PREVENTING MEDICAL ERRORS

TABLE OF CONTENTS

An error the breadth of a single hair can lead one a thousand miles astray.

Chinese Proverb

Introduction

For those of us in healthcare, medical errors are nothing new. The possibility of their existence and their consequences were introduced early in our professional education and long before our licensure. Their reality became clear to us from the onset of professional practice. We know that errors can and do occur at various levels and with diverse significance and outcomes. We also understand that the key is prevention, with the need to participate however is needed to ensure safety.

While our genuine desire to avoid errors is consistent, our responses to error at the many levels of the healthcare industry is variable. Some mistakes are superficially addressed. When this happens, contributing procedures and systems are left unaltered and the stage set for the next unfortunate incident to occur. Other mistakes are swiftly addressed by assigning blame, even

when the events were largely beyond their control. Individuals contributing to an error may not even be aware of their participating role. Health providers become frustrated at the perceived inconsistency in how errors are tolerated, and do not always trust "the system" to respond appropriately. Overall, a cycle of inaction through nonproductive change seems to prevail.

Awareness about medical error began on November 1999 when the landmark report of the Institute of Medicine (IOM) *To Err is Human: Building a Safer Health System* was first published. This publication initiated an unprecedented effort to break the cycle of ongoing error.[1] Sobering statistics justified its recommendations and declared that it is simply unacceptable for patients to be harmed by the same system one expects to heal and comfort. Effects of the report were widespread, evoking reaction from the public, from regulatory and governmental agencies, and from all segments of the healthcare industry. Numerous initiatives were created to reduce error, and many high-risk activities were identified and altered to promote improved safety. Multiple investigations were conducted and numerous healthcare processes were modified as the healthcare industry worked to reduce error. Standards for monitoring and reporting evolved into an effort to increase transparency, thus decreasing error. Many of the changes have been positive, and yet medical error has not been eliminated.

Technologic advances using the electronic medical record and automated decision making have been increasingly integrated into healthcare delivery as ways to improve safety. The many stakeholders in healthcare have increased their overall focus on safety, and most assumed that the incidence of medical error, estimated at 44,000-98,000 annually, was decreasing.

Just as health professionals and health facilities started to congratulate themselves for creating a safer healthcare environment, a new report was published. Authors of *Medical Error Statistics* (2020) estimated that medical error accounts for more than 250,000 deaths each year when considering billing errors, misdiagnoses, diagnostic errors, treatment errors, and medication errors.[2]

It is the goal of this course to look again at the evidence on medical error and pull together the many-leveled activities that are recommended to reduce error. Awareness of everyone's personal role in reducing error will be addressed, along with strategies to effectively promote safety.

Why is it important?

Statistics

The occurrence of medical errors and their associated costs are poorly understood by most. One of the most powerful drivers involves the shame and embarrassment associated with medical error, promoting an environment of secrecy with minimal reporting and documentation. Failure to talk about error dilutes the perception of the problem and allows those involved to forget. There is also the possibility of becoming immune to error when a health professional or manager minimizes the issue by insisting "we are all human and all make mistakes".

Public disasters get a lot of attention even when the number of those affected is fairly low, but the huge number of people affected by medical error is usually not acknowledged.

> ***The study of error is not only in the highest degree prophylactic, but it serves as a stimulating introduction to the study of truth.***
>
> Walter Lippmann (1889–1974).

The 1999 Institute of Medicine (IOM) report estimated 44,000 to 98,000 people died unnecessarily due to medical errors.[1] This statistic caught everyone's attention and sharpened the focus on problems associated with medical error. Even using the lower estimate, medical errors became recognized as deadly flaw within a system that is intended to provide superior healthcare. The problem of medical error was far greater than anyone suspected, and it prompted health agencies and professional organizations to develop guidelines and practice recommendations that could reduce error.

Current 2023 evidence does not suggest that medical error is decreasing. The Food and Drug Administration reports receiving more than 100,000 medication error reports each year.[2] Medication errors are occurring in pharmacies, hospitals, and patient homes.[3] A recent publication by Rodziewicz, Houseman, and Hipskind (2023)[4] indicated that approximately 400,000 hospitalized patients experience some type of preventable harm each year. Using a different data source, these authors also estimated that medical error directly contributed to the deaths of at least 100,000 patients in hospitals and clinics each year.

Medical error statistics are important measures used to identify safety trends and track responses to specific error reduction strategies. Measurable data help to track where you are, where you have been, and where you are going. It is hard to monitor trends and track improvements without consistent and valid measures to

rely upon. Data must be consistently accurate, credible, and accessible.

Costs associated with errors are enormous. They extend from the affected individuals to society as a whole. Not only do they result in higher overall healthcare expenses, but they also cause lost productivity, disability, and increased costs of personal care. Medical errors are costly to patients, their families, their employers and their insurers as well as to all health providers and facilities providing healthcare. Annual costs of measurable medical errors in the US are now estimated to be least $4 billion and possibly as high as $20 billion[4] and there is no indication that costs are declining. An older estimate, published in 2012, calculated an annual economic impact upwards of $1 trillion when quality adjusted life years are applied to those who died.[5]

Impact

The incidence of medical error has a substantial impact on the health and well-being of Americans. It is linked with estimations of significant cost to individuals, families, organizations and society as a whole. Affected individuals encounter needless pain and countless losses related to functional health status and financial stability. They may endure duplicate testing, repeated procedures, prolonged treatment and extended recovery time. Because of medical error, they may also experience lost productivity, disability, and increased costs of personal care. Unacceptably, thousands will die each year. Countless others, along with their family and friends, will have lost their trust in our healthcare system. The potential for experiencing harm while receiving healthcare threatens every American. As the 1999 IOM report noted, individuals should not be harmed by those who are trying to care for them.

Public perception on overall quality of healthcare, has not been favorable in the last two decades. Gallup poll findings released in December 2024 noted public concern about healthcare quality. Polls results reflect a 24 year low in satisfaction with American health care and only 19% were satisfied with the financial cost of healthcare.[6] Interestingly, many Americans worry about the potential for medical error yet approximately 5% have personally experienced a medical error.[7] The report further clarifies that Americans were most likely to experience medical error in an outpatient setting.

There are health care journalists who question the assertion that medical error should be listed as the leading cause of death because of statistically flawed data and unsubstantial causal connections between errors and death.[8] Yet Dr. John Makary and other researchers from Johns Hopkins in Baltimore assert that's medical mistakes remain seriously under-reported.[9] The current (healthcare) system fails to capture critical errors such as diagnostic mistakes, poor judgments, and communication breakdowns that can be fatal. In summary, the American public should appreciate that medical errors are unfortunately common. Any opportunity to clarify a misunderstanding or review a questionable medical decision is recommended as a way to prevent potential harm.

What are the errors?

Most of us think of medical error in terms of medication mistakes or mishaps in surgery. Indeed, the 1999 IOM report estimated that medication errors alone led to as many as 7,000 deaths annually. However, many types of medical errors exist. They penetrate every process and system and affect every healthcare professional. Medical errors threaten every healthcare consumer and can occur even with the most routine of tasks.

Categorizing types of medical error can be accomplished by using several frameworks. Some methods might look at legal definitions while others might consider severity of injuries or types of healthcare services, settings, or providers. Dr. Lucian Leape was one of the pioneers in studying medical error and his categorization method helps make sense of how multiple errors can occur. Major categories of medical error are named diagnostic, treatment, preventative and other.[10] These categories are still widely used in clinical practice and they are used in this review to more accurately describe each medical error category.

- ***Diagnostic oriented*** – Mistakes within this category typically present substantial health risks because of delayed or possibly absent treatment. [10] Diagnostic mistakes contribute to increased medical costs and usually worsen patient outcome. Diagnostic procedures are costly, but so is the potential for increased morbidity and mortality. Diagnostic mistakes include inaccurate or delayed diagnoses, failure to employ appropriate tests, use of outmoded tests or therapies, failure to accurately document and report testing results, and failure to act on the results of diagnostic monitoring or testing. A working definition of a diagnostic related error is to say that it occurs when the wrong diagnosis was made despite adequate data or clinical findings suggested a more accurate diagnosis. Diagnostic related errors are common and yet they don't receive as much attention as falls or medication errors. According to Graber (2013), incidence of diagnostic error is approximately 10-15%. [11] Another study by Singh, Meyer and Thomas (2014) estimates incidence of diagnostic errors in the outpatient setting at 5%, affecting 12 million adults every year.[12]

Some of the latest and most startling research comes from Dr. David Newman-Toker, a neurologist at Johns Hopkins University. Researchers report that diagnostic

errors alone are linked to nearly 800,000 deaths or cases of permanent disability in the US each year.[13] His research sounds the alarm by suggesting that diagnostic error could be the single largest source of deaths across all care settings from all patient safety concerns combined.

Examples of diagnostic related medical error are found on the Patient Safety Network (PSNet), a national web-based resource supported by AHRQ that features latest news and resources addressing patient safety. The PSN offers these examples from their content collection. [14]

- A patient with crushing chest pain was incorrectly treated for a myocardial infarction, despite clinical indications that an aortic dissection was present.
- Repeated positive blood cultures with Corynebacterium were dismissed as contaminants when they were not. The patient was eventually diagnosed with *Corynebacterium* endocarditis.
- A heroin-addicted patient with abdominal pain was treated for opioid withdrawal symptoms. Routine diagnostic work up procedures were not followed, yet later this patient was shown to have a bowel perforation.
- A false-negative rapid screening test for *Streptococcus* pharyngitis resulted in a delay in diagnosis.

The above examples represent categories of diagnostic related errors. In the first example, the patient diagnosis was made by providers who were not expecting the unexpected. Based on their typical experiences as providers, these providers filtered clinical findings in a way that conformed to their expectations. In the second example, the healthcare providers relied upon an initial impression and then failed to revise or re-think their conclusions. In the third example, providers framed their thinking by using assumptions and biases that ultimately endangered patient life. In the fourth example, the providers relied too heavily on a rapid screening test rather than continue their investigation of clinical symptoms.

It is reported in medical literature that misdiagnoses related to vascular events, infections, and cancers account for almost 75% of serious harms from diagnostic errors. These three disease categories are often named "The Big Three".[13] Just 15 diseases from these "Big Three" categories account for nearly half of all serious misdiagnosis-related harms in malpractice claims.[15,16] Researchers systematically reviewed 28 published studies reporting diagnostic error rates. Diagnostic error (false negative) rates ranged from 2.2% (myocardial infarction) to 62.1% (spinal abscess). Because of these findings the authors recommend diagnostic improvement initiatives to reduce error with a focus on conditions most prone to diagnostic error. Florida's Board of Medicine has taken this recommendation seriously by ensuring that licensed medical professionals review medical error content that includes the most mis-diagnosed conditions in Florida.

In 2024 the state of Florida updated portions of the Florida Administrative Code (F.A.C.) pertaining to Florida's Board of Medicine requirements for continuing education. In the applicable Rule 64B8-13.005, medical professionals seeking licensure (initial and/or renewal) must review required content for Prevention of Medical Error that includes the five most mis-diagnosed medical conditions in Florida as identified by the Board during the previous two years.[17]

Rule 64B8-13.005 within the F. A. C. currently specifies that "while wrong site/wrong procedure surgery continues to be the most common basis for quality of care violations, the following areas have been determined as the five most misdiagnosed conditions: oncology related conditions, gastroenterology related conditions, cardiology related conditions, infectious disease related conditions, and neurology related conditions."[17] These broadly identified categories are intended to provide data-driven focus on the most prevalent diagnostic errors within the state. Increased awareness is intended to prompt improved diagnoses and reduce diagnostic related error. Optimal patient outcomes with reduced harm and increased survival often depend on accurate and timely diagnoses.

Common medical conditions within each broad category are briefly described.

1) Oncology or cancer related misdiagnoses are usually linked to missed diagnosis, wrong diagnosis, or delayed diagnosis. Yet the full spectrum of cancer related care addresses routine screening practices, timely referral, accurate disease staging with appropriate management, scheduled monitoring with patient-provider communication, palliative care, and the many typical and atypical oncologic emergencies that may arise. Since Florida's Board of Medicine has identified oncology related conditions as being most often misdiagnosed, it is important to recognize how all these related activities contribute to a misdiagnosis.

Within the U.S. the top five misdiagnosed cancers are listed as lung, breast, colorectal, melanoma, and prostate.[13] In Florida, the majority of misdiagnosed cancers are identified as breast, lung, and colorectal.[18]

2) Gastroenterology related misdiagnoses are not identified within "The Big Three" categories nationwide but are identified by Florida's Board of Medicine. There is one 2015 study on leading causes of medical malpractice claims against gastroenterologists that found the most

common error was improper performance of a procedure (32%) followed by errors in diagnosis, and medication error.[19] There are a large number of colonoscopies and endoscopies performed in Florida related to a large senior population, and so it can be speculated that many misdiagnoses might be linked to such diagnostic findings that are poorly performed, misinterpreted, delayed, or unreported. Missing and inaccurate diagnoses in these settings are then typically linked to delayed or inappropriate treatment and/or unresolved bleeding that becomes more critical over time.

3) Cardiology related misdiagnoses include vascular conditions and the conditions most misdiagnosed in the U.S. are stroke, thromboembolism (venous and arterial), aortic aneurysm and dissection, and myocardial infarction.[13] Florida identifies similar conditions. Missed heart attacks and embolic events are often due to subtle symptomology that doesn't fit a "classic" symptom pattern and then inadequately followed with diagnostic workups. Practice guidelines now recommend thorough assessment with diagnostic workup whenever myocardial infarction, embolism, and aortic aneurysm is suspected.

Missed diagnosis in vascular stroke remains problematic despite wide prevalence of public and professional education outlining presumptive signs and symptoms. Medical continuing education now highlights the recommended assessment and diagnostic tests needed for accurate and timely diagnosis.

4) Infectious disease related diagnostic error addresses multiple scenarios such as viral syndromes, atypical disease, and the underappreciated subtle symptoms of early infection. U.S. and Florida statistics both identify the conditions of sepsis, pneumonia, meningitis and encephalitis, spinal abscess, and endocarditis.[13] Vulnerable populations (pediatric, older adults, immunocompromised) are particularly prone to missed diagnoses. Errors in diagnosing infections are problematic because they predictably worsen patient outcome, become more costly to treat, and can negatively impact community health.

5) Neurological related misdiagnoses have been found in emergency rooms across the nation to be linked to knowledge gaps, cognitive errors, and systems-based errors.[20] Erroneous neuroimaging interpretations and missed cerebellar lesions were identified as widespread. In Florida, the traumatic injuries such as concussion and spinal cord damage were listed as being most common. Many neurologic conditions are quite challenging to diagnose and so it is recommended that thorough assessments with detailed history and timely consultation are critical to an accurate diagnosis.[20]

- ***Treatment oriented*** – Mistakes within this category include errors in:
  - performance of an operation, procedure, or test
  - treatment administration
  - dose or delivery method of a drug
  - omission or delays in treatment
  - inappropriate or non-indicated care

A high percentage of treatment related errors involve medication administration. These errors occur so often that most health professionals categorize them separately as "medication errors". Another high percentage of treatment related errors involve surgery. Some errors are less visible than others. A post-operative patient with slow, insidious bleeding at the surgical site that goes untreated due to insufficient monitoring is considered treatment oriented. A more prominent type of surgical treatment error is the wrong site – wrong procedure – wrong patient error category. Errors within this category are termed "never events" because they should never occur.[14]

"Wrong site surgery" occurs when the incorrect body part is operated upon. One example describes the case of a women who had the right side of her vulva removed when the cancerous lesion was on the left. System breakdowns occur allowing the patient to be vulnerable to "the system" that can be busy and confusing with numerous distractions exposing multiple levels of possible failure.

"Wrong procedure" occurs when the patient is subjected to a procedure or surgery that was not indicated, while the appropriate procedure or surgery was withheld. For example, the person scheduled for the creation of an arteriovenous fistula (intended for dialysis access) instead received the insertion of a central line port (intended for chemotherapy administration).

"Wrong patient" error occurs when the planned procedure or surgery is performed on the wrong individual. A classic example of wrong-patient surgery involved a patient who underwent a cardiac procedure intended for another patient with a similar last name.

- ***Preventive*** – Errors within this category include failure to provide preventative treatment, or inadequate monitoring or follow-up of treatment. These are the kinds of errors that occur when information "gets lost in the system" or someone "falls through the cracks". High volume workload can be a significant factor contributing to these types of errors. A fast-paced emergency department, and overwhelmed health provider, or busy medial office setting are all situations conducive to preventative errors. Consider the patient with an abnormal laboratory value. The abnormal value might be an early indicator of a serious condition, and yet it is

unfortunately overlooked and not addressed. This abnormal value may eventually resolve and never become problematic, but then again it might represent a trigger to investigate further symptoms more carefully. Failure to adequately address the abnormal value is a preventative error.

Another example of preventative error occurs when patients are discharged from a healthcare facility without adequate follow up. There may have been clinical indications of a stenosed carotid artery, with a recommended follow-up for further evaluation. Failure to provide appropriate and timely access for that follow up care becomes a preventative error.

- ***Other*** – Errors within this category include failures in communications and technology, equipment function, medical coding and billing errors, and other types of system failure. Administrative contributions to error may include unresponsive management or scarce provision of supplies and equipment. Even when these failures do not directly cause medical error, they are typically linked to the circumstances surrounding error.

Healthcare professionals will acknowledge the above categories but may have difficulty applying these concepts to their own practice setting. Unique circumstances and workplace scenarios contributing to error are embedded into each professional discipline's activities. Many will recognize some of these common examples.

Physicians, physician assistants and nurse practitioners report that the potential for diagnostic or treatment error is present during virtually every patient encounter. Patients can be poor historians, records may be incomplete, and relevant information may be missed, omitted, misinterpreted, or discounted. Cost and time constraints also contribute to preventable error, and any combination of factors can set the stage for adopting a "most likely" diagnosis, prescribing the "usually works" treatment plan, or a failing to pursue routine screening guidelines.

Clinical laboratory professionals explain that the potential for diagnostic error is always present while collecting, labeling and processing specimens. Equipment failure and miscommunications are also common contributors to error. Clinical laboratory professionals typically work in fast paced, high volume environments that can quickly fail if patient and specimen identification is compromised.

Nurses indicate that the potential for diagnostic and treatment error most frequently involves one of two scenarios:

1) inadequate or inaccurate assessments
2) problematic medication administration involving complex mathematical calculations

Because nurses monitor their patients' responses to illness and treatment, ongoing assessments with timely communication of findings become critical to patient safety. Nurses also devote much of their time to medication administration, and multiple medications require careful attention to avoid potential error.

Psychologists, Clinical social workers, mental health therapists, and marriage and family therapists reveal that their potential for treatment error essentially revolves around the limited resources for behavioral health and the unpredictability of clients in crisis. Most community healthcare systems are simply unable to accommodate everyone's mental health needs. Thus, the required prioritization of available resources inevitably leads to error when violent, homicidal or suicidal tendencies are missed.

Physical therapists suggest that their potential for error is primarily related to unrecognized medical instability. Recommended or standard treatments may be contraindicated for those with unresolved cardiopulmonary problems, and therapists must rely on documentation to recognize these circumstances. Failed communication becomes a primary contributor to error. The majority of events involving fainting, "falling out", respiratory distress or cardiac arrest develop when underlying medical problems are unknown, unresolved, or not adequately appreciated.

Pharmacists indicate that medication errors are their constant concern. Some health professionals view medication errors simply as an infraction of one of the "five rights": "right patient, right drug, right dose, right route, and right time." This, however, is an oversimplification. Because there are several components involved with patient medications (prescribing, dispensing, dosing, and administering), errors can occur in any of those areas. However, many medication errors are considered preventable.[21] Common medication errors include overriding medication-use safeguards, mistakenly administering a similar-sounding medication, or using out-of-date medications. Miscommunication can impact order entry, product labeling, packaging, compounding, and dispensing. Poorly understood patient education can impact administration, monitoring, and use."[21] It is important to note that medication errors can involve near misses, a feature that can helps to identify processes and events before they affect an actual patient. A near miss is defined as *an event that could have resulted in an accident, injury or illness, but did not either by chance or through timely intervention*.

Why do they occur?

"Human" Error

Have you ever made a mistake? It happens, despite attempts to carefully "double-check" or review what has been done. Collectively, healthcare professionals all share a genuine desire to avoid error. Yet physicians, nurses, pharmacists, and all other health professionals, being human, make mistakes. These mistakes occur despite how much we care, how hard we work, and how much we know. Consequently, *systems that rely on error-free performance by humans are likely to fail.*

Reasons why people make errors have been studied for many years. While there is no single answer, it is generally recognized that no one intentionally makes a mistake. Cognitive psychologists have explored the way people think. Human-factor specialists have analyzed the interrelationships between humans, the tools they use, and the environment in which they live and work.[22] Improved system and process designs have been implemented based on their findings.

According to Dr. Leape, human mental function occurs in two basic modes, automatic and problem-solving. Each mode has unique errors associated with it.[23]

Automatic mode, as its label implies, functions quickly and requires little conscious effort. This mode draws on one's accumulated learning of situation recognition and response. Errors while in automatic mode are called "slips" and are typically due to distraction and breaks in attention at critical moments. Humans are particularly vulnerable to "slips" during busy time periods because the brain is attempting to reduce overload and burden. An example might be the required pharmacy label informing the patient to *keep medication refrigerated* that is not applied.

Problem-solving mode requires greater concentration because information must be gathered, processed through comparison to stored knowledge, and then applied to some decision rule. Consequently, problem-solving processes are slower, sequential, demanding, and difficult to sustain. Errors in this mode are referred to as "mistakes." They result from selecting the wrong rule or misapplying the correct rule, and these types of error most often occur when there is staffing shortage. Various factors influence mistakes and affect our ability to solve problems. These factors include insufficient knowledge, pattern matching, biased memory, the availability heuristic (defined below), confirmation bias, and overconfidence.

- *Lack of sufficient knowledge* leaves us with no programmed solution, particularly in an unfamiliar situation.
- *Pattern matching* involves discovering patterns in situations so that previously thought out responses can be applied.
- *Biased memory* results from over generalizing and assuming that patterns have universal applicability, e.g. not verifying a potential allergy problem with the physician by assuming Dr. Always wants this patient with a history of severe penicillin allergy to get cefazolin pre-operatively because he always says to do so when he is asked about allergies.
- *Availability heuristic* is the tendency to use the first information that comes to mind, e.g. grabbing the "amber" vial to administer a diuretic without realizing you had grabbed a similar appearing multiple dose vial of epinephrine.
- *Confirmation bias* involves selection of data that supports the initial thinking and discards that which contradicts or fails to support it.
- *Overconfidence* is the tendency to favor the chosen action and evidence that supports it.

Factors that decrease attention or create distraction can cause errors in both automatic and problem-solving activities.[22] These factors may be physiological, psychological, or environmental. Fatigue, illness, loss of sleep, alcohol, and drugs are examples of physiological factors. Psychological factors include various emotional states and distraction from other activities. These can be triggered by external factors such as overwork, interpersonal relations, or other forms of stress. Environmental factors such as temperature, noise level, lighting, and visual activity can cause distraction. Many of these are accepted as a normalcy without linking them as factors that might cause an error.

The cause of error can have many dimensions, can be quite complex, and can result from the convergence of many contributing factors. As with other complex industries, safe healthcare has many requirements such as: good managerial decisions, reliable, functional, and well-maintained equipment; a skilled and knowledgeable workforce; reasonable work schedules and well-designed jobs; and clear guidance on desired and undesired performance. These requirements have been labeled pre-conditions and their absence or insufficiency can be viewed as latent failures embedded in a system, which through interaction of the system and the production process, can contribute to many unsafe acts.[24]

"Invisibility" of Error

Have you ever been advised to "forget" an error or keep error-related information "quiet"? Medical errors are often surrounded by secrecy and shame allowing others to remain unaware of their existence. Embarrassment, fear of retribution, and the potential of career-ending

litigation keep many from revealing their mistakes. When errors are silenced and covered, they also remain undocumented and unreported, thus contributing to their "invisibility". A perceived lack of time also keeps many from reporting error. Comprehensive reporting requires added time that is simply not available and doing so may result in a missed lunch break, added time at the end of a busy shift, or an unwelcome shifting of priorities. This relative "invisibility" of error is dangerous because it prevents us from recognizing what went wrong, and it keeps us from working towards resolution or improving conditions to prevent recurrence. "Invisible" errors also have a high probability of being repeated and are likely to trigger a cascade of additional mistakes and inaccuracies that only compound the original error.

The "invisibility" of error also leads to a generalized under-appreciation of its incidence and encourages a diluted perception of the medical error problem. Iatrogenic mistakes are not generally discussed; therefore, errors within the scope of personal involvement are rarely noted. Limited access to the aggregate data on medical error is unnecessarily protective and blunts our comprehension of "the bigger picture". This silent accumulation of error keeps us from fully appreciating its larger impact and even larger solution. Consider the unrelated example of a disaster involving an aircraft that immediately claims the lives of 200 persons. This one disaster is so visible it will elicit a more emphatic impact than the nearly invisible 200 deaths attributable to medical error. Because our knowledge of isolated errors and "near misses" accumulates over time and occurs over a large geographical area, we tend to respond more passively than we do when there is a single publicized large-scale disaster.

"System" Error

When an error has occurred, have you ever been asked to isolate a human "cause" and then assign blame? This kind of response is common, yet extensive analyses reveal that most errors occur as a result of "a chain of events set in motion by faulty system design that either induces errors or makes them difficult to detect."[19] In other words, *mistakes usually happen with system contribution - not just because of people!* Focusing on the unfortunate individual closest to the mistake does not address system flaws or complex organizational processes that neglected to prevent the error. In fact, neglecting system-wide influences only promotes repetition of the same error.

Charles Perrow, in his analysis of the Three Mile Island nuclear accident, elaborated on how systems can cause or prevent accidents.[25] He characterized organizations and systems according to their complexity and whether they are coupled loosely or tightly.

Complex systems have multiple components that interact in a variety of unexpected and invisible ways, setting the stage for mistakes and accidents. As any health professional will attest, *our current healthcare system qualifies as a complex system.* The combination of system variability, professional specialization, continually evolving technology, and layered governmental regulation produces a challenging complexity that is often difficult to navigate.

Coupling refers to the slack or buffer between steps in a process. Tightly coupled systems have more time-dependent processes and sequences and accommodate less flexibility in how things can be accomplished. *Tight coupling characterizes most of the quick paced events in healthcare*. Tight coupling is particularly problematic in urgent and emergent situations where elapsed time can compromise patient survival. Acknowledging these characteristics helps us to understand why healthcare systems are so vulnerable to error.

Recognizing that our healthcare systems are both complex and tightly coupled suggests that we should focus attention on organizational infrastructure and system re-design when addressing medical error.

To concisely review why errors occur, experts believe that it is a combination of "human error", system error, the relative "invisibility" of error, the under-reporting of error, and the potential for one error to trigger a cascade of additional mistakes.

How do we respond?

After categorizing and analyzing the multiple dimensions of medical error, it has become apparent that no single solution can be universally effective. Still, a unified approach to evaluation and response can guide appropriate action.

How should we begin?

Should we focus on the individual? Traditional responses focusing on individual error have relied upon "naming, blaming and shaming" and then add education or training to correct poor performance. Misdemeanor or felony charges are sometimes filed. However, current evidence suggests that focusing on the individual can limit the effectiveness of our response. This process is neither appropriate nor cost-effective. Individuals contributing to error may or may not even be aware of their participating role and some will be unjustly blamed for matters that were clearly beyond their control. Mandatory education and re-training is costly and is only partially effective within environments characterized by

high employee turnover and evolving organizational changes.

Should we focus on technology? Traditional responses to equipment malfunction, performance limitations and technical "glitches" have relied upon procedural revisions, product manual updates and continuous employee re-training. How effective are these responses when both the technology and the organizational needs keep changing? Traditional responses to "human error" often involve elaborate technological re-designs that can still be circumvented by frustrated employees. Current recommendations call for improved technology but with built in redundancies and added safety features to override human-generated errors.[26]

Should we focus on the organizational infrastructure? Traditional responses to problematic organizational and management systems have relied upon policy and procedural revisions, or targeted personnel replacement. How effective are these reactionary "band-aids" when new situations continually arise? Restrictive guidelines can never address every potential problem and broad-based policies allow for wide variations in interpretation. Instead, the Quality Interagency Coordination Task Force (QuIC) suggests system-wide solutions such as allocating adequate resources to error prevention and nurturing solutions that foster professional responsibility and accountability.[26]

Ultimately, we must shift our attention from the individual to the system. There is a need to confront error- both potential and actual. Designs and strategies must be created to alert professionals BEFORE the potential error occurs. Once we appreciate that error reduction and performance improvement require proactive system-wide changes rather than reactive person-oriented strategies, we can begin to embrace what is now called a "culture of safety". We must begin to appreciate the importance of developing a non-punitive workplace culture and promote a healthcare system with built in checks, safeguards and redundancies to protect against inevitable human failure. Initial steps in this process include differentiating error types and identifying those "pre-conditions" that are most likely to contribute towards error.

Identifying Active vs. Latent Error

Differentiating between active and latent errors helps guide a more effective response to error. *Active* errors are easily identified and occur at the level of the frontline worker. These errors are most often attributed to human error and their effects are felt almost immediately. Common *active* errors include administering the wrong medication or documenting on the wrong medical record. *Latent* errors tend to be removed from the direct control of the worker. These errors are less obvious and they occur "behind the scenes". Latent errors often remain undetected unless someone is actively investigating all the factors contributing to an active error. Typical *latent* errors are attributed to faulty systems and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations.

Latent errors and active errors are inevitably linked, supporting the assumption that no one sets out to intentionally make an error. A less threatening response to any active error involves focusing on the contributing latent error. The following examples use different groups of healthcare professionals to illuminate some of the connections between active and latent error.

Among physicians, physician assistants and nurse practitioners, well publicized examples of *active* error incidents involve wrong site surgery. Wrong site surgeries are most common among orthopedic procedures and associated risk factors include multiple surgeons involved in the case, multiple procedures performed during a single operating room visit and unusual time pressures. Wrong site surgery represents the kind of mistake that provokes outrage, assigns blame to the operating surgeon and results in costly litigation. Yet several *latent* errors contribute to the end result. For example, all operating room staff, as well as the patient have a role in verifying the correct surgical site. The patient's initial interview and verification in pre-op, surgical prep and draping of the wrong extremity, repeated failure to correctly verify the affected extremity, and inaccurate or inadequate preoperative documentation are all system errors that contribute to wrong site surgery.

Among clinical laboratory professionals, an *active* error might involve the conscious decision to override scheduled, routine calibration checks. Routine calibration checks are required to assure test result accuracy, yet busy clinical laboratory workers may repeatedly prioritize the high volume of specimens over the performance of scheduled calibration checks on equipment. The *latent* errors in this example might include the timing of scheduled calibration checks, a lack of duplicate/back-up instruments, or instrument programming that allow over-ride functions.

A nursing example of an *active* error is the erroneously free-flowing IV caused by incorrect loading of tubing into an infusion pump. When the free flow of fluid overloads the system or delivers toxic amounts of medication, the outcome can be particularly dangerous to the patient. The *latent* errors in this example might include the pump design that allowed the improper loading of the tubing or the absence of technology that could prevent free-flow from occurring.

Among psychologists, clinical social workers, mental health therapists and marriage and family therapists, a common example of an *active* error is the failure to adequately communicate a worsening symptom that could compromise safety. Counselors and therapists rely on communication alerts when suicidal and/or homicidal ideation is expressed, and discounting these indicators can endanger the lives of others. The *latent* errors in this example could include delays in transcription or an inadequate relay of messages.

A physical therapist example of an *active* error is the inappropriate choice of minimal documentation to describe a client's response to therapy. Detailed communication of any contrary patient response is absolutely vital to successful rehabilitation. Failure to adequately document patient response can result in harm during subsequent therapeutic sessions. The *latent* errors in this example might include time constraints because of a busy schedule or documentation forms that discourage added therapy comments.

Among pharmacists, an example of an active error is the inaccurate filling of a medication order by dispensing a wrong medication or an incorrect dose. Pharmacists report that they carefully check filled prescriptions to avoid these types of error and yet they still occur. The latent errors contributing to this example might include drugs that look or sound alike or a written prescription that is difficult to decipher.

Identifying Pre-Conditions

Another effective response to error involves identifying those factors or influences that potentially support a platform for error. These pre-conditions could be the "root causes" of error, or they might serve as stimuli that foster or encourage error. Recognition of these pre-conditions and identification of their links to error can be used to implement specific remedies. In a study examining preventable adverse events in a primary care outpatient setting, pre-conditions to error came from four distinct sources. Each source category was then labeled and described.[27]

Clinician factors, those pre-conditions directly attributable to the healthcare professional, include individual errors in judgment, procedural skills errors, failure to recognize signs/symptoms, forgetfulness, and execution related errors ("stupid mistakes"). Regrettably, clinicians involved in these types of errors are often disciplined and risk termination of employment. Yet the sad reality is that any clinician involved in a serious error usually learns from that circumstance and often becomes more careful, and more safer, than others. Why would someone want to terminate the clinician who will probably be the safest clinician going forward?

Unfortunately, healthcare professionals in any setting will recognize these person-oriented contributions to medical error. The experienced health professional can usually identify this type of error easily, and often catch the error before it actually occurs. The newly licensed or newly hired health professional will not always recognize this type of error, but that is why preceptorships and mentorships are put into place to guide the novice and protect the patient.

Anticipated responses to clinician-generated errors most appropriately focus on the individual. What has been learned from past analyses is that the focus shouldn't stop there. Every error analysis should also look for system-wide problems that fail to detect or prevent human error.

Communication factors contributing to error include failure to understand, cultural and language difficulties, conflicting information, and delayed exchange of information. Since accurate and timely communication is essential within any healthcare organization, it is easy to understand how these pre-conditions influence and encourage medical error. When communication-oriented errors are identified, a diverse team representing all levels of personnel may be needed to adequately develop an improved communication process.

An example of a communication driven medical error is the incorrect interpretation of a physician order.

Administrative factors contributing to error include a large number of system-wide problems that may or may not already be known. Rushed personnel, missing charts and broken or unavailable equipment were most often identified in the study focusing on a family practice clinic. In other practice settings, administrative contributions to error might include scarce supplies, unresponsive management or unscheduled computer downtime. Think about how often a worker identifies a situation as "a mistake waiting to happen", and then consider how and when the situation was remedied. Appropriate responses to these identified contributions will typically involve both short term and long term action plans in an attempt to limit their influence on error.

Blunt end factors contributing to error include those influences that are outside the affected system's span of control. Examples might include physical size and location of the healthcare setting, or corporate level decisions affecting an individual facility or organization. An unusual example might include the occurrence of any community-wide disaster that limits access to usual resources, such as hurricane or flood. For many healthcare systems, it is the complexity of multi-layered interactions with outside insurance and government

agencies that contribute to error. When identified contributions to error are external to the affected healthcare system, necessary internal adaptations are advised.

What is being done?

Actions to define and correct medication errors existed prior to the IOM (1999) report and continue to this day. Current web-based programs sponsored by the Agency for Healthcare Research and Quality (AHRQ) greatly assist in providing accessible education and resources for healthcare providers, researchers, and policy makers. In the spirit of interdisciplinary collaboration, there are numerous sites that support ongoing researcher activity in safety and quality. There is a systematic review repository, grants online database, and practice-based research networks. AHRQ also supports up to twenty-two separate sites to support education to healthcare providers and organizations. For example, the Patient Safety Network (https://psnet.ahrq.gov/) provides timely explanations of current patient safety findings and discussion of they may be implemented. The site also provides educational resources for those who are new to patient safety concepts. The National Guideline Clearinghouse (https://www.guideline.gov/) is a database providing evidence based clinical practice guidelines. This site offers numerous practice guidelines with explanations and rationales supporting each recommendation. Many guidelines also offer the guideline, expert commentary, links to further resources and technical assist videos to synthesize content in an easily understandable format.

There are also several web sites that support content specifically designed to prevent frequently occurring medical errors. For example, the Patient Safety Network (PSNet) has a web page explaining “Never Events”. The history about how these never events earned their name is explained. Never events are devastating and are largely preventable. They are now defined as adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. Each of the 29 events, which are also categorized as "sentinel events” by the Joint Commission, required mandatory reporting along with the recommendation to disclose the event, apologize to the patient and family, report the events, and waive all costs associated with the event.[14]

The Institute for Safe Medication Practices (ISMP), located in Philadelphia, is the nation’s only nonprofit organization exclusively devoted to medication error prevention and safe medication use. They offer numerous educational materials and newsletters designed to promoted medication safety, and they are a key player in expanding knowledge about medication error and its prevention.

Many of the agencies and organizations devoted to preventing medical error publish practice recommendations that can be used by healthcare providers and administrators to support safety improvements. For example. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) lists multiple statements and recommendations to address specific practice concerns.[28] A partial listing of these topics are provided below.

- Statement opposing the criminalization of errors in healthcare.
- Recommendations to weigh patients using a metric scale to decrease weight-based calculation errors.
- Recommendations to enhance accuracy of prescription/medication order writing via electronically typed orders.
- Recommendations to reduce medication errors associated with verbal medication orders and prescriptions.
- Recommendations for avoiding medication errors with drug samples by requiring a legitimate prescription before providing samples.
- Promoting the safe use of medications with similar suffixes in prescription drug names
- Recommendations for healthcare professionals to reduce medication errors associated with labeling and packaging of pharmaceutical (drug) products and related devices.
- Recommendations for bar code labels on pharmaceutical (drug) products to reduce medication errors.

The NCCMERP also shares a site named NAN alert. The NAN alert is a National Alert Network that publishes alerts from the National Medication Errors Reporting Program. This site encourages sharing and reporting of medication errors so that lessons can be learned to increased medication safety. Past examples included information and warnings about medication shortages, leaky syringes, new changes with heparin labeling, and a recommendation to switch totally to a metric system and abandon dosing that uses fluid drams as a measure.[29]

1999 IOM Recommendations

The 1999 IOM recommendations for initiating the move to improve patient safety addressed the following four general areas:

- Create a national center to oversee and direct medical safety efforts.
- Require mandatory and voluntary error reporting.
- Insist on safety performance standards for healthcare professionals.

- Promote safe practices at the delivery level.

These recommendations have been followed and remain in effect more than twenty years later. The Agency for Healthcare Research and Quality has taken the lead in establishing a national center to oversee and direct medical safety efforts, plus other agencies are contributing. The Food and Drug Administration works to establish and maintain safe products. The National Institutes of Health (NIH) is a large biomedical research agency that coordinates research programs. The Centers for Disease Control and Prevention (CDC) work to protect Americans for health, safety, and security threats.

AHRQ has also supported each of the remaining IOM recommendations. Each of the national web sites addressing medical error and promoting safety have taken steps to set safety performance standards and establish safe practices. There are also clear mandates set forth by federal, state, and professional regulatory agencies about reporting error. Standardized reporting of specified errors has been mandated, with sharing of related information (type of errors, analysis, and resolution) to facilitate data collection and analysis. The one recommendation that has had the most difficulty is in getting healthcare providers to voluntarily report error.

Numerous professional organizations have urged healthcare providers to report error, and there are efforts to move away from punishing the person reporting the error. Most healthcare organizations encourage a culture of safety with non-punitive systems for reporting and analyzing errors. Healthcare providers however are still reluctant to report. The mandate to report is straight forward and easily understood, but in reality, the reporting of error remains a complex and highly emotional subject that continues to be the focus of significant discussion. Because of reporting deficiencies, a likely gap continues to exist in uncovering the true magnitude of the problems of patient safety.

What can you do?

There is no single or best way to prevent medical error and improve patient safety, but it clearly becomes each healthcare professional's responsibility to focus pro-actively on error reduction and prevention. Major emphasis at the individual level relies on 1) willing participation in comprehensive and timely reporting of error, 2) collaborative analysis of individual and system practices designed to reduce error, 3) routine recognition of error prone situations and 4) voluntary adoption of recommended practice changes designed to minimize error. When each healthcare professional fully participates in these activities, the ultimate goal of optimal patient safety can be realized.

Reporting

Of the four recommendations outlined above, it is voluntary reporting of error that is vital to error reduction. Each healthcare professional can substantially contribute to error reduction by consistently identifying and reporting actual errors, "near misses", and flawed systems that can contribute to error. Reports can be submitted within an organization (internal) or to an outside agency (external) using either *mandatory* or *voluntary* reporting strategies. Mandatory reporting typically focuses on serious faults in performance, promotes provider accountability, and addresses public issues of safety and the public's "right to know" by disclosing serious inadequacies. Voluntary reporting is generally done in response to errors that result in minor or no injury, and the information generated is used to alter processes and systems to improve safety.

Voluntary reporting is one of the largest safety related functions that delivery-level health professionals will encounter. It is the initial step in learning from past mistakes and is vital to identifying system designs that can contribute to error. As previously mentioned, system problems that contribute to error are particularly harmful because they are difficult to recognize and can combine with a multitude of events to cause more errors.

As a delivery-level health professional, ask yourself the following questions:

- Do you feel your organization's error rate (medication variance, etc.) is accurate?
- When you discover an error, do you document all, some, or only those errors a supervisor tells you to report?
- When you identify and report an error do you feel it will result in: a) an improvement to a system or process that will make the error less likely to be repeated, or b) someone getting into trouble?

Usual answers to these questions quickly identify the common barriers to reporting. We tend to "name, blame and shame" and are often irregular about preparing reports. Most health providers are unwilling to voluntarily engage in additional documentation to report error. They are worried about embarrassment and fear of retribution. They Re worried about potential litigation, or career ending decisions. Authorities are aware of these obstacles. They acknowledge that our current "culture of blame" needs to be replaced by a "culture of safety"; they recognize that reporting needs to be non-punitive; they agree that documentation needs to be more streamlined. Working towards these goals will take time, yet many caution that more exhaustive reporting at the delivery-level will be required until there is a complete understanding of error.

Error Analysis

Practicing healthcare professionals need to actively participate in error analysis. Analyzing all of the contributing factors to an error is an important tool in recognizing and learning from past mistakes. The importance of analyzing all the contributing factors is underscored by The Joint Commission's mandate for organizations to complete a thorough and credible root cause analysis (RCA) whenever a sentinel event or never event occurs and whenever a "critical effect" is identified. Critical effects are defined as possible serious effects on the patient from failure or undesirable variation in a process. Critical effects might be identified at any time and by any individual and are sometimes identified retrospectively when conducting the Failure Mode and Effects Analysis (FMEA) process.[30,31]

Root Cause Analysis: Healthcare professionals routinely conduct intensive analyses of physical disease by exploring the condition at a cellular and/or chemical level. This analytic process is designed to understand the underlying or "root cause" of the condition. Similarly, the RCA process allows clinicians to explore and understand the underlying reasons contributing to medical error. Through this "cellular level" scrutiny, system and practice modifications are made so that reoccurrence can be prevented. RCA is a retrospective form of analysis, comprehensive and systematic. It is based on the premise and philosophy of the National Patient Safety Foundation that most errors result from faulty systems rather than human error and that people are in essence set up by them to make errors for which they are not fully responsible. Using RCA, events are intensively scrutinized to discover: (1) the main reason an accident occurs (its proximate cause); (2) systematic variances and/or problems that might lead to other mistakes (common causes); (3) contributors that could not have been foreseen or prevented (special causes); and (4) areas where the event could have been avoided had things been done differently (risk points).

Conducting a Root Cause Analysis and Implementing an Action Plan

The Joint Commission publishes a step-by-step process for conducting the RCA. These steps are identified below.[31]

1. Assign an interdisciplinary team to assess the sentinel event.
2. Establish a way to communicate progress to senior leadership.
3. Create a high-level work plan with target dates, responsibilities, and measurement strategies.
4. Define all the issues clearly.
5. Brainstorm all possible or potential contributing causes and their interrelationships.
6. Sort and analyze the cause list.
7. For each cause, determine which process(es) and system(s) it is a part of and the interrelationship of causes.
8. Determine whether the causes are special causes or common causes, or both.
9. Begin designing and implementing changes while finishing the root cause analysis.
10. Assess the progress periodically.
11. Repeat activities as need (brainstorming for example).
12. Be thorough and credible.
13. Focus improvements on the larger systems.
14. Redesign to eliminate the root cause(es) and the interrelationship of root causes that can create an adverse outcome.
15. Measure and assess the new design.

Most Common Root Causes of Medical Error: The Agency for Healthcare Quality and Research has categorized results from multiple root cause analysis findings.[32] They identified a diverse group of factors that cause medical error, and then developed the following categories: communication problems, inadequate flow of information, human problems, patient-related issues, organizational transfer of knowledge, staffing patterns or workflow, technical failures, and inadequate policies and procedures.

1. *Communication problems*, the most common cause of medical errors, results in many different types of errors and involve all members of a healthcare team. These failures include both verbal and written communication amongst the many users of health-related information and involve all types of medical information including physician orders, prescriptions, and laboratory results. These may exist between individuals in different agencies, facilities, departments or disciplines and can involve illegible, unintelligible, misspoken, misunderstood, lost, incomplete, or other failed communication.
2. *Inadequate information flow* problems are those that prevent critical information from being available when prescribing decisions are made; delay or diminish reliability of critical test results; or fail to coordinate medication orders at points of interface or transfer of care.
3. *Human problems* relate to how standards of care, policies, or procedures are followed. Examples include failure in following policies, guidelines, protocols, and processes. Such failures also include sub-optimal documentation and inadequate labeling of specimens. These human problems may be a related to lack of knowledge, but they are more often related to distraction and just "not thinking".

4. *Patient-related issues* can include improper patient identification, incomplete patient assessment, failure to obtain consent, and inadequate patient education. While patient related issues are listed as a separate cause by some reporting systems, they are often nested within other human and organizational failures of the system.
5. *Organizational transfer of knowledge* can include deficiencies in orientation, education, or training for those providing care. This is of particular concern in areas where new employees or temporary help is often used and in academic medical centers where physicians in training often rotate through numerous centers of care.
6. *Staffing patterns/work flow* can cause errors when work conditions become stressful due to insufficient staffing, high patient acuity, excessive volume, or when supervision is inadequate.
7. *Technical failures* include device/equipment failure and complications or failures of implants or grafts. These events can cause great harm to patients. Instructions may be difficult to understand or even missing; device design may be poor. Frequently the fault of the device or equipment is not obvious, with blame focused on the operator, until a more thorough evaluation, such as RCA, is undertaken.
8. *Inadequate policies and procedures* guiding the delivery of care can contribute to many medical errors when they are poorly designed, inadequate or adhered to variably.

RCA has been used successfully for several decades in other settings, such as the nuclear and aviation industries. Justification to this labor-intensive process is improved outcomes and the avoidance of costly (and deadly) mistakes. Difficulties encountered when applying RCA to healthcare include inadequate staff, insufficient time, fear of retribution, and stopping the analysis too soon. Both people and time are scarce in contemporary healthcare settings, and everyone shares a wariness of discussing and documenting mistakes for fear of possible legal action. However, the benefits of using RCA are undeniable. The process itself helps those I an organization develop an understanding of the contributing factors to error, and the interrelationship of those factors. Increasingly this process used not just in sentinel or never events, but close calls or near misses. The practice of applying the RCA process before serious harm has occurred is more proactive and reactive and is a desirable characteristic of high functioning organizations.[32]

Failure Mode and Effects Analysis (FMEA): This bottom-up analysis is used in an organization's ongoing, proactive program to identify risks to patients' safety and reduce error. It is different from the RCA process because instead of focusing on what went wrong, the FMEA process focuses on what could go wrong.[33] This process is also called potential failure mode and effects analysis. Using this process the analysis lists each possible failure mode, all various effects, and then performs the critical analysis (FMECA). The FMEA process is an industry process not just used in healthcare but has become a valuable resource when trying to analyze potential for medical error. FMEA is outlined by the American Society for Quality as follows:

1. Assemble an interdisciplinary and/or cross-functional team of people with diverse knowledge about the process, product or service and customer needs.
2. Identify the scope of the FMEA. Is it for concept, system, design, process or service? What are the boundaries? How detailed should we be? Use flowcharts to identify the scope and to make sure every team member understands it in detail.
3. Fill in the identifying information at the top of your FMEA form. Form categories will typically include identification of potential failure mode, potential effects of failure, current processes to avoid failure, development of an action plan assigning responsibility and target dates.
4. Determine how serious each potential failure effect is (S) using a numerical rating system to signify range from insignificant to catastrophic.
5. For each failure mode, list all the potential root causes. Use tools classified as cause analysis tools, as well as the best knowledge and experience of the team.
6. For each cause, determine the occurrence rating (O). This rating estimates the probability of failure occurring for that reason during the lifetime of your scope. Occurrence is usually rated on a scale from 1 to 10, where 1 is extremely unlikely and 10 is inevitable.
7. For each cause, identify current process controls. These are tests, procedures or mechanisms that you now have in place to keep failures from reaching the customer. These controls might prevent the cause from happening, reduce the likelihood that it will happen or detect failure after the cause has already happened but before the customer is affected.
8. For each control, determine the detection rating (D). This rating estimates how well the controls can detect either the cause or its failure mode after they have happened but before the customer is affected. Detection is usually rated on a scale from 1 to 10, where 1 means the control is absolutely certain to detect the problem and 10 means the control is certain not to detect the problem (or no control exists).
9. (Optional) Is this failure mode associated with a critically necessary characteristic? (Critical

characteristics are measurements or indicators that reflect safety or compliance with regulatory controls.)

10. Calculate the risk priority number, or RPN, which equals S (severity) × O (occurrence) × D (detection). Also calculate criticality by multiplying severity by occurrence, S × O. These numbers provide guidance for ranking potential failures in the order they should be addressed.
11. Identify recommended actions. Actions may be design or process changes to lower severity or occurrence. They may be additional controls to improve detection. Also note who is responsible for the actions and target completion dates.
12. As actions are completed, document results and dates. Record any changes in occurrence rating, severity, or detection rating as a way to document progress.

As the team works through the FMEA process, there may be multiple potential failure effects. The numerical scores represented by S (severity rating), 0 (occurrence rating) and D (detection rating) are then used to assign priorities. When there are several high priority potential failure effects identified, the team may want to identify the estimated 20% of potential failure effects that contribute to 80% of the overall variability.

The FMEA process is meant to be proactive so that processes, system designs, and performance can be analyzed using a sequential review process *before* error occurs. For example, FMEA can be used to analyze the error potential of a new drug being considered for formulary addition in the pharmacy. Does the drug under consideration have ambiguous or difficult to read labeling? Is the packaging potentially error-prone? Do product names have sound-alike or look-alike problems? Could there be any dosing confusion? Is there any special patient monitoring needs? How will the drug appear on a computer screen while performing varied processing functions?

Individual Professionals Recognizing Potential Error

In addition to the more formalized RCA and FMEA processes, individual healthcare professionals need to consider their own common error prone populations and error prone situations. Continuously evaluating risk and probability of error heightens awareness and reduces overall occurrence of medical error.

Vulnerable populations: When asked, most healthcare professionals within any discipline immediately identify the very old and the very young as being particularly vulnerable to error. Individuals at these extreme ends of the age continuum are not as physically stable, their bodies are more significantly impacted by concomitant medical conditions, they metabolize their medications differently than the general adult population and they often use alternative forms of communication to alert clinicians about impending problems. Additionally, each profession identified some unique sub-populations that are particularly prone to error.

- **Clinical laboratory professionals** focus much of their attention on obtaining adequate specimens for subsequent analysis. They indicate that their most problematic patients are also those most subject to collection errors. These patients include the very obese, the very frail, those who are classified as a ”difficult stick”, those who are immune-compromised, and anyone who is in an emergently unstable life-threatened situation.

- **Retail pharmacists** have identified tourists (those having no available drug profile) and patients with multiple (and sometimes conflicting) drug files as those who are more likely to be involved with a pharmaceutical error. Pharmacists also report a higher potential of error when working with anyone who cannot adequately communicate because of illiteracy or a language barrier. Communication and patient teaching/reinforcement is a critical part of a pharmacist’s job and problematic communications makes it difficult to verify and clarify relevant information.

- **Psychologists, Clinical social workers, mental health therapists and marriage and family therapists** explain that their suicidal, homicidal and psychotic patients are most unpredictable and thus lead their list of those most vulnerable to errors in assessment and/or treatment. Aggressive or violent individuals pose the greatest threat to overall safety, but errors are also common when individuals conceal relevant information or offer conflicting information. Examples include persons with HIV disease, the chronically mentally ill, gay/lesbian/trans persons, the uninsured, and the homeless.

- **Physical therapists** are most concerned about error when working with depressed persons and those with impaired judgment (left sided CVA affecting frontal lobe). These individuals do not always respond appropriately during a therapeutic session, and so a therapist cannot rely on the patient to verify information or correct therapist assumptions. PT professionals also realize that clients receiving oxygen during therapy or those utilizing medicated topical ointments are at a higher risk for the development of untoward reactions.

- **Nurses** consistently indicate that their highest safety risk populations include those who are combative and/or confused, those who are critically ill (and

thus subject to hundreds of medical interventions each day), and those who have no desire to survive (patient lacks incentive to participate in care).

Error-prone practice settings. Healthcare professionals also identify special situations and circumstances that are more likely to contribute to error. Human factors such as stress or fatigue can interfere with cognition. System inadequacies such as insufficient staffing, computer downtime or other technology failure can inject variability into "routine" processes or diminish anticipated capabilities. These and similar situations should clearly signal potential for mistakes and alert practitioners to take special measures. These might include seeking a second opinion from a co-worker, avoiding fatigue by delegating tasks, prioritizing activities, or utilizing additional reference materials.

Of interest, healthcare professionals working in different practice settings all identify additional, unique practice situations that pose the highest risk for error.

- **Physicians** comment that their highest potential for error arises whenever they are asked to emergently consult an unstable patient, primarily because "everyone" is expecting the impossible: a quick response offering definitive treatment that will immediately resolve a complex medical situation.

- **Clinical laboratory professionals** report that the majority of their errors involve situations with improper or inadequate patient identification.

- **Nurses** report that most of their high-risk situations are related to inadequate staffing and emergent patient circumstances. They also consistently identify medication administration errors as a primary situational risk, particularly among those with multiple medications.

- **Psychologists, Clinical social workers, mental health therapists and marriage and family therapists** explain that their potential for error is highest when they are asked to strategize a minimal solution that has few or any backup contingencies. Regarding personal safety, they are most concerned when practicing alone during evening or "off" hours because they are dealing with unstable patients and/or unstable family members.

- **Physical therapists** report that the highest risk situations involve patients with underlying conditions that are undetected, and patients receiving pharmacologic products that can precipitate untoward responses (hypotension, vertigo, nausea, impaired judgment).

- **Pharmacists** indicate that some of their riskiest situations occur when there are computer failures, because they rely so heavily on computerized patient profiling and the automated identification of potential drug interactions. They also identified multiple distractions and illegible prescriptions as major contributors to error.

Recommendations for Change

Individual healthcare professionals have a professional duty to embrace recommended practice changes designed to minimize error and enhance patient safety. America's nationally based safety initiatives are evidence driven, using both voluntary and mandatory reporting data that were collected by centralized agencies like Joint Commission, the National Patient Safety Foundation (NPSF), United States Pharmacopeia (USP) and the Agency for Healthcare Research and Quality (AHRQ). Recommendations may not always seem necessary to every healthcare professional, but these reflect a genuine desire to change practices that have been repeatedly implicated in medical error. Primary opportunities for patient safety are broadly categorized under medication administration, patient practice, technology applications, and education (both professional and consumer).

1. Medication-related safety*:* Safety initiatives pertaining to medication errors are widespread because 1) medications are extensively utilized in healthcare and 2) the complexity of several interacting professions and systems offer substantial opportunities for error.

Numerous contributors to medication-related error have been identified. Distractions and workload increases are consistently mentioned whenever individual error is identified, but many system-wide factors are also named. These include the following: [34]

- ✓ Prescriptions and drug orders with ambiguous strength designations on label or packaging
- ✓ Drug product nomenclature with look-alike or sound-alike names
- ✓ Use of lettered or numbered prefixes and suffixes in drug names
- ✓ Equipment failure or malfunction
- ✓ Illegible handwriting
- ✓ Improper transcription
- ✓ inaccurate dose calculation
- ✓ Inadequately trained personnel,
- ✓ inappropriate abbreviations used in prescribing
- ✓ Labelling errors
- ✓ Excessive workload
- ✓ Lapses in individual performance
- ✓ Medications are unavailable

The Institute of Safe Medication Practices (ISMP), the Joint Commission, and the Food and Drug Administration all warn against using dangerous dose designations, "stemmed names", apothecary or mathematical symbols, and other abbreviations because of the high potential for error. ISMP published a listing of error-prone "confused" drug names that is available online.[35] FDA and ISMP jointly published a list of lookalike drug names and use of Tall Man Lettering to better distinguish each drug.[36] Most of these recommendations have been readily adopted, but use of Tall Man lettering is less common. Healthcare professionals of all disciplines are impacted by these recommendations, most particularly within the disciplines of pharmacy, medicine and nursing.

Clinicians working with medications are particularly advised to recognize "high alert medications", the small number of medications that have a high risk of injury when misused. Medications are included in these lists not simply because of the high number of errors, but because of their serious consequences when not properly used. High alert medications are separated into three categories of use: acute care settings, community/ambulatory settings, and long-term care settings (includes assisted living and skilled nursing facilities).

ISMP's list of high alert medications in acute care settings[37] include the following:

- Adrenergic agonists such as epinephrine
- Adrenergic antagonists such as propranolol
- Anesthetic agents such as propofol
- Antiarrhythmics such as lidocaine
- Cardioplegic solutions
- Chemotherapeutic agents – parenteral and oral
- Hypertonic dextrose solutions - 20% or greater
- Dialysis solutions
- Epidural or intrathecal medications
- Hypoglycemics, oral
- Inotropic medications such as digoxin
- Insulin – subcutaneous and intravenous
- Liposomal forms of drugs such as liposomal amphotericin B
- Moderate sedation agents such as midazolam
- Narcotics/opioids – oral, transdermal and IV
- Neuromuscular blocking agents such as succinylcholine
- Parenteral nutrition preparations
- Radiocontrast agents – IV
- Sterile water for injection, inhalation, irrigation in containers of 100 mL or more
- Sodium chloride for injection, hypertonic, greater than 0.9% concentration

ISMP's list of high alert medications in community/ambulatory healthcare settings[35] include the following:

- Antiretroviral agents such as ritonavir
- Chemotherapeutic agents, oral (excluding hormonal agents)
- Hypoglycemic agents, oral
- Insulin – all formulations
- Opioids – all formulations
- Pediatric liquid medications that require measurement
- Pregnancy category X drugs such as Bosentan, Thalidomide, Diethylstilbestrol, Warfarin.

ISMP's list of high alert medications in community/ambulatory healthcare settings[35] include the following:

- Anticoagulants – parenteral and oral
- Chemotherapeutic agents, parenteral and oral (excluding hormonal agents)
- Hypoglycemics, oral
- Insulins – all formulations
- Parenteral nutrition preparations
- Opioids – parenteral, transdermal, oral – including liquid formulations, immediate and sustained release formulations, and combination products

With all the emphasis on clinical healthcare providers, the responsible roles of pharmaceutical companies and patients themselves should not be overlooked. The *National Coordinating Council on Medication Error Reporting and Prevention* defines a medication error as any preventable event which 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. This definition implies that patients and consumers also play a role in promoting medication safety.

Centers for Disease Control and Prevention (CDC) advocates an active role for consumers.[38] Consumers, including family members and their caregivers, also have a role in preventing medical error. The basic message is that it is always appropriate and permissible to ask questions seeking clarity whenever there is confusion or concern.

What Consumers Can Do

- Know what kind of errors can occur. The FDA evaluated reports of fatal medication errors that it received from 1993 to 1998 and found that the most common types of errors involved administering an improper dose (41 percent), giving the wrong drug (16 percent), and using the wrong route of administration (16 percent). The most common causes of the medication errors were performance and knowledge deficits (44 percent) and communication errors (16 percent). Almost half of the fatal medication errors occurred in people over

60. Older people are especially at risk for errors because they often take multiple medications. Children are also a vulnerable population because drugs are often dosed based on their weight, and accurate calculations are critical.

- Find out what drug you are taking and what it's for. Rather than simply letting the doctor write you a prescription and send you on your way, be sure to ask the name of the drug. Cohen says, "I would also ask the doctor to put the purpose of the prescription on the order." This serves as a check in case there is some confusion about the drug name. If you are in the hospital, ask (or have a friend or family member ask) what drugs you are being given and why.

  Find out how to take the drug and make sure you understand the directions. If you are told to take a medicine three times a day, does that mean eight hours apart exactly or at mealtimes? Should the medicine be stored at room temperature or in the refrigerator? Are there any medications, beverages, or foods you should avoid? Also, ask about what medication side-effects might be expected and what you should do about them. Read the bottle's label every time you take a drug to avoid mistakes. In the middle of the night, you could mistake ear drops for eye drops, or accidentally give your older child's medication to the baby if you're not careful. Use the measuring device that comes with the medicine, not spoons from the kitchen drawer. If you take multiple medications and have trouble keeping them straight, ask your doctor or pharmacist about compliance aids, such as containers with sections for daily doses. Family members can help by reminding you to take your medicine.

- Keep a list of all medications, including OTC drugs, as well as dietary supplements, medicinal herbs, and other substances you take for health reasons, and report it to your health care providers. The often-forgotten things that you should tell your doctor about include vitamins, laxatives, sleeping aids, and birth control pills. One National Institutes of Health study showed a significant drug interaction between the herbal product St. John's wort and indinavir, a protease inhibitor used to treat HIV infection. Some antibiotics can lower the effectiveness of birth control pills. If you see different doctors, it's important that they all know what you are taking. If possible, get all your prescriptions filled at the same pharmacy so that all of your records are in one place. Also, make sure your doctors and pharmacy know about your medication allergies or other unpleasant drug reactions you may have experienced.

- If in doubt, ask, ask, ask. Be on the lookout for clues of a problem, such as if your pills look different than normal or if you notice a different drug name or different directions than what you thought. It is best to be cautious and ask questions if you're unsure about anything.

2. Patient practice related safety. In 2005, the AHRQ first published a brochure addressing the 30 safe practices for better healthcare.[39] These recommendations, listed by category, continue to be relevant and are listed below.

- Create a health care culture of safety by encouraging reporting of error in the spirit of improving health care.
- Match health care needs with service delivery capability by matching clinical expertise of the providers with patient needs, and informing patients about risk when undergoing elective, high-risk procedures.
- Facilitate information transfer and clear communication by recording all verbal orders as soon as possible and conforming to recommendations about medical abbreviations and dose designations. Implement a computerized physician order entry system, and ensure that witnessed preferences for life-sustaining treatments is prominently displayed.
- In care specific settings, evaluate patients on admission and periodically thereafter for risk of common problems such as developing pressure ulcer, venous thrombosis, catheter associated blood stream infections, and contrast media-induced kidney failure.
- Increase safe medication use by keeping clean workspaces where medications are prepared, standardize packaging, identify high-alert medications, and dispense medications in unit dose packaging when possible.

Added opportunities to promote safe clinical practice include the utilization of evidence based clinical protocols, standardization of routine tasks and available equipment, and ongoing efforts to educate staff, patients and their families. Studies have shown that standardization of equipment, guidelines, and protocols have dramatically reduced error rates.

3. Technology enhanced safety. The use of advanced technology, computerized applications and sophisticated digitized equipment has grown exponentially over the last decade, impacting healthcare systems along with everything else in our environment. Positive changes include the increased consistency and readability of the computerized medication administration record (MAR) and computerized physician order entry (CPOE), safer intravenous infusion pumps, and real time documentation with inventory control using bar code technology. Some of the negative impacts include issues regarding the confidentiality of medical records, the cost

of added hardware, software and information technology staff, and the ongoing training of all personnel.
One of the biggest barriers to technology enhanced safety is the reticence of staff that cannot or will not embrace computerization. Healthcare professionals within every professional discipline and at all levels of healthcare delivery are actively contributing to error reduction and patient safety when they can accept and adapt to computerized technology. Reliance on outdated methods and old equipment may have worked in the past but they always had limitations that can now be overcome. Since healthcare professionals who cannot use the newer methods and updated equipment become a potential source of error themselves, their acceptance of newer technology becomes an ethical imperative. Examples of how technology enhanced systems can reduce error are provided below.

Clinicians worry about caring for patients using a "cookbook" approach rather than individualizing care, and therefore want to resist the use of computerized decision support systems. However, using evidence based artificial intelligence to guide thinking (prompt, suggest and remind – not demand) can improve both clinical and financial outcomes. Regional and/or cultural bias is minimized and evidence-based strategies are promoted. Published evidence suggests that patients will significantly benefit when computerized decision support systems are used - with a better chance of survival.[36]

One strongly recommended clinical practice approach now being promoted to reduce diagnostic error is the consistent application of sound medical practices such as performing thorough histories and physicals, reviewing lab findings and other diagnostic tests, and then discussing both findings and implications with patients. Documentation of this practice along with patient communication is critical so that multiple providers and service providers stay informed. These are not new ideas but more like strong encouragement to continue with basic medical care. These recommendations come from the Committee on Diagnostic Error in Health Care out of Washington DC.[40]

Providers agree, and health systems are incorporating these recommendations. Patients with adequate insurance will receive the most benefit, but those who are underinsured or uninsured present high risks for medical error because they cannot afford the recommended examinations, the procedures, and continued monitoring.

Physicians and other prescribing practitioners understand that hand-written prescriptions may be misinterpreted with sometimes disastrous results. CPOE offers a clearly legible order that can be processed more efficiently. When combined with some sophisticated alerts programmed into the system, CPOE has demonstrated significant contributions to error reduction.

Clinical laboratory professionals find that the time and resource constraints significantly increase opportunities for error, particularly human error. There may be misplaced or mislabeled test tubes, delayed turnaround time, or communication of erroneous test results. Replacing manual tasks with automated procedures (automated alliquotters, closed-tube sampling systems to eliminate manual uncapping and capping of test tubes, electronic auto-validation of results) contributes to error reduction and also results in improved productivity, worker safety, and cost savings.

Nurses, mental health counselors, physical therapists and other direct care professionals recognize that documentation of care delivery is important, yet they have always encountered barriers when trying to complete all the required information. The electronic medical record (EMR) offers these professionals the opportunity to eliminate most barriers while documenting even more comprehensive and timely information. Additional technology such as voice recognition software and bar-coding devices further optimize documentation by inputting real time data directly into the EMR and then populating all the required fields.

Radiographers are required to adjust kilovoltage peak (kVp), milliamperage (mA) and exposure time based key variables such as on source to image receptor distance (SID), thickness and tissue type of the body part and pathology. Using automatic exposure control (AEC) technology reduces errors in film screen imaging and contributes to improved patient safety by limiting radiation exposure.

4. Education to Promote Safety. Promoting and enhancing awareness of medical error is the initial step in developing a "culture of safety". The topic of medical error can no longer remain invisible, and so educational efforts focusing on patient safety must become clear, strong, and visible. Continuing education (mandatory and voluntary) using journal articles, live presentations and web-based programs all contribute needed knowledge and stimulate further discussion. Ultimately, it is the availability and promotion of ongoing education that becomes crucial in laying the foundation for collaborative initiatives that will reduce medical errors. This education is needed at the professional level, the support staff level, and the consumer level.

Education of the general public is also needed to increase awareness of the consumer's role in providing safe medical care. Responsibility for solving the medical error problem does not lie solely with healthcare

professionals. Patients, their families, and their lay advisers must also become active members of the patient's healthcare team. Healthcare organizations should support consumer education by using different venues to communicate how consumers must share in preventing errors.

Education leads to empowerment, of both the professional and the lay public. When individuals are empowered, they become involved and energetic in error prevention efforts.

So, what is next?

Continuous Quality Improvement Programs

Since the landmark IOM report was published in 1999, many health organizations took to heart the teachings of business quality leaders by looking for ways to improve their complex systems. The Joint Commission recognized the benefit of such improvement efforts and mandated them in their standards. Many methods are still being used and offer healthcare providers and healthcare organizations some structured approaches as they seek to reduce medical error. Examples include FOCUS-PDCA, Six Sigma, RCA, FMEA, Quality Related Events and Continuous Quality Improvement programs.

Clinical Simulation

There is growing consensus that practicing interdisciplinary clinical simulation can play a major role in preparing healthcare providers for safer clinical practice.[38] The AHRQ publication specifically addressed simulation strategies to prepare clinicians treating new conditions such as Ebola, COVID, and Monkeypox, and interdisciplinary simulation is being considered as a way to meet the multiple challenges in any health care situation. Procedural skills, team performance, communication techniques, technological competencies, and rapid response scenarios are all areas in which interdisciplinary collaboration and clinical expertise is required. Simulation centers around the country are embracing simulation as a way to verify clinical competency, and there is growing interest in and proactively planning coordinated team responses. Clinical simulation provides the perfect opportunity for validating selected competencies, but it is also the perfect opportunity to operationalize and test team responses to infrequent emergent situations. [39]

Data-Driven Care and Practice

Rodziewicz , Houseman, and Hipskind (2023) assert that creating and maintaining a culture of safety is best accomplished when data are continuously collected, analyzed, displayed, and used to drive quality improvement.[4] Data-driven care is more than using national or regional recommendations derived from published studies. Data-driven care becomes meaningful and empowering when it uses actual organizational data over time to identify trends and targeted outcomes in daily practice. Data driven practice is reinforced by the state of Florida as they begin alerting medical professionals to the most commonly misdiagnosed health conditions. Health providers are more inclined to trust the data because it is theirs – and more likely to follow recommendations for improved practice because they have a connection to their colleagues, their organizations, and their patients.

Organizational data collected from electronic medical records, laboratory and pharmacy databases, and other integrated technologies will help to guide decision analysis and direct quality efforts. Data can also reveal inconsistencies and outliers to be identified and addressed. Only the larger health systems are now able to install and utilize such large data sets, but the ability to outsource these services to other private companies may allow even small or rural areas to participate.

Conclusion

Medical error continues to be a very serious and complex national concern. What we have learned is that error reduction strategies need to focus on system redesign rather than individual chastisement. We have also learned the importance of building a culture of safety in which people are not afraid to identify errors and learn from each other's mistakes. In this evolving culture of safety, there should be no retribution for reporting errors or "near misses". Healthcare professionals have been identified as essential participants in the team approach to error reduction and remain central to the varied efforts promoting resolution. Through additional study of best practices, organizational guidelines and technical support strategies, our nation hopes to build a healthcare system that can offer the safest and highest quality patient care possible.

References

[1] Institute of Medicine Division of Healthcare Services Committee on Quality of Healthcare in America. (1999). *To Err Is Human: Building A Safer Health System*. Washington, DC: National Academy Press.

[2] MyMedicalScore (2020). *Medical errors*. Available at https://mymedicalscore.com/medical-error-statistics/. Last accessed January 12, 2025.

[3] SingleCare (2023). *Medication errors statistics 2023*. Available at https://www.singlecare.com/blog/news/medication-errors-statistics/. Last accessed January 12, 2025.

[4] Rodziewicz, T. L., Houseman, B., & Hipskind, J. E. (2023). Medical Error Reduction and Prevention. In *StatPearls*. StatPearls Publishing.

[5] Andel C, Davidow S.L, Hollander M, Moreno D.A. (Fall 2012). The economics of health care quality and medical errors. *Journal of Health Care Finance*. 39(1):39-50.

[6] Timotija, F. (Dec 6, 2024). Health care quality rating at 24-year low: Gallup. Available at Americans' view of health care quality at record low, poll shows. Last accessed January 12, 2025.

[7] NORC at the University of Chicago and IHI/NPSF Lucian Leape Institute. (2017). *Americans' experiences with medical errors and views on patient safety*. Cambridge, MA: Institute for Healthcare Improvement and NORC at the University of Chicago. Available at IHI_NPSF_NORC_Patient_Safety_Survey_2017_Final_Report.pdf. Last accessed January 12, 2025.

[8] Jaklevic, MC. (July 27,2023). Medical errors are the third leading cause of death and other statistics you should question. Available at 'Medical errors are the third leading cause of death' and other statistics you should question | Association of Health Care Journalists. Last accessed January 12, 2025.

[9] Hopson, J. (May 10, 2024). Johns Hopkins study points to medical errors as America's third leading cause of death. In The Baltimore Times. Available at Johns Hopkins Study Points to Medical Errors as America's Third Leading Cause of Death - The Baltimore Times. Last accessed January 12, 2025.

[10] Leape L.L., Lawthers A.G., Brennan T.A. et al. (1993). Preventing Medical Injury. Quality Review *Bulletin.* 19(5):144-49.

[11] Graber ML. The incidence of diagnostic error in medicine. *British Medical Journal of Quality & Safety*, 2013; 22: ii21-ii27.

[12] Singh H, Meyer A.N.D. and Thomas E.J. (2014). The frequency of diagnostic errors in outpatient care: observational studies involving US adult populations. *British Medical Journal of Quality and Safety*, 0:1-5.

[13] Newman-Toker, D., Wang, Z., Zhu, Y., Nassery, N., Saber Tehrani, A., Schaffer, A., Yu-Moe, C., Clemens, G., Fanai, M. & Siegal, D. (2021). Rate of diagnostic errors and serious misdiagnosis-related harms for major vascular events, infections, and cancers: toward a national incidence estimate using the "Big Three". *Diagnosis*, *8*(1), 67-84. Available at https://doi.org/10.1515/dx-2019-0104. Last accessed January 12, 2024.

[14] Patient Safety Network (Sent). *Never events*. (2019). Available at https://psnet.ahrq.gov/primers/primer/3/never-events. Last accessed January 12, 2025.

[15] Nassery, N., Saber Tehrani, A. S., Schaffer, A. C., Yu-Moe, C. W., Clemens, G. D., Fanai, M., & Siegal, D. (2020). Rate of diagnostic errors and serious misdiagnosis-related harms for major vascular events, infections, and cancers: toward a national incidence estimate using the "Big Three". *Diagnosis (Berlin, Germany)*, *8*(1), 67–84. https://doi.org/10.1515/dx-2019-0104.

[16] Newman-Toker, D., Nassery, N., Schaffer, A., Yu-Moe, C., Clemens, G., Wang, Z., Zhu, Y., Tehrani, A., Fanai, M., Hassoon, A. & Siegal, D. (2024). Burden of serious harms from diagnostic error in the USA. *British Medical Journal Quality & Safety* 33: 109-120. Abstract available at https://pubmed.ncbi.nlm.nih.gov/37460118/. Last accessed January 12, 2025.

[17] Florida Department of State. Florida Administrative Code & Florida Administrative Register. Available at 64B8-13.005 : Continuing Education for Biennial Renewal - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking. Last accessed January 12, 2025.

[18] Dolan Dobrinsky Rosenblum Bluestein Law Practice. Cancer misdiagnosis in Florida: What patients need to know. Available at Cancer Misdiagnosis in Florida: What Patients Need to Know - Dolan Dobrinsky Rosenblum Bluestein, LLP. Last accessed January 12, 2025.

[19] Lane, A.M., Bloomfeld, R.S. (October 2015). Leading causes of medical malpractice claims against gastroenterologists in the United States. *American Journal of Gastroenterology*. 110(pS920).

[20] Dubosh, N.M., Edlow, J.A., Lefton, M., et al. (February 2015). Types of diagnostic errors in neurological emergencies in the emergency department. *Diagnosis* 2(1):21-28.

[21] Rodziewicz, T.L., Houseman, B., Vaqar, S., et al. (Updated 2024 February 12). Medical error reduction and prevention. In *StatPearls.* StatPearls Publishing; Available from: https://www.ncbi.nlm.nih.gov/books/NBK499956/.

[22] Weinger M.B, Pantiskas C., Wiklund M., Carstensen P. (1998). Incorporating human factors into the design of medical devices. *Journal of the American Medical Association.* 280(17):1484.

[23] Leape L.L. (1994). Error in medicine. *Journal of the American Medical Association.* 272:1851-57.

[24] Leape L.L., Bates D.W., Cullern D.J. et al. (1995). Systems Analysis of Adverse Drug Events. *Journal of the American Medical Association.* 274:35-43.

[25] Perrow C. *Normal Accidents*. New York: Basic Books; 1984.

[26] Carayon P. and Wood K. (2010). Patient safety: The role and human factors and systems engineering. *Studies in Health Technology and Informatics* 153: 23-46. No. 04-RG005.

[27] Elder N.C., Dovey S.M. (2005). Classification of medical errors and preventable adverse events in primary care: A synthesis of the literature. *Journal of Family Practice.* 51(11):927-32.

[28] National Coordinating Council for Medication Error Reporting and Prevention. (2023). Recommendations and Statements. Available at http://www.nccmerp.org/recommendations-statements. Last accessed January 12, 2025.

[29] National Coordinating Council for Medication Error Reporting and Prevention. (2023). NAN Alert Archive. Available at http://www.nccmerp.org/nan-alert-archive . Last accessed January 12, 2025.

[30] Joint Commission. (2001). Root Cause Analysis: Common Barriers to Conducting Effective Root Cause Analyses. *Joint Commission Perspectives on Patient Safety*. 1(1):4-5.

[31] Joint Commission. (2017). Root Cause Analysis in Health Care: Tools and Techniques. 6th ed. *Joint Commission Resources*.

[32] Agency for Healthcare Research and Quality. (December, 2003). *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk*. Rockville, MD: AHRQ Publication No. 04-RG005. Available at https://archive.ahrq.gov/research/findings/final-reports/pscongrpt/psini2.html. Last accessed January 12, 2025.

[33] American Society for Quality (ASQ). Failure Mode Effects Analysis (FMEA). Available at http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html. Last accessed January 12, 2025.

[34] American Society of Hospital Based Pharmacists. *ASHP Guidelines on Preventing Medication Errors in Hospitals.* Available at Preventing Medication Errors in Hospitals. Last accessed January 12, 2025.

[35] Institute for Safe Medication Practices. (2019). *ISMP's List of Confused Drug Names*. Available at https://www.ismp.org/Tools/confuseddrugnames.pdf. Last accessed January 12, 2025.

[36] Institute for Safe Medication Practices. (2016). *FDA and ISMP Lists of Look-Alike Drug Names with recommended Tall Man Letters.* Available at TallManLetters-v3_revised8-31-16_highAlert07-31-08-v1.qxd. Last accessed January 12, 2025.

[37] Institute for Safe Medication Practices. (2024). *High alert medication list for acute care settings updated for 2024.* Available at Volume 29, Issue 1, January 11, 2024. Accessed January 12, 2025.

[38] Centers for Disease Prevention and Control (CDC). (2024). *Medication safety and your health.* Available at Medication Safety and Your Health | Medication Safety | CDC. Last accessed January 12, 2025.

[39] Agency for Healthcare Research and Quality. (2005). *30 Safe Practices for Better Healthcare*. AHRQ Publication No. 05-P007.

[40] Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. (2015). Improving diagnosis in health care. Washington (DC): National Academies Press (US). COMMITTEE ON DIAGNOSTIC ERROR IN HEALTH CARE. Available at https://www.ncbi.nlm.nih.gov/books/NBK338605/. Last accessed January 12, 2025.)