

## Medical Errors – Physical Therapy

### Goals & Objectives

#### Course Description

“Medical Errors” is an asynchronous online continuing education course for physical therapists and physical therapist assistants. The course focuses on the issue of medical errors. It includes sections on types and causes of errors, prevention strategies, documentation, rehabilitation indications and contraindications, therapy’s role in pharmacological management, patient management, and root cause analysis.

#### Course Rationale

The information presented in this course is critical for physical therapists and physical therapist assistants in all settings. The problem of medical errors impacts all aspects of society. It is imperative that all healthcare professionals educate themselves to facilitate effective strategies to reduce the occurrence of errors in health care.

#### Course Goals & Objectives

Upon completion of this course, the learner will be able to:

1. classify the many types of medical errors.
2. identify the causes of medical errors.
3. list effective strategies to prevent medical errors.
4. identify the basic concepts required to improve patient safety
5. define the components of health care team collaboration
6. Identify barriers to effective communication
7. define the therapy professional’s role in reporting medical errors
8. define root cause analysis
9. define the therapy professional’s role in assisting the physician with pharmacological management of the patient

**Course Provider** – Innovative Educational Services

**Course Instructor** - Michael Niss, DPT

**Target Audience** - physical therapists and physical therapist assistants

**Level of Difficulty** – introductory/intermediate

**Course Prerequisites** - None

**Method of Instruction/Availability** – Online text-based course available continuously.

**Criteria for Issuance of CE Credits** - A score of 70% or greater on the course post-test.

**Continuing Education Credits** – 2 hours

**Fees** - \$19.95

**Conflict of Interest** – No conflict of interest exists for the presenter or provider of this course.

**Refund Policy** - Unrestricted 100% refund upon request. The request for a refund by the learner shall be honored in full without penalty or other consideration of any kind. The request for a refund may be made by the learner at any time without limitations before, during, or after course participation

## Medical Errors – Physical Therapy

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## **Errors in Healthcare**

Tens of thousands of Americans die each year, and hundreds of thousands are injured by the American health care system. This is the astounding conclusion made by The Institute of Medicine (IOM) in their landmark publication *To Err Is Human: Building a Safer Health System*. That report and its companion, *Crossing the Quality Chasm*, have had a profound impact on how health care is viewed. The information and perspectives moved conversations regarding patient safety and quality care from inside health care institutions to the mainstream of media, corporate America, and public policy. These reports also raised awareness of the depth and complexity of quality challenges and prompted the marked expansion of quality improvement efforts through research and other means.

## **Error Classification**

### **Defining Error**

#### **Human Error**

While one frequently finds references to human error in the mass media, the term has actually fallen into disfavor among many patient safety researchers. The reasons are fairly straightforward. The term lacks explanatory power by not explaining anything other than a human was involved in the mishap. Too often the term ‘human error’ connotes blame and a search for the guilty culprits, suggesting some sort of human deficiency or lack of attentiveness. When human error is viewed as a cause rather than a consequence, it serves as a cloak for our ignorance. By serving as an end point rather than a starting point, it slows further understanding. It is essential to recognize that errors are simply the symptoms or indicators that there are defects elsewhere in the system and not the defects themselves.

#### **Near Miss**

A “near miss” represents the identification of a potential safety problem, prior to it resulting in an injury.

#### **Adverse Event**

Adverse events are defined as injuries that result from medical management rather than the underlying disease. While the proximal error preceding an adverse event is mostly considered attributable to human error, the underlying causes of errors are found at the system level and are due to system flaws; system flaws are factors designed into health care organizations and are often beyond the control of an individual. In other words, errors have been used as markers of performance at the individual, team, or system level. Adverse events have been classified as either

preventable or not, and some preventable adverse events (fewer than one in three) are considered to be caused by negligence.

### **Sentinel Event**

A sentinel event is defined as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness. Sentinel events include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome.

### **Error Taxonomy**

The origins of the patient safety problem are classified in terms of type of error:

- Communication - failures between patient or patient proxy and practitioners, practitioner and non-medical staff, or among practitioners
- Patient management - improper delegation, failure in tracking, wrong referral, or wrong use of resources
- Clinical performance - before, during, and after intervention.

### **Error Domains**

The types of errors and harm are further classified regarding domain, or where they occurred across the spectrum of health care providers and settings.

The root causes of harm are identified in the following terms:

#### **Active Failure**

Active errors occur at the point of contact between a human and some aspect of a larger system (e.g., a human-machine interface). They are generally readily apparent (e.g., pushing an incorrect button, ignoring a warning light) and almost always involve someone at the frontline. Active failures are sometimes referred to as errors at the sharp end, figuratively referring to a scalpel. In other words, errors at the sharp end are noticed first because they are committed by the person closest to the patient. This person may literally be holding a scalpel (e.g., an orthopedist operating on the wrong leg) or figuratively be administering any kind of therapy (e.g., a nurse programming an intravenous pump) or performing any aspect of care.

#### **Latent Failure**

Latent errors (or latent conditions) refer to less apparent failures of organization or design that contributed to the occurrence of errors or allowed them to cause harm to patients. For instance, whereas the active failure in a particular adverse event may have been a mistake in programming an intravenous pump, a latent error might be that the institution uses multiple different types of infusion pumps, making programming errors more likely. Thus, latent errors are quite literally "accidents waiting to happen." Latent errors are sometimes referred to as

errors at the blunt end, referring to the many layers of the health care system that affect the person "holding" the scalpel.

### **Technical Failure**

Technical failures include device/equipment malfunction or failure. In many instances diagnostic, monitoring, or therapeutic equipment can fail and lead to significant harm to patients.

### **Organizational System Failure**

Organizational system failure includes indirect failures involving management, organizational culture, protocols/processes, transfer of knowledge, and external factors.

## **Human Factors**

Two types of cognitive tasks may result in errors in medicine. The first type of task occurs when people engage in well-known, oft-repeated processes, such as driving to work or making a pot of coffee. Errors may occur while performing these tasks because of interruptions, fatigue, time pressure, anger, distraction, anxiety, fear, or boredom. By contrast, tasks that require problem solving are done more slowly and sequentially, are perceived as more difficult, and require conscious attention. Examples include making a differential diagnosis and readying several types of equipment made by different manufacturers. Errors here are due to misinterpretation of the problem that must be solved and lack of knowledge. Keeping in mind these two different kinds of tasks is helpful to understanding the multiple reasons for errors and is the first step in preventing them.

People make errors for a variety of reasons that have little to do with lack of good intention or knowledge. Humans have many intellectual strengths (e.g., large memory capacity and an ability to react creatively and effectively to the unexpected) and limitations (e.g., difficulty attending carefully to several things at once and generally poor computational ability, especially when tired).

When errors occur, the deficiencies of health care providers (e.g., insufficient training and inadequate experience) and opportunities to circumvent rules are manifested as mistakes, violations, and incompetence. Violations are deviations from safe operating procedures, standards, and rules, which can be routine and necessary or involve risk of harm. Human susceptibility to stress and fatigue; emotions; and human cognitive abilities, attention span, and perceptions can influence problem-solving abilities.

Human performance and problem-solving abilities are categorized as skill based (i.e., patterns of thoughts and actions that are governed by previously stored patterns of preprogrammed instructions and those performed unconsciously), rule based (i.e., solutions to familiar problems that are governed by rules and

preconditions), and knowledge based (i.e., used when new situations are encountered and require conscious analytic processing based on stored knowledge).

### **Skill-based Errors**

Skill-based errors are considered “slips,” which are defined as unconscious aberrations influenced by stored patterns of preprogrammed instructions in a normally routine activity. Distractions and interruptions can precede skill-based errors, specifically diverting attention and causing forgetfulness.

### **Rule-based Errors**

Rule-based and knowledge-based errors are caused by errors in conscious thought and are considered “mistakes.” Breaking the rules to work around obstacles is considered a rule-based error because it can lead to dangerous situations and may increase one’s predilection toward engaging in other unsafe actions.

Work-arounds are defined as “work patterns an individual or a group of individuals create to accomplish a crucial work goal within a system of dysfunctional work processes that prohibits the accomplishment of that goal or makes it difficult”. Work-arounds could introduce errors when the underlying work processes and workflows are not understood and accounted for, but they could also represent a “superior process” toward reaching the desired goal.

### **Knowledge-based Errors**

Knowledge-based errors occur when individuals do not have adequate knowledge to provide the care that is required for any given patient at the time it is needed.

## **Most Common Therapy-Related Errors**

### **Devices and Equipment**

Health professionals generally believe technology will improve healthcare efficiency, lower cost, increase quality, and promote safety; however, these same technologies may also introduce errors and adverse events. Given that there are approximately 5000 types of medical devices used by millions of healthcare providers throughout the world, device-related errors are inevitable. The benefits of technology may not be realized due to four common pitfalls:

- Inadequate maintenance
- Inadequate plan for implementing technology into practice.
- Poor technology design that does not consider human factors and ergonomic principles.
- Poor technology interface with the environment and patient

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Medical and equipment flaws in design, mishandling, user-error, and malfunction are common causes of medical errors. User errors are often attributable to:

- Differences in function between devices from different manufacturers.  
Inadequate testing.
- Lack of standardization.
- Poor design.
- Poor maintenance.

There is also a tremendous increase in the number and type of medical devices implanted in patients such as pacemakers, defibrillators, nerve and brain stimulators to control pain and seizures, and shunts. Malfunction of these devices may result in life-threatening events.

Workplaces, instruments, and equipment should be developed to consider human factors in design. A health professional user can maximize safety through the selection process, confirming that equipment is maintained, and proactive risk-assessment methods.

Health professionals should: Be involved in setting and evaluating institutional, organizational, and public policy related to technology. Make sure that technology used meets quality and safety standards.

Institutions should: Make decisions concerning technology with the input of critical stakeholders Have policies and processes related to maintenance, training, monitoring, and reporting adverse events related to technology.

### **Iatrogenic Infections**

Healthcare-related infections are considered a failure of the system. As much as one in 20 hospitalized patients may acquire a healthcare-related infection which may increase complications, length, and cost of the hospital stay. Healthcare-related infections add close to \$35 billion to the annual cost of healthcare in the United States. Nosocomial infections are a common problem in hospitalized patients. Preventing them requires adherence to infection control protocols.

Appropriate handwashing is one of the single most effective methods to decrease infection transfer. High-risk procedures such as indwelling Foley catheter and vascular catheter infection rates can be decreased by adhering to the use of sepsis bundles. Effective hand washing is linked to decreased morbidity and mortality rates. Sink availability or alcohol-based hand rubs prevent nosocomial infections. The Centers for Disease Control and Prevention guidelines include:

- Avoiding artificial nails.
- Changing gloves after each patient is evaluated or treated.
- Keeping natural nails less than one-fourth of an inch long.

- Use alcohol-based hand rubs.
- Washing hands with soap and water.

Hospital-acquired pneumonia causes significant morbidity and mortality. Risk factors include anemia, malnutrition, chronic renal failure, depressed mental status, thoracic surgery, and recent hospitalization.

## **Falls**

Falls are a common problem. Each year, over one-third of people over the age of 65 suffer a fall, and one-third of these falls cause injuries (Erin et al., 2013). In a healthcare setting, several factors may further increase the risk of falls, including:

- Blood loss.
- Medication side effects.
- Post-anesthesia effects such as diminished lower-body sensation.
- Volume loss.
- Decreased blood sugar.
- Altered mental status.
- Environmental change.
- Urge to void or defecate.
- Decreased strength or balance.

Factors that induce falls may be divided into two types: intrinsic and extrinsic. Intrinsic factors include vision, gait, and health history. These factors are not typically modifiable. Extrinsic factors include environmental hazards and medications. These may be modifiable and preventable.

Prevention - Patient falls decrease when patients who are assessed as at risk of falling are attended to hourly. To decrease the incidence of falls:

- Identify high-risk patients with armbands or other visual cues alerting providers of the fall risk.
- Provide safety companions to aid patients who fall risks.
- Educate families about fall prevention.
- Set bed alarms for close monitoring of at-risk patients.
- Do frequent safety rounds on all high-risk patients.

## **Changes to Improve Safety**

Changes in health care work environments are needed to realize quality and safety improvements. Because errors, particularly adverse events, are caused by the cumulative effects of smaller errors within organizational structures and processes of care, focusing on the systemic approach of change focuses on those factors in the chain of events leading to errors and adverse events. From a systems approach, avoidable errors are targeted through key strategies such as



effective teamwork and communication, institutionalizing a culture of safety, providing patient-centered care, and using evidence-based practice with the objective of managing uncertainty and the goal of improvement.

All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability; and to improve the health and functioning of the people of the United States. For this recommendation to be realized, health care has to achieve six aims: to be safe, effective, patient-centered, timely, efficient, and equitable.

Health care for the 21st century needs to be redesigned, ensuring that care be based on a continuous healing relationship, customized inclusion of patient needs and values, focused on the patient as the source of control, and based on shared knowledge and the free flow of information. Patient-centered care would improve health outcomes and reduce or eliminate any disparities associated with access to needed care and quality.

### **Patient-Centered Care**

Patient-centered care is considered to be interrelated with both quality and safety. The role of patients as part of the “team” can influence the quality of care they receive and their outcomes. Clinicians must partner with patients (and the patient’s family and friends, when appropriate) to realize informed, shared decision-making, improve patient knowledge, and inform self-management skills and preventive behaviors. Patients seek care from competent and knowledgeable health professionals to meet their physical and emotional needs. Within this framework, the clinician’s recommendations and actions should be customized to the patient and informed by an understanding of the patient’s needs, preferences, knowledge and beliefs, and when possible, enhance the patient’s ability to act on the information provided. It follows then that an effective clinician-patient partnership should include informed, shared decision-making and development of patient knowledge and skills needed for self-management of chronic conditions.

Patients and families have been and are becoming more involved in their care. Patients who are involved with their care decisions and management have better outcomes than those patients who are not. Patient self-management, particularly for chronic conditions, has been shown to be associated with improvements in quality of life and health status, decreased utilization of services, and improved physical activity.

Patient-centeredness is increasingly recognized as an important professional evolution and holds enormous promise for improving the quality and safety of health care. Yet, patient-centered care has not become the standard of care throughout care systems and among all clinicians. For patient-centered care to

become the “standard”, care processes need to be redesigned and the roles of clinicians need to be modified to enable effective teamwork and collaboration throughout care settings.

### **Teamwork and Collaboration**

It is nonsensical to believe that one group or organization or person can improve the quality and safety of health care in this Nation. In that patient safety is inextricably linked with communication and teamwork, there is a significant need to improve teamwork and communication. The Joint Commission has found communication failures to be the primary root cause of more than 60 percent of sentinel events reported. Ineffective communication or problems with communication can lead to misunderstandings, loss of information, and the wrong information. There are many strategies to improve interdisciplinary collaboration, including using multidisciplinary teams as a standard for care processes.

Interprofessional and intraprofessional collaboration, through multidisciplinary teams, is important in the right work environments. Skills for teamwork are considered non-technical and include leadership, mutual performance monitoring, adaptability, and flexibility. Teamwork and interdisciplinary collaboration have the potential to mitigate error and increase system resilience to error. Clinicians working in teams will make fewer errors when they work well together, use well-planned and standardized processes, know team members’ and their own responsibilities, and constantly monitor team members’ performance to prevent errors before they could cause harm. Teams can be effective when members monitor each other’s performance, provide assistance and feedback when needed, and when they distribute workloads and shift responsibilities to others when necessary.

The importance of training members to work effectively in multidisciplinary teams to achieve high reliability in patient (e.g., no adverse events) and staff outcomes (e.g., satisfaction working with team members and improved communication) are especially significant when team members are given formal training to improve behaviors. Conversely, lack of effective teamwork, such as poor communication and collaboration within and between disciplines, have been found to have negative effects on patient outcomes (e.g., surgical errors) and higher mortality. Poor teamwork as well as disrespectful, rude, and insulting behaviors have no place in health care and can potentially increase unsafe practices.

### **Leadership**

The work environment, communication and collaboration among clinicians, and decision-making are also linked to leadership and management within health care organizations. The performance of organizations and the use of evidence in practice are factors dependent upon leadership, particularly among middle/unit-

based clinical management. The personality and attitudes of leaders has been shown to have an impact on safety and on perceptions about how safety is managed. Visible, supportive, and transformational leadership to address clinical practice and work environment issues is critical as is leadership to ensure that the work environment supports caregivers and fosters collaborative partnerships.

Unfortunately, giving encouragement is not generally stated as a high-priority role of health care supervisors. Traditionally, technical skills and productivity on the job were aspects that received the supervisor's primary focus. However, there is a growing appreciation that encouragement is a transformational leadership technique that is related to productivity on the job and to quality work. Use of encouragement is a leadership technique that fits in today's people-oriented work climate.

### **A Culture of Safety**

The creation of cultures of safety within all health care organizations is critically important. A safety culture is defined as “the product of the individual and group values, attitudes, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety programs. An organization’s culture is based on its history, its mission and goals, and its past and current leadership. Organizations with a positive safety culture are characterized by communication guided by mutual trust, shared perceptions of the importance of safety, and confidence that error-preventing strategies would work.

Organizational climate refers to the atmosphere of aggregate attitudes and perceptions of how individuals feel about their places of work, which are associated with both individual and team motivation and satisfaction. The climate within an organization represents a moveable set of perceptions related to conditions within the workplace which can be changed by the values, attributes, skills, actions, and priorities of organization leaders and managers. A safety climate is a type of organizational culture and is the result of effective interplay of structure and processes factors and the attitude, perception, and behavior of staff related to safety. A climate of safety is represented by employee perceptions of: the priority of safety within the work environment on their unit and across the organization, and is influenced by management decisions; safety norms and expectations; and safety policies, procedures, and practices within the organization.

It follows then that the higher the safety culture, the safer and better the quality of care. Researchers have compared the safety cultures of hospitals to the aviation industry—which has been associated with high safety cultures—and found that the safety climate in hospitals was worse; and within hospitals, the safety culture was worse in operating rooms and emergency departments. The perception of safety within a hospital has been found to be more positive among leaders and

managers than among those directly involved in care. The perceptions of hospital staff of the patient safety culture have also been found to be associated with empowerment.

Additionally, more errors are found in organizations with poor safety cultures. In fact, some researchers found that the safety climate predicted the occurrence of medication errors, that the level of safety was associated with the unit-specific and hospital-wide climates, and that a positive safety climate in a unit could compensate for the detrimental effects of a low hospital-wide climate.

Developing and transitioning to a culture of safety requires strong, committed leadership by executives, hospital boards, and staff. The essential elements of an effective safety culture include the commitment of leadership to safety and empowering and engaging all employees in ongoing vigilance through communication, nonhierarchical decision-making, constrained improvisation, training, and rewards and incentives. Creating such a patient safety culture also requires the following components: (1) a reporting culture, (2) a flexible culture, (3) a learning culture, (4) a wary culture, and (5) a just culture.

It should be understood that changing the culture within an organization is difficult and can happen only over time. Historically, clinicians have been blamed if they were involved in an error/adverse event because they stood between errors. Thus, for health care providers to not be at the sharp end of blame, it is important for organizational leaders and managers to establish a just culture that values reporting, where errors can be reported without fear of retribution; where staff can trust leaders to make a distinction between blameless and blameworthy; and where the organization seeks to ferret out the root causes of that error, focusing on systems and process factors. Just as important, organizational leaders, managers, and staff need to learn from the continuous assessment of safety culture and make efforts to continually improve organizational performance and demonstrate success in safety improvements.

If an organization's culture is based on secrecy, defensive behaviors, professional protectionism, and inappropriate deference to authority, the culture invites threats to patient safety and poor-quality care. Several factors can impede the development of a culture of safety, including:

- a clinician's tendency to view errors as failures that warrant blame
- the focus of training on rules rather than knowledge
- punishing the individual rather than improving the system
- assuming that if a patient was not injured, that no action is required.

Each of these factors stems from organizations and the people in them having unrealistic expectations of clinical perfection, refusing to accept the fallibility of humans, and discounting the benefit of effective multidisciplinary teams.

Changing an organization's culture of safety should begin with an assessment of the current culture, followed by an assessment of the relationship between an organization's culture and the health care quality and safety within the organization. Several tools have been developed to measure the safety culture within organizations to inform specific interventions and opportunities for improvement. They have focused on dimensions of a patient safety climate, including leadership and management (e.g., personality and attitudes), teamwork, communication, staffing, attitudes/perceptions about safety, responses to error, policies, and procedures. Some of these tools could be used for individual or team assessment, or to compare organization-wide perceptions or unit-specific perceptions. A recent tool that was developed can be used to differentiate patient from staff safety and types of clinicians. Another of these tools ([www.ahrq.gov/qual/hospculture/#toolkit](http://www.ahrq.gov/qual/hospculture/#toolkit)) has been used to compare safety cultures among hospitals.

### **The Challenge of Change**

The question has been whether efforts to improve the quality and safety of care have been moving quickly enough. Many leaders have raised concern that clinicians, administrators, policymakers, and researchers have not been moving quickly enough toward safe care.

Organizations such as the Institute of Medicine (IOM), Agency for Healthcare Research and Quality (AHRQ), the Joint Commission, and Centers for Medicare & Medicaid Services (CMS) have been emphasizing the need for significant improvements in quality and patient safety. Yet depth and breadth of organizational quality and safety improvement changes are variable. Organizations need to be flexible to keep pace with the rapid changes in health care and the growing evidence base. To do so, they need to be willing to adopt new knowledge and innovations, which entails a social and political process, which nearly always involves debate and reference to others' views, a process that needs to include all leaders, managers, and staff.

Employees within organizations, particularly clinical leaders and staff, need to redesign care processes and revisit the roles and responsibilities of team members. Several organizations have reported difficulties in improving patient safety because of the need for transparency in reporting on performance measures, lack of standardization and functionality of information technology, and no clear pathway identified for improvement. Other difficulties could be associated with the results of the improvement initiative itself. For example, the introduction of computerized provider order entry systems for medication therapy prevents some errors from happening (e.g., related to illegible handwriting), but introduces other errors that might be avoided with better implementation strategies.

There are many change strategies, from single focus to multifaceted, that center on a structural approach and have been used successfully to create quality and patient safety improvements. One approach would be to implement bundles of evidence-based interventions to simultaneously improve multiple outcomes, using health information technology when possible. Other strategies have focused on the components of the change process that need to be addressed.

Successful quality improvement strategy is based on the alignment of the goals of the organization with goals for quality and patient safety improvement, collaboration using interdisciplinary teams, applying evidence-based practice, and monitoring and assessing excellence. Quality improvement strategies that align with the values and beliefs of individuals and build on current processes can determine the pace and diffusion of change.

While organizations' characteristics differ, as do characteristics of leaders and managers, success can be realized through continuous improvement with careful attention to finding a balance that avoids so much change that change fatigue results. Improvements must target organizational factors by using information technologies, developing effective teams, standardizing procedures with evidence, and using data and information to monitor performance. Focusing on the role, the influence, and the complexity of health care systems by thinking about the "big picture" involves understanding how a specific issue or outcome of concern interacts with numerous factors, both within and external to the system. In doing so, it may be more feasible to solve recurring problems with ineffective processes and poor outcomes, even when previous attempts have failed.

For health care systems and organizations to improve safety and quality, they need to learn to improve existing knowledge and processes, understand what is and is not working well, and both adopt and discover better ways to improve patient outcomes.

Organizational changes should be targeted using multifaceted strategies and interventions that focus on redesigning structural factors (e.g., staffing levels, roles and responsibilities of nurses, etc.), revising policies and procedures, and using multidisciplinary teams. Because the factors and issues involved in patient safety and quality improvement are complex, mirroring the complexity of health care systems, no one single intervention will accomplish performance goals and standards. Using a systematic approach to changing practice based on evidence when possible is required to improve patient safety and contribute to the evidential knowledge base and generalizability that can be used eventually for purposes of diffusion. Improving the quality and safety of health care may require the use of mixed or multiple methodologies to continually monitor and evaluate the impact and performance, because no one single method would be expected to be appropriate for the depth and breadth of change interventions.

Change can be slow because it is a process that involves many people and issues. Efforts to improve quality and safety need champions throughout the key areas within the organization as well as executive and midlevel managers. Champions can also be found among individuals for whom adverse events have had incredible impact on their lives. It would follow then that when an opportunity is present to adopt new knowledge and evidence into practice, that individual professionals and professional groups have the power to impede or to facilitate the diffusion process. Adoption of new knowledge and evidence for change is a process that needs leadership involvement and support, fostering effective relationships and enabling action, utilizing ongoing monitoring and evaluation, and demonstrating flexibility according to findings from evaluation and changing needs. Yet the effect of this could be mitigated by the commitment and direction of senior leadership, who co-lead/co-coach with clinical leaders to use evidence in practice, and to continuously evaluate progress and make changes accordingly, to therefore improve organizational performance and patient outcomes.

For changes of care processes to be effective, interventions must not be first-order, short-term problem-solving that offers quick fixes but not lasting change. Instead, second-order problem-solving should be used, where the underlying causes and processes are examined. Even when processes and procedures have changed and demonstrated positive effects on patient outcomes, there is a concern about sustainability over time because the tendency of health care providers to deliberately deviate from the new standard of practice may be unavoidable. Ongoing monitoring and management of these new processes and procedures is required. How do you institutionalize change? Change initiatives are successful when they are built on the current way of doing things, are visible and have positive outcomes, are consistent with employees' values and beliefs, are manageable, and are generalizable to the organization.

### **Basic Concepts in Patient Safety**

Opportunities to improve safety have been drawn from numerous disciplines such as engineering, psychology, and occupational health. The IOM report brought together what had been learned in these fields and then applied the opportunities to health care, as described in the nine categories that follow.

#### **1. User-Centered Design**

Understanding how to reduce errors depends on framing likely sources of error and pairing them with effective ways to reduce them. The term “user-centered design” builds on human strengths and avoids human weaknesses in processes and technologies. The first strategy of user-centered design is to make things visible (including the conceptual model of the process) so that the user can determine what actions are possible at any moment, for example, how to return

to an earlier step, how to change settings, and what is likely to happen if a step in a process is skipped. Another principle is to incorporate affordances, natural mappings, and constraints into health care. Although the terms are strange, their meaning can be surprisingly easily applied to common everyday tasks, both in and out of the workplace.

An affordance is a characteristic of equipment or workspace that communicates how it is to be used, such as a push bar on an outward opening door that shows where to push or a telephone handset that is uncomfortable to hold in any but the correct position. Marking the correct limb for before surgery is an affordance that has been widely adopted. Natural mapping refers to the relationship between a control and its movement, for example, in steering a car to the right, one turns the wheel right. Other examples include using louder sound or a brighter light to indicate a greater amount.

Constraints and forcing functions guide the user to the next appropriate action or decision. A constraint makes it hard to do the wrong thing. A forcing function makes it impossible to do the wrong thing. For example, one cannot start a car that is in gear. Forcing functions include the use of special locks for syringes and indwelling lines that have to be matched before fluid can be infused, and different connections for oxygen and other gas lines to prevent their being inadvertently switched. Removing concentrated potassium chloride from patient units is a (negative) forcing function because it should never be administered undiluted, and preparation should be done in the pharmacy.

## 2. Avoid Reliance on Memory

The next strategy is to standardize and simplify the structure of tasks to minimize the demand on working memory, planning, or problem-solving, including the following two elements:

**Standardize process and equipment.** Standardization reduces reliance on memory and allows newcomers who are unfamiliar with a given process or device to do the process or use a device safely. For example, standardizing device displays (e.g., readout units), operations, and doses is important to reduce the likelihood of error. Other examples of standardizing include standard order forms, administration times, prescribing protocols, and types of equipment. When devices or medications cannot be standardized, they should be clearly distinguishable. For example, one can identify look-alike, but different, strengths of a narcotic by labeling the higher concentration in consistent ways, such as by shape and prominent labeling. When developed, updated, and used wisely, protocols and checklists can enhance safety. Protocols for the use of anticoagulants and perioperative antibiotics have gained widespread acceptance. Laminated dosing cards that include standard order times, doses of antibiotics, formulas for calculating pediatric



doses, and common chemotherapy protocols can reduce reliance on memory.

**Simplify key processes.** Simplifying key processes can minimize problem-solving and greatly reduce the likelihood of error. Simplifying includes reducing the number of steps or handoffs that are needed. Examples of processes that can usually be simplified are writing an order, then transcribing and entering it in a computer, or having several people record and enter the same data in different databases. Other examples of simplification include limiting the choice of drugs and dose strengths available in the pharmacy, maintaining an inventory of frequently prepared drugs, reducing the number of times a day a drug is administered, keeping a single medication administration record, automating dispensing, and purchasing equipment that is easy to use and maintain.

### **3. Attend to Work Safety**

Conditions of work are likely to affect patient safety. Factors that contribute to worker safety in all industries include work hours, workloads, staffing ratios, sources of distraction, and shift changes (which affect one's circadian rhythm). Systematic evidence about the relative importance of various factors is growing with particular emphasis on health care staffing.

### **4. Avoid Reliance on Vigilance**

Individuals cannot remain vigilant for long periods of time. Approaches for reducing the need for vigilance include providing checklists and requiring their use at regular intervals, limiting long shifts, rotating staff, and employing equipment that automates some functions. The need for vigilance can be reduced by using signals such as visual and auditory alarms. Also, well-designed equipment provides information about the reason for an alarm. There are pitfalls in relying on automation, if a user learns to ignore alarms that are often wrong, becomes inattentive or inexperienced in a given process, or if the effects of errors remain invisible until it is too late to correct them.

### **5. Train Concepts for Teams**

People work together throughout health care in multidisciplinary teams, whether in a practice; for a clinical condition; or in operating rooms, emergency departments, or ICUs. In an effective interdisciplinary team, members come to trust one another's judgments and expertise and attend to one another's safety concerns. Whenever it is possible, training programs and hospitals should establish interdisciplinary team training.

## **6. Involve Patients in Their Care**

Whenever possible, patients and their family members or other caregivers should be invited to become part of the care process. Clinicians must obtain accurate information about each patient's medications and allergies and make certain this information is readily available at the patient's bedside. In addition, safety improves when patients and their families know their condition, treatments (including medications), and technologies that are used in their care.

At the time of discharge, patients should receive a list of their medications, doses, dosing schedule, precautions about interactions, possible side effects, and any activities that should be avoided, such as driving. Patients also need clear written information about the next steps after discharge, such as follow-up visits to monitor their progress and whom to contact if problems or questions arise.

Family caregivers deserve special attention in terms of their ability to provide safe care, manage devices and medication, and to safely respond to patient needs. Yet they may, themselves, be affected by physical, health, and emotional challenges; lack of rest or respite; and other responsibilities (including work, finances, and other family members).

Attention is now being given to problems resulting from lack of patient and family health literacy. For example, information may be too complex to absorb or in a language unfamiliar (even to educated and English-speaking patients)—and frightening. A simple example is rapidly given instructions on home care of a Foley catheter when, as often occurs, the patient is being discharged shortly after surgery and knows nothing about sterile technique or the design of the device. Another ubiquitous example is the warnings and dosage information on medication bottles, which many patients cannot understand how to apply.

## **7. Anticipate the Unexpected**

The likelihood of error increases with reorganization, mergers, and other organization-wide changes that result in new patterns and processes of care. Some technologies, such as computerized physician order entry systems (CPOE), are engineered specifically to prevent error. Despite the best intentions of designers, however, all technology introduces new errors, even when its sole purpose is to prevent errors. Indeed, future failures cannot be forestalled by simply adding another layer of defense against failure. Safe equipment design and use depend on a chain of involvement and commitment that begins with the manufacturer and continues with careful attention to the vulnerabilities of a new device or system. Health care professionals should expect any new technology to introduce new sources of error and should adopt the custom of automating cautiously, always alert to the possibility of unintended harm, and should test these technologies with users and modify as needed before widespread implementation.

## **8. Design for Recovery**

The next strategy is to assume that errors will occur and to design and plan for recovery by duplicating critical functions and by making it easy to reverse operations and hard to carry out nonreversible ones. If an error occurs, examples of strategies to mitigate injury are keeping antidotes for high-risk drugs up to date and easily accessible and having standardized, well-rehearsed procedures in place for responding quickly to adverse events. Another strategy is to use simulation training, where learners practice tasks, processes, and rescues in lifelike circumstances using models or virtual reality.

## **9. Improve Access to Accurate, Timely Information**

The final strategy for user-centered design is to improve access to information. Information for decision-making (e.g., patient history, medications, and current therapeutic strategies) should be available at the point of patient care. Examples include putting lab reports and medication administration records at the patient's bedside and putting protocols in the patient's chart. In a broader context, information is coordinated over time and across settings.

## **Communication and Team Collaboration**

Communication failures are the leading root cause of the sentinel events. Lack of communication creates situations where medical errors can occur. These errors have the potential to cause severe injury or unexpected patient death.

In today's health care system, delivery processes involve numerous interfaces and patient handoffs among multiple health care practitioners with varying levels of educational and occupational training. During the course of a 4-day hospital stay, a patient may interact with 50 different employees, including physicians, nurses, therapists, and others. Effective clinical practice thus involves many instances where critical information must be accurately communicated. Team collaboration is essential. When health care professionals are not communicating effectively, patient safety is at risk for several reasons: lack of critical information, misinterpretation of information, and overlooked changes in status.

Collaboration in health care is defined as health care professionals assuming complementary roles and cooperatively working together, sharing responsibility for problem-solving and making decisions to formulate and carry out plans for patient care. Collaboration between physicians, nurses, therapists, and other health care professionals increases team members' awareness of each other's type of knowledge and skills, leading to continued improvement in decision making.

Effective teams are characterized by trust, respect, and collaboration.

When considering a teamwork model in health care, an interdisciplinary approach should be applied. Unlike a multidisciplinary approach, in which each team member is responsible only for the activities related to his or her own discipline and formulates separate goals for the patient, an interdisciplinary approach facilitates a joint effort on behalf of the patient with a common goal from all disciplines involved in the care plan. The pooling of specialized services leads to integrated interventions. The care plan takes into account the multiple assessments and treatment regimens, and it packages these services to create an individualized care program that best addresses the needs of the patient. The patient finds that communication is easier with the cohesive team, rather than with numerous professionals who do not know what others are doing to manage the patient.

It is important to point out that fostering a team collaboration environment may have hurdles to overcome: additional time; perceived loss of autonomy; lack of confidence or trust in decisions of others; clashing perceptions; territorialism; and lack of awareness of one provider of the education, knowledge, and skills held by colleagues from other disciplines and professions. However, most of these hurdles can be overcome with an open attitude and feelings of mutual respect and trust.

### **Components of Successful Teamwork**

- Open communication
- Non-punitive environment
- Clear direction
- Clear and known roles and tasks for team members
- Respectful atmosphere
- Shared responsibility for team success
- Appropriate balance of member participation for the task at hand
- Acknowledgment and processing of conflict
- Clear specifications regarding authority and accountability
- Clear and known decision making procedures
- Regular and routine communication and information sharing
- Enabling environment, including access to needed resources
- Mechanism to evaluate outcomes and adjust accordingly

Unfortunately, many health care workers are used to poor communication and teamwork, as a result of a culture of low expectations that has developed in many health care settings. This culture, in which health care workers have come to expect faulty and incomplete exchange of information, leads to errors because even conscientious professionals tend to ignore potential red flags and clinical discrepancies. They view these warning signals as indicators of routine repetitions of poor communication rather than unusual, worrisome indicators.

Although poor communication can lead to tragic consequences, effective communication can lead to the following positive outcomes: improved information flow, more effective interventions, improved safety, enhanced employee morale, increased patient and family satisfaction, and decreased lengths of stay.

### **Barriers to Effective Communication**

Health professionals tend to work autonomously, even though they may speak of being part of a team. Efforts to improve health care safety and quality are often jeopardized by the communication and collaboration barriers that exist between clinical staff. Some of the more common barriers to inter-professional communication and collaboration include:

- Personal values and expectations
- Personality differences
- Hierarchy
- Disruptive behavior
- Culture and ethnicity
- Generational differences
- Gender
- Historical inter-professional and intra-professional rivalries
- Differences in language and jargon
- Differences in schedules and professional routines
- Varying levels of preparation, qualifications, and status
- Differences in requirements, regulations, and norms of professional education
- Fears of diluted professional identity
- Differences in accountability, payment, and rewards
- Concerns regarding clinical responsibility
- Complexity of care
- Emphasis on rapid decision making

Creating opportunities for different groups to just get together is a highly effective strategy for enhancing collaboration and communication. These group interactions can be either formal or informal. Encouraging open dialogue, collaborative rounds, implementing pre-op and post-op team briefings, and creating interdisciplinary committees or task forces that discuss problem areas frequently provides an upfront solution that reduces the likelihood of disruptive events.

### **Reporting Errors**

Reporting errors is fundamental to error prevention because it holds providers accountable for performance and provides information that leads to improved safety. Conceptually these purposes are not incompatible, but in reality, they can

prove difficult to satisfy simultaneously. Nonetheless, reporting potentially harmful errors that were mitigated before harm was done, errors that did not cause harm, and near-miss errors is as important as reporting the ones that do harm patients. Patient safety initiatives target systems-related failures that contribute to errors within the complex environment of health care. Because many errors are never reported voluntarily or captured through other mechanisms, these improvement efforts may fail.

Errors that occur either do or do not harm patients and reflect numerous problems in the system, such as a culture not driven toward safety and the presence of unfavorable working conditions. To effectively avoid future errors that can cause patient harm, improvements must be made on the underlying, more-common and less-harmful systems problems most often associated with near misses. Systems problems can be detected through reports of errors that harm patients, errors that occur but do not result in patient harm, and errors that could have caused harm but were mitigated in some manner before they ever reached the patient. Reporting near misses (i.e., an event/occurrence where harm to the patient was avoided), which can occur 300 times more frequently than adverse events, can provide invaluable information for proactively reducing errors. Analysis of reported errors have revealed many “hidden dangers” (near misses, dangerous situations, and deviations or variations) that point to system vulnerabilities, not intentional acts of clinician performance that may eventually cause patients harm.

Just because an error did not result in a serious or potentially serious event does not negate the fact that it was and still is an error. Since reporting both errors and near misses has been key for many industries to improve safety, health care organizations and the patients they serve can benefit from enabling reporting. Reporting sets up a process so that errors and near misses can be communicated to key stakeholders. Once data are compiled, health care agencies can then evaluate causes and revise and create processes to reduce the risk of errors. As such, organizations have implemented strategies, such as staff education, elicitation of staff advice, and budget appropriations, to ease the implementation of patient safety systems and to improve internal reporting and disclosure to patients and families.

Health care providers are typically so devastated and embarrassed by their mistakes that they may attempt to conceal them or defend themselves by shifting the blame to someone or something else. Some attribute failure of honestly acknowledging health care mistakes to providers’ personal difficulty with admitting mistakes and incriminating other providers. Ethical frameworks operate when health care mistakes are made. Respect for patient autonomy is paramount, as is the importance of veracity. Fidelity, beneficence, and nonmaleficence are all principles that orient reporting and disclosure policies. Providers might benefit from accepting responsibility for errors, reporting and

discussing errors with colleagues, and disclosing errors to patients and apologizing to them.

When providers tell the truth, practitioners and patients share trust. The fiduciary responsibility of institutions exists in patients' and families' trust that providers will take care of them. If providers cover up errors and mistakes, they do not necessarily stay hidden and often result in compromising the mission of health care organizations. Consistent with their mission, institutions have an ethical obligation to admit clinical mistakes. Professional and organizational policies and procedures, risk management, and performance improvement initiatives demand prompt reporting. When patients, families, and communities do not trust health care agencies, suspicion and adversarial relationships result. Likewise, the breach of the principle of fidelity or truthfulness by deception damages provider-patient relationships. Fidelity and trust, implicit to the provider-patient relationship, do not coexist with deception.

Health care providers have legal and ethical obligation to report risks, benefits, and alternative treatments through informed consent mandates. Legal self-interest and vulnerability after errors are committed must be tempered by the principle of fidelity (truthfulness and loyalty). This ethical principle has been reinforced by practical lessons learned from errors; especially when an adverse event causes serious harm or even death, there is an ethical and moral obligation to disclose information. Candid reports and disclosure of errors by physicians as well as other health care providers (or institutional leadership if the physician refuses to disclose) might result in greater patient trust and less litigation. Furthermore, it is essential to act after errors are reported, with interventions aimed at protecting the welfare of patients by targeting iatrogenic problems and documenting the care given.

Additionally, the ethical principles of beneficence (doing good) and nonmaleficence (preventing harm) are violated when errors are not reported or disclosed. These ethical principles, beneficence and nonmaleficence, shape caring practice, and caring presupposes that providers act in the best interests of patients. For example, sharing information and preventing harm to patients through truth telling, regardless of good or bad news, build relationships between elder residents and nursing home staff. Thus, failure to disclose health care mistakes can be viewed from the perspective of provider control over the rights of patients or residents.

### **Barriers to Error Reporting**

Many errors go unreported by health care workers. The major concern they have is that self-reporting will result in repercussions. Providers' emotional responses to errors inhibit reporting, yet some are relieved when they share the events of the error with patients. Health care professionals report feeling worried, guilty, and depressed following serious errors, as well as being concerned for patient

safety and fearful of disciplinary actions. They also are aware of their direct responsibility for errors. Many clinicians accept responsibility and blame themselves for serious-outcome errors. Similarly, physicians responded to memorable mistakes with self-doubt, self-blame, and shame. The need of clinicians for support may be fulfilled by discussing their mistake with another person. However, many received support most often from spouses rather than colleagues. Instead of bearing the pain of mistakes in silence, clinicians should admit them, share them with peers, and dispel the myth of perfect practice. However, this support might keep disclosure within the disciplinary culture and practice of medicine rather than bringing mistakes to multidisciplinary teams.

Self-reporting errors can be thwarted by several factors.

First, clinicians fear career-threatening disciplinary actions and possible malpractice litigation and liability. Health care leaders who do not protect reporters of errors from negative consequences reinforce this fear, as does the criminalization of fatal health care mistakes. Fear of these negative consequences can lead to reporting errors only when a patient is harmed or when the error could not be “covered up”; yet more health care providers are vulnerable to legal action if detailed error reports are documented for events that could formerly be concealed. Additionally, the moral residue of previous mistakes may also restrict disclosure of errors. This residue could be replaced in providers’ memories by efforts encouraging reporting in a non-punitive milieu and incorporating the systems improvements that follow. Clinicians do not want to intentionally harm patients; yet when they conceal errors, they place patients at increased risk of some type of harm.

Second, clinicians working in a culture of blame and punishment do not report all errors, primarily because they fear punishment. A long-held tradition in health care is the “name you, blame you, shame you” mantra. Many organizations have been challenged to provide an environment in which it is safe to admit errors and understand why the errors occurred. Fears of reprisal and punishment have led to a norm of silence. But silence kills, and health care professionals need to have conversations about their concerns at work, including errors and dangerous behavior of coworkers. Among health care providers, individual blame has been the predominant reaction for errors. When individuals and organizations are able to move from individual blame toward a culture of safety, where the blame and shame of errors is eliminated and reporting is rewarded, organizations are enabled to institutionalize reporting systems and increase reporting of all types of errors. To do so, clinicians and others must know that safety can be improved by non-punitive reporting of error and that organizational flaws cause errors. As communication, collaboration, and safety are inextricably linked in the pursuit of quality care, risk managers, safety officers, and other leaders in health care institutions are encouraging the development of a culture of safety. In a culture of safety, open communication facilitates reporting and disclosure among



stakeholders and is considered the norm. Yet even in organizations with a culture of safety, creating a non-punitive environment is a work in progress.

Third, there is significant variation in how errors are defined, what information is reported, and who should be involved in reporting and mitigating the effects of errors. Differing definitions of errors and near misses and significant differences in reporting—among health care providers working in the same institution and across health care systems—make it difficult to act and prevent similar errors. One of the greatest challenges confronting the patient safety movement is agreeing on standard definitions of what constitutes errors. Reporting near misses can facilitate a blame-free approach (a hallmark of a culture of safety) and fewer cultural and psychological barriers. Yet, clinicians who believe that an error or near miss was unimportant or caused no harm, especially if intercepted, might decide that a report of a near miss is not warranted; near misses are not frequently reported.

Lastly, error reports are difficult to complete, and feedback about needed system changes to improve safety is not commonly given. The lack of standardization in the information that is reported and collected makes comparisons and trending as well as preventing future errors difficult. Implementing and using standardized reports of error events, such as those available in hospital databases, is just one example of an open communication strategy, benefiting both clinicians and ultimately the patients they serve. However, the process for reviewing events is not consistently applied nor conducted in a manner conducive to providing feedback and improving safety.

These and other barriers to reporting and disclosing errors must be breached to accomplish safer health care. Reporting errors and near misses through established systems provides opportunities to prevent future similar, and perhaps even more serious, errors. Failure to report and speak up about errors and near misses is unacceptable because the welfare of patients is at stake. Investigations into the reporting behaviors of clinicians have found that clinicians are more likely to report an error if the patient was not harmed. Clinicians would also be likely to report an error made by a colleague regardless of patient harm.

Several factors are necessary to increase error reporting: having leadership committed to patient safety; eliminating a punitive culture and institutionalizing a culture of safety; increasing reporting of near misses; providing timely feedback and follow-up actions and improvements to avert future errors; and having a multidisciplinary approach to reporting. Only through reporting errors can health care providers learn which system design and operational failures contribute to human fallibilities and subsequently improve the quality of care.

## Error Disclosure

Disclosure of health care errors is not only another type of error reporting; it is also an account of a mistake. It involves an admission that a mistake was made and typically, but not exclusively, refers to a provider telling a patient about mistakes or unanticipated outcomes. Disclosure addresses the needs of the recipient of care (including patients and family members). However, while providers' willingness to disclose errors may be stimulated by accountability, honesty, trust, and reducing risk of malpractice, clinicians may hesitate to disclose because of professional repercussions, humiliation, guilt, and lack of anonymity.

Disclosure also sometimes calls for a formal verbal apology, in some institutions presented in writing by patient safety officers. Often the providers involved in the error apologize. The central element of disclosure is the trust relationship between patients (or residents of long-term care facilities) and health care providers. Agency policies specify the disclosure approach and identify the person—for example, the primary care provider or safety officer—who communicates the error, adverse event, or unanticipated outcome to the patient or resident or family member. Some institutions make error disclosure mandatory, and some disclose errors on a voluntary basis.

Providers are concerned about disclosure. They feel shame and fear about their mistakes. “Medical missteps” are transformed into clinical mistakes after practice standards are developed; next, malpractice suits follow. As a result, mistakes are subsequently hidden, creating a negative cycle of events. Furthermore, clinicians' anxiety about malpractice litigation and liability and their defensive behavior toward patients block individual and group strategies for preventing and reducing medical errors, thus hindering error reduction attempts.

When patients' concerns are not addressed, they are more unwilling to return for future care needs and follow medical advice, and are more likely to seek malpractice lawsuits. Several surveys of patients and the general public have found that they believe health care to be only moderately safe and that they are concerned about errors affecting them if they seek care in hospitals. Specifically, patients are concerned about misdiagnoses, physician errors, medication errors, nursing errors, wrong test/procedure errors, and problems with medical equipment.

Another dimension of reporting and disclosing errors is the role patients can have. Patients can understand, perceive the risk of, and are concerned about health care errors. As more is learned about errors, patients and clinicians have opportunities to improve health care quality. Patients want full disclosure and to know everything about medical errors that impact them. Disclosure can avert patients seeking another clinician and can improve patient satisfaction, trust, and positive emotional response to an error, as well as decrease the likelihood of

patients seeking legal advice following the error. Patients have the right to know; patients and the public strongly desire disclosure. Failure to disclose mistakes and unanticipated outcomes limits opportunities for evaluation of systems and processes, and for sharing knowledge gained by publishing safety alerts across organizations, conducting educational sessions, modifying practice, and offering opportunities for improved performance. Disclosure is also an element that contributes to the creation of a culture of safety and as such must be accepted as a strategy in health care institutions interested in becoming high-reliability organizations, “those in which error seldom occurs even in dangerous environments”.

A significant barrier to disclosing errors is the clinicians’ willingness to do so. This may in part be due to the lack of clarity as to exactly what should be disclosed, when the discussion should take place, and who (e.g., a hospital administrator, physician, or nurse) should disclose the error. When it comes to what should be disclosed, research has found that providers want to disclose only what had happened, but there are no universal rules for doing so. Decisions to disclose or not to disclose are complex and depend on how errors are defined and if they are recognized or detected. Health care providers are heavily influenced by their perceived professional responsibility, fears, and training, while patients are influenced by their desire for information, their level of health care sophistication, and their rapport with their provider.

Although there is no legal requirement to do so, both health care providers and patients seem to agree that disclosure of errors should take place whenever an adverse event occurs and a patient is harmed. Other research has found that the likelihood of disclosure increased as the severity of the error increased. Somewhat conflicting with this is the assertion that patients would suffer additional harm when “unnecessary” information was shared about a mistake. Unfortunately, this line of reasoning has its roots in the dubious contention that patients might be more harmed when told the truth as compared with disclosing the mistake.

Because there are instances when error disclosure has been followed by the “victims” seeking further action, the disclosure of errors in practice may not reflect all errors that have harmed patients, nor all those that could or should have been disclosed. In many instances, patients are less likely to seek legal action if the error is disclosed and if they do not suspect a cover-up. However, it is not known if there is a causal relationship between disclosure of errors and adverse consequences such as litigation.

### **Root Cause Analysis**

A retrospective approach to error analysis, called root cause analysis (RCA), is widely applied to investigate adverse events in medicine. RCA provides a

structured and process-focused framework with which to approach sentinel event analysis. Its cardinal tenet is to avoid the pervasive and counterproductive culture of individual blame. Systems and organizational issues can be identified and addressed, and active errors are acknowledged. Systematic application of RCA may uncover common root causes that link a disparate collection of accidents (i.e., a variety of serious adverse events occurring at shift change). Careful analysis may suggest system changes designed to prevent future incidents.

To be credible, RCA requires rigorous application of established qualitative techniques. Once a sentinel event has been identified for analysis, a multidisciplinary team is assembled to direct the investigation. The members of this team should be trained in the techniques and goals of RCA, as the tendency to revert to personal biases is strong. Multiple investigators allow triangulation or corroboration of major findings and increase the validity of the final results. Based on the concepts of active and latent error, root cause analysis is generally broken down into the following steps:

1. *Data collection*: establishment of what happened through structured interviews, document review, and/or field observation. These data are used to generate a sequence or timeline of events preceding and following the event.
2. *Data analysis*: an iterative process to examine the sequence of events generated above with the goals of determining the common underlying factors:
  - Establishment of how the event happened by identification of active failures in the sequence.
  - Establishment of why the event happened through identification of latent failures in the sequence which are generalizable.

To ensure consideration of all potential root causes of error, all factors influencing clinical practice must be reviewed. Categories include institutional/regulatory, organizational/management, work environment, team factors, staff factors, task factors, and patient characteristics. Each category can be expanded to provide more detail. A credible RCA considers root causes in all categories before rejecting a factor or category of factors as non-contributory. At the conclusion of the RCA, the team summarizes the underlying causes and their relative contributions, and begins to identify administrative and systems problems that might be candidates for redesign.

### **Pharmacological Components and Management in Therapy**

Therapists can play a vital role in reducing the frequency and severity of medical errors. The following recommendations outline some of the many ways that rehabilitation professionals can assist referring physicians with the pharmacological management of their patients.

1. Take a complete and accurate subjective history from each patient that includes:
  - A. All previous and current medical problems, noting any inconsistencies or omissions from previously reviewed medical records.
  - B. All current medications including dosage, frequency, and subjective side effects.
2. Collection of objective data which includes an assessment of all common therapy relevant pharmacological side effects associated with the medications the patient is taking.
3. Design safe and effective rehabilitation programs that address or accommodate for possible common pharmaceutical side effects.
4. Continuous monitoring and documentation of each patient's overall condition throughout their entire rehabilitation process.

Undoubtedly, the most important thing that any therapist can do is continuously communicate with the referring physician. Because therapists often times see the patient much more frequently than the physician does, it is imperative that they act as the doctor's eyes and ears concerning pharmaceutical management. Therapists should always notify the physician immediately if they suspect that the patient has not provided the doctor with complete or accurate information, if the patient appears to be experiencing side effects from the medication, or the medication is not effectively achieving the desired outcome.

## **Glossary**

### **Active Error**

Active errors are those taking place between a person and an aspect of a larger system at the point of contact. Active errors are made by people on the front line such as clinicians and nurses. For example, operating on the wrong eye or amputating the wrong leg are classic examples of an active error.

### **Adverse Event**

Adverse events may be preventable when there is a failure to follow accepted practice at a system or individual level.

- An adverse event attributable to an error usually is a preventable adverse event.
- An adverse event is a type of injury that most frequently is due to an error in medical or surgical treatment rather than the underlying medical condition of the patient.
- Not all adverse outcomes are the result of an error; hence, only preventable adverse events are attributed to medical error.

- An unintended injury is medical or surgical patient management that results in prolonged hospitalization, measurable physical disability, or both.
- An unintended injury or complication is the result of prolonged hospitalization or disability or is caused by factors inherent in the healthcare system rather than a disease.

### **Latent Error**

- These are errors in system or process design, faulty installation or maintenance of equipment, or ineffective organizational structure.
- These are present but may go unnoticed for a long time with no ill effect.
- When a latent error occurs in combination with an active human error, some type of event manifests in the patient.
- The active human error triggers the hidden latent error, resulting in an adverse event.
- Latent errors are basically "accidents waiting to happen." A classic example is a hospital with several types of chest drainage sets, all requiring different connections and setups, yet not all frontline clinicians and nurses are familiar with the intricacies of each setup, creating the scenario for potential error.

### **Medical Error**

- The failure to complete the intended plan of action or implementing the wrong plan to achieve an aim.
- An unintended act or one that fails to achieve the intended outcome.
- Deviations from the process of care, which may or may not result in harm.
- When planning or executing a procedure, the act of omission or commission that contributes or may contribute to an unintended consequence.

### **Negligence**

Failure to meet the reasonably expected standard of care of an average, qualified healthcare worker looking after a patient in question within similar circumstances. For example, the healthcare worker may not check up on the pathology report which led to a missed cancer, or the surgeon may have injured a nerve by mistaking it for an artery.

### **Negligent Adverse Events**

- A subcategory of preventable, adverse events that satisfy the legal criteria used in determining negligence.
- The injury caused by substandard medical management.

### **Near Miss**

- Any event that could have had an adverse patient consequence but did not.

- Potential adverse events that could have caused harm but did not, either by chance or because someone or something intervened.
- Near misses provide opportunities for developing preventive strategies and actions and should receive the same level of scrutiny as adverse events.

### **Never Events**

Errors that should not ever have happened. A classic example of a never event is the development of pressure ulcers or wrong-site surgery.

### **Noxious Episode**

Untoward events, complications, and mishaps that result from acceptable diagnostic or therapeutic measures deliberately instituted. For example, sending a hemodynamically unstable trauma patient for prolonged imaging studies instead of the operating room. The result could be a traumatic arrest and death.

### **Potentially Compensable Event**

An error that could potentially lead to malpractice claims. An event due to medical management that resulted in disability, and, subsequently, a prolonged hospitalization.

### **Root Cause**

A deficiency or decision that, if corrected or avoided, will eliminate the undesirable consequence.

Common root causes include:

- Changes in mental acumen including conducting healthcare in an automatic fashion, not seeking advice from peers, misapplying expertise, not formulating a plan, or not considering the most obvious diagnosis.
- Communication issues, having no insight into the hierarchy, having no solid leadership, not knowing whom to report the problem, failing to disclose the issues, or having a disjointed system with no problem-solving ability.
- Deficiencies in education, training, orientation, and experience.
- Inadequate methods of identifying patients, incomplete assessment on admission, failing to obtain consent, and failing to provide education to patients.
- Inadequate policies to guide healthcare workers.
- Lack of consistency in procedures.
- Inadequate staffing and/or poor supervision.
- Technical failures associated with medical equipment.
- No audits in the system.
- No one prepared to accept blame or change the system.

### **Sentinel Event**

The Joint Commission defines a "sentinel event" as “any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof...The phrase 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.” (The Joint Commission, 2017). Sentinel events are so called because, once discovered, they frequently indicate the need for an immediate investigation, discovery of cause, and response.

### **Supplemental Information**

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## Medical Errors – Physical Therapy

### Post-Test

1. An injury that results from medical management is called a(n) \_\_\_\_\_. (p. 3-4)
  - A. near miss
  - B. medical error
  - C. adverse event
  - D. sentinel event
2. A therapist accidentally drops an exercise weight onto a patient's foot causing an injury. This is an example of \_\_\_\_\_. (p. 4-5)
  - A. active failure
  - B. latent failure
  - C. technical failure
  - D. organizational / technical failure
3. A therapist routinely chooses not to use a policy mandated gait belt when performing transfer training activities with patients. This is an example of \_\_\_\_\_. (p. 6)
  - A. skill based error
  - B. rule based error
  - C. knowledge based error
  - D. None of the above
4. Which one of the following strategies is NOT part of a systems approach for improving safety in health care? (p. 6-9)
  - A. Patient-centered care
  - B. Teamwork & collaboration
  - C. Elimination of human error
  - D. A culture of safety
5. A button on a piece of equipment is labeled "Push Here to Start". This is an example of \_\_\_\_\_. (p. 15-16)
  - A. affordance
  - B. constraint
  - C. forcing function
  - D. natural mapping
6. \_\_\_\_\_ is the leading root cause of sentinel events. (p. 19)
  - A. Communication failure
  - B. Equipment malfunction
  - C. Surgical error
  - D. Clinical overutilization

7. Which of the following should be reported? (p. 21-23)
  - A. An error that results in harm to a patient.
  - B. A mitigated error that does not result in harm to a patient.
  - C. A near miss
  - D. All of the above
  
8. Which of the following regarding error disclosure is CORRECT? (p. 26-27)
  - A. Health care providers are legally required to disclose to patients all medical errors that may have contributed to an adverse event.
  - B. There is a strong causal relationship between disclosure of errors and patient litigation.
  - C. Neither A nor B is correct
  - D. Both A & B are correct
  
9. Which of the following is FALSE regarding root cause analysis? (p. 27-28)
  - A. RCA is a retrospective approach to error analysis.
  - B. RCA provides a structured and process-focused framework with which to approach sentinel event analysis.
  - C. RCA focuses on the assignment of systemic and individual blame.
  - D. Systems and organizational issues can be identified and addressed, and active errors are acknowledged.
  
10. The most important thing that a therapist can do to assist a physician with the pharmacological management of a patient is: (p. 28-29)
  - A. Carefully examine the patient's medication
  - B. Continuously communicate any adverse findings or responses with the referring physician.
  - C. Include medication management in all ADL training sessions
  - D. Alter the patient's medication dosage if side effects become too great.

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