Reduction of Medical Error
Promoting a Culture of Patient Safety

Developed by Baptist Health Systems of South Florida

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I Introduction

Experts estimate that in any given year, more people die from medical errors than from motor vehicle accicidents, breast cancer or AIDS. The number of reported medical errors is continuing to rise throughout the nation and public safety has been spotlighted as a major health care concern by consumers, the media and regulators. The federal and state governments, regulatory agencies and health care organizations have made safety a key priority quality health care. Patients have a right to expect health care in an environment free from accidental injury and risk, and health care workers have an expectation of working within systems that support safe and effective care.

Purpose

This learning program will provide an introduction to the safety concerns facing health care systems today, including data and background on the magnitude of the problem, error reduction and prevention, and root cause analysis. Processes to design blameless systems, which promote patient safety as well as ways to analyze data, will be reviewed. Current industry changes including the Florida Hospital Association (FHA) models, new Joint Commission on Accreditation of Healthcare Organization (JCAHO) patient safety standards and presidential and congressional activities are identified. Culture changes, analysis tools, improvement approaches, reporting processes, and risk management issues will be discussed. Finally, individual practitioner issues related to medical errors such as medication errors, surgical errors and other aspects will be reviewed. These topics will describe ways to promote safety and improve outcomes for patients including special populations. Patients and family participation and care will be highlighted as a key component to safety.

Objectives

- Describe the magnitude of medical errors and the effect on patient safety.
- Identify process to approach error reduction and prevention.
- Recognize error prone situations/processes
- Identify factors that impact the occurrence of errors
- Define the process and benefits of multi-causal analysis (root causes)
- Delineate your facility's policies and procedures for reporting medical errors
- Describe processes to improve patient outcomes
- Identify safety needs of special populations
- Discuss educational needs of patients/families
- Explain what each of us can do to protect patients and ourselves from accidental injury

II Safety concerns and magnitude of the problem

"**There are some patients we cannot help; there are none we cannot harm"**
Arthur Bloomfield, MD

How did the focus on quality and patients safety come to the attention of the nation? In 1998 the Institute of Medicine (IOM), working under The National Academy of Sciences, inititated several reports for the Quality of Healthcare in the America Project. The IOM was established in 1972 as an adviser to the Federal Government to identify issues of medical concern, research and education. Their study was the result of both congressional and public media attention on the negative effects of hospital stays and untoward effects. The first of a series of reports "To Err is Human: Building a Safer Health System" was released in 1999 with staggering results.

The primary research was conducted in New York, Colorado and Utah. Extrapolation of the data to the 50 United States estimates that of the 33.6 million admissions to the hospitals in 1997, between 44,000 – 98,000 deaths resulted from adverse events, making is the 8th leading cause of death ahead of death crashes, breast cancer, and AIDS. Adverse events occur in 2,9 -3,7 % of hospitalizations costing in excess of $17 Billion in lost income, disability and healthcare costs. If we were to compare the error rate to the worldwide traffic controllers, it would be the equivalent of 2 747's crashing each week.

Definitions by IOM

Adverse event: Injury caused by medical management rather than underlying diseases/condition of patient.

Error:	Planning –	Use of a wrong plan to achieve the desired aim
	Execution-	Failure of a planned action to be completed as intended.

Not all, but a sizable number of adverse events are the result of medical error. Errors can become adverse events but many do not because of "luck" influencing in these events. Careful planning can help influence and prevent these medical errors from happening. The IOM report has impacted the way healthcare providers think, both nationally and internationally. The report, through data, depicts a grave picture of the current healthcare environment. Because of this report, new collaborative alliance have been created to focus on patient safety. Legislation has been sparked at the state and federal level with the media continuing to focus on medical errors.

III People factors and process factors.

Why people make mistakes

Human factors engineering (HFE) has evolved as a discipline to help explain how people think and behave in systems. The research in this field and study of other industries such as long distance trucking, aviation and nuclear power has offered insight into how people make mistakes and how we can use this learning in health care to improve systems and make patient care safer. Some key learnings show that people make mistakes for the following reasons:

- Fatigue and exhaustion degrade performance, making mistakes more likely as people get tired
- Inattention and distraction when multiple events are occurring divert attention to the task at hand
- Seeing what we expect to see because we are "used" to seeing it that way, even if it is incorrect, leads to mistakes that we don't even recognize (familiarity breeds contempt, familiarity can also breed errors).
- Encountering a new situation or problem for which you have not been trained and do not know how to handle can lead to "trial and error" solutions, usually resulting in error
- Trying to solve a new problem with and old solution or a old technology that no longer applies can create errors because the situation has now changed
- Equipment design flaws also contribute to errors, such as free flow design of certain infusion pumps.
- Labeling of medications or equipment instructions may be misleading or not completely describe correct usage leading to improper use or errors. Many label for different medications come in the same color or package.
- Communication gaps (lack of communication, misinterpretation, using words that have several meanings) contribute to errors. This reminds us of the childhood game in which a message is whispered rapidly to others in a circle. The final message is quite different from the original with lots of laughs. When this happens in health care, it is never a laughing matter.
- Illegibility such as handwritten notes/orders contributes to "guessing" and often an error.

- Certain working conditions such as loud noises, poor lighting or slippery surfaces can all contribute to people making mistakes. The environment plays a crucial role in being conducive to safe work practices.

Key points

So we can see that people make mistakes because they are human and unable to perform perfectly 24/7. Bu\t they also make mistakes when equipment, supplies or the environment are not conducive to the safest practices.

These factors should be considered when either Failure Node and Effects Analysis (FMEA) or Root Cause Analysis (RCA), which are explained later in the module, are conducted, and the team analyzes ways to prevent errors from occurring and to improve care.

Why processes may fail and lead to error

Just as people are vulnerable to making mistakes, so certain processes are more prone to lead to errors. The following characteristics of high-risk processes increase the risk of failure and should be included as part of FMEA and RCA analysis to also be used in creating the safest processes.

- *Variable input*: A process that receives a variable input (often changing and unpredictable) is more prone to malfunction or fail because modifications must be made to accommodate this different input. In health care, patients are very variable with different conditions, preferences, and tolerance levels, and it is the patient who is considered “the input”. So any process involving multiple patients is prone to have failures.
- *Complexity*: Complex processes are more prone to fail because each additional step in a process adds one more chance for mistake to happen. “Keep it simple, sweetie (KISS)” relates the need for simplicity to minimize complexity and greater chance for errors.
- *Inconsistency*: Standardization of processes, procedures, equipment and tasks will reduce the risk for failure or error due to inconsistent approaches. Standardization helps reduce variation by getting the team together to work from the same page.
- *Human intervention*: Any process that depends on people is more prone to failure than a process that does not. For example, automated functions often proceed smoothly and without interruption. Computer alerts, calculators and automatic reminders are examples of technologies that maintain process stability without people having to do the work.
- *Tight coupling*: Coupling is defined as the relationship between the steps in a process and described as loose or tight. In a tightly couples process the steps follow closely and problems in one step cannot be recognized or responded to before the next step is made. For example, in situations like the emergency department or code situations, patient care actions must proceed rapidly and if a mistake is made in one of the steps, it may not be recognized before the next step occurs.

- *Tight time constraint*: Time constraints often go hand in hand with coupling. When time is limited for a process or must occur rapidly then additional pressure and stress is applied to the people taking action, allowing less opportunity to identify, analyze, and respond appropriately. Just as nerves get frazzled during rush hour traffic, so too does rushing to complete a test, move a patient or give medications contribute to time pressures and risk for errors.
- *Hierarchal culture*: "The captain is always right" exemplifies the culture in which there are different levels of reporting relationships. This culture may make it difficult to raise questions for fear of being embarrassed or wrong.

IV Culture change

"Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals". *Lucine L Leape, MD, Harvard School of Public Health.*

Why people make mistakes:
▪ Fatigue ▪ Inattention/distraction ▪ Unfamiliar situations / new problems ▪ Using past solutions ▪ Equipment design flaws ▪ Illegible labeling ▪ Communication errors ▪ Mislabeling/instructions
Why processes/systems fails:
▪ Variable input (ex patient personalities) ▪ Inconsistency ▪ Complexity ▪ Too many/complicated steps ▪ Human intervention ▪ Tight time constraints ▪ Hierarchical culture

A common misconception is that patient safety can be improved by simply reminding healthcare personnel to be more careful. Health care providers are some of the most careful people on earth. While people do make mistakes, it is a system failure, not blame of individuals, which must be the focus. Instead of focusing on blaming an individual for an incident, the focus should be on reviewing the processes and factors that surrounded the unfortunate event. A change in focus can occur only by healthcare organizations objectively evaluating their values and culture and then systematically making the necessary positive changes. Improving patient safety is about changing the culture in healthcare.

Given the complexity of the health care system and the historically hierarchical culture, it is necessary to identify the important steps toward changing the culture for patient safety. The include understanding how accidents occur and concepts in the

scientific study of error reduction and prevention. Through increasing knowledge and improving processes, healthcare professionals can decrease the risk of medical errors and potential or actual harm to patients. The following are ways to improve safety in key areas of concern while focusing on creating a culture of patient safety.

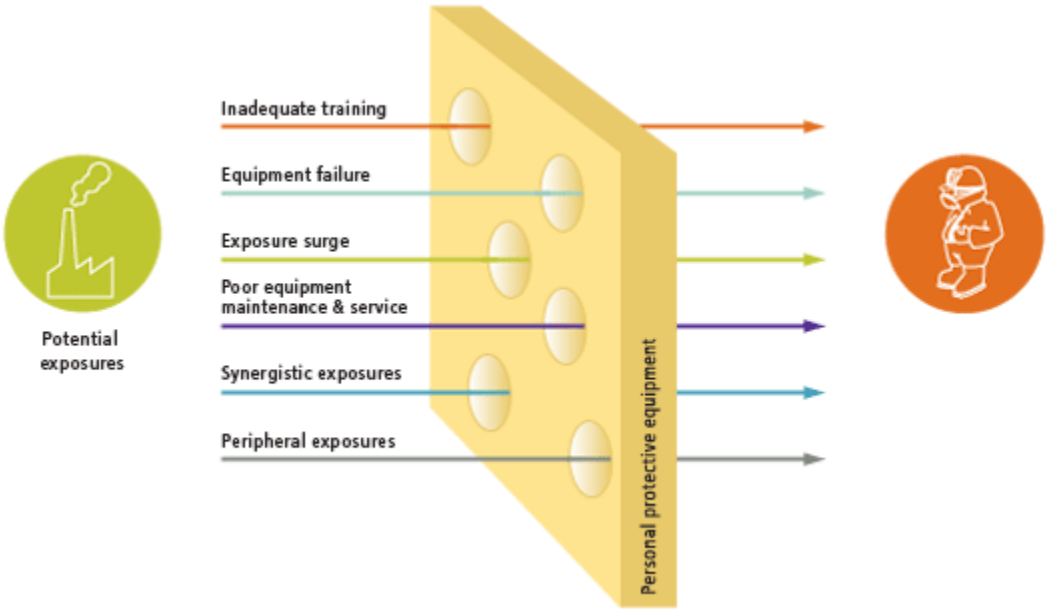
Several models which illustrate these points are described. The models should be considered in explaining how errors and are usually viewed.

Swiss Cheese Model

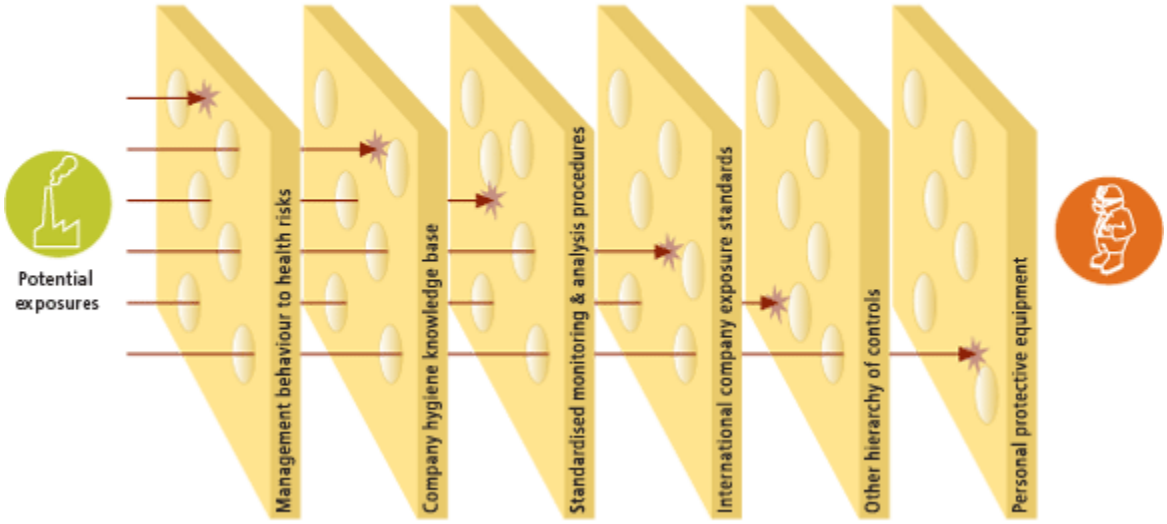
The "Swiss Cheese Model" illustrates that an accident is not the result of one single failure. When an accident occurs it is the result of a series of failures aligning and therefore, allowing the mistake to reach the patient.

There are many types of defenses that organizations have to deflect failures and them from reaching the patient. To help minimize the vulnerability for accidents, organizations need to systematically examine how failures move past the defenses in place. Systems that rely on error-free performance are doomed to failure as all systems involve people who make mistakes. However, we should continue to strive for perfection and always work to improve care by reducing the risk for errors.

For example, one of the pieces of cheese could be a certain type of equipment like an infusion pump. If the equipment is unavailable, then caregivers may work to still provide the case needed by timing the IV infusion and monitoring infusion rate without the equipment. If the device is difficult to obtain, then the staff may hide them on the unit to have available for patients. In these examples the staff is always trying to do the right thing for the patient but working around systems or barriers.



There may be many reasons why personal protective equipment alone may not be sufficient to protect against potential exposures.



Control measures for reducing potential exposures

Blunt and Sharp end

The next concept is that of blunt and sharp end the blunt en usually encompasses policies, procedures and resource allocation systems that impact how supplies, procedures and work ate organized. The blunt end influences the systems in which practitioners work. Direct caregivers are considered the sharp end in the system because they are the direct interface with the patient. Combined with the Swiss Cheese model it is easy to see that when and errors occurs, it is “visible” where the final error occurred, but all of the other systems, departments and other factors are not easily recognized. This point will be important to remember during an error analysis since multiple reasons or

causes usually contribute to an error. The blunt end in a system may either be a barrier or an enable for caregivers depending on how policies and procedures are designed.

For example, if a medication error it may be easy to blame the single nurse. What is nor readily apparent are factors that may have contributed to the error such as the medication delivery being late; or delivered to the wrong patient; or a policy that required purchase of medications that were cheaper but look alike. These other" blunt end" contribute to potential errors but are only noticed when made at the "sharp end".

Hindsight Bias

Hindsight bias is the phenomenon where it seems obvious how an error happended after the fact. However, before the error occurred, it was not obvious that the process or system was error prone. Because health care professionals do not really identify a problem weith a procedure or process, it is difficult to make improvements, so sometimes gaps are not corrected. Hindsight Bias is the primary obstacle to accident analysis and understanding, thus jeopardizing and organization's ability to uncover other areas for potential accidents.

Hindsight Bias is similar to "Monday morning quarterbacking" because it narrows the focus on the cause of any failures or errors without considering the whole picture, including all of the environmental, emotional, and political and system issues surround the event. Just as it is easy to blame the coach on Monday, it certainly wasn't easy during game time to predict how the other team would play or just how an individual player would perform. This approach will limit a complete and thorough investigation and focus on individual action as the cause of the problem as someone to "blame".

For example, when evaluating and unfamiliar patient, there are many factors to consider in the diagnosis and treatment as well as liability issues and pressures from sources such as health plans. Often, a review of decisions made about care occurs after all of the diagnostics information is available and it seems easy to state what should have been done the day before.

V. Tools for prevention and analysis.

In the scientific process of error reduction and prevention are two models that examine the study of incidents and patient safety. The first model is applied **before** an error occurs and is designed to prevent errors by examining processes to determine failure points and risks. While several approaches can be used such as "Checklist Analysis", "What-if-Analysis", and "Barrier Analysis", the most common model used and the one identified by the Joint Commission is "Failure Mode and Effects Analysis (FMEA). FMEA is a proactive approach which emphasizes prevention of errors or events. This hazard analysis works on planning and designing processes with tools to prevent failure.

The second model is applied **after** an event occurs and is designed to determine the multiple factors that most contributed to the event so that corrective action can be taken to fix the causes so the event does not happen to another patient. The approach used for this process is called "Root Cause Analysis (RCA). While the term "root cause" is used, rarely is a single cause found to contribute to an error. Usually multiple causes are discovered in the analysis and each cause will need to be assessed and prioritized for corrective action. RCA is a corrective action which occurs after the error (hindsight bias) to analyze the "why" not the "who" and implement an action plan for future prevention.

Failure Mode, Effects, and Analysis

FMEA is a systematic way of examining a design prospectively for possible ways in which failure can occur. In this way, one can analyze a procedure(s) before an error occurs.

It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur. FMEA steps:

+ Define high-risk processes. Identify what could wrong, the significance of the error and what needs to be done to prevent failures.
+ Assemble a multidisciplinary team which includes both content experts and process experts.
+ Flow-chart the current process
+ Brainstorm potential failures at each step
+ Determine the criticality of each failure. Criticality = frequency X severity of the failure X detectability if the failure occurs
+ Discover what causes critical failures and their effect.
+ Redesign the process in the way it should be done to minimize the risk of the failure occurring to protect patients.
+ Eliminate the chance for failure; make it easier for people to do the right thing before the error reaches the patient.
+ Pilot / test the design.
+ Implement the process.
+ Re-evaluate.

For example, in the medication delivery process, one potential failure mode is "look-alike" drugs. The potential effect on the patient, if dispensed, is potentially dangerous. The likelihood of the drug reaching the patient is dependent on the particular organization and safeguards built in to separate look-alike drugs or not to purchase them in the beginning. The criticality of the failure mode is a result of multiplying the frequency of the failure (perhaps low) X the severity of the failure (serious or greater) X detectability (perhaps high because the patient would exhibit untoward symptoms). The causes may include an open formulary, purchasing practices, ambiguous labeling by the vendor, storage practices or other factors. The redesign strategies to eliminate the failure would be to eliminate the look-alike drugs. This may include a review of the formulary by the P&T Committee; review of vendor products and labels; storage/dispensing practices; and alerts to those who administer medications. Then the organization must test the redesign, implement the changes and reevaluate.

Root Cause Analysis

RCA is a process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. RCA determines what happened, why it happened, determines which processes were involved and what underlying causes exist, then defines a corrective action plan(s), implements the plan and measures its effectiveness.

Root Cause Analysis steps:

+ Define the problem / gather the facts
+ Assemble an interdisciplinary team
+ Determine the sequence of events
+ Identify the sequence of events

+ Select root causes
+ Develop corrective action & follow-up plan

Through continued reporting of incidents or near incidents and follow through of these processes, systems processes that are contributing to errors can be identified and changed to prevent future medical mishaps/errors from occurring.

For example, surgery may be done on the wrong limb (left versus right). RCA of the event finds the following factors were contributory to the mistake:

+ Emergency admission of the patient with several patients having X-ray exams
+ Documentation in the record reflecting both left and right leg pain after a fall
+ The medical areriving to OR after the patient as ED staff completed notes
+ Emergency procedure being performed after normal hours
+ OR on-call staff included staff working from another sister organization
+ The operating surgeon has been on call for the past 24 hours with 4 emergency procedures
+ The assistant in the OR is a new employee

It is possible that all these factors contributed to the problem. An analysis would determine those most important and a corrective plan would be developed to ensure future surgeries are performed on the correct site.

The language of safety

The way we talk and words we use to describe events helps shape our culture. Redefining our culture for safety must include replacing words/concepts and understanding the "why"

Accident/failure vs. error

Accident describes a breakdown in a system, is complex and needs analysis. Error suggests one cause, usually notes as human error.

Multicausal vs. root cause

Studies show that several failures must occur and line-up for an accident to happen (Swiss Cheese Model). This demonstrates there is no such thing as root cause or single source accidents.

Learning vs. Judgment

To prevent repeat failures we must learn from mistakes. If we are judgmental we are placing blame and failing to learn from failures

System vs. Isolated events

Accidents are not isolated events, they are the results of weaknesses in a system

Study/Examination vs. investigation

An examination is what we do to learn how systems. An investigation assigns/presumes blames.

Accountable vs. blame

Health care professionals are accountable for their knowledge, competence and work. Blame is used to find an excuse for failure bot to predict and prevent future incidents.

Blameless vs. Punitive/retaliatory

A blameless environment promotes comfort to report failures for study. Punitive cultures promote fear and hiding.

Hierarchy vs. bureaucracy

Hierarchy is a system of formal rules, procedures, training and decision-making based on evidence. Bureaucracy is a system of administration marked by fixed rules and authority by position not expertise.

What happened? Vs. Whose fault is it?

"What" uncovers facts. "Who" places the blame

VI Creating a change and improving safety

The goal of a patient safety program is to create a non-punitive / blameless culture. This means that should an incident occur, instead of placing blame on the individual who was involved, exploration of the situation and the surrounding factors should be analyzed. Through such an analysis, many times it is discovered that the individual was not to blame, but instead the process or procedure allowed room for error.

Establishment of an environment of trust where reporting of errors is the norm, and policies are developed to promote Multicausal analysis rather than placing blame on the individual is essential. People must be "rewarded" for reporting adverse events and near misses. The reporting of errors is necessary to be able to see what is wrong with a process of a procedure.

Leaders must be involved in investigations for performance/process improvements to occur. In this way administrators and leaders can assess problems and make improvements. The language of safety is a positive one. Through these changes, staff will become empowered to correct safety hazards with leadership, medical staff, risk management and legal counsel aligning with the same patient safety agendas while protecting the patient and the organization.

By designing and implementing systems that identify risks, analyze incidents and change c\language and attitudes from blame to system failure, healthcare organizations can reduce the number of medical errors and improve patient safety

What changes should be considered to processes to make patient care safer?

- Simplify; Reduce the number of steps and hand-offs
- Standardize; Limit unneeded variety in drugs, equipment, supplies, policies and processes.
- Reduce reliance on memory; Design processes with automatic prompts
- Checklists; Use tools as reminders to ensure complete accurate actions.

- Constraints and forcing function; Make sure certain positive conditions are met before action can occur. For example, use non-interchangeable connections to" force" the right route to be used.
- Eliminate look alikes and sound alikes; Eliminate similar labels that can increase the risk of choosing the wrong item.
- Training; Train staff on patient safety, error analysis techniques and tools and process improvement.
- Increase communication and feedback. Use feedback to modify or correct error-prone behaviors.
- Teamwork. Use teams to provide both content experts, process experts and provide multiple perspectives in problem identification and solutions.
- Environmental adjustments. Identify factors in the environment that may contribute to errors and modify or correct them.
- Adjusting work schedules. Identify factors in schedules that may contribute and modify or correct them.

Frontline health care workers, those having direct patient contact, are the last line of defense between the patient and the error. If we wish to accomplish our goal to protect the patient from medical errors, then we must be proactive and examine the risk prone processes/systems in which we work. Examining the current research, recurrent causes of errors appear. The more complicated the task, the greater the number of steps involved, then the greater the chances for mistakes. It is important to realize that a medical error may not necessarily cause patient harm. "Near miss" errors are errors that get "caught" before they reach the patient. Identifying and analyzing errors that considered "near miss" errors can prevent patient harm by determining where the weak points are in the care delivery system and strengthening them (FMEA).

Medication administration is an extremely complicated task. In fact, medication errors rank higher in injuries than do on-the-job accidents to workers. Procedural/surgical mishaps, falls and improper patient identification are other areas that require special attention to prevent patient harm.

Emphasis on the age-specific needs of patients as well as special populations is important as we work to improve our systems.

Considerations

For example when considering different age groups and safety needs the following factors must be considered:

- Emotional development of children and their ability to cooperate with care
- Patients who need additional watching due to inability to care for self
- Reduced dosing for neonates, infants, children, elderly and those with conditions of impaired renal, liver, immune function
- Ability of different age groups to follow directions related to safety and asking for help

Assessing cultural differences may also play a role in providing safe care. For example, the following factors should be considered:

- Language barriers that inhibit understanding about care
- Cultural differences in expressing health concerns to others
- Cultural differences in exposing the body to others
- Cultural differences in asking for help
- Cultural differences in "alternative" medicine but not reporting it.

Special populations may also need additional consideration related to safety needs and include:

- Children and neonates who require special dose calculations and equipment for administration
- Elderly patients with compromised metabolism of medications who require reduction of dosage
- Chronically ill patients who have multiple conditions; take numerous medications; have limited tolerance, and have a greater chance for drug interactions
- Patients with renal or liver impairment with a need for dosing modifications
- Patients with immune system impairment (oncology, AIDS, transplant) with a need for special drug monitoring

You can probably think of other patients who have needs for additional monitoring or special consideration to reduce the risk of error.

VII Special Topics

Medication Safety

The IOM study estimates that as many as 7,000 patients die each year as a result of medical errors, with an estimated additional hospital cost of $4,700 for each preventable medical error. These figures don't take into account the intangible cost - the physical and emotional effects of medication errors.

Medication errors are the most common type of nursing error, the second most common JCAHO sentinel event and the second most common error in physician offices.

Medication errors have been defined by the American Hospital Association as "any happening which is not consistent with the routine operation of the hospital (or health care organization) or the routine care of a particular patient." The National Coordinator Council for Medication Error Reporting and Prevention (NCCMERP) has a more comprehensive definition:

"A medication error is any preventable event that may lead to inappropriate medication use or patient harm while the medication is in the control of a health care professional, patient, or consumer. Such events may be related to professional practice, health are products, procedures, and systems, including prescribing; order communication; product labeling/nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

Medication errors can be broadly categorized into four major categories ordering/prescribing, dispensing, administration, and monitoring. Almost 80% of

medication errors can be classified as ordering/prescribing or administration erros. This provides that is both high volume and high risk as an improvement opportunity.

The Patient Safety Steering Committee is a multi-organizational interdisciplinary collaborative team spearheaded by the FHA. The Committee has taken a leadership role in providing guidance, direction and priorities for initiative related to patient safety, focusing on medical errors. They have developed four practice model guidelines in medication safety. These guidelines can be used to assist healthcare organization develop their own processes to ensure safe medication administration (www.fha.org/quality.html)

Phase 1: Ordering/Prescribing

\ In order to ensure a safe ordering/prescribing process it is important to have essential information readily available to those involved in the ordering/prescribing of medications. This includes diagnosis, allergies/sensitivities, age, weight, lab values, current medication regimens and any other key information about the patient. It also includes having essential information references (such as PDR, Nurses Drug Handbook, MicroMedex, etc.) readily available on the units where medications are ordered or prescribed.

Review of the organization's formulary in collaboration with the medical staff to limit, where appropriate, the number of therapeutically and generically equivalent products can reduce the potential for errors by reducing the number of choices the doctor has to make. Below are specific guidelines for medication error reduction:

- Development os special procedure or protocols for the use of "high risk" medications such as heparin, insulin, chemotherapy, concentrated electrolyte solutions etc. can help reduce errors by providing prompts for the ordering physician.
- Standardize processes where possible, such as medication administration times, inpatient order format, and protocols for verbal orders to reduce variability in our medication administration systems.
- Develop policies that prohibit the use of potentially confusing orders such as "resume same medications" or" resume pre-op medications".
- Decrease athe possibility of illegible or confusing orders. Illegible physician orders are a high risk for incurring a possible mistake.

Consideration should be given to computer generated order entry systems. For handwritten orders, policies and procedures should address acceptable order format. Abbreviations and acronyms should be avoided. Always use leading zeros before a decimal point e.g. 0.2mg. Never use trailing zeros e.g. 2.0 mg. Medication should be ordered by the total dose required, and not by volume, number of ampules or number of tablets. Patterns and trends in ordering or prescribing errors should be analyzed through peer review committees.

Safe practices for Verbal Orders
▪ **Ordering/prescribing practitioners must be identified** ▪ **Patients must be clearly identified** ▪ **Must be clear and concise** ▪ **Verbal orders from on-site practitioners should only be taken in emergencies** ▪ **Verbal orders should NOT be taken for chemotherapy** ▪ **All verbal orders should be repeated for verification**

Phase 2 Dispensing

The pharmacy staff also needs access to key information about the patient prior to dispensing of a new medication order. If information is not available on-line, the development of pharmacy data profile to include this is important. Appropriate and current drug reference texts and/or on-line resources should be readily available as well. The environment for the medication dispensing area should be readily available as well. The environment for the medication dispensing area should have minimal distractions and interruptions, appropriate lighting, air condition/air flow, safe noise levels, and should include ergonomic consideration of equipment, fixtures and technology.

Use of technologies designed to ensure consistency and ease of administration should be considered such as prefilled syringes, premixed IV solution etc. Ensure that prefilled syringes have appropriate route noted and, if possible, use non-interchangeable connections to prevent the inadvertent administration by another route. Consider using automated dispensing devices such as Pyrix®, Acudose®, or others to increase security and accountability of necessary medications stocked in patient care areas.

If changes occur in product availability, purchasing contracts, new drug concentrations or packaging, notify users such as anesthesia, emergency department, and critical care staff. Procedures should be established whereby proposed changes are reviewed prior to being implemented to reduce error potential.

To avoid human error, all mathematical calculations for neonatal and pediatric dilutions, parenteral nutrition solutions, and other compounded pharmaceutical products should be double-checked by a pharmacist. Additionally, all orders involving antineoplastic agents should be double-checked by a second pharmacist for accuracy of order entry and dose calculations. Determine other high-risk drugs dispensed in your facility that require double-checking.

Phase 3: Administration

Once the medication had been ordered and dispensed it has to be administered to the patient. When administering medications, it is the responsibility of the professional nurse to be knowledgeable about the drug's indications, precautions, contraindications, potential adverse reactions, interactions and proper methods of administration. If a nurse is not familiar with a medication, then she/he should find out. Appropriate and current drug reference text and/or online resources should be readily available to nurses. It is also important that essential patient information is double0checked prior to giving medication. Orders tat are incomplete, illegible or otherwise questionable should be clarified using and established process prior to administering the medication.

It is imperative that confirmation of all of the “rights” prior to administering a medication should be done every time a medication is administered. Only medications that been fully labeled with medication name, dose to be administered, dosage form, route, special storage instructions, expiration date and all other applicable warnings should be given.

When a mathematical calculation of a dose is necessary, a second nurse should verify the calculation to avoid human error in the calculation. Double-checking infusion pump settings when critical, high risk drugs are infused is another essential safety check that should be incorporated into the medication administration procedure. Ensure that nursing staff receives adequate education on the operation and use of infusion pumps and other devices used for medication administration.

Educate patients about their role in taking medications and questions they should ask, Patients should be made aware of the therapeutic purpose of the medications they are taking and any side effects to be aware of.

The right way to give medications:
▪ **Right patient** ▪ **Right drug** ▪ **Right dose** ▪ **Right dosage form** ▪ **Right route** ▪ **Right time** ▪ **Right education**

Phase 4: Monitoring.

Development of non-punitive processes for reporting medication erros, near misses, and adverse drug reactions lays the foundation for a strong patient safety program. Track, trend and review these events as part of a regularly scheduled interdisciplinary committee such as Pharmacy and Therapeutics Committee. Focus on implementing changes to improve systems and processes.

Procedural and Surgery Mishaps

Procedural mishaps include a variety of errors that occur or have the potential to occur, while patients are navigating through the health care system. These mishaps may be as simple as discharging a patient with a saline lock still in place or as serious as performing surgery on the wrong patient. We have all read and heard about errors occurring during surgical procedures; the wrong foot amputated, the wrong breast removed. In two major studies of medical errors half of the adverse events occurring in hospitalized patients were related to surgery. A patient safety program developed with an emphasis on identifying the correct surgery site, the right patient and the right procedure is essential to prevent serious adverse events from occurring.

The surgeon plays an important role in identifying the correct site for a surgery. It begins with informed consent process and the exact site to be operated on should be clearly documented. The patient and family should be included in this process. Remember, an informed patient is a safe patient. Next is marking the either the correct sote or the incorrect side with “YES” or “NO”. Using an indelible marking pen (e.g. “ Do

not cut here" or " Do cut here") clearly mark the site. Make sure the patient is not allergic to the marking pen! The use of an "X" or other nondescript marking may be misleading; does "X" mark the spot or does "X" indicate this is not the right site? Be sure there is no room for mistaken interpretation. Have all relevant patient information available before the surgery/procedure and ensure that all sources match with the same site(medical record, X-rays, tests, etc.). The patient's chart, the OR schedule and the consent form must all be in agreement and should be reviewed with the patient of the patient's family prior to the patient entering the surgery suite. It may be helpful to use a body diagram in documentation clearly marking the correct site. Once in the operating room, prior to prepping and draping, the surgeon, circulator, charge nurse, and the anasthesiologist/anasthetist, should have a process to re-verify the proper surgical site. Ensure that all members of the surgical team can "interrupt" for a verification check of the proper site. Documentation of the verification process should be included in the surgical record.

Care should be taken to ensure that there is buy in from all members of the team. One health system reported that the burden of the verbal consensus process became the circulating nurse's responsibility. The initiation of the verbal consensus was made more difficult for the circulating nurse because some physicians did not appear to value the process. When key physicians became champions and helped to educate their colleagues about the importance of the process it became effective.

While the potential for surgical mishaps seem obvious, non-operative errors, including therapeutic mishaps and diagnostic errors can cause significant injury to patients. All disciplines should examine key processes and implement measures to ensure patient safety. Refer to **Table 1** for specific high risk areas and error prone procedure.

Table 1: Other high risk areas with potential for medical errors

Respiratory therapy

Medication administration
- Medication mixing
- Missed treatments
- Patient education

Medical gas administration and connection
- Medical gas mix ups

Cardiopulmonary resuscitation
- Intubation of esophagus
- Esophageal trauma

Use of ventilator
- Volume, pressure, rate, alarms, equipment management

Physical therapy/Occupational therapy

Heat/cold applications
- Potential for skin irritation

Splints/orthotic applications

- Potential for skin problems if not applied or used correctly.

Assisted devices

- Potential for falls, improper use.

Radiology/Nuclear Medicine

Monitoring during procedures

- Falls
- Inadequate shielding
- Allergies /.reactions (Contrast media)
- Wrong site exam

MRI

- Protection from metal objects

Social services

Patient discharge

- Access to accurate information
- Patient education/appointments
- Ordering proper equipment for discharge
- Assistance with medications

Unpredictable patient/family

- Lack of follow up care
- Incorrect use of equipment/meds/violence

Lab

Venipuncture

- Potential for vessel damage/bleeding
- Vwnipuncture of wrong site such as arm with shunt

Lab specimens

- Mislabeled specimens
- Contamination of specimen such as cultures
- Improper preparation of specimen

Performing tests

- Equipment calibration/control problems
- Interpretation of results

Results reporting

- Incorrect results reported
- Results reported on wrong patient
- Delay in results reporting

Dietary

Food temperatures

- Potential for burns

Nutritional supplements
- Missed snacks
- Calculations of calorie needs/TPN
- NGT feedings

Nursing

Medication delivery
Blood transfusions
Using restraints/seclusion
Preparation and monitoring for procedures and surgery
Falls prevention
Using equipment
Treatments
Vital sign monitoring

Pharmacy

Storing medication
Dispensing medication

Falls Prevention

All caregivers face the problem of patient falls. Patients are at risk for serious injury and institutions must deal with the financial liability that results from such accicidents. Fallas are a major cause of injury and death among the elderly. The older the person, the more likely death may be a result of a fall or its complications. Falls may be cause by environmental factors such as clutter, wet floors, rugs, or by physiological factors including vertigo, CNS impairment, muscular weakness, broken bones, etc. Other causes include communication issues (non-compliance, incomplete history, lack of identification of falls risk, transportation issues). In the hospital, the risk of falls is highest during the first week of a stay. The best medicine is prevention. Falls prevention basics include:

- Assessment of patient risk for falling
- Correct potential environmental dangers
- Patient/family teaching
- Continuous monitoring
- Implementation of a patient specific plan for safety

Many tools have been developed to assess patients' risk of falling. For example, the Morse Falls Prevention Scale, developed by Janice Morse following 8 years of extensive research, is a predictor of the likelihood of falling. Using this scale, patients with a score of 45 or higher are at an increased risk of falling and should have a comprehensive fall prevention program/protocol implemented. Patients should be re-evaluated daily.

Providing a safe institutional environment includes removing any physical hazards, providing adequate lighting, locking bed/wheelchair wheels, placing objects within the patient's reach and always ensuring the call bell is within reach. Patient/family education should include information on safety concerns and risk, how to fall safely, wearing nonskid footwear and rising slowly. Answering patient call lights at regularly defined intervals will assist in decreasing the risk of falls. A comprehensive plan of preventive strategies identifying the specific medical needs of the patient will prevent mishaps.

Restraints

Restraints pose special concerns when it comes to patient safety. Historically, restraints were used and viewed as a means to contain and protect the patient from falls/injury however research has proven differently.
Alternatives to these devices should be considered for high risk patients, such as pressure pad alarms and added supervision. Implementation of a restraint safety plan that assesses the patient every hour and limits the use of restraints to 24 hours without reassessment and reorder by the physician will reduce the risk of patient injury. Remember that closed doors seclude the patient and may be considered a form of restraint.

Siderails

Thought for decades to be standard devices used to protect patients, side rails have proven to increase the risk of entrapment and falls. In the July 2001 issue of AJN (2), research is presented to document that siderails may be restraints and that older people or confused patients often try to climb over the perceived obstacle, increasing the risk of serious injury. In 1995, the FDA issued a Safety Alert concerning hazards associated with side rail use. In October 2000, the FDA brochures" A guide to bed safety: B ed rails in hospital" and "Nursing homes and home health care; The facts", became available (www.fda.gov/cdrh/beds)

When used appropriately, following a thorough nursing assessment, the use of bedrails as a tool for patient safety can be a comprehensive Falls Prevention Program.

Alternatives to siderails that pose less physical & psychological threat:

- Low height beds
- Floor mats
- Bed/motion sensors
- Body pillows
- Toileting rounds
- Adequate nighttime pain control
- Increased supervision

Evaluation

Any falls prevention program cannot be complete without evaluation of its success. Evaluation enables estimation of the cost of falls to the health care system,

identifies patterns of falls within the institution and provides a system of monitoring the effectiveness of the falls prevention efforts of the multidisciplinary team. Continued reporting of incidents where no harm occurred will help system FMECA/ root cause analysis studies to incorporate fall prevention strategies protecting the patient. If a patient falls, it is a failed strategy, not a nurse's fault. Falls prevention is a total institutional commitmrnt.

VIII Patient Rights and Protection

When agreement has been reached to pursue a course of medical treatment, patients should have the assurance that it will proceed correctly and safely so they have the best chance possible of achieving the desired outcome.

The Role of Risk Management

Risk management programs assist organizations in designing systems to prevent and control adverse effects. Healthcare risk managers are concerned with the prevention of patient injury and loss prevention for the organization. These programs are intended to minimize adverse effects of losses on human, physical and financial assets through identification system errors. Risk management, historically, has collected data from incident reporting and lawsuits. By analyzing these events, causes for medical errors are determined and processes can be changed.

Reporting

Organizations must develop systems both for internal and external reporting. As defined by the Florida Statute 395.0197, hospitals have an affirmative duty to report any adverse event or untoward incident in which the healthcare provider had control. These events result in a Code 15 or Code 24 report to the Agency for Health Care Administration (ACHA) within 15 days of the occurrence.

In 1996 JCAHO initiated a sentinel event reporting system. These events are called "sentinel" because they signal the need for immediate investigation and response. This voluntary reporting plays a valuable role in encouraging improvements in patient s safety. All sentinel events must be followed by root cause analysis focused on identifying the processes that contributed to the sentinel event and making changes in the organizational systems. JCAHO also examines the performance improvement (PI) processes that an organization has in place to reduce the risk of sentinel events. The accreditation agency publishes a regular newsletter *Sentinel Event Alerts,* to raise awareness, which identifies specific events, describes their common causes and suggests steps for prevention.

Internally, organizationbs need a system of reporting incidents in a timely and confidential manner. ACHA requires that the incident report must be received by the Risk Management Department within 3 business days of the incident occurring. An incident can be defined as any occurrence, accident or event that is not anticipated and has the potential to result, or has cause injury, or that is not consistent wit the expected operation of the hospital.

Sentinel Event

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. (JCAHO Sentinel Event Policy and Procedure)

Incident reports can be generic, patient/visitor/employee related, unit specific or medication specific. Reporting of all incidents includes near misses or things that may be viewed as contributing to a mistake occurring. Incident reporting identifies trends, problem areas and provides the necessary information to establish effective system processes to promote hospital safety and improve staff development. Generally, patient and visitor incidents are reported to the risk management department and employee incident/injuries are reported to the employee health office. An established line of communication, through the manager of leader of your department assists in the performance improvement process.

Organizational leaders need to remain focused on improving systems through reporting and analysis of systems – not blaming individuals. The IOM report made several recommendations regarding reporting of medical errors. The goal of reporting systems is to analyze the information gathered and identify ways to prevent future errors from occurring.

Barriers to reporting

- **Lack of time**
- **Fear of punishment**
- **Unclear reporting protocols**
- **Poor record of improvement**
- **Forgetting to complete from**

Disclosure

ASHRM (American Society for Healthcare Risk Management) defines disclosure as communication of information regarding the results of of a diagnostic test, medical treatment or surgical intervention.

An *unanticipated outcome* is defined as a result that differs significantly from what was anticipated to be the result of a treatment or procedure.

From the American Medical Association (AMA) to the National Patient Safety Foundation (NPSF), statements of principle in ethics and the disclosure of medical errors/injury to patients and their family have come to the forefront. All agree, that patients/families of their representative are entitle to a prompt, truthful and compassionate explanation of how the injury occurred, the remedies provided and its short- and long term effects. The AMA ethically obligates physicians to openly and

honestly inform patients. Ultimately, what will influence the patient's reaction is their report with the physician and ongoing communication with the health care team.

Risk managers must encourage and develop institutional polices and/or position statements on disclosure of anticipated outcomes. Organizations must also determine who will be responsible for informing the patient/family and/or legal representative about unanticipated outcomes. Educating caregivers and staff about your organization's policiers covering this issue and communications training for those responsible for disclosure discussions should be considered. Review your organization's policy on how disclosure is managed. Lastly, specific documentation requirements and staff education regarding these policies need to be addressed.

Communication from the initial consent to treat to disclosure of an unanticipated outcome is an integral part of the patient safety program for a healthcare organization. Communication is key, the physician as the health care team should maintain open communication with the patient and family.

IX Patient/Family Education

By confidently including our patients and their families as members of the health care team we can improve both safety and outcomes. Through open, ongoing communication and education we can include the patient to the degree they are comfortable in health care decisions. Teaching patients/family members to observe, question and assist in the proper manner can contribute to the patient's care in a safe, effective way.

Adults learn in a variety of ways- by seeing, hearing, touching and doing. Remember to incorporate as many teaching techniques as possible to ensure the maximum amount learned and retained. Provide brochures and other written materials when ever possible. Allow time for reflection and follow-up with time for questions and review.

Key aspects of education should include:

- Active involvement of the patient and family
- Inform patient o provide all information to include prescribed medications, OTC medications, herbals or alternative therapies being used.
- Inform patient to provide information about allergies and adverse reactions
- Inform patients to ask questions – of caregivers, in the hospital, in the physician's office, and the pharmacy to be sure they understand prescriptions.
- Inform patients to ask questions about treatment plan to be sure they understand what will be done.
- Provide patients with written information.
- Teach patients about their condition and assist them to be knowledgeable about their helath, history, medications etc.
- Teach patients to follow instructions on medications or other treatments to obtain the desired outcome.

X Conclusion

Patient safety encompasses those actions undertaken by individuals and organizations to protect health care recipients from being harmed by the side effects of health care services. Traditionally, health care has designed well-structured systems, developed explicit processes, established professional standards of practice and conducted individual competence reviews. All of these approaches are essential to ensure a safe environment and safe practices. Most errors are a result of system and process.

Incompetent people are, at most, 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it's the processes that set them up to make mistakes.

Dr. Lucien Leape, Harvard School of Public Health

Patient safety is freedom from accidental injury. Safety systems in health care organizations seek to prevent harm to patients and deliver quality and effective care of services. The strategic objective is to design processes so that simple mistakes don't end up harming patients. We can accomplish this by eliminating opportunities for error and building better safeguards to catch and correct errors before they reach the patient. We must recognize practical solutions that reduce medical errors and improve patient safety. Error-reduction practices must be tested, implemented and proven to reduce risk. They must be scientifically/researched based, practical to implement and administer, transferable across the organization, creative and innovative.

Designing safe systems in healthcare must include the following principles:

- Leadership
- Changing organizational culture to prevent and analyze systems
- Respect for human limits in process design
- Effective multidisciplinary teams
- A preventive/proactive approach to error reduction
- Creation of a learning environment

Systems must empower staff to question and challenge situations by moving beyond blame. The ultimate goal is protecting our patients. Each of us can improve safety by watching – really looking at situations and potentials for errors; listening - to patients/families/coworkers; asking – there are no stupid questions, but there are preventable mistakes; acting – point out your observation and finally, reporting – develop a proactive not just a reactive approach. Continuous reporting of not only errors but of near misses will enable organizations to conduct both failure mode as ell as root cause analysis to change systems. Together we can reduce medical errors and improve patient safety.

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