Chapter

Patient Safety: Preventing Patient Harm and Building Capacity for Patient Safety

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Abstract

Patient safety is a global public health concern. It is a health care discipline with ever evolving advancement and complexity resulting in consequential rise in patient harm. Since the pandemic, patient safety has been threatened even more by laying bare the inadequacies of health systems. Many unsafe care practices, risks, and errors contribute to patient harm and overall economic burden. These include medical, diagnostic, and radiation errors, healthcare associated infections, unsafe surgical procedures and transfusion practices, sepsis, venous thromboembolism, and falls. Although patient safety has become an integral part of the healthcare delivery model and resources have been dedicated towards it, much still needs to be achieved. An attitude of inclusivity for all care teams and anyone in contact with the patient, including the patients themselves, would enhance patient safety. Incorporating this attitude from educational infancy will allow for better identification of medical errors and inculcate critical analysis of process improvement. Implementing the 'Just Culture' by health care organizations can build the infrastructure to eliminate avoidable harm. To reduce avoidable harm and improve safety, a constant flow of information and knowledge should be available to mitigate the risks. Lastly, proper communication and effective leadership can play an imperative role to engage stakeholders and reduce harm.

Keywords: Patient safety, medical errors, diagnostic errors, and radiation errors, healthcare associated infections, COVID-19 pandemic, unsafe surgical procedures, unsafe transfusion practices, sepsis, venous thromboembolism, falls, patient safety education

1. Introduction

"First, do no harm"- The Hippocratic Oath. Patient safety is pivotal to high-quality health care. The World Health Organization (WHO) defines patient safety as "a framework of organized activities that creates cultures, processes, procedures,

behaviors, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur" [1]. Ideally, the goal of all healthcare is zero preventable harm to patients, however, we are far from this target. Medical error is a global and system wide phenomenon which is present in all aspects of medicine and resources must be implemented at every level to recognize and limit its occurrence to improve patients' wellbeing. In this chapter, we will discuss topics that pose risks to patients in healthcare and ways systems and individuals can help mitigate them.

2. Reasons of patient harm

"To err is human"- Alexander Pope. Preventable medical errors can be attributed to several factors, including actions by healthcare professionals, systematic failures, or a combination of factors on multiple levels of care [2]. Although medical error is recognized as a leading cause of mortality worldwide, lack of reliable data at the organizational, national or international level, challenges in redesigning and implementing new healthcare systems, and difficulty engaging medical professionals in patient safety improvement activities contribute to continued lack of progress [3].

Certain healthcare settings and situations are also prone to higher levels of hazards and chances of error. For example, intensive care unit (ICU) patients' care is complex with multiple disciplines involved performing numerous activities and procedures that increase the potential risk of error [3]. A recent study reports that drug management (25%, 95% confidence interval 16% to 34%, I^2=98%) and other therapeutic management incidents (24%, 21% to 30%, I^2=98%), surgical procedures (23%, 9% to 38%, I^2=98%) and healthcare infections (16%, 11% to 22%, I^2=98%) are the leading causes of preventable patient harm [2, 4, 5]. Lastly, fear around reporting medical errors manifests strongly within the healthcare culture in numerous places around the world, and contributes to stunting advancement towards error prevention and patient safety [5].

3. The burdens of harm

Though patient safety is an essential principle of health care, yet many medical practices and risks related with healthcare are major challenges for patient safety. In high-income countries, one in 10 patients experiences an adverse event during their hospital stay [4]. In the United States, medical error is the third leading cause of death after cancer and heart disease, resulting in 250,000 deaths annually, and in the United Kingdom, a patient is reported to be harmed every 35 seconds [5, 6]. Low and middle-income countries fare far worse as one in four patients is estimated to be harmed, which results in 2.6 million yearly deaths [4].

Additionally, the cost of medical errors associated with poor care is an enormous economic burden. Unsafe practices which result in death or permanent disability have cost some countries between US $6 billion and US $29 billion per year [5]. Furthermore, the psychological cost to the patient and families associated with a loved one's death or disability, and loss of trust in the healthcare system are immeasurable [5]. Studies report that annual global economic growth could be boosted by over 0.7% if harmful medical practices are eliminated [4].

The joint commission gathers new evidence on emerging patient safety issues to inform goals for every year. Below are the brief descriptions of common safety issues, its burden, and the steps that can be taken to improve each.

3.1 Medical errors

Medical errors are events that occur during medical care which can lead to adverse consequences to patients. It is the third leading cause of death in the United States behind heart disease and cancer; about 250,000 deaths can be attributed to medical errors, including medication errors [7, 8]. They can be related to events when a wrong action was taken (error of commission) or when an action was not taken (error of omission). Additionally, medical errors can have consequences to health care professionals and institutions due to negative financial outcomes [9]. Healthcare providers can experience negative psychological responses with fear of punishment, and therefore be hesitant to report errors. It has been suggested that acknowledging healthcare providers are fallible and promoting a culture that focuses on mental health can lead to improved care for patients [10].

Several aspects of medical care can lead to medical error, including misdiagnosis, procedures, medication and/or dosage, patient identification and billing. It is important to recognize why they occur, foster a culture that encourages quality improvement, and cautions against an environment of blame and punishment [11]. There is often multiple causes of medical error: insufficient training, responsibilities performed by inappropriate staff, rare diseases, complexity of illness, unsatisfactory testing, time restraints, patient's age, and newer procedures, amongst others [7]. It is important for all members of the healthcare delivery team to be involved in all aspects of patient safety and improvement.

3.2 Diagnostic errors

Diagnostic errors have been estimated to be associated with up to 40,000 to 80,000 deaths or injuries per year. These include situations when a diagnosis was an unintentional delay, incorrect, or overlooked, and can occur in all specialties over a wide range of diagnoses. Preventing errors in diagnosis is a multifaceted approach, ranging from ensuring awareness of conditions that are often misdiagnosed, acknowledging first impression bias, discussion with appropriate specialists, and clear communication and documentation. This includes a complete differential diagnosis, appropriate handoffs, if applicable, and knowing which patients are at higher risks of diagnostic error, such as those with multiple medical conditions, patients with language and socioeconomic barriers, and patients with poor follow-up and compliance. Interventions to reduce diagnostic errors should not only be at the individual level, but should ideally be focused at the systems based level. System related errors include technical and equipment problems, organizational failures, "no-fault" errors like unusual presentation or conditions, and patient-related issues, such as compliance and misrepresenting symptom concerns [12–14].

The COVID-19 pandemic brings to light the importance of medical errors, including diagnostic errors as it relates to learning a new disease entity, as well as compromised physical and psychological aspects of healthcare providers that can affect clinical reasoning [15]. Additionally, system-based factors, such as staffing, capacity of the healthcare facility, and new care delivery systems, could be prone to delayed diagnosis due to postponement in patients coming to seek evaluation of symptoms or preventive screenings. It has been suggested that strategies to mitigate diagnostic error during these challenging times can be helpful: decision support tools, electronic health record, triage protocol, optimized use of telemedicine and follow-up, encouraging patients to seek care, education on safety protocols, a strong healthcare leadership team, open door for concerns without fear of judgement, continued support for education of trainees, and opportunities for discussion among colleagues for challenging cases and situations [16].

3.3 Sepsis

Sepsis is a syndrome characterized by life-threatening organ dysfunction in response to an infection. It is frequently not diagnosed early enough to save a patient's life. Because these infections are often resistant to antibiotics, patients are at high risk for complications and death and have higher health care costs [17]. **Sepsis** affects an estimated 31 million people worldwide and causes over 5 million deaths per year [18]. Even though there is a sepsis campaign guideline, the mortality from sepsis worldwide is still high at 34–46% [19]. The incidence of severe sepsis increases by approximately 13% each year in the United States, and it is a leading cause of morbidity and mortality worldwide [20]. Sepsis accounted for more than $20 billion or 5.2% of total hospital costs in year of 2011 alone in the United States [21].

In October 2015, the Centers for Medicare and Medicaid Services (CMS) began requiring U.S. hospitals to report compliance rates with the sepsis CMS core measure SEP-1 (Severe Sepsis and Septic Shock Management Bundle). It puts out guidelines for frontline hospital clinicians fighting sepsis. SEP-1 focuses on timely sepsis recognition and early intervention with lifesaving therapies [22]. Preliminary data from CMS indicate that the majority of SEP-1 cases nationally fail the measure and cases that fail have higher mortality rates than cases that pass [23]. E*ach hour of delay before a septic patient is treated is associated with a 4% increased risk of mortality*. In another multicenter retrospective cohort study, crude mortality rates were higher in sepsis cases that failed versus passed SEP-1 [24]. Early recognition and treatment of sepsis is associated with decreased mortality and improved patient outcomes.

3.4 Radiation errors

Radiation therapy, consisting of targeting malignant cells with ionized radiation, is an increasingly important cancer therapy with approximately 50% of all cancer patients receiving radiation during their illness [25]. Toxicities and adverse side effects of this therapy are related to the dose of radiation given and therefore dose calculation and regulation is of concern with regards to patient safety.

Radiation therapy safety and regulation has been under scrutiny and overhaul following a New York Times article from 2010 describing several patient stories with devastating outcomes [26, 27]. Many of the errors described are related to patients receiving several times the intended dose of radiation or miscalculations of the field resulting in areas of the body receiving radiation which were not intended or planned. Unfortunately, these errors are caused by flaws in an exceedingly complicated series of calculations and considerations depending heavily on computers systems and software. In fact, data shows that in radiation oncology, 30% of errors occur in the planning phase of therapy and 29% of errors are discovered in the treatment step of therapy [27]. This may suggest that the planning phase needs a more robust universally standardized control system and many studies have attempted to elucidate areas of improvement regarding geometric discrepancies resulting in errors [28–30].

As medicine becomes increasingly more complex, so does error analysis. In the field of radiation oncology, the multidisciplinary team adds to this complexity. The specific skill sets that are required to plan and execute a radiation treatment cannot be expected of one provider and so several health care providers are needed to successfully implement a complex therapy, including a highly specialized physician, medical physicist, and radiation therapist/dosimetrist. This is no doubt overall beneficial in the big picture for patient outcomes, however, advanced software

and multiple highly specialized providers means that the way providers consider their options when an image or patient is in front of them requires far more critical thinking than what may have been expected from an average physician 30 years ago. Each provider must critically look at the information in front of them and understand and accept that there are parts of the treatment plan and the method in which they were derived that they do not fully comprehend. This requires all the members of the treatment team to trust the computer systems and software, as well as other providers, which are all integral in planning of radiation therapy. At the same time, all involved must realize the limitations of technology and consider human error on the part of their colleagues. This makes error analysis in the field of radiation oncology intricate, and one might argue that a key consideration in the future may be cognitive biases among providers and need for structured training to minimize them [27].

3.5 Unsafe surgical practices

Every year, millions of people undergo surgical treatment for various ailments and disease processes. Surgical interventions account for an estimated 13% of the world's total disability-adjusted life years (DALYs). These procedures are intended to improve and save lives; however, unsafe surgical care can cause substantial harm. A modeling study, published in Lancet in 2008, estimated that 234 million operations are carried out every year across the world [31]. This translates to one operation for every 25 people, which is more than the number of children born worldwide each year. Current estimates of morbidity and mortality following surgery indicate that over 7 million people (about twice the population of Oklahoma) worldwide will suffer complications following surgery. One million of these people will die as a result. This correlates to an overall mortality rate of 0.5-5%. Complications in inpatient operations occur in up to 25% of our patients, which accounts for nearly half of all adverse events in hospitalized patients [31]. Regrettably, it is estimated that in at least half of the cases, in which surgery led to harm, were considered preventable. Several surgical societies and hospital administrations have put forth recommendations, and in many cases requirements, to help ensure our patients have a safe journey through our operating rooms.

On a global scale, the World Health Organization (WHO) is the leading authority on patient safety and has undertaken essential global and regional initiatives to address surgical safety. WHO established the Second Global Patient Safety Challenge, "Safe Surgery Saves Lives," in 2007. This program proposed to improve the safety of surgical care around the world by defining a core set of safety standards which led to the Surgical Safety Checklist, a 19-item tool created by WHO in association with the Harvard School of Public Health. This safety checklist aims to decrease errors and adverse events by increasing communication and teamwork in surgery [32]. Improving teamwork and communication is one of the main goals of using a checklist. The checklist is a simple tool designed to improve the safety of surgical procedures by bringing together the whole operating team (surgeons, anesthesia providers and nurses) to perform key safety checks during vital phases of perioperative care: prior to the induction of anesthesia, prior to skin incision, and before the team leaves the operating room. Between October 2007 and September 2008, the effect of the Checklist was studied in eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, The Philippines; Ifakara, Tanzania; London, UK; and Seattle, USA) representing a wide variety of health-care settings, economic circumstances and diverse patient populations and demonstrated dramatic improvements in both processes and outcomes. The study showed use of the WHO Surgery Checklist, reduced the

rate of deaths and surgical complications by more than one-third across all eight pilot hospitals. The rate of major inpatient complications dropped from 11% to 7%, and the inpatient death rate following major operations fell from 1.5% to 0.8% [33].

Many hospitals are already performing most of the items on the list but not reviewing them as a team. Good data has now proven that implementation of the 19-item checklist results in a significant reduction in both morbidity and mortality [33]. The WHO continues to develop patient safety action plans with an action-oriented framework to facilitate the implementation of strategic patient safety interventions at all levels of health systems. Because complications will strike, we must strive for perfection, by adhering to proven protocols, meticulously preparing, conducting, and caring for our surgical patients.

3.6 Blood transfusion safety

Each day, life-saving blood transfusions are needed in hospitals and emergency treatment facilities across the United States. There are more than 13.2 million blood donors in the U.S., resulting in a total of 17.2 million transfused blood product units per year. Worldwide, approximately 118.5 million blood donations are collected [34]. How do we ensure safety with this staggering number? In the U.S., the federal agencies responsible for keeping our blood safe are the Centers for Disease Control (CDC), protecting health through investigations and surveillance [35]. The U.S. Food and Drug Administration (FDA) ensures safety of blood donations by protecting the health of donors. The National Institutes of Health (NIH) performs research on blood transfusion basic science, epidemiology, and clinical practices. Safety is also the responsibility of the blood centers and hospitals that collect and transfuse millions of units of blood each year. On the donor end, each donor is screened for risk of transmissible disease by questionnaire, which asks standard health questions to determine eligibility to donate. Additionally, each unit of donated blood in the U.S. is routinely screened for various infectious disease pathogens, using FDA approved assays [35]. The blood is then tested for blood type (ABO group) and Rh type (positive or negative). Prior to transfusion, the donor and blood unit are also tested for certain proteins (antibodies) that may cause adverse reactions in a person receiving a blood transfusion.

Presently, the most significant risk for a transfusion complication occurs due to noninfectious hazards from deficient processes [36]. The goal of providing safe transfusion therapy depends on a complex process that requires integration and coordination among multiple hospital services, including laboratory medicine, nursing, anesthesia, surgery, clerical support, and transportation. Most healthcare institutions in the United States have formed a multidisciplinary hospital-based transfusion committee to review blood transfusion practices and adverse outcomes. The Center for Medicare/Medicaid Services (CMS) requires such a process to receive payment for transfusion services. However, CMS does not require a specific committee be assigned to oversee the review process. This process must include a program of quality assessment and performance improvement, which is ongoing, hospital-wide, data-driven, reflects the complexity of the hospital's organization and services, and involves all hospital departments and services (including those contracted) [37]. If a hospital elects not to receive payments from Medicare, it must still comply with applicable sections of the Code of Federal Regulations pertaining to transfusion services.

3.7 Venous thromboembolism

Venous thromboembolism (VTE) is a frequent complication of hospitalized patients and a leading cause of preventable hospital death and increased hospital

length of stay in the United States and worldwide. Hospital-acquired VTE is defined as VTE occurring during or within 3 months after hospitalization and accounts for >50% of the population burden of VTE in the United States. Although, the precise number of people affected by VTE is unknown, it is estimated as many as 900,000 people are affected (1 to 2 per 1,000) each year in the United States, resulting in an estimated loss of 60,000-100,000 American lives. As one might expect, there is an exponential increase with age from 1 per 10,000 in young adults to 1 per 100 in the elderly. Data from two large U.S. studies place the estimated absolute risk of VTE after age 45 to be 8.1% overall, 10.9% in obese patients, 11.5% in blacks, 17.1% in those with factor V Leiden mutation, and 18.2% among blacks with sickle cell trait [38]. Of these patients, two-thirds will present with Deep Vein Thrombosis (DVT) only and the remaining presenting with Pulmonary Embolism (PE) as the first manifestation and primary cause of VTE related mortality.

Early data regarding COVID-19 patients developing VTE suggests substantial risk. Reports have ranged from 1.1% in non–intensive care unit (ICU) hospital wards to 69% in ICU patients. More data is necessary regarding the relationship between COVID-19 and increased risk of VTE. Currently, many of reports are from small sample sizes and retrospective in design. However, it seems prudent that all patients admitted to a hospital unit receive pharmacologic prophylaxis. The question of whether to administer full therapeutic dose versus prophylactic dose anticoagulant in critically ill patients is controversial and is actively being studied [39].

Venous thromboembolism remains one of the most preventable causes of hospitalized patients. Risk stratification and prophylactic measures have proven to be safe, cost effective, and most importantly, save lives. The data regarding VTE morbidity and mortality is not new yet, despite decades of solid evidence from multiple randomized clinical trials, thromboprophylaxis remains either underused or misused. The key is for health care providers to adhere to proven protocols and policies. Multiple policy statements have been published focusing efforts to eliminate unnecessary human death and suffering. Five major areas of policy guidance have put forth by the American Heart Association that they believe will lead to improved implementation, tracking and prevention of VTE events. They include assessment and reporting the level of VTE risk in all hospitalized patients, integrating preventable VTE as a benchmark for hospital comparison and pay-for-performance programs, supporting appropriation to improve public awareness of VTE, tracking VTE nationwide with the use of standardized definition and developing a centralized data steward for data tracking on VTE risk assessment, prophylaxis, and rates [40].

Diagnosis and defining exactly who should be screened remains challenging because the clinical features are often non-specific, and testing can be falsely negative or positive. Therefore, risk stratification scoring systems have been proposed and used widely. The Wells DVT and Wells PE scoring systems, as well as the Geneva PE score, have been adopted by many major medical centers in the U.S. and around the world. These scoring systems have been used in conjunction with objective diagnostic imaging, providing a high degree of accuracy in making the diagnosis of VTE. Some of these diagnostic testing modalities includes compression ultrasonography, computed tomography angiography, ventilation-perfusion scintigraphy or single-photon emission tomography, magnetic resonance angiography and echocardiography.

Another method of making healthcare administrator's and medical practitioners take notice is by making them financially aware of the devasting avoidable cost to our healthcare industry. When factoring in the VTE-related morbidity of VTE, including post-phlebitic syndrome occurring in 30-50% of patients with proximal DVT, and chronic thromboembolic pulmonary hypertension occurring in 4% of patients within 2 years of PE survival, the estimated annual cost of preventable

hospital acquired VTE is $7-10 billion per year [41]. Regardless of the method, it is our duty as healthcare providers to take on the challenge by educating our healthcare colleagues and soliciting the support of our administrators in establishing hospital wide protocols to prevent this devastating, albeit preventable, disease process.

3.8 Healthcare associated infections

Health-care associated infections (HCAIs) are infections acquired by patients 48 hours or more to within 30 days after receiving care from various health care settings, which include acute-care facility, long-term facility, family medicine clinics, ambulatory care and home care [42]. HCAIs are the most common complications of hospital care and one of the top 10 causes of mortality worldwide [42]. Numerous factors heighten the risk for developing HCAIs, such as increased age, immunosuppression, multiple underlying comorbidities, increased length of hospital stay, admission to the intensive care unit (ICU), mechanical ventilatory support, recent invasive procedures, indwelling devices, frequent visits to healthcare facilities, and infection-control practices at the healthcare facility [43]. Patients' risk of developing antimicrobial resistance increases highly if they received intravenous antibiotics within 90 days of administration [43]. Even though $28-45 billion is spent annually in the United States, 90,000 deaths still occur due to HCAIs [42]. The World Health Organization (WHO) reports that 7 out of 100 hospital patients in high income countries and 10 out of 100 hospital patients in low-to-middle income countries will acquire HCAIs at any given time [44]. These statistics continue to highlight a major concern to patient safety worldwide.

Surgical site infections (SSIs), also known as wound infections, central line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), ventilator-associated pneumonia (VAP), hospital-acquired pneumonia (HAP) and *Clostridioides difficile* infections are the most common types of HCAIs [42, 43]. Most are caused by about 22 microorganisms, including Gram-positive bacteria, Gram-negative bacteria, fungal and viral species [42, 43, 45–48]. Formation of mono-or-poly-microorganism biofilms on indwelling devices or surgical wounds is also a major cause of resistant HCAIs [47].

The most important practice to prevent and control HCAIs is effective hand hygiene [42, 49]. The World Health Organization (WHO) advocates education and training for all healthcare workers to encourage washing hands for at least 30 seconds before and after touching a patient or their environment, after body fluid exposure, and before and after aseptic procedures using soap and water or alcohol-based sanitizers [42, 49]. Widespread and consistent hand hygiene practices can decrease infection rates by 50% [49].

Personal protective equipment (PPE), for example, face masks, gloves, gowns, protective eyewear, and face shields, reduce transmission of microorganisms and body fluids between healthcare workers and patients [42]. Organisms transmitted through aerosols, such as influenza virus, *Hemophilus influenzae*, and *Neisseria meningitidis*, are dispersed easily through droplets from one person to another in closed settings [42]. The most recent notable example of a highly transmissible respiratory virus is SARS-CoV-2, a type of coronavirus that caused COVID-19, emerged in 2019 and was responsible for a global pandemic which continued for more than a year and lead to millions of deaths worldwide. Basic handwashing for 30 seconds or using an alcohol-based hand sanitizer, use of face masks covering the nose and mouth, social distancing of at least 6 feet amongst people and proper ventilation of indoor spaces are largely attributed to the control of the pandemic [50]. Another very important factor was mRNA COVID-19 vaccinations against the virus among frontline healthcare workers and the greater community, starting with the most

vulnerable, such as nursing home residents, people older than 75, essential workers, and patients with underlying health conditions, for example, cancer, diabetes type 1 and 2, and chronic lung diseases [50–52].

Cleanliness of equipment used by healthcare workers is also important to patient safety. A study found medical residents' coat sleeves (50%), stethoscopes (36.3%), and pagers (36.3%) carried methicillin sensitive *Staphylococcus aureus* (MSSA) and serve as potential sources of nosocomial transmission of pathogens to vulnerable patients [53]. High-touch surfaces by patients and staff in hospitals should be decontaminated with appropriate products as regularly as possible, especially bedrails, over-bed tables, call buttons, and reusable patient-care equipment [47]. Continued staff education and training about personal and environmental hygiene cannot be overstated and significantly contribute towards patient safety.

3.9 Falls

The estimated number of inpatient falls in United States is between 700,000 to 1,000,000, with reported fall rates ranging from 1.3 to 8.9 per 1000 bed-days [54, 55]. In general, fall related injuries are the most common cause of accidental death among hospital patients over 65, resulting in 41 fall-related deaths per 100,000 people per year [54].

Per the World Health Organization, falls are defined as "inadvertently coming to rest on the ground, floor, or other lower level, excluding intentional change in position" and in the inpatient setting, they include slips, trips, faints, collapses and any patient found on the floor unwitnessed [56]. As of 2008, Centers for Medicare & Medicaid Services (CMS) does not reimburse hospital for certain types of traumatic injuries while patients are in the hospital, many of which occur after a fall [57].

Preventing falls in the hospital setting can be challenging. Hospital staff needs to treat patient for their acute condition, keep them safe and help patients maintain and recover physically and mentally. When an adverse event like a fall happens, it may result in high-impact outcomes for a patient, such as decline in function, increased length of hospital stays, and increased cost of health care services. Damage resulting from a fall can affect as many as 50% of patients, and about 44% of falls can result in serious injuries and even death [56]. About 1-3% of falls in hospitals results in fractures [58]. Even without injury, harm to patients, caregivers and hospital staff can manifest as psychological distress, including anxiety and depression, reduced physical activity, fear of future falls, prolonged hospital stay, increased use of restrains and sedating drugs, complaints, litigations, guilt, and dissatisfaction [55, 59]. Fall prevention often consists of managing patients' underlying fall risk factors. Such risk factors include age, limited mobility, visual impairment, use of some classes of medications (especially psychotropics), medication side effects, change in medications, delirium, change in environment, frequent toilet needs, urinary incontinence, orthostatic hypotension, fall history, and fear of falling. In addition to the elderly, patients with recent diagnoses of stroke or cancer, and patients hospitalized in neurology and rehabilitation units are at increased risk of falls [60]. There are several fall-risk tools to help stratify patients at risk, but many of them are not validated due to their lack of sensitivity and specificity for clinical use. Three of these have been validated in multiple studies across the populations. These are the St Thomas's Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY), the Morse Fall Scale (MFS), and the Hendrich Fall Risk Model (HFRM). Based on the risk stratification, there is usually a multimodal intervention for inpatient fall prevention, and it can include patient education, bedside risk sign, staff education, alert wristband, footwear, toileting schedules, environmental modifications, movement alarms, bedrail review, hip protection, exercise, restrains,

and a review after a fall to identify causes. High quality evidence shows that multi-component intervention can reduce the risk of inpatient falls by up to 30% [61].

4. Key terms in patient safety

A common taxonomy is needed to standardize and track events to measure particularly when healthcare workers are working between and within different professional backgrounds. The core terms that are essential to know and understand are described below.

Sentinel Event: A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: death; permanent harm; severe temporary harm. The Sentinel Event Policy explains how The Joint Commission partners with hospitals that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

Safety Patient Events: An event incident, or condition that could have resulted or did result in harm to a patient. A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error.

Adverse Events: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom or disease temporally associated with the subject's participation in the research.

Near Miss, Near Hit, Close Call or Nearly a Collision: An unplanned event that has the potential to cause, but does not actually result in human injury, environmental or equipment damage, or an interruption to normal operation.

Near misses also may be referred to as close calls, near accidents, accident precursors, injury-free events and, in the case of moving objects, near collisions.

A near miss is often an error, with harm prevented by other considerations and circumstances.

The phrase "near miss" should not be confused with the phrase "nearly a miss" which would imply a collision.

A No-Harm Event: A patient safety event that reaches the patient but does not cause harm. A close call (or "near miss" or "good catch") is a patient safety event that did not reach the patient. Unsafe conditions are hazards that have the potential to cause injury or death to an employee. Some of these hazards include erroneous safety procedures, malfunctioning equipment or tools, or failure to utilize necessary safety equipment, such as goggles and masks.

5. Building capacity to change and proactive approach to preventing harm

A coordinated and practical strategy in which systemwide safety processes are applied across entire healthcare fields through collaboration among diverse stakeholders has been proven to provide the best outcomes. Risks are to be expected as healthcare is and will continue to be an ever evolving. Preventing harm and improving systems will not happen in a vacuum. It takes effort from frontline personnel, educators, trainers, and organizational leaders to create a systemwide approach. In the following section, we will discuss how we can prevent harm with our proactive attitude and build a capacity to improve patient safety when we try to conquer risks and errors spanning the myriad layers of healthcare.

5.1 Education and training

The crucial step towards lowering errors and harms to the patients is educating healthcare professionals about patient safety. Since there is involvement of many individuals at different layers of the system in the delivery of health services, education and training also needs to be multidisciplinary and multi -professional. Education cannot be based on a linear or hierarchical educational model as medicine is often approached. Multimodal approach should be implemented at each level of health professional education.

Association of American Medical Colleges (AAMC) addressed Competency Based Education (CBE) in 2019 with suggestions for improvement for patient safety education. It acknowledges the importance of developing curricula based on competency at each level of learning- undergraduate, graduate, and continued education [62]. The same look but from a distinct perspective - as one accrues knowledge, they begin to see more clearly the finer aspects of how to prevent harm. Multiple avenues exist for formal coursework in patient safety education. Continued Medical Education (CME) is available by multiple formats such as lectures, testing, reading materials. It is the most pervasive patient safety education model; not only does updating clinical knowledge leads to improved outcomes but direct patient safety courses enhance its implementation. Certification courses are available, as well. In recent years there has been as rise in Master's degrees in patient safety and healthcare quality.

Several ongoing activities for trainees and experts, either directly or indirectly, enable patient safety education. Accreditation Council for Graduate Medical Education (ACGME) has mandated Quality Improvement (QI) projects in residency. They require pattern recognition for process improvement, inadvertently propelling involved parties to become educated on areas of patient harm. ACGME has appropriately made QI a requirement in physician training [63]. More informally, training occurs in the break rooms or during lunch when knowledge is shared openly, and indirect learning occurs from other's experience. The table below provides list of some of the pros, cons, and growth opportunities for each educational setting (**Table 1**).

WHO has recognized the need for an international leader in patient safety education. In 2013, WHO published a Multi-professional Patient Safety Curriculum Guide for standardization of patient safety education, an update to its earlier Curriculum Guide for Medical Schools published in 2009 [64]. Additionally, during their 2021 assembly, the WHO adopted the first ever Global Patient Safety Action Plan 2021 – 2030, a global initiative to eliminate avoidable harm. Amongst other things, it will focus on involving patients and families for patient safety [44]. Smaller entities, such as Improvement for Healthcare Safety (IHI) or Patient Safety Network (PSNET), have perceived this necessity and invested in producing a concise platform for medical professionals as well [65, 66] attempting to innovate this field of learning.

Having recognized the need for such courses in medical educational infancy, the new trend has been to incorporate patient safety education across the globe [67]. By creating patient safety education early on, lifelong learners of patient safety can be made.

COVID-19 pandemic has provided fertile ground for medical errors as the medical system was stretched thin [68]. Much learning and teaching had internationally shifted to the virtual world. If this shift can be harnessed to standardize patient safety education as we continue to grapple with COVID as a reference, it may allow us to build a more robust patient safety instruction. Updating courses in medical school to incorporate patient safety is a new trend [69]. While each organization and individual will need to adapt proposed training, interactive learning curriculums improve student learning of difficult concepts such as patient safety and "just

Type	Description	Pros	Cons	Potential sources of improvement
M&M conference	Healthcare teams thoroughly analyze a case often using the Ishikawa Diagram to discuss errors with an audience to educate and identify improvement	1. Involves root cause analysis of errors involving multiple factors from system to individual 2. Nonjudgmental review of errors 3. Residents /Fellows are involved in M&M committees	1. Can devolve into blame-oriented discussion	1. Pursue effective implementation of learnings from a case
QI projects	Process improvement using the PDSA cycle	1. Improves critical thinking analysis for process improvement to prevent errors 2. Can be multidisciplinary 3. Mandated in residency 4. Addresses evolving nature of medicine 5. Improves vigilance for patient care	1. Administrative obstacles may delay improvement in processes thus potentially allowing for preventable patient harm 2. Disinterest in project after implementation may lead to loss of an opportunity for process improvement leading to continued errors	1. Publish/share positive AND negative findings within systems/ nationwide/ worldwide
Case analysis	Experts reviewers who are familiar to the system and individuals find issues leading to patient harm	1. If internal, usually experts reviewers are familiar to the system and individuals so can provided enhanced insight to prevent of future errors 2. Can lead to learner/expert specific improvements for typical and atypical cases	1. Reviewer specific identification of errors 2. Retrospective review can miss factors present at time of decision making 3. Can lead to blame oriented identification of errors	1. Apply case analysis at all levels of education and not just as a part of M&M
CME	Short formal sessions on specific topics on patient safety	1. Multimodal 2. Universal approach to complete provider requirements	1. Can be dated 2. Learners can lose interest usually if in non-interactive format/because it is mandatory	1. Create interactive sessions/ simulations to showcase patient safety

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Type	Description	Pros	Cons	Potential sources of improvement
Courses	Longer formal training on specific topics on patient safety	1. Multimodal 2. Allows time for in depth dive into patient safety for greater understanding	1. Long time commitment required for completion 2. May be taught by non-clinical staff 3. Usually, didactic teaching	1. Mandate instructors to have ongoing patient contact so teaching can better tailor for real world timely application
Multidisciplinary rounds	Involve multiple patient team member-such as provider, nurse, pharmacist, residents, fellows, etc to oversee patient care and provide increased oversight to prevent patient harm	1. Dynamic discourse allows each to provide teaching from the perspective of their role for patient safety 2. A platform for patient safety and education innovation 3. Trainees directly or inadvertently can learn to keep patient safer by listening to diverse team members	1. Can be uninviting to innovative ideas/teaching depending on discussion leader	1. Prompt providers and even other clinical staff to discuss new advances in methods to prevent patient harm 2. Provide infrastructure for more multidisciplinary rounds
Books/Articles/ News	Dedicated books on/patient-oriented perspectiveopinions on patient safety	1. Fresh and new perspectives on errors 2. Can highlight changing nature of patient safety 3. Books can provide a well thought of, comprehensive view on patient safety	1. Biased understanding of patient errors as non-clinical or uninvolved persons may be writing 2. Lengthy reads not always suitable for patient facing staff	1. A less litigious society would provide a better platform for open discussion in literature

Table 1.
Avenues for patient safety education.

culture". With the correct attitude, continually renewed educational offerings, and standardization of basics globally, we can navigate the complex and evolving nature of medicine better.

5.2 Role of healthcare organization leaders in patient safety

Effective leadership is necessary to lead an organization down the path to establishing a culture of safety. Primarily, the leadership needs to be persistent and well-balanced. Stable organizational leadership allows organizations to grow and transform successfully. According to the American College of Healthcare Executives and the Lucian Leape Institute, there are 6 key domains that healthcare leaders need to focus on to create a long-lasting organizational culture of safety [70]:

1. Establishing a compelling vision for safety
2. Build trust, respect, and inclusion
3. Select, develop, and engage your Board
4. Prioritize safety in the selection and development of leaders
5. Lead and reward a just culture
6. Establish organizational behavior expectations

These domains do not exist by themselves and must always be looked at as a cohesive unit.

To successfully lead an organization on its path to a safer patient experience, the leader must set clear priorities and communicate a sharp vision. A shared vision is a fundamental part of highly effective organizations, and this endeavor is no different. Because so much of patient safety initiatives involves voluntary reporting by staff, the role of leadership building trust amongst their employees and selecting managers who prioritize safety cannot be understated. Many staff members view patient safety reports as "snitching" and do not understand the fundamental importance of identifying these sentinel events. Leaders and managers leading by example in reporting events concerning them and by ensuring the principles of "just culture" are on display is necessary to ensuring the organization becomes a champion for patient safety.

The pairing of high-quality education and transformative leadership based on the 6 domains are two-parts to a successful, patient-focused organization. Neither will be successful alone and without coordination of educational programming and leadership efforts, they will not be successful either. Leaders will need to work with organization educational designers to create engage, transformative educational material that will motivate staff to focus on patient safety as a core value of the organization [71].

5.3 A fair and just culture

"Just Culture" refers to a system of shared accountability in which organizations are accountable for the systems they have designed and for responding to the behaviors of their employees in a fair and just manner. Employees are accountable for the quality of their choices and for reporting errors and system vulnerabilities. While the organization has a duty and responsibility to employees and to patients, all employees are held responsible for the quality of their choices [72].

Promoting a just culture is to implement a nonpunitive response to error in improving patient outcome and safety. Just culture encourages employee to focus on compliance and corrective actions instead of fear of punitive actions. Creating a safe and transparent environment encourages reporting of mistakes and hazards and improves the care provided to patients. Lack of reported information decreases the organization ability to proactively address patient-safety issues and improves the existing work infrastructure.

For health care systems to be successful in achieving the above goals of patient safety they need to foster a just culture [72].

These examples address an aspect of just culture that goes beyond ensuring that employees feel free to report errors. Exceptionally reliable organizations and industries promote mindfulness in their workers.

Weick and Sutcliffe describe mindfulness in terms of 5 components [73]:

1. A constant concern about the possibility of failure

2. Deference to expertise regardless of rank or status

3. Ability to adapt when the unexpected occurs

4. Ability to concentrate on a task while having a sense of the big picture

5. Ability to alter and flatten the hierarchy to fit a specific situation

Mindfulness throughout an organization considers moves beyond events and occurrences. Everyone in the organization is continually learning, adjusting, and redesigning systems for safety and managing behavioral choices.

A fair and just culture improves patient safety by empowering employees to proactively monitor the workplace and participate in safety efforts in the work environment. Improving patient safety reduces risk by its focus on managing human behavior (or helping others to manage their own behavior) and redesigning systems. In a just culture, employees are not only accountable for their actions and choices, but they are also accountable to each other, which may help some overcome the inherent resistance to dealing with incompetency [72].

Secondary benefits of a just culture include the ability to develop a positive patient safety profile to respond to outside auditors, such as The Joint Commission. When implemented, a just culture fosters innovation and cross-departmental communication. An example is the opportunity to revitalize the morbidity and mortality conference to cross specialty lines and develop a patient-centered focus. In a just culture, both the organization and its people are held accountable while focusing on risk, systems design, human behavior, and patient safety [72].

The process of implementing the just culture is not one that happens overnight. However, a health care organization can build an infrastructure to embed this methodology by achieving it through education and allocation of resources to training the employee.

5.4 Patient engagement

"Engagement of patients and families resides at the core of the framework for safe, reliable, and effective care. In safe and reliable organizations, patients and families are as much members of the care team as clinicians and other health care staff" [74].

The joint commission mandated that healthcare organizations "encourage patient's active involvement in their own care as a patient safety strategy". Because

of this action, hospitalized patients, as well as patients receiving care on outpatient basis, are routinely surveyed about their satisfaction with the care they received [75].

Studies in the in-patient setting have found that patients often report errors that were not detected through traditional mechanisms, such as chart review [75]. Unless patient involvement through surveys after service was considered, these errors would not have been detected. Therefore, patient engagement and involvement practices in the day-to-day functions of an organization is essential in ensuring a safe environment.

Some examples of safety targets in patient care that show patient outcome improvement and risk reduction through patient engagement in hospitals and outpatient settings include: improved anticoagulation management with reduction in risks of thromboembolic events and mortality, improved hypoglycemia management in diabetes, increased medication adherence, reduced medication administration errors, improved hospital readmissions rates, and reduced hospital acquired infections when patient education and engagement is optimized and encouraged [76].

With all the evidence demonstrating patient involvement and participation supporting positive outcome, the next step is for health care teams to partner with patients and caregivers to integrate effective patient engagement into clinical practice and health care systems.

The following elaborates on proposed methods to involve and engage patients in the care they receive from organizations to ensure patient satisfaction and safety outcomes [74]:

1. Patients should be included in decision making process. While it is the clinical team's responsibility to provide key facts and advise to patients, the patients and/or their representatives should be given opportunity to have input in decision-making process. It is easier to reach a common goal when all parties are informed and well educated on real expectations. This will minimize unnecessary steps and reduced risks and negative outcomes associated with those steps.

2. Healthcare teams and organizations should provide a safe environment for patients to express concerns, questions, and ideas openly and without judgment. The clinical team should avoid negative reactions to foster more comprehensive and accurate information exchange between patients and organizations/ healthcare teams. As a result, patients will be more forthcoming about their incompliances and will provide more accurate information. This process will help providers utilize factual data to come up with a plan of care that reduces unintentional harm to patients.

5.5 Agency for healthcare research and quality (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ) is one of twelve agencies within US Department of Health and Human services (HHS). It is a lead federal agency charged with improving the quality and safety of America's health system performance, offers practical and research-based tools with resources to support healthcare organizations, providers, hospital staff, patients and others that make care safer in healthcare settings. These organized tools and resources help staff in hospitals, emergency departments, long-term care facilities, and ambulatory settings to prevent avoidable complications of care. AHRQ contributes to forming a higher performing health system in three main ways: investing in research and evidence to improve safety and quality of healthcare, creating materials to teach and train healthcare professionals to catalyze the improvements in care, and generating measures and data used to track and evaluate progress of US healthcare [77].

AHRQ assists and provides various tools and resources by different settings, quality measures, reports and resources, engaging patients and families, education, and training, etc. Teams STEPPS, is one such teamwork system developed by AHRQ and Department of Defense (DoD) that offers a powerful solution to improving collaboration and communication among healthcare professionals [78]. There are many other quality improvement tools and information, including AHRQ Quality Indicators Hospital Toolkit, ambulatory clinical performance measures, and talking quality, to help staff build the knowledge and develop the skills that impact organizational culture and lead to sustained improvements in safety.

5.6 Effective use of data (collecting, analyzing, using to drive improvement)

Since quality improvement is a driving force and is a vital part at every level of service delivery in healthcare, collecting and analyzing data are therefore central to the function of quality improvement at all levels. Data not only allows us to accurately recognize problems, it also supports to prioritize quality improvement initiatives, and qualifies objective assessment of whether change and improvement have indeed occurred. Making changes to improve quality is complex business, thus solid evidence in the form of data is required to support decision-making rather than isolated occurrences, assumptions, emotions, or politics.

Role of data in quality improvement is helpful in all five phases of quality improvement: project definition phase (what is the problem?), diagnosis phase (what can we improve?), intervention phase (how can we achieve improvement?), impact measurement phase (have we achieved improvement?), and sustainability phase (have we sustained improvement?) [79].

With good data, we can access: current performance, identify performance gaps, identify problem steps, prioritize opportunities for improvements, establish clear objectives for improvement, prioritize most appropriate interventions, compare the benefits of alternative interventions and implementation strategies, assess impacts of interventions, demonstrate the success of improvement project to stakeholders, provide feedback to reinforce change, demonstrate benefits, identify problems in practice, and need for repeated intervention.

To get quality, unbiased data, one must use sound data collection techniques, appropriate tools, correct sampling techniques, ensure data validity, and confirm it is secured.

6. Conclusion

The dynamic nature of healthcare delivery where innovative technologies and approaches to care are incorporated constantly into the regular practice, new occasions for unsafe practices are continually created. An attitude of inclusivity for all care teams with necessary education, proper communication, just culture, and engaging leadership will lower errors and harms and improve patient safety. Besides these, proper collection and review of safety data can help serve as a catalyst for increased resources dedication to most needed facet of healthcare in that setup. Thus, if we integrate the science of safety into our daily healthcare practices, we are certain to lessen the magnitude and extent of harm and economic burden and improve patient safety.

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