electronic health record (EHR) alerts, better clinician education and creating protocols to include pharmacists in the care of patients taking opioids.

Case 2

The patient is a 47-year-old female with a history of anxiety, low back pain status post spinal fusion, multiple spinal injections, and failed physical therapy (PT), who is unable to tolerate non-steroidal anti-inflammatory drugs (NSAIDs) due to

gastritis. Her PCP prescribed immediate-release oxycodone for CNCP. Her PCP refills the prescription at monthly appointments, and the patient demonstrates no aberrant behaviors. Her PCP leaves the practice, and the patient's new PCP refuses to refill her opioids, and refers her to a pain management specialist who has limited availability. The patient experiences opioid withdrawal and seeks oxycodone from emergency departments (ED) and urgent care clinics. Her chart is labeled with "drug-seeking behavior," and she receives dismissive treatment in the ED.

To self-medicate her pain and avoid opioid withdrawal syndrome, she seeks non-prescribed opioids. The patient's daughter finds her at home, unresponsive, and calls 911. Emergency medical services (EMS) arrives and administers 4 mg of intranasal naloxone twice, and she responds by regaining consciousness. In the ED, confirmatory urine testing reveals fentanyl. She is monitored in the ED, evaluated for OUD, and offered treatment with buprenorphine.

Analysis

The second case illustrates the combined risks of opioid prescribing and abrupt cessation of opioid prescriptions.

Many factors contribute to the inappropriate prescribing of opioids, including pressure for high patient satisfaction scores, time constraints that clinicians experience, and the rush for a "quick-fix." The lack of a clear transition from one clinician providing opioids to another without a clear plan in place also put the patient at risk of an overdose.

This patient's first PCP prescribed opioids to treat back pain without first trying non-opioid therapy and without discussing the risks of opioid therapy. Compounding matters, the new PCP abruptly stopped the opioid prescriptions without an adequate plan to taper and try alternative therapies to the current opioid therapy. These failures put the patient at risk of overdose and death [17].

The providers also missed a critical, lifesaving step: medication for addiction treatment (MAT) (https://www.samhsa.gov/medication-assisted-treatment). MAT is approved by the Food and Drug Administration (FDA), and MAT programs are clinically driven and tailored to meet each patient's needs. MAT includes medications for opioid use disorder (MOUD)—buprenorphine, methadone, and extended-release naltrexone.

Although MOUD is highly effective, it remains underused. Due to lack of standardized education on substance use disorders, prevalence of stigma, and lack of administrative buy-in from key stakeholders to influence culture change in hospital systems, many patients lack access to MOUD [18]. Clinicians also do a poor job of communicating risk and of mitigating risk by providing naloxone to patients taking chronic opioids [19]. Time constraints may make it easier for a clinician to simply refill an opioid prescription than to try to reduce or eliminate opioids [20]. As patients can become physically dependent on opioids after only 5 days of continuous usage, adequate risk discussions are essential [21].

Patients receiving chronic prescription opioids also face heightened risk during staff transitions at any given healthcare center, particularly in settings without a standard method to transfer patients receiving opioids to another clinician [22]. The lack of standardized education on opioid prescribing and addiction, liability concerns, siloed medical specialties, and burnout among clinicians due to lack of administrative support can lead to poor patient outcomes [20]. In addition, pressure to see many patients can impair treatment decisions.

Stigmatization of individuals with chronic pain syndromes and substance use disorders (SUD) can exacerbate risk. Labeling someone as "drug-seeking" can impair the patient–clinician relationship [23]. Clinicians may also view MOUD in a negative way, that of "trading one drug for another" [24].

The limited value of the PDMP has been noted above. Bias against patients taking controlled substances may engender use of the PDMP to dismiss a patient from the practice. Per the CDC in 2016, "Experts agreed that clinicians should not dismiss patients from their practice based on PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, non-opioid pain treatment, naloxone, and effective treatment for substance use disorder)."

Despite their limited use, many practices require patients to sign treatment contracts prior to obtaining controlled substances. Patient-provider agreements have not been shown to prevent misuse or diversion nor improve patient's understanding of potential harms [25]. When clinicians use these agreements in a punitive manner to stop a controlled substance without a plan to treat opioid withdrawal, this puts patients at risk of using opioids not prescribed by a clinician to avoid withdrawal. Turning to illicit opioids increases overdose risk, as street drugs are unregulated [26]. Reliance on a controlled substance agreement can falsely assure a clinician that s/he is making the correct "moral" decision without fully examining patient risk [27].

Urine drug testing to monitor for treatment compliance and decrease risk for diversion is nuanced, as well. Urine drug testing interpretation can be difficult, false positive results occur and send-out tests may take weeks to result [25].

Solutions

These two clinical scenarios illustrate the deadly risks of opioid prescribing. Given the steep rise in opioid-related deaths, clinicians, healthcare systems, and the US public health system must work together to develop improved opioid safety protocols.

Patient #1

The first step in addressing CNPC remains the patient–clinician relationship. Clinicians should discuss the risks of opioid medications and offer alternatives. Opioids have not proven to offer improvement over non-opioid pain relievers for the treatment of musculoskeletal pain, and their use may worsen outcomes [9]. When caring for a patient complaining of chronic orthopedic pain, clinicians should prescribe NSAIDs, physical therapy, and other nonpharmacologic modalities, such as physical therapy, acupuncture, and yoga, and monitor their patient's progress closely. Patients with inadequate pain responses should be referred to specialists for such treatment as joint injections and surgery. Health systems need to develop robust non-opioid pain services [28].

For patients experiencing significant pain despite trying non-opioid modalities, clinicians may prescribe opioids at the smallest effective dose for the shortest amount of time. Studies show that doses greater than 90 morphine milligrams equivalents (MMEs) (https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf) daily portend an increased risk for overdose.

Patients with certain conditions and patients concurrently taking other CNS depressants face greater risks when taking opioids to treat CNPC. Clinicians should avoid prescribing opioids in patients who have also been diagnosed with OSA or COPD. If clinicians must prescribe opioids for these patients, they should discuss the risks, monitor their patients frequently, and provide naloxone kits to family members and other people living in the household which can be used to reverse an accidental overdose.

Increasingly, clinicians co-prescribe opioids with gabapentin. Gabapentin is both riskier and less effective for the treatment of chronic pain than many clinicians recognize, and the risk of respiratory suppression, overdose, and death due to gabapentin increase when co-prescribed with opioids. Clinicians should prescribe gabapentin with caution and avoid dose escalation (900–1800 mg/daily), as this increases the risk.

The increase in the co-prescription of opioids and benzodiazepines is one of the more alarming trends presented in this chapter [29]. Combining these medications, particularly in patients with common comorbidities, greatly increases the risk of a poor outcome [29]. Clinicians should choose safer options to treat these conditions, including non-pharmacotherapy for the treatment of insomnia and SSRIs for the treatment of anxiety and need to engage in frank discussions with patients asking for benzodiazepines who are also taking chronic opioids. Health care systems can use electronic medical records alerts to notify patients of risky co-prescribing practices. Clinicians should check the PDMP before prescribing any controlled substance. Educating all clinical staff, including clinicians, nurses, and pharmacists on the risk of co-prescribing gabapentin, benzodiazepines, and opioids can promote safer choices [30].

Patient #2

This case underscores the dangers of the abrupt cessation of prescribed opioids. Health systems should provide safe alternatives to the abrupt cessation of prescribed opioids. These methods include risk/benefit analysis of continuing the prescriptions, slow tapers, and referral for MOUD.

Despite its effectiveness, clinicians underutilize medications for OUD treatment. The US lacks enough clinicians trained in MOUD to meet the growing need, and the stigma of addiction often dissuades patients from seeking MOUD, even if desired [31]. With federal expansion of MOUD availability**,** practices can add MOUD treatment without adding additional staff and at minimal additional cost [32].

Bias against patients with OUD and stigma also undermine treatment efforts**.** Meeting patients where they are and utilizing shared decision-making is key to health equity [33]. Advocating for health equity, expanded Medicaid, and culturally competent medical care can also address stigma and hidden barriers to treatment. The hub and spoke model in which patients seeking MOUD are stabilized on medication, then referred to their PCPs for continued medication, can enhance treatment availability [34].

The US faces a significant addiction treatment care gap. Only about 10% of teens and adults meeting OUD criteria received treatment in 2019 [35]; this gap increased during the pandemic when overdoses increased. Importantly, minority and rural communities often lack access to MOUD. In addition to race and geography, bias against patients seeking addiction treatment limits adequate care. "Physician bias, media portrayal of opioid use disorders, and governmental regulation are a polyfactorial root of racial inequity in the opioid epidemic. As part of the national response, addressing these issues will be an important factor in curbing this epidemic" [36]. In general, non-whites are more likely to be undertreated than their white counterparts [36]. Addressing social determinants of health such as housing, employment, and transportation must be part of a larger strategy to improve MOUD access. A trauma-informed care model can also lead to more effective treatment [37].

Health systems can overcome these treatment deserts by helping more clinicians train in MOUD and by expanding telehealth for MOUD [38]. Evidence-based training for clinicians and access to mentors can help provide the education and skills needed to implement office-based treatment.

When the benefits of the medication cease, clinicians should discuss alternative therapies or tapering of opioids. Tapering opioid pain medicine too quickly puts patients at risk. Clinicians may require training to intervene in this critical period so patients do not seek opioids from other clinicians or from non-medical sources, increasing the risk for death [39].

Eight to 12% of patients on chronic opioids develop an OUD [40]. Clinicians should offer these patients medication for opioid use disorder (MOUD). Health care systems can set a goal of offering MOUD to all patients via in-person or telehealth visits. Integrating treatment for OUD in primary care settings can improve access to MOUD; recent federal changes permit easier MOUD prescribing. PCPs can obtain an X-waiver to prescribe buprenorphine in an office-based setting with minimal training, via updated Substance Abuse and Mental Health Services Administration (SAMSHA) guidelines [41].

Clinicians can use hotlines that provide real-time advice on treating OUD in primary care and ED settings [42]. Initiation of MAT by hospitalists also improves treatment compliance after discharge [43]. See Fig. 16.1 for information on how best to start MAT in hospitalized patients [44].

Patients who do not have OUD should continually be reassessed for harms associated with chronic opioid use. Hospitals and clinics can help educate clinicians on how to taper opioids and can expand comprehensive pain management clinics**.** When opioid withdrawal symptoms do arise, clinicians can prescribe adjuvant medications. Prolonged tapers help minimize these symptoms. Patients can also benefit from referrals to chronic pain support groups and therapy aimed at improving coping skills [45].

Conclusions and Next Steps

We suggest implementing the following steps to promote opioid safety:

- Establish system-wide initiatives to minimize opioid prescriptions, including limits on initial prescriptions, EHR alerts on benzodiazepine co-prescribing, EHR alerts on chronic disease and opioid prescribing, and mandatory PDMP checks.
- Develop robust pain management services that provide patients experiencing chronic pain with multi-modal non-opioid pain management.
- Expand MOUD services using in person and virtual care to all patients who meet DSM-5 criteria for OUD.
- Develop efforts to collect unused opioid medications for safe disposal.
- Implement robust initiatives to educate physicians, mid-level practitioners, nurses, pharmacists, and other clinical staff on safe opioid prescribing practices.

Clinicians require support to address opioid use. Given the steep rise in opioid-related deaths, clinicians, healthcare systems, and the US public health system must work together to develop improved opioid safety protocols and plans to treat OUD. Only then can we as concerned clinicians start to put the genie back in the bottle.

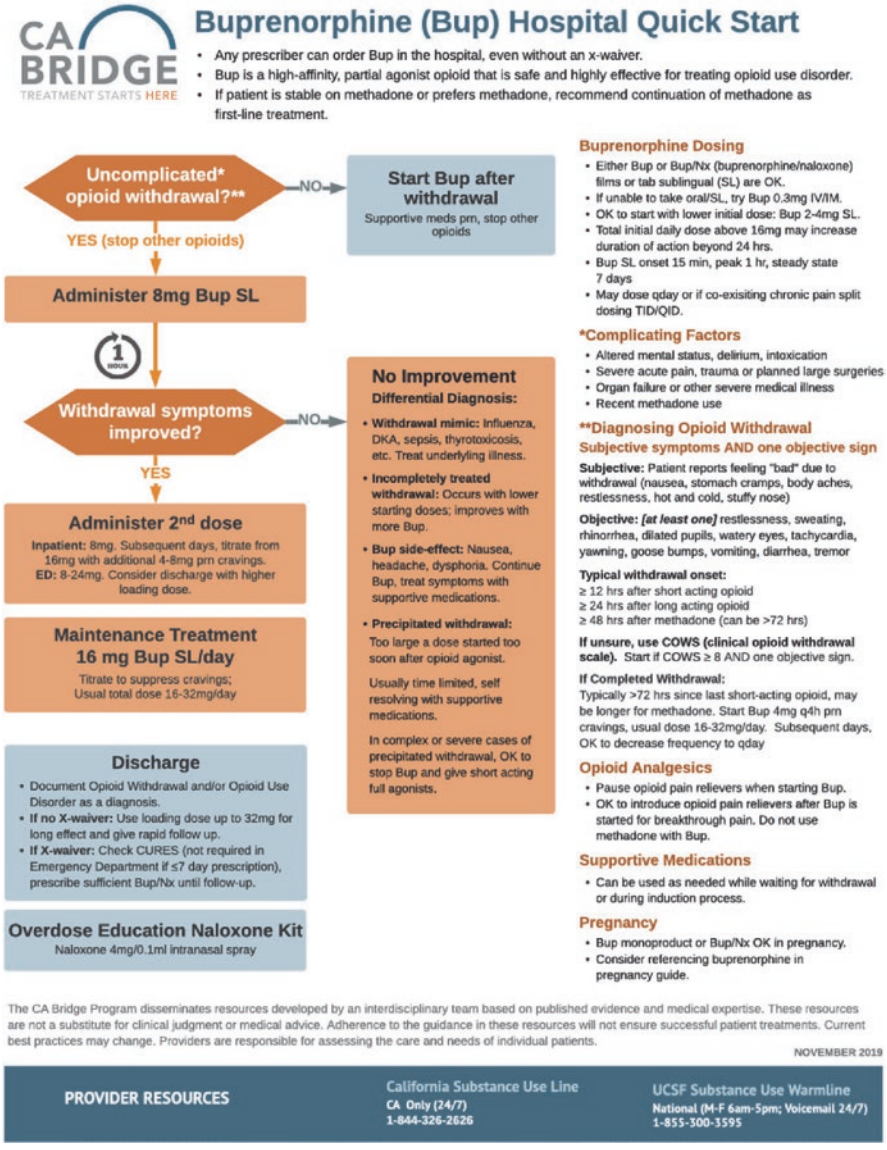

Fig. 16.1 Example of a buprenorp hine induction for opioid use disorder. https://cabridge.org/ Last accessed Aug 12 2023

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Part IV
Special Considerations

Chapter 17
Patient Safety in Pediatrics

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Introduction

Providing safe medical care is one of the most important Institute of Medicine pillars, but to do so consistently is challenging given the complexity of the medical system at the individual, systemic, and national levels. Medical errors and patient harm events that occur in pediatric patients differ from those of adults, due to different physical characteristics, developmental issues, and the dependent/legal/vulnerable state of the child [1, 2]. Although error and harm due to medications [3–6] are most prevalently cited, diagnostic errors, patient misidentification [7], communication failures, and lack of information system customization are some of the other frequent problems associated with pediatric safety events [8, 9]. It is also important to keep in mind that the definition of a pediatric patient is not always limited by age; young adults with chronic and/or unusual diseases are often cared for in the pediatric healthcare setting [10]. Healthcare safety failures for children are

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many and include lack of proper equipment (e.g., adult-sized oxygen saturation monitor probes causing erroneous results); over or misuse of technology (e.g., radiation dosing for computed tomography higher than necessary to produce adequate image); lack of awareness of age-specific norms (e.g., vital sign changes misinterpreted, resulting in either excessive or conversely no action taken); and failure to anticipate environmental influences (e.g., hypothermia due to cold rooms or lack of bundling resulting in physiologic stress) [2, 3, 7, 9].

To date, reports on the epidemiology of pediatric safety events have been focused primarily on the hospital setting [2]. Medication errors are not surprisingly the most commonly cited safety event (5–50% of errors) and include a combination of calculation, formulation, dispensing, and administration errors [2, 5]. There is potentially greater risk of error commitment in the medication process for pediatric patients than for adult patients due to weight-based prescribing needs, dynamic age and disease-state physiologic and developmental changes, and medication delivery issues that are unique to children [2, 5]. In addition to patient misidentification, delays in care, miscommunication, intravenous access problems, and other incidents have also been reported, some at rates of up to 10% [3, 7, 9]. Although ambulatory reports are fewer, one multi-center study similarly demonstrated that medication errors occurred most commonly (32%); however, administrative (documentation) and diagnostic errors were also often reported (22 and 15%, respectively) [6]. Importantly, communication was deemed a contributing factor in 67% of all reported events [6]. In all settings, there are challenges to obtaining accurate and timely error reports and to implementing durable solutions. Despite these unique challenges, the approach toward identification, resolution, and abatement of pediatric harm follows the same tenets of healthcare safety mentioned elsewhere in this book.

A number of case examples could serve to instruct on pediatric error and harm. As noted, although most information has come from inpatient reports, ambulatory errors are of great importance as well but largely underreported [2]. Several entities have worked to call attention to pediatric errors and system solutions, including the Institute for Healthcare Improvement (IHI) (High Alert Medications in Pediatrics) [11], the American Academy of Pediatrics (AAP) (Patient Safety Policy statement) [2], The Joint Commission (TJC) (various resources) [12], and the Agency for Healthcare Research and Quality (AHRQ) (Patient Safety Indicators) [13]. These groups suggest both technology-based solutions such as pediatric-specific electronic health record and computerized decision support systems as well as some very basic changes. Such as mandatory weight recording in kilograms, that highlight the stark contrast in work yet to be done in pediatric healthcare safety. While the case examples below cannot address all aspects of pediatric error and harm, they call out some of these issues unique to children that deserve attention.

Case Studies

Case 1A: Delayed Diagnosis Leading to Orchiectomy in a 9-Month-Old Infant

Clinical Summary

A.B. is a 9-month-old, previously healthy, term male seen at a community emergency department (ED) with parental concern for crying and fussiness for several hours. On arrival, vital signs were noted to be stable except for an elevated heart rate thought to be due to crying. Examination was normal except for left-sided scrotal swelling. Over the next 4½ h, the ED physician obtained a scrotal sonogram which was read as non-diagnostic for torsion; the on-call pediatrician was called to admit the patient for pain management and further evaluation. Upon assessment in the ED, the pediatrician called for urgent transfer to the local children's hospital and immediate urologic consult. The child was met in the children's ED by the urologist and taken directly to the operating room where left orchiectomy was performed due to a necrotic testis.

Case 1B: Missed Diagnosis of Inflammatory Bowel Disease in an Adolescent

Clinical Summary

L.M. is a 16-year-old boy with inflammatory bowel disease (IBD) admitted to a large community hospital for upper arm cellulitis thought to be due to an abrasion that occurred when he fell (helmeted) from his bicycle 2 days prior to admission. The cellulitis improved with treatment. On the day of discharge, the patient had a bloody stool and abdominal pain which was recorded by the nurse. A resident assessed the patient when the parent was at work. The patient stated he "was fine" and wanted to go home; he was discharged. One day later, the patient was admitted to the children's hospital for a severe IBD flare.

Case 1c: Delayed Diagnosis of Diabetic Ketoacidosis (DKA) in a 23-Month-Old Infant

J.H. is a 23-month-old previously healthy, term child who presented with tactile fever, fussiness, and poor feeding during winter season. Upon arrival and assessment in the Emergency Department (ED), he was noted to be febrile, tachycardic,

and tachypneic per the cardiorespiratory and pulse-oximeter monitors, but the assessment was difficult due to the patient crying and difficulty getting an accurate reading from the monitors. The child was reported in triage to otherwise look well. Vital signs were thought to be attributed to the history of fever and associated crying/fussiness. The child was taken back to a room in the busy ED, where nursing staff checked the monitor's vital signs from the door intermittently. It was a busy day in the ED. Upon being seen by a provider, the child was noted to be afebrile and well-appearing appearing, but the respiratory rate after undressing was in the 70s. Lungs were clear, and there was no evidence for URI. Further evaluation revealed that he was in DKA, and appropriate treatment and management were taken thereafter.

Analysis: Case 1A, Case 1B, Case 1C

These three cases highlight the added vigilance needed when caring for pediatric patients of varied ages. What happened in each case? The first caser underscores the need for age and/or disease state-specific criteria for pediatric assessments in community settings as is recommended by the Emergency Medical Services for Children and the American Academy of Pediatrics [14]. Delay in obtaining and interpreting radiological images and delay in transfer to a facility where definitive treatment can be rendered are not uncommon at sites where personnel and facilities do not frequently care for infants. The second case highlights the need to recognize the impact of unrelated acute medical needs on underlying chronic disease states, to assess and account for clinical changes in the face of patient denial, and to balance adolescent autonomy with family engagement when rendering medical decisions. Adolescents are a special challenge, particularly those with chronic disease who may hesitate to complain, do not want to stay in the hospital, or fail to advocate for themselves when they have issues they would like raised. What can be done to prevent recurrence of these failures? Protocols should be written for pediatric consultation and testing that acknowledge skill sets available for rendering services to children of different ages and underlying disease states. Patient and family centered care (PFCC) principles [15] and a team approach toward care for adolescents should be fostered. Pediatricians should have a presence on relevant hospital committees and should participate in case reviews of pediatric-aged patient events that occur at any site in the facility. While these short cases focus briefly on the importance of advocacy in community settings, the children's hospital case below offers detail on a review process and solution planning that can translate to any setting. In the third case, the history of tactile fever and crying status was assumed to be due to the winter respiratory viral illness and the infant was not initially undressed to get a more comprehensive respiratory assessment.

Case 2: Pediatric Patient Harm Due to Multiple Systems Failures

Clinical Summary

H.M. is a 5-year-old female, ex-28 week gestation preterm with chronic lung disease (CLD), developmental delay, status post gastrostomy tube (GT) with fundoplication in infancy and GT closure 1 year ago, history of oral aversion, admitted with CLD exacerbation. During the hospitalization, she was diagnosed with atypical pneumonia, started on macrolide therapy, given increased dose of intravenous (IV) steroids, and her home medications were changed IV form due to severe respiratory distress and both metabolic and respiratory acidosis noted on blood gas analysis. She was improving with treatment by hospital day (HD) 5 but the following day the Code Blue Team was called for respiratory failure. She spent 3 days intubated in the intensive care unit and was eventually discharged home on HD 12.

What happened? The critical event unfolded over approximately 36 h (see Table 17.1). When the Code Blue Team was called, the child had no respiratory drive and had low blood pressure (75/40). After she was intubated, it was clear she had pulmonary edema but despite adequate ventilator support, she required significant cardiovascular medication infusions to maintain her blood pressure. She was re-started on her IV steroids at the same dose she had received on admission (2 mg/kg every 8 h). Over the next several hours, her blood pressure was under much better control and she was weaned off the cardiovascular medications the following day. It was noted that she had not been placed on oral steroids on HD5 after her IV steroids were stopped. She had been on 1 mg/kg/day as an outpatient for the week prior to admission due to her increasing respiratory symptoms and had been on every other day steroids for the past several months for her CLD.

Root Cause Analysis

What was the next step? A Root Cause Analysis (RCA) led to the discovery of multiple failures and proposed solutions. The RCA process includes asking "why" and "how," offers solutions, and expects actions based on these proposed solutions. Questions on normal policy/procedures, process disruptions, human factors, training, individual performance, equipment, environment, information technology, as well as solution planning are included. The commonly used TJC RCA template [16] goes further to identify organizational leadership investment in promoting the culture of safety and assuring systems are in place to recognize and report errors.

How did this particular event happen? In this case, the hospital staff did not follow established *policies and procedures* (Table 17.2). The hospital's "Ask More" policy directs staff to notify the Charge Nurse if urgent patient care changes have not been resolved with usual conversation and interventions, and to continue to pursue resolution of the concern by elevating the issue to the covering physician and

Table 17.1 Case 2: Relevant timeline

Hospital day (HD) and time	Event	Note
HD#5		
09:30	Bedside clinical rounds performed; patient is off oxygen with stable baseline respiratory effort and vital signs. Heart rate (HR) 74, blood pressure (BP) 108/65, respiratory rate (RR) 22, oxygen saturation 94%. Plan made to stop the intravenous (IV) steroids and change to oral steroids	1
11:00	Nurse calls intern for orders. Intern discontinues the IV steroids. No order for oral steroids is placed	2
16: 30	Mother arrives at the hospital and notes her daughter "looks tired." Nurse encourages mother to get her daughter to nap	3
19:10	Father arrives at bedside for the night; mother goes home to care for siblings. Father is updated on the plans of the day	4
19:32	Night nurse calls intern with concern that the patient has had poor oral intake all day. Intern orders IV fluids at maintenance rate	5
HD#6		
02:35	Night nurse is taking vital signs, notes HR elevated to 110, patient asleep. Father is sleeping at the bedside. Nurse calls intern about elevated HR. Intern believes this is due to inadequate fluids and orders a 20 mL/kg bolus of normal saline and increases the rate of the IV fluids to 1.5 times maintenance	6
06:35	Mother arrives and father leaves for work, stating things "were fine" overnight	7
07:15	Mother calls nurse with concern about her daughter's breathing and says she is more "clingy." Nurse reassures mother	8
09:30	Bedside clinical rounds are performed. The monitor alarms while the patient is fussy with the exam. Mother re-states her concerns and is told the patient will be monitored carefully	9
11:12	Mother calls the nurse to watch her daughter's breathing. Intern is called for "needing oxygen—saturation dips." Orders given for oxygen to keep oxygen saturations greater than 95%. Charge nurse notified. (RR 38, oxygen saturation is 89–90%, HR 118, BP 89/54)	10
13:10	Nurse records respiratory rate at 33; oxygen saturation on 1 liter (L) is 88–90%. She notes breathing a bit more labored but patient is "calmer." Nurse increases the oxygen to 2 L per minute. Intern notified "turning up the oxygen"	11
14:11	Mother calls the nurse, stating she is concerned that her daughter does not want to eat and is "tired." Nurse reassures mother	12
15:08	Nurse calls intern because the monitor is alarming for HR. IIntern is told the patient is sleeping on 3 L oxygen and that the saturations have been "off" and "not picking up well." The nurse has called for a new monitor saturation probe	13
15:22	Nurse enters room to change probe and finds patient cyanotic and pale, with RR of approximately 6. Code Blue is called	14

Table 17.2 Case 2: Root cause analysis (RCA)

(Only applicable issues listed)				
Patient: H.M.		**MRN: 1234567**		
Participants				
Attending physician; Quality Management Medical Director; Pediatric Residency Associate Program Director; Patient Safety Officer; Risk Management/Quality Management nurse specialist; Nursing Unit Director; bedside nurse; Unit Charge Nurse; Pediatric Chief Resident; participant pediatric resident; Quality Management Nurse Coordinator				
Issue type	**Issue**	**Root cause**	**Actions and solutions**	**Discussion Involved party ( ) Associated timeline note number from** Table 17.1 **[ ]**
Policy/procedures	Normal policy/ procedures followed?	X	Re-education	No. "Ask More" Policy not followed (nurse, intern) [11–13]
Policy/procedures	Any missteps in the process?	X	Re-education; "Ask More" Policy change	Yes. Verbal and written communication not clear (nurse, intern, Charge Nurse) [6, 9–11, 13]
Policy/procedures	Other concerns?	X	Re-education	Yes. Failure to examine and communicate (intern) [5, 6, 10, 13]
Human factors	Relevant human factors?	X	Rounds change; Pediatric Early Warning System (PEWS)	Yes. Failure of critical thinking skills; communication; distraction (nurse, intern, resident, attending physician) [2, 6, 8–13]
Performance Factors	Did performance meet expectations?		Training	No. (intern, nurse) [2, 5, 6, 8–13]
Recurrence Risk	Could this event happen to other patients? In other areas?		Dissemination	Yes

Solutions Planned

List here details on Actions and solutions. Include pilots, dissemination plan, and assessment of outcome of changes made

Solution	**For Whom?**	**Responsible Party**
Re-education: Provide re-education on: Documentation; communication; "Ask More" Policy; use of Situation-Background-Assessment-Recommendation (SBAR) tool; CLD patient risks	Nurse, intern	Unit Nursing Educator; Pediatric Chief Resident; Pediatric Residency Associate Program Director; attending physician

(continued)

Table 17.2 (continued)

Policy change: Revise "Ask More" Policy to require Charge Nurse bedside assessment for any patient about whom s(he) is called. Assessment to include review of documentation and care plans	Nursing	Quality Management Department with Nursing and Medical Staff leadership
Rounds change: Pilot medication review and order writing on rounds for resident patients (all units). Pharmacist to participate when available	Residents, nurses, pharmacy	Nursing Unit Directors, Pediatric Chief Resident; Pediatric Residency Associate Program Director; Pharmacy Director
New education and orientation: 1. Add SBAR, PEWS, Rapid Response Team (RRT) and Code Blue Team scenario to hospital staff annual education 2. Revise family hospital orientation to emphasize family-initiated RRT	Hospital staff, families	Human Resources; Hospital Education Department; Customer Service; Nursing Unit Directors
Dissemination: 1. Re-distribute SBAR tool, revised "Ask More" Policy, revised family hospital orientation, and notification of addition to annual hospital staff education to all clinicians 2. Give participant family feedback on plans and actions taken	Medical staff, hospital staff, residents, family	Nursing Unit Directors; Associate Pediatric Chief Resident; Pediatric Residency Associate Program Director; Risk Management/Quality Management nurse specialist
System intervention: Pilot PEWS program on this Nursing unit	All on unit	Nursing Unit Director
Training: 1. Successfully complete communication education that includes role play 2. Successfully participate in mock scenarios that include use of PEWS and RRT	Nurse, intern	Unit Nursing Educator; Pediatric Residency Associate Program Director
Assessment of Changes: Track PEWS and rounds outcomes at 30 and 60 days. Disseminate these practices across all units within 90–120 days (pending pilot results)	Medical staff, hospital staff	Quality Management Department

others including the Chief of Staff. The Charge Nurse stated she was told by the nurse that "the patient is a little worse but the resident has been called" and inferred that the issue was being resolved. Documentation of communications between the nurse and intern was unclear or missing. While there was a notation that the nurse notified the intern of changes in the patient's condition, detail on what changes were reported was not documented and the notation indicated only "MD aware." The intern failed to examine H.M. and notify the supervising resident or attending physician of the concerns as he thought his management plan had resolved the problem.

Human factors overlaid these procedural failures. Critical thinking was not evident a number of times. The intern did not order resumption and arguably a taper of oral steroids on HD5 as the IV steroids were discontinued, and further, on HD6 the medication list was not reviewed by the team as this could have alerted them to the omission of the steroid. The nurse stated she was distracted and did not document her work on HD6 until late morning, so early morning events and vital signs were not available for the rounding team. The rounding team and in particular the intern separately likely committed one of a variety of cognitive errors: anchoring (fixation on initial features of a case and not adjusting for later information); availability bias (focusing on what readily comes to mind as the source of the problem); and posterior probability (undue influence by what has happened with the patient or similar patients in the past) [17, 18]. Failure to recognize shock, in this case due initially to sudden discontinuation of steroids, is not uncommon in children [19]. The interpretation of heart rate elevation due to inadequate volume status instead of assessing for all causes of tachycardia resulted in excessive IV fluid administration in this fluid sensitive CLD patient and ultimately led to pulmonary edema. Hypoxia was interpreted as a "normal" variation seen in CLD patients; however, these patients rely on hypoxia for respiratory drive [20]. Administration of oxygen to this patient, without addressing respiratory support needs, removed the drive and caused the respiratory rate to drop. The nurse interpreted patient "calm" as overall improvement. As much of the tachypnea was an attempt to compensate for metabolic acidosis from shock, the inability to ventilate caused a precipitous drop in pH and resulted in cardiorespiratory failure. Children are at greater risk for respiratory failure than adults due to anatomic issues (such as limited cartilage support of airway, small airway diameter, larger and more horizontally placed epiglottis, and narrow subglottis), limited gas exchange (fewer and smaller alveoli and fewer collateral channels for ventilation between alveoli), and immature respiratory drive (underdeveloped central respiratory control and respiratory muscles, and compliant chest wall) [21]. CLD patients on steroids and diuretics have limited reserve but also develop tolerance for chronic hypoxia and hypercapnia. Often symptom changes are subtle (tiring or decreased appetite) with a dramatic worsening and more classic signs of respiratory failure then occurring within minutes [20, 21].

Communication failed numerous times. While the intern did admit hearing the words "tachypnea" and "desats [sic]," the level of concern was not apparent in the tone used by the nurse on the phone and the importance of these did not register with the intern. The hospital's communication tool using the situation-background-assessment-recommendation (SBAR) [22] format was not used. The intern was not asked to reassess the patient and thus assumed H.M. had improved with increasing the oxygen level. The mother was concerned, but was repeatedly told her child had CLD so "the breathing can get better and worse again like this." Ignoring parental concerns, in particular related to a patient with chronic disease, is not uncommon but leads to errors and decreased family satisfaction [15, 23].

Other considerations such as staffing, resource availability, environment of care, information technology, leadership, presence of proactive error surveillance

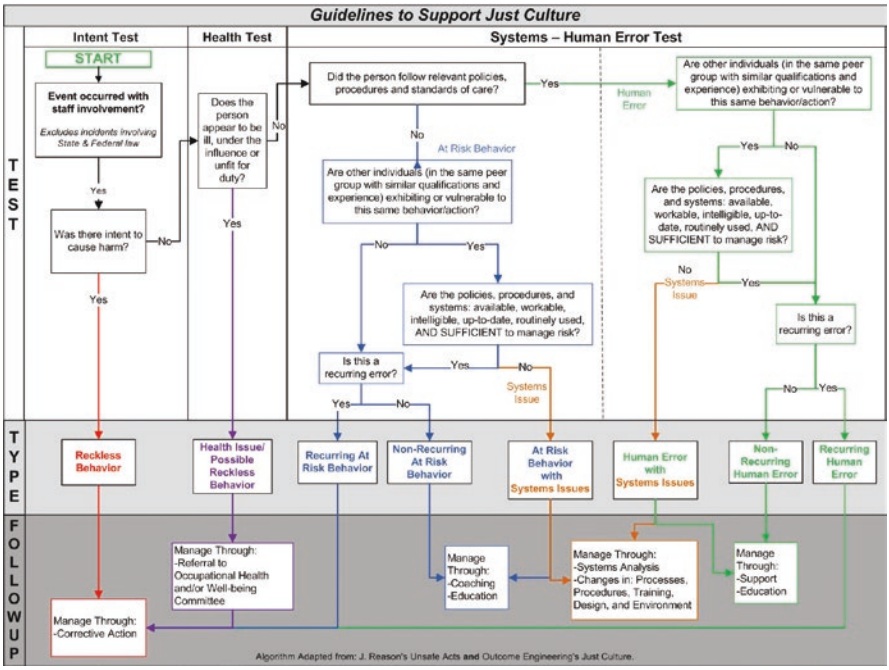

Fig. 17.1 Just Culture algorithm from Rady Children's Hospital San Diego. With permission from Dr. Glenn Billman, Quality Management and Patient Safety, Rady Children's Hospital San Diego

systems, and culture of safety were not found lacking. The event was deemed at high risk for recurrence, as the failure points were not unique to the patient, personnel, or environment. Despite this, it was also agreed that nurse and intern *performance expectations* were not met as noted above.

What can be done to prevent this from happening again? Solution planning used quality improvement tools such as failure mode effects analysis (FMEA) and cause-and-effect diagram, [24] available facility rapid response team activation data, and the organization's Just Culture algorithm (Fig. 17.1). Just Culture acknowledges that humans are fallible and provides an atmosphere of trust in which people are encouraged to report errors while individuals are still held accountable for risky or unacceptable behavior [25]. Key issues identified in this case were as the following: lack of clarity of roles within the "Ask More" Policy; limited team discussions about what clinical changes warrant notification of more experienced clinicians; lack of awareness of high risk populations' more subtle signs of deterioration; difficulty in interpreting level of parental or nursing concerns; and over-reliance on judgment and experience despite concerning objective data such as vital signs. FMEA scores for each of these failures were rated high, each with low likelihood of ability to be detected and high likelihoods of recurrence and risk for future patient harm. Using the Just Culture algorithm (Fig. 17.1), the nurse and intern's actions in this event were best described as consistent with "at risk behavior with systems

Pediatric Early Warning Score

Vital signs are based on normal ranges for age

	3	2	1	0	score
Behavior	Lethargic **OR** Confused **OR** Reduced response to pain	Irritable **OR** Agitated and not consolable	Sleeping **OR** Irritable but consolable	Playing or Alert **AND** Age appropriate **AND** At baseline level of consciousness	
Cardiovascular	Grey/Mottled/Cyanotic **OR** Capillary refill ≥ 5 seconds **OR** Heart rate > 30 above normal rate **OR** Bradycardia	Grey/Dusky **OR** Capillary refill 4 seconds **OR** Heart rate 20-30 above normal rate	Pale **OR** Capillary refill 3 seconds **AND** Normal heart rate	Pink **OR** Capillary refill ≤ 2 seconds **AND** Normal heart rate	
Respiratory	Respiratory rate 5 below or > 40 above normal rate **OR** Moderate to severe retractions **OR** Grunting **OR** FiO2 ≥ 50% **OR** > 8Liters/min oxygen	Respiratory rate > 20 above normal rate **OR** Mild Retractions **OR** FiO2 ≥ 40% **OR** ≥ 5Liters/min nasal cannula or ≥ 6Liters/min mask oxygen	Respiratory rate > 10 above normal rate **OR** Accessory muscle use **OR** FiO2 ≥ 30% **OR** > 2Liters/min oxygen	Respiratory rate normal **AND** No retractions **AND** No oxygen requirement	

Extra points: Nebulizer treatments 4 or more per hour =2 points
Persistent vomiting after surgery =2 points

Frequency of nursing assessments are noted below. Use the PEWS algorithm.

0-2	3	4	≥ 5
Green: Every 4-6 hours	Yellow: Every 2 hours	Orange: Every 1 hour	Red: Every 30 minutes

Fig. 17.2 Pediatric Early Warning Score action algorithm from Rady Children's Hospital San Diego. With permission from Dr. Glenn Billman, Quality Management and Patient Safety, Rady Children's Hospital San Diego

issues," which resulted in targeted training. Of solutions implemented (Table 17.2), the revision to the parent orientation on rapid response team (RRT) use and piloting of a new Pediatric Early Warning Score (PEWS) required the most investment of resources and cultural sensitivity. The PEWS tool, first described in the United Kingdom and since modified by others, rates the cardiac, respiratory, and behavior (neurologic) status of a patient [26]. The rating in each category is associated with a point value that is combined to yield a composite score (Fig. 17.2). The real power of the PEWS tool, however, comes from the associated action algorithm (Fig. 17.3), which prescribes specific tasks based on the patient's composite score. Staff's concerns regarding overuse of the RRT system and also of over-reliance on the

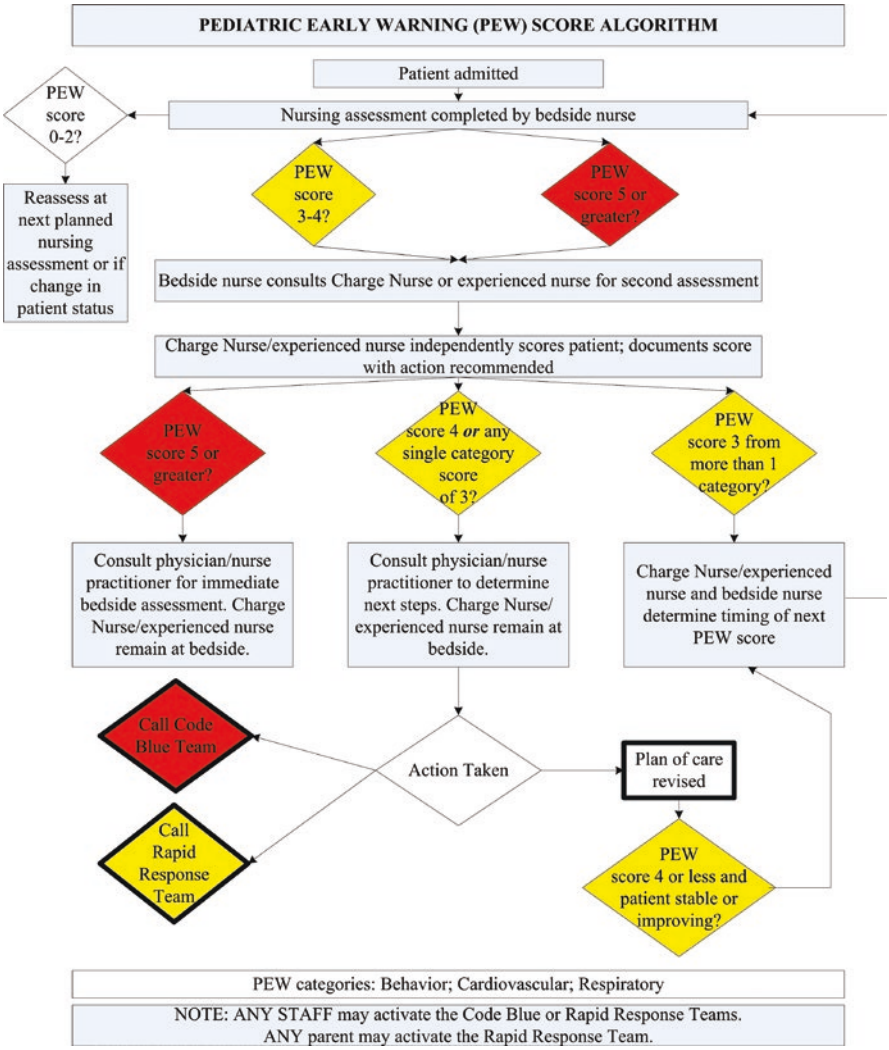

Fig. 17.3 Pediatric Early Warning Score (PEW) score algorithm

PEWS system for patient assessment were abated through engagement in development of the parent orientation materials and the PEWS algorithm, respectively.

Dissemination of lessons learned across the system included the addition of a PEWS scenario to annual education as well as the agreement to study, report on, and diffuse best practices learned from the PEWS pilots initiated for residents and the involved unit. Importantly, the participant family received feedback gave suggestions on communication strategies for families of children with chronic conditions and was supportive of the modifications to the parent orientation on RRT.

Conclusion

Pediatric patient safety events share elements common to those of adult patients yet differ in critical areas due to multiple factors such as disease states, communications, and dependent/ vulnerable state of children. Current technological advancements have resulted in improved safety through decision rules, order sets with lock-out dose ranges, and embedded clinical practice guidelines in protocols [27]. However, these are typically locally created and not easily shared nationally [3–5, 28, 29]. Attention to human factors and communication cannot be emphasized enough. Concerns have been raised due to the perception of "presence of safety inherent in computerized systems." [30, 31] As electronic and moreover remote communication systems are developed for healthcare, the importance of direct clinician–clinician and clinician–patient interaction must be addressed. For pediatrics, this is particularly salient as patient and family involvement in error recognition and resolution has been shown to be valuable on many levels [32].

Key Lessons Learned

- Children, in particular those with chronic diseases, are at increased risk for patient safety events due to different physical characteristics, physiology, development, and dependency that vary significantly by age and contrast with those found in adults.
- Communication failures can be mitigated by integration of PFCC principles, clearly written policies, constructive education, Just Culture, and use of appropriate technological support.
- In all healthcare settings, advocacy for, initiation of and engagement in pediatric safety initiatives is essential to ensure safe healthcare delivery for children. This is particularly poignant in settings where children are cared for less frequently and/or pediatric expertise is limited.
- Pediatric patient safety events should be reviewed in an interdisciplinary manner. System and human factors solutions should be disseminated across the facility wherever possible, with targeted education, training, and coaching applied as appropriate.

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Chapter 18
Patient Safety in Radiology and Medical Imaging

Alexander Ding, Jonathan Joshi, and Emily Tiwana

Introduction

Over the past several decades, medical imaging has grown at a rapid rate and continues to grow steadily [1–3]. Imaging studies provide tremendous value to clinical care, particularly in increasing diagnostic certainty and reducing the need for more invasive procedures, thus improving health outcomes.

This chapter addresses radiology and medical imaging-specific patient safety issues. However, it should be stated that other critical patient safety issues already covered in this book remain relevant to radiology, including proper patient identification, medication safety, fall risks, and staff safety. Image-guided procedures have similar patient safety concerns as in surgery, and procedural area-related safety topics, such as sterile procedure and universal protocol for the right patient, right procedure, right side, are nearly all universally germane to interventional radiology.

Errors in radiology may occur anywhere along the course of a study, from as early as ordering the examination by a referring clinician, through the operations of the imaging department, to the acquisition of images, technology infrastructure, interpretation of images, communication of results, and follow-up or next steps. This chapter will touch upon each of these areas of potential error but will focus its lessons primarily for the general practitioner and ordering clinician of imaging studies.

One of the critical items of consideration in radiology is exposure to ionizing radiation. Ionizing radiation is associated with risks, primarily its carcinogenic effects, but in high enough doses can produce burns and other more acute ill effects [4]. With the rapid growth and utilization of CT scans, the population's exposure to

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ionizing radiation has grown significantly. It has been estimated that about half of the US population's [5] and nearly 70% of the UK population's [6] radiation exposure can be attributed to medical imaging with continued growth anticipated. As with the rest of medicine, the decision to expose a patient to ionizing radiation involves a cost-benefit analysis weighing the risk associated with receiving the radiation to the clinical diagnostic or therapeutic benefit [7].

Case Studies

Case 1: Ordering Incorrect Diagnostic Test

Clinical Summary

A 70-year-old male, with a past medical history of coronary artery disease and cervical carotid artery stenosis, presented to the emergency department with 2 h of new altered mental status and ataxia, which were questionably worsening. The emergency clinician suspected a vascular stroke and wanted to evaluate the brain, and the vessels of the head and neck. So she ordered a head CT with and without IV contrast and a neck CT with IV contrast.

The order indication contained only the text "critical" without other clinical information, and the studies were performed as requested. The ordered studies were correctly interpreted as negative. However, the patient's symptoms continued to worsen, and a neurologist was consulted. The neurologist ordered CT angiograms (CTAs) of the head and neck and an MRI of the brain. The CTAs show a basilar artery dissection, and the MRI of the brain demonstrated an acute brainstem stroke. The patient died from the stroke.

Analysis/Discussion

This case illustrates the importance of initially ordering the correct diagnostic tests for a given clinical scenario and the adverse outcomes that can occur when incorrect tests are ordered. Specifically, the initially ordered tests were of low sensitivity for the clinical scenario (rule out potential stroke) resulting in a delay in diagnosis of a basilar artery dissection. This leads to a delay in the initiation of treatment (typically anticoagulant and/or antiplatelet agents), which could have mitigated the progression of the stroke and prevented the patient's death.

An inappropriate initial diagnostic workup occurred because of multiple oversights. First, the initial inappropriate orders would have been identified as incorrect by the radiology team and, through a discussion between the emergency provider and the radiologist, the orders would have been corrected. Unfortunately, the ordering provider only provided "critical" as the indication for the exams. Therefore, the order was assumed to be appropriate, and the imaging was performed as ordered.

This error could have been prevented by the ordering provider supplying a more detailed indication and by the radiology team requesting a more precise indication from the ordering provider, either would have allowed the radiologist to determine that the ordered exams were not the most appropriate for the patient's presentation and either alternated the examination to an appropriate modality or protocol.

It is critical that the right test with the right imaging protocol is ordered for the diagnosis suspected or for the clinical indication. In cases of uncertainty with a clinical presentation or inexperience with certain imaging orders, consultation with a radiologist is important to minimize the errors identified in this case. Alternatively, an ordering provider may consult with the American College of Radiology (ACR) Appropriateness Criteria® or a clinical decision support module, which are increasingly embedded in the electronic health record (EHR), due to anticipated regulatory requirements [8]. The ACR Appropriateness Criteria® "…are evidence-based guidelines to assist referring providers in ordering the most appropriate imaging or treatment decision for a specific clinical condition. Using these guidelines helps providers enhance quality of care and contribute to the most efficacious use of radiology [8]."

In this case, according to the Appropriateness Criteria® for the indication "New focal neurologic deficit, fixed or worsening. Less than 6 h. Suspected stroke," a head CT with and without contrast is usually not appropriate and a neck CT with IV contrast does not appear in the list of studies to order [8]. These studies are inappropriate because CTA studies are necessary to adequately evaluate the head and neck arteries. The ACR Appropriateness Criteria® have been proven to decrease inappropriate imaging utilization, increase the frequency of indicated studies, and decrease the frequency of low-yield studies [9, 10].

Case 2: Unnecessary Avoidance of Diagnostic Imaging

Clinical Summary

A 28-year-old healthy G2P1001 at 28 weeks presented to triage with a 1-day history of sharp, non-radiating, right lower abdominal pain with nausea and non-bilious emesis, but no vaginal bleeding or pelvic cramping. Vitals revealed tachycardia. Physical exam was positive for rebound tenderness localized to the right lower quadrant. Leukocytosis was found on the CBC but no other lab abnormalities. Bedside transabdominal ultrasound showed a vertex occiput anterior fetus measuring appropriate for gestational age with a posterior placenta.

The obstetrician was suspicious for acute appendicitis but the appendix was not well visualized on ultrasound due to fetal size. She discussed with the patient her recommendation to obtain a CT abdomen/pelvis with contrast to further evaluate. During this discussion, the obstetrician warned the patient of possible risks, which, according to her knowledge, included the risk of fetal malformation as well as an increased risk of developing childhood cancer. The patient elected to follow the

alternative treatment plan of "watchful waiting" rather than expose her child to potentially harmful radiation.

Within 24 h the patient had returned to the emergency department with progression of symptoms. She was febrile, tachypneic, and tachycardic. Surgical management was indicated, and she was definitively treated for perforated appendicitis after undergoing laparotomy [11].

Analysis/Discussion

This case emphasizes how knowledge of radiation risk, including fetal radiation exposure, can potentially induce or circumvent an adverse patient safety event, which, in this case, is centered on the unnecessary avoidance of diagnostic imaging. Understanding and appropriately explaining radiation dose risk could have avoided the breakdown in patient safety in this case. Additionally, awareness of alternate imaging modalities could have prevented the delayed and more complicated diagnosis of perforated appendicitis.

We start with a basic understanding of terminology: to define radiation absorbed dose as well as stochastic and deterministic risk. Absorbed dose is a measurement of the radiation absorbed locally, per unit mass, in Gray (Gy), where 1 Gy is equal to 1 J of energy deposited in 1 kg of tissue [12]. Absorbed dose is then used to find additional useful measurements of radiation such as equivalent dose (a quantification of biologic damage caused by different forms of radiation, in Sieverts) and effective dose (the dose sum of all organs exposed to the radiation while accounting for each organ's radiosensitivity, in Sieverts). The most important value is the absorbed dose, which provides us with a benchmark for radiation risk.

Radiation risk is subdivided into two major categories: deterministic and stochastic. Deterministic risk refers to the threshold absorbed organ (or fetal) dose that is required to produce an adverse tissue reaction and stochastic risk refers to the risk of cancer induction because of irradiation. Deterministic means "determined by a cause" in which no randomness is involved, while stochastic means "randomly determined" in a system of probabilities [13].

Deterministic effects include all tissue-level reactions associated with local cell death and can range from mild erythema or hair loss to major skin burns and cataracts. Because this case involves a pregnant patient, it is necessary to mention fetal deterministic effects, which include malformation, intrauterine growth restriction, developmental delay, increased risk of developing a seizure disorder, and fetal death [14]. The risk of experiencing a deterministic effect by the primary patient or a fetus follows a threshold, below which there is *no* risk of developing the tissue reaction, but above which the severity of reaction increases linearly with increasing radiation dose [14–16]. Deterministic effects usually occur at high levels of radiation, such as 1–2 Gy, but the widely accepted lowest threshold for deterministic effects of all kinds is 100 mGy, including to the fetus [14, 16]. Exposure to a radiation absorbed dose less than 100 mGy is not expected to produce a clinically significant deterministic effect. Temporary skin erythema does not occur until a

threshold dose of 2 Gy and temporary hair loss does not occur until a threshold dose of 3 Gy. A Sentinel Event, which results in an immediate documented root cause analysis of the exposure to the Joint Commission, occurs only after a field of view is exposed to 15 Gy [15].

Using these values as a frame of reference, now consider our case scenario in which a pregnant patient is counseled that a single abdominopelvic CT scan could expose her 28-week fetus to a level of radiation which carries risk of fetal malformation. First, consider the absorbed dose to the fetus. When the fetus is in the field of view (within the radiation beam pathway), the dose to the fetus is roughly proportional to the CTDIvol (CT dose index by volume), which is a standard reproducible dose estimate utilizing a phantom irradiated in a CT scanner [14, 16, 17]. The CTDIvol of an abdomen/pelvis CT is approximately 25 mGy, far below the 100 mGy fetal deterministic effect threshold. Studies suggest that deterministic effects from exposure to an absorbed dose of 50–100 mGy remain clinically undetectable, and exposure to an absorbed dose less than 50 mGy results in negligible organ (and fetal) dose. Commonly ordered radiographic exams with their corresponding estimated fetal absorbed doses are depicted in Tables 18.1 and 18.2.

Second, consider the gestational age of the fetus. At 28 weeks, the fetus is well beyond the period of organogenesis, which occurs during the embryonic period of development in weeks 3–8. Radiation-induced organ malformation at this gestational age is therefore highly unlikely [18]. The other possible deterministic effects of IUGR, developmental delay, or development of seizure disorder would not be expected at a single absorbed dose of approximately 25 mGy, as outlined in Table 18.3. The final, and understandably terrifying, risk of possible fetal death is

Table 18.1 Estimated conceptus doses from radiographic and fluoroscopic examinations

Examination	Typical conceptus dose (mGy)
Cervical spine (AP, Lateral)	<0.001
Extremities	<0.001
Chest (PA, Lateral)	<0.002
Thoracic spine (AP, Lateral)	<0.003
Abdomen (AP)	
21-cm patient thickness	1
33-cm patient thickness	3
Lumbar spine (AP, Lateral)	1
Limited IVP[a]	6
Small bowel study[b]	7
Double contrast barium enema study[c]	7

AP anteroposterior projection, *PA* posteroanterior projection
Adapted with permission, from reference in the first edition
McCollough CH, Schueler BA. Atwell TD, Braun NN, Regner DM, Brown DL, LeRoy AJ. Radiation Exposure and Pregnancy: When should we be concerned? Radiographics 2007; 27:909-917
[a] Limited IVP assumed to include 4 abdominopelvic images. Patient thickness 21 cm assumed
[b] A small bowel study is assumed to include a 6-min fluoroscopic examination with the acquisition of 20 digital spot images
[c] A double contrast barium enema study is assumed to include a 4-min fluoroscopic examination with the acquisition of 12 digital spot images

Table 18.2 Estimated conceptus doses from single CT acquisition

Examination	Dose level	Typical conceptus dose (mGy)
Extra-abdominal		
Head CT	Standard	0
Chest CT		
Routine	Standard	0.2
Pulmonary embolus	Standard	0.2
CT angiography of coronary arteries	Standard	0.1
Abdominal		
Abdomen, routine	Standard	4
Abdomen/pelvis routine	Standard	25
CT angiography of Aorta (chest through pelvis)	Standard	34
Abdomen/Pelvis (stone protocol)[a]	Reduced	10

Adapted with permission, from reference in the first edition
McCollough CH, Schueler BA. Atwell TD, Braun NN, Regner DM, Brown DL, LeRoy AJ. Radiation Exposure and Pregnancy: When should we be concerned? Radiographics 2007; 27:909-917
[a] Anatomic coverage is the same as for routine abdominopelvic CT, but the tube current is decreased and the pitch is increased because standard image quality is not necessary for detection of high contrast stones

Table 18.3 Summary of suspected in-utero induced deterministic radiation effects

Menstrual or gestational age	Conception age	<50 mGy	50–100 mGy	>100 mGy
0–2 weeks (0–14 days)	Prior to conception	None	None	None
3rd and 4th weeks (15–28 days)	1st–2nd weeks ((1–14 days)	None	Probably none	Possible spontaneous abortion
5th–10th weeks (29–70 days)	3rd–8th weeks (15–56 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Possible malformations increasing in likelihood as dose increases
11th–17th weeks (71–119 days)	9th–15th weeks (57–105 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable	Increased risks of deficits in IQ or mental retardation that increase in frequency and severity with increasing dose
18th–27th weeks (120–189 days)	16th–25th weeks (106–175 days)	None	None	IQ deficits not detectable at diagnostic doses
>27 weeks (>189 days)	>25 weeks (>175 days)	None	None	None applicable to diagnostic medicine

American College of Radiology. ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with ionizing Radiation. Reston Va: American College of Radiology 2008

also not a warranted part of the informed consent process at this absorbed dose (25 mGy) at any stage of pregnancy. With a few emergent exceptions, any mention of possible fetal death would cause most expectant mothers to stop listening altogether and refuse whatever intervention is being offered. Thus, evidence-based counsel provided to a pregnant patient at 28 weeks prior to consent for a single abdomen/pelvis CT scan would include reassurance that the examination carries negligible risk of any deterministic effects.

Stochastic radiation risk is a slightly different conversation. Stochastic risk refers to the increased risk of cancer induction as a result of irradiation. Unlike deterministic risk, stochastic risk does not begin at a defined threshold but rather is a probability of developing cancer that increases with increasing doses of radiation.

Stochastic risk is less predictable than deterministic risk because it follows the "Linear No Threshold" model described above of linearly increasing probability with no known threshold. Therefore, to build a frame of reference, consider the following: a person with no radiation exposure outside of that which is considered environmental (background atmospheric radiation) has approximately a 40% total lifetime risk of developing a cancer (any cancer, including fatal cancers) [19]. Within that same person's childhood, there is a 0.2% risk of developing any childhood cancer. Animal studies have shown that exposure to absorbed doses as little at 10–20 mGy can have carcinogenic effects in proportion to 1.5–2 times the background cancer incidence. Thus, our pregnant patient undergoing an abdomen/pelvis CT scan should be counseled that this exam may expose her fetus to a level of radiation capable of increasing background childhood cancer risk by an additional 0.2%, effectively doubling the probability to 0.4%. Again, this news would be understandably terrifying to an expectant mother, but in a medical scenario where the diagnostic value and benefit of the examination are sufficiently high, a single abdomen/pelvis CT scan only minimally increases the stochastic risk to the mother and fetus.

We close the discussion of this case by mentioning another source of error. The clinician suggested an imaging modality that, while effective in diagnosing acute appendicitis when ultrasound is non-diagnostic, misses the option of a third modality: MRI [20]. Depending on the institution, this may or may not be available in a timely manner for emergent cases. Consideration of all testing modalities available is of great importance when considering any diagnostic dilemma but particularly when the patient is pregnant and facing a possible surgical procedure. The use of MRI (without contrast) for diagnosis of appendicitis, or a multitude of other etiologies of abdominal pain in pregnancy, can reduce negative appendectomy by up to 50%—all without the use of ionizing radiation (Fig. 18.1a–c).

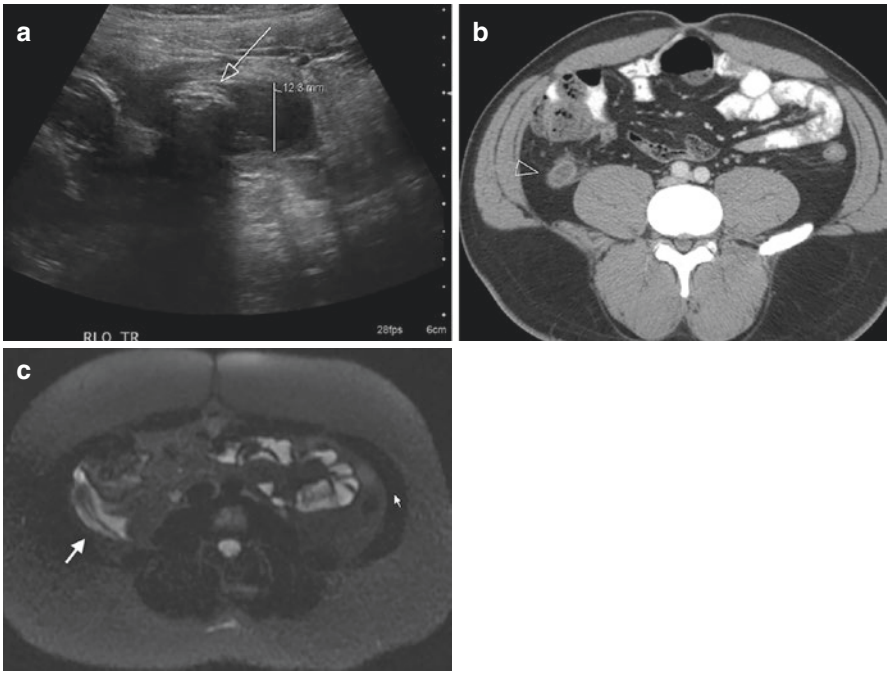

Fig. 18.1 (**a**) Ultrasound of the right lower quadrant demonstrating a dilated appendix (12.3 mm) with an appendicolith in the lumen (arrow). (**b**) CT scan of the abdomen and pelvis at the level of the iliac crests demonstrating a dilated appendix (arrowhead) with surrounding inflammatory change. (**c**) MRI of the pelvis, using T2* weighted fat suppression technique demonstrating a mildly dilated appendix with surrounding edema. (Source: Authors from first edition)

Case 3: Missed Finding in a Radiology Report

Clinical Summary

A 50-year-old male, with a past medical history of long-standing tobacco use disorder and emphysema, presented to the emergency department after a helmeted motorcycle collision. The patient was hemodynamically stable and was taken to CT for a whole-body trauma CT. The radiologist interpreting the chest CT identified a high-grade traumatic aortic injury (aortic rupture) at the aortic isthmus. Upon seeing this critical finding, the radiologist directly and expeditiously discussed the finding with the ordering provider. Next, the radiologist quickly reviewed the remainder of the study to make sure the radiology report was accessible to the clinicians caring for the patient as soon as possible. The review found several fractures, pulmonary contusions, and a mediastinal hematoma, which were included into the radiologist's final report.

The patient's traumatic aortic injury was successfully treated with a minimally invasive thoracic endovascular aortic repair (TEVAR). A CT angiogram of the chest

was performed the next day to evaluate the aortic repair. This study was interpreted by a different radiologist, who saw, and reported the expected postoperative findings. Apart from the aortic repair findings, several incidental findings were identified on the study, including severe centrilobular emphysema, moderate coronary artery atherosclerotic calcifications, and a solid 2-cm right upper lobe pulmonary nodule.

The radiologist correctly described all the findings in the "Findings" section of the radiology report and, also within the findings section of the report, provided a recommendation to consider a 3-month follow-up CT of the chest, FDG PET/CT, or tissue sampling for further evaluation of the 2-cm indeterminate pulmonary nodule, given that it could be malignant. In the "Impression" section of the report, the radiologist's first impression point described the aortic repair and states that the appearance is as would be expected after such a repair, without evidence of a postoperative complication. The radiologist's second impression point was, "Other incidental findings, as described above."

The patient was discharged from the hospital and recovered from his traumatic injuries. However, over the next year, the patient suffered a 25-pound unintentional weight loss. His workup for the weight loss revealed the previously seen 2-cm pulmonary nodule had significantly enlarged. The nodule was biopsied and found to represent a primary lung cancer. The patient also now was found to have distant metastatic disease and died 2 years later.

Analysis/Discussion

The radiologist interpreting the initial imaging (Rad1) correctly identified a severe aortic injury and appropriately discussed the finding with the ordering provider. Rad1 also identified several other traumatic injuries the patient suffered in the motorcycle collision. However, Rad1 was likely so fixated on the severe posttraumatic findings that she failed to identify a sizable pulmonary nodule that ultimately represented a primary lung cancer. The cause of this error was likely a combination of satisfaction of search (i.e., the radiologist was content with their search that yielded several posttraumatic abnormalities and therefore did not rigorously evaluate the images for additional abnormalities) and under-reading (i.e., simply missing a finding).

The second radiologist (Rad2) who interpreted the chest CT angiogram performed to evaluate the aortic repair correctly identified all the findings, including the large pulmonary nodule, and reported them in the "Findings" section of their report. Rad2 also provided appropriate management recommendations per the most current version of the Fleischner Society guidelines [21]. However, the pulmonary nodule and the follow-up recommendations went unnoticed by the ordering provider, likely because they were not specifically restated and highlighted in the "Impression" section of the report. If the radiologist had specifically listed the important finding of the large indeterminate pulmonary nodule and the associated proper follow-up recommendations in the "Impression" section of their report, as recommended in an

ACR Practice Parameter [22] and in the radiology literature [23], the patient's cancerous nodule would likely have been diagnosed before metastatic disease developed and the patient could have been treated earlier with a likely better outcome.

Another action that could have prevented the adverse outcome would have been a direct phone call discussion between the radiologist and the ordering provider about the concerning pulmonary nodule and the recommendations. According to an ACR Practice Parameter, findings that are significant, unexpected, and "have a reasonable probability of impacting the patient's health…, if not acted on," may warrant communication between a radiologist and the ordering provider. Further, because the large indeterminate pulmonary nodule had a significant chance of being malignant (calculated risk of nodule malignancy of 13.2% using the Brock University cancer prediction equation) [24], direct discussion about this finding between the radiologist and the ordering provider would have been particularly helpful in this case even if the finding is not germane to the immediate acute clinical scenario. See Fig. 18.2 for a fishbone schematic example of a root cause analysis of this case.

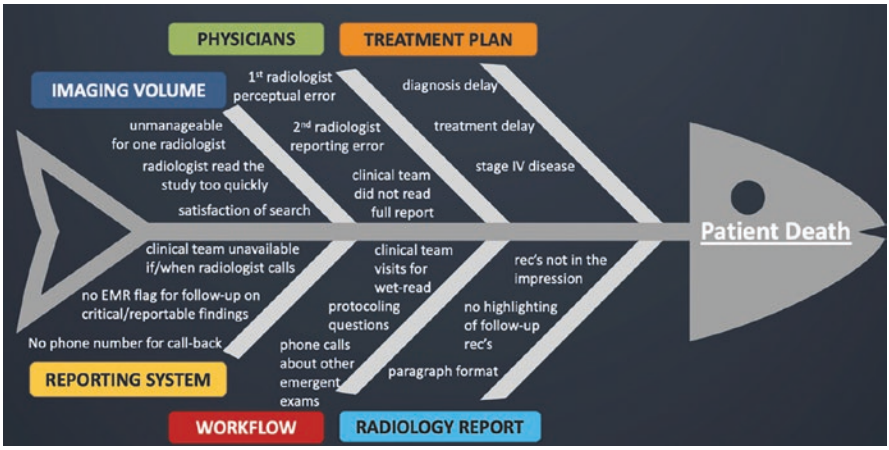

Fig. 18.2 Fishbone schematic for root cause analysis of case 3. People = ***Physicians*** → both the Interpreting Radiologists & Ordering providers → the actual people involved in the human error. Method = ***Workflow*** → includes all distractions while the radiologist is working. Machine = ***Reporting System*** → PACs and EMR inefficiencies which make it difficult for radiologist to call an ordering provider. Materials = ***Radiology report*** → the physical report and its style or aesthetic which can lead to skipping over the important parts while reading quickly (missing reportable or critical findings). Measurement/Environment = ***Imaging Volume*** → the number of studies that a radiologist is responsible for per unit of time, which may lead to misses related to speed of interpretation. Also includes the measurable ebb and flow of high-acuity work in a level 1 trauma center, which is a "mother-nature" cause uncontrollable by the radiologist and ordering provider, but can lead to misses of "non-critical" findings in the face of an emergency. ***Treatment plan*** → Delay in follow-up of workup and treatment is a real cause of stage IV disease. (Source: Authors)

Causes of Imaging Interpretation Errors

In addition to the described safety concerns and errors that might arise from technical issues or system faults in the radiology department, it is important to understand that the process of image interpretation is also subject to error. It is important to recognize existing cognitive biases that can contribute to errors to develop recognition and strategies for error reduction. The estimate of the true prevalence of radiologic interpretation errors is around 4% [25, 26].

There are two broad categories of radiologic error, perception and cognition errors [27]. Perceptual errors occur when a finding is not seen and account for the majority of radiologists' errors [28]. These are at increased risk with poor conspicuity of the lesion on the image, reader fatigue, disruptions, and rapidity of case review. This points to the importance of technical image acquisition quality, and radiologist workflow and productivity expectations. Cognitive errors involve a finding being seen, but that the clinical significance of the finding is erroneously placed. These errors may be associated with insufficient fund of knowledge or incomplete connection or synthesis of a constellation of seemingly disparate findings.

A commonly cited classification system for radiology error was first developed by Renfrew [29] in 1992 and further developed by Kim and Mansfield [30]. This categorization scheme includes a further breakdown of the above causes of error. Perception errors include missed findings, limitations of the technique, location of finding outside the area of interest, and satisfaction of search. Cognitive errors include misattribution of a finding to the wrong cause, faulty reasoning, and lack of knowledge of the cognitive category. Several other causes of error such as poor availability of clinical history, lack of prior comparison examinations, and overreliance on a prior reported examination, can lead to both perception and cognition misses. Finally, communication errors and complications from the performance of an examination are additional sources of error.

The reason such categories may be beneficial, other than for academic purposes, is that they can inform strategies for error reduction and improve patient safety. Faulty or biased cognitive processes may be addressed through understanding cognitive biases and addressing them directly [30]; although the empirical evidence for such efforts remains to be proven [31]. Other interpretive error reduction efforts such as the use of checklists have been shown to reduce errors of omission in other areas of medicine [32]. The analogue in radiology is the use of structured reporting templates, although this remains controversial in mandated use [33]. Conventional quality improvement cycles "plan, do, study, act" can focus on certain error categories that are more common in the department or with individual practitioners to focus improvement efforts.

Special Considerations for Ionizing Radiation

In addition to the general concerns about radiation and its risks, special considerations should be made for populations more sensitive to ionizing radiation, including pediatric and pregnant patients. These patient populations are more sensitive to ionizing radiation exposure for several reasons. Children and fetuses are smaller than adults, and the same dose on a smaller cross-sectional area means a higher effective dose [34]. They are still growing and, therefore, their tissues are more radiosensitive [35]. Finally, their longer remaining life spans allow a prolonged latency period before the stochastic effects of radiation may manifest [36].

The radiology community has long espoused the "as low as reasonably achievable"—ALARA principle in practice. As the growth of CT has increased exposure to medical ionizing radiation, radiology professional associations have collaborated on an Image Wisely [37] campaign to lower the amount of radiation used in medical imaging and to eliminate unnecessary procedures to reduce needless or low-value exposure.

Similarly, an Image Gently [38] campaign has been raising awareness of the importance of decreasing radiation dosing when imaging children. Imaging protocols should be tailored for children with smaller body habitus, such that they receive the right dose of radiation for the imaging to be acquired. This is a similar analogy to pediatric patients receiving medications dosed to their age, height, and weight, which are generally lower than those of adult doses.

When deciding on whether an ionizing imaging study or procedure should be performed, the above points should be considered, particularly for these radiosensitive populations. The proper risk/benefit analysis must still be considered because if the medical benefit outweighs the risks, despite the above concerns, the procedure should still be recommended.

MRI Safety

Magnetic resonance imaging (MRI) utilizes rapidly changing electromagnetic fields to create images that can produce exquisite contrast of soft tissues. This technology does not use ionizing radiation and there remain no documented health risks associated with MRI scans. However, there are some important safety issues specific to this technology that warrant discussion.

It is critical to know that even when an MRI scanner is not acquiring a study, the machine and its powerful magnetic field remain on. There have been reported events of oxygen tanks being pulled into the MRI machine striking and killing patients [39]. This author has personally seen a code cart being pulled into the scanner during a code where the code team was unaware that the magnetic field is always on (Fig. 18.3). Therefore, care must always be taken and screening for metal done before entering an MRI room.

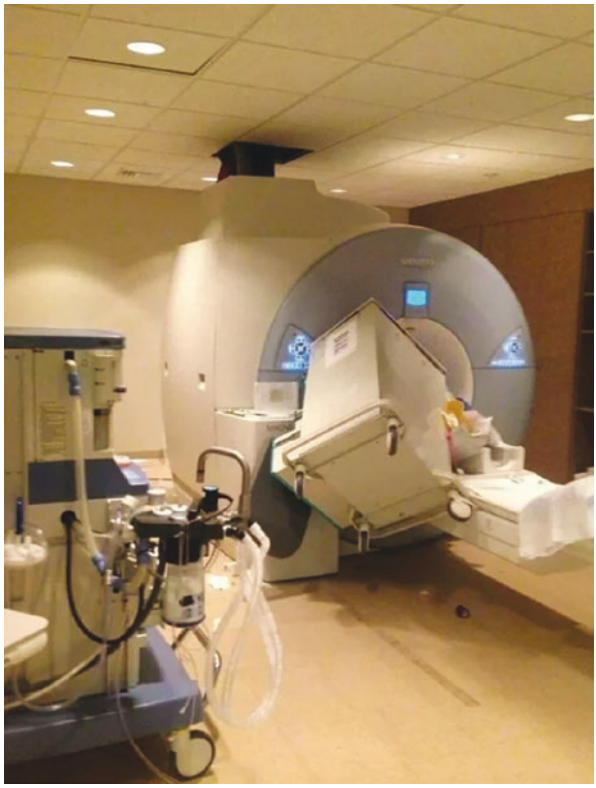

Fig. 18.3 Code cart pulled into an MRI scanner despite no examination being run at the time. It is critical to realize that the magnet is ALWAYS on. (Source: Image available at Reddit. Last accessed 11 Jan 22)

Screening should also be performed for internal compatibility of implants or devices. For ferromagnetic items, such as aneurysm clips, shrapnel, and implants, there may be a risk of dislodgement or movement. MRI also utilizes radiofrequency energy which can also induce electrical voltages and currents in non-ferromagnetic conductive materials including some implants, pumps, and pacemakers, and can heat up certain items. MRI technologists are well-trained to perform these screenings but referring providers for MRI exams should be aware of these limitations and restrictions and should consult with a radiologist with any questions or concerns at the time of ordering the exam. The American College of Radiology has a comprehensive MRI safety manual that serves as a useful reference guide [40].

Burgeoning Technologies

Radiology prides itself as an innovation and technology-forward specialty having pioneered digitization, natural language processing, and most recently augmented intelligence (AI). AI, as another tool, has the opportunity to improve medical imaging and diagnosis. There are opportunities to use AI as a tool to improve patient

safety and quality. AI can serve as a layer of redundancy, further providing a layer of safety protection within the Swiss Cheese model. For example, AI tools can be used for queue management to prioritize studies with critical findings for immediate review, quality assurance for image acquisition, tailoring radiation reduction protocols, providing second reads, or eye-tracking algorithms that can figure out blind spots of study interpreters.

However, important limitations exist for AI algorithms that users should understand to ensure that these algorithms do not serve as a new source of error and safety concerns. AI models perform as a function of the underlying data on which the algorithms are trained. Therefore, inherent issues with data may be perpetuated by AI algorithms. The two most concerning issues are bias and generalizability. A seminal study in *Science* exhibited that AI models can perpetuate racism in healthcare [41]. As models are trained on a data set from a particular population and validated on its performance, it is important to understand that the application of that AI model to your own institution's population or the general public may not perform as well as on its trained population [42]. Therefore, it is important to recognize that the performance of AI algorithms may deteriorate when used on different populations and that the validity may be lost if models are overfitted to the training population or if your population is significantly different.

Key Lessons Learned

- When ordering an imaging exam, providing a good clinical history or suspected diagnosis to rule out is an important component to ensuring the right test and protocol is performed, to maximize diagnostic yield and minimize errors.
- Consider consulting with radiologists or clinical decision support mechanisms, prior to ordering studies, particularly when there is uncertainty or limited experience with which study to order.
- Accurate knowledge of radiation risk can prevent unnecessary exposure due to inappropriate medical imaging and can also help clinicians with the calculation of risk/benefit when determining whether to subject a patient to ionizing radiation.
- Strongly consider direct radiologist and ordering provider discussion of unexpected or significant imaging findings that, if not acted on, could go on to cause adverse patient outcomes. Institutions should facilitate and remove barriers to communications by providing accurate contact information for ordering providers and/or a secure communications software that easily facilitates communication.

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Chapter 19
Patient Safety in Anesthesia

Sachin "Sunny" Jha, Jerome Adams, and Jesse Ehrenfeld

Introduction

Anesthesia is a field of medicine that takes pride in the advances made to promote patient safety. As recently as the 1970s, anesthesia caused death in one to two per 10,000 patients [1], yet today, that statistic has improved to one in 250,000. Despite the inherently hazardous nature of undergoing anesthesia, improvements in perioperative safety are a model for the rest of healthcare to emulate. The Institute of Medicine cites anesthesia as a realm where "impressive improvements in safety have been made" [2, 3]. A careful commitment to introspection, data collection, and a culture shift to promote safety have been critical to enhancing anesthesia outcomes worldwide.

Organizations such as the Joint Commission, Center for Medicare and Medicaid Services, and the Institute of Medicine, and programs such as the Surgical Care Improvement Project and the National Patient Safety Goals have attempted to standardize quality metrics and goals across hospitals and health systems [4]. These metrics have allowed individuals, accrediting bodies and payors to directly compare health entities and reward or penalize safety and performance metrics. Additionally, these safety standards have enabled the distribution of best practices across health entities, ensuring that patient safety and quality improvements remain at the forefront of healthcare delivery [5].

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Within the clinical practice of anesthesia, many departments have instituted localized quality tracking and care indicators such as first case starts, turnaround times, operating room utilization, and staff emergency preparedness [6]. Tracking these localized quality indicators is an additional strategy to improve clinical care delivery [7]. Further, adopting the Standardized Nomenclature in Medicine (SNOMED) has promoted a uniform standard for trackable metrics [8]. Organizations such as the Association of Anesthesia Clinical Directors and Benchmark International assist with data collection and comparison across different health entities [9].

Through the 1980s, the American Society of Anesthesiologists (ASA) made a concerted effort to lead systemic changes in anesthesia practice to promote uniform standards of care. In 1985, the Anesthesia Patient Safety Foundation (APSF) and the ASA Closed Claims Database were founded. The APSF was created as an independent organization (enabling flexibility to target all issues within anesthesia) with the vision that "no patient shall be harmed by anesthesia" [10]. The organization strives to normalize the safety culture and raise awareness of anesthesia delivery. The development of different technologies to aid in the monitoring and delivering of anesthesia, such as video laryngoscopes, oxygen and carbon dioxide analyzers, and continuous monitoring of critical vital signs have also dramatically improved our ability to monitor and intervene within seconds [11].

The ASA Closed Claims Database has been used to identify strategies for risk mitigation, safety lessons, and quality improvement by the systemic review of settled insurance cases [12]. Among other standards, the study of closed claims has ushered in the adoption of pulse oximetry and carbon dioxide monitoring, resulting in dramatic improvements in anesthesia safety [13]. Continuous database analysis has been critical to identifying new targets for improving anesthesia practice and has contributed to numerous practice bulletins [14].

The field of anesthesia is a recognized leader in promoting and advancing patient safety, via systemic review and dissemination of best practices through organizations such as the APSF and the ASA. These organizations have been critical in achieving safety improvements in anesthesia and effects have been pronounced, with morbidity and mortality improving, and litigation decreasing [15]. The continued emphasis on safety above all will be paramount as anesthesia care continues to evolve.

Case Studies

Case Study 1: Appropriate Candidates for Outpatient Surgery

Summary

A 78-year-old male with a history of chronic left knee pain and hypertension presented to the hospital for an elective outpatient left total knee replacement. His outpatient prescription medication regimen included carvedilol 25 mg daily, pregabalin 100 mg twice daily, and hydrocodone-acetaminophen 5–325 mg every

4–6 h. His surgeon wished to perform the procedure under general anesthesia because he had “a bad experience with nerve blocks,” and his patients “do not like sedation.” After undergoing the procedure under general endotracheal anesthesia at an outpatient surgery center, while in the recovery room, the patient received a total of hydromorphone 3 mg IV and oxycodone 10 mg PO over the next three hours to achieve appropriate pain control before being discharged. Later that evening, his pain returned, and increased to the point where he felt it was the worst he had ever experienced, and his prescribed pain regimen failed to adequately improve his condition. Unable to walk and with his elderly spouse overwhelmed and unable to take care of him, he called an ambulance and was taken to the emergency room. He received an additional 3 mg of hydromorphone IV before achieving pain control. After being admitted, he continued to have difficulty with pain control and rehabilitation. On postoperative day three, he was finally discharged, albeit on a a substantially higher pain regimen.

Analysis of Root Causes and Systems in Need of Improvement

In this case, the patient underwent a procedure in an inappropriate setting, received a non-standard anesthetic regimen for the surgery, required an inordinately high amount of narcotics immediately post-operatively, was inappropriately discharged and ultimately required admission to a hospital for pain control and rehabilitation. Viewing this case through the lens of the Swiss Cheese model, a series of medical errors and decisions that continued to compound led to an adverse outcome.

This patient should not have undergone this procedure in an outpatient setting based on his history of chronic pain. Using robust systems and criteria to determine appropriate candidates for outpatient surgery is critical. Numerous human touch points should and typically do exist to catch and prevent patients like this from being scheduled inappropriately. However individuals such as the facility medical director, other surgeons, and support staff often approve cases, but may not be the individuals actually performing them. This creates situations where the onus transfers to the clinicians taking care of the patient at the last mile. Unfortunately, the anesthesiologist, who serves as the patient's final and often most critical advocate, too frequently learns about the patient they are taking care of only immediately before surgery is scheduled, and may not have appropriate records to review. Fragmented data sharing systems, ineffective electronic medical records, poor communication between the various entities, an inability to close the loop, and reliance on human decision-making trees that can be easily automated are faults that led to this outcome.

A crucial aspect of a patient’s ability to successfully undergo an outpatient knee replacement involves using modern strategies to combat pain and minimize the effects of undergoing anesthesia. The anesthetic plan did not utilize advanced methods that have become standard care for patients undergoing total joint replacement. A more collaborative approach between the surgeon and anesthesiologist could have avoided this outcome. The use of peripheral nerve

catheters for postoperative pain control, a spinal anesthetic and avoidance of general anesthesia have become the best practice for patients undergoing total knee replacement. Additionally, anesthesiologists must always advocate for their patients' immediate and long-term clinical outcomes by addressing red flags proactively, such as their home pain regimen.

Further, a patient requiring such a significant amount of pain medication in the acute phase of recovery necessitates transfer to an inpatient facility where a physician can prescribe a more effective pain regimen. Similar to the criteria used to determine the appropriateness of a patient to undergo outpatient surgery, standards exist regarding safely discharging a patient. This patient did not achieve a reasonable degree of pain control in the recovery room and should have received further evaluation. Too often, staffing pressures, cost-control measures, physical space, and scheduling limitations can inappropriately hasten discharges.

Discussion

As outpatient surgery continues to increase, systems that ensure the appropriate patients, anesthetic strategies, and surgeons in this setting need to be in place. Clinicians need to appreciate the differences between the ambulatory and hospital setting, such as staffing and post anesthesia care limitations, and varying time pressures.

Candidates for elective outpatient surgery need to be carefully screened and selected [16]. Patients with numerous co-morbidities, such as obstructive sleep apnea or chronic pain, have been considered high risk and likely poor candidates for outpatient surgery [17]. Similarly, patients need to be medically optimized, expectations set, and appropriate follow-up strategies well elucidated. Numerous societies, particularly within orthopedics, have prepared guidelines to assist clinicians in creating outpatient surgical programs maximizing safety and throughput [18]. Central concepts in these strategies include multidisciplinary approaches to patient care and collaboration across all key partners, particularly the patient.

An emphasis on narcotic reduction has been an overwhelming theme over the past several years due to the significant impact of the opioid epidemic. The United States has 4.4% of the world's population yet accounts for 80% of opioid usage worldwide [19]. For many individuals, their exposure to opioids begins in their operative encounter [20]. Outpatient surgery must emphasize using non-narcotic treatments for pain management, acutely and post-operatively. Tools such as nerve blocks, non-narcotic oral medications, and pre-conditioning patients have been proven effective in reducing the perioperative consumption of narcotics [21]. Despite these strategies, patients are still prescribed an overabundance of opioids on discharge, creating a risk for dependency and diversion [22]. Enhanced recovery after surgery (ERAS) principles have been adopted widely across hospitals and surgical centers, allowing for postoperative reductions in ongoing opioid use with retained surgical outcomes [23]. Many strategies have called for outright elimination of opioids perioperatively; however, an outpatient surgical encounter's acute and

transient nature may lead to inadequate pain control resulting in patient dissatisfaction and unintended emergency room visits [24]. Regardless, clinicians and patients are responsible for reducing the emphasis on narcotics for pain control.

Avoiding items that can delay discharge or lead to unintended postoperative admission is a critical goal for all clinical care members. Protocols addressing blood pressure, prolonged anesthesia, urinary retention, excessive pain, postoperative nausea/vomiting, medical equipment, rehabilitation, home health and other social issues must be adhered to [25]. Unintended admissions and prolonged postoperative unit stays can negatively impact the cost of care, patient satisfaction, and a myriad of other outcomes. Minimizing complications such as these are critical for an effective outpatient surgery program. Operating rooms need to be run efficiently and cost-effectively and cannot be a financial drain, particularly in an outpatient setting. Success is judged by management and optimization of operating room time and the number of cases performed. Patient intake and discharge processes require streamlined precision to maximize time spent in the facility on the revenue generating aspects of care, while minimizing inefficiencies such as prolonged recovery time.

Finally, maintenance of patient safety is always critical, and ambulatory surgery centers should strive to function as high-reliability centers maintaining strong quality and clinical standards. Patient trust and public scrutiny will soon follow if safety and quality standards lapse [26].

Case Study 2: Medication Administration Errors Can Have Dramatic Adverse Outcomes

A 65-year-old male with a history of poorly controlled hypertension is undergoing a robotic radical prostatectomy. After an uneventful surgery and post-operative extubation, the patient's blood pressure is 205/110 with a heart rate of 60 beats per minute. The anesthesiologist removes a vial from the automated medication dispensing machine which they presume to be hydralazine. While distracted by the operating room nurse, the anesthesiologist draws up half the bottle and administers it. The heart rate drops to 20 beats per minute within one minute, with a repeat blood pressure of 320/130. The anesthesiologist calls a code blue. A second anesthesiologist arrives. The primary anesthesiologist stated they intended to administer hydralazine for hypertension, pointing to the bottle sitting atop the ventilator. The second anesthesiologist notes that the vial is phenylephrine, a potent vasoconstrictor that raises blood pressure and reduces the heart rate. After confirming the hypothesis of a medication error, they give nitroglycerin until the blood pressure and heart rate normalize. Upon arrival to the recovery room, the patient interacts appropriately with no apparent abnormalities.

Analysis of Root Causes and Systems in Need of Improvement

In this case, the anesthesiologist inadvertently administered an incorrect medication resulting in the hypertensive emergency. Upon reviewing the bottles, they noted that both bottles were present next to each other in the automated medication dispensing system in vials with nearly the same-colored top and size (Fig. 19.1). The anesthesiologist failed to note the differences on the labels and administered the wrong medication.

At the end of a surgical case, the operating room is quickly disrupted by a cacophony of noise and activity. Scrub techs are breaking down their instrument setup, environmental service staff enters to clean the room, and there is a palpable rush to get the patient extubated and out of the room. During the emergence from anesthesia, arguably the most dangerous point of the procedure, urgency can cause the anesthesiologist to become easily distracted attempting to simultaneously give reports, complete charting, waste controlled substances and monitor the patient's vital signs. With haste and distraction, the anesthesiologist inadvertently chose the wrong drug in the automated drug delivery system, dismissed confirming the drug and administered the wrong medication.

Other factors contributed, including look-alike packaging and labeling. In this case, the placement of the two drugs in adjacent pockets with similar colored tops and sizes is ripe for a medical error. Color coding medication vials and using similar dimensions place a false sense of assurance on the contents of the actual vial reinforcing the notion that the physician does not have to read the label to verify the contents [28]. This sets a dangerous feedback loop leading to issues like the one described here.

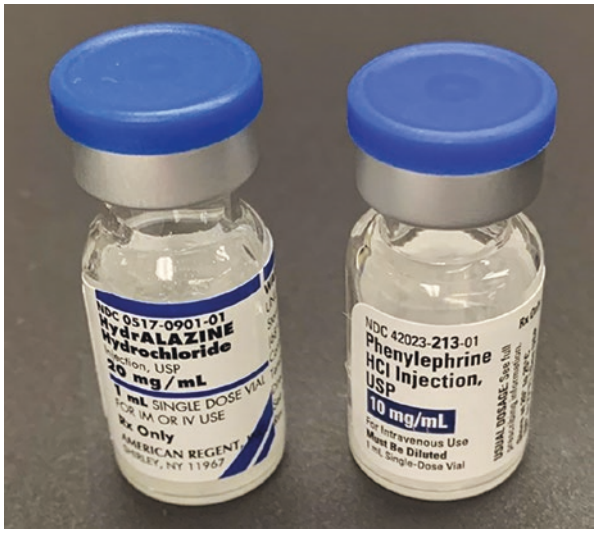

Fig. 19.1 Hydralazine and phenylephrine vials. A side-by-side comparison of hydralazine and phenylephrine bottles [27]

Discussion

Medication safety errors continue to plague the healthcare system, with an estimated incidence of 5% in the operating room [29]. Drug administration within the realm of anesthesia poses specific challenges. Anesthesiologists are unique in that they fill the pharmacist, nurse, and physician roles when prescribing, dispensing, preparing, and administering medications. Other clinicians have numerous checks and balances (which may also be sources of errors), including placing the order (often with electronic medical record guardrails), subsequent authorization from the pharmacy and, ultimately, final administration via a nurse at the bedside. Furthermore, medications administered by anesthesiologists tend to be much more rapid acting and potent than those used by any other physician requiring careful usage and monitoring with the distinct possibility of causing significant harm very quickly in the event of an error.

Medication errors under the auspices of anesthesia tend to involve miscalculation of dosages, concentrations, timings and infusions, and inadvertent substitution of vials or syringes [30]. Other errors described include incorrect route administration, dilution/concentration irregularities, electronic pump setup missteps, nonadherence to known allergies and failures to flush lines after administration [31]. Fortunately, most harm from medication errors within anesthesia tends not to result in catastrophe; however, lethal incidents occur.

Various organizations have authored guidelines to avoid medication mistakes; however, the challenges persist. Many procedures and recommendations outlined are based on expert opinion and have not been proven in trials. Attempting to isolate confounders and, ultimately, the human factor makes studying this issue very difficult.

In the perioperative setting, barcode scanning before administering medication is often an afterthought due to the very critical nature of the environment, where every second can matter. Even with scanning, medication errors still happen, as users have become numb to warning messages [32].

Additionally, look-alike drug names can be dangerous. Although phenylephrine and hydralazine have distinct names, similarities between drugs, such as versed and vecuronium, have led to fatal outcomes. In one such incident, a radiology-suite nurse mistakenly gave vecuronium, a paralytic, instead of versed (a sedative and brand name for midazolam) to a patient requiring sedation [33]. In this case, the nurse overrode numerous warnings on the automated drug delivery machine, ignored the warning labels on the bottle, dissolved the drug as it came in a powder form and ultimately administered it. The results were lethal, as the patient was given a paralytic, rendered physically unable to breath, left unmonitored and died of asphyxiation.

Reporting and reviewing of errors is key to elimination of future errors, and enabling others to learn from mistakes. Hospitals and health systems need structures to report safety events or critical incidents to allow for review by a safety committee with recommendations to address the incidents. A culture of safety, where attempts at improving it are applauded and requested, is critical to creating a high-reliability

organization [34]. Fear of retribution, punitive discipline and embarrassment can lead to medication errors being covered up and those committing the errors, dissuaded from reporting.

Organizations such as the APSF collect safety incidents and disseminate them to a larger audience to prevent safety lapses from repeating. Newsletters and articles that are freely accessible are critical to improving awareness of issues affecting the specialty. To err is to be human, but with appropriate systems and a culture promoting safety, the incidence and severity of medication errors will improve.

Key Lessons Learned

Case 1

- Systems need to be in place to select appropriate candidates for outpatient surgery.
- All clinicians and patients have a role in reducing the consumption of narcotics.
- Patient safety should be the most critical aspect of care.

Case 2

- Medication errors are challenging to prevent and causes are multifactorial.
- Medication errors within anesthesia are a unique subset compared to the rest of medicine.
- Critical incident review and information dissemination are essential to prevent future medication errors.

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Chapter 20
Patient Safety in Behavioral Health

Renuka Ananthamoorthy and Robert Berding

Introduction

Behavioral health patients pose unique and complex safety challenges in the modern healthcare environment. They may enter the hospital setting with a psychiatric diagnosis in addition to medical comorbidities and/or co-occurring addictive disorders. Therefore, it is imperative that healthcare organizations have well-established policies and procedures to assess safety risks, provide targeted interventions, communicate across disciplines/departments, and include all necessary stakeholders in the process.

This population requires safety planning that goes well beyond the development of ordinary healthcare risk mitigation strategies aimed to prevent unintended harm to all patients. Due to the nature of the illness, there are also risks of intended patient harm to self and/or others.

The threat of suicide is obviously the most serious intentional self-harm to safeguard against in the healthcare continuum. A self-harm analysis of inpatient suicide methods suggests that hospital prevention efforts should be primarily focused on mitigating risks associated with hanging while additional suicide prevention efforts may be best directed toward reducing the risk of suicide immediately following discharge. The Columbia Suicide Rating Scale is intended to be used by individuals who have received training in its administration as the questions are suggested probes for self-harm [1]. The safety risk assessment for self-harm has been updated annually since 2019 by The Joint Commission (TJC) within National Patient Safety

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Goal 15.01.01 which contains Elements of Performance for Environmental Risk Assessment, Validated/Evidenced Based Screening Tools, Validated/Evidenced Based Suicide Risk Assessment Tools, and Safety Planning upon Discharge. [2] TJC classifies an in-hospital suicide attempt as a sentinel event as it is not primarily related to the patient's illness or underlying condition and may result in death, permanent harm of severe temporary harm [3].

The threat of intentional harm to others may pose risks for other patients, visitors, and staff. In general, Workplace Violence (WPV) is a recognized hazard in the healthcare industry [4]. For behavioral health, in particular, one tool for assessing harm to others is the Broset Violence Checklist [5], which is a short-term violence prediction instrument assessing confusion, irritability, boisterousness, verbal threats, physical threats, and attacks on objects as either present or absent [6]. Ironically, the staff member is at risk of experiencing a role reversal from caregiver to victim when such harm occurs in the workplace. As such, healthcare organizations are expending a greater amount of resources to promote staff wellness programs that contemplate the trauma associated with these types of adverse events. According to the Centers for Disease Control and Prevention (CDC), eighty-three percent (83%) of hospitals now offer some type of workplace wellness program [7].

Overall, a culture of good teamwork should be fostered by the organization that places high value on respect, communication, role responsibility, and defined steps to escalate patient safety concerns. In addition, an organization should undertake a comprehensive risk analysis of potential safety pitfalls.

There are two basic analytic approaches that may be used to design safe systems for behavioral health patients. The first is a proactive approach involving multidisciplinary teamwork to examine the process of care from referral to discharge and then considering the possibilities for error at each step. This is a complex process in which different types of staff work together to share expertise, knowledge, and skills to impact on patient care [8]. The second is a reactive approach, or "causal method," involving learning from mistakes through a Root Cause Analysis (RCA). [9] Of course, a cause is not something found but rather constructed from the available evidence. Such causes of failure typically emerge from multiple sources [10]. These causes may range from direct to indirect, or from a true root cause to merely an opportunity for improvement. However, all causes should be appropriately addressed once identified through this process.

In this chapter, the causal method will be used by employing a fishbone model diagram to analyze systems breakdowns relating to (1) Communication; (2) Staffing; (3) Education; (4) Medications; (5) Environment; (6) Patient; (7) Provider; (8) Treatment Team; (9) Unit/Hospital, and (10) Electronic Health Record (EHR) in each of the following cases.

Case Studies

Case Study 1: Self-Harm

Clinical Summary

Beauregard is a 23-year-old male college graduate with a past psychiatric history of major depression recurrent with psychosis and no known history of substance abuse. He was last admitted to inpatient psychiatry a year ago for a suicide attempt in which his mother found him unconscious in the garage after inhaling exhaust fumes. On this occasion, he was brought into the psychiatry emergency room (PER) by Emergency Medical Services (EMS), after his mother called 911 for help. She reported that Beauregard called her at work to say that he was leaving New Jersey and going to Pennsylvania because the neighbors were tormenting him with fireworks. His mother begged EMS to take her son to the hospital because there was no one in Pennsylvania to care for him. Beauregard was evaluated and admitted to inpatient psychiatry for increased paranoia, suspiciousness, anxiousness, restlessness, and depressed mood. His prior medical records were on paper and not available to inpatient physicians through their new electronic health record (EHR). An initial treatment plan was made by the team while Beauregard waited outside the conference room even though he had actively participated in the treatment planning during his prior stays. Due to his increased agitation, he was placed on routine observation and started only on antidepressant medication. The following day, Beauregard took his medications and participated in all assigned activities but was unable to see the social worker who was attending a mandated, full-day in-service training program. He tried to contact his mother but was unable to do so. His mother called the unit to tell them that she had no transportation that evening but would visit Beauregard the next day. That message was taken by the unit clerk but no one informed the patient. She also asked to speak to the physician-in-charge who was too busy at the time and never returned her call. Shortly after visiting hours ended, another patient saw Beauregard hanging by his knotted bed sheets from the loopable door hinge awaiting hospital funding for replacement. An emergency code was initiated but Beauregard was pronounced dead.

Root Cause Analysis

The root cause analysis of the case revealed the following contributory factors (Fig. 20.1):

1. Communication: Despite his mother contacting the unit, Beauregard was never told of the telephone call. Perhaps this knowledge would have decreased his anxiety about her absence during visiting hours. In fact, there was no standard

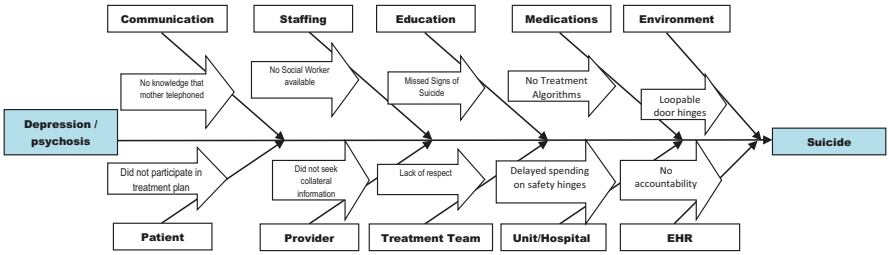

Fig. 20.1 Case 1—Multiple factors leading to a psychotic inpatient committing suicide

work in place to communicate outside information to patients. When creating communication protocols, it is necessary to include all stakeholders so that everyone has the information needed to support the treatment process.

2. Staffing: There was no back-up plan in place to fill the gap when the social worker was off the unit attending a training session. This could have been mitigated by rotating other staff onto the unit or planning the training as two half day sessions instead of one full day.
3. Education: When questioned about why the mother's telephone message was never shared with Beauregard, the clerk answered that she did not think it was as important as other duties. This demonstrated a lack of knowledge about the vital role that family members can play in the recovery effort. Also, staff's lack of understanding about the patient's agitation points to a gap in their clinical training. There is a need to provide ongoing education about the signs of suicide. If that type of training had been available, the staff may have made a better assessment about the potential for suicide in this case.
4. Medications: The patient was not started on anti-psychotics which would have helped with his command auditory hallucinations. It would have been helpful if appropriate treatment guidelines were used by the team.
5. Environment: In the behavioral health environment, it is imperative to minimize suicide risk by conducting an analysis of the potential environmental hazards. High on that list should be an assessment of door handles, hinges, and other loopable hardware. Likewise, close attention should be paid to sheets, blankets, towels, belts, and other items that may be fitted around the neck.
6. Patient: Beauregard was not invited to participate in the development of his treatment plan. However, he was aware of his role in the planning process but did not proactively attempt to have his voice heard by the team. While it is ultimately the team's responsibility to invite the patient into the process, the patient has the right to demand inclusion. This type of proactive participation is reflected in accreditation standards specially designed for promoting non-violent practices in behavioral health settings. [11]
7. Provider: The physician did not return the telephone call to seek out collateral information from Beauregard's mother. The information about his recent high-risk behaviors would have fostered a better understanding of the seriousness of his condition.

8. Treatment team: Treatment team should have included the patient in the planning process, especially because he was right outside the room at the time of discussion. This shows a lack of respect for the patient and his role as a team member.
9. Unit/Hospital: The administration was aware of the dangers associated with the current door hinge but decided to delay the purchase due to the costs. This type of purchase, especially identified through a proactive environmental risk analysis, should be prioritized or an alternate interim solution should be put in place.
10. Medical records: Although the staff were told to contact medical records for old paper charts, in practice no one ever called because there was no accountability built into the system. In such cases, it can be useful to add an attestation checkbox in the EHR that team members must check to affirm that they have received and reviewed the record.

Case Study 2: Harm to Others

Clinical Summary

Herbert is a 25-year-old male with a past history of mental illness, civil commitment, medication non-compliance, substance abuse, and criminally violent-related incarceration. He resides in a homeless shelter and is known to forego available outpatient services.

He was brought to the PER by the Police Department and EMS on a report of threats to shelter peers and staff. Upon presentation, Herbert was highly agitated, paranoid and extremely suspicious in accusing a shelter peer of stealing his jacket.

He was subsequently admitted to the adult psychiatric inpatient unit on a Friday night with a provisional medical clearance pending urine toxicology test results. There were no other follow-up laboratory tests recommended, and no review of prior inpatient records was conducted which would have revealed a history of violent behavior. His EHR behavior plan from a prior admission was viewed by the charge nurse but not shared with other staff assigned to monitor common patient areas.

Herbert was seen by the call physician the following day, who started him on a low dose of neuroleptics and a routine observation schedule, as opposed to a more frequent every 15 min (Q15), observation schedule. He refused his medications throughout the day and was observed pacing, gesturing, occasionally loud and threatening to staff and other patients. Despite this behavior, there was no call for a physician assessment of this aggressive behavior or potential STAT medication.

Early Sunday morning, around 0400, Herbert began to pace the hallway, muttering to himself and to a passing staff member who was conducting 1:1 observation on another patient. After a few minutes of pacing, he suddenly ran to a nurse,

punched her in the face without provocation and ran into his room closing the door behind him.

A code was then called but at that point the crisis team was unable to verbally de-escalate Herbert. He received a medication injection and physical restraints. The nurse was escorted to the ER and treated for a left mandibular fracture and orbital fracture of the face. The nurse filed a complaint with the local police precinct, and Herbert was transferred to a forensic unit for further care and treatment.

Root Cause Analysis

The root cause analysis of the case revealed the following contributory factors (Fig. 20.2):

1. Communication: The charge nurse failed to verbally communicate Herbert's prior violent tendencies and behavior plan to the other staff on the unit. This could have occurred at the time of admission, change of shift handoff, or special huddle to alert staff to a known risk.
2. Staffing: A Q15 observation should have been ordered for Herbert instead of routine observation. This oversight might have been due to either an improper distribution of staff or understaffing for the necessary number of persons needed for observation.
3. Education: Although situational awareness education had been provided for staff, no one reacted to the warning signs of pacing, loud speech, and threats. The staff would also have likely benefited from some ongoing de-escalation training and additional mock code drills. In addition, the details of this case should be added to ongoing data collection and analysis of adverse events to assist in improving future care.
4. Medications: The initial prescription for only neuroleptics was insufficient for Herbert. There was no consideration for the effectiveness of past medications or his present behavior on the unit.
5. Environment: Hallways present a unique challenge as long, narrow corridors tend to have varying traffic patterns, multiple entry points, and limited space for

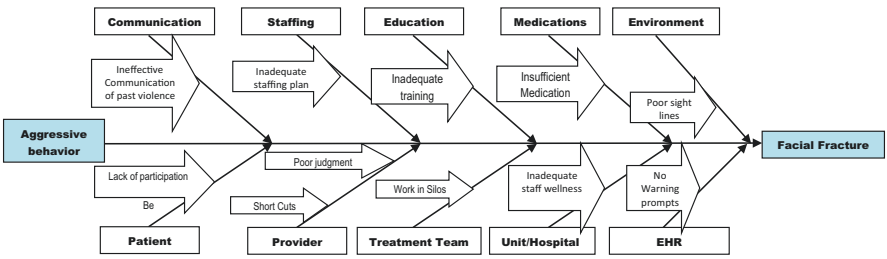

Fig. 20.2 Case 2—Aggressive behavior leading to restraints and patient/staff injury

meaningful engagement. In this case, Herbert should have been directed out of the hallway to a more manageable common area.

6. Patient: Herbert did not request any assistance for his agitation. This is not unexpected given his highly paranoid state of mind but there are times when a patient articulates upset feelings which can then be acted upon by staff. However, the behavior plan did not include this possibility.
7. Provider: The on-call physician failed to conduct a comprehensive evaluation. Oftentimes, clinicians will rely heavily on the "dynamic" presentation of the patient such as erratic behavior, loud speech, and/or threatening movements. The full evaluation includes a standardized test that would have rated Herbert at risk for aggression based on the "static" factors of age, gender, diagnosis, involuntary admission status, past psychiatric history including incidents of violence.
8. Treatment team: Herbert was clearly agitated and aggressive throughout his brief stay. This type of behavior should have been noticed by anyone on the treatment team early on and de-escalation techniques employed to redirect the behavior. There was a silo approach to tasks that was ineffective in managing the therapeutic milieu.
9. Unit/Hospital: The hospital could continue to build on its staff wellness efforts. Since this case extended beyond the hospital to the local police, the staff member should continue to be supported throughout any legal procedures.
10. Medical record: The medical record held the pertinent information that would lead a reasonable reader to be alert for harm to others. However, it did not have a proactive alert to direct an alternate course of action that could have averted this assault.

Discussion

The cases described above highlight some of the typical harm risks encountered in behavioral health settings. In a recently published handbook, the American Psychiatric Association (APA) Committee on Patient Safety identified and categorized six types of safety risks commonly associated with this population. These can be described using the SAFE MD mnemonic and include **S**uicide, **A**ggressive Behavior, **F**alls, **E**lopement, **M**edical Co-morbidity and **D**rug Errors [9]. Suicide and any serious adverse outcome relating to the other safety risks rise to the level of a sentinel event which TJC defines as "any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness." TJC requires each accredited organization to define sentinel events for its own purposes in establishing mechanisms to identify, report, and manage these events [12]. At a minimum, an organization's definition must include any occurrence that meets any of the following criteria: (1) Any unanticipated death or major permanent loss of function, not related to the natural course of the individual's illness or underlying

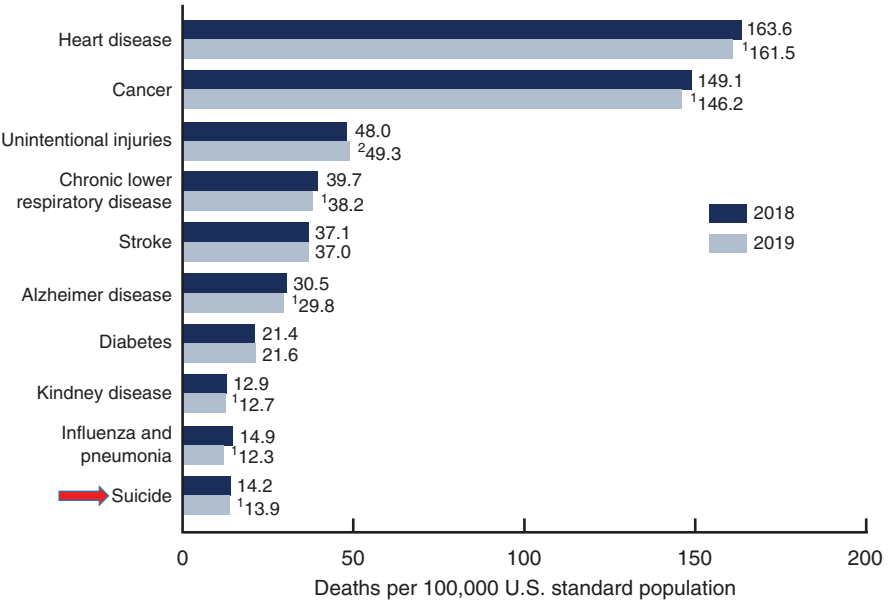

Fig. 20.3 Top 10 causes of death according to the Centers for Disease Control and Prevention (2019) in the year prior to the COVID-19 pandemic

condition; (2) suicide of any individual served receiving care, treatment, or services in a staffed around-the-clock setting or within 72 h of discharge; (3) abduction of any individual served receiving care, treatment, or services; and (4) rape.

Suicide consistently ranks high among the most frequently reported causes of death. In 2019, prior to the pandemic, the CDC reported that suicide ranked as the tenth highest cause of death in the United States [13] (Fig. 20.3).

The greatest *clinical* root cause of inpatient suicide is a failure in clinical assessment. In one study, the risk was not adequately assessed in about 60% of suicides, or else the risk level was not accorded appropriate precautions [14]. Upon all admissions, the assessment should begin with the use of a standardized tool that ideally produces a rating of the suicide risk. This rating is often expressed in terms of a "score" that can be used in conjunction with an assessment of the patient's thoughts, plans, means, and ability to complete the suicidal act. For those at risk of suicide, the assessment should be repeated following any traumatic occurrence during the stay and upon discharge. The risk of suicide is higher during the period immediately following discharge from inpatient psychiatric care than at any other time in a service user's life [15]. TJC considers suicide sentinel events as those occurring to an individual receiving care, treatment, or services in a staffed around-the-clock setting or within 72 h of discharge. Suicide continues to be among the most frequently reviewed sentinel events by TJC [16].

In the case of Beauregard, many of these factors existed. There was a poor assessment by the provider who did not recognize the presence of command auditory

hallucinations. Concurrently, there was a clear breakdown in communication among team members and in failing to inform the patient about the contact from his mother.

Aggression in psychiatric settings is a complex workplace problem. Patient factors found to be related to violence include being a young male with a diagnosis of schizophrenia, particularly with neurological impairment; having a history of violence; and being involuntarily admitted to the hospital. Research examining staff factors found that the incidence of violence was higher on wards where staff members were uncertain of their roles or where larger proportions of shifts were worked by substitute nursing staff. Similar to assessing suicide risk, the treatment team should use a combination of standardized rating tools, observations, and interviews in order to identify the likelihood of aggression on the unit. Beyond the obvious direct harms associated with aggression, there is also indirect risk of injury when attempting to manage this behavior, such as injuries resulting from attempts to subdue an aggressor. In addition, patients are at risk for self-injury if held in seclusion. Issues surrounding reduction and/or elimination of episodes of seclusion and restraint for patients with behavioral problems in crisis clinics, emergency departments, inpatient psychiatric units, and specialized psychiatric emergency services continue to be an area of concern and debate among mental health clinicians [17].

In the case of Herbert, human factors played a major role in the injury that occurred to the nurse. The charge nurse failed to alert the treatment team about his past violent behavior and behavior plan. The on-call physician failed to conduct a full assessment and prescribe appropriate medication. The staff did not demonstrate situational awareness or de-escalation techniques.

While the two cases above focused on self-harm and harm to others, there is a need to mitigate the other risks identified through SAFE MD. For example, falls may occur while patients are in behavioral health units or while experiencing altered mental status elsewhere in the hospital. There are many fall assessment tools available but the preferable ones will include the following risk factors: mental state impairment; gait and mobility; elimination problems; medications; and fall history [18]. One study showed that behavioral health patients were more likely to fall if prescribed sedatives and/or hypnotics, and experienced altered mental status or elimination problems [19].

Elopement is always a concern when persons are unwillingly detained through civil commitment and sometimes even when housed on a voluntary status. In order to minimize elopement risk, a healthcare organization should create an environment conducive to the ongoing observation of potential elopers. In addition, there should be procedures in place for searching for successful elopers and returning them to the unit if found.

It has long been acknowledged that behavioral health patients as a group were more likely than non-behavioral health patients to have a co-occurring medical illness. For example, one recent study showed that persons with schizophrenia were more likely to have a greater number of conditions spanning several disease categories including cardiovascular, pulmonary, neurological, and endocrine

diseases [20]. These comorbidities pose greater prescribing challenges and increase the likelihood of adverse drug interactions.

The prevalence of unintended and untoward drug–drug interactions is increasing in concert with both the increasing number of pharmaceuticals available and the number of patients on multiple medications. The risk of poly-pharmacy is found to be greater in patients who are on psychiatric medications such as antidepressants [21]. Therefore, prescribers should consider how medications may interact on the basis of their pharmacodynamics and pharmacokinetics along with the intended therapeutic use.

From a legal perspective, behavioral health patients may be admitted on a voluntary basis or an involuntary one, known as civil commitment. The general standard for involuntary civil commitment is whether or not the person poses a danger to self or others. An individual's "dangerousness" is clinically evaluated by one or more psychiatrists, but accurately predicting future harmful acts is far from an exact science [22]. It is the element of dangerousness that heightens the need for safety planning from prudent care management to legal obligation for this population. These legal standards have evolved through the power of the U.S. Constitution, which provides eighth Amendment protection from Cruel and Unusual Punishment and gives Congress the 13th Amendment right to enact laws aimed to prevent harms stemming from discrimination. While not a specific protected class, behavioral health patients may be subjected to sanism, which has been defined as, "the irrational prejudice that causes, and is reflected in, prevailing social attitudes toward persons with mental disabilities" [23]. These rights are generally protected by using "least restrictive alternatives" such as limiting the use of restraints and seclusion that might otherwise cause undue physical and/or psychological injury. This safety principle can be extended by the use of "safe behavior plans" in which patients contract to behave in a certain manner or else be subject to a consequence of a mutually agreed upon staff intervention. This approach can only be utilized if the patient exhibits the competence to complete a safe behavior plan.

Risk Reduction Strategies

Establish team roles and responsibilities—A well-delineated team structure assists all staff to work together. It is helpful to define the team membership, size, coordination of duties, and leadership lines. Collaboration among health professionals is the key to positive patient outcomes [24]. Often, it is just assumed that staff will perform their individual responsibilities and blend seamlessly together in the process. However, without clearly coordinated roles, they are more likely to operate within the narrow silos of their clinical expertise. This lack of coordination could cause patients' needs to go unidentified or unattended, thereby increasing safety risks.

Establish work standards for communicating clinical information—One method of sharing such information is through an interdisciplinary SBAR

(Situation—Background—Assessment—Recommendation/Request) handoff among staff. This is a technique for communicating critical information that requires immediate attention and action concerning a patient's condition. SBAR provides a description of what is happening now, the clinical context, a general assessment of any problems and an approach to correcting any problems. The SBAR is ideally given multiple times during the day in a short, huddle style. In addition to the SBAR technique, staff should be made aware of how to expeditiously escalate concerns when there is a change in patient behavior.

Establish clear guidelines for escalating safety concerns—Once the roles and work standards are in place, it is important for team members to have a mutually supportive method to escalate any perceived emerging safety issues. Sometimes staff are reluctant to challenge team leaders in fear of offending egos, overstepping professional boundaries, and/or retaliation. These fears must be put aside when they have an overriding safety concern. It becomes possible to allay such concerns if there is an organizational commitment to creating a culture whereby staff can respectfully advocate for the patient in a firm and assertive manner.

Formalize guidelines for de-escalating crisis situations—Balancing the safety of patients, visitors and staff require targeted training to prevent crisis from occurring when possible and effectively manage the environment when it becomes unavoidable. The primary concern becomes how to limit the use of restraint so that the patient is not exposed to excessive force. There are several nationally recognized training programs designed to mitigate the risks associated with harm intended by a patient. There are also some state and local regulations that give prescriptive guidelines. In New York State, for example, the Office of Mental Health has a restraint policy [25] which requires a 3-day minimum training, with a 2-day review program for Preventing and Managing Crisis Situation (PMCS) [26]. It calls for all clinical staff, including professional staff, as well as any staff that may be involved in restraint, receive orientation and instruction in alternatives to restraint, the appropriate techniques of applying the restraint, the potentially traumatic impact of restraint, and the laws, regulations, policies, and procedures governing the use of restraint.

Conduct ongoing environmental risk audits—Assemble a multidisciplinary team to periodically assess environmental risks. There are audit tools available such as the United States Department of Veteran Affairs National Center for Patient Safety's "Mental Health Environment of Care Checklist" [27]. This checklist was primarily designed to reduce the risk of suicide but is also useful for identifying objects that might be used in aggression toward others.

Promote culture of respect and sensitivity to potential sanist attitudes—It is a fundamental principle that all persons deserve to be treated with dignity and respect. However, due to many largely unspoken myths about the underlying etiology of mental disability, staff may unwittingly dismiss important warning signs. For example, an increased volume of speech may be perceived as a sign of escalating aggression when in fact the patient is experiencing physical distress and simply lacks the cognition skills to identify and articulate the pain sensation. Beyond this, staff sometimes "blame" behavioral health patients for aggressive actions and feel justified in punishing them by using excessive force in return. This is not meant to

minimize the importance of staff safety when it is necessary to resort to self-defense. However, no force should be applied to satisfy angry motives or exceed the minimum amount of force required to maintain the safety of all persons in the behavioral health environment.

Utilize safe behavior plans—The use of safe behavior plans presumes that there is mutual respect between patient and staff to be able to honor their agreements. Furthermore, these plans reinforce that the behavioral health patient has choices and is willing to accept the agreed upon consequences if not adhering to the contract. Overall, it is a formidable tool for promoting self-determination, self-esteem, and status as an important decision-maker in treatment.

Conclusion

While the behavioral health patient poses unique safety risks, the lessons learned from these cases include:

- Complete individualized risk assessments as a basis to inform an ultimate clinical evaluation for potential of harm.
- Make sure all staff have received appropriate competency training.
- Use risk reduction strategies that balance safety concerns and individual liberty rights.
- Foster a culture that centers around respect, communication, and teamwork.
- Devise strategies to safeguard against workplace violence especially as related to intentionally inflicted harm from patients exhibiting aggressive behavior.
- Promote a full spectrum of staff wellness and healing modalities for staff who have been a victim of workplace violence.
- Promote awareness of the insidious dangers of sanism.

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Chapter 21
Patient Safety in Outpatient Care

Urmimala Sarkar and Kiran Gupta

> Freedom is not worth having if it does not connote freedom to err.
> Mohandas K. Gandhi

Introduction

Defining Ambulatory Patient Safety

In conceptualizing patient safety in the outpatient setting, we employ the National Academy of Medicine's (NAM, formerly the Institute of Medicine) definition of patient safety: "the prevention of harm to patients." The NAM further specifies that both errors of commission, such as prescribing a contraindicated medication, and errors of omission, such as failure to perform recommended medication monitoring, can jeopardize patient safety. A unique aspect of outpatient settings is the central role of the patient and caregiver in ensuring safe delivery of care. While most definitions of patient safety do not directly address the patient as an active participant in care, in the outpatient setting, patients' self-management capacities and behaviors are critical for safety [1].

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Ambulatory safety encompasses several distinct areas. First, safety risks exist for medication use, both for administration of medications in ambulatory care sites, and for patient/caregiver self-administration of medications at home [2]. Second, the prevalence of missed and delayed diagnosis in ambulatory settings constitutes a critical area of patient safety which has gained increased attention over the last decade and has been identified as an important contributor to preventable patient harm [3]. Third, with increasing numbers of procedures performed in ambulatory settings, examining procedural errors has grown in importance [4]. Fourth, with widespread adoption of electronic health records (EHRs) over the last two decades, the volume and complexity of health information and patient communication that providers are required to manage on a regular basis have increased significantly and the implications for patient safety are profound, at times contributing to significant diagnostic delays [5]. Fifth, partly catalyzed by the COVID-19 pandemic, a growing proportion of ambulatory care is now provided virtually via telemedicine which may require important safety considerations especially with regard to access for certain patient populations [6]. Sixth, while NAM defined equity as one of the 6 key aspects of high-quality healthcare over two decades ago, significant healthcare disparities persist with regard to patient safety, with certain patient populations disproportionately at risk for both adverse events and adverse outcomes in the ambulatory setting [7]. Finally, because outpatients must actively recognize symptoms and seek care, as well as perform daily health-related activities, these patient roles are critical to safe outpatient care [8].

Contrasting Acute Care and Ambulatory Settings

The patient safety movement emanated from adverse events in acute care [9], which differs substantially from the community and outpatient settings where the majority of healthcare takes place. In acute care, patients are under close observation and often passively receive care. In ambulatory care, patients must decide when to seek medical care, interact with outpatient health systems, and perform their own daily health- related tasks. For those who have multiple chronic diseases, this includes following a disease-specific medication, diet, and exercise regimen as well attending numerous follow-up appointments with multiple specialists. Some also adjust their medications based on various measurements, such as using glucose monitoring to adjust insulin dosing. When patients have difficulty with these self-management activities, they are at risk for adverse events. Moreover, ambulatory practices tend to lack specific organization structures to address quality and safety improvement. In addition, most outpatient practices are not subject to accreditation requirements such as strict staffing ratios and adherence to regulatory standards by organizations such as the Joint Commission [10].

Epidemiology and Impact of Adverse Events in Ambulatory Care

While tremendous progress has been made with regard to patient safety in the last two decades, efforts have largely focused on the inpatient setting and tremendous opportunity to improve ambulatory patient safety remains [11, 12]. Adverse events are frequent in ambulatory care. Nationally representative surveys suggest that approximately 4.5 million outpatient visits each year in the USA alone are related to adverse drug events [9]. One study using 2013–2014 surveillance data estimated that 4 ED visits per 1000 patients occur annually for adverse drug events [13]. A study examining ambulatory safety events at 165 healthcare organizations over time found that these events occurred most frequently at surgical clinics followed by medical clinics and that almost 50% of the events resulted in moderate or severe harm and 1.9% resulted in death; medication events were the most common type of safety event while diagnostic errors were noted to result in a higher degree of harm [3]. One estimate suggests that in the U.S. diagnostics errors in the outpatient setting impact 12 million patients every year [14]. A systematic review of safety in primary care found that there are about 2–3 safety incidents per 100 office visits [15].

The types of errors that predominate in ambulatory care also differ from acute care. Treatment errors predominate in inpatients, whereas diagnostic errors and medication events do in outpatients [14, 16, 17]. In one study, about 10% of preventable outpatient adverse events resulted in serious permanent injury or death [18].

Adverse events lead to significantly increased care utilization and associated healthcare costs. The burden associated with malpractice claims from ambulatory adverse events is also significant [19, 20]. Finally, there are varying estimates of significant patient harm related to ambulatory adverse events. One study estimated that ambulatory care adverse events lead to ~400,000 hospitalizations per year [21] while another representative sample estimated that around 75,000 hospitalizations per year are due to preventable adverse events that occur in the outpatient setting [18].

Case Study

Hyponatremia from Poor Outpatient Care Coordination

Clinical Summary

Mr. F was a 66-year-old Mandarin-speaking male with diabetes, hypertension, and heart failure. He presented to the primary care physician for a 3-month follow-up appointment, having seen his cardiologist and his endocrinologist in the interim since his last appointment. Through the medical interpreter who was present for the visit, he reported increased fatigue for 1 month.

He reported that both the cardiologist and endocrinologist had made changes to his medication regimen, but he did not bring the medicines and could not report the changes. His primary care doctor did not have any documentation from the subspecialist visits.

The patient also had not had his electrolytes, BUN, and creatinine checked as ordered by his primary care physician at the prior visit, which were expected to be reviewed at today's visit. His daughter who cares for him stated that his endocrinologist had ordered laboratory tests the prior month, so she thought he did not need any more blood drawn. He reported feeling generally weak and unwell.

The primary care physician decided that the subspecialty visit information would be helpful and had his office call their offices to obtain it. The clinical documentation arrived by fax from the endocrinology office, and it was found that the endocrinologist increased the dose of metformin from 500 mg twice daily to 850 mg twice daily. The blood test the patient and daughter referred to was a hemoglobin A1c of 7.4 mg/dL obtained last month. The cardiology office had not yet faxed the last visit note.

Upon further history, the patient denied localizing symptoms. On physical examination, his vital signs were normal. In contrast with his usually elevated blood pressure, his blood pressure at this visit was 110/65 with a pulse of 70. A thorough physical examination was unrevealing, but the primary care physician elected to order a stat panel of electrolytes, BUN, and creatinine. While the patients' blood was being analyzed, the primary care office received the cardiology documentation from 2 months ago, which includes a dose escalation in furosemide from 20 mg daily to 40 mg daily. There was no mention of laboratory monitoring following this medication change. Mr. F and his daughter were able to corroborate the addition of a second "water pill." Mr. F's daughter explained that the cardiology visit was a phone visit due to the COVID-19, that there was no interpreter present and that she may have misunderstood the need for close lab monitoring after starting the additional dose of furosemide.

A few hours later, the chemistry panel showed a serum sodium of 125 mg/dL, accounting for Mr. F's symptoms.

Root Cause Analysis: Why Did This Happen?

Fundamentally, this adverse event stemmed from suboptimal self-management of chronic diseases [8] and, similar to most adverse events, can be attributed to multiple contributing factors. The most important root causes and potential solutions are discussed below.

Treatment Complexity

Mr. F has multiple comorbid conditions, and as such, multi-morbidity is known to be associated with adverse drug events and poor health outcomes [22]. Evidence suggests that adverse drug events are less related to any particular medication than

to the overall number of medications prescribed [23], which implies that complex regimens, as well as "high-risk" medicines, should be considered a safety risk [24].

Medication Understanding

Neither Mr. F nor his daughter is able to name his medications. This type of medication confusion is the norm rather than the exception due to the high cognitive demand in managing medications [25]. Literature shows that most patients cannot name all of their medications or report medication changes accurately even immediately following an outpatient visit [26].

Mr. F's medication confusion could be due to limited health literacy that leads to a lack of medication understanding [27] or to visual impairment leading to difficulty reading medication labels. Individuals with limited health literacy and language barriers report greater problems across a range of communication domains, including informed consent, shared decision-making, and elicitation of concerns. Mr. F could also have cognitive impairment, a common condition for which there is often a delay in diagnosis, further impairing medication understanding.

Patient–Physician Communication

Mr. F's medication confusion also stems from inadequate patient–physician communication [28]. The adequacy of communication between patients/caregivers and providers is crucial to patient safety. Suboptimal clinician–patient communication in chronic disease care is a consequence of multiple influences at the practice and system level, including medication labeling procedures and the communication practices of physicians and pharmacists. Most physicians fail to explain the four key aspects of a medication—name, dose, indication, and potential adverse effects—when initiating a new medication in the outpatient setting [29]. Time pressure in the outpatient visit is often cited as a reason for suboptimal medication communication [29].

Aggressive Treatment Goals

Mr. F's various physicians were likely trying to achieve recommended blood pressure and glucose targets by intensifying his medications. Increased attention to stringent treatment goals may paradoxically lead to adverse events, as has been demonstrated for elders [30]. Aiming aggressively for lower blood glucose or blood pressure in hopes of reducing risk of future complications may increase adverse treatment effects such as symptomatic hypoglycemia or orthostasis, in certain older adult populations and society guidelines recommend shared decision-making between providers and patients when establishing targets for blood pressure and glycemic control in older adults, especially when frailty is a concern [31, 32].

Symptom Recognition

Mr. F. experienced fatigue for 1 month after initiating a new medication, but did not report his symptoms either to the prescribing physician (cardiologist) or his primary care provider. Recognition of medication-related symptoms is part of self-management. Had Mr. F. reported his symptoms earlier, the medication could have been discontinued sooner without the resulting morbidity.

Lack of Interpreter Use and Limited English Proficiency

An interpreter was not used during Mr. F's virtual cardiology visit, which may have contributed to gaps in understanding the importance of lab monitoring after the change in furosemide dose. Limited English proficiency (LEP) is known to place patients at increased risk for safety events [33]. One study regarding post-hospital discharge follow-up found that LEP patients face greater difficulty with self-management tasks including filling prescriptions, comprehending instructions, and identifying new symptoms, as well as several others [34]. Professional interpreter use can improve communication between providers, patients, and caregivers to decrease safety risks and improve the overall quality of care provided [35]. However, national estimates of interpreter use in the ambulatory setting from one study involving 273,796 outpatient physicians found that nearly 40% of physicians never used professional interpreters [36]. While communication with LEP patients has improved over the last decade, significant gaps remain and constitute a barrier to safe and equitable care for this population [37].

Telemedicine

Mr. F's visit was a virtual one, in part due to limited in-person clinic access because of the COVID-19 pandemic. While the expansion of telemedicine has improved access for many who may live far away from sites of care, may be too frail to travel and may enhance the ability of local providers to more optimally care for patients with certain conditions in rural areas [38], the use of phone and video visits has increased significantly, catalyzed by the COVID-19 pandemic [39] and further research is needed to better understand the impact of providing care virtually on patient safety [40]. While the accuracy of telemedicine has been better assessed for certain conditions and areas of practice such as dermatology and stroke care, less is known about diagnostic accuracy when primary care is provided virtually [41]. Delayed and missed diagnosis in the ambulatory setting is a well-established patient safety concern and it remains to be seen how telemedicine may impact this. In addition, certain patient populations, such as older patients and those with LEP status like Mr. F, may experience greater challenges when accessing care virtually. One study using EHR data from all ambulatory care visits from October 2019 through September 2020 at a large health system found that while expansion of

telemedicine was critical for access to care during the COVID-19 pandemic, patients accessing care virtually were older, more likely to speak English and had access to a patient portal; the authors found that without audio-only visits (as compared to video), vulnerable populations would have had further limited access to care [42].

Given the virtual nature of Mr. F's visit, physical exam was likely limited and communication was further hampered by lack of interpreter use. Further research is needed to better understand how the expansion of telemedicine may impact distinct patient populations with certain chronic conditions.

Equity

While NAM cited equity as one of the 6 aims of improving healthcare over two decades ago, significant disparities in health status and access persist [43]. Despite the fact that the Affordable Care Act expanded access to insurance, disparities in access, use of healthcare, and health spending remain significant. One study demonstrated that minority patients on Medicare experience more limited access to outpatient care than white patients [44]. Another study shows that from 2002 to 2016, healthcare spending differed significantly by race and ethnicity after adjusting for age and health condition with white individuals receiving about 15% more spending on outpatient care than the all-population mean and black individuals receiving about 26% less spending than the all-population mean on outpatient care and Hispanic individuals receiving about 33% less spending per person on outpatient care than the all-population mean [45]. For safety specifically, there is evidence of disparities as well: people from non-White racial and ethnic backgrounds had higher rates of procedure complications and medication errors when compared to the overall population [7, 46, 47]. Disparities by race in cancer screening and mortality from cancer are well established and while some improvements have occurred in the last decade, research shows that overall cancer screening is lower among minorities compared to whites and that non-whites may receive later stage diagnoses and experience inequity in treatment [7, 48]. Research is needed to understand how the COVID-19 pandemic has impacted both access to care and outcomes for minority and LEP patients with chronic disease (like Mr. F).

Transitions Among Multiple Providers

Communication

Mr. F sees multiple physicians who all adjust his medications and perform monitoring. It is well documented that transitions between care settings, and between primary care, specialty care, pharmacy, other providers, caregivers, and home care, pose a risk for adverse events [49]. In current outpatient practice, providers often rely on patients to report the outcome of subspecialty visits. However, many chronic disease patients like Mr. F cannot report the result of physician visits to the

subsequent physician reliably and accurately. Therefore, Mr. F's primary care provider must rely on documentation from subspecialists, outside his practice, which he did not receive.

This case highlights the risk inherent in the transitions between ambulatory physicians (safety risks in care transition and handoff during inpatient settings are discussed in another chapter). Timely communication among providers is critical for co-management of chronic conditions [50] and is known to be inadequate [51]. The use of electronic health records (EHRs) has expanded rapidly over the last decade. However, lack of system interoperability creates barriers to sharing of information between providers using different EHR systems [52]. As a result, providers still communicate with each other using faxed or mailed information which often leads to delays and missing information. The lack of information about Mr. F's cardiology and endocrinology visits made it more difficult for his primary care provider to determine the cause of his fatigue, which turned out to be related to hyponatremia from an increased dose of his diuretic medication.

Medication Monitoring

One would expect that changing the dose of a diuretic medication would require monitoring for symptoms and a blood test to ensure that electrolytes remain within normal limits. The cardiologist did not specifically document that she planned to monitor the patient following his medication change or use an interpreter and teach back to ensure that Mr. F and his daughter understood the need for labs and what symptoms to lookout for. This omission of medication monitoring is a frequent problem in the ambulatory setting [53]. Mr. F's daughter did not take him to have the blood tests ordered by his primary care physician because she assumed that the prior month's blood test ordered by the endocrinologist would be sufficient and would be communicated to the primary care physician. Had Mr. F undergone the blood test as scheduled prior to his primary care visit, he would have been diagnosed earlier.

Shared Physician Responsibility

When multiple providers are involved in a patient's care, it is often unclear which provider assumes responsibility for following up on a problem. It is possible that the cardiologist thought that the primary care provider would be checking the patients' electrolytes and thus decided not to order blood tests following the medication change. There is currently no clear standard about who should follow-up in an area of subspecialty-primary care overlap, and this lack of clarity leads to safety problems [54].

Table 21.1 summarizes the root causes and solutions/best practices applicable to Mr. F's case.

Table 21.1 Case study — Inadequate medication monitoring: root causes and solutions/best practices

Root cause	Recommendations
Treatment complexity	• Reconcile all medications at all ambulatory visits • Consider simplifying medication regimen whenever possible
Medication understanding	• Use the Universal Medication Schedule, a validated template [55, 56] with clear language. For example, use the instruction "take 1 pill in the morning and 1 pill at night," instead of "take one pill twice daily" • Embed medication instructions with simple language as default choices into the electronic prescribing function of the EHR • Provide medication counseling delivered by a pharmacy professional at the time of hospital discharge
Patient–physician communication	• When prescribing a new medication, ask the patient to "teach-back" to the prescriber the name, dosing, purpose, and potential adverse effects of the new medication
Aggressive treatment goals Symptom recognition	• Tailor treatment targets, such as HbA1c in diabetes, to overall health status and patient preference • Teach patients about potential adverse effects of treatments. For example, "if you feel sweaty, shaky, or lightheaded, your sugar may be too low. Please check it with your glucose meter"
Lack of Interpreter Use and Limited English Proficiency	• Use professional interpreters when communicating between providers, patients, and caregivers
Telemedicine	• Support audio-visual encounters for as many patients as possible • Provide patients with resources to mitigate technical challenges when using telemedicine
Equity	• Ensure providers have adequate training of equity as a crucial domain of providing safe care • Clinical practices should develop mechanisms for measuring equity among their patient population in terms of both access to care and outcomes
Transitions among multiple providers: communication	• For subspecialist providers: promptly convey written medical records to the patients' medical home/primary care physician • Use a single pharmacy for each patient so that potential drug interactions can also be assessed there • Consider participating in a health information exchange program or implementing interoperable EHRs to facilitate seamless communication among ambulatory providers
Transitions among multiple providers: medication monitoring	• Prescribing provider should document the monitoring plan for all medications he/she prescribes
Transitions among multiple providers: shared physician responsibility	• A physician initiating a diagnostic or therapeutic intervention must assume responsibility for obtaining and acting on results unless another provider is made aware of the pending test and clearly agrees to take responsibility for follow-up

Discussion

Chronic Diseases and Safety

The case above concerns patients with chronic health conditions. Wagner's Chronic Care Model describes the factors needed to achieve optimal chronic disease health outcomes [57]. In Fig. 21.1, we apply this well-established Chronic Care Model to address patient safety issues in ambulatory care. This model addresses *underlying conditions,* which includes the community and health system; *individual context,* which includes communication between all participants in outpatient care, transitions in care, and patients' health status and disease burden; and *behaviors* (of patients and providers). These factors interact over time to affect safety among outpatients with chronic conditions. We believe that high-quality primary care is the cornerstone of patient safety in the outpatient setting, and recommendations below underscore the importance of those with chronic conditions having a longitudinal relationship with a primary care provider.

Underlying Conditions: Health System and Community Factors

Although individual clinicians may not be able to address the health system and community factors associated with patient safety problems, an awareness of these issues can identify risky situations, prompt closer oversight, and inform processes

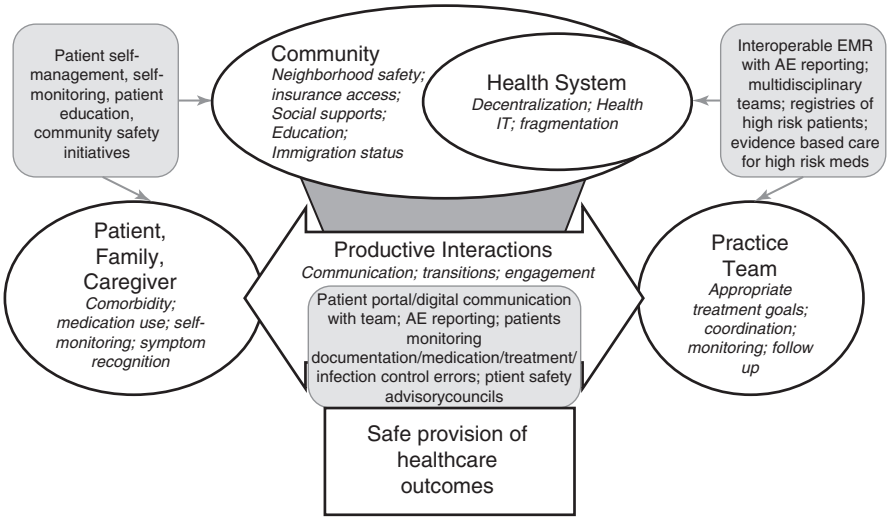

Fig. 21.1 Ecological model for ambulatory patient safety in chronic disease. (Adapted from Sharma AE et al. Health Aff (Millwood). 2018)

of care. The case above reveals challenges inherent in the organization of outpatient healthcare systems. Because many ambulatory practices are small, patients often receive care at geographically and organizationally distinct locations: the primary care office, subspecialists, and ancillary services such as pharmacy care. Such complex systems of care can be confusing for patients and caregivers, leading to erroneous assumptions like those that Mr. F's daughter made, about the flow of information among providers. Systems-oriented approaches such as patient navigators could help to address this complexity.

Lack of integration among outpatient providers and hospitals contributed to safety issues in both cases, with lack of clinically relevant and timely information as a significant problem. Missing information contributes to diagnostic and treatment delays [58]. In prior studies, diagnostic delays [19] and lack of real-time information [59] have been shown to contribute to outpatient errors and resulting malpractice claims. Thus, best practices in clinical care include informing primary care providers of significant interventions, such as changes in medications, and of abnormal test results. It is critical, moreover, to inform and educate patients about the need for monitoring and follow-up of abnormal results. The expectations for provision of results to patients vary widely; many patients never receive notification of normal test results. We recommend that all test results, regard less of whether the results are normal or abnormal, are conveyed in written form to patients in a timely fashion.

While outpatient health systems have increasingly adopted EHRs over the last decade, they are likely to lag behind acute-care settings even with recent legislation on "meaningful use" of health information technology [60]. Technologies such as computerized physician order entry and computer-based medication monitoring, which are integral to patient safety improvement, remain the exception rather than the rule in outpatient settings. Specific strategies to improve safety using health information technology include (1) requiring providers to acknowledge receipt of patient test results; (2) creating an "audit trail" for patient results; and (3) automating the provision of results to patients.

In the outpatient setting, in-depth investigation of adverse events seldom occurs. Accreditation is a driver for root cause analysis in inpatient settings, and most out patient–physician offices are not accredited by the Joint Commission [10]. While mandatory public reporting and pay-for-performance initiatives have enhanced patient safety in the inpatient setting by prompting healthcare systems to implement interventions that have helped drive down the rates of certain hospital-acquired conditions such as central line associated blood stream infections [61] and decrease other sources of patient harm such as readmissions, [62] public reporting and pay-for-performance in the outpatient setting remain less robust. In the absence of regulatory scrutiny, the actual prevalence and reporting of adverse events in the outpatient setting remains unclear. We recommend performing rigorous root cause analyses for adverse events in ambulatory care and using the results to imple met system changes.

In rural areas, access to health care and lack of health system capacity remain important issues [63]. Similarly, community-level influences, such as insurance

access, neighborhood safety, and social support, can constitute important barriers to provision of safe chronic disease management. Interventions directed at such community barriers, such as transportation assistance for follow-up appointments, may improve care for vulnerable chronic disease patients.

While the COVID-19 pandemic has prompted widespread expansion of telemedicine in the ambulatory setting and improved access to care for some patients and communities, further research is needed to fully determine the impact of such rapid adoption of telehealth on ambulatory patient safety. Indeed, for certain patients, the physical exam may be crucial to determining the correct diagnosis and necessary treatment; increased reliance on patient/caregiver ability to communicate accurately through video or audio may adversely impact the ability to perform adequate medication reconciliation and medication safety in general [40].

Individual Context: Communication, Care Transitions, Health Status

In order for outpatient chronic disease care to be safely delivered, patients must be "activated and informed" and providers "prepared and coordinated" as the Chronic Care Model describes.

Patient–provider communication is essential to patient safety for outpatients with chronic diseases because patients and families are performing day-to-day self-management. Abundant evidence exists that patient–provider communication is suboptimal [64]. Many patients, like Mr. F, are unable to read and correctly interpret medication labels [65]. Clinicians often use jargon that is misinterpreted by patients, and there is a striking lack of agreement between patients and providers, even immediately after visits, about symptoms, medication changes, and barriers to self-management [66]. Best practices in communication, such as use of clear communication and techniques such as "teach-back," in which clinicians ask patients to repeat back information in order to confirm their understanding, should be routinely used. Similarly, medication instructions should be specified in plain language, using evidence-based wording such as Universal Medication Schedule [56].

Transitions between care settings, including primary care, specialty care, pharmacy, caregivers, and home care, carry an inherent risk for adverse events. At each point, patients must understand and carry out the plan of care, and providers must make clinical decisions within the limitations of available data. Communication among providers is critical for the provision of safe care in any setting, but in outpatient care, where brief visits are separated by months, such communication is all the more critical. Because most patients encounter disparate healthcare systems, clinicians must proactively communicate with each other, usually by sending clinical documentation via mail or fax. This requires clinicians to actively remember and act to share documentation; we know that, as in Mr. F's case, such documentation

may not be sent. Moreover, even when it does occur, sharing of clinical documentation does not constitute a complete handoff between providers. Without the opportunity to ask and answer questions, quality of communication declines. Mechanisms to share and update clinical data among multiple clinicians, via interoperable EHRs or a personal health record, could improve ambulatory safety by improving communication among clinicians.

Illness burden also plays into risk of adverse events for outpatients. Often patients with multiple chronic illnesses are at risk simply because of frailty, and aggressively treating one condition can worsen another, as when patients with heart failure experience worsening renal function with diuresis. Moreover, with each additional medication, the risk for adverse drug events increases [67]. This underscores the need for medication regimen simplification, whenever possible.

Behaviors: Patient and Provider Actions

Both patient and provider behaviors, influenced by the context and interactions in care, directly affect patient safety. Ambulatory patients must perform a series of actions for appropriate medication use, including making decisions in an office encounter, obtaining a prescription, bringing the prescription to a pharmacy, receiving the medicines and instructions, taking the medication *correctly* at home on an ongoing basis, monitoring oneself for side effects, and following up with laboratory testing or provider visits. Problems at any of these junctures may lead to adverse drug events. Mr. F's case illustrates that patient and caregiver errors can lead to harm, as Mr. F did not complete the requested blood tests, and he also did not recognize that his symptom of severe fatigue was related to a newly prescribed medication. Although it is not possible to avoid all adverse drug events, there are medications that are known to cause many adverse drug events, including insulin [13], warfarin [13], and others with known serious adverse effects, such as methotrexate and amiodarone. For these medications, symptom recognition is a crucial aspect of self-management, and appropriate communication must be the standard of care. In addition, medication management is only one aspect of patient self-management, which also includes appropriate diet and exercise, appointment adherence, and recognition of symptoms. Because appropriate patient behaviors are needed to ensure outpatient safety, we recommend provision of self-management support to foster safety, particularly for chronic disease populations. Indeed, research suggests that there is ample opportunity to better engage patients in self-management behaviors to promote safety; a review of recent studies suggests that the evidence is strong for engaging patients in anticoagulation management and perhaps more mixed for chronic disease self-management, reporting adverse events and ensuring accuracy of the medical record [68]. The same study also suggests that mechanisms for effectively engaging patients, such as patient portals, have not been widely implemented.

Conclusion and Key Lessons Learned

- Patients and caregivers are critical patient safety champions in the outpatient setting.
- Promoting effective patient–provider communication is critical to improving outpatient safety.
- "Warm" handoffs (interactive communication) among outpatient care providers can prevent adverse events.
- Management of abnormal test results constitutes an important aspect of patient safety.
- The implementation of interoperable EHRs that enable seamless sharing of information among providers and personal health records (PHRs) that enable information sharing between providers and patients present important opportunities to improve safety through technology.

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Chapter 22
Patient Safety in Nursing Homes

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Introduction

Overview of Long-Term Care (LTC) Settings

The growing older adult population in need of supportive care has contributed to greater complexity and strain on long-term care facilities (LTCFs) and has highlighted the urgent need to address resident safety and quality concerns within those settings [1]. LTCFs are those that provide room and board, 24-h on-site staff, assistance with activities of daily living (ADLs), as well as varying amounts of support and management of chronic health conditions (older adults that live in a LTCF will be referred to in this chapter as residents). LTCFs include a broad range of setting types—NHs (skilled nursing facilities or SNFs and nursing facilities or NFs), long-term acute care hospitals (LTACs), inpatient rehabilitation facilities (IRFs), assisted living residences (ALRs)—each of which provides a specific level of care depending on the complexity of the resident's health and psycho-social needs. Because of differences in the level of independence, functional capacity, and cognitive status of residents living in different settings, the level and types of safety risks also differ.

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What Do we Mean by Patient Safety?

The National Patient Safety Foundation (United States) defines resident/patient safety as freedom from accidental or preventable injuries or harm produced by medical care [2]. This includes preventing diagnostic errors, medical errors, injury, or other preventable and iatrogenic harm to a resident during the process of health care and reduction or risk of unnecessary harm associated with health care [3].

Nursing Homes

There are over 15,000 nursing homes (NH) in the U.S. with about 1.16 million residents as of July 2022 [4]. NHs may include Medicare certified beds (SNF beds) for individuals that require skilled services by a nurse or therapist (these are sometimes referred to as post-acute care or PAC, since most older adults come after a hospitalization). SNFs primarily provide three types of services: skilled nursing, rehabilitation, and long-term care designed to support residents in recovering from illness or acute injury. NHs may also have nursing facility (NF) non-skilled beds or units designated for older adults that do not qualify for SNF (they do not have a skilled need) but require more hands-on care or supervision than can be provided safely in their community (regulatory definitions may be found in the Centers for Medicare and Medicaid Services (CMS) State Operations Manual, updated 2017, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf). CMS has periodically updated nursing home regulations to promote adequate resident care; however, NHs still face significant challenges that pose safety concerns for nursing home residents. Most of the nation's NHs face current staff shortages that contribute to staff dissatisfaction, burnout, and high rates of staff turnover [5]. These issues can have serious effects on resident safety and quality of care, including inappropriate antibiotic use, more pressure ulcers, frequent urinary tract infections, dehydration, higher hospitalization rates, and other negative outcomes.

Different Types of Long-Term Care Settings

LTACs are health facilities that admit complex, less medically stable residents with health care needs beyond what may be provided in a SNF or other non-hospital setting [6] (differing from NHs which focus on services to meet older adults' social, personal, and/or healthcare needs). Due to the multifaceted medical history of residents in LTACs, these settings face safety challenges due to rapidly fluctuating conditions and frequent medication and treatment changes.

Inpatient Rehabilitation Facilities

Inpatient rehabilitation facilities (IRFs) provide intense rehabilitation services to residents with complex conditions that are able to participate in about 3 h of therapy each day and have the potential to improve their functional status, strength, balance, and self-care. Due to serious recent illness or injury, many IRF residents are at high risk for falls with injury ([7, 8]. Between one and five residents out of ten will fall as least once during their stay. Falls can lead to further complications, including reduced mobility and increased morbidity. Falls not resulting in injury can also be detrimental to residents by instilling a fear of falling, anxiety, distress, and depression.

Assisted Living Residences

ALRs provide room and board, assistance with activities of daily living and sometimes personal care by personal care aides within private living spaces (rooms or apartments) and shared common areas. In contrast, NHs provide on-site health care and 24-h care by licensed professionals such as nurses or therapists. ALRs focus mainly on helping residents with ADLs and maintaining a healthful, active lifestyle vs. a greater focus on health care in NHs. ALRs are regarded as the fastest-growing institutional component of the long-term care industry ([9–11].

Direct care workers (DCWs) or personal care aides are the primary staff that provide care for residents in ALR. Many of the tasks DCWs conduct, dressing, bathing, and feeding, have implications for resident safety; however, state requirements of DCWs vary, with some states requiring little to no certification [12]. Additionally, high staff turnover (as high as 70% in some ALRs) contributes to a limited culture of safety and may result in lapses in resident safety. There is a series of issues across all LTC settings but this chapter will continue to focus only on NHs.

Why Nursing Home Safety Is Important

A culture of resident safety is critical in NHs. Resident safety culture involves the extent to which an organization's culture supports and promotes resident safety. It encompasses the values, beliefs, and norms that are shared by the healthcare team throughout the nursing home that influence their actions and behaviors (AHRQ). Residents who receive care in settings with a favorable safety culture are more likely to experience better outcomes [9, 10]. Addressing resident safety in NHs is non-negotiable and CMS provides guidelines and rules for safety and quality that are regularly updated. COVID showed clearly how poorly our nation was prepared to meet the needs of these residents with horrific infection and death rates. In the post-Covid era, scrutiny will only increase and the need for support systems and

appropriate funding is essential. The push for policy reform regarding ensuring quality of care and resident safety across all NHs is underway [13].

Specific Efforts to Address Nursing Home Quality and Safety

A 2022 report conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM) outlined seven overarching, comprehensive goals to continue working toward making high-quality, person-centered care equitable and safe [14]. Many of the recommendations to achieve these goals are interdependent and are part of a holistic approach to improve quality of care and quality of life in NHs. These major reforms will require short- and long-term actions to be tested and implemented in the coming years. The seven goals outlined below will reduce many of the resident safety risks outlined above.

1. Deliver comprehensive, person-centered, equitable care that ensures the health, quality of life, and safety of nursing home residents; promotes resident autonomy; and manages risks
2. Ensure a well-prepared, empowered, and appropriately compensated workforce
3. Increase transparency and accountability of finances, operations, and ownership
4. Create a more rational and robust financing system
5. Design a more effective and responsive system of quality assurance
6. Expand and enhance quality measurement and continuous quality improvement
7. Adopt health information technology in all NHs.

A 2-year initiative funded by the John A. Hartford Foundation and led by the *Moving Forward Nursing Home Quality Coalition* will develop and test action plans based on the seven categories of NASEM goals and recommendations. Over 50 national organizations and individual stakeholders have joined the Coalition and committed to working toward meaningful change (https://movingforwardcoalition.org/).

The Agency for Healthcare Research and Quality (AHRQ) is another agency focused on improving resident safety. They have focused on providing nursing home clinical staff the tools and resources to help support better care [15].

Some key aspects include educational materials that address:

- Detecting resident change in condition
- Communicating change in a resident's condition
- Falls prevention and management
- Reducing catheter-associated urinary tract infections and healthcare-associated infections
- Nursing home antimicrobial stewardship

If staff are given the time to use those materials, such resources have the potential to improve care and build a more resident-centered work environment. Staff

feedback and modification of materials should also be ongoing for continuous quality improvement.

The most frequent, serious, and potentially avoidable adverse events in NHs include pressure ulcers, health-care related infections, adverse medication events, and fracture and head trauma [16]. Adverse events in NHs may be categorized in terms of primary resident outcomes, including:

- Prolonged SNF stay or required transfer to a higher setting of care (e.g., hospital)
- Need for life-saving interventions
- Permanent harm
- Contributing to death (~5% of incidents)
- Impact on quality of life, including preventable functional decline (https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf)

How Are Systems Currently Addressing Safety in NHs?

The biggest issue facing NHs today is staff shortages. Prior to the COVID-19 pandemic, staffing was always challenging but at this juncture it is the number one issue for nursing home administrators. As of 2020, Xu and colleagues reported that of the 11,920 NHs, (NHs), 15.9%, 18.4%, 2.5%, and 9.8% reported shortages of licensed nurse staff, nurse aides, clinical staff, and other staff, respectively [17]. Georgia and Minnesota reported the highest rates of shortages in licensed nurse and nurse aides (both >25%). Analyses suggest that shortages in licensed nurses and nurse aides were more likely in NHs having any resident with COVID-19 and any staff with COVID-19. Having a 1-week supply of personal protective equipment (PPE) was associated with a lower probability of staff shortages. NHs with a higher proportion of Medicare residents were less likely to experience shortages. This study has clear implications for the retention of staff [18]. The lack of consistent and systematic guidance resulting in frequently changing infection prevention protocols was also reported [18]. Finally, it has long been documented that increasing the proportion of staff to residents improves resident safety. As Harrington reports, “On the whole, higher nurse staffing improves both the process and outcome measures of nursing home quality. The impact of registered nurses (RNs) is particularly positive, but total nursing staff including licensed vocational nurses or licensed practical nurses (LVNs/LPNs) and certified nursing assistants (CNAs) is also important” [19]. NHs that have better ratios, increase pay and provide benefits, and support staff moral are more likely to recruit and retain staff [20].

Age-Friendly Health Systems

The age-friendly health systems (AFHS) movement is an important way to support person-directed living, nursing home quality, and staff support [21]. Nurse-led practice changes in cooperation with the interdisciplinary team including implementing the AFHS framework that addresses the 4Ms, (what Matters, Mentation, Medication, and Mobility) in a systematic way can do much to facilitate the coordination of care as well as the transmission of information across care settings. Information sharing and transfer is poor [22]. However, there is some progress toward a digital health transformation.

The beauty of the 4M model is that it captures clinical care that is already being conducted but not well organized in documentation and change of shift reporting. It reduces cognitive burden by simplifying and streamlining essential content that should be documented. Measuring age-friendly nursing home care enables all NHs to consider how to build sustainable systems that support the care of older adults in a reliable and sustainable way [23]. A strong example is the promotion of mobility and strength training for prevention of injury due to falls. It is well known that falls are a "never event" and cause considerable distress for residents and staff when they occur. Switching the paradigm to promote and improve mobility for older people with strength training is a more effective way to stay ahead of these types of iatrogenic events.

Age-Friendly Public Health Systems

Most support and care for residents take place in the home setting. Family members and other informal caregivers are the largest sources of support for residents [9, 10]. However, recent changes in family structure due to geographic dispersion have limited the ability of many older adults to have local family members act as caregivers. Coupled with the limited age-friendly physical and social infrastructure of cities, residents face significant barriers to healthy aging. Examples of such barriers include limited public transportation, and a lack of safe, accessible walking paths or safe streets creates challenges for people with mobility issues. [24].

Creating a long-term care model that connects with the public health system strengthens the ability for residents to receive adequate care for and improve the capacity of NHs to discharge people safely ([25, 26]. Specifically integrating age-friendly public health systems can help alleviate the burden on families by supporting, complementing, and enhancing aging services to help ensure the needs of residents are met. The shift to adopting an age-friendly public health system allows for existing establishments to acknowledge the importance of assessing the interrelation between individual needs and the residents' preferences with their surrounding environment and thus greatly improve residents' quality of life.

Trust for America's Health (TFAH) has provided recommendations for how existing public health systems can work in tandem to become more age-friendly. These are outlined below:

1. Connecting and convening multiple sectors and professions that provide the supports, services, and infrastructure to promote healthy aging.
2. Coordinating existing supports and services to avoid duplication of efforts, identify gaps, and increase access to services and supports.
3. Collecting data to assess community health status (including inequities) and aging population needs to inform the development of interventions.
4. Conducting, communicating, and disseminating research findings and best practices to support healthy aging
5. Complementing and supplementing existing supports and services, particularly in terms of integrating clinical and population health approaches

The current model of long-term care is segmented and uncoordinated with many programs having various eligibility criteria, costs, and availability [27]. TFAH's guidelines provide a framework through which public health systems can work cohesively to support and contribute to the improvement of health and well-being of residents.

Working with the Administration for Community Living (ACL) and the Office of Disease Prevention and Health Promotion, (ODPHP) of Health and Human Services, (HHS) TFAH along with John A. Hartford Foundation (JAHF) staff have held national meetings, bringing together the public health organizations with the aging organizations in order to look at where there is synergy, overlap, and opportunity. These meetings, now in their fourth year, have been extremely successful in doing just that and we are identifying creative new ways to partner together, especially in rural communities but also in urban and suburban communities where resources are limited and opportunities for cooperation and collaboration make all the difference [28].

Special Considerations for Older Adults in SNF/NF

Atypical Presentation of Illness and Care Transitions

Individuals living in NHs today are slightly older, have more chronic conditions, cognitive challenges, and are unable to manage safely in less supervised community settings [29]. One of the fundamentals of working with older adults to promote health and well-being has been the atypical presentation of illness, particularly in more frail or complex individuals. Older adults may present as less engaged, having a flat affect, unusually quiet, sleeping during the day, eating less than usual. These characteristics may be attributed to daily fluctuations or personality changes when

they may indicate an underlying condition such as an infection, adverse medication event, or cognitive changes [30].

Atypical presentations of illness are even more likely to be missed when older adults transition from one care setting or one set of providers to another, since the new team may be unfamiliar with the older adult's baseline and communication between the teams may be limited [31]. Programs have been designed to connect teams across settings, such as hospital or emergency department to SNF, SNF to home health, home health to non-skilled care partners or family members [32, 33].

The complexities of caring for older people across settings were highlighted during the COVID-19 pandemic [34]. Many older adults were hospitalized with either documented or empirical evidence for COVID-19 infection, and their family members or care partners were not permitted to accompany them or stay in the hospital with them. For those with underlying cognitive disease, or those with delirium or confusion due to COVID-19 infection, many residents were unable to communicate clearly, so underlying signs or symptoms went undetected, and their condition worsened before the care team recognized the seriousness of the situation. Much has been written about the dire situation facing skilled nursing facilities during COVID and ultimately a National Academies of Science Engineering and Medicine report laid bare gross inequities facing finance and staffing in the morass of policy in our country's nursing homes [35].

Mental and Behavioral Health Challenges

Many of us are living longer, including those with lifelong or late-life mental or behavioral health challenges such as schizophrenia, borderline personality, bipolar disorder, depression, anxiety, and other mental health issues [36]. Often, individuals who may not be cared for safely in the community transfer to either an assisted living residence, a rest home, or a nursing home. Because a high number of people in NHs also have serious illness, cognitive conditions such as mild cognitive impairment (MCI), dementia or a related disorder, the incidence of behaviors that may be harmful to the resident or people around them is higher than in the community [37]. Newer methods of screening, assessing, and intervening to prevent and support residents with such behaviors now focus on behavioral and interpersonal approaches as opposed to psychoactive medications, which are generally only considered appropriate if other measures have not been successful.

The lack of qualified and available psychiatrists and psychologists or behavioral coaches/social workers have been identified as a significant resource and workforce issue in NHs [38]. Due to low reimbursement rates, travel requirements, and significant paperwork, many providers choose not to practice in this setting. In addition, getting reimbursed for time spent counseling and teaching behavior management techniques to the nursing home nursing and social work staff is a major challenge. As a result, many behaviors continue to occur, despite evidence

that nursing home staff members may learn and practice assessment and interventions that would prevent them.

Delirium in the Nursing Home

A common condition that impacts both physical and mental health of nursing home residents is delirium. The underlying causes of delirium are well described in the literature [39]. Because delirium is often a manifestation of a life-threatening condition such as an infection, adverse drug events, stroke, dehydration, or other clinical condition, the recognition of delirium and rapid action is vital. Researchers have found that NHs do not have protocols for delirium screening and assessment, and staff members are unable to define or describe delirium and how to identify if and intervene [40]. Because delirium often goes unrecognized, by the time the underlying medical condition is identified, treatment may fail, and the resident may not get back to their previous baseline.

There are opportunities to increase staff and care partner awareness about the importance of delirium, its impact on resident quality of life and functionality. There are staff training programs, approaches to quality improvement that include content on delirium, tools and templates such as the CAM and Ultra Brief Screen 2 (UB-2) that guide staff in delirium screening and assessment [40]. In addition, state and federal surveyors should look for ways to acknowledge NHs that are following evidence-based guidelines for delirium detection, assessment, and treatment, and should hold NHs accountable if they fail to be in compliance with the Code of Federal Regulations related to delirium [41].

Promoting Mobility

One of the most frequent reasons given by care partners or family members for someone transferring to a nursing home is limited or unsafe mobility at home [42] including frequent and/or injurious falls. There is a common misperception that an older person will fall less often or is less likely to sustain an injury due to a fall if they live in a nursing home. There is no evidence to support that idea—in fact, older adults may walk less frequently and may become deconditioned in a nursing home, so their risk of falling may go up over time [43].

Numerous studies have developed and tested educational and mixed method interventions to screen, assess, and intervene to prevent falls. Systematic literature reviews suggest that because most studies are multi-modal and include different combinations of interventions, there is no clear evidence for one fall prevention program over others [44].

Federal regulations require that NHs have policies to prevent accidents and provide an appropriate level of supervision for each individual resident [45]. Failure to

comply with these regulations is almost always reported in the list of the Top Ten Citations by state surveyors each year [46]. NHs are often acutely aware of the need to not only develop but to actively, consistently, and reliably implement fall prevention protocols with each resident, and to design person-centered fall prevention approaches into each resident's care plan, particularly those at high risk for falls such as short-stay residents.

NHs are exploring more ways to promote resident mobility, such as training and employing mobility technicians/aides, providing more training for CNAs in how to promote mobility, integrating mobility programs into therapeutic recreation/activities, teaching care partners or family members how to promote safe mobility, and other methods [43]. Effective fall prevention involves teamwork and close communication among nursing home staff members, access to all documentation by everyone on the resident care team, integration of care partners/family members, and a focus on What Matters to the resident themselves.

Adverse Medication Events

Medication-related adverse events are one of the top three categories of harm described in the HHS OIG 2014 Report. These types of errors may involve any steps in the medication use process: prescribing, transcribing/ordering, dispensing, administering, monitoring.

In NHs, many residents come from the community, in which they may or may not have had consistent primary and/or specialty care. Often, older adults are admitted on medications—some of which have not been reviewed or changed in years, some of which do not have a clinical indication, some of which have been prescribed to counteract the side effects of other medications, etc. Medication side effects may not have been identified or reported, yet the person continues to take the medication without asking any questions about their new symptoms.

Nursing home physicians or nurse practitioners may not know the older person and may be hesitant to change medications without having a more thorough medication history from the previous team, which is often not available [47]. Therefore, multiple medications may be continued for months or years (polypharmacy) instead of clinicians attempting to deprescribe using standardized protocols. The updated Beers list is a useful guide to some high-risk medications—although nursing home residents may be sensitive to more medications than are on the Beers list. Other resources on prescribing for older people living in NHs are also available [48].

Pressure Ulcers

Prevention of pressure ulcers in nursing home residents is well described in the scientific literature and by national groups such as NPUAP [49]. In addition, AHRQ, CMS, and other federal agencies have published detailed guides on how to implement pressure ulcer prevention programs [50]. The QIN-QIO network has also developed materials which are online and freely available to anyone [51].

Best practices and examples of very low-pressure ulcer rates—or zero pressure ulcers—have been reported by some NHs, even in residents on hospice or bedrest. Consistent, reliable application of basic quality improvement principles, comprehensive step-by-step guides to pressure ulcer prevention and management, teamwork and close communication have led to improved outcomes in many cases.

Two Case Studies

Case Study #1

Mrs. Jiminez is an 85-year-old long-term care resident with mild cognitive impairment, advanced COPD, arthritis, and anxiety. One Saturday, her family takes her out to attend her grand-daughter's 18th birthday party with a large group of family and friends. When she returns to the nursing home, she tells everyone what a good time she had reconnecting with relatives. She plays cards with her friends that evening—she is typically very social.

Over the next 4–5 days, Mrs. Jiminez is less active than usual and starts to sleep more during the day. One of the CNAs that knows her well asks if something is wrong and Mrs. Jiminez responds, "It's none of your business—I don't even know who you are. Get out of my home!" Then Mrs. Jiminez falls back to sleep. The CNA tells the nurse, who says, "I don't know that resident very well—I got floated over here from the other unit. Let's just wait until MaryJane is back in a few days—she's on vacation." The next day, Mrs. Jiminez has a temperature of 101 °F, a productive cough, and is unarousable. She is sent to the emergency department for evaluation and found to have a left lower lobe pneumonia and delirium. She is admitted for intravenous (IV) antibiotics, respiratory treatment, and support.

What Happened in this Case?

When Mrs. Jiminez spent time with a large group of family members outside of the nursing home, she was most likely exposed to one or more infected people and developed pneumonia. While the CNA knew Mrs. J, the rest of the nursing staff was not familiar with Mrs. J's baseline functional status. They delayed investigating the

changes in her mental status and activity level for a number of days. Mrs. J. developed delirium, most likely related to the pneumonia.

Was this Episode of Delirium Preventable?

There were a number of issues that led to this adverse event (delirium and hospitalization). First, the CNA had valuable information about the resident, but the nurse did not act on it. Second, the nurse did not review the resident's chart or check vital signs when the change was initially reported. Third, there was no communication with nurses on other shifts over the next few days, resulting in a lack of assessment for an acute change in condition.

A common systems issue in NHs is that licensed nurses may not listen to (or "hear") information brought to them by CNAs. Another systems issue is a failure to communicate across shifts and among team members, particularly when usual staff members are not working, and agency or floater staff are caring for residents. This is an issue of not having high reliability in the system.

In terms of human factors, the nurse did not recognize the signs and symptoms of delirium, which were accurately described by the CNA. The nurse could have acted more quickly to assess the resident and monitor her more closely over the next several hours and days.

One approach to reducing these types of adverse events (undetected delirium) would be to include education about delirium in orientation for all nursing home staff members. This could also be integrated into annual refresher trainings required for all clinical staff, and daily or regular huddles in which delirium cases are reviewed and the potential for improved outcomes are discussed by the team. The health system could also review their policies on how to communicate and share information when one of the regular staff members is going to be off.

(Incidence of delirium in NHs, specific programs with documented results).

Case Study #2

Mr. Bixby is a 79-year-old man recently transferred from the hospital to a SNF for a few weeks of rehabilitation after a hip fracture that occurred from a fall injury, which required surgery. He was previously living at home with his wife, who provided daily care and supervision due to Mr. Bixby's moderate Alzheimer's disease. His diagnoses include gait instability resulting in frequent falls, and the recent hip fracture, Alzheimer's disease, arthritis, hypertension, and atrial fibrillation. His medications include an ace inhibitor, acetaminophen for pain, warfarin based on his INR, which is an international normalized ratio, a type of calculation based on prothrombin results. Prothrombin is a protein made by the liver. It is one of several substances known as clotting (coagulation) factors. He is also on a seven-day course of and ciprofloxacin for a current urinary tract infection.

On admission, when the hospital paperwork is reviewed, the last documented INR was several days ago. Because the nursing home is in a rural area, the lab technologists only come about once a week or for stat labs. The nurse practitioner admitting the resident orders the next INR in one week, to coincide with the lab schedule.

On SNF Day 1, Mr. Bixby is assessed by Physical Therapy (PT) and Occupational Therapy (OT) and starts his rehabilitation program with supervised walking twice a day with a walker and touch down weight bearing. Four days later, during the evening shift, Mr. B. becomes confused and tries to climb out of bed without asking for assistance. He falls, hits his head on the linoleum floor, and is found unconscious by the staff several minutes later. They call 911 and he is evaluated in the emergency department. A CT scan shows a subdural hematoma and blood work reveals a dangerously elevated INR of 10.2. He is admitted to the neurology Intensive Care Unit (ICU).

What Happened in this Case?

This was a combination of systems factors (the hospital did not provide a recent INR at the time of transfer, the nursing home did not have ability to obtain daily labs (except for emergencies), and the nurse practitioner did not know the resident's baseline or recent history. The APRN took a chance on waiting for a week, when the resident was on warfarin and ciprofloxacin, an antibiotic that can prolong a person's INR. The APRN should have obtained the INR sooner.

The nursing home may not have thoroughly assessed this new resident for his potential to try to ambulate independently, and his potential for confusion (particularly when the lighting is low, such as on evenings). They did not address the need for a one-to-one attendant or family member to come and stay with him on the evening and possibly the night shift. There were no systems in place to alert the nursing staff when the resident was moving around or trying to climb out of bed.

Was this Adverse Event Preventable?

This case reflects the urgent need for reliable processes on admission and transfer. Of older adults, one intervention in this nursing home would be to explore an arrangement with the lab to train nursing home staff how to obtain and transport certain types of blood samples that do not require a higher level of training (per state or federal nursing home regulations). A full review of the nursing home's fall prevention/mobility programs may reveal opportunities to strengthen screening, assessment and individualized, person-centered interventions to reduce the risk of falls.

Discussion and Key Lessons Learned

These two cases illustrate some common issues that were also identified in the HHS OIG report on adverse events in SNFs. One major cross-cutting theme is the interaction of human factors (errors by one individual) with systems-related failures (such as designing workflows that fail to structure consistent and reliable communication among team members and during care transitions). By conducting a thoughtful and comprehensive quality improvement review of events, including root cause analysis and/or other evidence-based techniques, teams may be able to identify potential opportunities for improvement and ways to reduce adverse events. One example of such as system is the INTERACT program (http://pathway-interact.com/) that has been tested and implemented in many U.S. NHs.

We need more evidence that substantiates which interventions lead to improved resident outcomes, lower staff turnover, greater Joy in Work, and improved quality measures. Because many of these issues are multifactorial, identifying which aspects of the interventions are most effective has been challenging. What levels and types of nursing home staff or outside (external) organizations are needed for adequate oversight of quality and safety in NHs? That is still an open question.

Summary

The COVID-19 pandemic exposed the significant safety and quality issues facing nursing homes in the United States. The lack of salary parity, deficient reimbursement rates, and overall excessive and punitive regulatory approaches must be addressed if we are to move forward.

In this chapter, we have laid out the issues along with solutions and believe that the way to actualize better health and health care for older adults is certainly within our scope and within our power [52]. Using an age-friendly health system approach that recognizes nursing homes as a central and essential component of health care in our country is a beginning. The ageism we continue to see is incompatible with nursing home improvement and we need to call it out when we see it and give people alternatives in order to promote a true culture of safety and quality in our nursing homes [52]. The importance of workforce training and retention cannot be underscored enough and improving the engagement of our public communities and health care leaders in this endeavor seems obvious but we have progress to make. Using a quality improvement approach in order to get to a reliable system of quality care in nursing homes is everyone's responsibility.

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Chapter 23
Patient Safety in Emergency Medicine

Dana E. Loke and Garth Walker

Introduction

Emergency Departments (EDs) exist to provide timely and safe emergency care to all patients. However, the unique ED environment is prone to patient safety issues. Brief encounters, high acuity, limited information, fragmented records, and high volumes contribute to an environment prone to errors. Providers are frequently interrupted, often during information exchange and at high census, predisposing to errors [1–4]. Sequential handoffs are common and associated with errors, perhaps related to changes in patient status going unnoticed [5, 6]. ED overcrowding and boarding create distinct issues, including delayed and missed care and higher rates of patients Left Without Being Seen (LWBS), a considerable portion of whom actually require emergency care [7, 8].

The ED offers a unique environment in which to consider and improve upon patient safety issues. Numerous vulnerable populations seek care mainly in the ED, whether due to financial necessity, poor access to care, or cost-prohibitive factors when seeking care elsewhere, including [9]:

- Uninsured and underinsured patients (20 million visits annually) [10]
- Undocumented patients (20% of uninsured Americans) [10, 11]
- Undomiciled patients (552,000 annual visits, which is increasing at a faster rate than for domiciled patients [12, 13]
- Sex trafficked individuals (57% of visits occur in EDs) [14]

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- Mental health patients (50% of frequent ED users have a mental health diagnosis) [15]
- Patients with substance use disorders
- Sex workers
- Victims of gun violence
- Formerly incarcerated individuals

In the trying ED environment where at-risk patients present, patient safety events happen at an alarming rate. One study found that 8.5% of ED patients were affected by an adverse event, often preventable [16]. About 6% of discharged patients experience an adverse events—often preventable and some resulting in return visits [17]. About 12% of return visits within 72 h were related to adverse events, leading to hospital admission, disability, and/or death [18]. Some visits, deemed "Ambulatory care sensitive conditions" (ACSCs), are preventable and related to diagnoses for which timely and effective outpatient care can help prevent or treat [19]. About 75% of ACSCs occur in the ED and are associated with ED crowding [19]. Overall, diagnostic errors are the most common adverse event, accounting for 37–58% of ED malpractice claims, followed by medication errors [20, 21]. Adverse drug events are an important segment of ED presentations, however many go undiagnosed and lead to prolonged harm [22, 23]. Regardless of the error type, 70% of ED-based errors are preventable, demonstrating an immense opportunity for improvement [24].

There are several long-standing attempts aimed at mitigating safety events in ED patients. The first involves laws and regulatory sanctions. The Emergency Medical Treatment and Labor Act (EMTALA), enacted in 1986, specifies emergency care obligations and guarantees emergency care regardless of ability to pay. EDs are required to provide screening and stabilization prior to transfer to another facility, rejecting the "no duty of care" principle [25]. EMTALA also prevents "dumping," or transferring uninsured or Medicaid patients to public hospitals without providing emergency care and ensuring stability for transfer. Despite risk of violation causing steep penalties and litigation, there were 4772 investigations and 2118 citations for EMTALA violations from 2005 to 2014 [26].

Safety net hospitals represent another attempt at optimizing access to emergency care for vulnerable populations. Safety net hospitals are defined as "those that by legal mandate or stated mission offer care to all patients regardless of ability to pay" [27]. Safety net hospitals typically treat a larger share of low-income, Medicaid, and under- and uninsured patients than other hospitals and thus often operate on thinner financial margins. Often financially insecure and resource-limited, safety net hospitals are not a cure for inequitable access to care. There is persistent socioeconomic, racial, and ethnic segregation in safety net hospitals despite Medicaid expansion, raising the concern that structural racism and residential segregation prevent patients from transferring to other hospitals [28]. Patients transferred to safety net hospitals may have delays in care; it is unclear if unprincipled transfers for financial reasons may contribute to this despite EMTALA [29].

Considering the gravity of ED-based errors and the vulnerable populations who present for emergency care, it is imperative that patient safety be at the forefront of

all ED providers' minds. Despite many attempts at addressing patient safety, errors persist in ED care. ED utilization is exceeding utilization rates than those predicted from demographic changes, leading to additional opportunities for harm and higher rate of patients LWBS [30]. Next, we consider several of the factors presented above in a case study involving a patient safety event in emergency medicine.

Case: Breakdown of Information Exchange at a Care Transition

Clinical Summary

A 44-year-old patient presents to the ED with traumatic wrist pain. An X-ray demonstrates a radius fracture. Orthopedics is consulted and plans for admission for operative intervention; however, no inpatient beds are available and the patient boards in the ED for 24 h. The patient's pain is difficult to control. Multiple rounds of morphine are given, including before transfer to the inpatient service. The ED provider gives handoff to the hospitalist but does not discuss the medications given. On arrival to the floor, the patient complains of pain and is given morphine, with the assumption that analgesia had not been given. Shortly after, the patient is found to be hypoxic with pinpoint pupils. The patient improves with Narcan, but is no longer deemed an operative candidate due to this event.

Root Cause Analysis

A Root Cause Analysis (RCA) was performed after these events. An RCA is a structured, systematic approach used to identify the causative issue(s) leading to an adverse event. Solutions and preventative measures are then developed to help mitigate the risk of the event recurring. A timeline of events was developed (Table 23.1). The RCA identified several failures that led to the adverse event (Table 23.2). The majority of the failures involved breakdown in communication and information exchange at a care transition, specifically: lack of a standardized template for care transition handoffs, frequent interruptions leading to breakdown in information exchange, and frequent handoffs. ED boarding was also identified as an additional failure leading to this patient safety event.

The first failure identified is the lack of a standardized communication template for care transition handoffs. Errors including omission of critical information (such as medications administered in the case) and transfer of erroneous information during care transition handoffs are common [31]. Certain measures, like computerized printable sign-out templates, can be used to improve handoff quality [32]. Standardized communication templates can especially help mitigate the risk of

Table 23.1 Case timeline

Time	Event	Note
00:00	Patient checks-in to the ED	1
00:05	Patient is triaged and placed in ED room 3	2
00:10	Patient is evaluated by the ED Physician #1	3
00:15	Initial orders are placed, including X-ray right wrist and Morphine 4 mg IV	4
00:17	ED Nurse #1 places IV and administers Morphine 4 mg IV (first dose)	5
00:45	Patient completes X-ray imaging and requests more pain control	6
01:05	Morphine 4 mg IV is ordered and administered (second dose)	7
01:10	X-ray shows displaced distal radius fracture	8
01:28	Orthopedic surgeon is consulted and performs reduction with splint placement, after which patient is again found to be in significant pain	9
01:37	Morphine 4 mg IV is ordered and administered (third dose)	10
01:50	Shift change occurs; ED Physician #2 and ED Nurse #2 assume care of patient. A total of six interruptions or distractions occur during these handoffs	11
02:00	ED Nurse #2 communicates patient's pain level to ED Physician #2, who orders Morphine 4 mg IV several times as the patient boards in the ED (fourth, fifth, and sixth doses). Patient continues to board and does not have a medication reconciliation completed and ultimately is not administered her home pain medications, which unknowingly compounds her pain	12
08:15	ED Physician #2 gives handoff to hospitalist over the phone. Neither ED Physician #2 nor hospitalist reviews medications given. Two interruptions occur during this handoff	13
08:25	Patient arrives to floor and is given Morphine 6 mg IV after endorsing persistent pain (seventh dose)	14
08:33	Patient is found to be hypoxic and apneic with pinpoint pupils by inpatient nurse. Bag-valve-mask ventilation is initiated	15
08:35	Narcan is administered with return of spontaneous respirations and resolution of hypoxia	16
09:15	Orthopedic surgeon is notified and now declines inpatient operative intervention	17

errors. These tools may be particularly helpful for resident physicians, as the Accreditation Council for Graduate Medical Education requires training programs to provide formal handoff instruction and monitor handoff quality [33].

Several handoff communication tools have been studied and utilized (Fig. 23.1). The I-PASS handoff bundle has been shown to lead to reduction in errors and preventable adverse events and improvement in provider workflow and preparedness [33, 34]. Implementation of the SBAR communication tool has led to perception of improved safety climate, fewer communication and order entry errors, and improved medication management [35–37]. One systematic review found moderate evidence for improved safety after implementation of the SBAR communication tool, especially for phone handoffs [38]. These results are especially applicable to the ED, where phone handoffs are common [39]. Aimed at standardizing the consultation process, the 5Cs of Consultation has been shown to increase the effectiveness of consultation communication and improve resident consultation assessment scores [40]. Templates for I-PASS, SBAR, and 5C's of Consultation are available online.

Table 23.2 Case: Root cause analysis (RCA) (only applicable issues listed)

Patient: K.B.			**MRN: 9876543**	
Participants				
ED Physician #1, ED Physician #2, ED Nurse #1, ED Nurse #2, Orthopedic surgeon, Hospitalist, Inpatient Nurse, Inpatient Unit Charge Nurse, ED Medical Director, ED Nursing Director, ED Quality Director, Hospital Patient Safety Officer, Director of Risk Management				
Issue type	**Issue**	**Root cause**	**Actions and solutions**	**Discussion Involved party ( ) Associated Timeline Note Number from** Table 23.1
Communication	Any missteps in the process?	X	Standardization, education	Yes. Omission of medications administered in care handoffs (ED physician #1, Orthopedic Surgeon, ED Physician #2, Hospitalist, ED Nurse #1, ED Nurse #2, Inpatient Nurse) [9, 11, 13]
Communication	Normal policy/ procedures followed?	X	Education, culture change, environment change	No. Frequent distractions during handoffs (ED physician #1, ED Physician #2, Hospitalist, ED Nurse #1, ED Nurse #2) [11, 13]
Communication	Other concerns?	X	Staffing model change	Yes. Frequent and sequential handoffs within short period of time (ED physician #1, Orthopedic Surgeon, ED Physician #2, Hospitalist, ED Nurse #1, ED Nurse #2, Inpatient Nurse) [9, 11, 13]
Boarding	Other concerns?	X	Staffing	Yes. Prolonged stay in an uncomfortable ED bed and missed medications (ED physician #2, ED Nurse #2, Hospitalist) [12, 13]
Recurrence risk	Could this event happen to other patients? In other areas?		Dissemination	Yes

(continued)

Table 23.2 (continued)

Solutions Planned List here details on actions and solutions. Include pilots, dissemination plan, and assessment of outcomes of changes made		
Solution	**For whom?**	**Responsible party**
***Standardization*:** Implement standardized communication process at care transition handoffs, universally across units and specialties (for instance, SBAR)	Physicians, nurses	Nursing Educators, ED Medical Director, Inpatient Medical Director, IT, Director of Quality Management
Education: 1. Add SBAR to staff orientation and bi-annual education sessions 2. Include strategies to decrease distractions and interruptions at handoffs in staff orientations and bi-annual education sessions	Physicians, nurses	Hospital Onboarding Committee, Director of CME, Nursing Educators, IT, Director of Quality Management, Chief of Staff
***Culture Change*:** Ensure all staff understand importance of safe care transitions by piloting process to divert non-emergent phone calls and clinical tasks during care transition handoffs	Physicians, nurses, clerical staff	ED Medical Director, Inpatient Medical Director, Manager of Clerical Staff, IT, Director of Quality Management
***Environment Change*:** Implement changes to the handoff environment, including designated handoff space with highly-visible positioning of a "Handoff in Process" sign	Physicians, nurses	ED Medical Director, Inpatient Medical Director, Environmental Services Staff, Departmental Quality Director
***Staffing Model Change*:** Pilot overlapping "waterfall" shifts to reduce frequency of handoffs	Physicians, Nurses	ED Medical Director, Inpatient Medial Director, Chief of Staff, Nursing Unit Director(s)
***Dissemination*:** Distribute SBAR tool and notification of environmental changes, culture changes, and staffing model changes	Medical staff, clerical staff	Chief of Staff, ED Medical Director, Inpatient Medical Director, Director of Quality Management

The second failure identified during the RCA was frequent interruptions leading to breakdown in information exchange. Distractions and interruptions are common during handoffs, leading to errors and adverse events. Common distractions include pages, phone calls, background noise, and other conversations, leading to increased handoff length and poorer handoff quality [41–43]. The Joint Commission includes limiting interruptions during handoffs as a key element of its Target Solutions Tool® for Handoff Communications [44]. Some distractions can be mitigated by finding a private, quiet space for handoff delivery. Other simple interventions have been found to significantly decrease interruptions and handoff length and improve provider perception of handoff safety culture, including an overhead chime, diversion of phone calls and non-emergent tasks, and highly visible positioning of a

"handoff in process" sign [45]. Use of standardized communication tools can decrease handoff length and result in fewer interruptions [46]. However, in addition to these interventions, culture change is often needed to ensure that all staff have the same perceptions about the importance of safe handoffs.

The third failure identified during the RCA involved handoff frequency. The case involved numerous handoffs, including physicians and nurses. Each handoff represents an opportunity for error, whether through misinformation or omission of critical information (such as morphine administration in the case). Sequential handoffs are common and have increased in frequency as resident work hours have been reduced [5, 33]. Interventions to decrease the number of handoffs inherently decrease the opportunity for entry of error or misinformation. Optimizing staffing models shows the most promise for decreasing handoff frequency, through longer but fewer shifts or overlapping "waterfall" shifts [47].

A fourth failure was identified involving ED boarding. ED boarding is a pervasive and long-standing national patient safety issue, with one national survey reporting that 84.9% of EDs had boarded in the week prior [48]. ED boarding involves holding patients in the ED after the decision is made to admit due to lack of bed availability and typically occurs when hospital occupancy is at or near capacity, causing a bottleneck effect that in turn results in ED overcrowding, longer wait times, and higher waiting room numbers [49]. ED boarding leads to unsafe, delayed, and inequitable care through delayed or missed care (such as the patient's missed home medications in this case) and higher morbidity and in-hospital mortality [50–54]. ED boarding also leads to longer hospital length-of-stay (LOS)—on average nearly one day longer [55]. This increased inpatient LOS occurs across different acuities and diagnoses, indicating that the effects of boarding are far-reaching and not specific to any one group [55]. There are currently several regulatory measures

Tool	Component	Definition	Example
I-PASS	**I**llness Severity	Describe the patient's severity of illness.	"I am calling to give handoff for an ED patient with a GI bleed that is stable."
	Patient Summary	Provide a summary statement and events leading up to the handoff.	"She is 55 years old with a known gastric ulcer. Her hemoglobin is 7.8. We have started her on pantoprazole."
	Action List	Explain the "to do" list for the patient's management thus far.	"The patient needs an inpatient GI consult and hemoglobin trending."
	Situation Awareness and Contingency Plan	Anticipate and plan for what might happen.	"If the patient's hemoglobin drops, she will need to be given a blood transfusion."
	Synthesis by Receiver	Ask the receiver to summarize your report and answer any questions.	"What questions do you have about this patient and their plan of care?"

Fig. 23.1 Handoff communication tool templates

SBAR	**S**ituation	Describe what is going on with the patient.	"The patient is a 28 year old male with abdominal pain who is stable, who needs to be admitted."
	Background	Provide a summary statement and events leading up to the handoff.	"He presented with right lower quadrant abdominal pain, anorexia, and nausea for three days. He has been given Morphine 4mg IV and Zofran 4 mg IV."
	Assessment	Describe the patient's problem.	"He has uncomplicated appendicitis diagnosed on CT. We started antibiotics and Surgery has consulted on the patient."
	Recommendation	List the next steps in management of the patient.	"The patient will go to surgery in the morning and continue on IV antibiotics overnight."
The 5 Cs of Consultation	**C**ontact	Introduce yourself and your role to the consultant.	"Hi Dr. Cardiology. I am the ER attending taking care of bed 4."
	Communicate	Give a concise story about the patient.	"He is a 55 year old with prior history of cardiac stenting presenting with chest pain. His EKG shows a STEMI. We have given aspirin 325 mg PO."
	Core Question	Present a focused question to the consultant.	"Do you think he meets criteria for emergent catheterization?"
	Collaboration	Discuss together about the management of the patient.	"OK, it sounds like you agree the patient needs emergent catheterization. How do I facilitate that?"
	Closing the Loop	Confirm that both parties are on the same page regarding the patient's plan moving forward.	"Great. So, I will activate the catheterization lab and after the procedure he will be admitted to the Cardiology floor."

Fig. 23.1 (continued)

that create cost implications for boarding. However, they mostly provide incentive for reporting, but not improving, ED boarding since penalties are not imposed when hospitals fail to reduce boarding [52]. The Joint Commission does require that hospitals address ED boarding for accreditation purposes; however, the requirements are vague and therefore less likely to affect change [52].

Despite these measures, there are no regulatory measures related to the use of proven hospital-wide strategies for reducing ED boarding. These strategies are underutilized in general and include: moving boarders to inpatient halls, smoothing elective surgical and catheterization schedules, active bed management, use of a discharge lounge, aggressive management of inpatient discharges, monitoring of bed-cleaning turnaround time, simplified admissions protocols, and reverse triage at

full-capacity [52]. Until regulatory measures include implementation of these proven strategies, the approach to ED boarding must focus on the delivery of safe, high-quality care.

This case highlights the myriad ways in which safety events can occur at information exchange. By standardizing handoff communication, removing distractions and interruptions, and decreasing handoff frequency, errors can be minimized. However, a safety culture that highlights the importance of safe handoffs is needed to effectively implement any of these interventions and improve patient safety.

Conclusion

The unique ED environment is prone to patient safety issues. Vulnerable patient populations, limited information, and a busy environment represent just a few factors that contribute to a complex, error-prone environment. Communication issues, regular interruptions and distractions, and frequent handoffs further compound this issue. Many solutions to mitigate these ED safety issues have been proposed, including using standardized communication tools, limiting interruptions during handoffs, and reducing sequential handoffs through optimizing staffing.

Key Lessons Learned

- The ED is a busy environment prone to patient safety issues due time constraints and limited information.
- Some vulnerable and medically underserved populations seek care in the ED, leading to potential for harm should safety issues arise.
- Errors associated with care handoffs can be mitigated by using a standardized handoff tool, such as I-PASS, SBAR, and 5C's of Consultation.
- Minimizing interruptions and decreasing handoff frequency through optimized staffing models can also help mitigate patient safety issues.
- ED boarding is a pervasive national patient safety issue. Proven hospital-wide strategies to mitigate ED boarding exist but are underutilized.

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Chapter 24
International Patient Safety Considerations

Abdulelah Alhawsawi and Mawahib Wang

Introduction

Patient safety is defined as the absence of harm in healthcare. Practically speaking, most safety issues and/or harm happen at the bedside, which is referred to by many patient safety experts as the "Sharp End" (Fig. 24.1). So how do matters happening at the national and international level, the "Blunt End" affect what happens at the bedside level, the "Sharp End"?

To answer this question, it helps to view patient safety through a system thinking lens, where microsystem means the bedside level, mesosystem means healthcare organization level, and macrosystem means the national level (Fig. 24.2).

Case Studies

The cases we are illustrating in this chapter are on public record as they were discussed on June 27, 2011, by JoNel Aleccia on NBC news [1]. We will argue that despite the geographic and income differences among countries, the challenges of patient safety (healthcare safety in general) are more or less the same. They have to do with the five leading causes of the persistent implementation gap between knowledge and the practice in almost every country and the healthcare system. Below is a list of five leading causes:

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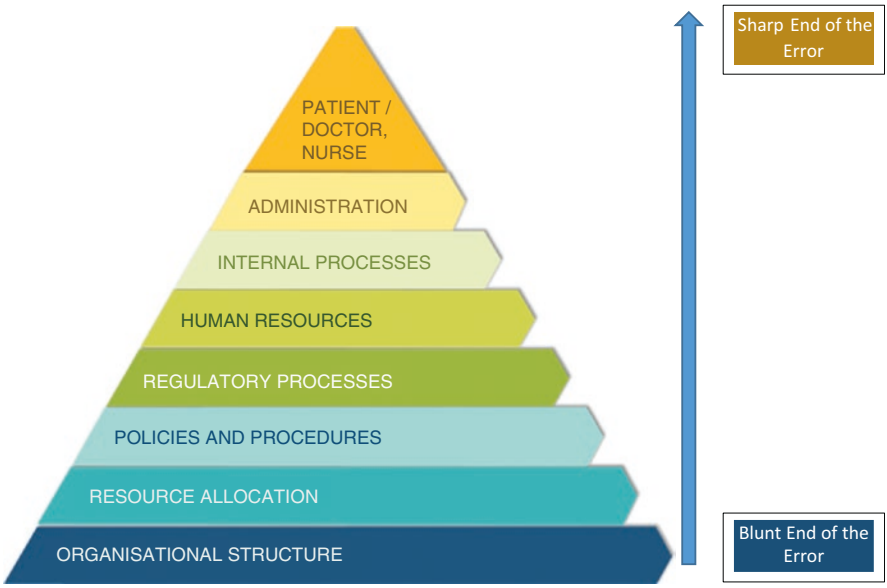

Fig. 24.1 Blunt end/sharp end of error

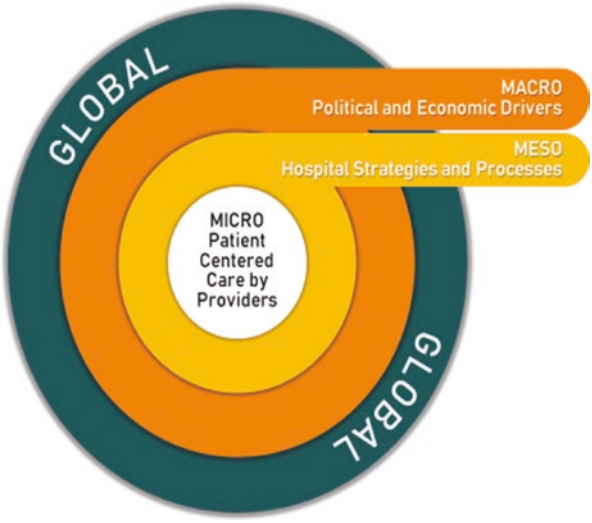

Fig. 24.2 Microsystem, mesosystem, macrosystem and global levels of patient safety

1. Safety culture: lack of safety culture in everyday practice from board to bedside.
2. Advocacy: poor understanding and implemetation of patients' and healthcare practitioners' rights.

3. Resilience: not embedding systems and processes that consider that healthcare workers are humans from different backgrounds, levels of knowledge, and experience, and come from different cultures with their own biases.
4. Collective wisdom and learning: not disseminating lessons and knowledge gained from errors to all healthcare workers who are working inside and outside the organization to prevent the same errors from being repeated time and time again.
5. Information symmetry: not sharing all information among clinicians and the patient in this process. At the same time, ensuring that the information reaches the patient in a language the patient understands.

Case 1: Medication Overdose: USA, September 2010

When the 50-year-old critical care veteran nurse (with 27 years of experience) went to work on just another ordinary day in September 2010, she didn't know that the unfortunate mistake she was about to make would kick start a domino effect of events that would eventually result in her taking her own life 7 months later.

Here's what happened: On September 14, 2010, Ms. Kimberly Hiatt came to work as usual in the cardiac care unit and was assigned to care for 8-month-old Kaya whom she had cared for several times before. While she was administering a required dose of calcium chloride which was ordered by the intensive care physician, she realized that she had made a medication error. She had mistakenly given 1.4 grams of calcium chloride instead of 140 milligrams, which is ten times the prescribed dose. Kimberly was the first one to notice that she made a medication error. She immediately reported herself and logged the error in the hospital reporting system stating "I messed up! I've been giving calcium chloride for years and never made an error. I was talking to someone while I was mixing the medication and miscalculated the dose." Her honesty and the fact that the State lawyers and physicians were never able to prove that the medication error directly caused the death of Kaya, who died 5 days after the event, did not prevent the tragic sequence of events in this case. Kimberly was escorted out of the hospital, placed on probation, and fired a few weeks later from the job she loved.

Kimberly never forgave herself for the fatal mistake and ended up taking her own life becoming "*The Second Victim*" of this tragic incident. The second victim is a term coined by Dr. Albert Wu, professor of Health Policy and Management at John Hopkins Bloomberg Public Health School [2]. Dr. Albert Wu describes "the second victim" as someone who suffers emotionally when the care they provide leads to harm.

To err is human, and nurses are human too. Doctors and nurses were raised with what we call the "First Amendment," also known as the Hippocratic Oath: "First, do no harm." With this hardwired in the healthcare culture, it is hard for healthcare professionals to accept that they are capable of hurting the very same patients that they are trying to heal.

Case 2: A Surgeon Accused of Manslaughter: U.K., October 2010

Lately there has been a lot of talk about the concept of *just culture* in healthcare settings. David Marx expanded the concept of just culture into healthcare in 2001 [3]. It is a concept based on reporting and learning from mistakes to build a safer healthcare system. It is the opposite of the *blame culture* where a single person takes the responsibility for an error.

However what happened to Dr. David Sellu, a veteran of medicine for 44 years, was anything but just. On a winter evening, Dr. Sellu got a call from his orthopedic colleague to see a patient with acute abdominal pain. The patient had undergone knee replacement surgery 5 days prior at a private hospital in Harrow, UK.

Dr. Sellu went to see the patient an hour after the consultation request and ordered a pain killer followed by an urgent Computerized Tomography (CT) scan in the morning. The CT scan showed a perforated bowel; therefore, Dr. Sellu tried to book an operating room (OR) immediately. However, the first available OR slot was in the evening. Furthermore, even this slot was delayed three hours to wait for an anesthesiologist. During the surgery, the patient experienced excessive bleeding, likely due to his liver cirrhosis. Two days after the surgery, the patient died. "When something like that happens, you go through a very difficult time. You agonize about whether you could have done anything different – this happens after every death." Dr. Sellu said.

After the investigation of the case, Dr. Sellu was charged with manslaughter and perjury. After a full trial lasting 5 weeks, he was convicted of manslaughter and the perjury charges were dropped.

Dr. Sellu served 15 months in a maximum security prison with murderers and violent criminals before three appeal judges overturned his sentence. Dr. Sellu lost more than 15 months of his life and he and his family lost trust in the fairness of the system which made his son drop out of medical school.

Reflecting on both cases, we see several elements of the same 5 causes of the persistence of the implementation gap in patient safety. Unless we address these head on, it will be tough for us to achieve the vision of Zero Harm [4]. The concept of Zero Harm is a core value for healthcare professionals to strive to reduce serious safety events.

Analysis and Discussion

In 2020, during the Saudi presidency of the G20,[1] one of the authors, Dr. Abdulelah AlHawsawi, served as a Director-General of the Saudi Patient Safety Center and introduced patient safety, for the first time, on the G20's global agenda. He presented the following five causes as the main culprit behind the ongoing implementation gap in patient safety (Fig. 24.3).

(a) ***Safety Culture:*** According to a 1993 report by the Advisory Committee on the Safety of Nuclear Installations, "The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations

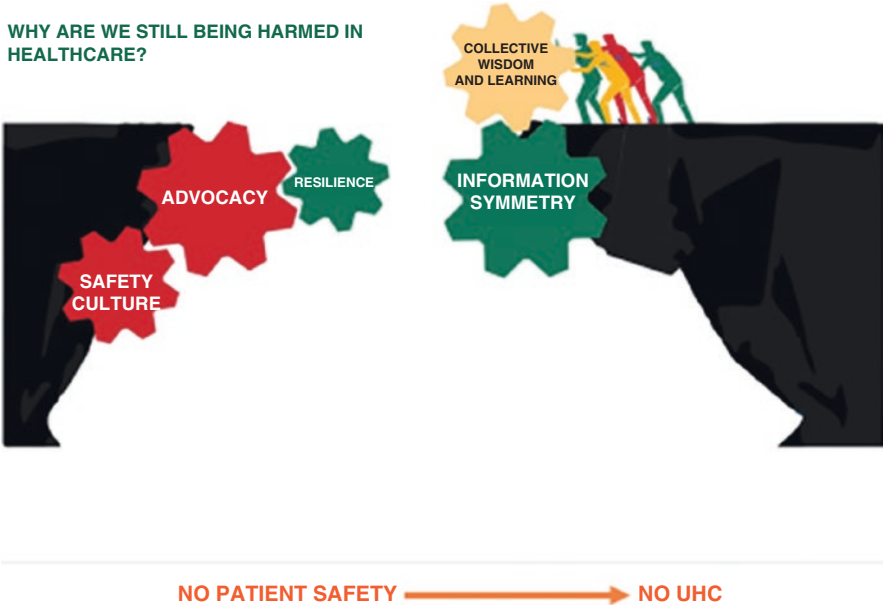

Fig. 24.3 Five main causes of persistent medical harm around the world. (*UHC*= Universal Health Coverage)

[1] The G20 is a strategic multilateral platform connecting the world's major developed and emerging economies. The G20 holds a strategic role in securing future global economic growth and prosperity. Together, the G20 members represent more than 80% of world GDP, 75% of international trade, and 60% of the world population. Accessed 19 June 2022.

with a positive safety culture are characterized by communications founded on mutual trust, shared perceptions of the importance of safety, and confidence in the efficacy of preventive measures" [5].

The culture of safety is a cornerstone of any organization, whether in healthcare or not. When you examine the safety culture in the High Reliability Organization (HRO) industry (e.g., Aviation, Nuclear, Oil & Gas), it becomes abundantly clear that these industries view safety as paramount to their day-to-day activities. According to Cantu et al., "high reliability organizations are high-quality operations that are relatively error-free over long periods of time. HROs are examples of high-risk operations involving multiple people and multiple decisions that perform at an exceptionally high level. HROs are not in one specific industry, but their approach to risk and mindset are similar [5]."

For a safety culture to thrive, the organization's leadership has to be fully invested in the safety agenda. Safety culture and leadership are two sides of the same coin, where there is no effective leadership without safety culture and vice versa.

A very effective and practical way of integrating a safety culture within the organization is to make safety part of the organization's goals and values. Here are some examples of organizational goal statements grounded in patient safety:

- To recruit and hire employees according to their patient safety track record and commitment.
- To integrate safety in the employee performance appraisal.
- To put patient safety on the board of directors' agenda.
- To ensure that safety is part of the evaluation of the healthcare leadership.
- To conduct patient safety culture surveys on a regular basis and work on improvement projects based on the survey results.

(b) ***Global Advocacy:*** Let me ask you to do the following exercise: ask ten individuals (family & friends) if they ever heard of the "global climate change agenda." Most likely you would end up with all 10 of them replying in the affirmative (I've done that with my own family, and I got 100% response from three different generations!). Ask the same ten individuals if they have ever heard of the "global patient safety agenda," and you would be lucky if you get 50% yes to your answer. This huge difference in response is due to the lack of visible global advocacy for patient safety.

The global patient safety movement has to learn from the global climate change agenda. Their very successful advocacy resulted in making the climate change agenda a constant presence in almost all multi-national platforms, e.g., G7, G20, European Union, and United Nations. The brilliant advocacy efforts were successful despite the presence of industries (e.g., oil & gas) that didn't embrace global climate change readily. Still, they arguably had to join such efforts because of the large and diverse critical mass of global advocates which developed over the years. In the global patient safety movement, we have a lot to learn from global climate change advocacy efforts to move the patient safety

agenda forward. Here are some practical recommendations to promote the global advocacy for patient safety:

- Make safety part of the organization's values.
- Make hiring and firing decisions based on safety performance.
- Integrate commitment to safety as part of the evaluation of healthcare leadership.
- Establish a "Politicians for Patient Safety" group.
- Establish a "CEOs for Patient Safety" group.
- Establish a "Sportsmen / Sportswomen for Patient Safety" group.
- Establish an "Artists (Singers, Actors) for Patient Safety" group.

(c) ***Resilience (Human Factors Engineering / Ergonomics)*:** Human Factors Engineering (HFE) is defined as: "the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize human well-being and overall system performance" [6]. Given the volume and complexity of processes in healthcare, the human interface (including interactions amongst clinicians, and/or interactions between clinicians from one end and patients /families from the other end), as well as the human-technology interface, are potential sources of risk, and subsequent medical errors by healthcare professionals.

This is another area where HROs in non-healthcare sectors have shown clear superiority [7]. While the healthcare industry still has neither a proactive nor a comprehensive approach to HFE, industries like aviation have integrated HFE into their day-to-day operations. For example, Crew Resource Management (CRM) which is rooted in HFE is one of key practices that has transformed the aviation industry. CRM refers to a set of principles dealing with cognitive and interpersonal behaviors that contribute to optimal team performance. In 2006, the American College of Surgeons (ACS) published an article about the seven main CRM principles that the operating room (OR) environment should adapt from the aviation industry [8].

These **7 CRM** principles are as follows:

1. **Command:** Even though the OR should have a teamwork environment, in the end, one final person must be the decision-maker who should accept responsibility and accountability for their team's actions.
2. **Leadership:** Leaders must be willing to allow team members to exercise their rights and responsibilities to ensure a safe and positive outcome. Although there is only one commander, any member of a team can show leadership. Surgeons who encourage teamwork are more respected.
3. **Communication:** Many studies have shown that poor communication is the root cause for many medical errors. Leaders should emphasize improving communication because it is often the prime indicator for an evaluator to assess whether specific objectives were achieved.

4. **Situational awareness:** A safe & effective leader understands the fluidity and complexity of the OR and is always thinking ahead (What if… happened?) and involves the entire team.
5. **Workload management:** Staffing and working hours could lead to stress/overwork and consequently, could jeopardize patient safety. Leaders should strategically distribute work throughout the workforce to maximize employee or application skills and performance.
6. **Resource management:** Making sure ***all*** resources (human, financial, equipment, medications, supplies, etc.) are used towards improving quality & patient safety.
7. **Decision-making:** In a high complexity, fast-paced, high-stakes environment like OR, collaborative and consultative decision-making is most effective to enable high-performance teams. A leader must avoid analysis – paralysis.

The above 7 CRM principles are examples of what can be applied in many clinical units and settings beyond ORs.

Here are some practical recommendations to improve resilience and consequently safety in healthcare:

- Introduce proactive clinical risk management as a key part of the overall Continuous Quality Improvement (CQI) in healthcare. Proactive Clinical Risk Management asks the following questions regularly:
  1. What went wrong yesterday (in the past)?
  2. What went right yesterday (in the past)?
  3. What could go wrong today and/or in the future?
- Hire a human factors engineer within healthcare organizations.
- Integrate HFE in all healthcare processes (clinical/non-clinical).
- Always ask yourself the following question: what can we learn from other industries, e.g., aviation, nuclear, oil, & gas.

(d) ***Information Symmetry (Patient/Family Empowerment)*:** One of the main challenges in healthcare is the knowledge gap between the providers of care (hospitals, clinics, and medical centers) and recipients of care (patients and families). This level of information asymmetry makes patients and families vulnerable and has negative implications on healthcare quality and patient safety.

If we are serious about transforming safety in healthcare and reaching zero harm, we have to re-define patient safety as the absence of harm, for EVERY patient, in EVERY place and time. Such a personalized definition of patient safety is only achievable if we empower patients and families to participate actively in their healthcare throughout the entire care continuum (inside and outside hospitals).

A crucial part of the solution is the co-production of care. According to Ford and Dickson [9], co-production involves joint efforts between two parties who jointly determine the output of their collaboration. In our context, the two parties mean the consumer (patient and family) and the producer (healthcare pro-

fessional). Co-production in healthcare implies that if we wish to achieve high-quality and safe care for patients, we won't be able to do it alone as healthcare professionals; instead, we must empower patients and families with the right tools to help them become active participants in their own care. Co-production has three main components: (a) Co-design, (b) Co-delivery, and (c) Co-assessment.

Here are some practical recommendations to promote patient/family empowerment:

- Make patient-centeredness and co-production an integral part of the organization's strategy.
- Establish Patient and Family Advisory Councils (PFAC).
- Introduce "mystery shoppers" (patients) as part of the organization's plan to improve quality and patient safety.

(e) ***Collective Wisdom and learning*:** To bridge the patient safety implementation gap, we must move from the reactive approach to dealing with safety incidents to a proactive approach. Currently, many safety incidents and sentinel events continue to happen repeatedly not only at the country or sector level but many times even in the same department and/or clinical unit.

A key element to the proactive safety approach includes the introduction of common learning platforms where lessons learned from previous safety incidents are shared at all levels of the healthcare system starting from the microsystem (within the same clinical unit/department) to mesosystem (at the level of hospital/sector), all the way to the macrosystem (national level), and global level.

Here are some practical recommendations to enhance collective wisdom and learning:

- To standardize patient safety taxonomy and classifications across healthcare systems.
- To introduce the International Classification of Adverse Events (ICAE) which could be based on the International Classification of Diseases (ICD-11).
- To establish national and global patient safety alerts and learning platforms.

In the sections below, we apply these five critical factors to each of the case studies above to discern what lessons and learning points can be gleaned from these cases.

(a) **Safety Culture**: What did we learn from the tragic case of nurse Kimberly? Was there a culture of safety in place to prevent this? Clearly, it was the systems factors that contributed to the medication error leading to the loss of two lives.

The first error was the lack of a safety culture that ensures that the organization protects both healthcare professionals and patients. The hospital administration did not support the traumatized nurse; instead, she was escorted outside the hospital and employment terminated. In the case of Dr. Sellu, it was a series of events that led to the death of the patient and his imprisonment. There was no system in place to accommodate urgent or emergent surgeries including a lack of adequate OR slots and support personnel such as anesthesiologists. The sec-

ond missed opportunity was the patient not being informed enough to share that he drank alcohol every day and that he had liver cirrhosis. The third mistake was blaming the individual and not the system to the extent of prosecution and incarceration.

Both cases show a lack of accountability at the level of leadership. Rather than integrating safety measures that span from the level of the board to the ward, the leadership in both stories failed to do that and engaged in a "shame and blame" knee-jerk reaction. This resulted in the suicide of nurse Kimberly, and the imprisonment followed by the end of career of Dr. Sellu.

(b) **Advocacy**: Kimberly faced the traumatic incident alone. As any healthcare professional whose action led to the harm of a patient, she did not need punishment from outside. The guilt, shame, anxiety, and depression on top of the grief tormented her to death, a classic case of "second victim." The case of Kimberly is certainly not the first case, nor will it be the last one as long as the healthcare community does not value the need to advocate and put safeguards in place to support all healthcare professionals when they commit medical errors. Dr. Sellu was also a second victim who did not find enough support to help him face the situation. He was blamed for a whole system failure and was left alone to face it. Lack of advocacy made it very difficult for the average healthcare professional in both the US and UK (where these two cases happened) and around the world to appreciate the magnitude of the safety challenges in healthcare, and what they need to do to work towards solving it. Unless patient safety becomes a mainstream issue, unfortunately, we will continue to have recurring stories of harm for both patients and healthcare professionals.

(c) **Resilience**: There will be no healthcare resilience unless we embed human factors engineering into our day-to-day processes and procedures. This means studying the abilities, limitations, biases, and other characteristics of certain groups of humans in specific roles and then applying them to their work environment, systems, technology, or even communication. In the first case, Kimberly mixed the high concentrated electrolyte while talking to a coworker. The hospital did not have a system that required no interruption while preparing medications such as the sterile cockpit rule in aviation that clearly defines when it is necessary to set aside anything else other than the task at hand to avoid any distractions. The second system failure in this case is allowing nurses to mix critical medications. The regulatory bodies, such as the Joint Commission, require that these medications be mixed by licensed pharmacists and double-checked by two nurses before being administered. However, this practice is not uniformly implemented in all healthcare facilities. Almost every healthcare professional has seen or heard of a similar incident regarding critical medications. Yet HFE is not put in place to provide a safer, more efficient environment for both healthcare professionals workers and patients.

In the second case, lack of system resilience is quite obvious. Neither the interaction between Dr. Sellu's colleagues and him (clinician-to-clinician interaction) nor the clinical encounter between Dr. Sellu and the patient could identify the life-threatening nature of the situation. Even when the urgent CT

scan showed that the patient needed to have surgery, there were a lot of delays. The liver cirrhosis was identified as a surprise inside the operating room.

Proper human factor engineering practices would have put in place triggers that would have identified the severity and urgency of the situation and could have saved the patient's life.

(d) **Information Symmetry**: In the case of Dr. Sellu, a critical piece of information, that the patient had liver cirrhosis, was missing prior to the surgery. Suppose the patient was well-informed and better engaged about his condition and understood that liver cirrhosis was vital information to discuss with his surgeon, the outcome might have been different. There is potential for missed or misunderstood information taking place in almost every healthcare encounter every day. What action is the healthcare community taking to mitigate this complex issue of information sharing between healthcare professionals and their patients? There is no one solution fitting all settings or situations but it is clear that patients need to be more educated about their conditions, treatment options, and medications. The responsibility for information sharing belongs to both: patients to seek education and healthcare professionals to use language and terminology that patients can understand to provide safer care.

Also, as evident in Kimberly's case, if the family of the baby in the intensive care unit were empowered to ask questions about the day-to-day care plan including medications, work-up, and/or intervention, potential harm to the patient could have been avoided.

(e) **Collective wisdom and learning:** Of all the concepts discussed in analyzing these two cases, this is the one that would produce the most profound effects if it had been done consistently and collectively. If we are to aim for zero harm, then we need to learn to share knowledge and lessons learned with all healthcare professionals at all levels: clinical unit, healthcare organization, national, and global. It is unacceptable to continue watching these errors that lead to patient harm continue daily without learning from them and finding ways to mitigate and prevent them from repeating themselves.

Global Patient Safety Initiatives

Global Ministerial Summit on Patient Safety

One of the very important initiatives to improve patient safety is the Global Ministerial Summit on Patient Safety. Thanks to the leadership of both the UK and Germany, this significant initiative was introduced to the global scene with the aim of having the health ministers as key decision-makers and patient safety subject matter experts meet under one roof. There have been four patient safety summits so far: London Summit 2016 [10], Bonn Summit 2017 [11], Tokyo Summit 2018 [12],

and Jeddah Summit 2019 [13]. The fifth summit was supposed to be held in Montreux, Switzerland in 2020 but was postponed due to the Covid-19 pandemic.

The summit series had a big impact on the global patient safety agenda. Here are some of the positive outcomes of the summit series [14]:

- WHA 72.6 Global Action on Patient Safety resolution which was passed in 2019 [14].
- Tokyo Declaration in 2018 [12].
- Jeddah Declaration in 2019 [13].

WHA 72.6

On May 28, 2019, a key milestone in patient safety was achieved with the passage of the World Health Assembly's resolution titled, Global Action on Patient Safety. This was a momentous achievement of international collaboration to promote and push the patient safety agenda forward. It was the fruit of efforts that started more than 3 years before and it set in motion a key WHO flagship initiative called, "A Decade of Patient Safety 2020–2030 [15]."

Patient Safety on the G20 Agenda

With the Kingdom of Saudi Arabia's leadership, patient safety was introduced for the first time on the G20 agenda during the Saudi G20 presidency in 2020. The message was clear that not only patient safety is essential to the resilience of healthcare systems, but to the sustainability of the overall economy.

Safe Staffing: An International Perspective

In 2018, an interaction between a staff nurse and a nurse executive in a pediatric ward in Dammam, Kingdom of Saudi Arabia, started a domino effect that moved the nation to find solutions for extreme variation in nursing staffing levels. It began with an honest yet eye-opening conversation with a young nurse who broke down crying when a new nurse executive made her rounds in the hospital for the first time. The young nurse was assigned to take care of 30 pediatric patients with the help of one nursing assistant. The two tried to give the best care possible but the workload led the young nurse committing several medication errors, including giving the wrong antibiotic to the wrong patient and missing other scheduled medications. Upon inquiry, the nurse manager shared that three other staff had called in sick that morning and since the country did not have a system of calling in help from outside when needed, the situation ended up in these tragic results.

The nurse executive sought the help of the healthcare branch that was responsible for advocating for patient safety in the country — The Saudi Patient Safety Center (SPSC). A survey of staffing in both public and private healthcare organizations showed extreme variation in nurse-to-patient ratios. Some hospitals within the same city had adequate nurse-to-patient ratios while others were dangerously low. It was clear that the healthcare system needed regulations or at least guidelines to safeguard both nurses' and patients' safety.

The Director-General of the SPSC assembled a group of nurse experts to draft a white paper in collaboration with the International Council of Nurses (ICN). The work was based on lessons learned from the experience of California's Safe Staffing Law, Wales Safe Staffing Act, and Victoria's Safe Patient Care Act [16–18]. All these legislations showed commitments of governments to ensure that the minimum number of staffing is met to provide adequate care for their citizens. The paper was first presented in the 2019 ICN Congress in Singapore and became the precursor to one of the resolutions that were presented in the Jeddah declaration later that year at the fourth Ministerial Summit held in Jeddah, Saudi Arabia [19].

The group then worked with the highest regulatory body for healthcare facilities, the Saudi Central Board for Accreditation of Healthcare Institutions (CIBAHI), to make safe staffing ratios for nursing and other critical specialties as a mandatory standard for accreditation in the country [19]. The new regulation was presented at the 2021 ICN congress making Saudi Arabia the first country to mandate safe staffing in all its regions [20]. What we learn from this story is how the efforts of a few dedicated individuals can change healthcare to be a safer place for both healthcare workers and patients.

Conclusion and Lessons Learned

- Healthcare is a very complex environment with many factors that directly impact patient safety. Healthcare leaders and clinicians need to fully understand the five leading causes of medical errors and implement systems and processes that address potential pitfalls. From the two cases covered in this chapter, we learned the following:
  - A need to provide healthcare professionals with an environment that ensures the delivery of safe care. Any time a healthcare professional needs to perform a high-risk task or procedure, there should be an environment free from distraction.
  - The importance of information symmetry. All information should be shared between healthcare professionals, patients, and administrators involved in delivering care to patients. Information loss can lead to potential harm.
  - Patients and healthcare professionals need to know their rights, and everyone is responsible for advocating for both.
- Based on the cases we've shown (one from the U.S. and the other from the UK), it is clear that unsafe care is a global problem that has less to do with the geogra-

phy, or the level of a country's income (high income vs. low-mid income) but it has everything to do with healthcare industry itself.

- Global challenges require global collaboration to implement solutions. The only way to transform patient safety and reach sustainable development goals [21] is for the entire global community to work together and learn from each other.

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Part V
Organizational Issues

Chapter 25
Communication and Resolution Programs

Richard C. Boothman

Case Studies

Case 1: Ahmad

Ahmad, a 28-year-old man, presented to the emergency room of an academic hospital, with bleeding from the nose and mouth. He was cyanotic, struggling to breathe with O_2 saturations in the mid to high 80s. History included two prior visits to urgent care at a local community hospital for unexplained nose bleeds; each time he had been referred to his primary care physician. Imaging in the emergency room revealed a mass which appeared to be in his pulmonary artery and a working diagnosis of clot vs tumor was made. Bronchoscopy by pulmonary medicine revealed active bleeding but the origin was unclear. Following bronchoscopy, physicians met to discuss treatment options when the pulmonary artery ruptured leading to sudden cardiopulmonary arrest. Resuscitation failed, and the patient was pronounced dead. Ten family members (only one of whom spoke English) had assembled in the waiting area while the patient was being seen. A clerical staff member, indifferent to the unfolding crisis, was the family's only point of contact until a physician bluntly informed them that the patient had died. The family reacted emotionally with death threats and broken furniture. Police were called, family members were subdued and eventually escorted out of the hospital.

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Case 2: Caroline

Emergency Medical Services (EMS) transported Caroline, a 46-year-old single mother of two teenagers, found down on the kitchen floor for no known reason. She had a high BMI, but was otherwise healthy. EMS recorded her complaint: "I can't move my legs" with their impression of "R/O kidney stones." Caroline was evaluated and labs and images were obtained. She was admitted to a med surg floor. Two hours later, she was able to ambulate without pain. The workup failed to reveal evidence of kidney stones and the patient was ambulatory and seemed improved. Worried that her teenage children were unsupervised, Caroline expressed a strong desire to go home. Vital signs were stable and she was discharged by the hospitalist with instructions to follow up with her primary care physician.

Two days later, she was found dead on a couch at home. On autopsy, the cause of death was a ruptured aorta. An attorney retained by the family filed a notice of intent to file a wrongful death claim alleging medical malpractice for failing to diagnose and treat an aortic dissection.

Introduction

According to Donald M. Berwick, the birth of the modern patient safety movement can be marked definitively by Lucian Leape's "magisterial December 1994 article in the Journal of the American Medical Association: Error in Medicine" and as he describes it, "Within just a few years of Lucian's call to arms, massive shifts were underway in healthcare's awareness of and concern about patient safety and its defects" [1]. Since then, the scope of patient safety has expanded as experts from fields as disparate as aviation, the nuclear industry and the automotive industry have sought to apply their processes to make healthcare "safe." The most ambitious among those advancing the "science of safety" are the proponents of "high reliability organizations" who argue that the only acceptable goal for clinical medicine is "Zero Harm." [2].

But what exactly is "harm" in clinical medicine? Clinical medicine is inherently dangerous. Almost nothing in clinical medicine does not cause or risk harm of some sort. No surgery can be accomplished without damage to skin and tissues, structures like nerves and blood vessels with concomitant exposure to unintended bleeding and infection. Radiology studies expose patients to harmful radiation. Screening colonoscopies risk injury by introducing tissues to foreign objects that sometimes cause tears or perforations while tumors can be missed due to technological and human limitations. Even the most seemingly benign clinical treatment, like the routine prescription of an antibiotic for a child's first ear infection can cause horrific consequences, like the children in two different malpractice claims I defended, one in Michigan and one in Ohio, who died gruesome deaths when a standard dose of Amoxicillin triggered Stevens-Johnson syndrome that spiraled into life-ending complications in each. Others can grapple with the challenge of defining "harm" in

clinical medicine and wrestle with whether attaining "zero harm" is even realistic, but for this chapter, the ambiguity is a suitable place to begin a critical examination of the way clinical medicine has, for a very long time, responded to unintended clinical outcomes.

Paradoxically, responsibility for healthcare's response to adverse clinical outcomes has been, and remains today chiefly the province of legal and insurance professionals, not clinical leaders. Those who lead clinical medicine and patient safety, arguably the very best suited to direct the response to patients harmed, have accepted and continued to accept the status quo in spite of the myriad ways that litigation-influenced responses impede efforts to improve clinical safety and actually perpetuate the litigation cycle in a sad spiral that only intensifies harm to patients, families, and healthcare professionals alike. The harm enigma bedevils clinical medicine even now while it keeps busy a sizeable portion of the legal profession and court systems both civil and criminal, a legion of regulatory agencies, patient safety experts, peer review processes, and so on.

There is a better approach. Communication and Resolution Programs (CRPs) conspicuously align the foundations of patient safety improvement with organizational and personal responses to patients who suffer unintended clinical outcomes. The model breaks the entrenched addiction to litigation-as-the-only-response by intentionally meeting patients' and families' emotional and informational needs after clinical harm; the combined compassion, honesty, and speed of engagement offers the chance to mitigate further harm to those patients and clinical staff involved in adverse events while speeding clinical improvement. Yet, movement toward CRPs continues at a snail's pace. In this chapter, I will discuss operational and outcomes differences with CRPs but in order to understand the fundamental difference, it is useful to understand how the status quo became the status quo.

Historical Perspective on Malpractice

Scholars, historians, and commentators variously trace the concept of medical malpractice as far back as 2030 BC when the Code of Hammurabi reportedly declared, "If the doctor has treated a gentleman with a lancet of bronze and has caused the gentleman to die, or has opened an abscess of the eye for a gentleman with a bronze lancet, and has caused the loss of the gentleman's eye, one shall cut off his hands" [4]. Commentators report that the first recorded medical malpractice case in English jurisprudence occurred in 1374 when a physician was sued for improperly treating a patient's hand [5]. By the 1800s, medical malpractice lawsuits appeared with some regularity in American civil litigation reports. "By the mid-nineteenth century," Kenneth De Ville, author of *Medical Malpractice in Nineteenth Century America: Origins and Legacy* [6], writes, "commentators in medical literature rarely expressed incredulity or astonishment when a patient sued a physician. They had begun to view the malpractice suit as ***a ubiquitous and possibly permanent fixture of medical practice***" [6] (emphasis added).

Two hundred years of conditioning taught American physicians two unfortunate lessons, both of which confound patient safety today: (1) because patient harm is unavoidable, being sued is inevitable and consequently, (2) these are matters for the legal profession (and by extension, the insurance industry) to manage. "Professional liability insurance has become society's chief agency for the distribution of the cost of malpractice by the medical profession" proclaimed the Duke Law Journal [7]. The year was 1960 and with remarkable prescience, the author(s) predicted the sharp rise in malpractice claims and judgments, the deterioration of the patient–physician relationship, increases in insurance premiums, and a growing demand for higher and higher policy coverage. In recognition of "the greatly increasing incidence of malpractice litigation," the author(s) acknowledged that responsibility would fall to the insurance industry to employ "risk controls" for the protection of their financial assets. Centuries of resignation to patient harm and the inevitability of litigation did not just prioritize financial loss over all other considerations, they left the medical community almost completely off the hook for injuries caused by avoidable errors. It is hardly surprising that the embrace of a response to injured patients expressly designed to serve patient safety toward an audacious goal of achieving zero harm has been glacial.

Yet, traditional legal/insurance-driven responses to patient harm have not been helpful to healthcare's healing mission. As early as 1940, commentators were decrying the loss of the traditional patient–physician relationship [8]. In 1959, an article in the Saturday Evening Post observed:

"American doctors are well aware of the restorative effect that their sympathetic interest can have on a patient. But today many people have an image of the modern doctor that is infinitely far from this ideal of medicine. In the place of the kindly, concerned doctor they see a bronzed man in a white coat who sits in his office, cold and bored….

The medical profession is frank to admit that some bad blood has welled up recently between patients and physicians, and it is worrying about how to get rid of it. The profession fears that something may be going wrong with American medicine's proudest boast, the warm and wonderful "doctor-patient relationship" [9].

Professional liability insurance companies challenged steadily increasing lawsuits with armies of malpractice trial lawyers incentivized by billable hours who leveraged a cottage industry of expert witnesses willing to testify for handsome fees. As predicted in 1960, costs soared, verdicts were publicized, insurance premiums rose steadily, insurance underwriting and renewal practices were refined and unhappy patients were labeled "litigious." The self-fueled spiral was established and the medical community soon viewed itself as prey for opportunistic patients spurred on by lawyers:

"Physicians revile malpractice claims as random events that visit unwarranted expense and emotional pain on competent, hardworking practitioners…" [10].

"For over a century, American physicians have regarded malpractice suits as unjustified affronts to medical professionalism and have directed their ire at plaintiffs' lawyers… and the legal system in which they operate" [11].

Physicians marched on state capitals [12] and pressured lawmakers for tort reforms [13] that increasingly shielded them (and their insurance companies) by making claims procedurally more difficult to bring and less lucrative. They banded together to resist meaningful peer review which led to regulatory devices like the National Practitioner Data Bank in an effort to track erstwhile physicians allowed to move freely by a profession that resisted meaningful self-policing.

Almost lost in the adversarial spiral was the uncomfortable truth that far too many patients were being harmed by preventable and avoidable (sometimes even criminal) errors. Lucian Leape recalls that in 1985, medical malpractice was considered a full-blown crisis. "Doctors seemed to complain about being sued all the time, but no one knew the facts," he writes. And specifically, no one knew how many patients were harmed by substandard care, no one knew how many suits were really being filed and no one knew the cost of the paradigm in place, the only paradigm anyone really knew at that point [14]. Neither did anyone openly question the incongruity of a physician holding a patient's life in their hands one moment and abandoning the unfortunate patient who sustained an unplanned clinical outcome the next.

Still, some thought to explore the causes of the malpractice crisis. Gerald Hickson, MD and his team concluded that 43% of a group studied sued their caregivers for damages from perinatal injuries when they suspected that those caregivers and healthcare organizations had been less than forthright about mistakes in care [15]. Moved by two large malpractice judgments in 1987 against the Veterans Administration Hospital in Lexington, KY, Chief of Staff Steve S. Kraman, MD and VA attorney Ginny Hamm envisioned a "humanistic risk management policy" that relied on early detection of patient harm, honest disclosure, and negotiation of settlements where appropriate. Defying conventional wisdom that honesty would lead to increased claims and financial catastrophe, their experience "suggests, but does not prove the financial superiority of a full disclosure policy" [16].

The Michigan Model

In 2001, in what became known as "the Michigan Model," the University of Michigan Health System systematized key elements described by Kraman and Hamm but for a markedly different reason: to prioritize patient safety. Michigan dared to question the centuries-old resignation that litigation was an inescapable part of Medicine. The Michigan model marked an important shift that would prioritize patient safety goals instead of claims, but would also eliminate the ways in which "deny and defend" impeded safety improvement [17]. The Michigan Model alternative not only demonstrated financial cost savings in the short term for the same reasons Kraman and Hamm reported, but several other measures improved: the approach truncated the time from the "date of loss" to closure, for instance [18]. The effort pointedly aimed to reinforce a culture of clinical accountability which logically should lead to safer care, durable claims reduction, and important collateral

benefits including improved clinical staff morale, and an approach to peer review that is a proactive and integral component to their culture of safety.

The Michigan Model came to the attention of Senators Clinton and Obama [19] who also sponsored the National Medical Error Disclosure and Compensation Act (MEDiC) [20]. Though it failed to pass, as Lucian Leape observes, patient safety as the fix for malpractice was "on the national agenda." In 2008, the Agency for Healthcare Research and Quality (AHRQ) awarded multiple grants to study the wider application of the model which eventually led to the publication of the CANDOR toolkit [21].

Communication and Resolution Program (CRP)

Academics have since called the approach Communication and Resolution Programs (CRP), an unfortunate label that spotlights potential claims instead of clinical accountability for preventable errors and prompts patients to bristle at the notion that they ever experience full "resolution" of the consequences of the medical mistake which harmed them. As a result, many organizations still view CRP through a claims lens, selectively recognizing and settling some cases without litigation—a helpful, but hardly new risk and claims management practice that misses the deeper benefits of a true CRP [22].

CRP's primary goal is to complement patient safety efforts, not simply amend a litigation-oriented claims management reaction to a potential malpractice claim. It is a goal realized by a consistent, compassionate and honest approach to patients harmed in their care. The organizational response to patient harm should mirror the values underpinning organizational commitment to high reliability, clinical excellence, and patient centricity.

Nine Essential Elements of CRP Elements

In this section, I describe how the nine essential elements of CRP complement the cultural foundations of medicine and discuss the practical application to the above case studies.

1. **Capture all unintended clinical outcomes, not only potential claims.** Consistent with the fundamental instinct of a healer and healing institution to instinctively run to a patient who needs healing, it is opposite of the pronounced caution of traditional risk-averse responses that results in functional abandonment of the patient harmed in an adverse event. Medicine's inherent risk—the reality that even reasonable care can lead to tragic outcomes and decades of concern about being sued - conditions healthcare professionals to treat every patient who experiences a less-than-desirable outcome as a potential claimant, precisely the opposite of the ideal compassionate patient–provider relationship.

2. **Secure the clinical environment.** Traditional legal instructions not to change the way the clinical care in an adverse event was delivered for fear of having the improvement portrayed as an admission that the previous care was negligent is at best short-sighted to the point of cynical, unethical and immoral at worst: if one patient was harmed, others are at risk. To expose other patients to a known risk in a misguided attempt to preserve a defense to a potential malpractice case is simply unjustifiable and the harm from that traditional instruction expands to the broad audience of healthcare providers involved, eroding any effort to build a culture of continuous clinical improvement. Needless to say that from a practical perspective, it is short-sighted and ill-advised.

   In Caroline's case, the missed diagnosis was "defensible" even with a careful critical analysis of her presentation and the emergency medicine care. In a defensive approach, the business of constructing that defense would have masked the real gap in Caroline's care: she was admitted with a very serious clinical complaint—she could not move her legs—which was left unexplained at the point of discharge. The dangers of "anchoring" to a presumed diagnosis and not viewing her clinical presentation broadly to entertain plausible explanations was an important lesson to be learned and communicated [23], but might have been obscured by a myopic defensive response to allegations made in a lawsuit.
3. **Engage and support the patient and family.** Defensive responses would have surely led to labeling Ahmad's family as disruptive or dangerous. In both cases, stonewalling traumatized family members would only have deepened and extended the trauma as they struggled to understand the deaths of their loved ones. Survivors would have formed conclusions based on their worst fears applied to incomplete or inaccurate information. The sooner traumatized people receive a compassionate and high-quality response, the better chance of ameliorating the emotional impact and duration [24]. CRP-modeled responses call for engaging the families of patients harmed in any adverse events even before the quality of the care can be evaluated fully; the goal is not to "disclose" any speculation in that first engagement. Healthcare staff instead is trained to demonstrate continuing and compassionate commitment to the patient and family, concentrating on the patient's new needs, committing to a *future* disclosure once facts are confidently understood while avoiding uninformed explanations in the heat of the moment.

   Engaging the patient and family immediately offers another unique benefit: a critical opportunity to learn information that only the patient may know that could be valuable to causal investigations to follow. In a litigation-oriented response, that information is rarely collected except maybe in testimony years later and never used in root cause analyses. In Ahmad's case, the discovery of the clerk's otherwise well-known-but-never-discussed aversion to people of Arab descent was important to an organization dedicated to patient centricity, one that had already invested considerable resources to improving patient experience. There was no way to know how many other patients and families the clerk had offended, but the revelation only obtained by engaging Ahmad's family could assure that no others would be harmed.
4. **Engage and support the caregivers.** For generations, healthcare providers have been effectively isolated after an adverse event by risk management admonitions

not to talk to anyone other than their assigned defense counsel [25, 26]. Perhaps no other characteristic of traditional legal responses has been so damaging to clinicians' best interests: healthcare professionals already reeling from the event with complex emotions are further isolated and other patients are at risk by healthcare professionals expected to resume clinical duties while distracted, defensive, distraught. Responding to unintended clinical outcomes and not waiting for claims to be asserted opens an important opportunity to attend to healthcare professionals' emotional well-being quickly and compassionately.

5. **Conduct a rigorous investigation in collaboration with safety.** This element is a key change from traditional ways of responding to patient harm. In a deny-and-defend culture, instances of patient harm often come to light only after a claim is asserted. And at that point, the key question: "Is this case defensible?" usually translates to: "Can we find an expert to support this defense?"

   "Is this defensible?" is the wrong question to ask! In a CRP model, the more important questions are, "Did this care meet our expectations?" "Are we proud of this care?" and "*Should* we defend this care?" These questions often lead to different responses. In Ahmad's case, the clinical care was entirely appropriate. Instead of labeling the family as dangerous, the family was called to a meeting with the five physicians involved in Ahmad's care. And though the meeting began in an emotionally charged atmosphere, one-by-one with compassion, with images and models, the physicians described the clinical challenge, their actions and their reasoning. They demonstrated their own humanity and the family could readily see that the physicians themselves were struggling with their inability to save Ahmad. By the end of a nearly three-hour meeting, family members were consoling Ahmad's physicians. The clear, compassionate explanation averted a misguided lawsuit.

   Understandably Caroline's family focused on the emergency care she received which was, even after intense scrutiny, deemed appropriate. In a litigation-focused response, risk management's advice would be to avoid any contact with the family entirely and wait to see if they pursued a claim. A significant percentage of patients harmed never come to the attention of the legal system [27, 28] and even if the family sought legal advice, there was a substantial chance that the lawyers would not get it right. Plaintiffs' lawyers' ability to analyze the quality of care is dependent on the accuracy of the factual information and quality of experts available to them; a layman with limited guidance could easily focus on the emergency medicine decisions, overlooking the clinical decisions that were made after Caroline had been admitted. If the goal is mainly to avoid financial payment for medical errors and optimally positioning the case for litigation, stonewalling this family may have been a rational choice. Defending a case in which the care was problematic, however, communicates the same financial priorities to the organization's staff at the expense of a culture of openness and honesty pivotal to a safety priority.

6. **Communicate widely to patient, caregivers, and organization.** This element is completely counterintuitive to proponents of deny and defend. It challenges the hardwired fight or flight response and flies in the face of longstanding

conventional-but-unproven certainty that we cannot afford to be honest about mistakes let alone broadcast the truth or memorialize mistakes in writing. True CRPs are highly disciplined, requiring risk management staff and clinical leadership to know the difference between speculation and hard facts, but appreciating the critical importance of open acknowledgment of mistakes to a culture of safety. Within weeks of the investigation of Caroline's death, all three emergency departments operated by the health system were in-serviced with her story and the case was embedded into residency training. The story was shared with the patient safety organization operated by the state's hospital association and presumably shared with the PSO's members.

In Ahmad's case, a family meeting was arranged. Using imaging and an anatomical model, five physicians chronologically presented what they did in Ahmad's care and why. The family received a thorough explanation of what happened. No lawsuit was filed.

7. **Respond consistently with conclusions from the investigation.** In this element, health systems respond in ways that are congruent with their findings. In this regard, CRPs represent a departure from long-established claims management decisions to defend even care that may privately be regarded as substandard, but conversely to settle cases for financial and risk avoidance reasons even where the care met standards of care. In litigation-driven responses, it is customary to view every case as having some settlement value, often measured against the anticipated cost of defense no matter how baseless the allegations. Both practices are counterproductive to patient safety. Publicly defending substandard care effectively eliminates meaningful peer review that may be warranted and sends seriously mixed signals to the clinical staff about organizational priorities. So-called nuisance settlements telegraph to patients, the trial bar and healthcare professional that responding to unplanned harm is a "lawyers' game."

   CRPs instead, rely on early communication in all cases of harm, including those in which the care proved to be reasonable. In this way, patients are reassured that the patient–provider relationship remains unshaken and misguided lawsuits are intercepted before patients, families, and their lawyers invest in litigation before they know the full facts. One of the most consistent ways in which CRPs save money is the avoidance of claims not pressed. Winning the confidence of the medical staff is critical to a CRP's goal of achieving accountability for mistakes that cause harm. As sad as Ahmad's death was, the organization refused to behave as though his physicians did anything wrong clinically to cause his death. Making a full explanation headed off an expensive claim. In Caroline's case, litigation was also avoided: despite the family's clinically-unwarranted focus on her emergency medical care, a settlement was reached after fully disclosing that though the emergency medicine course was reasonable, the discharge decision was problematic. They were reassured that lessons were learned, and efforts made to protect future patients. Patient safety was advanced, the individual interests of everyone involved were served and all involved avoided the high costs of litigation, emotional and financial.

8. **Hardwire lessons learned.** In both cases, the healthcare system embraced the lessons learned, building Caroline's clinical presentation into a grand rounds and residency education and using the discovery of the clerk's prejudice from Ahmad's case to highlight ethnic sensitivity across the system.
9. **Measure different metrics.** What an organization chooses to measure speaks volumes about its priorities. In organizations with litigation-sensitive responses to patient harm, overall malpractice costs are measured and used as proof that the organization and its staff are victims of windfall-motivated patients. Consider how paradoxical that patient image is to the central clinical mission of healthcare organizations! How incompatible it is compared to the reasons individual professionals dedicate themselves to medicine! That measure warns the organization and its staff that the patients they aim to treat could turn on them as soon as clinical care doesn't go as planned. The cost exceeds dollars and cents: it erodes the very mission itself. In finance-preoccupied healthcare environments, executives can recite to the penny how much they spend on malpractice, but they can never answer a more pertinent question: "How much *should* you have spent?" As careful as some healthcare organizations may consider themselves, none are immune from harming patients by avoidable, preventable medical mistakes. If they're not distinguishing between undesirable clinical outcomes that happened despite appropriate care from harm caused by avoidable medical errors, and if they're not doing their best to rectify the harm they caused in such cases, by definition they are not accountable. And if they are not accountable, they will predictably not advance the safety of their clinical care, they will not maintain an environment where their staff can find joy and meaning in their work, they will not offer a uniformly positive clinical care experience to their patients and their peer review efforts will never advance clinical care.

Conclusions and Key Lessons Learned

- Healthcare professionals have known since Hammurabi's time that intended clinical outcomes cannot be guaranteed and their patients can find themselves worse off for their efforts. Compared with "an eye for an eye" justice, litigation as an outlet for unhappy patients surely represented serious evolutionary progress. Lawyers and courts consequently preceded patient safety experts by hundreds of years, so it should be no surprise that even today we instinctively regard patient safety concerns as a legal matter before viscerally recognizing opportunities to advance clinical safety.
- CRP-style approaches represent the next evolutionary step on Medicine's path to zero harm. As tragic as unintended clinical harm may be to the patient affected, organizations employ CRPs because the most important patient in their eyes is the person who has not been harmed yet. CRPs are careful to align organizational responses to unplanned clinical outcomes with that imperative in mind while attentively eliminating the myriad ways in which "deny and defend" undermines

the predicates to patient safety. CRPs require discipline and consistency and carry their own risks, but happily the approach effectively promotes patient safety as a priority, saves money by right-sizing malpractice costs and effectively puts a reliable price tag on preventable mistakes. Consistently applied principled responses enhances organizational reputations and increases public trust. On an individual level, CRP's outcomes generally serves all concerned: patients and staff alike are spared the brutal experience and expense of unnecessary litigation, lasting emotional harm is ameliorated for patients and staff, patient safety-as-a-priority is emphasized and real and useful peer review is energized.

- No patient chooses to be harmed when they entrust themselves to healthcare; healthcare, however, can choose its response when unintended harm occurs. Before the patient safety movement, patient harm seemed unavoidable, litigation inevitable. There is a better way, but it is up to clinical leaders to insert themselves, raise their voices and insist that all patients benefit from their missions, visions, and values, including patients harmed in the course of their care and especially patients who have not been harmed yet.
- Questions to ask:

1. Have you thoughtfully examined the way your organization responds to unintended clinical harm? Do the practices serve or undermine patient safety?
2. Patient safety is not only the responsibility of clinical care professionals but must be a priority for those entrusted non-clinical critical functions in complex organizations. Does your organization clearly communicate that at all organizational levels including risk and legal professionals? And measure performance against impacts to the mission, vision, and values of your organization?
3. Does your organizational structure afford clinical leaders a voice in the way its risk and claims management processes serve its mission, vision, and values, promotes patient safety as a priority, and avoids practices that undermine investments in patient safety?
4. Have your organization's risk and claims management professionals been charged with the responsibility to advance, not impede patient safety priorities?
5. In its response to patient harm, does your organization confidently differentiate care that caused harm despite reasonable care from harm caused by preventable medical mistakes? And does it respond to the affected patient consistently with those conclusions?

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Chapter 26
Second Victim

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Introduction

Throughout the history of Medicine, the second victim phenomenon has been ever present. Poignant moments of life altering psychological distress spanning centuries of medical errors and patient events in healthcare illustrate the developmental course how healthcare organizations support the second victim. In 1817, Sir Richard Croft, the Obstetrician to Princess Charlotte of Wales, completed suicide following the deaths of a stillborn son and the princess herself. Nearly 200 years later in 2011 Kimberly Hyatt, a pediatric nurse with an excellent reputation and 25 years of experience, committed suicide following a medication error associated in the death of a pediatric patient.

Moral distress and injury are common occurrences in healthcare. Delivery of care is complex, multi-dimensional and, when at its best, an intensely intimate process. Healthcare providers see their patients in their most fragile moments. The human connection established during provision of care becomes integral to the process, though not always without significant cost. In 1954, two surgeons shared their experiences with unexpected patient events and the impact on their own emotional well-being, noting that there is "nothing more catastrophic" for the patient's family and the care team than losing a patient unexpectedly [1]. Experiences such as these remained undefined and only recognized secondarily or more remotely in relationship to patient safety and organizational risk.

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The second victim phenomenon, a concept coined by Dr. Albert Wu in 2000, is defined as psychological trauma experienced by healthcare team members following a medical error and/or a patient related event [2]. The concept created a greater understanding of the psychological impact of significant patient events on healthcare team members. Those experiencing the second victim phenomenon can manifest physical (sleep and appetite disturbance, somatic experiences), emotional (guilt, shame, hopelessness), behavioral (social isolation, substance misuse), and cognitive responses (intrusive thoughts, distractibility, difficulty concentrating) in response to significant patient events. These experiences can range in intensity and duration based on multiple factors. Contributing factors can include patient outcome, level of real or perceived responsibility in the event, and personal factors related to psychological resilience, supportive factors, and biopsychosocial elements such as gender, years of service, etc. [3].

Organizational response also has impact on the intensity and duration of the psychological trauma associated with significant patient events. There is ample historic evidence of imposed punitive measures by employers, professional boards, even the legal system through criminalization of a medical error. The healthcare industry is becoming more adept at recognizing the intersections of burnout, compassion fatigue, moral distress/injury, and patient safety/ satisfaction. The Triple Aim—a guide to improve population health, enhance the patient experience, and reduce cost—evolved to the quadruple aim in 2014, recognizing that the experience of the healthcare team, both individually and collectively, served as the underpinning for successful achievements of other targets [4].

Understanding the psychological impact of the second victim phenomenon sets the stage to identify and establish appropriate support and intervention for healthcare team members. Amidst nursing shortages and future physician shortages, it is becoming increasingly important to develop healthy organizational cultures positioned to support and retain valuable healthcare team members. As a function of multiple factors contributing to a "high reliability organization," support of the second victim has not only become the right thing to do from a humanistic standpoint, but rather a best practice [5]. In fact, the World Health Organization's Global Patient Safety Action Plan 2021–2030 (Strategy 4.4) establishes to "*Ensure that patients, families and health care staff (the 'second victims') are given ongoing psychological and other support in the aftermath of a serious patient safety incident*" [6]. The second victim phenomenon includes (a) stages of transition from event to outcome, (b) the comprehensive impact on individuals and systems, and (c) coordinated deployment of resources and supports to individuals and teams following significant and sentinel patient events.

With the onset of the COVID-19 pandemic in 2020, the healthcare industry faced yet another maturational opportunity. Those on the front lines have experienced significant and chronic moral distress, grief and loss, and concern for their own well-being and the well-being of loved ones. The emergence of post-traumatic stress symptoms and post-traumatic stress disorder in previous pandemics, such as H1N1, reveals that those working in high-risk settings are more likely to be met with short- and long-term psychological impact [7]. With its multifaceted nature

and its equity, socio-economic, and political challenges, the COVID-19 pandemic has created even more complex emotional vulnerability and behavioral dysregulation for healthcare providers. During COVID-19 and future pandemics, healthcare systems with established systems of support for healthcare team members experiencing the second victim phenomenon are positioned to capitalize on existing processes to capture healthcare team members and provide proactive support and intervention. Dr. Albert Wu foreshadowed that organizations who deployed second victim support mechanisms to healthcare team members experiencing trauma related to the pandemic would benefit financially and organizationally [6].

The ability to mitigate acute and chronic psychological distress and move individuals, more adeptly, into post-traumatic growth can be accomplished by flexion and expansion of existing support processes. Tapping into employee assistance programs, peer support systems, event reporting systems, chaplaincy programs, the designs of delivery and incorporated resources provided differ across organizations. All hold in common an integration into existing infrastructure and work in tandem with the cultural shift from "blame and shame" to "just culture" [8]. The ongoing development and refinement of second victim support process continues as more is explored and recognized about the psychological challenge of working in healthcare.

Case Studies

Case #1: COVID-19 Second Victim, Primary Casualty

Janet Stafford, a 42-year-old highly experienced Registered Nurse, received a call from a member of her organization's second victim support system. The system had expanded its scope to provide support to healthcare team members experiencing distress related to COVID-19. Janet was receiving an outreach call because she had tested positive for the virus after being exposed at work. She told the outreach provider that she had never been so ill. During the call, she discussed the complex emotional responses related to caring for COVID positive patients as well as her own exposure and illness.

Experiencing isolation from her family, including her husband and children, she expressed concern about the potential risk of being in the same house with them and causing them to become ill. Her ability to compartmentalize her work and personal life was much more challenging. A confident and independent person and professional, her emotional reaction was both surprising and overwhelming.

During the call Janet expressed gratitude for the support. The conversation helped her gain clarity, feel connected and understood and served as a starting place for her to continue working through the complex psychological impact of being at the bedside during this pandemic. A year and 4 months later, Janet has recovered from COVID and is still working in the same healthcare organization and on the same unit.

Case Discussion

Healthcare workers have experienced exposure to psychological challenges on multiple fronts. “Clinicians are dying not only of physical manifestations of COVID-19, but also of the emotional and mental health repercussions of caring for persons who are suffering without loved ones by their side” [9]. Additional assaults on mental well-being of healthcare workers include fear of personal exposure and illness, potential exposure of their own loved ones, stigma of being a healthcare worker within the worker’s larger community, lack of support, moral distress, and exhaustion. A systemic analysis conducted by Kisley and colleagues, documented mental health effects of previous pandemics such as H1N1, SARS, and Ebola and showed that those delivering direct care to patients experienced higher levels of post-traumatic stress and psychological distress [10].

COVID-19 has highlighted the need for our healthcare organizations to implement approaches to support and care for those on the front lines during crucial times. The nature of second victim support systems can allow for creative flexibility within existing infrastructures to expand provision of proactive care for healthcare workers like Janet. These systems can provide mechanisms promoting the preservation of mental health and well-being, the ability of healthcare team members to function in their roles, and a more sustainable career. Organizations also have the opportunity to mitigate employees’ sense of isolation and lack of support from their employer.

Case #2: Effects of a Possible Medication Administration Error

AR, a 35-year-old male, was referred to the otolaryngology clinic with reports of bilateral ear pain and a history of multiple ear infections in the past. The advanced care practitioner, JP, assessed AR’s ears to be without fluid, infection, or acute changes. No mouth, or external nose lesions were noted. To assess the nasal passages, tetracaine was placed in the nares prior to placement of the nasal scope. The nasal passages were open without obstruction. When withdrawing the scope, JP noted the mucous membranes to be blanched in the areas where the anesthetic was applied. The patient tolerated the procedure well and without complaints and left the office with a scheduled appointment in one month.

JP reflected on the encounter and the unexpected blanched mucosal membrane. This led to JP’s concern of unintentionally causing harm. JP inspected the bottle of liquid anesthetic with concern of a possible medication error. Then, phoned the patient to disclose the possibility of an adverse event during the procedure and advised Mr. R to report to the emergency department (ED). JP arrived in the ED within the hour. The patient received treatment for a chemical burn and was discharged home.

After this encounter, AR phoned JP in anger. Through yelling and cursing, he threatened legal action multiple times. As part of the event analysis, the liquid in question was sent for testing to an independent lab. Six weeks later it was confirmed

that the liquid was, in fact, tetracaine, the intended anesthetic. Three months later, AR submitted a complaint to the medical board detailing his experience with JP.

After 8 months of review, the medical board concluded the health and safety of AR was not compromised, and the care rendered was reasonable and appropriate. The 8 months of waiting for a decision led to additional trauma, anxiety, and doubt for JP. Despite using the correct medication and doing the right thing for the patient by advocating for his safety, JP continues to be triggered to relive the scenario as a second victim.

Case Discussion

Individuals like JP, who are reported to medical boards, are often psychologically impacted. This second victim phenomenon began attracting the attention and focus of researchers in the early 2000s [11]. Evidence supports that affected individuals benefit from interventions as they go through the stages of recovery [12]. The University of Missouri Health System has analyzed these stages into six predictable recovery stages (Table 26.1) [13].

During the chaos and accident response stage (stage 1), JP had support from colleagues and felt comfort knowing that she was doing the right thing for her patient. She immediately filed an event report which triggered a phone call from the local second victim support team or TRUST Team. At the time, JP politely declined any further needs.

Over the next weeks while waiting on the testing results of the liquid, the intrusive reflections of the event flooded JP's mind. She frequently re-enacted the scenario over-and-over in her mind (stage 2). She had trouble sleeping and grew terrified of being sued and/or receiving disciplinary action. At this point in the second victim response, JP felt the need to restore her personal integrity (stage 3) while concurrently reaching out to obtain emotional first aid (stage 5). She reached out to the risk department for the TRUST Team contact information. Through this support, she discussed the experience with a peer who listened and provided empathy and reassurance. She felt comfort in knowing she was supported and not alone.

When the medical board complaint came to her months later, the feelings of intrusive reflections (stage 2) and anxiety resurfaced, and she requested another consultation with the TRUST Team to obtain emotional first aid (stage 5). This was her first complaint and potential negative outcome with a patient. She was deeply saddened by the thought of harming a patient, and afraid of this experience ruining her reputation.

Weeks after this event, JP felt she needed a new start and transferred to another service line within the organization (stage 6A). She is currently excelling in her new role, yet frequently reflects on the event with AR (stage 6B). She is considering joining the TRUST Team's peer response efforts to help others when an adverse event occurs (stage 6C). She recognizes the importance of emotional first aid in response to being a second victim and is ready to give back and help others heal; thus, demonstrating the stage of thriving and healing.

Table 26.1 A proposed organizational approach to intervention by stage of second victim recovery

Stages of second victim recovery	Stage	Characteristics	Recommended interventions
Impact realization	1. Chaos and accident response	Event realization Patient stabilization A "wave" of emotion	Assessment of ability to deliver continued care safely Focus on stabilization of patient and supportive engagement in doing so as able Establish collegial support and single point of contact for updates on patient outcomes
	2. Intrusive reflections	Haunted reenactments Self-isolation Internal inadequacy	Initiate leadership support Post event "Time out" Triage emotional/psychological impact Supportive assessment of ability to continue work Provision for basic needs/safety concerns Trigger second victim response processes
	3. Restoring personal integrity	Fear is prevalent Work/Social structure angst	Ongoing support from leaders and co-workers Ongoing provision for basic needs/safety concerns, assessment of ability to work. Access system resources for time away Initiate second victim response protocol • Establish rapport, safety, and parameters for confidentiality • Provide well-being assessment • Provide psychoeducation and psycho-social support • Refer to additional resources as needed (Peer Support, EAP) • Establish a regular cadence of frequency for follow-up check points
	4. Enduring the inquisition	Reiterates case scenario Responds to multiple "why's" from numerous employees	Provide education on system processes Support team members continue with Second Victim Response • Re-assess cadence for frequency for follow-up check points • Provide psychoeducation and psycho-social supports

Table 26.1 (continued)

Stages of second victim recovery	Stage	Characteristics	Recommended interventions
	5. Obtaining emotional first aid	Open to support, attempts to access social support	Support team members to continue to engage in second victim support processes • Re-assess across second victim Response check points to evaluate for additional needs • Engage or refer for trauma-based care, such as cognitive processing therapy
Moving on	6A. Dropping out	Transfers to another unit, department, hospital Considers leaving the profession	Second victim support team members continue to present and engage in second victim support processes. Shift focus into support of decision making, investigation of resources, and personal impact potential transition
	6B. Surviving	Coping but doesn't return to baseline	Engage in counseling/coaching or intensive levels of mental health intervention
	6C. Thriving	Gains insight, perspective and wisdom. Learns from event and helps others, advocates for patient safety	Present opportunities to support other second victims Present opportunities to provide presentations and continuing education both formally and informally System/organizational learning

Discussion

The Six Stages of the Second Victim Phenomenon

In this section, we discuss the six stages of the second victim phenomenon and recovery and the recommended interventions for each stage as outlined in Table 26.1. In general, a linear recovery occurs although the second victim may progress through each stage at a variable pace.

Stage 1: Chaos and Accident Response

This initial stage sets the path of impact and recovery for clinicians. As patient events unfold, chaos ensues, critical responses are put in place to rectify clinical challenges and reduce patient harm/mortality. Multiple factors in this initial stage impact the recovery for clinicians. These factors can include patient outcome, real or perceived responsibility for the event, response and supports from leaders and

team members, and individual psychological factors. A clinician's response to a patient event is highly dependent on these factors and can result in mild to severe acute stress responses/disorder. Four important processes are key to support during this phase. (1) assessment of clinician functioning, both professional and personal, (2) implementation of safety measures, both professionally and personally, (3) assessment of workplace needs and implementation of appropriate resources, and (4) referral into second victim support processes, psychological first aid, or critical incident response (when involving multiple clinicians.)

Stage 2: Intrusive Reflections

The stage of intrusive reflection is characterized by the second victim's feelings of insecurity, isolation, and repeatedly asking themselves "what did I miss to cause this event" or "I should have been able to prevent this from occurring." Throughout this period, the second victim will also traditionally reevaluate, reflect, and experience intrusive thoughts regarding the event. The reflections can include extremes such as haunting reenactments and self-doubt in their ability and skills. This vulnerable time is characterized by the clinician being easily distracted and preoccupied from events at hand which may increase risk for additional errors. Some options for support during include a temporary pause of clinical duties and ensure contact from the second victim response team of the institution to provide psychological first aid.

Stage 3: Restoring Personal Integrity

Restoring personal integrity is thought to be a critical stage if the second victim is to restore their personal and professional self-confidence. It is dependent upon institutional culture and available resources to support the affected individuals or team. This stage is often characterized by indecision or fear that originated from the concern of a negative reaction from peers or being unaware of where to find support and available resources. A negative response, whether punitive or insincere, can impede emotional recovery. A recommended institutional response includes an event debrief of the individual or team through a standardized second victim support program and event management which includes incident event reporting.

Stage 4: Enduring the Inquisition

In the fourth stage of second victim syndrome, the health care team member is pulled back into the situation and relives the event. This personal re-traumatization coincides with the reflection of potential professional ramifications such as the

threat of litigation. This negative impact of reliving the event can be mitigated during the initial outreach with the second victim by reviewing with them what to expect post event and how to access support. Best practice of second victim support is the adherence to just culture values during the event review and a focus on system improvements. This approach builds trust, fosters healing, and promotes contribution to uncover enhanced solutions.

Stage 5: Obtaining Emotional First Aid

The fifth stage, obtaining emotional first aid, is characterized by the second victim being open to support and considering available options. The practice of second victim response teams reaching out to the individual soon after the unexpected event establishes the knowledge of the existence of support services and contact information when needed. An effective strategy is peer support by a colleague of the same specialty, or a trusted professional teammate [14]. Recommended support at this stage is emotional first aid a form of cognitive processing therapy and can be effective to reduce symptoms of PTSD [15].

Stage 6: Dropping Out, Surviving, and Thriving

The final, and sixth stage, of the second victim response pertains to pathways leading toward closure [16]. Although the healthcare team member will likely remember the situation intermittently throughout their career, this stage branches into three different directions: dropping out, surviving, and thriving. Typically, the trajectory toward healing moves through one of these pathways. It is important to respect and support the healthcare team member's chosen pathway.

There are times when the healthcare team member may resign from the job role where the event occurred or leave the occupation entirely (dropping out). This stage allows the healthcare team member to focus their energy elsewhere such as another unit, or another career path altogether. Questioning professional competency and choosing a fresh start should be supported and validated during this phase.

The clinician may decide to remain in their current job role and continue the same path (surviving). Routine reflection on the event may illicit guilt and worry. These individuals need continued support and understanding as they are often reminded of the event and may struggle with frequent reminders causing angst.

Some individuals may fully embrace their healing journey and use the event as an opportunity to grow and share with others (thriving). This subset of individuals may choose to assist others in a peer support capacity. They have moved forward from the event and are ready to give back to their profession in various capacities.

Recommended Practices

Lessons learned and recommendations to consider for establishing a second victim support program are numerous and should be designed to meet the specific needs of a healthcare workforce. Early in the pandemic, it became evident that at our own health system, the existing second victim support program could evolve and deploy a proactive approach to support health care team members experiencing unprecedented events and distress related to the pandemic. Examples of expansion of second victim support in response to the COVID-19 pandemic are outlined in Table 26.2. We strongly advocate for a C-level executive to serve as the executive sponsor of the second victim support team. This serves to strategically enculturate the resource support assuring alignment with organizational mission, vision, and values. Another essential design element is to integrate the second victim support processes into the daily operational workflow of the institution. For example, an event created in the hospital's event reporting system could trigger a referral to the support team. Multiple points of referral of potential outreach opportunities should exist such as from clinical administrators, unit leaders, and quality and safety personnel or through established processes such as following the deployment of the behavioral emergency response team and from a hospital's mortality review team. Infrastructure consideration should include dedicated phone lines, email address, and communication protocols with the second victim. Details of the event are not discussed in order to protect the privacy of the involved healthcare team members.

Table 26.2 Structure of expanded second victim support systems in response to COVID-19

Existing support resource: Second victim		
Assessment of distress	Education provided to leaders and staff on nursing units, practice managers, employee health, occupational health	Education includes identifying distress related to care delivery, COVID exposure, COVID positivity
Trigger second victim response processes	Education on referral processes	Education includes using existing referral mechanisms, scripting to support referrals, parameters for referrals
Initiate second victim processes	Educate providers of support processes	Education to provide shift in focus from second victim to COVID distress, additional information pertaining to assessment, considerations for establishing check points, and refresh web-based educational offerings
Data collection	Refine data collection to capture COVID specific supports	Address means of capturing data specific to support for those experiencing COVID distress Consider establishing discrete data sets Analyze data for trends and recommend systemic adjustments to organizational supports

Our experience supports that outreach via phone call has greater success versus email contact.

Outreach to the second victim is best provided by a behavioral health professional with at least a master's degree in the mental health field. The primary goal of the post event outreach is to triage and assess team member well-being, provide psychoeducation regarding the second victim phenomenon, typical human trauma responses, and potential grief processes as indicated by the nature of the event. The outreach provider works with the healthcare team member providing emotional support and to determine additional needs which can include peer-to-peer support, referral into an existing employee assistance program (EAP), or a community mental health resource. Outreach providers can support through follow-up with the healthcare team member to assess for baseline functioning and serve as point of contact in cases of prolonged distress [17].

A peer support network is established by seeking volunteers who are healthcare team members who have experienced the second victim phenomenon. Training of the peer supporters includes active listening skills and role clarity as a non-behavioral health second victim support team member. Outreach providers and peer supporters work collaboratively should the need for escalation to a formally trained behavioral health professional be necessary.

Existing employee and faculty assistance programs can increase the number of sessions provided to employees in order to support resolution of presenting problems or to help bridge healthcare team members to longer term or more intensive care if clinically indicated. As a measure of efficacy, employee and faculty assistance programs can assess the increase in resolution of the presenting problem without a referral to longer term or more intensive care.

Additional considerations for creative interventions include providing onsite mental health professionals who will round on units, respond to events of aggression or violence, provide direct support to units during times of increased distress, partner with chaplains to provide grief support, round with pet therapy teams focusing support of staff, and provide debriefings and training pertaining to well-being. Embedding mental health support in the workplace can destigmatize the distress experienced by healthcare team members and provide greater accessibility and intervention. Mental health professionals can also be included in active shooter training as a means of providing trauma informed care and psychoeducation regarding psychological impacts of trauma.

Conclusion

Hospitals and healthcare institutions continue the recovery and rebuilding process in a post-COVID world that has brought the second victim phenomenon into view. Supporting the well-being of healthcare team members is an integral aspect of a post pandemic transformation of healthcare [18]. The magnitude of the second

victim phenomenon and its consequences reinforces the worthwhile investment of establishing an infrastructure for second victim support.

The challenges within healthcare today are novel to our team members. Listening, supporting, and honoring the healthcare team members' choices will go a long way for the individual and for the system. It is recommended to have the second victim response team available and advertised conspicuously to staff. This work should be promoted to decrease any feelings of defeat or shame in asking for help from the response team. Our culture needs to shift from viewing trauma as an accepted part of a career in healthcare to the acknowledgment and support of the second victim response.

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