Chapter 17
Classification and Analysis of Error

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Background

The Institute of Medicine estimates that medical errors cause between 44,000 and 98,000 preventable hospital deaths and one million injuries per year in the USA [1]. One study has suggested that 70% of adverse events are preventable, with the most common types being technical errors (44%), diagnostic errors (17%), failure to prevent injury (12%), and medication errors (10%) [1, 2]. Preventable errors result in a total estimated cost of between $17 billion and $29 billion per year in US hospitals [1]. The National Quality Forum (NQF) in 2002 defined "never events" as errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients and that indicate a real problem in the

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safety and credibility of a healthcare facility [3]. In 2011, the NQF updated this list and delineated five specific events for surgery or invasive procedures: (a) surgery or other invasive procedure performed on the wrong site, (b) surgery or other invasive procedure performed on the wrong patient, (c) wrong surgical or other invasive procedure performed on a patient, (d) unintended retention of a foreign object in a patient after surgery or other invasive procedure, and (e) intraoperative or immediately postoperative/post-procedure death in an ASA Class 1 patient [4].

It is estimated that over 4000 surgical "never event" malpractice claims occur each year in the USA, resulting in mortality in 7% of these cases, permanent injury in 33%, and temporary injury in 59% [5]. Since the Institute of Medicine's report *To Err Is Human*, there has been considerable attention to improving patient safety through identification and reduction of potentially avoidable errors across all healthcare delivery systems.

Medical Error

A *medical error* is an unintended act or action that does not achieve its intended outcome and can range from non-consequential to life-threatening [6]. Errors can stem from the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim [1]. *Human errors* in medicine are further defined as a flaw in reasoning, understanding, or decision-making of a health problem or execution of a clinical task [7]. Examples in the care of surgical patients include transfusion errors, medication errors, wrong-site surgery, wrong-procedure surgery, retained foreign objects, and iatrogenic injuries. Factors that contribute to errors include individual factors as well as flaws in healthcare systems that fail to prevent errors from occurring. Due to the high acuity and high stress environment, errors with serious consequences are most likely to occur in operating rooms, emergency departments, and intensive care units. Common medical error terms are defined in Table 17.1.

Table 17.1 Error definitions and related terms

Term	Definition
Medical error	Unintended act or one that does not achieve its intended outcome and can range from non-consequential to life-threatening [6]
Human error	A flaw in reasoning, understanding, or decision-making of a health problem or execution of a clinical task [7]
Active failure	Unsafe acts committed by providers in the form of slips, lapses, mistakes, and procedural violations [8]
Latent failure	Healthcare system failures that are often hidden and can lead to either error-prone situations or holes in the defense against active failures [7]
Adverse event	An unexpected and undesired incident that harms a patient as a direct result of the care or services provided [7]
Sentinel event	Patient safety event that results in death, permanent harm, or severe temporary harm [9]
Surgical never event	Medical errors associated with serious harm to patients, such as retained foreign bodies, wrong-site surgery, wrong-patient surgery, and wrong-procedure surgery [5]
Near miss	A "close call" or event that had the potential to result in an adverse event but did not [7]
Patient safety	Prevention of healthcare-associated harm caused by errors of commission and omission [10]
Root cause analysis	A formal process of focused review that aims to identify a chain of events and wide variety of contributory factors that lead up to an adverse event or near miss at the systems level [11, 12]

Adverse Events and Near Misses

Errors can lead to *adverse events* or *near misses*. An *adverse event* is an unexpected and undesired incident that harms a patient as a direct result of the care or services provided [7].

In healthcare, the most common root cause of adverse events is poor communication [13]. A *near miss*, or "close call," is an event that had the potential to result in an adverse event but did not [7]. Near misses can occur when a potential or impending error is identified and avoided. Alternatively, a near miss can occur when a provider makes an error, but this error is identified and corrected prior to harm to the patient [1]. Near misses offer a critical opportunity for the providers and healthcare system to perform a root cause analysis and intervene before the error occurs again and leads to an adverse event. Near misses may occur many times before an actual harmful incident and typically outnumber adverse events by a factor of more than 300 [14]. Taking advantage of near misses has the real potential to improve patient safety by analyzing error-prone situations or practices which can be the basis of "error traps" waiting to catch other patients and providers. In addition, there can be less anxiety about blame since no one has been harmed. They serve as key opportunities for process improvement and prevention of future adverse events.

Surgical adverse events and near misses are frequently used as metrics of quality care in healthcare systems and national organizations such as the Joint Commission. Among analysis of errors reported by surgeons at teaching hospitals, 66% were intraoperative errors, 27% preoperative, and 22% postoperative [13]. The most common factors contributing to errors in this study were inexperience/lack of competence in a surgical task, communication breakdown, and fatigue/excessive workload [13]. Eighty-six percent of these adverse events were identified to have cognitive factors contributing to the error, such as error in judgment (63%) and failure of vigilance (49%) [13].

Sentinel Events

Sentinel events are patient safety events which are not primarily related to the patient's underlying condition and result in the death, permanent harm, or severe temporary harm of a

patient [9]. The reporting of most sentinel events by a hospital or healthcare system to the Joint Commission is voluntary and therefore represents only a proportion of actual sentinel events [9].

The Joint Commission Sentinel Events [9]

- Surgical
  - Invasive procedure, including surgery, on the wrong patient, at the wrong site, or the wrong procedure
  - Unintended retention of a foreign object in a patient after an invasive procedure or surgery
  - Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care or procedure
- Nonsurgical
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
  - Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
  - Severe neonatal hyperbilirubinemia (>30 mg/dL)
  - Unanticipated death of a full-term infant
  - Discharge of an infant to the wrong family
  - Any intrapartum maternal death
  - Severe maternal morbidity not primarily related to the natural course of the patient's illness when it results in permanent harm or severe temporary harm
  - Abduction of any patient receiving care, treatment, and services
  - Elopement of a patient from staffed care setting leading to death, permanent harm, or severe temporary harm to the patient
  - Rape, assault, or homicide of any patient receiving care, treatment, and services while on site at the hospital

- Rape, assault, or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
- Suicide of any patient receiving care, treatment, and services in a staffed care setting or within 72 h of discharge from the hospital or emergency department

Surgical Never Events

Surgical never events represent a subset of sentinel events causing serious harm to patients and include events such as retained foreign bodies, wrong-site surgery, wrong-patient surgery, and wrong-procedure surgery [5]. Of 9744 paid malpractice claims for surgical never events in the USA between 1990 and 2010, retained foreign body was the most common (49.8%), followed by wrong procedure (25.1%), wrong-site surgery (24.8%), and wrong-patient surgery (0.3%) [5]. In multivariable logistic regression, surgeons with clinical privilege disciplinary reports or state licensure disciplinary reports were more likely to have surgical never events (adjusted OR = 1.73, 95% CI, 1.47–2.03) [5]. Based on paid malpractice claims, the estimated annual incidence of surgical never event claims is 4082 in the USA each year [5]; however, the true incidence is likely much higher as many do not reach the legal process. Between 1990 and 2010, malpractice payments for surgical never events totaled $1.3 billion [5].

Based on data published by the Joint Commission, from 2012 to 2018, there were 700 reported retained foreign objects (Fig. 17.1), with the most common retained objects being surgical sponges, guidewires, and instruments [9, 15–17]. The three most frequent locations for retained sponges are the abdomen/pelvis (50%), vagina (24%), and chest (9%) [17]. In general surgery cases of retained sponges, sponge counts were performed in 90% of cases, and 86% of those counts were considered correct at the time of the count [17].

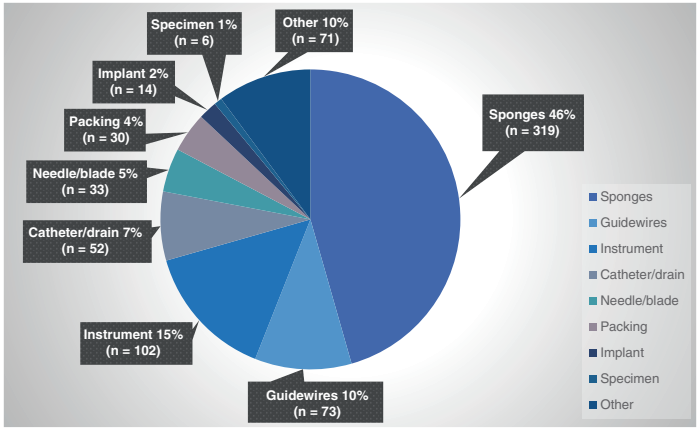

FIGURE 17.1 Retained foreign objects reported to the Joint Commission, 2012–2018. (Adapted from data reported by the Joint Commission and Steelman et al. [9, 15–17])

Error Classification

Active and Latent Failures

Error is commonly classified as *active* versus *latent failure*. *Active failure* is typically a human error that results from a person's inappropriate behavior and can be subclassified into slips, lapses, and mistakes [7, 18]. Slips and lapses are *errors of execution*, with slips defined as a failure to recognize information that the individual would typically identify and lapses defined as moments of attention loss [7]. In these types of error, the provider's intent was correct but due to the slip or lapse, an error occurred. On the other hand, mistakes are *errors of intention* or *errors of planning*, often due to incorrect or inadequate plan [7]. In the case of mistakes, the correct outcome will not occur even with good execution of the plan. Mistakes can be subclassified into *knowledge-based* or *rule-*

based errors. Knowledge-based mistakes occur when a healthcare provider makes an error based on inadequate knowledge or expertise, such as iatrogenic injury due to poor understanding of surgical anatomy [7]. Rule-based errors occur when there is either misapplication or failure to apply a correct protocol [7]. Active failures can also be classified as *errors of commission,* such as administration of an incorrect medication or treatment, versus *errors of omission*, such as failure to order an indicated treatment [1].

Latent failures are healthcare system failures and can lead to either error-prone situations or holes in the defense against active failures [7]. These latent failures include defensive gaps, weaknesses, or absences that can be unidentified in a healthcare system for a significant period to time before a combination of active failures exposes them [8]. Types of latent failures include preconditions for unsafe acts such as fatigue, unsafe supervision of trainees, and failures at the organizational level [18]. Examples of organizational level failures include inadequate peer reviews, improper or incomplete credentialing, failure to proactively review high-risk processes for error, inappropriate staffing, and lack of review of adverse events [18]. Poor communication can be classified as a latent failure if it represents an organizational culture that does not promote open and effective communication [18]. When identified and exposed, these latent failures can be addressed, corrected, and eliminated as sources of error.

Types of Errors

One method of classification proposed by Leape et al. organizes errors by diagnosis, treatment, and prevention [2]:

- Diagnostic
  - Error or delay in diagnosis
  - Failure to employ indicated tests
  - Use of outmoded tests or therapy
  - Failure to act on results of monitoring or testing

- Treatment
  - Error in the performance of an operation, procedure, or test
  - Error in administering the treatment
  - Error in the dose or method of using a drug
  - Avoidable delay in treatment or in responding to an abnormal test
  - Inappropriate (not indicated) care
- Preventative
  - Failure to provide prophylactic treatment
  - Inadequate monitoring or follow-up of treatment
- Other
  - Failure of communication
  - Equipment failure
  - Other system failure

Error-Catalyzing Factors

Multiple factors have been identified that can catalyze error in medicine [10]. These catalyzing or contributing factors can be divided into organization- or team-related factors, individual-related factors, and patient-related factors [10]. Examples of organization- or team-related factors include unhealthy patient safety culture, poor communication systems, inadequate resources, system inefficiencies, failure to promote informed shared decision-making, and failure to seek an independent opinion when warranted [10]. Individual-related factors can include knowledge deficits, technical skill deficits, inexperience, poor communication skills, haste, work overload, cognitive biases, cognitive overload, fatigue, and distractions [10]. Patient-related factors include language barriers, compliance, and biases of systems related to a patient's age, gender, race, or socioeconomic status [10]. Although one factor may play a primary role in medical error, most commonly multiple factors coexist.

The Swiss Cheese Model

To a certain degree, slips, lapses, and mistakes by providers are inevitable in every healthcare system. Adverse events are more likely to occur when both active and latent failures coexist or when multiple latent conditions occur simultaneously, which is referred to as the Swiss cheese model of system accidents [8]. In this model, first described by British psychologist James Reason, a systems approach is taken with the premise that humans are fallible and that errors are consequences of systemic factors such as recurrent error traps and flawed organizational processes [8]. This model describes multiple layers of defenses in a healthcare system (slices of cheese) which are safeguards to block errors. Ideally, each of these layers of defense would remain intact, but in reality there are defects in these processes (holes in the cheese) that are continually opening, shutting, and shifting their location [8]. If an error were to occur, a "hole" in any single layer of defense would not normally lead to patient harm. However, when multiple holes in layers of defense momentarily align, errors can lead to patient harm. In the Swiss cheese model of error, holes in defenses typically arise due to a combination of both *active failures* and *latent failures* [8]. Thus, it is imperative that organizational leaders identify and address latent failures in the healthcare system in order to prevent, protect, and mitigate against the effects of active failures. By examining near misses and adverse events using the Swiss cheese model, we can attempt to understand why the error occurred and identify methods to correct these holes.

Stein and Heiss built upon Reason's Swiss cheese model by further defining each layer of defense. In their model (Fig. 17.2), the layers of defense, or "slices," include education, training, institutional policies and procedures, technology, communication, and checklists. Training can include prior experience, simulation, didactic exercises, and ongoing exposure [18]. Institutional policies and procedures can be organization-specific or nationally accepted and are designed to promote safe, standardized care [18]. Examples of technol-

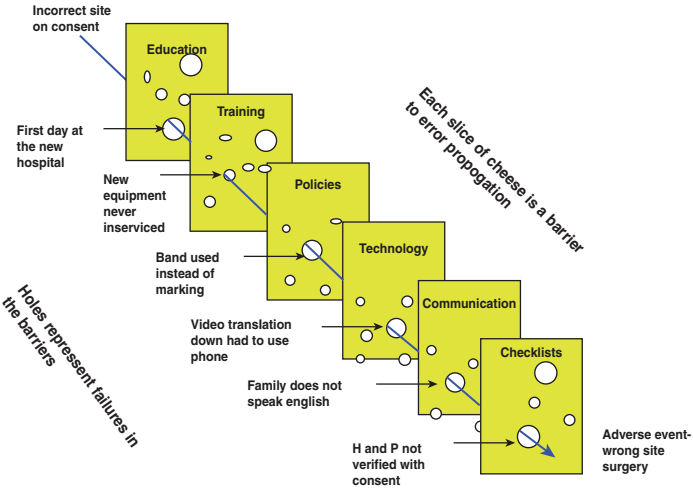

FIGURE 17.2 Swiss cheese model of adverse events. (Visual model portraying the adverse event of wrong-site surgery in a child with right inguinal hernia using a modified Swiss cheese model. Figure originally published in Stein and Heiss, Seminars in Pediatric Surgery, 2015 [18]. Reproduced with permission from Elsevier)

ogy can include electronic medical record pop-ups or best practice alerts, which are vulnerable to alert fatigue [18]. Checklists provide a layer of defense by ensuring confirmation of critical patient information and structured surgical briefings, debriefings, and handoffs [18].

Error Analysis

At the basis of error analysis is the concept that error is not the conclusion but rather the starting point of an investigation [7]. Learning from adverse events and near misses is a cornerstone of patient safety and improvement. There are several methods for investigation and analysis of medical errors, including clinical case review at forums (such as morbidity and mortality conference or peer review), contributory

factors, root cause analysis (RCA), failure mode and effects analysis (FMEA), and fishbone diagrams.

Contributory Factors

One method for analyzing medical errors builds off the work of James Reason and classifies error-producing conditions and organizational factors in a single broad framework [19]. This model requires that the user starts by examining the series of events leading to the adverse event or near miss and then further investigates the conditions and organizational context in which the incident occurred [19]. Table 17.2 outlines this framework with examples of common contributory factors to errors.

Table 17.2 Framework of factors influencing clinical practice and contributing to adverse events

Framework	Contributory factors	Examples of problems that contribute to errors
Institutional	Regulatory context Medicolegal environment	Insufficient priority given by regulators to safety issues; legal pressures against open discussion, preventing the opportunity to learn from adverse events
Organizational and management	Financial resources and constraints Policy standards and goals Safety culture and priorities	Lack of awareness of safety issues on the part of senior management; policies leading to inadequate staffing levels

Table 17.2 (continued)

Framework	Contributory factors	Examples of problems that contribute to errors
Work environment	Staffing levels and mix of skills Patterns in workload and shift Design, availability, and maintenance of equipment Administrative and managerial support	Heavy workloads, leading to fatigue; limited access to essential equipment; inadequate administrative support, leading to reduced time with patients
Team	Verbal communication Written communication Supervision and willingness to seek help Team leadership	Poor supervision of junior staff; poor communication among different professions; unwillingness of junior staff to seek assistance
Individual staff member	Knowledge and skills Motivation and attitude Physical and mental health	Lack of knowledge or experience; long-term fatigue and stress
Task	Availability and use of protocols Availability and accuracy of test results	Unavailability of test results or delay in obtaining them; lack of clear protocols and guidelines
Patient	Complexity and seriousness of condition Language and communication Personality and social factors	Distress; language barriers between patients and caregivers

Adapted from Vincent et al. NEJM 2003 [11]

Root Cause Analysis (RCA)

Root cause analysis, also called systems analysis, is a formal process of focused review that aims to identify a chain of events and wide variety of contributory factors that lead up to an adverse event or near miss at the systems level [11, 12]. The objective of this analysis is to reveal gaps and inadequacies in the healthcare system which can then be addressed in order to prevent future events. Root cause analysis is an event analysis tool that can be applied retrospectively to identify and understand what happened, why it happened, and what should be done to correct it [7]. In comparison with traditional clinical case review, it follows a predefined protocol for identifying specific contributing factors [7]. A formal root cause analysis is typically conducted by an interdisciplinary team of four to five individuals [12]. Five goals of root cause analysis are (1) to determine human and other factors involved in critical incidents, (2) to determine related processes and systems, (3) to analyze underlying causes and effect systems through a series of "why" questions, (4) to identify possible risks and their potential contributions, and (5) to determine a potential improvement in processes and systems [7]. When identifying *root causes* (RC) and *contributing factors* (CF), each human error should have an identified preceding cause and statements should include both cause and effect [12]. A root cause analysis of surgical never events submitted to the Joint Commission between 2004 and 2010 cited lack of leadership and communication as the most common causes of wrong-site surgery and retained foreign bodies. Figure 17.3 outlines common steps in the root cause analysis process.

The Institute for Healthcare Improvement has proposed a modified root cause analysis termed "root cause analysis and actions" or RCA^2 [20]. This process utilizes the basic framework of a root cause analysis with emphasis on a standardized process, action, risk-based prioritization, and understanding that multiple causes usually contribute to an adverse event [20]. RCA^2 focuses on the identification and

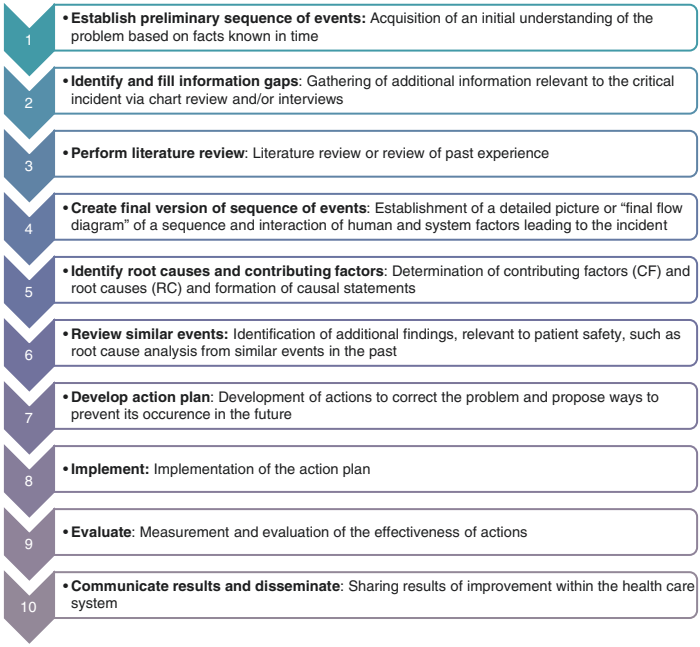

FIGURE 17.3 Steps of root cause analysis (RCA). (Steps adapted from *Medical Error and Harm: Understanding, Prevention, and Control* by Milos Jenicek and VA National Center for Patient Safety *Root Cause Analysis (RCA) Step-By-Step Guide* [7, 12])

implementation of sustainable systems-based improvements to make patient care safer [20].

Failure Mode and Effects Analysis (FMEA)

Failure mode error analysis is a team-based, systematic technique used to prospectively identify potential vulnerabilities or failure points in high-risk systems prior to the occurrence of an adverse event [18, 21]. This process was initially developed in the aerospace and nuclear power industries but is increasingly being applied in healthcare systems. The five

primary steps of FMEA are (1) create a flow diagram of the process under evaluation to identify its component steps, (2) identify potential errors or failure modes at each step, (3) score the failure modes numerically to prioritize them according to the risk they pose, (4) identify possible causes for the failures, and (5) generate corrective actions to address these failures [21]. The process of FMEA has been recommended by several national organizations, including the Institute for Safe Medication Practices, the Joint Commission on Accreditation of Healthcare Organizations, and the National Patient Safety Agency in the UK [21].

Fishbone Diagram

A fishbone diagram (Fig. 17.4), also referred to as a cause-and-effect diagram or Ishikawa diagram, is a cause analysis

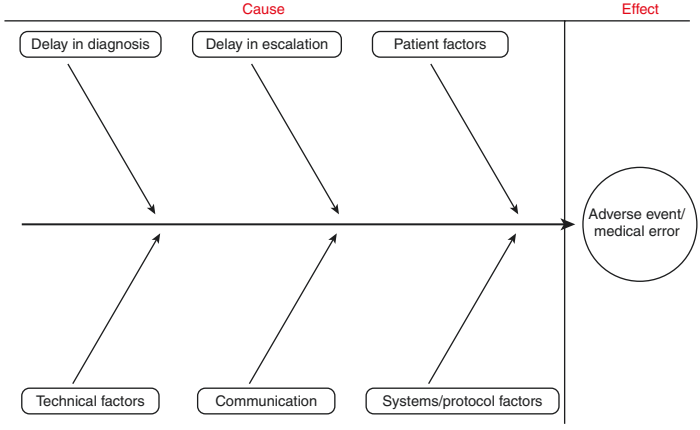

FIGURE 17.4 Fishbone diagram. Example of fishbone diagram to represent contributing factors and causes of an adverse event

tool that can be used to analyze adverse events [22]. These can easily be adapted into morbidity and mortality conference discussions and help educate all attendees and trainees in error analysis and to start thinking broadly about factors that contribute to adverse events.

Prevention of Error in Surgery

Strategies to reduce medical errors in a healthcare system should aim to reduce the frequency of errors by taking human limitations into account, make errors more visible when they occur so their impacts can be mitigated, and provide remedies to rescue patients when errors have occurred [23]. The Joint Commission has created annual National Patient Safety Goals, which inform their sentinel event alerts, standards and survey processes, performance measures, and Joint Commission Center for Transforming Healthcare projects [24]. Additionally, the National Quality Forum has developed safe practice recommendations to prevent never events (Fig. 17.5) [5].

Checklists, such as the World Health Organization Surgical Safety Checklist (WHO SSC) and Surgical Patient Safety System (SURPASS), can improve patient outcomes in surgery and reduce error [26]. A nonrandomized clinical trial has demonstrated that adherence to the postoperative SURPASS checklist is associated with decreased readmission and adherence to both the WHO SSC and preoperative SURPASS checklists is associated with reduced surgical complications and need for reoperation [26].

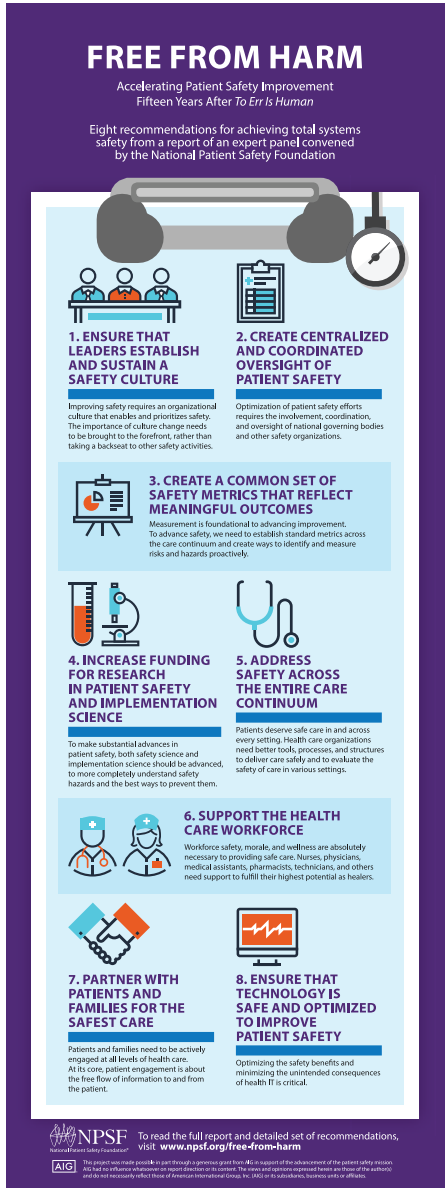

Figure 17.5
National Patient Safety Foundation recommendations for achieving total systems safety. (Adapted from: National Patient Safety Foundation. *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human*. Boston, MA: National Patient Safety Foundation; 2015. Available at ihi.org [25])

Summary

In all healthcare systems, human error is inevitable. While it is not possible to eliminate medical error completely, strategies can be put in place to design safer healthcare systems to reduce error and mitigate its consequences [23]. Even apparently single error events are typically due to a convergence of multiple contributing factors or latent failures, and prevention requires a systems approach to correct the conditions that contributed to the errors [1].

Errors in healthcare can be classified as near misses and adverse events and can be divided into active failures, such as slips, lapses, and mistakes, or latent failures, such as defensive gaps or weaknesses. Multiple latent failures within a healthcare system increase the likelihood that human error will result in an adverse patient event, as illustrated by the Swiss cheese model. Latent conditions present an opportunity to identify and proactively correct systems-based failures or weaknesses prior to the occurrence of an adverse event. Error and adverse event reporting is key to prompt identification and correction of latent failures. Root cause analysis is a key strategy in the accurate identification of error and modification of latent conditions to prevent future occurrences.

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