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Contact Hours: 7

Medical Errors
Prevention and Patient Safety

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LEARNING OUTCOME AND OBJECTIVES: Upon completion of this course, you will understand current, evidence-based interventions to prevent medical errors in the practice setting. Specific learning objectives to address potential knowledge gaps include:

- Define medical errors and associated terminology.
- Discuss the scope of medical errors in the U.S. healthcare environment.
- Describe the causes of medical errors.
- Review the most common medical errors and strategies to prevent them.
- Summarize the elements of effective clinical communication and documentation.
- Identify populations with special vulnerability to medical errors.
- Describe various initiatives of the patient safety movement in healthcare.
- Discuss healthcare accrediting agency standards and goals as they relate to preventing medical errors.
- Outline institutional strategies to identify and reduce the risk of medical errors.

INTRODUCTION

It would seem obvious and essential that every healthcare encounter a person has should be safe and free from harm. Unfortunately, this is not always the case. Although the vast majority of Americans are having positive experiences with the healthcare system, many report having personally experienced a “medical error.” Errors occur in hospitals, clinics, surgery centers, dialysis centers, medical offices, dental offices, nursing homes, pharmacies, and even in patients’ homes—anywhere patients receive care.

Medical errors are a serious public health issue, with every patient involved in the healthcare system a potential recipient of harm. Injuries and death can occur, for example, when patients receive a wrong medication or dose of medication, experience mistakes in surgery, receive treatments meant for another patient, experience a fall in the hospital, develop a pressure injury, or are subjected to a misdiagnosis, misinterpreted medical order, or equipment failure.

Errors can occur at any point while in the healthcare system. Analyzing why medical errors happen has traditionally been focused on the human factor, concentrating on individual responsibility for making an error, and the solutions have involved training or retraining, additional supervision, or even disciplinary action. The alternative to this individual-centered approach is a system-centered approach, which assumes that humans are fallible and that systems must be designed so that humans are prevented from making errors.

Acknowledging that errors happen, learning from them, and working to prevent errors in the future are important goals and represent a major change in the culture of healthcare—a shift from blame and punishment to analysis of the root causes of errors and the creation of strategies to reduce the risk of errors. In other words, healthcare organizations must create a culture of safety that views medical errors as opportunities to improve the system. Every person on the healthcare team has a role in making healthcare safer for patients and workers (Rodziewicz et al., 2021).

DEFINING MEDICAL ERRORS

In 1999, the Institute of Medicine (IOM, 2000) defined a medical error as "the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)." Errors can include problems in practice, products, procedures, and systems.

In 2008 the National Patient Safety Foundation defined medical errors as unintended healthcare outcomes caused by a deficit in the delivery of care to a patient, noting that there are two major types of medical errors:

- Errors of **omission** that occur as a result of actions not taken. Examples may include failure to put on the brakes of a wheelchair before transferring a patient from bed to chair.

- Errors of **commission** are the result of taking the wrong action. Examples may include administering a medication to a patient who has a known allergy.
  (Rodziewicz et al., 2021)

Errors can be further described as **adverse events**. Important subcategories of adverse events include:

- **Preventable:** Adverse events that can be avoided by any means currently available unless the means is not considered standard care. Preventable adverse events involve care that falls below the standard expected of healthcare professionals in their community.

- **Unpreventable:** Adverse events that result from complications that cannot be prevented. Example: A patient not known to have an allergy has an allergic reaction to a drug that was appropriately prescribed, dispensed, and administered.

- **Ameliorable:** An event that is not preventable but for which the severity of the injury could have been substantially reduced if different actions or procedures had been performed or followed. Example: A clinician fails to respond to a patient with medication-related symptoms.
  (AHRQ, 2019a)

The most common adverse events reported in the literature are:

- Related to surgical specialties
- Medication- and fluid-related
- Healthcare-associated infections
  (Skelly et al., 2020)

Other Terminology Associated with Medical Errors

In addition to adverse events, other terms used to describe medical errors include *near misses*, *sentinel events*, and *never events*.

NEAR MISSES

A near miss is any event that could have had adverse consequences but did not and was indistinguishable from fully fledged adverse events in all but outcome. In a near miss, an error was committed, but the patient did not experience clinical harm, either through early detection or sheer luck. Example: A nurse recognizes a potential drug overdose in a physician's prescription and does not administer the drug but instead calls the error to the physician's attention (AHRQ, 2019a).

SENTINEL EVENTS

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from the events. A sentinel event is a safety event that reaches a patient and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm and intervention required to sustain life
  (TJC, 2021a)

Not all sentinel events occur because of an error, and not all medical errors result in sentinel events. Sentinel events can include:

- Suicide of any patient receiving care, treatment, or services in a staffed, around-the-clock care setting or within 72 hours of discharge, including from the emergency department
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, or services
- Any elopement of a patient from a staffed, around-the-clock care setting leading to death, permanent harm, or severe temporary harm of the patient
- Rape, assault, or homicide of any patient receiving care, treatment, or services, or any staff member, licensed independent practitioner, visitor, or vendor while on site
- Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for the patient
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia
- Prolonged fluoroscopy to a single field or any delivery of radiotherapy to the wrong body regions or delivery of the wrong radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital (staff do not need to be present)
- Any intrapartum maternal death
- Sexual abuse/assault involving a patient and another patient, staff member, or other perpetrator while being treated or on hospital premises
  (TJC, 2021a)

NEVER EVENTS

The National Quality Forum has compiled a set of 29 **serious reportable events (SREs)**, which are consequential, largely preventable, and harmful clinical events. This list is designed to help those in the healthcare field assess, measure, and report performance in providing safe care in a range of clinical settings. Also referred to as *never events* (events that should never happen), SREs are grouped into seven categories, as follows:

Surgical SREs

- Surgery/invasive procedure performed on the wrong site
- Surgery/invasive procedure performed on the wrong patient
- Wrong surgical/invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists class I patient (an otherwise healthy person with no medical problems beyond those which the proposed surgery is intended to address)

Product/Device SREs

- Patient death/serious injury associated with use of contaminated drugs, devices, or biologics provided by the healthcare setting
- Patient death/serious injury associated with use or function of a device in patient care where the device is used for functions other than as intended
- Patient death/serious injury associated with intravascular air embolism occurring while being cared for in a healthcare setting

Patient-Protective SREs

- Discharge or release of a patient/resident of any age who is unable to make decisions to other than an authorized person
- Patient death/serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm resulting in serious injury while being cared for in a healthcare setting

Care Management SREs

- Patient death/serious injury associated with a medication error involving:
    - Wrong drug
    - Wrong dose
    - Wrong patient
    - Wrong time
    - Wrong rate
    - Wrong preparation
    - Wrong route

- Patient death/serious injury associated with unsafe administration of blood products
- Maternal death/serious injury associated with labor or delivery in a low-risk pregnancy while in a healthcare setting
- Death/serious injury of a neonate associated with labor/delivery in a low-risk pregnancy
- Artificial insemination with the wrong donor sperm/wrong egg
- Patient death/serious injury associated with a fall while cared for in healthcare settings
- Any stage 3, stage 4, or unstageable pressure ulcer/injury acquired after admission/presentation to a healthcare facility
- Patient death/serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death/serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

Environmental SREs

- Patient/staff death/serious injury associated with electric shock in the course of a patient care process in a healthcare setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances
- Patient/staff death/serious injury associated with burns incurred from any source in the course of the patient care process in a healthcare setting
- Patient death/serious injury associated with the use of physical restraints/bedrails while cared for in a healthcare setting

Radiological SREs

- Patient/staff death/serious injury associated with the introduction of a metallic object into an MRI area

Potential Criminal SREs

- Any instance of care ordered or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting

(NQF, 2021a)

Active and Latent Errors

Active errors (human errors) are those that occur at the point of contact between a human and some aspect of a large system (e.g., a machine). They are generally readily apparent (e.g., pushing an incorrect button or ignoring a warning light) and almost always involve someone at the frontline. Active errors or active failures are sometimes referred to as errors "at the sharp end," referring figuratively to a scalpel. They are noticed first because they are committed by the person closest to the patient. Example: A surgeon amputates the wrong foot.

Latent errors refer to a less apparent failure of organization or design that contributes to the occurrence of errors or allows them to cause harm to patients. Latent errors are those at the other end of the scalpel, the "blunt end," referring to the many layers of the healthcare system that affect the person "holding the scalpel." They are errors in system or process design, faulty installation or maintenance of equipment, or ineffective organizational structure. They are accidents waiting to happen. Example: A hospital does not follow a consistent system for stocking central supply carts.

When a latent error combines with an active human error, an event occurs. Example: The hospital's lack of a consistent system for stocking central supply carts (latent error) may cause a nurse to select the wrong intravenous drip size tubing (active error), resulting in a drug overdose in a patient (AHRQ, 2019c).

CASE

St. Vincent Hospital

At St. Vincent Hospital all cylinders containing medical gases used in the operating room are stored in metal tubes in a tank room. All cylinders containing any concentration of carbon dioxide are color-coded grey and labeled "carbon dioxide." Beneath that, a continuation of the label identifies any other gas with which it is combined, such as oxygen. When the cylinders are in their metal tubes, the capped connecting neck and top several inches of each cylinder, as well as several inches of the top of the label, are visible above the top of the tube. (Since the full label is not visible, this is an example of a **latent error**.)

On Tuesday a delivery of medical gas cylinders containing CO_2 was accepted by a logistics technician from the cardiac catheterization lab. The delivery included at least one cylinder containing a CO_2/O_2 blend. As there was inadequate storage space for the entire delivery in the cath lab's tank room, the technician asked his counterpart in the OR to store an extra tank of the gas blend. The OR logistics technician agreed but did not inform anyone in his or the OR's chain of command.

On Thursday, during a routine laparoscopic cholecystectomy, the alarm for the pressure indicator in the gas delivery system sounded. The circulating nurse went to the tank room to obtain a cylinder replacement. She unknowingly selected the tank with the CO_2/O_2 blend and used it to replace the empty pure CO_2 tank in the OR. (Selecting an incorrect medical gas cylinder is an example of an **active error**.)

The surgeon activated the electrosurgical cautery unit to stop oozing from the area of the liver from which the gallbladder had been bluntly dissected. There was a millisecond flash of flame (not an electrical arc, which can occur with the use of cautery) followed by a puff of smoke. The incident was confined to the contact area of the electrosurgical instrument, and careful examination indicated that there was no evidence of injury to the patient. (This is an example of a **near miss**; by chance, no adverse event occurred.)

Investigation of the incident used the "fire triangle" concept and revealed that the patient's tissue was the fuel; the medical-grade CO_2/O_2 blend gas used to expand the patient's abdomen was the oxidizing agent; and the instrument, the cord connecting it to the electrical generator, and the generator were the ignition source.

All elements of the system were eliminated as possible causes for the flash of flame except for one. The medical gas cylinder was found to contain not just CO_2 but a CO_2/O_2 blend. The erroneous presence of this gas mixture was determined to be the single deviation from normal practice and the cause of the accident.

(Continued under "Root Cause Analysis" later in this course.)

SCOPE OF THE MEDICAL ERROR PROBLEM

The World Health Organization reports that 1 in every 10 patients around the world is harmed while receiving hospital care, and 4 out of every 10 patients are harmed in primary and outpatient care, where the bulk of services are offered, often resulting in hospitalization.

In the United States, diagnostic error occurs in about 5% of adults in outpatient care settings, and about half of these errors have the potential to cause severe harm. Extensive autopsy research has shown that diagnostic errors contribute to approximately 10% of patient deaths. Furthermore, medical record reviews demonstrate that diagnostic errors account for 6% to 17% of all harmful events in hospitals (WHO, 2019).

Medication errors are among the most common errors in both outpatient and inpatient settings. Each year in the United States, 7,000 to 9,000 people die due to a medication error. In addition, many other patients experience but often do not report an adverse reaction or other complications related to medication. Medication errors may be due to human errors but often result from a flawed healthcare delivery system with inadequate backup to detect mistakes (Tariq et al., 2021).

High error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments. Medical errors are also associated with extremes of age, new procedures, urgency, and the severity of the medical condition being treated (Carver et al., 2020).

Global Burden of Disease study results suggest that mortality associated with adverse effects of medical treatment has decreased modestly over the past 25 years, although the degree of improvement varies by state. Data indicate that:

- Adverse effects of medical treatment are common.
- The vast majority of adverse events that occur in patients who die are not the primary cause of death.
- Only a relatively small fraction of these events is due to medical error.
- Population-adjusted adverse effects of medical treatment rates have been slowly decreasing.
  (Sunshine et al., 2019)

HOW IS MORTALITY ESTIMATED?

Since the term *medical error* is also used to include any adverse effect of medical treatment, rather than just those caused by a healthcare worker's error, it has been previously estimated that medical errors are the third leading cause of death in the United States, with 250,000 to 400,000 deaths annually being due to medical errors. This estimate, however, has been found to be based on highly flawed studies that included **any** adverse event in the final mortality estimate whether it was due to a medical error or not.

Based on recent studies, a more accurate estimate of deaths resulting from medical errors is in the range of 2% of total deaths, or 15,000 to 35,000 deaths per year. Just as most deaths do not involve medical errors, most medical errors do not produce death—but they can still produce substantial morbidity, costs, distress, and enduring suffering (Gorski, 2019; Dorian et al., 2019).

Looking at malpractice payout statistics in all settings provides a broad view of medical errors overall; however, these show only a fraction of the actual number of medical errors, as most patients who are harmed by error do not seek damages, and many who do are denied compensation. An analysis of malpractice payout statistics for 2019 based on the U.S. Department of Health and Human Services' National Practitioner Data Bank Public Use Data File are reported in the table below.

MALPRACTICE PAYOUTS*	
By patient type	• 44% inpatient • 39% outpatient • 7% unknown • 10% both
Related to errors in …	• Diagnosis, 34% • Surgery, 21% • Treatment, 21% • Obstetrics, 10%

	• Medication, 5% • Monitoring, 3% • Anesthesia, 3% • Equipment, 1% • Behavioral health, 1% • IV and blood products, 1%
Severity of outcome	• Death, 30% • Significant permanent injury, 18% • Major permanent injury, 19% • Quadriplegic, brain damage, lifelong care, 12% • Minor permanent injury, 8% • Major temporary injury, 8% • Minor temporary injury, 4% • Emotional injury only, 1%
* Figures may be rounded.	
(NPDB, 2020)	

Progress in Patient Safety

More than two decades have passed since the modern patient safety movement began, and errors remain a serious concern. However, the movement has made significant inroads into understanding why medical errors occur and effective strategies for their prevention.

MILESTONES IN PATIENT SAFETY	
Year	**Accomplishments**
1999	• Institute of Medicine's *To Err Is Human: Building a Safer Health System* is published, breaking the silence surrounding medical errors and their consequences. • The Healthcare Research and Quality Act of 1999 is signed into law, designating the agency as the federal lead in patient safety.
2000	• The first National Summit on Medical Errors and Patient Safety is held to review information needs involved in the process of reducing medical errors and improving patient safety. • *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact* details more than 100 actions federal entities can take to address threats to patient safety.

2001	• *Evidence Report No. 43: Making Health Care Safer* is published, aiming to collect and critically review existing evidence on practices relevant to improving patient safety.
2002	• The National Patient Safety Goals program releases its first list of standards, including the creation of an organizational culture of commitment to safety, resulting in a 62% reduction in fall-related injuries.
2003	• Patient Safety Indicators are introduced, which include a set of measures that can be used with hospital inpatient discharge data to provide a perspective on patient safety. • AHRQ WebM&M, Morbidity & Mortality Rounds begins online, which includes expert analyses of medical errors and interactive learning modules on patient safety.
2004	• The Institute for Healthcare Improvement encourages hospitals and providers to take six key steps to reduce patient harm, resulting in 122,000 fewer preventable deaths. • AHRQ health information technology portfolio identifies challenges and provides solutions, best practices, and tools for utilization of new information technology by hospitals and clinicians. • Implementing Reduced Work Hours to Improve Patient Safety is developed to help address patient safety issues related to extended work hours.
2005	• AHRQ Patient Safety Network: *Advances in Patient Safety: From Research to Implementation* focuses on implementation of change to incorporate new practices.
2006	• TeamSTEPPS is introduced, which is an evidence-based teamwork system to improve communication and teamwork skills among healthcare professionals by empowering any team member to speak up to prevent medical errors.
2007	• Transforming Hospitals: Designing for Safety and Quality reviews the case for evidence-based hospital design and how it increases patient and staff satisfaction and safety, quality of care, and employee retention. • Questions Are the Answer campaign begins, designed to promote better two-way communication between providers and patients. • The World Health Organization addresses the goal of reducing surgical errors. Its Safe Surgery Saves Lives global effort focuses on surgical site infections, safe anesthesia, safe surgical teams, and measurement of surgical services.
2008	• Project RED's *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* is introduced, which is a protocol for Re-Engineered Discharge (RED) to improve patient safety, reduce costs, and boost patient satisfaction. • The Association of American Medical Colleges creates the Integrating Quality Initiative to help member medical schools and teaching hospitals achieve safe, high-quality, and high-value care.

2009	• AHRQ coordinates the development of common formats for reporting and analysis of patient safety data.
2010	• Johns Hopkins University School of Medicine develops a checklist that results in a dramatic drop in the infection rates in their hospital from 11% to zero. • The I-PASS Handoff Bundle, created by the I-PASS Study group to teach a standardized approach to handoffs in inpatient settings, is begun and yields a 30% drop between 2010 and 2013 in harmful medical errors that occur with handoffs. • The Affordable Care Act of 2010 helps advance patient safety through collaborations such as the Partnership for Patients, which focuses on reducing hospital-acquired conditions such as infections, pressure injuries, and adverse drug events.
2017	• AHRQ estimates that hospital-acquired conditions are reduced by 13% from 2014 to 2017.
(AHRQ, 2019a; Haskins, 2019)	

More than twenty years after the 1999 publication of *To Err Is Human*, medical errors continue to be a serious concern. While much work has been done to date, much remains to be accomplished. The patient safety movement has had many significant successes, one of which is recognizing that errors in healthcare are typically not related to one person's error or lack of education, but rather they occur because of a series of miscommunications, loss of information, or other system errors and flaws (Haskins, 2019).

COMMON CAUSES OF MEDICAL ERRORS

The majority of medical errors are not caused by individual recklessness or the actions of a particular group. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Individuals, of course, should still be held accountable when an error can be attributed to them; however, blaming an individual does little to make the system safer and prevent someone else from committing the same error. A blaming culture can also result in reluctance to disclose or report an error, which may contribute to increased harm to a patient and risk to other patients in future.

Medical errors are likely to occur in situations where providers are challenged to make decisions in dynamic, fast-paced, complex environments under tight time constraints. Errors stem from technical, organizational, or human factors that set off a chain reaction that could result in an adverse event (Carver et al., 2020).

The ten **most common causes of medical error** include:

1. Altered ability to make good judgments and quick decisions, including:
    - Not seeking advice from peers
    - Misapplying expertise
    - Not formulating a plan
    - Not considering the most obvious diagnosis
    - Conducting healthcare in an automatic fashion
2. Communication issues:
    - Lacking insight into the hierarchy
    - Having no solid leadership
    - Not knowing whom to report a problem to
    - Failing to disclose an issue
    - Having a disjointed system with no problem-solving ability
3. Deficiencies in:
    - Education
    - Training
    - Orientation
    - Experience
4. Inadequate methods of identifying patients, incomplete assessment on admission, failing to obtain consent, and failing to provide education to patients
5. Inadequate policies to guide healthcare workers
6. Lack of consistency in procedures
7. Inadequate staffing and/or poor supervision
8. Technical failures associated with medical equipment
9. No audits in the system
10. No one prepared to accept responsibility or change the system
(Rodziewicz et al., 2021)

Classification of Errors

The classification of different types of errors involved in healthcare are based on human cognitive processes that involve planning, storage, and execution. One such classification system

is the **Skill, Rule, and Knowledge (SRK)**–based approach. It refers to the degree of conscious control that an individual exerts over activities.

SKILL-BASED ERRORS

Errors that occur at the skill-based (automatic) mode involve execution/action failures (slips) and storage/memory failures (lapses). Skill-based errors are associated with familiar and frequently performed tasks that require little conscious attention. Slips are usually errors of inattention or misplaced attention where the intention is correct, but failure occurs while carrying out the activity. Memory lapses occur after formation of a plan and before execution during the time the plan is stored in the brain. They may include instances of forgetting to do something, losing one's place in the sequence of actions, or even forgetting the overall plan. Examples include omissions of steps in an action or repetition of steps in an activity (Khemani, 2019).

RULE-BASED ERRORS

The rule-based (intuitive) mode refers to rules that may have been learned through education, formal training, and experience. Rule-based processing is used when a person becomes aware that there is a problem. The conditions of the problem are matched with the conditions of problems the individual has encountered in the past. The solution used for the similar situation in the past is then applied using the "if this happens, then do that" rule.

Rule-based mistakes can occur if the current problem is assessed incorrectly, and therefore incorrectly matched to a previous problem, or when a usually good rule is applied at the wrong time. Such mistakes (planning failures) include using a good rule incorrectly or using a bad rule. When rule-based processing includes bypassing rules or safety procedures, it is known as a *violation* (Khemani, 2019).

KNOWLEDGE-BASED ERRORS

In the knowledge-based (analytical) mode, the person is focused on problem solving, and the task at hand must be carried out in an almost completely conscious manner taking considerable mental effort to assess the problem. This would occur in a situation where a provider is performing a task that is new or when an experienced provider is faced with a completely novel situation and has no experience or rules to fall back on.

In such an instance the person must create a solution. When the solution arrived at is incorrect, the error is called a *planning failure* or *mistake*. Knowledge-based mistakes arise from the considerable demands placed on the information-processing capabilities of the provider (Khemani, 2019).

COMMON CATEGORIES OF MEDICAL ERRORS AND HOW TO PREVENT THEM

Errors can be placed into five general categories: surgical, diagnostic, medication, devices and equipment, and systems failures (including healthcare-associated infections, falls, and healthcare technology). Common areas in each of these categories are described below.

Surgical Errors

Wrong-site, wrong-procedure, and wrong-patient surgical errors are relatively rare. It is estimated that in the United States such errors occur in approximately 1 of 112,000 surgical procedures and are infrequent enough that an individual hospital would only experience one such incident every 5 to 10 years. However, this includes only procedures performed in an operating room. If procedures performed in other settings such as ambulatory surgery are included, the rate of error may be much higher (AHRQ, 2019d).

Retained foreign bodies (also called *retained surgical items*) and unintentionally retained foreign objects are defined as objects retained after skin closure following an invasive procedure. It is estimated that 1 in every 5,500 procedures involves a retained foreign body, leading to adverse outcomes, including the need for additional operations, readmission or prolonged length of stay, infections, other health risks, and even death. Most unintended retained foreign bodies are associated with failures in leadership, communication, or other human factors that should be under the control of the operating team.

The Joint Commission indicates that between 2012 and 2018, the following items were retained:

- 102 instruments
- 52 catheters and drains
- 33 needles and blades
- 30 instances of packing
- 14 implants
- 6 specimens
  (Pellegrini, 2019)

The most frequent **anesthesia-related adverse events** include:

- Breathing circuit disconnections
- Inadvertent gas flow change
- Syringe swap
- Gas supply problem
- Intravenous apparatus disconnection

- Laryngoscope malfunction
- Premature extubation
- Breathing circuit connection error
- Hypovolemia
- Tracheal airway device position changes
  (Rayan et al., 2019)

PREVENTING WRONG-SITE, WRONG-PROCEDURE, OR WRONG-PERSON SURGERIES

Surgical errors are not the sole responsibility of the operating surgeon. All operating room personnel have a role in ensuring patient safety by verifying the surgical site and pointing out a possible error.

To reduce the risk of wrong-site, wrong-procedure, or wrong-person surgeries, the Joint Commission has developed a Universal Protocol checklist that includes the concept of a surgical "**timeout**," a planned pause before beginning a procedure in order to review important aspects of the procedure with all involved personnel. Although it was initially designed for operating room procedures, timeouts are now required before any invasive procedure. Comprehensive efforts to improve surgical safety have incorporated timeout principles into surgical safety checklists.

It should be noted, however, that many cases of wrong-site, wrong-procedure, or wrong-patient errors would still occur despite full adherence to the Universal Protocol. Errors may happen well before the patient reaches the operating room, a timeout may be rushed or otherwise ineffective, and production pressures may contribute to errors during the procedure itself. Preventing such errors depends on the combination of system solutions, strong teamwork, safety culture, and individual vigilance (AHRQ, 2019d).

The WHO **Surgical Safety Checklist** was developed after extensive consultation aimed at decreasing errors and adverse events, and increasing teamwork and communication in surgery. This checklist has gone on to show significant reduction in both morbidity and mortality and is now used by a majority of surgical providers around the world (WHO, 2021).

ELEMENTS OF THE WHO SURGICAL SAFETY CHECKLIST

A surgical checklist is an algorithmic listing of actions to be taken in any given clinical situation intended to make everyone aware that others expect these things to be done.

"SIGN IN" checklist must be completed orally and in writing before induction of anesthesia (with at least a nurse and anesthetist).

1. Has the patient confirmed their identify, site, procedure, and consent?
2. Is the site marked?

3. Is the anesthesia machine and medication check complete?
4. Is the pulse oximeter on the patient and functioning?
5. Does the patient have a:
    - Known allergy?
    - Difficult airway or aspiration risk?
    - Risk of >500 ml blood loss (7 ml/kg in children)?

"TIME OUT" checklist must be completed orally and in writing before skin incision (with nurse, anesthetist, and surgeon).

1. Confirm all team members have introduced themselves by name and role
2. Confirm the patient's name, procedure, and where the incision will be made
3. Has antibiotic prophylaxis been given within the last 60 minutes?
4. For the anticipated critical event:
    - To surgeon:
        - What are the critical or nonroutine steps?
        - How long will the case take?
        - What is the anticipated blood loss?
    - To anesthetist:
        - Are there any patient-specific concerns?
    - To nursing team:
        - Has sterility (including indicator results) been confirmed?
        - Are there equipment issues or any concerns?
5. Is essential imaging displayed?

"SIGN OUT" checklist must be completed orally and in writing before the patient leaves the operating room (with nurse, anesthesia provider, and surgeon).

1. Nurse verbally confirms:
    - The name of the procedure
    - Completion of instrument, sponge, and needle counts
    - Specimen labeling (read aloud specimen labels, including patient name)

- Whether there are any equipment problems to be addressed

2. To surgeon, anesthetist, and nurse:
    - What are the key concerns for recovery and management of this patient?

(WHO, 2021)

PREVENTING RETAINED FOREIGN OBJECTS

Recommendations to reduce incidents of unintended retained foreign objects related to human factors include:

- Provide team training
- Address disruptive behavior
- Minimize distractions and interruptions
- Account for objects inserted in the wound
- Methodologically explore the surgical site prior to closure
- Verify integrity of objects upon removal
- Educate staff about risks of retained foreign objects and risk-reduction strategies
- Assess competency (initial and maintenance) of personnel

Recommendations for leadership issues include:

- Prioritize a culture of safety
- Conduct a proactive risk assessment and implement policies and procedures based upon it
- Celebrate successes, but also encourage reporting of near misses

Recommendations for communication issues include:

- Verbally acknowledge removal of objects
- Discuss removal of objects during standardized debriefing after procedures
- Discuss the need for packing removal during handoff
- Document verification of removal and integrity of objects
(Pellegrini, 2019)

CASE

Cheryl, a left-hand-dominant author, was scheduled for a left carpal tunnel release to alleviate her left-hand pain. Immediately prior to her being transferred to the operating room, her surgeon verified the procedure and side with her and marked the surgical site with a purpose-made surgical site marker in accordance with facility policy.

After the "time out" and induction of general anesthesia, the site was prepped and draped, the surgeon made a Z-shaped incision from the proximal phalanx of Cheryl's left middle finger to the middle of her left palm and began to carefully dissect down through the soft tissue. The scrub, an experienced perioperative nurse, was perplexed by the placement of the incision, since the usual incision for a carpal tunnel release goes from the palm (in line with the ring finger) toward the wrist. The scrub did not say anything, since the surgeon was new to the facility, had just completed a fellowship in hand surgery, and had already performed several newly developed procedures with which the nursing personnel were not familiar.

After examining the tissue in Cheryl's palm, the surgeon commented on the lack of thickening of the ligament in the palm and the inconsistency between his findings and her reported symptoms of ring finger pain and difficulty in doing keyboard work. At this point, both the circulating nurse and anesthesia provider stated that the proposed procedure was a carpal tunnel release. This was confirmed by the surgeon, anesthesia provider, circulating nurse, and scrub visualizing the surgical schedule and Cheryl's chart (history and physical, surgical consent, and surgical safety checklist).

The surgeon closed the incision and made an appropriate incision for a carpal tunnel release, and the procedure was completed without further issue. After Cheryl was transported to the postanesthesia care unit (PACU), the surgeon spoke with her husband. He informed him of the incident and told him that a complete review of all that had transpired would be done that day. The surgeon later spoke to Cheryl and told her that he would give her a complete explanation the following day once all of the medications she had received were no longer affecting her understanding or memory.

The surgeon met with Cheryl and her husband and adult daughter the following day. He described the nature of the error (that a trigger finger release incision was made instead of the carpal tunnel release incision intended), how it had occurred, and what steps would be taken to improve that aspect of OR safety. The night of surgery, the family had briefly considered filing a lawsuit, but after meeting with the surgeon, they were satisfied with the full and honest disclosure of the incident and decided not to sue.

Diagnostic Errors

Diagnostic errors are common, accounting for 17% of preventable errors in hospitalized patients. A systematic review of autopsy results done over four decades found that almost 9% of the deceased patients experienced a major diagnostic error that was not detected prior to death. One in every six patients is affected by a diagnostic error, and 1 in every 1,000 primary care visits causes preventable harm.

Most diagnostic errors that occur in primary care settings include failure to order appropriate tests, faulty interpretation of data, failure to follow-up, and failure to refer. A common error is closing the diagnostic process prematurely, which can result in a common, benign diagnosis for a patient with uncommon, serious disease. Delaying treatment after the diagnosis is made is the third most common error, resulting in increased costs for readmission and further treatment (AHRQ, 2019e; Rodziewicz et al., 2021).

Making a diagnosis is a very complex process, with over 10,000 known diseases and 3,500 kinds of laboratory tests, but only a small number of symptoms, so that any one symptom may have dozens or hundreds of possible explanations. Diagnostic testing may be helpful in clarifying the issue, but it is mostly a matter of observing the clinical course, which takes time. An error can occur at any step in the diagnostic process: getting a complete patient history, doing an appropriately thorough examination, obtaining the right tests, or interpreting tests correctly (SIDM, 2021).

Cognitive psychology applied to healthcare has shown that clinicians frequently use **heuristics** (shortcuts or "rules of thumb"), also called *cognitive bias,* to come up with a provisional diagnosis, especially when faced with a patient with common symptoms. Heuristics allow people to solve problems and make judgments quickly and efficiently.

Heuristics lead to diagnosis of a current patient biased by experience with past cases, relying on initial diagnostic impression despite subsequent information to the contrary, and placing undue reliance on test results or "expert" opinion.

Clinicians are frequently unaware of diagnostic errors that they have committed, particularly if they do not have an opportunity to see how their diagnoses turned out over time. Therefore, regular feedback to clinicians on their diagnostic performance is helpful. Unfortunately, reliable decision support or feedback systems do not yet exist (AHRQ, 2019e).

Traditionally the autopsy has been the gold standard for diagnosis, but autopsy rates have progressively declined over the past few decades, and teaching institutions have not followed the recommendation to perform autopsies on 25% of inpatient deaths. As a result, clinicians are not receiving feedback on their diagnosis (AHRQ, 2019e).

HIGH-RISK DIAGNOSES

Prevention must include clinician awareness of the most commonly misdiagnosed conditions and taking extra precautions to seek and confirm the diagnosis. Clinicians must be aware of and carefully consider the following common "high-risk" diagnoses:

- Acute renal failure
- Acute pyelonephritis
- Acute vascular occlusion
- Adverse effect of medication

- Aneurysms
- Angina
- Appendicitis
- Arrhythmias
- Asthma exacerbation
- Cellulitis
- Decompensated heart failure
- Hypertension
- Metastatic cancer
- Metabolic disorders like hypoglycemia, gout
- Osteomyelitis
- Primary malignancy
- Pneumonia
- Spinal cord compression
- Symptomatic anemia
- Urinary tract infection
  (Rodziewicz et al., 2021)

CASE

A serious outbreak of the Ebola virus was underway in Liberia in western Africa. A man traveled from Liberia back to his home in Texas, where he began to experience fever, nausea, and abdominal pains, prompting him to go to the emergency department (ED). There he reported to the nurse his recent travel to Liberia but denied contact with sick people. He was misdiagnosed and sent home. Days later he returned to the ED, tested positive for Ebola, began receiving care, but died soon after.

Investigation of this misdiagnosis discovered that the patient's travel history was obtained by the nurse and entered into his electronic medical record (EMR). The patient, however, had not mentioned the fact that he had had contact with an Ebola patient prior to leaving Liberia. Additionally, the examining physician did not see the travel portion of the patient's history because it was in the nursing section of the EMR, which physicians can, but often don't, routinely check. Every facility makes choices about what information shows up routinely in what part of the EMR, and this hospital chose not to include the travel history in the physician section of the EMR.

Nurses are not required to inform doctors about everything they do and document. However, important information is generally personally communicated to the physician. Although the importance of this patient's travel history should have been recognized because of the amount of publicity surrounding the Ebola outbreak at that time, the nurse did not inform the physician personally.

The nurse asked the right questions about travel, but the patient failed to disclose important information for an unknown reason. The nurse correctly entered the travel history into the medical record but failed to verbally inform the physician, and the physician chose not to read the nurse's notes. All of these actions illustrate the importance of communication in the prevention of medical errors such as this misdiagnosis and delayed treatment.

Medication Errors

Every year in the United States, 7,000 to 9,000 people die due to a medication error. In addition, hundreds of thousands experience but often do not report an adverse reaction or other complication related to a medication. Clinicians have access to more than 10,000 prescription medications, and nearly one third of adults in the United States take five or more medications.

Each year, adverse drug events account for nearly 700,000 emergency department visits and 100,000 hospitalizations. Nearly 5% of hospitalized patients experience an adverse drug event, making them one of the most common types of inpatient errors. Ambulatory patients may experience adverse drug events at even higher rates, and transition in care is also a well-documented source of preventable harm related to medications (Tariq et al., 2021; AHRQ, 2019e).

Medication errors may be due to human errors but often result from a flawed system with inadequate backup to detect mistakes. Medication errors may occur at any step, including:

- Ordering/prescribing. The clinician must select the appropriate medication, dose, frequency, and duration.
- Transcribing. In a paper-based system, an intermediary must read and interpret the prescription correctly.
- Dispensing. The pharmacist must check for drug-drug interactions and allergies and release the appropriate quantity of the medication in the correct form.
- Administering. The correct medication must be supplied to the correct patient at the correct time, either by a nurse, other trained staff, patient, or caregiver.
- Monitoring. This includes laboratory tests, side effects, effectiveness of therapeutic action, and vital signs.
- Documenting. The name, strength, and quantity of drug; the date and time administered; and the name of the person administering the drug must be entered in the patient's medication administration record in a timely manner.
  (Tariq et al., 2021)

ERRORS IN PRESCRIBING AND TRANSCRIBING

Errors occur most commonly during the ordering/prescribing and transcribing stages, accounting for almost 50% of medication errors. Even with the increasing use of electronic health records, which has helped avert errors at the ordering and transcribing stages, such errors continue to occur.

The most common errors in the ordering/prescribing step include:

- Ordering the incorrect drug
- Ordering the incorrect dose
- Ordering the wrong interval or drug schedule
- Ordering the wrong route of administration
- Ordering the wrong infusion rate
- Ordering the wrong dose form (tabs, liquid, immediate-release instead of extended-release)
- Distortions, including illegible handwriting, misunderstood symbols, use of abbreviations, or improper translation
- Use of abbreviations
- Inappropriate use of decimal points
- Incomplete order
- Ordering and not being alerted to allergies
- Lack of awareness of known contraindications
- Ordering and not being aware of pre-existing medical conditions
- Ordering without reviewing and being aware of current medications being taken (Tariq et al., 2021)

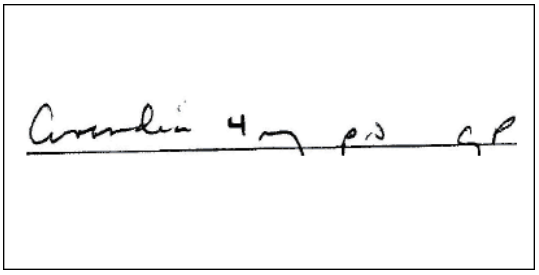
The National Medication Error Reporting program permits subscribing healthcare institutions to report and track medication errors and finds that medical abbreviation errors account for 4.7% of those errors reported to MedMarx. The most common medical abbreviation error was the use of "QD" (one daily), accounting for 43.1% of all errors, followed by "U" for units, "cc" for "ml," and other decimal errors.

The most common drug abbreviation name that led to an error was the use of "MS" or "MSO4" for morphine sulfate. At least 81% of the errors were noted to occur at the time of ordering the medication, while errors at the transcribing and dispensing stage occurred at a lower frequency (Tariq & Sharma, 2020).

The Institute for Safe Medication Practices has developed a list of abbreviations that are routinely misinterpreted (see "Resources" at the end of this course).

BAD HANDWRITING

Bad handwriting by physicians has become such a major problem that the Institute of Safe Medication Practices has recommended the complete elimination of handwritten orders and prescriptions. Although the handwriting problem can be solved by using electronic records in which everything is typed, errors may still occur from entering the wrong drug, dose, or frequency (Tariq et al., 2021).



Illegible prescription: Avandia (a diabetic medication) confused with Coumadin (an anticoagulant), both available as 4 mg oral tablets. (Source: AHRQ, 2003.)

Preventing Prescription and Transcription Errors

The first line of defense against medication errors should be the prescribing clinician, who must have all the information needed to make the best possible prescribing decisions for each patient. Such information includes evidence-based recommendations on medications for different illnesses or conditions, including correct dosing, benefits and potential risks, and accurate and complete information about the patient's current medications, illnesses, comorbid conditions, known allergies, or past history of adverse reactions to medication.

Strategies for preventing errors when prescribing include avoiding unnecessary medications by adhering to **conservative prescribing principles,** which include:

- Maintaining heightened awareness concerning side effects
- Exercising skepticism about new drugs
- Remaining alert for high-risk medications
- Involving the patient in decision-making
- Considering long-term impacts of medications prescribed
- Considering patient age and body weight
- Considering liver and kidney function

Use of a **computerized provider order entry (CPOE)** allows clinicians to directly place orders electronically, with orders transmitted directly to the recipient. CPOE avoids the necessity for transcribing an order and thus reducing risk of error.

A third strategy is to perform a **medication reconciliation** at times of transitions in care, such as when transferring a patient from one facility to another or from one unit in a facility to another. Medication reconciliation refers to the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission, transfer, or discharge and comparing it with the regimen being considered for the new setting of care. This involves reviewing each medication and comparing it against the medication administration record.

To reduce transcription errors, a **double-check procedure** is recommended in which another nurse on the same shift or incoming shift reviews all new orders to ascertain that each order is correctly noted and transcribed on the physician's order and on the medication administration record. **Read-back** to another professional is another procedure in which a nurse reads back an order to the prescribing physician or another nurse to make certain the medication ordered is correctly transcribed (APF, 2020; Saljoughian, 2020).

ERRORS IN DISPENSING

The second line of defense against medication errors is the individual who is dispensing the medication. Dispensing medications involves preparing and packaging a prescription drug or device in a container and labeling the container with information required by state and federal law.

Dispensing errors in U.S. clinical and community pharmacies occur at an average rate of 4 in 250 prescriptions. Forty-one percent of all medication incidents related to information technology are due to choosing the wrong drug. One third of incidents are associated with confusion of similar drug names, and nearly half were associated with drug strength confusion. Errors by pharmacists are usually judgmental or mechanical.

Judgmental errors include:

- Failure to detect drug interactions
- Inadequate drug utilization review
- Inappropriate screen
- Failure to counsel the patient appropriately
- Inappropriate monitor

Mechanical errors include:

- A mistake in dispensing or preparing a prescription

- Administering an incorrect drug or dose
- Giving improper directions
- Dispensing the incorrect dose, quantity, or strength

The most **common causes** for dispensing errors involve:

- Workload
- Similar drug names
- Interruptions
- Lack of support staff
- Insufficient time to counsel patients
- Illegible handwriting
  (Tariq et al., 2021)

Preventing Dispensing Errors

Strategies to reduce the risk of medication dispensing errors because of drug confusion include:

- Verifying the prescription entry is correct
- Clarifying any ambiguous information such as prescriptions that are illegible or use nonstandard abbreviations and other symbols
- Checking prescriptions thoroughly and verifying by another person
- Providing patient counseling
- Checking for drug-to-drug interactions and allergies
- Supervising dispensing medications by pharmacist assistants
- Opening containers and showing them to the patient (patients may raise an alert if the medication looks different from what they usually take)
- Using tall-man lettering (TML), a technique that uses uppercase lettering to highlight the differences between similar drug names by capitalizing dissimilar letters (e.g., “CISplatin” vs. “CARBOplatin”)
- Using barcode scanners to check whether the selected drug from the shelf is the same as the selected drug on the dispensing screen
  (Campmans et al., 2018; FDA, 2020a)

ERRORS IN ADMINISTRATION

In the administration stage, errors include:

- Failing to follow the "**five rights**" to medication administration:
  - Right patient
  - Right drug
  - Right dose
  - Right route
  - Right time
- Failing to educate the patient as to why the drug is being prescribed
- Leaving a medication at the bedside without knowing if it was taken
- Omitting medications
- Administering an unauthorized medication
- Not shaking a medication that should be shaken before use, leading to overdose or underdose
- Crushing medications not intended to be crushed
- Failing to follow facility policies and procedures

Most medication-related errors occur in **hospital settings**, where nurses administer the majority of medications. Studies have found an estimated median error rate of 8% to 25%. About one third of all medical errors causing harm to hospitalized patients occur during the medication preparation and administration phase.

The most common type of error has been found to be wrong time of administration, followed by omission and wrong dose, wrong preparation, or wrong administration rate for intravenous medications. Administration of **intravenous medications** has the highest error rate estimate, ranging from 48% to 53%. One study estimated a 73% probability of at least one error occurring during a single administration of intravenous medication.

Errors in medication administration can occur as a result of individual-level slips and lapses, but may also result from system-level failures such as understaffing, human factor problems, and other latent conditions. The strongest risk factors for adverse drug events are polypharmacy and hospitalized pediatric patients, since many medications must be dosed according to their weight.

Another substantial source of medication administration error includes patients and caregivers, who are responsible for the vast majority of medication **administration at home**. Error rates have been found to range from 2% to 33%, with dosage errors, omissions, and wrong medications the most common types of errors (AHRQ, 2019f; Hanson & Haddad, 2020; APF, 2020).

Preventing Administration Errors

In inpatient settings, interventions to prevent medication administration errors include:

- Barcoding for both medications and patients
- Adherence to the "five rights" of medication safety
- Smart infusion pumps for intravenous administration
- Single-use medication packages
- Package design features such as tall-man lettering for look-alike drug names
- Minimizing interruptions

"RIGHTS" OF MEDICATION SAFETY

Efforts have been made to increase the number of "rights" beyond the original five. However, an increasing number of recent studies have also identified inadequacies of the "five rights" in significantly removing errors due to factors that place workplace strains on staff. Workload problems, understaffing, and interruptions have all been found to make the five rights difficult to comply with all of the time. Thus, adding new "rights" to be considered and followed will likely not improve the outcome (Hanson & Haddad, 2020).

Few of these interventions are likely to be successful in isolation, and efforts to improve safe medication use must also focus on transitions to home, primary care, and patient caregiver understanding and administration of medication. These efforts include:

- Patient education
- Revised medication labels to improve patient comprehension of administration instructions
- Multicompartment medication devices for patients taking multiple medications in ambulatory or long-term care settings

(AHRQ, 2019f)

Individually, those who administer medications must also safeguard against medication errors by:

- Being proficient in medication calculations
- Maintaining up-to-date pharmacologic knowledge
- Informing patients of a medication's therapeutic effects
- Documenting accurately once a medication has been administered

PATIENT-CENTERED CARE AND MEDICATION COMPLIANCE

Research has found medication noncompliance in 20% to 59% of elderly patients. Patients who are noncompliant tend to have multiple chronic conditions, be forgetful, and experience adverse effects from medications. Patient noncompliance may result in medication errors that can lead to hospitalization or serious injury.

Patient-centered care establishes a partnership between clinicians and patients. Joint decisions are made that incorporate patients' wants, needs, and preferences, which result in better decision-making and active participation by patients in their own care (APF, 2020).

ERRORS IN MEDICATION MONITORING

Monitoring and assessment are essential to the process of administration of medications. Errors can occur regarding the assessment of vital signs, lab values, ability to swallow, and patient's self-report. Monitoring involves observing the patient to determine if the medication is working, is being used appropriately, and is not harming the patient. Types of errors in monitoring that can occur include:

- Failure to monitor effectiveness of therapeutic action of a medication
- Lack of awareness of side effects of a medication
- Failure to monitor, assess, and report laboratory tests
- Failure to monitor, assess, and report vital signs
- Failure to educate patients about potential side effects
- Failure to comply with a pain management program
- Communication failures during handoff procedures to accepting nurse
  (Tariq et al., 2020, AHRQ, 2020e)

ERRORS AND HIGH-ALERT MEDICATIONS

The Institute for Safe Medication Practices (ISMP) defines a *high-alert medication* as a drug that has a heightened risk of causing significant patient harm when used in error. Although errors may or may not be more common with such medications, the consequences of errors are much more devastating. High-alert medications are at the top of the list of drugs involved in moderate-to-severe patient outcomes when an error occurs.

The ISMP lists high-risk medications according to what is commonly used in acute care settings, community settings, and long-term settings. These lists are updated every few years based on error reports submitted to ISMP, reports of harmful errors in the literature, and input from practitioners and safety experts.

High-alert medications specific to acute care settings include:

- Adrenergic agonists, IV (e.g., epinephrine, norepinephrine)
- Adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
- Anesthetic agents, general, inhaled, and IV (e.g., propofol, ketamine)
- Antiarrhythmics, IV (e.g., lidocaine, amiodarone)
- Antithrombotic agents (e.g., anticoagulants, Factor Xa inhibitors, thrombotics)
- Cardioplegic solutions
- Chemotherapeutic agents, parenteral and oral
- Dextrose, hypertonic, 20% or greater
- Dialysis solutions, peritoneal and hemodialysis
- Epidural and intrathecal medications
- Inotropic medications, IV (e.g., digoxin, milrinone)
- Insulin, subcutaneous and IV
- Liposomal forms of drugs (e.g., liposomal amphotericin B)
- Moderate sedation agents, IV (e.g., dexmedetomidine, midazolam, lorazepam)
- Moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam)
- Opioids, including IV, oral, and transdermal
- Neuromuscular blocking agents (e.g., succinylcholine)
- Parenteral nutrition preparations
- Sodium chloride for injection, hypertonic, greater than 0.9% concentration
- Sterile water for injection, inhalation, and irrigation in containers of 100 ml or more
- Sulfonylurea hypoglycemics, oral (e.g., chlorpropamide, tolbutamide)

(ISMP, 2018)

Preventing Errors with High-Alert Medications

The Institute for Safe Medication Practices makes the following recommendations for reducing errors with high-alert medications:

- Standardize the ordering, storage, preparation, and administration of these medications

- Improve access to information about these drugs
- Limit access to high-alert medications
- Use auxiliary labels and automated alerts
- Employ redundancies—duplicate devices used for backup purposes to prevent or recover from the failure of a specific part of the process (e.g., asking another nurse to perform an independent check)
- In community/ambulatory settings, it is recommended that mandatory patient education should occur

  (ISMP, 2018)

FDA Warnings for High-Risk Medications

The FDA requires high-risk medications with serious or life-threatening risks be given a label referred to as a *black box warning,* the FDA's strongest labeling requirement. Before adding a box warning, however, the FDA must have evidence that the drug poses a significant risk. This comes from observations and studies conducted after the drug has been on the market. Unfortunately, this means that new drugs that have just been put on the market rarely will have these warnings.

Despite these warnings, however, it has been shown there has been no associated reduction in prescribing such medications. This may be attributed to:

- Unawareness by prescribers that the FDA has issued the warnings
- Prescribers thinking that even though there is a high risk, the drugs have a superior benefit-risk ratio to alternative medications
- Prescribers thinking that the safety concern is not as severe as the warning suggests
- Prescribers choosing to continue prescribing them while using strategies to reduce risk, such as close monitoring of patients

  (ISMP, 2018)

PREVENTING ADVERSE EVENTS DUE TO PATIENT-CONTROLLED ANALGESIA (PCA)

Checklists for safe use of PCA pumps are available. The Physician-Patient Alliance for Health and Safety checklist recommends certain steps be taken when initiating, refilling, or reprogramming PCA pumps, and PCA checks to be done at shift change and hourly.

PCA pump initiation, refilling, or programming a change requires:

- Assessment of the patient for increased risk of respiratory distress due to:
  - Obesity
  - Low body weight
  - Current medication that can potentiate sedative effects
  - Preexisting conditions such as asthma, COPD, and sleep apnea
  - Advanced age
- Preprocedural cognitive assessment to determine the capability of the patient to participate in pain management (may not be suitable for pediatric patients)
- Provision of information to the patient on proper use of the PCA and purpose of monitoring
- Two healthcare providers independently verify the patient's:
  - Identification
  - Allergies, if any
  - Drug selection and concentration as prescribed
  - Dose adjustment, if any
  - PCA pump settings
  - Line is attached to the patient and tubing is inserted into the pump
- Electronic monitoring:
  - Pulse oximetry
  - Capnography

Change of shift and every hour requires:

- Assessing patient for level of pain, alertness, and adequacy of ventilation
- Verifying PCA pump settings
- Verifying electronic monitoring of pulse oximetry and capnography
- Documenting patient assessment and condition, PCA dosing, and monitoring

(PPAHS, 2020)

CASE

In a large Midwestern city, a nurse working on the obstetrics unit of a local hospital was halfway through the second of two eight-hour shifts, and she asked to go home because she was tired. The hospital denied her request, stating staffing would be inadequate (fatigue and RN staffing). The nurse was assigned a young female in active labor. The patient stated that she had spoken to her doctor beforehand and had agreed to an epidural for delivery.

In order to save time (workload and time pressures), the nurse took a bag of epidural anesthesia from a storage locker without a doctor's order, brought it to the patient's room, and laid it on the work counter (deliberate violation of medication administration guidelines, policies, and procedures). The IV bag had a bright-red label that read "for epidural use only."

In the meantime, an IV antibiotic was ordered and delivered to the patient's room. The nurse picked up what she believed was the IV antibiotic (similar packaging or product) and hung it (deliberate violation of medication administration guidelines, policies, and procedures). Shortly thereafter, the patient had a seizure and died. Her infant was delivered live by cesarean section.

The investigation of the incident revealed that the nurse:

- Was fatigued and under time pressure
- Failed to follow hospital procedures requiring a doctor's order before removing drugs from the storage locker
- Failed to recognize the bright-red intrathecal warning label on the IV bag
- Failed to follow the hospital's policy and procedure to scan medication labels before drugs were administered
- Failed to follow the "rights" of medication administration as described in the hospital's policy and procedure manual

Investigation further revealed that shortcuts were common practice on the unit.

Initially the nurse was charged with a felony, which was later reduced to civil charges, and her license was suspended.

Tubing Misconnections

The FDA reports that medical device misconnections can occur when one type of medical device is attached in error to another type of medical device that performs a different function. Tubing misconnections can occur for several reasons, including:

- Similar design of many connectors and the widespread use of connectors with similar shapes and in similar sizes

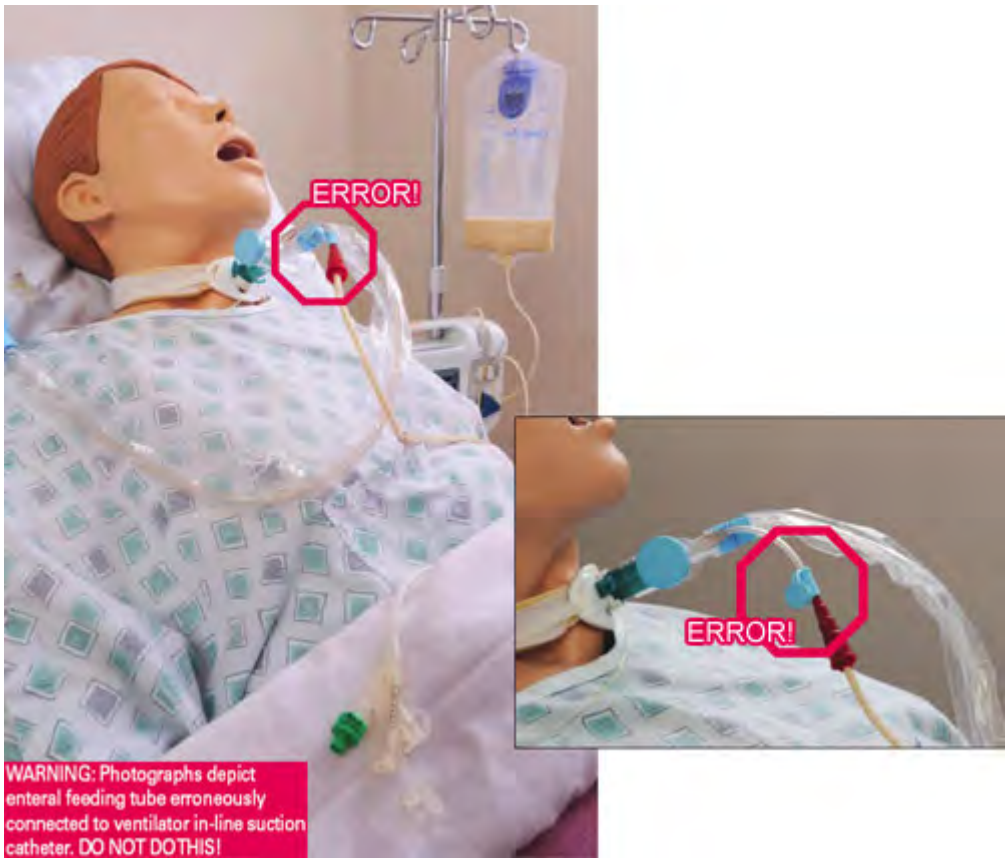
- Human error arising from conditions such as:
    - Multiple connections for one patient
    - Poor lighting
    - Lack of training
    - Time pressure
    - Fatigue
    - High-stress environment

  (FDA, 2018)

EXAMPLES OF TUBING MISCONNECTIONS

- Enteral feeding tube connected to an IV
- Enteral feeding tube connected to ventilator-inline suction catheter
- Blood pressure cuff tubing connected to an IV port
- IV tubing connected to trach cuff
- IV tubing connected to nebulizer
- Oxygen tubing connected to a needleless IV port
- IV tubing connected to nasal cannula
- Syringe connected to trach cuff
- Epidural solution connected to a peripheral or central IV catheter
- Epidural line connected to an IV infusion
- Bladder irrigation solution utilizing primary IV tubing connected to a peripheral or central IV catheter
- Foley catheter connected to NG tube
- IV infusion connected to an indwelling urinary catheter
- IV infusion connected to an enteral feeding tube
- Primary IV tube connected to a blood product meant for transfusion

  (FDA, 2017)



Patient's feeding tube is incorrectly connected to the instillation port on the ventilator in-line suction catheter, delivering tube feeding into the patient's lungs, causing death. (Source: FDA, 2017.)

PREVENTING TUBING MISCONNECTIONS

Attempts to prevent device misconnections have included color-coding, labels, tags, and training. However, these methods alone have not effectively solved the problem, because they have not been consistently applied, nor do these methods physically prevent the misconnections.

The FDA, the standards community, the International Organization for Standardization, and the medical device industry have taken actions to reduce the likelihood of medical device misconnections. These actions include the development of standardized connector designs for the specific medical applications intended to physically prevent connections with devices used for other medical applications.

In order to reduce the chances of tubing misconnections, non-Luer lock connections have been introduced. These include the NR-Fit connector for neuraxial and regional anesthesia catheters and the Enfit connectors for feeding tubes.

These connectors are designed to be incompatible with Luer adaptors, which are commonly used in IV applications. The connectors look and secure very similar to a Luer threaded lock system,

although the design is larger and, therefore, incompatible with connectors for unrelated delivery systems such as trach tubes, IV lines, and catheters (Rodziewicz et al., 2021).

Until new connectors are universally adopted, the following interventions offer healthcare providers with strategies such as the use of ACT to prevent device misconnections (see table):

"ACT" TO PREVENT DEVICE MISCONNECTIONS		
Label	**Step**	**Actions**
A	Assess equipment	• Assess and clearly label each device, including low-risk devices and high-risk catheters.
C	Communicate	• Ensure communications between healthcare staff during patient transfer. • Inform nonclinical staff, patients, families, and caregivers that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or tubing.
T	Trace	• Trace a tube from the patient to the point of origin prior to connecting any new devices or replacing an old one. • Vigilantly check and recheck fittings and connectors to ensure proper connections prior to each use.
(FDA, 2018)		

Risk managers, nurse managers, clinical educators, and similar personnel may:

- Inform clinicians, patients, and caregivers in home-based or ambulatory care when new devices are intended for use in the healthcare facility or at home
- Emphasize the risk of tubing and catheter misconnections in clinical staff orientation and training
  (FDA, 2018)

Errors Related to Medical Devices and Equipment

The FDA regulates devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury by using a process of scientific and regulatory review to evaluate safety and effectiveness. The FDA has the following three levels of classification for medical devices and equipment:

- **Class I devices** do not come into contact with a patient's internal organs, the central nervous system, or cardiovascular system. Examples include:
  - Bedpan
  - Tongue depressor

  - Oxygen mask
  - Bandages

- **Class II devices** are more likely to come into sustained contact with a patient, such as those that come into contact with a patient's cardiovascular system or internal organs and diagnostic tools. Examples include:
  - Catheters
  - Blood pressure cuffs
  - Syringes
  - Blood transfusion kits
  - Surgical gloves

- **Class III devices** usually sustain or support life, are implanted, or present a potential unreasonable risk of illness or injury. Examples include:
  - Breast implants
  - Pacemakers
  - Defibrillators
  - High-frequency ventilators
  - Fetal blood sampling monitors
  - Implanted prosthetics or other devices

  (FDA, 2020b)

As experience and knowledge about a device increase, the original classification of a device can be changed through reclassification. To reclassify a device, the FDA must:

- Publish a proposed order that includes a summary of valid scientific evidence that supports the reclassification
- Convene a device classification panel meeting
- Consider comments from the relevant public docket
  (Rodziewicz et al., 2021; FDA, 2019)

Design flaws, misuse, and malfunction of medical devices and equipment are all common causes of medical errors. Subtle differences in a familiar pattern using a device can affect the speed and accuracy of data entry, and the lack of standardization invites user mistakes. Poor medical device design and lack of usability testing have also been repeatedly discussed as being key factors in many device-related incidents.

An increasing number of medical devices are also implanted in patients. These include complex programmable cardiac pacemakers, defibrillators, deep-brain stimulation neurotransmitters, and laser surgical devices. Any malfunction of such devices can be serious and even life threatening.

Each year the FDA receives several hundred thousand reports of suspected device-associated deaths, serious injuries, and malfunctions.

Mandatory reporting of such events must be done by manufacturers, importers, and device user facilities. Healthcare professionals, patients, caregivers, and users are also encouraged to voluntarily report adverse events to MedWatch, the FDA's Safety Information and Adverse Event Reporting Program. User facilities **must report** suspected medical device-related deaths to both the FDA and the manufacturer. A user facility is not required to report a device malfunction but can voluntarily advise the FDA of such product problems. The FDA uses the reported information to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products (FDA, 2020c).

CASE

Jory, a 17-year-old boy, fractured his arm in several places following a tackle and fall while playing football. He was taken to the nearby hospital, where he underwent surgical repair. Postoperatively he was placed on morphine delivered via a pump. His heart rate, respirations, and blood oxygen levels were being monitored. Through the evening hours, Jory was alert, oriented, and had stable vital signs. When the night shift took over, it was ordered that the morphine should be shut off and that he should be placed on routine vital sign checks and oral pain medication.

During the night, the nurse entered his room to assess his vital signs and found that he was nonresponsive and barely breathing. It was discovered that the morphine pump, a newly acquired piece of equipment, had not been shut off but had accidently been turned to the "high" setting. Jory was lucky; he survived the overdose.

The following investigation found that the new device was designed differently than the old one, with an additional step required in the shut-off process, and the nurse had not received training in the use of the new pump.

PREVENTING ERRORS RELATED TO MEDICAL DEVICES AND EQUIPMENT

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

Health professionals should:

- Standardize equipment, such as infusion pumps and monitors, in similar care environments
- Be involved in setting and evaluating institutional, organizational, and public policy related to technology
- Make sure that the technology used meets quality and safety standards

Institutions should:

- Make decisions concerning technology with the input of critical stakeholders (those with a financial interest, medical leaders, clinicians, patients, and vendors)
- Have policies and processes related to maintenance, training, monitoring, and reporting adverse events related to technology
  (Rodziewicz et al., 2021)

Healthcare-Associated Infections (HAIs)

HAIs are infections that occur while receiving healthcare in a hospital or other healthcare facility and that first appear 48 hours or more after admission or within 30 days after having received healthcare. HAIs are considered system failures and are often preventable.

As many as 1 in 31 hospitalized patients acquire an HAI, resulting in increased complications, length, and cost of the hospital stay. AHRQ reports that HAIs are the most common complications of hospital care (CDC, 2020a).

Common types of HAIs include:

- **Catheter-associated urinary tract infections (CAUTIs)** occur at a rate of approximately 3% to 10% per day of catheterization, making duration of catherization an important risk factor. Complications of CAUTIs include sepsis, bacteremia, and involvement of the upper urinary tract (Fekete, 2020).
- **Surgical site infections (SSIs)** occur in 2% to 4% of all patients undergoing inpatient surgical procedures. Although most infections are treatable with antibiotics, SSIs remain a significant cause of morbidity and mortality after surgery. They are the leading cause of readmissions to the hospital following surgery, and approximately 3% of patients who contract an SSI will die as a result (AHRQ, 2019g).
- **Central line–associated bloodstream infections (CLABSIs)** are laboratory-confirmed bloodstream infections that are not secondary to an infection at another body site, due to the presence of an intravascular catheter that terminates at or close to the heart, or in one of the great vessels that is used for infusion, withdrawal of blood, or hemodynamic monitoring (NHSN, 2021). Ninety percent of all bloodstream infections are caused by central venous access devices.
- **Peripheral vascular catheter (PVC)-associated bloodstream infections** occur in approximately 0.18% of patients (Blauw et al., 2019).
- ***Clostridioides (Clostridium) difficile (C. diff)*** **infections (CDIs)** cause life-threatening diarrhea. It is usually a side-effect of taking antibiotics. Those most at risk are patients, especially older adults, who take antibiotics and also receive medical care and people staying in hospitals and nursing homes for a long period of time (CDC, 2019a).

- **Hospital-acquired pneumonia (HAP)** occurs 48 hours or more after hospital admission at a rate of 5 to 10 per 1,000 hospital admissions. **Ventilator-associated pneumonia (VAP)** is a subset of HAP occurring in intensive care units that presents more than 48 to 72 hours after tracheal intubation and is thought to affect 10% to 20% of patients receiving mechanical ventilation for more than 48 hours (Shebl & Gulick, 2020).

Many efforts to prevent HAIs have focused on acute care settings, but increasingly, healthcare delivery, including complex procedures, is being shifted to outpatient settings such as ambulatory surgical centers, end-stage renal disease facilities, and long-term care facilities. These settings often have limited capacity for oversight and infection control when compared to hospital-based settings. Patients with HAIs, including those caused by antibiotic resistant organisms, often move between various types of healthcare facilities, and prevention efforts must now expand across the continuum of care (ODPHP, 2020a).

One of the most important reasons in healthcare settings for the spread of bacteria, some of which are antibiotic-resistant and can prove life threatening, is the failure of physicians, nurses, and other caregivers to practice basic hand hygiene. Studies show that on average healthcare providers clean their hands less than half of the times they should, contributing to the spread of HAIs (CDC, 2020b).

PREVENTING CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

The CDC (2019b) recommends the following actions supported by evidence-based research for preventing urinary tract infections:

- Insert catheters only for appropriate indications.
- Leave catheters in place only as long as needed.
- Avoid use of urinary catheters in patients and nursing home residents for management of incontinence.
- Avoid routinely using urinary catheters in operative patients unless necessary.
- Perform hand hygiene immediately before and after insertion or any manipulation of catheter device or site.
- Ensure that only properly trained persons insert and maintain catheters.
- In acute care hospital settings, insert catheters using aseptic technique and sterile equipment.
- In nonacute care settings, use clean technique for intermittent catheterization.
- If ultrasound bladder scanners are used, ensure that equipment is cleaned and disinfected between patients.

- Properly secure indwelling catheters after insertion to prevent movement and urethral traction.
- Unless clinically indicated, use the smallest-bore catheter possible consistent with good drainage.
- Follow aseptic insertion and maintain a closed drainage system.
- If breaks in aseptic technique, disconnection, or leakage occur, replace the catheter and collection system.
- Maintain unobstructed urine flow.
- Keep collecting bag below level of bladder at all times.
- Do not rest collecting bag on the floor.
- Empty collecting bag regularly using separate, clean container for each patient; avoid contact of spigot with the container.
- Obtain urine samples aseptically. If small amount needed, aspirate from needleless sampling port with sterile syringe/cannula adapter after cleaning the port with a disinfectant.
- If obstruction occurs and catheter material is contributing to obstruction, change the catheter.
- Comply with CDC hand hygiene recommendations and Standard Precautions.

Also consider:

- Alternatives to indwelling urinary catheterization in selected patients
- Urinary catheter systems with preconnected, sealed catheter-tubing junctions
- Use of portable ultrasound devices for assessing urine volume to reduce unnecessary catheterizations

CASE

Brenda is a nursing assistant instructor at the local technical college. Today she has taken a group of students to their clinical site, the Marshall Green Nursing Home, which has had a higher than usual number of urinary tract infections over the last several months. One of her students, Annie, is assigned to an elderly gentleman who has an indwelling urinary catheter in place. The care plan indicates he should use a bedside drainage bag during the night and a leg bag during the day. The nursing assistant assigned to the patient tells Brenda his leg bag is in the bedside stand wrapped in a towel.

When Annie locates the bag, it is in a washbasin wrapped in a towel. She finds there is no cap on the end of the tubing that is to be inserted into the catheter, and she shows this to Brenda. Annie has been taught that the end of the tubing must be protected by capping it with a sterile cap in order to maintain a closed system and to prevent bacteria from contaminating the system. Brenda approaches the nursing assistant and tells her about the lack of the cap and the risk for infection. The nursing assistant replies, "We never put a cap on the end of it."

Brenda tells Annie to obtain a new leg drainage bag, instructing her to ensure that she cleans the end of the bedside drainage bag connection and caps it with the cap removed from the new leg-bag tubing before storing it in the bedside cabinet. She then brings the contaminated leg bag to the supervising nurse, who says she will report it and speak to the nursing assistant about it. With the help of Brenda, Annie completes an incident report.

PREVENTING SURGICAL SITE INFECTIONS

The CDC recommends the following measures for the prevention of surgical site infections (SSIs):

- Administer preoperative antimicrobial agents only when indicated by published clinical practice guidelines, and time the administration so that a bactericidal concentration is established when incision is made.
- Administer appropriate parenteral prophylactic antimicrobial agents before skin incision in all cesarean section procedures.
- In clean and clean-contaminated procedures, do not administer additional prophylactic antimicrobial agent doses after the surgical incision in closed in the OR, even in the presence of a drain.
- Do not apply antimicrobial agents (i.e., ointments, solutions, or powders) to the surgical incision with the aim of preventing SSI.
- Application of autologous platelet-rich plasma is not necessary for the prevention of SSI.
- Consider the use of triclosan-coated sutures for the prevention of SSI.
- Implement perioperative glycemic control, and use blood glucose target levels lower than 200 mg/dL in patients with and without diabetes.
- Maintain perioperative normothermia.
- Advise patients to shower or bathe the entire body with either antimicrobial or nonantimicrobial soap or an antiseptic agent on at least the night before the day of the procedure.
- Perform intraoperative skin preparation with an alcohol-based antiseptic agent unless this is contraindicated.

- Application of microbial sealant immediately after intraoperative skin preparation is not necessary for prevention of SSI.
- The use of plastic adhesive drapes with or without antimicrobial properties is not necessary.
- Consider intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution.
- Do not withhold transfusion of necessary blood products from surgical patients undergoing prosthetic joint arthroplasty as a means of preventing SSI.
- In clean or clean-contaminated prosthetic joint arthroplasties, do not administer additional antimicrobial prophylaxis doses after the surgical incision is closed in the OR, even in the presence of a drain.
  (Singhal, 2019)

PREVENTING CENTRAL LINE–ASSOCIATED BLOODSTREAM INFECTIONS

AHRQ (2018a) guidelines for prevention of CLABSIs include the following:

Catheter Insertion

- Use aseptic technique:
  - Use appropriate hand hygiene using soap and water or a waterless hand sanitizer.
  - Use face mask, cap, and sterile gloves.
  - Wear a sterile gown with neck snaps and wrap-around ties properly secured.
  - Instruct anyone assisting to wear the same barriers.
  - Cover the patient entirely with a large sterile drape.
  - Create a sterile working surface that acts as a barrier between the insertion site and any possible source of contamination.
- Prepare skin with antiseptic/detergent chlorhexidine 2% in 70% isopropyl alcohol.
- Apply a sterile dressing to the insertion site before the sterile barriers are removed.
  - Transparent dressings are preferred to allow visualization of the site.
- Use chlorohexidine for skin preparation.
- Use full barrier precautions during central venous catheter insertion.
- Avoid using the femoral vein for catheter in adult patients.

CV Catheter Site Selection

- Use the subclavian site unless medically contraindicated (anatomic deformity, coagulopathy, renal disease that may require dialysis).
- If the internal jugular vein is chosen, use the right side to reduce risk of noninfectious complications since it has a larger diameter and a straighter path to the superior vena cava.

CV Catheter Selection

- Use a single-lumen central venous access device (CVAD) for patients requiring long-term access (more than 30 days) or a PICC or cuffed CVAD for patient requiring access for greater than 2 weeks.

Arterial Line Site Selection

- Radial artery is the preferred site.
- Dorsalis pedis is the alternative site.
- Femoral sites have higher infection rates, brachial/maxillary site are last resort.

Postinsertion Care

- Evaluate the need for CVAD daily.
- Remove catheter when not needed or change to a single-lumen CVAD when possible.
- Replace the dressing when it becomes damp, loosened, or soiled.
- Replace gauze dressing used on short-term central venous catheter (CVC) sites every 2 days.

PREVENTING PERIPHERAL IV CATHETER–RELATED BLOODSTREAM INFECTIONS

Guidelines for prevention of peripheral IV catheter–related bloodstream infections include the following:

Site Selection

- In adults, use an upper-extremity site for catheter insertion.
- In pediatric patients, use the upper or lower extremities or the scalp (in neonates or young infants).

Catheter Selection

- Avoid use of steel needles for administration of fluids and medications that might cause tissue necrosis if extravasation occurs.

- Use a midline catheter or peripherally inserted central catheter (PICC), instead of short peripheral catheter, when duration of IV therapy will exceed six days.

Catheter Insertion

- Perform hand hygiene before insertion.
- Prepare clean skin using a chlorhexidine-based solution. If contraindicated, tincture of iodine, an iodophor or 70% alcohol can be used. Allow to dry prior to placing catheter.
- Maintain aseptic technique for insertion of peripheral IV (PIV).
- Wear clean gloves, rather than sterile, for insertion of a peripheral intravenous catheter if the access site is not touched after application of skin antiseptics.
- Use maximal sterile barrier precautions (cap, mask, sterile gown, sterile gloves, and sterile full body drape) for insertion of PICCs.
- Use either sterile gauze or sterile, transparent, semipermeable dressing to cover site.

Catheter and Site Care

- Perform hand hygiene procedures before and after palpating catheter insertion sites as well as before and after, replacing, accessing, repairing, or dressing an intravascular catheter.
- Evaluate catheter insertion site daily both visually and by palpation through the dressing to discern tenderness and by inspection if a transparent dressing is in use. If local tenderness or other signs of possible infection occur, an opaque dressing should be removed and the site inspected visually.
- Replace catheter site dressing if it becomes damp, loosened, or visibly soiled.
- Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheter.
- Remove peripheral venous catheter if patient develops signs of phlebitis, infection, or a malfunctioning catheter.
- Wear either clean or sterile gloves when changing the dressing on catheter sites.
- Replace dressing every 7 days for transparent dressing, except in pediatric patients in which risk for dislodging catheter may outweigh the benefit.
- Do not submerge catheter or catheter site in water; cover during showering.
- In both adult and pediatric patients, leave peripheral venous catheters in place until IV therapy is completed, unless a complication occurs.

- For catheters inserted under emergency conditions, insert a new catheter at a different site within 24 hours.

- Encourage patients to report any changes in their catheter site or any new discomfort to their provider.

Replacement of Administration Sets

- Replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, unless clinically indicated.

- Replace tubing used to administer blood, blood products, or lipid emulsions within 24 hours of initiating the infusion.

(Jacob & Gaynes, 2020; CDC, 2017a)

PREVENTING CLOSTRIDIOIDES DIFFICILE INFECTIONS (CDIs)

Strategies for the prevention of *Clostridioide*s (formerly known as *Clostridium*) *difficile* infection include the following:

- Isolate and initiate Contact Precautions for suspected or confirmed CDI.

- Maintain Contact Precautions for at least 48 hours after diarrhea has resolved, or longer, up to the duration of hospitalization.

- Adhere to recommended hand hygiene practices.

- Use dedicated patient-care equipment (e.g., blood pressure cuffs, stethoscopes).

- Implement daily patient bathing or showering with soap and water.

- When transferring patients, notify receiving wards or facilities about the patient's CDI status.

- Perform daily cleaning of CDI patient rooms using *C. difficile* sporicidal agent at least once a day, including toilets.

- Clean and disinfect all shared equipment prior to use with another patient (e.g., wheelchair).

- Perform terminal cleaning after CDI patient transfer/discharge using a *C. difficile* sporicidal agent.

- Clean additional areas that are contaminated during transient visits by patients with suspected or confirmed CDI (e.g., radiology, emergency rooms, physical therapy) with *C. difficile* sporicidal agent.

- Restrict use of antibiotics with the highest risk for CDI (e.g., fluroquinolones).
- Ensure that patients receive the shortest effective duration of antibiotic therapy.
- Limit use of nonantibiotic patient medications (e.g., proton pump inhibitors, H2-receptor blockers) that are hypothesized to increase risk for CDI.
- Consider additional disinfection of CDI patient room with no-touch technologies (e.g., UV light).
- Dedicate healthcare personnel to care only for patients with CDI only to minimize risk of transmission to others.

  (CDC, 2017b)

PREVENTING MULTIDRUG-RESISTANT ORGANISM (MDRO) INFECTIONS

The CDC recommends the use of Contact Precautions in inpatient acute care settings for patients known to be colonized or infected with epidemiologically important MDROs, including methicillin-resistant *Staphylococcus aureus* (MRSA). However, there is debate as to the most beneficial way to manage patients with MDRO infections. Despite current guidelines, cluster-randomized trials have failed to show a benefit of initiating Contact Precautions over usual care for the prevention of MRSA or vancomycin-resistant enterococci (VRE) infections in hospitals.

Based on current evidence, however, the CDC continues to recommend the use of Contact Precautions for MRSA-colonized or -infected patients. The CDC will continue to evaluate the evidence on Contact Precautions as it becomes available.

In acute care hospitals, CDC recommendations state:

- Promote the judicious use of antimicrobial agents.
- Follow Standard Precautions during all patient encounters in all healthcare settings.
- Use a mask according to Standard Precautions when:
  - Performing a splash-generating procedure
  - Caring for patients with open tracheostomies
  - In circumstances where there is evidence of transmission from heavily colonized sources, such as burn wounds
  - Not recommended during routine care
- Implement Contact Precautions for all patients known to be colonized/infected with target MDROs.

In long-term care facilities:

- Consider the individual patient's clinical situation and prevalence or incidence of MDROs in the facility when deciding whether to implement or modify Contact Precautions in addition to Standard Precautions for a patient infected or colonized with a target MDRO.

In ambulatory and home care settings:

- Follow Standard Precautions.
- Limit the amount of reusable patient care equipment that is brought into the home of patients infected or colonized with MDROs.

(CDC, 2020c)

PREVENTING VENTILATOR-ACQUIRED LUNG INFECTIONS

Strategies for the prevention of ventilator-associated pneumonias includes:

- Use of routine infection control practices and hand hygiene
- Prophylactic antibiotic administration
- Sedation interruption
- Keeping head of bed elevated 30 to 45 degrees
- Limitation of ventilation times
- Endotracheal suctioning
- Avoiding gastric overdistention
- Draining ventilator tube condensate
- Kinetic bed therapy
- Changing ventilator circuit if visibly soiled or mechanically malfunctioning
- Using sterile suctioning techniques and handling of respiratory equipment
- Performing oral care at least every 2 to 4 hours with an antiseptic swab to clean the oral cavity and teeth; brushing the teeth twice a day. Antiseptics to include:
    - Chlorhexidine in different applications as oral rinse, gel, or foam
    - Povidone-iodine 10%

(Shebl & Gulick, 2020)

Falls

Falls are the most common type of accidents in people 65 years of age and older, with over 30% of such individuals falling every year. In approximately one half of these cases, the falls are recurrent. These percentages increase to around 40% in individuals 85 years and older.

Approximately 10% of falls result in serious injuries, including fracture of the hip, other fractures, traumatic brain injury, or subdural hematoma. They are the major cause of hospitalization related to injury in those 65 years and older and are associated with increased mortality. The associated use of ambulance services, social care, and hospital care results in substantial financial costs.

Falls in institutional settings occur more frequently and are associated with greater morbidity than falls that occur in the community. Approximately 50% of individuals in the long-term care setting fall yearly (Appeadu & Bordoni, 2020; Kiel, 2020).

FALL RISKS

The Joint Commission identifies the most common **contributing factors** to falls with injury as follows:

- Inadequate assessment
- Communication failures
- Lack of adherence to protocols and safety practices
- Inadequate staff orientation or supervision
- Inadequate staffing levels or skill mix
- Deficiencies in the physical environment
- Lack of leadership
  (TJC, 2021b)

Falls risk can be categorized as either intrinsic or extrinsic. Intrinsic factors include issues that are unique to the individual and concern medical, psychological, and physical issues. Extrinsic factors generally can be changed and address environmental risks that patients encounter.

Intrinsic Risk Factors

- Advanced age
- Previous falls
- Gender (women fall more often than men)
- Race (Whites fall most often)

- Taking more than four medications
- Lower extremity weakness
- Impairment in gait and mobility
- Immobility/deconditioning
- Post-fall anxiety syndrome (fear of falling following a recent fall)
- Inner ear disorders
- Cardiovascular or cerebrovascular disorders
- Cognitive disorders
- Poor nutrition
- Poor vision
- Alcohol use
- Postural hypotension
- Chronic conditions such as arthritis, stroke, incontinence, diabetes, Parkinson's disease
- Foot problems leading to balance issues
  (Appeadu & Bordoni, 2020)

Extrinsic Risk Factors (account for 30% to 50% of falls in the older population)

- Lack of stair handrails
- Lack of bathroom grab bars
- Insecure toilet seat or handrail
- Low toilet seat
- Dim lighting or glare
- Obstacles and tripping hazards
- Slippery or uneven surfaces, raised thresholds, missing floor tiles
- Unstable or lightweight furniture
- Hard-to-reach personal items
- Improper use of assistive devices
- Ill-fitting or inappropriate footwear
- Hard-to-manage clothing
- Use of restraints
- Wheelchair issues (e.g., missing parts, incorrect fit, inadequate seating)
  (AHRQ, 2017b)

Older patients are not the only population at risk. Any patient who has had excessive blood loss may experience postural hypotension, increasing the risk of falling. Maternity patients or other patients who have epidural anesthesia are at risk for falls due to decreased lower-body sensation (AHRQ, 2017b).

PREVENTING FALLS

Preventing falls involves assessing patients for risk for falls, developing a personalized plan of care, and utilizing consistent preventive interventions. Fall prevention interventions are to be considered in both hospitalized and ambulatory settings.

Hospitalized Patients

Risk factors for falls and injury in hospitalized patients include:

- Age or frailty
- Osteoporosis or a recent fracture
- Bleeding disorders/taking anticoagulants
- Recent surgery

A fall risk assessment should be done on admission, and reassessment should be done whenever there is a change in a patient's condition or when a patient is being transferred to another unit. A reliable, standardized, and validated assessment scale should be used that includes a history of falls, mobility problems, use of assistive devices, medications, and mental status.

While some institutions have created their own **assessment tools,** tools that have been extensively studied and recommended include:

- Morse Fall Scale
- STRATIFY Scale
- Schmid Fall Risk Assessment Tool

After assessment of fall risk, collaboration with the patient and family takes place in order to develop a personalized plan that addresses each identified risk factor. Tailored **prevention interventions** may include:

- For gait instability/lower-limb weakness:
    - Nonskid footwear
    - Assistive devices
    - Physical therapy evaluation/treatment
    - Assistance getting out of bed and with ambulation

    - Avoiding bedrest
- For urinary incontinence, frequency, and/or need for toileting:
    - Hourly rounding
    - Toileting schedule
    - Incontinence briefs
- For agitation, confusion, or impaired judgment:
    - Frequent rounding/surveillance plan
    - Activity schedule
    - Continuous virtual monitoring
    - Bed/chair alarms
    - Floor mats to reduce trauma from bed-related falls
    - Assess for alcohol or drug withdrawal, place on appropriate protocol
    - Rule out delirium
- Due to medications:
    - Consulting the pharmacist
    - Assessing for and treating orthostatic hypotension
    - Assessing for medication side effects
    - Avoiding hypnotics

(Dykes et al., 2018)

Community-Dwelling Patients

The Centers for Disease Control and Prevention's **STEADI** (Stop Elderly Accidents, Deaths, and Injuries) initiative is a coordinated approach for the implementation of practice guidelines for fall prevention in community-dwelling adults. The STEADI initiative is a coordinated approach to implementing clinical practice guidelines for fall prevention that consists of the three core elements of **screen**, **assess**, and **intervene**. The STEADI Algorithm for Fall Risk Screening, Assessment, and Intervention outlines how to implement these three elements, as follows:

1. **Screen** for fall risk annually, or any time the patient presents with an acute fall:

    - For patients found **not at risk,** prevent future risk by recommending effective prevention strategies:
        - Education patient about fall prevention.
        - Assess vitamin D intake and recommend supplement if deficient.
        - Refer to community exercise or fall prevention program.

- Reassess yearly or any time the patient presents with an acute fall.

2. **Assess** those who are found to be **at risk:**

- Assess the patient's modifiable risk factors and fall history and evaluate gait, strength, and balance. Common assessments include:
  - Timed Up and Go (TUG)
  - 30-second Chair Stand
  - 4-stage Balance Test
- Identify medications that increase fall risk (e.g., using Beers criteria) (see "Resources" at the end of the course).
- Ask about potential home hazards.
- Measure orthostatic blood pressure.
- Assess visual acuity (Snellen eye test).
- Assess feet and footwear.
- Assess vitamin D intake.
- Identify comorbidities (e.g., depression, osteoporosis).

3. **Intervene** to reduce identified risk factors:

- Discuss patient and provider health goals and develop an individualized patient care plan.
  - Poor gait, strength, and balance observed:
    - Refer for physical therapy evaluation
    - Refer to evidence-based exercise or fall prevent program.
  - Medication(s) likely to increase fall risk
    - Optimize medications by stopping, switching or reducing dosages of medication.
  - Home hazards as described
    - Refer to occupational therapist to evaluate home safety.
- Orthostatic hypotension observed:
  - Stop, switch, or reduce dose of medications that increase fall risk.
  - Educate about importance of exercises (e.g., foot pumps).
  - Establish appropriate blood pressure goal.
  - Encourage adequate hydration.
  - Consider compression stockings.

- Visual impairment observed:
    - Refer to ophthalmologist/optometrist.
    - Stop, switch, or reduce dosage of medication affecting vision (e.g., anticholinergics).
    - Consider benefits of cataract surgery.
    - Provide education on depth perception and single-vision multifocal lenses.
- Feet/footwear issues identified:
    - Provide education on shoe fit, traction, insoles, and heel height.
    - Refer to a podiatrist.
- Vitamin D deficiency observed or likely:
    - Recommend daily vitamin D supplement.
- Comorbidities documented:
    - Optimize treatment of conditions identified.
    - Be mindful of medications that increase fall risk.
- Follow-up with the patient in 30 to 90 days to discuss ways to improve patient receptiveness to care plan and to address barrier(s).

(CDC, 2020d)

MORSE FALL SCALE (MFS)

The MFS is used widely in both hospital and long-term care inpatient settings. The MFS requires systematic, reliable assessment of a patient's fall risk factors upon admission, after a fall, upon change in status, and at discharge or transfer to a new setting. MFS subscales include assessment of:

Risk Factor	Score
History of falling, immediate or within 3 months	• No = 0 • Yes = 25
Secondary diagnosis	• No = 0 • Yes = 15
Ambulatory aid	• None, bed rest, wheelchair, nurse = 0 • Crutches, cane, walker = 15 • Furniture = 30
IV/heparin lock	• No = 0 • Yes = 20
Gait/transferring	• Normal, bed rest, immobile = 0 • Weak = 10 • Impaired = 20
Mental status	• Oriented to own ability = 0 • Forgets limitations = 15

MFS Score	Risk Level	Action
0–24	None	Basic nursing care
25–50	Low	Standard fall prevention interventions
51+	High	High-risk fall prevention interventions

(AHRQ, 2018b)

ROLE OF PHYSICAL THERAPY IN FALL PREVENTION

For patients who are found to be at fall risk, a physical therapist will perform a thorough **evaluation**, including:

- Review of medical history
- Review of medications
- Simple vision test

- Balance, strength, range of motion, and walking ability
- Home safety assessment
- Simple test of cognitive abilities
- Assess orthostatic blood pressures
- Assess feet and footwear

Based upon the findings, the physical therapist designs a **treatment plan** tailored to the patient's needs, which may include:

- Balance training
- Prescribed exercise program that includes walking and/or gait training
- Dual-task training program
- Strength training
- Endurance training
- Pain management
- Education on nutrition, sleep, choosing appropriate footwear
- Fear management
- Referral to community programs
- Home safety guidance

(APTA, 2018)

ROLE OF OCCUPATIONAL THERAPY IN FALL PREVENTION

Occupational therapists consider how the person functions in their day-to-day environment. They assess for hazards and patient limitations that contribute to falls and offer safety education to patients and/or caregivers during activities of daily living. Occupational therapists can also earn specialty certification in fall prevention.

Fall risk factors addressed by occupational therapy include:

- Lower-extremity weakness
- Impaired balance
- Cognitive impairment
- Urinary incontinence
- Sensory impairment

- Fear of falling
- Side effects of medication
- Throw rugs and loose carpeting
- Lighting and glare
- Pets
- Clutter
- Uneven sidewalks and thresholds
- Unstable or nonexistent handrails
  (AOTA, 2021)

Health Information Technology (IT) Problems

Healthcare facilities across the United States have made great efforts in moving from paper to electronic systems and processes since the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed in 2009. But while health IT systems have great potential to improve patient safety and help ensure high-quality healthcare, they can also present unintended risks. As these systems become more and more integrated into the delivery of healthcare and the monitoring of safety and quality, how providers interact with these systems as users has become increasingly significant.

Health IT that is poorly designed or poorly applied may contribute to miscommunication, delay, confusion, or distraction. Decision support tools that are not usable may be ignored or, worse, interfere with the delivery of high-quality patient care. In addition, adverse events with the potential for causing significant harm, such as delayed diagnosis, medication errors, and incorrect treatment decisions, have been associated with the use of health IT.

Training is essential to ensure that all users understand how to operate the technology in a safe manner and take advantage of its time-saving features. Feedback from end users over time can help drive improvements in systems, processes, and training resources (Health IT.gov, 2019; AHA, 2018).

DEVELOPING EFFECTIVE DOCUMENTATION AND COMMUNICATION

It is clear that good communication lies at the heart of good practice and thus promotes patient safety. Many errors have been demonstrated to arise from the lack of adequate or accurate communication. There is a great deal of support for the development of effective documentation and communication in the provision of safe patient care.

Documenting to Prevent Errors

Documentation is a form of communication. It must be credible and timely and must accurately reflect the patient's condition as well as the actions taken in response to that condition. Healthcare professionals must learn and follow their facility's policies and procedures about documenting care.

COMMON DOCUMENTATION MISTAKES

Common documentation mistakes in patient records that can lead to errors in treatment include:

- Failing to record pertinent health or drug information
- Failing to record relevant details of a patient's treatment, especially when treating multiple patients and across shifts
- Failing to record that medications have been administered, including dose, route, and time
- Recording in the wrong patient's record (e.g., patients with similar names, similar conditions, physical proximity, or having the same attending physician)
- Failing to document discontinuation of medication
- Failing to record drug reactions or changes in a patient's condition
- Transcribing orders improperly or transcribing improper orders

Illegible writing and poor transfer of information (both within a department and when a patient is transferred to another department or facility) can also cause medical errors (NSO, 2020).

ELEMENTS OF PROPER DOCUMENTATION

Documentation in the patient's health information record should include, but not be limited to:

- Allergies (marked conspicuously)
- Current and past medications (prescribed, over-the-counter, holistic/alternative remedies) and adherence to prescribed regimen
- Medications administered and description of the patient's response
- Risk assessment findings, including:
    - Ambulation status
    - Bowel and bladder function
    - Mental status

  - Elopement risk
  - Fall risk
  - Nutritional status
  - Pain management
  - Skin and wound condition

- Discussions with the patient about medical issues requiring additional explanation by another healthcare provider
- Professional observations during patient contacts
- Encounters with other healthcare providers, including those via telephone, facsimile, and email, with summary of discussion and subsequent actions taken
- Actions taken to contact healthcare provider to report abnormal test results and any provider orders for additional testing or follow-up of tests ordered
  (NSO, 2020)

To help prevent medical errors, the following documentation (charting) do's and don't's are recommended:

Do's

- Before entering anything, ensure the correct chart is being used.
- Document often and include all pertinent details.
- Always provide complete descriptions.
- Document medication administration time, the route, and the patient response.
- Document precautions or preventative measures used, such as bed rails.
- Record any phone call to a provider, including the exact time, message, and response.
- If a patient refuses to allow treatment or take a medication, document it and be sure to report to a supervisor and the patient's provider.
- Always document patient care at the time provided to avoid forgetting details later on. If something must be added later to documentation, always indicate that information with a notation that it is a late entry, and include the time and date.

Don't's

- Don't document a symptom (e.g., "c/o pain") without also documenting how it was treated.
- Never alter a patient's record (a criminal offense).

- Don't use shorthand or abbreviations that are not approved.
- Don't write imprecise descriptions, such as "a large amount."
- Don't document excuses, such as, "Medication not administered because it was not available."
- Never document what someone else said, heard, felt, or experienced unless the information is critical. If absolutely needed, use quotations and properly attribute the remarks.
- Never document care ahead of time, as situations often change; documenting care that has not been performed is considered fraud.
  (NSO, 2021)

Communication Tools to Prevent Errors

Research indicates that poor communication is a root cause of the great majority of all sentinel events.

RISK FACTORS FOR POOR COMMUNICATION

Verbal communication is a common source of medical error. Risk factors for such errors include:

- Disruptive behavior, rudeness, or verbal abuse
- Environmental noise issues
- Cultural differences between patients and providers
- Hierarchy issues
- Providers acting as autonomous agents
- Personality differences
- Language barriers
- Failure to work as a team
- Multiple conversations occurring at the same time
- Education and literacy
  (HIPAA Journal, 2021)

TOOLS FOR EFFECTIVE COMMUNICATION

Communication among healthcare providers using a standard framework and proven tools for reporting and sharing information can enable more effective communication. Examples of such tools include:

- SBAR (see below)

- BATHE protocol (**B**ackground, **A**ffect, **T**rouble, **H**andling, and **E**mpathy) is an interviewing process utilized in outpatient settings to connect with patients, screen for mental health problems, and empower patients to handle identified issues more constructively.

- Ticket-to-Ride for handoffs is a short, in-house document ensuring that transporters and providers unfamiliar with the patient will have important information readily available if problems arise or the patient is away from the unit longer than expected.

- Hourly rounding to each patient's room or bedside is an intervention that helps to proactively anticipate and address each patient's needs.

- Patient teach-back is a technique for healthcare providers to ensure that medical information has been explained clearly so that patients and families understand the information given to them.

- I-PASS is a clinical handoff verbal and written protocol for patient in-house transfer that includes **P**atient summary, **A**ction to-do list, **S**ituation awareness and contingency plan, and **S**ynthesis or **S**ummary of the information by the receiver.

- Technological communication tools:
    - Bedside tablets for patients instead of call lights
    - HIPAA-compliant text messaging platforms for communicating among members of the care team

  (HIPAA Journal, 2021)

SBAR

SBAR is one of the most common communication tools used for structured communication to ensure that information is transferred accurately between two clinicians, such as during a shift transfer. *SBAR* stands for Situation (S), Background (B), Assessment (A), and Recommendation (R). It uses prompt questions in four areas to guide a conversation to ensure efficient transfer of concise information (IHI, 2021a).

S	Situation
B	Background
A	Assessment
R	Recommendation
(IHI, 2021a)	

Speak Up

Well-informed patients are better able to avoid serious medical errors. Clinicians should follow protocols that guide care, health education, and communication to help in both their own and their patients' decision-making about appropriate healthcare.

The Joint Commission encourages patient participation through their Speak Up initiative that encourages hospitals to inform patients about the importance of their contributions to the care they receive, making them active participants in avoiding medical errors (Rodziewicz et al., 2021).

S	Speak up if you have questions or concerns.
P	Pay attention to badges worn by healthcare staff and remind staff to wash their hands.
E	Educate yourself about your illness, medical tests, and treatment plan.
A	Ask a trusted family member or friend to be your advocate.
K	Know what medicines you take and why you take them.
U	Use a hospital, clinic, surgery center, or other facility that meets standards of care.
P	Participate in all decisions about your treatment; you are the center of the healthcare team.
(TJC, 2021c)	

ERROR RISKS AMONG POPULATIONS OF SPECIAL VULNERABILITY

The safety of all patients is of paramount concern for all healthcare providers. However, some patients—for example, the very young, the very old, and the very sick—are particularly vulnerable to the effects of medical errors, often due to their inability to participate actively as a member of the healthcare team due to communication issues. In addition, their physical status (including but not limited to body weight and body mass composition, nutritional status, and metabolism) may also cause them to react differently to interventions, putting them at special risk. Healthcare providers must recognize the special needs of these patients and act accordingly.

Older Adults

There are multiple issues of concern when providing healthcare to adults ages 65 and over. Failure to recognize the unique problems of this age group can result in adverse events.

POLYPHARMACY

Polypharmacy, the use of multiple medications, some of which may be clinically inappropriate and/or incompatible, creates a significant risk for adverse drug events. Multiple medications, often new to the patient during hospitalization, potentiate the risk of nutritional, functional, and cognitive decline during hospitalization as well as increase the overall mortality risk. Literature has reported an average polypharmacy rate of 40% to 50% in this population (Nguyen et al., 2020).

The older adult is more sensitive to the effects of certain drugs, particularly those that affect the central nervous system, and aging is associated with decreased regulatory functions. Therefore, an antihypertensive medication, for example, can more easily result in postural hypotension, increasing the risk for falls. Opiates can increase the risk of respiratory depression.

Older adult patients often have multiple comorbidities, putting them at risk for polypharmacy. When a patient enters a hospital, clinicians may not have access to the patient's current or previous medication list and/or may fail to realize that a new symptom is an adverse drug reaction or a side effect, and so another drug may be prescribed to treat that symptom.

Patients who see several different physicians at several different locations also have an increased risk of duplicate medications or drug interactions. Other problems may arise due to repeat prescribing without proper review, failing to do regular medication reviews with patients, and poor knowledge of drug interactions on the part of the clinician (Nguyen et al., 2020).

Polypharmacy can also negatively affect medication adherence in the older adult due to a number of associated factors, such as visual or hearing impairment, cognitive or functional impairment, social isolation, and complexity of the therapeutic regimen (Trotter et al., 2020).

Medication management in the older adult population involves considerations for drug dosing, drug interactions, adverse effects, adherence, social issues, clinical practice guidelines, and altered physiology.

One of the most commonly used tools for identifying and assessing patients for polypharmacy-related issues is the American Geriatrics Society Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (see "Resources" at end of this course).

COGNITIVE IMPAIRMENT

Confusion and/or delirium in the older adult, especially someone with preexisting cognitive impairment, can be due to certain aspects of hospitalization, such as changes in environment and sensory deprivation. Delirium can also be the result of polypharmacy. The most common medications to cause delirium are opiates, benzodiazepines, and anticholinergics. An anticholinergic effect can also worsen a developing dementia. Confusion can also worsen when sensory input is affected, such as when the patient does not have access to eyeglasses or hearing aids.

Effective measures include orientation protocols, environmental modification, nonpharmacologic sleep aids, early and frequent mobilization, minimizing use of physical restraints, use of vision and hearing aids, adequate pain relief, and reduction in polypharmacy (Mattison, 2020).

FUNCTIONAL DECLINE

Functional decline may be the result of lack of mobility resulting in physical deconditioning and muscle weakness. The older adult experiences functional decline when unable to engage in activities of daily living. When an older adult is hospitalized, functional decline can occur as early as the second day of hospitalization. Immobility can increase the risk for adverse events such as falls, delirium, skin breakdown, and venous thromboembolic disease.

Improved mobility during hospitalization has been linked to decreased risk of death. Activity order for bed rest should be avoided unless absolutely medically required. Patients should be assisted out of bed to a chair for meals, which can also decrease the risk of aspiration, and should be encouraged to walk several times a day (Mattison, 2020).

FALL RISK

Risk for falls is increased in the older adult and may be due to the effects of acute illness compounded by an unfamiliar environment and side effects of treatments. Tethering medical devices such as urinary catheters, IV lines, cardiac monitor leads, and restraints make it more difficult to mobilize patients safely and are associated with increased rates of delirium, infection, and falls.

Strategies to help prevent falls may include weighing the risks and benefits of medications with significant psychotropic and anticholinergic effects, monitoring patients when prescribed drugs that may increase fall risk, supervising high-risk patients when ambulating, and encouraging time out of bed walking or sitting in a chair to prevent orthostatic hypotension associated with prolonged immobility (Mattison, 2020).

MALNUTRITION/DEHYDRATION

Malnutrition and dehydration in hospitalized and nursing home older patients may result due to impairment in cognition, restriction of movement, no access to dentures, difficulty with self-feeding, missed or interrupted meals, reduced appetite due to illness or lack of activity, lack of assistance with meals and drinks, and severely restricted diet orders, such as nothing by mouth.

Simple interventions such as getting the person out of bed at mealtime and providing assistance with eating can be of benefit. Inpatient assessment by a nutritionist can identify deficiencies and, combined with nutritional follow-up after discharge, may decrease mortality (Mattison, 2020).

Infants and Children

The potential for **adverse drug events** is higher in the pediatric population than in hospitalized adult patients. Every year more than 200,000 medication errors are reported, and approximately 30% of these errors involve children under 6 years of age (Wu, 2018). Dosing errors are the most common medication error in this population. The factors that place them at higher risk include:

- Different and changing pharmacokinetic parameters between patients at various ages and stages in development
- Fewer internal reserves to buffer any medication errors that may occur
- Need for calculation of individualized doses based on the patient's age, weight, body surface area, and clinical condition (weight changes requiring recalculation can occur quickly, particularly in neonates)
- Inadequate availability of appropriate dosage forms and concentrations needed
- Need for precise dosage measurement and appropriate delivery systems

Clinical pharmacists can help by checking dosing calculation, screening for drug-drug interactions, and counseling caregivers on proper administration and medication-storage safety. Accurate weight scales that only measure in metric units (kilograms or grams), standardized equipment throughout a system, drug dose range limits, programmable "smart" infusion pumps for hospitals, and standardized order sets should be used.

Infants and young children do not have the communication abilities needed to alert clinicians to effects they experience. Parents of infants and children need to be fully informed and involved in their child's care during any encounter with the healthcare system and must be educated to question caregivers about medications and procedures. Studies have shown that in low-income populations, medication errors are more prevalent due to potentially inadequate or marginal literacy, leading to misunderstanding of medication-dosing instructions (Wu, 2018; Mueller et al., 2019).

Intensive Care Patients

Intensive care settings are one of the most complex environments in healthcare. Preventable harms contribute significantly to ICU morbidity, mortality, and costs. Medical errors and deaths due to preventable harms are more common in the ICU due to higher patient acuity and complexity of care.

A **safety smart list** integrated into intensive care patients' electronic health records has been found to decrease complications and length of stay in the ICU. The checklist covers common ICU conditions that, when left unaddressed, have been associated with HAIs, thrombosis, and worse clinical outcomes.

The checklist includes:

- Removing unnecessary catheters
- Verifying that deep venous thrombosis, gastrointestinal, and medication issues are addressed
- Assessing and managing sedation, analgesia, and delirium
- Advancing the patient's enteral diet and mobility
- Improving communication with family members and people with power of attorney (Lemkin et al., 2020)

Patients with Limited English Proficiency

Persons with limited English proficiency (LEP) have a limited ability to read, speak, write, or understand English. According to U.S. census data, there at least 25 million people in the United States over the age of 5 years who can be classified as LEP (Claros, 2021).

Individuals with LEP have problems with language competence that negatively affect communication and can greatly define the ease with which they navigate all areas of the healthcare system. An analysis of adverse incidents in the hospital setting found that 49.1% of LEP patients experienced physical harm, compared to 29.5% of English-speaking patients (Claros, 2021).

Patients with linguistic differences may have problems advocating for themselves and may not be able to describe or explain their chief complaints or express their level of pain. They are at higher risk for complications because of poor comprehension of medication errors, inaccurate assessment, increased psychological stress, and poor compliance with treatment and follow-up. In addition, the use of family or friends as interpreters increases chances of error (Claros, 2021).

Both the Joint Commission and the Affordable Care Act mandate adequate medical interpreter and translation services for patients with LEP. Translation and interpreter services provided by Certified Medical Interpreters is the gold standard, with studies showing the rate of error as being far lower when professional interpreters with more than 100 hours of training are used (Goodwin, 2018).

Patients with Low Health Literacy

Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Low health literacy may have a negative effect on a person's adherence to a treatment regimen, which may decrease its benefits. Patients with low health literacy also tend to use the emergency department more often and are more likely to return to the emergency department after 2 weeks (ODPHP, 2020b).

Low health literacy may impact parent/caregiver behavior (e.g., medication dosing) and children's health outcomes.

Factors that influence an individual's health literacy include

- Poverty
- Education
- Race/ethnicity
- Age
- Disability
- Cultural beliefs

Insurance status may also impact health literacy. Uninsured and Medicaid-insured individuals are at high risk for low health literacy. Older adult Medicare beneficiaries with low health literacy have higher medical costs, increased ER visits and hospital admission, and decreased access to healthcare.

Since limited health literacy is common and may be difficult to recognize, it is recommended that clinicians assume all patients and caregivers may have difficulty comprehending health information and that they communicate in ways that anyone can understand. This includes

- Simplifying communication
- Confirming comprehension for all patients
- Making the healthcare system easier to navigate
- Supporting patients' efforts to improve their health
  (ODPHP, 2020b)

PATIENT SAFETY INITIATIVES

When the book *To Err Is Human* made headlines across the country in 1999, it captured the attention of the public and launched the modern patient safety movement. Federal funding for patient safety initiatives increased, accreditation and reporting standards tightened, and research on effectiveness of patient safety measures expanded. Over the ensuing years, the patient safety movement has grown to involve many agencies and organizations in both the public and private sectors, and many important milestones have been achieved along the way.

Annually, the Patient Safety Movement Foundation meets to nominate and elect new patient safety challenges to be addressed for the following year in attempt to reach their primary goal of zero preventable deaths by 2030. In 2020, organizations were asked to commit to implementing and sustaining a foundation for safety and reliability that includes three critical components:

- A person-centered culture of safety
- A holistic, continuous improvement framework
- An effective model for sustainment

(PSMF, 2021)

AGENCIES AND ORGANIZATIONS IN THE PATIENT SAFETY MOVEMENT

AAAHC - Accreditation Association for Ambulatory Health Care. Develops standards to advance and promote patient safety, quality care, and value for ambulatory healthcare settings, including ambulatory surgery centers, community health centers, medical and dental group practices, medical home practices, and managed care organizations, as well as Indian Health Service and student health centers.

ABMS - American Board of Medical Specialties. Recognizes medical specialists and establishes standards for physician certification.

ACGME - Accreditation Council for Graduate Medical Education. Responsible for accrediting the majority of medical residency and internship programs.

AHRQ - Agency for Healthcare Research and Quality. Produces evidence to make healthcare safer, of higher quality, more accessible, more equitable, and more affordable, working with the U.S. Department of Health and Human Services.

ANA - American Nurses Association. Represents the interests of registered nurses to advance the profession to improve healthcare.

CDC - Centers for Disease Control and Prevention. Promotes health and disease prevention and preparedness.

ECRI - Economic Cycle Research Institute. A federally designated Evidence-based Practice Center, recognized as a trusted source of guidance and consulting on and monitoring of new and emerging medical technologies, procedures, genetic tests, and clinical guidelines.

HCUP - Health Care Utilization Project. Maintains hospital care data, enabling research on a range of health policy issues.

HRET - Health Research and Education Trust. A research and education affiliate of the American Hospital Association that promotes research and education efforts.

IHI - Institute for Healthcare Improvement. Redesigns healthcare into a system without errors, waste, delay, or unsustainable costs. In 2017, joined together with National Patient Safety Foundation.

IOM - Institute of Medicine. Asks and answers the nation's most pressing questions about health and healthcare.

ISMP - Institute for Safe Medication Practices. Watchdog organization devoted to medication error prevention and safe medication use.

NGC - National Guideline Clearinghouse. A public resource for evidence-based clinical practice guidelines.

NIH - National Institutes of Health. Conducts medical research.

NQF - National Quality Forum. Leads national collaboration to improve health and healthcare quality through measurement.

TJC - The Joint Commission. Accredits and certifies healthcare organizations and programs in the United States.

WHO - World Health Organization. WHO World Alliance for Patient Safety serves as the directing and coordinating authority for health within the United Nations system.

Federal and State Efforts

The National Action Plan centers on four foundational and interdependent areas, prioritized as essential to create total system safety:

1. **Culture, Leadership, and Governance**
    - Ensure safety is a demonstrated core value
    - Assess capabilities and commit resources to advance safety
    - Widely share information about safety to promote transparency
    - Implement competency-based governance and leadership
2. **Patient and Family Engagement**
    - Establish competencies for all healthcare professionals for the engagement of patients, families, and care partners
    - Engage patients, families, and care partners in the coproduction of care
    - Ensure equitable engagement for all patients, families, and care partners
    - Promote a culture of trust and respect for patients, families, and care partners
3. **Workplace Safety**
    - Implement a systems approach to workforce safety
    - Assume accountabilities for physical and psychological safety and a healthy work environment

- Develop and execute priority programs that equitably foster workforce safety

4. **Learning System**
    - Facilitate both intra- and interorganizational learning
    - Accelerate the development of the best possible safety learning networks
    - Initiate and develop systems to facilitate interprofessional education and training on safety
    - Develop shared goals for safety across the continuum of care
    - Expedite industry-wide coordination, collaboration, and cooperation on safety

(IHI, 2021b)

The Centers for Medicare and Medicaid Services (CMS) announced in 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered "never events." Since then, many states and private insurers have adopted similar policies. Since February 2009, CMS has not paid for any costs associated with wrong-site surgeries. Never events are also being publicly reported, with the goal of increasing accountability and improving the quality of care.

Since the National Quality Forum disseminated its original never events list in 2002, 11 states have mandated reporting of these incidents whenever they occur, and an additional 16 states mandate reporting of serious adverse events. Healthcare facilities are accountable for correcting systematic problems that contribute to the events, with some states mandating performance of a root cause analysis and reporting its results (AHRQ, 2019h).

PREVENTABLE COMPLICATIONS (NEVER EVENTS) NOT COVERED BY MEDICARE AND MEDICAID

The following preventable complications are not reimbursed by Medicare and Medicaid if acquired during an inpatient stay:

- Foreign object retained after surgery
- Air embolism
- Blood incompatibility reaction
- Stage 3 and 4 pressure injuries/ulcers
- Falls and trauma:
    - Fractures and dislocation
    - Intracranial injuries
    - Burns

    - Crushing injuries
    - Other injuries
- Manifestations of poor glycemic control:
    - Diabetic ketoacidosis
    - Nonketotic hyperosmolar coma
    - Secondary diabetes with ketoacidosis
    - Secondary diabetes with hyperosmolarity
- Catheter-associated urinary tract infection
- Vascular catheter-associated infection
- Surgical site infection following:
    - Mediastinitis following coronary artery bypass graft
    - Bariatric surgery for obesity
    - Laparoscopic gastric bypass
    - Gastroenterostomy
    - Laparoscopic gastric restrictive surgery
- Surgical site infection following certain orthopedic procedures:
    - Spine
    - Neck
    - Shoulder
    - Elbow
- Surgical site infection following cardiac implantable electronic device
- Deep vein thrombosis/pulmonary embolism following total knee or hip replacement
- Iatrogenic pneumothorax with venous catheterization

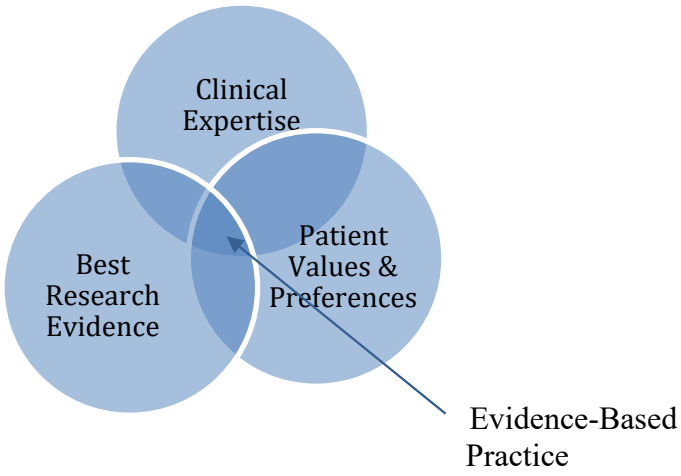
Medicare and Medicaid also will not reimburse for wrong-site, wrong-procedure, and wrong-patient surgery (CMS, 2020).

Since Medicare initiated its nonpayment policy for preventable errors, many private insurers have followed suit, further benefiting patient safety. In addition, some have implemented incentives for hospitals that adhere to standards designed to improve patient safety.

Evidence-Based Practice

Evidence-based practice (EBP) is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Evidence-based practice is vital for improvement in the quality of treatment and for assuring patient safety. EBP attempts to standardize practices in order to make outcomes more predictable. EBP involves collecting, evaluating, and implementing practices that can improve patient care safety and outcomes. EBP is beneficial in decreasing healthcare costs and reducing medical complications. It is the integration of clinical expertise, patients' values and preferences, and best research evidence into the decision-making process for providing patient care (Duke University Medical Center, 2020).



Components of evidence-based practice. (Source: J. Swan.)

FIVE STEPS TO IMPLEMENT EVIDENCE-BASED PRACTICE

Evidence based practice begins and ends with the patient.

1. **Assess** the patient and your own knowledge gaps.
2. **Ask** a well-built clinical question derived from the patient's case.
3. **Acquire** evidence by selecting an appropriate resource and by conducting a search.
4. **Appraise** evidence for validity and applicability.
5. **Apply** what has been learned, talk with the patient, and integrate the evidence with your clinical expertise and patient preferences.

Following this process, it is important to evaluate performance with the patient (Duke University Medical Center, 2020).

CASE

Jai, a pharmacist working in skilled nursing facilities, was involved in **assessing** and updating a facility's manual of medication policies and procedures. While reviewing the section on digoxin monitoring, he found that an apical pulse should be taken daily before administering digoxin and that the drug should not be given if the pulse is below 60 beats per minute.

While looking over medication administration records, he found that residents with hypertension receiving antihypertensives had their blood pressure taken once a week and other residents had vital signs done once a month. Apical pulses for residents receiving digoxin were obtained daily.

As he thought about this, he realized that in all the time he has been working as a pharmacist in healthcare facilities, he could only recall digoxin being withheld once or twice because of a pulse below 60. He began to question the necessity for performing apical pulses and **asked**, "Why are medication nurses in skilled nursing facilities checking apical pulses daily?"

With that question in mind, Jai began to **acquire** relevant resources by talking with medication nurses, directors of nursing, and other pharmacists about their experiences with digoxin monitoring. All of the nurses he questioned had been in nursing for 10 or more years in skilled nursing facilities, and none could remember holding digoxin more than once or twice for a pulse below 60 on a single day and that returned to normal on the next day. This number was compared to the hundreds of doses they had administered over their careers.

Jai then began to search databases for the best evidence for digoxin monitoring. He found that the initiation of digoxin occurred in hospital settings, and that it was critical to take apical pulses to determine the correct dosage. Once the patient was properly dosed and discharged, this monitoring was no longer required. Indeed, the research showed that patients discharged to "home" are not instructed to monitor their apical pulse every day, and there were no negative outcomes reported.

Following his critical **appraisal** of the resources, Jai determined that persons who reside in nursing homes have been discharged to their "home" and that medication nurses were performing a time-consuming, unnecessary procedure.

Jai brought his findings to the director of nursing and the medical director, and together they enacted (**applied**) a new policy that stated the apical pulse rate of residents receiving digoxin is to be obtained once a week. If the apical pulse is less than 60, digoxin should be given as ordered, and the apical pulse is to be monitored daily for three days while continuing to give the medication. If it continues to be below 60 after three days, the medication should be withheld and the attending physician notified.

The change in policy was explained to patients and their families so there would be no perception of the staff "cutting corners" once the new practice started. Aside from a few joking comments by patients about missing the "hand holding," there was no push back.

The policy was **assessed** after it was in place for nine months. During that time there was not a single dose of digoxin held. It was determined that this change resulted in one less procedure to be performed by the medication nurse, leaving more time to provide other care for the patients (Vogenberg, 2004).

Attitudes towards EBP are mostly positive within the nursing, occupational therapy, and physical therapy fields. There does remain, however, resistance to acceptance of EBP despite scientifically supported knowledge. Many practices that are **not** evidence-based continue, including:

- Taking vital signs every 4 hours during the night on stable patients, disrupting sleep needed for recovery
- Treating children with asthma in the emergency department using nebulizers instead of a bronchodilator with a metered-dose inhaler and spacer, which has been shown to be more effective
- Removing urinary catheters only upon a physician's order, even though a nurse-driven protocol is more efficient and may prevent urinary tract infections
- Continuing the practice of 12-hour nursing shifts when research evidence demonstrates adverse outcomes for both nurses and patients
  (Meinyk, 2016)

Quality Assurance and Performance Improvement (QAPI)

Quality Assurance (QA) is the process of meeting quality standards and assuring that care reaches an acceptable level, and Performance Improvement (PI) is the continuous analysis of performance and the development of systematic efforts to improve it. Beginning in 2011, the Centers for Medicare and Medicaid Services began mobilizing some of the best practices in nursing homes. QA and PI were combined, and a prototype QAPI program was begun in a small number of facilities, which provided the agency with best practices for helping nursing homes upgrade their current quality programs.

QAPI is made up of five elements:

1. **Design and Scope**
   - Must be comprehensive and ongoing
   - Should address all systems of care and management practices
   - Aims for safety and high quality with all clinical interventions
   - Emphasizes autonomy and choice in daily life for residents
   - Utilizes the best available evidence to define and measure goals

2. **Governance and Leadership**
    - Develops a culture that seeks input from facility staff, residents, and families
    - Assures adequate resources exist
    - Designates person(s) to be accountable
    - Ensures staff time, equipment, and technical training as needed
    - Ensures that policies are developed to sustain QAPI
    - Ensures a culture of safety
3. **Feedback, Data Systems, and Monitoring**
    - Uses performance indicators to monitor a wide range of care processes and outcomes
    - Reviews findings against established benchmarks or targets
    - Includes tracking, investigating, and monitoring of adverse events
    - Develops action plan to prevent adverse event recurrences
4. **Performance Improvement Projects**
    - Gathers information systematically to clarify issues or problems
    - Intervenes to make improvements
5. **Systematic Analysis and Systemic Action**
    - Uses a systematic approach to determine when in-depth analysis is needed
    - Uses a thorough and highly organized structured approach to examine the way care and services are organized or delivered
    - Develops policies and procedures and demonstrates proficiency in the use of root cause analysis
    - Takes systemwide actions to prevent future events
    - Focuses on continual learning and continuous improvement

(CMS, 2016)

JOINT COMMISSION AND AAAHC STANDARDS AND GOALS

The Joint Commission

The Joint Commission (TJC) is an independent, not-for-profit agency whose mission is to continuously improve the safety and quality of care provided to the public. The Joint Commission accredits and certifies more than 22,000 healthcare organizations and programs in the United States, including hospitals and healthcare organizations that provide ambulatory and office-based surgery, behavioral health, home health care, laboratory, and nursing care center services.

Accreditation by the Joint Commission is not mandatory. Healthcare organizations, programs, and services voluntarily pursue accreditation and certification. Joint Commission surveyors visit accredited healthcare organizations a minimum of once every 36 months (two years for laboratories) to evaluate standards compliance. This visit is referred to as a *survey*. All regular Joint Commission surveys are unannounced.

During a survey, the surveyors randomly select patients, and using their medical records, the surveyors evaluate standards compliance. As they review each patient's experience, they talk to doctors, nurses, and other staff who interacted with the patients. They also observe doctors, nurses, and other caregivers providing care and often speak to the patients themselves.

The Joint Commission Quality Reports give the public information on the safety and quality of care for all Joint Commission accredited/certified healthcare organizations. Reports include:

- Accreditation decision and date
- Programs and services accredited by the Joint Commission and other bodies
- National Patient Safety Goal performance
- Hospital National Quality Improvement Goal performance
- Special quality awards
  (TJC, 2021d)

SENTINEL EVENT POLICY

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. The policy explains how the Joint Commission partners with healthcare organizations that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

Each accredited organization is strongly encouraged, but not required, to report sentinel events to TJC. Benefits of reporting include:

- TJC can provide support and expertise during the review of a sentinel event.

- The opportunity to collaborate with a patient safety expert in TJC's Sentinel Event Unit of the Office of Quality and Patient Safety.
- Reporting raises the level of transparency in the organization and promotes a culture of safety.
- Reporting conveys the healthcare organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future. (TJC, 2021a)

NATIONAL SAFETY GOALS

Every year TJC gathers information about patient safety issues from widely recognized experts and stakeholders. This information is the basis for their National Patient Safety Goals, which are tailored for each specific healthcare setting. The information also informs their sentinel event alerts, standards and survey processes, performance measures, educational materials, and Joint Commission Center for Transforming Healthcare projects.

The National Safety Goals address multiple healthcare sites:

- Ambulatory healthcare
- Behavioral healthcare and human services
- Critical access hospital
- Home care
- Hospital
- Laboratory
- Nursing care center
- Office-based surgery

Specific goals for each may include any of the following that have been identified as pertinent for the setting:

- Identify patients correctly
- Improve staff communication
- Use medicines safely
- Use alarms safely
- Prevent infection
- Identify patient safety risks
- Prevent mistakes in surgery
- Prevent patients from falling
- Prevent bed sores (pressure injuries) (TJC, 2021e)

"DO NOT USE" ABBREVIATION LIST

Misreading medical abbreviations can be a cause of serious medication errors, and TJC has created a "do not use" list of abbreviations that endanger patients' safety and that it requires its members to follow (see table).

JOINT COMMISSION "DO NOT USE" LIST
Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on preprinted forms.

Do Not Use	Potential Problem	Instead Use
U, u	Mistaken for "0" (zero), the number "4" (four), or "cc"	Unit
IU	Mistaken for IV (intravenous) or the number 10 (ten)	International unit
Q.D., QD, q.d., qd	Mistaken for each other	Daily
Q.O.D., QOD, q.o.d, qod	Period after the "Q" mistaken for "I" and the "O" mistaken for "I"	Every other day
Lack of leading zero	Decimal point is missed	0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Morphine sulfate or Magnesium sulfate
MSO_4 and $MgSO_4$	Confused for one another	Magnesium sulfate
Trailing zero*	Decimal point is missed	X mg

* Exception: A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

(TJC, 2020)

The Institute for Safe Medication Practices has also compiled an extensive list of abbreviations, symbols, and dose designations that are frequently misinterpreted and involved in harmful medication errors, which can be accessed online (see "Resources" at the end of this course).

ROOT CAUSE ANALYSIS

Root cause analysis (RCA) has been adopted widely as a method for investigating serious adverse events. The Joint Commission has mandated use of RCA to analyze sentinel events since 1997. Many states and the District of Columbia have mandated reporting of serious adverse events, and many states also require that RCA be performed and reported after any serious event.

Root cause analysis identifies underlying problems that increase the likelihood of errors while avoiding focusing on mistakes made by individuals. The approach identifies both active errors

and latent errors and is one of the most widely used retrospective methods for detecting safety hazards.

RCAs follow a prespecified protocol, beginning with data collection and reconstruction of the events through record review and participant interviews. A multidisciplinary team then analyzes the sequence of events leading to the error, with goals of identifying how the event occurred (by identifying active errors) and why the event occurred (by systematic identification and analysis of latent errors). The steps in this process include:

- Prepare for root cause analysis
    - Organize a team
    - Define and study the problem
- Determine direct and underlying causes
    - Determine what happened
    - Identify contributing process factors
    - Identify other contributing factors
    - Measure, collect, and assess data
    - Design and implement immediate changes
- Identify root causes
    - Identify which systems are involved
    - Prune the list of root causes
    - Confirm root causes and consider their interrelationships
- Design and implement a corrective action plan
    - Explore and identify risk reduction strategies
    - Formulate improvement actions
    - Design improvements
    - Ensure acceptability of the corrective action plan
    - Implement the improvement plan
    - Develop measures of effectiveness and ensure their success
    - Evaluate implementation of improvement efforts
    - Take additional action
    - Communicate the results

The ultimate goal of RCA is to prevent future harm by eliminating the latent errors that often underlie adverse events.

Although RCA is widely used, its effectiveness is being debated. Studies have shown that RCAs often fail to result in the implementation of sustainable system-level solutions. The National Patient Safety Foundation has proposed that the process of root cause analysis be renamed to include **action** and as well as analysis (RCA2), emphasizing that a well-done RCA should yield strong corrective actions as well as risk reduction (AHRQ, 2020).

ROOT CAUSE ANALYSIS AND ACTION PLAN TEMPLATE

The Joint Commission has developed a template to be used while conducting a root cause analysis that recommends the following 24 questions be asked and answered and an action plan developed for any finding that can be considered a risk-reduction strategy.

1. What was the planned flow of the procedure?
2. What steps in the procedure did not occur as planned?
3. What human factors were pertinent to the outcome?
4. How did performance of equipment affect outcome?
5. What controllable environmental factors directly affected the outcome?
6. What external controllable factors affected the outcome?
7. Were there any other factors that directly affected the outcome?
8. In what other areas of the organization could this happen?
9. Was the staff properly qualified and currently competent at the time of the event?
10. How did real staffing compare with ideal levels?
11. What is the plan for dealing with unforeseen staffing problems?
12. Were such problems a factor in this event?
13. Did staff perform to expectations during the event?
14. Was all the necessary information available when needed? Was it accurate, complete, and explicit?
15. Was communication among participants sufficient for this situation?
16. Was this the appropriate physical environment for the situation?
17. What systems are in place to recognize environmental risks?
18. What planned and tested emergency and failure-mode responses are in place?
19. How does the culture support risk reduction?
20. What barriers exist to the communication of potential risk factors?

21. What methods are utilized to communicate the high priority of prevention of adverse outcomes?
22. What orientation and in-service training revisions are necessary to reduce risk of events in the future?
23. Was available technology used as intended?
24. What technology or redesign of technology might reduce risk in the future?

(TJC, 2017)

CASE

St. Vincent Hospital
(continued from above under "Active and Latent Errors")

Following identification of the cause of the accident in St. Vincent Hospital's operating room, a root cause analysis was begun that day. The root cause was determined to be the use of an inappropriate gas mixture to expand the abdomen during laparoscopic surgery.

Contributing factors included:

- All extra cylinders containing medical gases used in the OR are stored in metal tubes in a tank room, but only the top several inches of each cylinder and a portion of each tank's label is visible above the top of the storage tubes. The tube height is to provide adequate support for the cylinders, so shortening the tubes to allow visualization of the entire label is not an appropriate option.
- All tanks containing any percentage of CO_2 are color-coded the same (grey). This is an industry standard over which individual facilities have no control.
- When an OR logistics technician allowed a logistics technician from the catheterization lab to store an extra CO_2/O_2 tank in the OR tank room, no one in the OR, anesthesia, or logistics chain of command was informed. This is an example of well-intentioned interunit cooperation gone awry due to lack of appropriate communication.
- The circulating nurse mistakenly replaced an empty CO_2 tank with a blended CO_2/O_2 tank, not noticing the difference because they were both grey, with similar labeling, and because there was no history of anything but pure CO_2 being stored in the OR tank room or used in the OR.
- There was no pin indexing at the connection point between the cylinder and the gas delivery system that differentiates between pure CO_2 and CO_2/O_2 blends. Any cylinder containing any percentage of CO_2 fits to any yoke designed to accept CO_2 in any concentration.

Corrective actions included policy changes and an intensive education initiative for all involved personnel:

- Only medical gases intended for use in the OR are to be stored in the OR tank room.
- Should a deviation from this policy be indicated for safety reasons and no other alternatives exist:
    - Tanks containing gases not used in the OR are to be stored in the OR tank room only until safe storage elsewhere is available.
    - If no alternative storage is available, storage in the OR tank room may be approved only by the senior professional and technical personnel in the OR **and** the anesthesia service. If the decision is made during "off" hours by a shift charge person, that person is responsible for notifying the appropriate senior personnel by the next shift or delegating and documenting that this notification is to be made by a specific, named person.
    - Any such tanks are to be indicated by orange fluorescent tags reading "Not for use in the OR" and placed in the most remote storage tubes in the tank room.
    - Information about the temporary storage is to be conveyed at each OR and anesthesia shift report and in the OR shift change log until the tank is removed.
- Medical gases are elevated to the status of medications and the triple-check policy used for medications will be implemented for medical gases.
- The OR manager will personally brief each shift for the next two days to minimize rumors.
- All members of the involved surgical and logistics teams will be debriefed by their supervisors.
- A description of the incident and follow-up will be published in the quality assurance journal for the healthcare system.

CASE

Céline is an 82-year-old patient who has suffered a stroke and been transferred to a local nursing home where inadequate staffing has been a recurrent problem. Céline has right-sided paralysis and requires total care. Her care plan includes repositioning every two hours. Today the nurse does the required biweekly skin assessment and finds a small open crater with visible subcutaneous tissue on the heel of her right foot (i.e., a stage 3 pressure injury).

The nurse documents and reports this long-term care sentinel event per facility policy, and a root cause analysis is begun by a multidisciplinary team that will identify how and why the event occurred. By asking questions as outlined in the facility's root cause analysis template, the first step is to **identify and define the problem**:

- Stage 3 pressure injury (damage to tissue leading to death of tissue) has developed on the heel of the patient's right foot.
- Tissue damage has negatively impacted the goal of patient safety.

The second step is to **identify the cause**:

- Death of tissue caused by mechanical damage
- Mechanical damage caused by pressure
- Pressure injury due to patient remaining in same position
- Patient remaining in same position due to failure to reposition every 2 hours
- Failure to reposition every 2 hours due to inadequate level of staffing

The third step in the process is to **select the best solution** to reduce the risk of pressure injuries in the future.

- Reposition patients at risk every 2 hours and document the action.
- Utilize pressure-relieving devices such as beds, mattresses, or overlays.
- Review and revise staffing formulas; improve staffing to meet the U.S. Department of Health and Human Services recommendations of 1 hour per resident per day for total licensed staff, 27 minutes per day for RNs, and 2 hours per day for nursing assistants.

Following completion of the root cause analysis, the facility determines to **institute the action plan**:

- Alternating pressure pads are applied to the beds of all residents at high risk for pressure injuries.
- The use of heel/elbow protectors becomes standard for all patients with immobility issues.
- Documentation on the implementation and effectiveness of a turning schedule is instituted for each resident with immobility.
- Staffing issues remained unresolved due to budget restraints, but ongoing exploration of means to improve the staffing level is being carried out.

Accreditation Association for Ambulatory Health Care

The Accreditation Association for Ambulatory Health Care (AAAHC) was founded in 1979 and is the leader in ambulatory healthcare accreditation, with more than 6,100 organizations accredited. AAAHC accredits a wide range of outpatient settings that include:

- Ambulatory healthcare clinics
- Ambulatory surgery centers
- Birthing centers
- College and university health centers
- Community health centers
- Dental group practices
- Diagnostic imaging centers
- Endoscopy centers
- Federally qualified community health centers
- Health plans
- Independent physician associations
- Indian Health Service centers
- Lithotripsy centers
- Medical home organizations
- Military healthcare facilities
- Multispecialty group practices
- Occupational health centers
- Office-based anesthesia organizations
- Office-based surgery centers and practices
- Oral and maxillofacial surgeons' offices
- Pain management centers
- Podiatry practices
- Radiation oncology centers
- Single specialty group practices
- Surgery recovery centers
- Urgent or immediate care centers
- Women's health centers

AAAHC advocates for the provision of high-quality healthcare through the development and adoption of nationally recognized standards, providing a voluntary survey experience founded on a peer-based, educational approach to in-site review every three years.

The AAAHC Certificate of Accreditation demonstrates an organization's commitment to provide safe, high-quality services to its patients. It is recognized by third-party payers, medical professional associations, liability insurance companies, state and federal agencies, and the public (AAAHC, 2021).

INSTITUTIONAL STRATEGIES FOR ADDRESSING ERRORS

Essential strategies healthcare facilities must consider in their efforts to reduce medical errors include:

- Changes in organizational culture
- Involvement of leadership
- Education of providers
- Development of patient safety committees
- Adoption of safe protocols and procedures
- Use of technology

Creating a Culture of Safety

A culture of safety encompasses the following key features:

- Acknowledging the high-risk nature of an organization's activities and the determination to achieve consistently safe operations
- A blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources to address safety concerns

Specific measures, such as teamwork training, executive walk-arounds, and establishing unit-based safety teams, have been associated with improvements in safety culture measurements and have been linked to lower error rates. Other methods, such as rapid response teams and structured communication methods such as SBAR, are being implemented widely to help address cultural issues such as rigid hierarchies and communication problems, but their effect on overall safety culture and error rates remain unproven.

The culture of individual blame still dominates and is traditional in healthcare, which impairs the advancement of a safety culture. One issue of concern is that, while "no blame" is the appropriate stance for many errors, certain errors do seem blameworthy and demand accountability. In an effort to reconcile both needs for no-blame and appropriate accountability, the concept of just culture is now widespread (AHRQ, 2019i).

JUST CULTURE MODEL

A *just culture* is defined as organizational accountability for the systems they have designed and employee accountability for the choices they make. In such a setting, trust is critical to shared accountability. Trust in leaders is defined as the perception that healthcare employees will receive fair treatment from leaders following an adverse event, regardless of their position in the hospital or the event's severity. In such a highly reliable organization, employees routinely identify and report unsafe conditions and errors because they trust leaders want to know what is not working and will implement visible and meaningful improvements with this information.

All types of errors hold equal importance in a just culture, not just those with poor outcomes. To build trust, error identification and reporting are encouraged to provide opportunities for staff education and system redesign.

Two important features of a just culture include 1) a nonblaming incident investigation and 2) understanding the behavioral choices that a person makes. There are three types of behavioral choices made by people that can lead to errors:

- Human error: A mistake or an inadvertent action
- At-risk behavior: Choices made where risk is not recognized or believed to be justified
- Reckless behavior: Choices made to consciously disregard risk, which is substantial and unjustifiable
  (Paradiso & Sweeney, 2019)

Addressing Staffing Concerns

Studies have shown that hospital patients die when the number of patients under each nurse's care rises above an established safe maximum, which varies according to how sick they are. Nurses have noted that patient issues in hospitals and nursing facilities are becoming more complex, requiring the kind of care that was once reserved for intensive care units.

The high-risk nature of the work, stress caused by increased workload and interruptions, and the risk of burnout due to involvement in errors or exposure to disruptive behavior likely combined with unsafe conditions precipitated by low nurse-to-patient ratios result in an increased risk of adverse events.

A study conducted by Columbia University School of Nursing found an association between nurse understaffing and healthcare-associated infections in patients, demonstrating that understaffing increases the risk of HAIs.

Nurses are a constant presence at the bedside and regularly interact with all members of the healthcare team. Of all the members of the team, nurses play a critically important role in ensuring patient safety by monitoring patients for clinical deterioration, detecting errors and near misses, understanding care processes and weaknesses inherent in some systems, and performing countless other tasks to ensure patients are receiving high-quality care. It is logical that assigning increasing numbers of patients will eventually compromise a nurse's ability to provide safe care.

Several seminal studies have shown the link between nursing staffing ratios and patient safety, showing an increased risk of patient safety events, morbidity, and mortality as the number of patients per nurses increases. On the strength of this data, several states have established legislatively mandated minimum nurse-to-patient ratios. In California, for example, acute medical-surgical inpatient units may assign no more than five patients to each registered nurse. Mandatory overtime for nurses is also restricted in 16 states.

To determine adequate nurse staffing requires a complex process that changes on a shift-by-shift basis and requires close coordination between management and nursing based on patient acuity and turnover, availability of support staff, skill mix, and many other factors.

The Magnet Hospital Recognition Program, administered by the American Nurses Credentialing Center (a subsidiary of the American Nurses Association), seeks to recognize hospitals that deliver superior patient care and, partly on this basis, attract and retain high-quality nurses. To patients, this recognition means the very best care delivered by nurses who are supported so that they can be the very best they are capable of being.

Hospital administrators should ensure adequate nurse staffing to provide the safest patient care. This could be achieved through better nurse recruitment and retention practices, together with methods of managing burnout and fatigue (AHRQ, 2019j; QPC, 2021; Columbia University Irving Medical Center, 2019).

Leadership

As the field of safety has grown, so has the recognition that organizational leadership plays a significant role in prioritizing patient safety. In the past, hospital board members have been leaders in the community who may have little or no healthcare experience. Despite being accountable for the quality and safety of the care being provided in their organization, the boards, executives, and medical staff leadership at most U.S. hospitals placed little importance on identifying and addressing issues of safety. Today there is a shift toward more direct oversight of safety and quality of care at the organizational level.

Hospital boards now use strategic initiatives to influence quality and safety, however data shows that executives and management can further improve safety by having more direct interactions with frontline workers. Visits by management (walk-arounds) to clinical areas to engage in open and frank discussions with the staff about safety concerns have been shown to have a positive impact on safety culture. To be credible among frontline staff during these walk-arounds, however, it is important that issues raised by the staff be addressed promptly and that leaders follow up sufficiently after an error has been reported.

Leadership can also directly address safety concerns by recognizing and managing disruptive and unprofessional behavior by clinicians. As boards have oversight over the medical staff, they have the ability to ensure unprofessional or incompetent clinicians do not put patients at risk.

Some organizations have developed a structured approach that emphasizes early intervention by hospital leadership for clinicians who display recurrent unprofessional behavior or are the subject of multiple patient complaints (AHRQ, 2019k).

CONCLUSION

Everyone has a stake in the safety of the healthcare system—healthcare workers as well as the general public. In the past, patient safety was not a traditional part of the education of most healthcare workers, but today this is no longer true. All healthcare workers are being actively educated about their roles in the prevention of avoidable negative outcomes for those they care for. It is essential that all clinicians understand the journey every patient makes through the system, recognizing how the system can fail, and take action to prevent those failures.

To counter errors and safeguard patients, changes must continue to be made in how the workforce is deployed; in how work processes are designed; and in the leadership, management, and culture of healthcare organizations. Because communication issues are so commonly involved in medical errors, it is crucial that physicians, nurses, therapists, and other healthcare personnel work together as a team, respecting each other's contributions to the well-being of the patients in their care. Collaborative teamwork is essential for optimizing quality and safety in healthcare.

RESOURCES

AGS Beers Criteria (American Geriatrics Society)
https://www.elderconsult.com/wp-content/uploads/PrintableBeersPocketCard.pdf

Error-prone abbreviations, symbols, and dose designations (Institute for Safe Medication Practices)
https://www.ismp.org/recommendations/error-prone-abbreviations-list

Hospital Safety Grade
http://www.hospitalsafetygrade.org

Institute for Healthcare Improvement
http://www.ihi.org

List of high-alert medications (Institute for Safe Medication Practices)
http://www.ismp.org/Tools/highalertmedications.pdf

National Coordinating Council for Medication Error Reporting and Prevention
http://www.nccmerp.org

National Quality Forum
http://www.qualityforum.org

Patient Safety Network
http://psnet.ahrq.gov

VHA National Center for Patient Safety
http://www.patientsafety.va.govg

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1. A medical error is best defined as:

a. The development of a care plan that results in failure to achieve a certain aim.
b. The failure of a planned action to meet the patient's problem.
c. Not successfully helping the patient to make appropriate health-related changes.
d. An unintended healthcare outcome caused by a deficit in the delivery of care.

2. According to the Joint Commission, a patient safety event that results in death, permanent or severe temporary harm, and intervention required to sustain life is referred to as a(an):

a. Sentinel event.
b. Medical error.
c. Near miss.
d. Adverse event.

3. A surgical or invasive procedure performed on the wrong patient is a considered a(an):

a. Error of omission.
b. Latent error.
c. Never event.
d. Patient-protective serious reportable event.

4. In the U.S. healthcare environment, high error rates with serious consequences are **most** likely to occur in:

a. Both outpatient and inpatient settings.
b. Outpatient settings.
c. Operating rooms.
d. Stepdown care and nursing home units.

5. The majority of medical errors are caused by:

a. Reckless and impulsive behavior by an individual.
b. Dangerous actions by a particular group.
c. Inaction and idleness undertaken purposefully by an individual or group.
d. Faulty issues, processes, and conditions within a healthcare system.

6. According to the Skill, Rule, and Knowledge (SRK)–based classification system, skill-based errors in healthcare are caused by:

a. Planning failures.
b. Conscious mistakes.
c. Slips and lapses.
d. Bypassing safety procedures.

7. To reduce the risk of wrong-site, wrong-procedure, and wrong-person errors, the Joint Commission's Universal Protocol introduced the concept of:

a. A sign-in checklist before induction of anesthesia.
b. Completion of a surgical checklist following any invasive procedure.
c. Completion of an instrument, sponge, and needle count.
d. A "timeout" or planned pause before beginning a procedure.

8. Most diagnostic errors that occur in primary care practice settings include:

a. Failure to order appropriate tests and faulty interpretation of data.
b. Failure to observe the patient's clinical course.
c. The use of heuristics (rules of thumb).
d. Beginning treatment before confirmation of the diagnosis.

9. A physician prescribes the wrong dose of amoxicillin for a pediatric patient, unaware of the patient's current bodyweight. The physician's action is an example of an error in:

a. Administering.
b. Ordering.
c. Transcribing.
d. Dispensing.

10. All of the following are recommended strategies to help prevent medication administration errors, **except**:

a. Using "smart" infusion pumps for intravenous medications.
b. Package design features that differentiate between look-alike drug names.
c. Shaking all injectable medications before administration.
d. Documenting accurately once a medication has been administered.

11. When administering a high-alert medication to a patient, nursing best practice includes:

a. Using only preprinted orders.
b. Avoiding the use of infusion pumps.
c. Asking another qualified nurse to perform an independent double check.
d. Identifying high-alert medications based only on the FDA's "black-box" warnings.

12. Recommendations to reduce the incidence of line and tubing misconnections include:

a. Requiring that all Luer locks be discontinued.
b. Using tubing designed to be incompatible with Luer locks.
c. Eliminating tubing that contains phthalates.
d. Using catheters that have injection ports.

13. One of the most significant reasons for the spread of bacteria in healthcare settings is:

a. The failure of healthcare providers to comply with hand hygiene practices.
b. The standardization of healthcare devices and equipment.
c. Replacing dressings whenever they become damp, loosened, or visibly soiled.
d. Not wearing a mask during routine care.

14. Which is an assessment tool widely used in both hospital and long-term patient settings to prevent falls?

a. Morse Fall Scale
b. 30-second Chair Stand
c. Timed Up and Go
d. Stop Elderly Accidents, Deaths, and Injuries (STEADI)

15. The nurse is preparing to contact the patient's primary care provider about a new patient symptom. Which statement does the nurse make when communicating their "assessment" using the SBAR technique?

a. "The patient has a fever and purulent wound drainage."
b. "The patient had hip replacement surgery 3 days ago."
c. "The findings suggest a surgical wound infection."
d. "Would you like to prescribe an antibiotic after a wound culture is sent?"

16. The most common medical error among hospitalized infants and young children is:

a. Dose calculation errors.
b. Failure to screen for drug-drug interactions.
c. Inappropriate delivery systems.
d. Lack of available dosage forms.

17. Which condition would **not** be reimbursed by Medicare and Medicaid if acquired during a hospitalization?

a. Bowel obstruction
b. Urinary tract infection
c. Tenosynovitis
d. Obstetrical complications

18. Which is a **correct** statement regarding evidence-based practice?

a. It does not integrate patients' values or preferences.
b. It attempts to standardize clinical processes.
c. It excludes clinical expertise.
d. It frequently causes medical complications.

19. The ultimate goal of a root cause analysis is to:

a. Determine who was at fault.
b. Prevent future harm by eliminating latent errors.
c. Re-educate the person who made the error.
d. Determine the impact of the error on the patient.

20. A "just culture" model approach within healthcare includes:

a. Blaming the individual.
b. Organizational accountability.
c. Employee unaccountability.
d. Distrust in leaders.