

Medication Errors

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This course goes over the very common issue of medical errors in healthcare and utilizes Evidence Based strategies that can be used to prevent them. Those that complete this course and earn the CE will be able to discuss:

- * the high impact of human error
- * Identify where the errors occur
- * explain programs that are available to reduce medical errors

Florida Statute requirements: Section 456.013(7), Florida Statutes, now requires completion of a two-hour course relating to prevention of medical errors as part of the renewal process for licensure. The Board has amended rule 64B19-13.003, Florida Code (F.A.C.), to include this requirement

Audience includes: ARNP, CNA, CNS, RDN, EO, HHA, LPN, MW, OT, OTA, PT, PTA, RN and RT

Please note: To earn a certificate of completion, a test must be taken and passed with at least an 80%.

Objectives

After completing this course, the learner will be able to:

1. Identify programs to reduce medical errors,
2. Define Sentinel Event,
3. Define Root Cause Analysis,
4. Recognize human factors involved in medical errors,
5. Identify methods to avoid medical errors

Overview

“In December 2017, a reckless homicide charge was placed against a Tennessee nurse, who allegedly injected a 75-year-old patient with the paralytic anesthetic vecuronium instead of Versed, a sedative. The nurse supposedly chose to override safeguards when she could not find Versed in an automatic dispensing cabinet, typed “VE” into the cabinets system, and selected the first medication- vecuronium – that came up on the list” (Ross, 2019).

Think about this for a moment. Your loved one went to the hospital for a “simple” procedure, was given a wrong medication by a nurse and now life has changed forever.

Over the last fifty years there has been a wide variety of approaches that have all aimed at reducing medical errors, unfortunately with very limited success. One study by Johns Hopkins found that there were roughly 251,454 deaths attributed to medical errors, or “9.5 percent of all deaths each year in the United States”. This is a dramatic increase from the 98,000 in To Err

Is Human, a book written about safety concerns within healthcare in the year 2000. Makary and Daniel identify a medical error as “an unintended act or one that does not achieve its intended outcome, the failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or a deviation from the process of care that may or may not cause harm to the patient”.

John James, the president of the Joint Commission, feels that the following are contributing factors to preventable medical errors:

“Medical care in the United States is technically complex at the individual provider level, at the system level, and at the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients. Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level. Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines. At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care. Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens. Hence, the information a physician needs to optimize care of a patient is often unavailable”.

At the national level, the United States is distinguished for its incongruous parts of medical care subsystems that require patients to be bounced around in a highly complex maze of providers as they seek both effective care and cost-efficient care. As frustrating as this is for the patients, it is equally frustrating for the providers who have a high demand placed on them to provide quality care in what can only be described as a suboptimal working environment, with decreased staff and shortage of physicians. This perfect storm leads to fatigue among healthcare professionals and burnout. It is no surprise that PAE's that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry.

Medical errors increase expenses in additional patient care and possible litigation costs. Serious medical errors are devastating to the patient, family, and staff.

The severe consequences of medical errors are one reason that healthcare is a highly-regulated business. All healthcare organizations must be licensed. They also must meet industry standards, building and safety codes, and federal and state statutes.

Healthcare organizations are subject to inspection for compliance with statutes, regulations, and industry standards. Inspections can be scheduled or unscheduled. Scheduled inspections are conducted periodically. Unscheduled inspections can be conducted randomly, or they can be conducted for cause, like a patient complaint. One of the most well-known inspection agencies for hospitals is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). It is an independent organization, meaning that JCAHO is neither a government agency nor does it have a financial interest in any healthcare organization. If a healthcare organization meets industry standards, JCAHO accredits that organization for a certain period of time.

Qualifications?

What about checking for healthcare professionals' qualifications or credentials? Healthcare organizations must determine an individual's qualifications and ability to do the job. This involves checking an individual's education, license, experience, and credentials before an employee is hired. At least annually, staff performance is evaluated. Continued competency, current licensure, and continuing education should also be checked at least once a year. For licensed independent practitioners, such as physicians and nurse practitioners, this process is called credentialing and privileging. It should be a high priority for healthcare professionals to ensure competence is retained in relation to prevention of medical errors.

Performance Improvement (PI)

Healthcare organizations have ongoing programs to identify, correct and prevent medical errors. PI is a way to systematically monitor, analyze, and improve an organization's performance and outcomes. PI should improve an organization's performance by reducing factors that contribute to unanticipated adverse events and outcomes. Unanticipated adverse events and outcomes can be caused by poorly designed systems, system failures, or errors. Decreasing unanticipated adverse events and outcomes requires an environment where patients, families, staff, and leaders can identify and manage risks to safety. Such an environment encourages the following:

- Recognizing and acknowledging risks and unanticipated adverse events
- Initiating actions to reduce these risks and unanticipated adverse events
- Reporting internally on risk reduction initiatives and their effectiveness
- Focusing on processes and systems, with continuous monitoring of their effectiveness
- Minimizing individual blame or retribution for involvement in an unanticipated adverse event
- Investigating factors that contribute to unanticipated adverse events and sharing that acquired knowledge both internally and with other hospitals

The following are other concepts related to PI. Continuous Quality Improvement (CQI) is an approach that ensures that organizations always look for ways to improve processes and practices. Total Quality Management (TQM) is a management system that encompasses quality planning, quality control, and quality improvement. Six Sigma, lean management, and change management are performance improvement methodologies that have a systematic approach to dissecting complex safety problems and implementing effective solutions.¹

These programs are slightly different from PI, but you may hear the terms used interchangeably.

High Reliability

High Reliability is an ongoing quality improvement process that is used in highly technical industries where there is high risk involved. The concept of high reliability involves a safety culture of collective mindfulness in which all employees are acutely aware that even small failures in safety protocols or processes can lead to catastrophic adverse outcomes. Therefore, everyone in these organizations is always searching for the smallest indication that the environment or a key safety process has changed in some way that might lead to failure. Once a deficiency is identified, it is eliminated by improving the processes. There are three requirements for achieving high reliability:

- Leadership
- Safety Culture
- Robust Process Improvement

Quality Control

One of the terms that we are more familiar with in modern healthcare is Quality Control (QC), it can literally be defined as an ongoing, systematic measurement to determine compliance and accuracy. It is required for some equipment or measurement tests. Examples are checking the high and low control limits on a glucometer or the temperature of the medication refrigerator. QC is often a component of or is mentioned in relation to PI.

Risk Management

Risk Management (RM) is a program that is focused on eliminating or minimizing the effects of accidental losses to an organization. RM works closely with and sometimes overlaps functions with PI. The Risk Managers are involved with risk financing through insurance companies to minimize financial losses. They usually investigate serious medical errors, institute damage control, and consult with legal counsel as needed.

Incident reports are an important source of information for a Risk Manager. Aggregate data from incident reports is statistically analyzed to identify areas of risk and exposure. Risk control

techniques are then applied to those areas of focus. The usual techniques are avoidance, transfer, prevention, reduction, segregation, and duplication.

Avoidance is a technique that eliminates the possibility of a loss. This is also known as a forcing function. This technique involves designing equipment or processes to make it impossible to use it incorrectly. Examples are stocking only one concentration of a medication or removing concentrated Potassium Chloride from floor stock. These functions are effective but can be inconvenient and time consuming for personnel.

Transfer is the process of negotiating with insurance companies to transfer the financial burden of a loss. This technique assumes that the loss cannot be prevented so we must be insured against those times when it happens.

Loss prevention reduces the probability or frequency of a loss but does not eliminate the chance of loss, nor does it reduce the severity of that loss. This is also known as a constraint function. This means that equipment or a process is designed to make it difficult to use it incorrectly. Examples are limiting floor stock or a policy limiting verbal orders. Constraints can help prevent errors that might be made by less experienced or distracted personnel.

Loss reduction focuses on reducing the severity of damage. For example, frequent monitoring instituted for conscious sedation procedures does not reduce the risk of the sedation being too deep. However, it allows early intervention to reverse the sedation and provide adequate oxygenation.

Segregation means that a process is totally separated from the rest of a clinical setting to reduce or eliminate errors. For example, changing the medication administration system so the pharmacist fills the order and administers the medication to a patient. This eliminates the potential error at the point the pharmacy usually hands off the medication to nursing. However, as with most segregation techniques, it is too expensive and impractical.

Duplication means that there is a backup. For instance, having employees cross-trained. That way, someone is available to perform a job when the person who normally performs that job is unexpectedly unavailable.

Sentinel Events

JCAHO defines a sentinel event as “a Patient Safety Event that reaches a patient and results in any of the following: death, permanent harm, or severe temporary harm and intervention required to sustain life.” These events require immediate investigation and response to ensure they do not reoccur.

The following events are considered a Sentinel Event, even if the outcome is not death or major permanent loss of function: suicide; unanticipated death of a full-term infant; infant abduction or discharge to the wrong family; rape; hemolytic transfusion reaction; and surgery on the

wrong patient or wrong body part. A near-miss is a potential error that fails to cause injury by chance or because it is stopped before it occurs. The natural course of the patient's illness or underlying condition is not considered a sentinel event.

JCAHO requires accredited organizations to identify and respond appropriately to sentinel events. The appropriate response includes conducting a timely and thorough investigation, implementing improvements to reduce risk, and monitoring the effectiveness of the improvements. Healthcare organizations are encouraged to report sentinel events to JCAHO. The information from these reports is evaluated and published in the Sentinel Event Alert. It includes aggregate data, specific examples, and strategies for prevention. The Sentinel Event Alert is available on the Internet at <http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/>.

Root Cause Analysis

JCAHO requires the use of root cause analysis (RCA) to investigate the processes and systems that contribute to a sentinel event. RCA is a tool that helps identify and clarify the bottom line factors that precipitate an error or near miss. RCA focuses on systems and processes, not on individual performance.

The RCA process repeatedly digs deeper into an issue by asking “Why” questions until no additional logical answers can be identified. A team of people representing the areas that are involved in an event is brought together to do this analysis. The team begins with a standardized template called an Ishikawa diagram (Figure 1). This template is also known as a fishbone diagram or cause-and-effect diagram.

The team selects major headings for the diagram that will include categories of possible causes. The headings should be as independent of each other as possible to avoid confusion. The team identifies the potential factors that would cause the problem. These are written along the major branches of the diagram. For each cause listed, the team asks “why?” Those reasons are written down as smaller branches on the diagram. The rule of thumb is to ask “why” five times. When you reach a point where there is no additional logical answer to the question “why,” you have reached what is called a root cause.

Once the Ishikawa diagram is complete, the underlying causes of the event are summarized. Changes that could be made in systems and processes that would reduce the risk of similar adverse events are suggested.

One type of root is known as “special cause” found in clinical processes. Special cause is a factor that is intermittent and unpredictable. This causes a variation that is not inherent in the system. An example is a patient has an allergic reaction to a medication that they have successfully taken in the past. The other type of cause is common cause in organization’s process. Common

cause is a factor that results from variation that is inherent in the process or system. RCA seeks to identify potential areas for improvement in a process or system that might help reduce the risk of occurrence of an event. An example is allowing only premixed Potassium Chloride solutions on the nursing unit will prevent the possibility of making an error in the dilution.

RCA has a limitation, which is known as the blinder effect. That is the tendency for the team to look only at one part of the process that led to the event, instead of the entire process.

Human Error

By nature, humans are fallible. It is unreasonable to expect error-free performance by humans. Human beings have limited mental and information-processing capabilities. Excessive levels of stress or fatigue have a negative impact on performance. "Almost 90% of accidents that occur in the workplace are due to human errors."⁸

Every day we all face thousands of interactions with machines, systems, and each other. The vast majority of those interactions goes smoothly and unnoticed. A few interactions that force us to work outside of routine and intuition are simple annoyances with which we have learned to live. Occasionally, one of those interactions leads to an unintended result, an error. While humans can rapidly adapt to impediments blocking their path, and develop compensatory workarounds, these short-term solutions often introduce new risks. Human factors science offers a better understanding of the causes of errors, the workarounds already in place, and solutions which are less likely to have negative, unintended consequences.

Human error has been implicated in 60 to 80 percent of accidents that occur in complex systems. Accidents due solely to environmental and mechanical factors have been greatly reduced over the last several years; however, those attributable to human error continue to be a problem.

Healthcare has traditionally regarded error as a moral failing. This places an unsustainable burden of perfection on clinicians. This attitude impedes efforts to identify errors, their frequency, their effects, and how to best protect patients.

Solutions reached by trial and error or workarounds might simply shift the risk elsewhere. While "fixed by common sense" may often be sufficient, common sense can also benefit from science and engineering.

Human factors science discovers and applies information about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, systems, tasks, jobs, and environments for productive, safe, comfortable, and effective human use. Human factors science is not just applying checklists and guidelines, not just using oneself as the model for designing things, and it is not just common sense.

The human cognitive process is how we remember, think, develop and use motor skills to perform activities individually, in teams and within organizational systems.

- Perception equals input: information perceived through the sensory system. With distracted or blurred perception (insufficient light, ambient noise, etc.) you are unable to take in sensory information, and more prone to misread a label or mishear spoken words.
- Long-term memory: information acquired through education and experience are stored in long-term memory. When long-term memory experiences interference (e.g., distraction, multi-tasking) there is difficulty retrieving and applying previously learned information.
- Working memory: information from the sensory fields (perception) and long-term memory combine to do the work we label “thinking.” Thinking combines sensory input with stored knowledge to call up frequently used patterns and criteria that have been developed through common use to make decisions. When overloaded with physical or emotional demands, there is increased risk of making incorrect judgments based on confusion or applying learned rules incorrectly.

Impacts of Designs

The impact of design on human factors has four different types of interactions and a wide variety of applications. The science applies an understanding of theories of physical, cultural, and psychological factors to the reduction in flawed behavior.

Interaction with machines and objects is the most studied area of human factors problems. Most human errors related to human/machine interactions are due to either the condition or training of the operator, bad design of the machine interface, or both. A bad design is one that does not conform to intuitive application. Design flaws can lead to the incorrect use of equipment. Speed, stress, and fatigue increase the likelihood that bad design will lead to error.

Negative impacts of the work environment exist even with the best designed objects and machines. Human factors problems are encountered, stemming from the physical world around us. Physical space, layout, temperature, light, air quality, noise levels, and visual distractions can all interfere with or alter the ability to perform an activity. When these factors become obstacles, they can manifest as inconveniences or can be harmful. Fatigue from loss of sleep, circadian rhythm changes, and muscular effort expenditure has been identified as one of the major contributors to errors.

As creatures of habit, humans often seek to “workaround” a new system to maintain an old mindset. For example, to help technicians correctly assemble devices with multiple components, matching barcodes were encoded on adjoining components. By swiping each piece, correct assembly was assured. However, reviewers discovered that the procedure was frustrating for some users who, as a workaround, put matching copies of the barcoding on a

paper and scanned the paper instead of the equipment pieces, enabling incorrect assembly. Nurses, too, have found that it is easier to scan the patient label from the medication administration sheet rather than taking the medication cart with scanner to the patient bedside to scan the patient identification band on the patient's wrist.

When a system problem is solved in isolation and without consideration of how it might affect the rest of the system, unintended consequences can undo the benefit of the fix. An example of this is a computerized forcing function programmed into a hospital medication system to prevent the over-administration of potassium. This inadvertently prevented the administration of high doses when they were needed. A solution can exacerbate existing minor problems or actually create new opportunities for errors. This is the unintended consequence. Piloting and field-testing solutions help identify these "downstream consequences."

Human factors problems related to practice environment tend to be more transient than design problems. Lighting, noise, temperature, even physical space, can change from one patient encounter to the next. If the healthcare provider works in multiple practice settings, the opportunity for environmentally-related problems is equally multiplied. Other issues may include things like:

- Equipment models or brands vary
- Equipment storage is too high
- Equipment is not conveniently located
- Equipment is not located in a consistent place
- Environment is not set up to allow effective eye contact and discussion

Human factors always apply wherever humans work. In healthcare, work environments are hazardous. Instruments are potential weapons; drugs are a potential poison; and every worker is a potential killer. The following are human factors problem areas in healthcare:

- Equipment changes and upgrades (training inadequate)
- Handoffs (poor communication)
- Infusion pumps (poor human interface)
- Fatigue
- Labeling (look alike, sound alike)
- Handling sharps
- Retained foreign bodies in surgery
- Patient bed alarms (false alarms and falls)
- Physician order entry (illegible, verbal orders, transcription errors)

- Wrong site surgery

Accept human factors problems as an inevitable, although manageable, part of everyday practice. Shift from a punitive to a creative frame of mind that seeks out and identifies the underlying system failures. Efficient, routine identification of human factors need to be part of every practice, as well as routine investigation of all human factors problems that cause injuries.

Not all design flaws in healthcare environments are obvious hazards. One of the subtlest mistakes is a failure to realize that the best-motivated and most highly-trained professionals are potentially lethal agents. Fatigue management in healthcare is a big challenge. Fatigue resulting from an inadequate amount of sleep or insufficient quality of sleep over an extended period can lead to a number of problems, including:

- lapses in attention and inability to stay focused
- reduced motivation
- compromised problem solving
- confusion
- irritability
- memory lapses
- impaired communication
- slowed or faulty information processing and judgment
- diminished reaction time
- indifference and loss of empathy

Contributing factors to fatigue and risks to patients include:

Shift length and work schedules have a significant effect on health care providers' quantity and quality of sleep and, consequently, on their job performance, as well as on the safety of their patients and their individual safety. This fact has been borne out in numerous studies. Findings from a groundbreaking 2004 study of 393 nurses over more than 5,300 shifts – the first in a series of studies of nurse fatigue and patient safety – showed that nurses who work shifts of 12.5 hours or longer are three times more likely to make an error in patient care. Additional studies show that longer shift length increased the risk of errors and close calls and were associated with decreased vigilance, and that nurses suffer higher rates of occupational injury when working shifts in excess of 12 hours. Still, while the dangers of extended work hours (more than 12 hours) are well known, the health care industry has been slow to adopt changes, particularly with regard to nursing.

Recommended actions:

1. Assess your organization for fatigue-related risks. This includes an assessment of off-shift hours and consecutive shift work, and a review of staffing and other relevant policies to ensure they address extended work shifts and hours.
2. Since patient hand-offs are a time of high-risk – especially for fatigued staff – assess your organization’s hand-off processes and procedures to ensure that they adequately protect patients.
3. Invite staff input into designing work schedules to minimize the potential for fatigue.
4. Create and implement a fatigue management plan that includes scientific strategies for fighting fatigue. These strategies can include: engaging in conversations with others (not just listening and nodding); doing something that involves physical action (even if it is just stretching); strategic caffeine consumption (don’t use caffeine when you’re already alert and avoid caffeine near bedtime); taking short naps (less than 45 minutes). These strategies are derived from studies conducted by the National Aeronautics and Space Administration (NASA), which state that people can maximize their success by trying different combinations of countermeasures to find what works for them. The NASA studies stress that the only way to counteract the severe consequences of sleepiness is to sleep.²¹ Strategies for determining shift durations and using caffeine to combat fatigue can be found in chapter 40 of "Patient Safety and Quality: An Evidence-Based Handbook for Nurses."
5. Educate staff about sleep hygiene and the effects of fatigue on patient safety. Sleep hygiene includes getting enough sleep and taking naps, practicing good sleep habits (for example, engaging in a relaxing pre-sleep routine, such as yoga or reading), and avoiding food, alcohol or stimulants (such as caffeine) that can impact sleep.

Human Factors

Everyone needs some stress; otherwise, life would be dull and unexciting. Good stress is also known as “eustress.” Stress adds flavor, challenge, and opportunity to life. It has also been said that stress is a good motivator, but working when over-stressed, irritated, upset, or shaken will substantially alter one’s judgment and can compromise patient safety. Too much stress can seriously affect physical and mental well-being and becomes known as “distress.” The angry healthcare provider is aggressive, offensive, and careless, and as a result is dangerous. Stressful conditions involving personal or business life will cause distractions that can interfere with the provision of safe patient care. They should be recognized and addressed as negative influences on workplace habits.

The clinician should evaluate his or her state of mind before providing patient care such as medication administration. Providing patient care takes a clear and focused mind, uncluttered by thoughts of aggravation and distress. The healthcare provider with a wandering mind caused by any one of the aforementioned effects has a decreased awareness of the subtle changes in

patient status, a slower reaction time, and an overall lack of concentration. The ability to anticipate complications and to determine appropriate responses is also adversely affected. A major challenge in this stress-filled world of today is to use stress in a positive way and prevent it from becoming distress.

The emotionally distressed healthcare provider is more apt to make a medical error than is the rested, clear-headed provider. It should be made clear that tired, disturbed, or cluttered minds decreases critical thinking ability. When disturbed by emotions, the healthcare provider is not concentrating on what they are doing; he or she is concentrating on what has him or her upset. This could manifest in increased risk-taking behavior such as taking shortcuts, failing to follow policy, and not paying attention to the details. Unsafe behaviors can contribute to increased risk of medical error.

With severe emotional distress, an individual could turn to substance use or abuse to hide emotional pain. Combined with heavy workloads, this increases the likelihood of error. With the increased risk-taking behavior, aggression could result. The clinician is then labeled as “difficult to work with.” Unchecked emotions can lead to aggressive behavior and disciplinary action. The emotionally distressed mind is not capable of rational function or critical thinking required to provide safe patient care. Managers need to recognize the emotionally distressed clinician.

Standards of practice and hospital policies are instituted and established for patient safety. Policy may not specifically cover special situations; but, most clinicians agree there is a need for policies and standards of practice. Unsupervised and uncontrolled practice would lead to chaos. Some healthcare providers despise the increase in the number of “rules.” They stress the negative side of policies rather than the goal for increased patient safety. It must be understood that policies and standards of care can benefit them and should be supported and followed.

Patient safety focus by the following groups has increased the number of policies and standards of practice that decrease medical errors.

- Joint Commission on Healthcare Accreditation Organization (JCAHO)
- Agency for Healthcare Research and Quality (AHRQ)
- Leap-Frog Group
- National Quality Forum (NQF)
- National Patient Safety Foundation (NPSF)
- Institute for Safe Medication Practices (ISMP)

Healthcare providers should be aware that circumstances and attitude changes could dramatically affect practice habits. Some attitudes that predispose to risk taking behavior and increase the risk of errors are:

- Enjoying the thrill of crisis situations
- Enjoying impressing coworkers
- Disregarding personal safety
- The illusion of control or overestimating abilities
- Justifying risks because they are taken in a noble cause

Design work to minimize the requirements for particularly fallible human functions such as short-term memory and tasks requiring prolonged attention. For instance, don't rely on memory to retrieve a laboratory test result or the time a medication is due. Systemizing these tasks reduces memory related errors.

Reduce reliance on memory for high-risk procedures, or multi-step processes, by using checklists. Review checklists to ensure appropriateness and avoid increasing error through workarounds that make more errors. While surgical areas generally use preoperative checklists already, it may be wise to use checklists in handoff situations as well. Couple brief, useful protocols with procedures developed by the healthcare teams who provide the services. Standardize color match items that are used together to prevent slips such as clinicians combining items that should not be used together. Pre-package component items into kits.

As the volume of information increases, you need creative ways for making it more readily available, displaying it where clinicians need it when it is needed. Making information available at the point of care will make a significant impact on error reduction. Many medication-related claims are the result of clinicians making decisions about treatment without having all of the appropriate information available. Create forms to promote accurate documentation and electronic ticklers for tracking test results. Block avenues to workarounds that cut out important transmission of information.

Complexity increases the opportunity for errors. Where possible, critical tasks should be structured so that errors cannot be made. The reliability of a system can be improved by perfecting its parts and handoffs, but reducing complexity is even more powerful.

And then it happened....Medication Errors

Adverse drug events (ADEs) are a serious public health problem. It is estimated that¹²:

- 700,000 emergency department visits and 120,000 hospitalizations are due to ADEs annually;
- \$3.5 billion is spent on extra medical costs of ADEs annually;
- At least 40% of costs of ambulatory (non-hospital settings) ADEs are estimated to be preventable.

The numbers of adverse drug events will likely grow due to:

- Development of new medications
- Discovery of new uses for older medications
- Aging American population
- Increase in the use of medications for disease prevention
- Increased coverage for prescription medications

Nurses are most likely to be blamed for medication errors because they are involved at the administration point. However, medication errors are complex and are rarely the result of one person's actions. The medication system in hospitals is complicated. There are multiple steps and many individuals involved. Every time a document or medication changes hands, there is an increased potential for error

Administering medication is a crucial nursing responsibility. To ensure safe and effective drug therapy, the nurse must be familiar with indications, usual dosages, and intended effects of drugs. Remember the 5 rights: right patient, right drug, right dose, right route, and right time. Each patient must be assessed before administration, and the medication should be delayed or withheld if indicated.

One study found adherence by nurses to standard medication administration practice was very low. This adherence is reported below as ratios per item.

Only 45.6% of nurses verified the amount of medication indicated on the vial at least once for at least one second. In addition, only 6.5% read the name of the patient from the wristband. Administering the medication at the correct time guideline was observed 41% of the time. The guideline regarding hand washing before external and oral medications was followed only 4.5% of the time, although this figure was much higher for intravenous medications at 96.6%. Overall, among 31 categories regarding drug administration, 17.2 (\pm 3.6) items per person were followed, whereas 5.7 (\pm 1.2) items per person were violated. We found key instances in which nurses did not follow the guidelines, including many from the Five Rights. About one in four elements were violated overall.

Nurses' medication error interception practices are associated with lower rates of medication errors. One study defines these interceptive practices as:

- independent comparisons between the medication administration record and patient record at the beginning of a nurse's shift;
- determining the rationale for each ordered medication;
- requesting that physicians rewrite orders when improper abbreviations are used;

- and ensuring that patients and families are knowledgeable regarding the medication regimen so that they can question unexplained variances

The types of medication errors include: prescribing, omission, wrong time, unauthorized drug, improper dose, wrong drug preparation, wrong administration techniques, deteriorated drugs, improper monitoring and compliance, product errors, process errors and human errors. Areas that are particularly error-prone are:

- Verbal orders
- Handwritten orders
- High-alert drugs
- Infusion pump errors
- Confusing drugs names

Handwritten and manually transcribed physician orders leave a lot of opportunity for errors. A computerized physician order entry, in which the physician must enter all orders by computer, eliminates handwriting and transcription errors. It also makes it possible to automatically check doses, drug-drug interactions, allergies and significant patient characteristics, like allergies and impaired renal function.

Meta-analysis of the research revealed that computerized physician order entry decreases the likelihood of error on that order by 48%. Given this effect size, and the degree of adoption of computerized order entry and use in hospitals in 2008, we estimate a 12.5% reduction in medication errors, or 17.4 million medication errors averted in the USA in 1 year.

A computerized order entry system presents its own set of problems. There is a significant expense that smaller facilities may not be able to afford. Cost prohibitions or lack of space may limit the number of PCs to the point that practitioners have long wait times for computer access. It seems slow and inconvenient at times. In addition, physicians who are less computer savvy may be resistant to change.

High Alert Medications

There have been studies showing that the majority of medication errors resulting in death or serious injury were caused by a list of specific medications. The Institute for Safe Medication Practice (ISMP), is a nonprofit organization who is devoted entirely to medication error prevention and safe medication usage. The ISMP represents over 35 years of experience in helping healthcare practitioners keep patients safe as well as leading efforts to improve the medication use process.

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors and minimize harm. This may include strategies like providing mandatory patient education; improving information about these drugs; using auxiliary labels and automated alerts; employing automated or independent double-checks when necessary; and standardizing the prescribing, storage, dispensing, and administration of these products.

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harm in the literature, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential high-alert medications. During October 2011-February 2012, 772 practitioners responded to an ISMP survey designed to identify high-alert medications. The medications were most frequently considered high-alert drugs by individuals and organizations. Further, to assure completeness, the clinical staff at ISMP, members of our advisory board, and safety experts throughout the US review the potential list. This list of drugs and drug categories reflects the collective thinking of all who provide input.

Classes/Categories of Medications

adrenergic agonists, IV (e.g., Epinephrine, phenylephrine, 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, including:

- anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin)
- Factor Xa inhibitors (e.g., fondaparinux)
- direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin)
- thrombolytics (e.g., alteplase, reteplase, tenecteplase)
- glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)

cardioplegic solutions

chemotherapeutic agents, parenteral and oral

dextrose, hypertonic, 20% or greater

dialysis solutions, peritoneal and hemodialysis

epidural or intrathecal medications

hypoglycemics, oral

inotropic medications, IV (e.g., digoxin, milrinone)

insulin, subcutaneous and IV

liposomal forms of drugs (e.g., liposomal amphotericin B) and conventional counterparts (e.g., amphotericin B)

moderate sedation agents, IV (e.g., dexmedetomidine, midazolam)

moderate sedation agents, oral, for children (e.g., chloral hydrate)

narcotics/opioids

- IV
- transdermal
- oral (including liquid concentrates, immediate and sustained-release formulations)

neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)

parenteral nutrition preparations

radiocontrast agents, IV

sterile water for injection, inhalation, and irrigation
(excluding pour bottles) in containers of 100 mL or more

sodium chloride for injection, hypertonic, greater than 0.9% concentration

Specific Medications

epoprostenol (Flolan), IV

magnesium sulfate injection

methotrexate, oral, non-oncologic use

opium tincture

oxytocin, IV

nitroprusside sodium for injection

potassium chloride for injection concentrate

potassium phosphates injection

promethazine, IV

vasopressin, IV or intraosseous

*ISMP List of High-Alert Medications in
Community/Ambulatory Healthcare¹⁷:*

Background

Based on error reports submitted to the ISMP Medication Errors Reporting Program (ISMP MERP), reports of high-alert medications in the literature, and input from practitioners and safety experts, ISMP created a list of potential high alert medications. In June-August 2006, 463 practitioners responded to an ISMP survey designed to identify which medications were considered high alert drugs by individuals and organizations. In 2008, the preliminary list and survey data as well as preventable adverse drug events from the ISMP MERP, the Pennsylvania Patient Safety Reporting System, the National Drug Database, databases from participating pharmacies, public litigation data, literature review, and a small focus group of ambulatory care pharmacists and medication safety experts were evaluated as part of a research study funded by a National Healthcare Research and Quality (AHRQ) grant. This list of drugs and drug categories reflects the collective thinking provided input. This list was created as part of the AHRQ funded project "Using risk models to identify and prioritize high alert medications" (Grant # 1P20HS01710701).

Classes/Categories of Medications

antiretroviral agents (e.g., efavirenz, lamivudine, raltegravir, ritonavir, combination antiretroviral products)

chemotherapeutic agents, oral (excluding hormonal agents) (e.g., cyclophosphamide, mercaptopurine, temozolomide)

hypoglycemic agents, oral

immunosuppressant agents (e.g., azathioprine, cyclosporine, tacrolimus)

insulin, all formulations

opioids, all formulations

pediatric liquid medications that require measurement
pregnancy category X drugs (e.g., bosentan, Isotretinoin)

Specific Medications

carbamazepine

chloral hydrate liquid, for sedation of children

heparin, including unfractionated and low molecular weight heparin

metformin

methotrexate, non-oncologic use

midazolam liquid, for sedation of children

propylthiouracil

warfarin

The following are drug specific strategies for prevention of medication errors¹⁸:

Insulin:

- Establish a check system where one nurse prepares the dose and another nurse reviews it.
- Do not store insulin and heparin near each other.
- Spell out the word unit instead of using the abbreviation U.
- Build in an independent check system for infusion pump rates and concentration settings.

Opiates and Narcotics:

- Limit the opiates and narcotics available in floor stock.
- Educate staff about hydromorphone and morphine.
- Implement PCA protocols that include double checks of the drug, pump settings, and dosage.

Injectable Potassium Chloride (KCL) (or Phosphate):

- Remove concentrated KCL from floor stock.
- Move the drug preparation off the units and use commercially available premixed IV solutions.
- Standardize and limit drug concentrations.

Intravenous Anticoagulants:

- Standardize concentrations and use premixed solutions.
- Use only single-dose containers.

- Separate heparin and insulin.
- Remove heparin from the top of medication carts.

Sodium Chloride Solutions Concentration above 0.9%:

- Remove sodium Chloride concentration solutions above 0.9% from nursing units.
- Standardize and limit drug concentrations.
- Double check pump rate, drug concentration and line attachments.

Anticoagulants

The anticoagulants most commonly used and most frequently involved in medication error are unfractionated heparin, warfarin and enoxaparin. Contributing factors to medication error with the use of anticoagulants include:

- Inadequate screening of patients for contraindications and drug interactions.
- Lack of standardized naming, labeling and packaging
- Keeping up the changes to the different dosing regimens, drug interactions and reversal agents is difficult, particularly for practitioner who not routinely prescribe anticoagulants
- Failure to document or communicate individualized instructions and current lab results during hand-offs
- Pediatric administration errors because anticoagulants are formulated and packaged for adults,

Risk reduction strategies:

- Improve staff communication and information access
- Involve the patient in the management of anticoagulation therapy
- Implement a pharmacist managed anticoagulation service
- Use computerized provider order entry or barcoding technology

Other JCAHO recommendations:

For all anticoagulants:

1. Perform an organizational-wide risk assessment for anticoagulant therapy.
2. Use best practices or evidence-based guidelines regarding the use of anticoagulants.

3. Establish organization-wide dose limits on anticoagulants and screen all orders for exceptions (i.e., require a confirmatory override by the physician).
4. Clearly label or otherwise differentiate syringes and other containers used for anticoagulant drugs.
5. Clarify all anticoagulant dosing for pediatric patients.
6. Promptly re-evaluate patients whose anticoagulant is being held for a procedure. The re-evaluation should include an assessment of the need to reorder anticoagulant therapy.
7. Hospitals and ambulatory facilities should provide timely communication of all anticoagulant-associated lab values to the provider or the person managing the anticoagulation therapy.
8. Under the supervision of clinical staff, educate and assist inpatients who require anticoagulant drugs to practice administering their own medications. This will help reduce the risk of errors after discharge.
9. For heparin:
 - a. Consolidate and limit the number of institutional unfractionated heparin dosing nomograms. For all heparin medication orders (inpatient and outpatient), require prescribers to include the calculated dose and the dose per weight (e.g. milligrams per kilogram) or body surface area to facilitate an independent double-check of the calculation by a pharmacist, nurse or both. Note: For morbidly obese patients, the standard nomograms may not be accurate.
 - b. Before the start of a heparin infusion and with each change of the container or rate of infusion, require an independent double check of the drug, concentration, dose calculation, rate of infusion, pump settings, line attachment and patient identity.
 - c. Use heparin flush only for central lines and eliminate heparin flush of peripheral intravenous lines. Stock and use only pre-filled syringes commercially prepared at set unit doses for flush solutions.
 - d. Identify patients with heparin-induced antibodies and heparin-induced thrombocytopenia (HIT) to avoid life-threatening events from heparin exposure.
 - e. Dispense only preservative-free heparin to neonates and build an alert to pharmacists with this directive into order entry systems.
10. For warfarin:
 - a. Consider reports of INRs greater than three and episodes of vitamin K administration as possible indicators of warfarin-associated adverse drug events and take immediate steps to address these events.
 - b. Do not automatically discontinue warfarin according to automatic stop policies without verifying the drug's indication and contacting the prescriber.

Pediatric Considerations

Patient weight is the basis for calculating a lot of dosing of pediatric medications. Therefore, an accurate weight should be done before administering any weight based medications, except in emergencies. The kilogram should be the standard for all pediatric weights. Pediatric patients are more prone to medication errors and more likely to be harmed by medication errors because²⁰:

- Most medications used in the care of children are formulated and packaged primarily for adults. Therefore, medications often must be prepared in different volumes or concentrations within the health care setting before being administered to children. The need to alter the original medication dosage requires a series of pediatric-specific calculations and tasks, each significantly increasing the possibility of error.
- Most health care settings are primarily built around the needs of adults. Many settings lack trained staff oriented to pediatric care, pediatric care protocols and safeguards, and/or up-to-date and easily accessible pediatric reference materials, especially with regard to medications. Emergency departments may be particularly risk-prone environments for children.
- Children—especially young, small and sick children—are usually less able to physiologically tolerate a medication error due to still developing renal, immune and hepatic functions.
- Many children, especially very young children, cannot communicate effectively to providers regarding any adverse effects that medications may be causing.

JCAHO recommends the following pediatric-specific strategies for reducing medication errors:

- Standardize and identify medications effectively, as well as the processes for drug administration.
 - Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use.
 - To prevent timing errors in medication administration, standardize how days are counted in all protocols by deciding upon a protocol start date (e.g., Day 0 or Day 1).
 - Limit the number of concentrations and dose strengths of high alert medications to the minimum needed to provide safe care.
 - For pediatric patients who are receiving compounded oral medications and total parenteral nutrition at home, ensure that the doses are equivalent to those prepared in the hospital (i.e., the volume of the home dose should be the same as the volume of the hospital prepared products).
 - Use oral syringes to administer oral medications. The pharmacy should use oral syringes when preparing oral liquid medications. Make oral syringes available on patient care

units when "as needed" medications are prepared. Educate staff about the benefits of oral syringes in preventing inadvertent intravenous administration of oral medications.

- Ensure full pharmacy oversight—as well as the involvement of other appropriate staff—in the verifying, dispensing and administering of both neonatal and pediatric medications.
- Assign a practitioner trained in pediatrics to any committee that is responsible for the oversight of medication management.
- Provide ready access, including website access, to up-to-date pediatric-specific information for all hospital staff. This information should include pediatric research study data, pediatric growth charts, normal vital sign ranges for children, emergency dosage calculations, and drug reference materials with information about minimum effective doses and maximum dose limits.
- Orient all pharmacy staff to specialized neonatal/pediatric pharmacy services in your organization.
- Provide a dosage calculation sheet for each pediatric critical care patient, including both emergency and commonly used medications.
- Develop preprinted medication order forms and clinical pathways or protocols to reflect a standardized approach to care. Include reminders and information about monitoring parameters.
- Create pediatric satellite pharmacies or assign pharmacists and technicians with pediatric expertise to areas or services such as neonatal/pediatric critical care units and pediatric oncology units. At a minimum, pediatric medications should be stored and prepared in areas separate from those where adult medications are stored and prepared.
- Use technology judiciously.
- Use methods to ensure the accuracy of technology that measures and delivers additives for intravenous solutions, such as for total parenteral nutrition.
- If dose and dose range checking software programs are available in hospital or pharmacy information systems, enable them to provide alerts for potentially incorrect doses.
- Medications in automated dispensing cabinets that do not undergo appropriate pharmacist review should be limited to those needed for emergency use and/or to those medications under the control of a licensed independent prescriber, as specified in Joint Commission standard MM 4.10.
- Recognize that the use of infusion pumps, or smart pumps, is not a guarantee against medication errors. Appropriate education for nurses, pharmacists and other caregivers regarding these technologies is important for all institutions caring for pediatric patients.

- To prevent adverse outcomes or over sedation, use consistent physiological monitoring – particularly pulse oximetry – while children are under sedation during office-based procedures. Use age- and size-appropriate monitoring equipment and follow uniform procedures under the guidance of staff appropriately trained in sedation, monitoring and resuscitation.
- Providers are encouraged to develop bar-coding technology with pediatric capability. Potential errors should be carefully considered while adapting this technology to pediatric processes and systems. For example, a pediatric bar-coding solution must be able to provide readable code for small-volume, patient-specific dose labels.

Medication Reconciliation

Medication reconciliation is done to avoid medication errors. Hand-off situations are prone to errors. Errors can be omission, duplication, contraindications, prescription errors and administration errors. Therefore, the process should be done every time a patient has a hand off (transition in care). A hand-off includes change in setting, service, practitioner, or level of care. Medication reconciliation has five steps:

- develop a list of current medications
- develop a list of medications to be prescribed
- compare the medications on the two lists
- make clinical decisions based on the comparison
- communicate the new list to appropriate caregivers and to the patient.

When the patient has difficulty with the instructions, someone must be designated and taught about the patient's medications.

Risk reduction strategies include:

- Collect a complete list of current medications (including dose and frequency along with other key information) for each patient on admission.
- Validate the home medication list with the patient (whenever possible).
- Assign primary responsibility for collecting the home list to someone with sufficient expertise, within a context of shared accountability.
- Use the home medication list when writing orders.
- Place the reconciling form in a consistent, highly visible location within the patient chart (easily accessible by clinicians writing orders).
- Assign responsibility for comparing admission orders to the home medication list, identifying discrepancies, and reconciling variances to someone with sufficient expertise.

- Reconcile medications within specified time frames (within 24 hours of admission; shorter time frames for high-risk drugs, potentially serious dosage variances, and/or upcoming administration times).
- Adopt a standardized form to use for collecting the home medication list and for reconciling the variances (includes both electronic and paper-based forms).
- Develop clear policies and procedures for each step in the reconciliation process.
- Provide access to drug information and pharmacist advice at each step in the reconciliation process.
- Improve access to complete medication lists at admission.
- Provide orientation and ongoing education on procedures for reconciling medications to all health care providers.
- Provide feedback, on-going monitoring.

JCAHO recommendations include:

1. Placing the medication list in a highly visible location in the patient's chart and including dosage, drug schedules, immunizations, and allergies or drug intolerances on the list.
2. Creating a process for reconciling medications at all interfaces of care (admission, transfer, discharge) and determining reasonable time frames for reconciling medications. Patients, and responsible physicians, nurses and pharmacists should be involved in the medication reconciliation process.
3. On discharge from the facility, in addition to communicating an updated list to the next provider of care, provide the patient with the complete list of medications that he or she will be taking after discharge from the facility, as well as instructions on how and how long to continue taking any newly prescribed medications. Encourage the patient to carry the list with him or her and to share the list with any providers of care, including primary care and specialist physicians, nurses, pharmacists and other caregivers.

Infusion Pump Errors

The types of infusion pump errors seen are the use of pumps that do not protect from free-flow of fluids to the patient, the wrong drug concentration, or the wrong rate is set.

Free-flow of fluids occurs when the infusate flows freely, under the force of gravity, without being controlled by the infusion pump. Infusion pump tubing needs a built-in, anti-free-flow mechanism. This prevents gravity free-flow by closing off the tubing to prohibit flow when the administration set is removed from the pump. If an infusion pump does not have free-flow protection, devices that attach to the administration set are available. However, they are not recommended, because the mechanisms are packaged separately and must be manually attached to a set. Clinicians may forget to use the mechanism or may accidentally remove them.

Training and education are important in the prevention of infusion pump administration errors. Be sure to in-service staff who may not be administering medication, but may be handling the infusion pumps, such as aides, radiology technicians and transporters. Another concern is that patients, family members or visitors may mishandle pumps.

Key bump errors can cause errors in the volume or infusion rate. These should be double checked after entry and before starting the pump. Having a second nurse check calculations and settings for infusion pumps when high-alert drugs are used is recommended.

Tubing Disconnect

Misconnection of tubing can lead to patient deaths. Causative factors include:

- Luer connectors enable functionally dissimilar tubes or catheters to be connected
- the routine use of tubes or catheters for unintended purposes
- the positioning of functionally dissimilar tubes used in patient care in close proximity to one another
- movement of the patient from one setting or service to another
- staff fatigue associated with working consecutive shifts

Error reduction recommendations include:

1. Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female Luer IV line connector.
2. Conduct acceptance testing (for performance, safety and usability) and, as appropriate, risk assessment (e.g., failure mode and effect analysis) on new tubing and catheter purchases to identify the potential for misconnections and take appropriate preventive measures.
3. Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion.
4. Recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival to a new setting or service as part of the hand-off process. Standardize this "line reconciliation" process.
5. Route tubes and catheters having different purposes in different, standardized directions (e.g., IV lines routed toward the head; enteric lines toward the feet). This is especially important in the care of neonates.
6. Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions.

7. For certain high-risk catheters (e.g., epidural, intrathecal, arterial), label the catheter and do not use catheters that have injection ports.
8. Never use a standard Luer syringe for oral medications or enteric feedings.
9. Emphasize the risk of tubing misconnections in orientation and training curricula.
10. Identify and manage conditions and practices that may contribute to health care worker fatigue and take appropriate action.

Conclusion

Healthcare professionals have a responsibility to be knowledgeable about the PI process and to participate as opportunity presents. Healthcare professionals also have a responsibility to be aware of clinical situations that are prone to error and to participate in procedures to prevent those errors.

Systems redesign to prevent all such errors should be based on a balanced utilization of evidenced-based technology, training, on-going education, standards of practice and best practices, keeping in mind each human's inherent cognitive and physical limitations.

Human factors lead to medical errors. Human factors errors can be reduced through the application of scientific method. Human errors are inevitable within healthcare settings. Human factors analysis needs to be part of every medical error investigation.

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