

Promoting a Culture of Patient Safety



A Self-Study Module

Developed by



Baptist Health South Florida

Reviewed & Revised November 2012

Patient Safety Partnership

Geri Schimmel, RN, MS, LHRM

Director

This Professional Education Training Program is designed to meet the State of Florida continuing education requirements for Preventing Medical Errors including patient safety, root-cause analysis, error reduction and prevention, and patient safety. Contact hours: Approved for 2.0 contact hours. Florida Board of Nursing, Provider # 2321 and Respiratory Care Provider # RCE 58

Table of Contents

I. Introduction.....	1
BHSF Guiding Principles for Patient Safety.....	2
Purpose & Objectives	3
II. Safety concerns and magnitude of the problem.....	3
III. People factors and process factors	4
IV. Culture change.....	5
V. Tools for prevention and analysis.....	9
VI. Creating change and improving safety.....	12
VII. Special topics.....	14
Medication safety	14
Procedure/surgery safety	17
Falls prevention.....	21
VIII. Patient rights and protection	22
Role of risk management	22
Reporting.....	23
Disclosure	24
IX. Patient/Family Education	25
X. Conclusion	25
Glossary	28
References	31
Appendix A Summary of Major Initiatives Related to Patient Safety ..	34
Appendix B Reportable Events	42
Appendix C Root Cause Analysis Framework.....	44
Appendix D FMEA Example	47
Post Test.....	48

I. Introduction (2012 Update)

Patient safety has been the focus of attention nationally since 1999 with the release of the IOM report "To Err is Human". At Baptist Health South Florida (BHSF), we have always held the safety of our patients at the forefront. This self study, originally written in 2000, to meet the Florida licensing requirement for CEU's, contains information on prevention of medical errors and harm from the national perspective. This introduction serves as a brief overview of the philosophy, programs and processes that BHSF has put in place to address patient safety.

Nationally, progress has been made but if there is one error that harms a patient, then there is still work to be done. The National Patient Safety Foundation (www.npsf.org) continues to lead the way as well as other organizations.

Locally, Baptist Health South Florida (BHSF) continues its long standing history of a commitment to quality, patient safety and our community. In 2010, in an effort to raise the bar still higher, BHSF became certified as a component Patient Safety Organization (PSO) by the Agency for Healthcare Research and Quality (AHRQ), on behalf of the Secretary of the U.S. Department of Health and Human Services. The official name for the PSO is Baptist Health Patient Safety Partnership (PSP). Our goal was to build on our patient safety efforts at each entity, learn and share that learning system wide, developing best practices within our organization and then participating in the national effort and reporting to improve healthcare and reduce medical errors to zero. The PSP's mission and primary activity is to conduct activities that are to improve patient safety and the quality of health care delivery. The BHSF PSP offers its consultative expertise to each entity regarding patient safety events and quality improvement initiatives.

Through the Quality and Patient Safety Steering Council(QPSSC) the Accelerated Change Teams (ACT) continue to harmonize and standardize patient safety across all Baptist Health entities. Currently, ACT's are focusing on the Medication Safety process and error reduction with an opioid subgroup; the Discharge process, patient education and the reduction of readmissions; Anticoagulation therapy and Handoffs and Transitions of Care. This QPSSC reports directly to the BHSF Board Committee on Quality and Patient Safety.

To date, BHSF has trained over 5000 patient safety champions who represent departments from all aspects across the healthcare system. (Refer to the course catalog for Patient Safety champion training sessions).

While Baptist Health has always been patient/family focused, we are working diligently with our Patient & Family Advisor Group to truly be patient- and family-centered in our approach to the design, planning, implementation and evaluation of care. Patients receive a patient safety guide and can watch a video, on the in house TV station, created by our advisors, to help teach them how to better partner in their care.

We will continue to strive to provide the best possible patient- and family-centered care for our community, ensuring patient safety. If you would like information about any of the programs mentioned please contact the Patient Safety Partnership at 786-596-2794.

BHSF Guiding Principles for Patient Safety (Adopted 2004)

- ***Safety First*** – Our first obligation is to protect the patients who have entrusted their lives to our care. Safety is the foundation of quality.
- ***Teamwork*** – Together, we can create a barrier to errors and system failures. Every person's voice needs to be heard if they become aware of a potential safety risk, regardless of their role in the organization. (This includes patients, families, employees and physicians.) Remember, you may be the only one who sees a risk.
- ***Standardization*** – Standardizing patient safety practices at our various facilities is a benefit to the communities we serve. When we accomplish this, physicians and clinical staff don't have to remember a different way of doing things when they work at different locations. Consistency reduces the risk of error.
- ***Fail Safe Approaches*** – We know that to err is human. We strive to incorporate double checks, redundant systems and error prevention practices and technology into our procedures.
- ***National Patient Safety Goals*** – Certain patient safety best practices have been identified which, if implemented effectively, will prevent errors and injury to patients. We have adopted these best practices and rely upon our entire staff to implement them faithfully.
- ***Reporting Errors, Equipment or System Failures*** – Reporting is expected whether a patient is harmed or not. We recognize that errors usually occur due to breakdowns in systems and processes. In order to learn from each error and prevent another event, employees are required to submit incident reports. They may submit incident reports without fear of disciplinary action for making errors, except for intentionally unsafe behavior. (See Baptist Health Patient Safety Policy 250.01 for details.)
- ***Patient Safety is Everyone's Job*** – From CEO to volunteer, ensuring safe care for our patients is part of everyone's responsibilities.

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 systems, which promote patient safety, as well as ways to analyze data, will be reviewed. Current industry changes including the Joint Commission (TJC) patient safety goals and 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. Patient and family participation in care will be highlighted as a key component of safety.

Objectives

- ❑ Describe the magnitude of medical errors and the effect on patient safety.
- ❑ Identify processes to approach error reduction and prevention.
- ❑ Recognize error prone situations/processes
- ❑ Identify factors that impact the occurrence of errors.
- ❑ Define the process and benefit 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

Experts estimate that in any given year, more people die from medical errors than from motor vehicle accidents, 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 in providing 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.

How did the focus on quality and patient safety come to the attention of the nation? In 1998 the Institute of Medicine (IOM), working under The National Academy of Sciences, initiated several reports for the Quality of Healthcare in America Project. The IOM was established in 1970 to act as an advisor 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 admission to hospitals in 1997, between 44,000 – 98,000 deaths resulted from adverse events, making it the 8th leading cause of death ahead of car 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 health care costs. If we were to compare the error rate to the worldwide air traffic controllers it would be the equivalent of two 747’s crashing each week.

Definitions by IOM

Adverse Event: Injury caused by medical management rather than underlying disease / condition of patient.

Error: 1) Planning – Use of a wrong plan to achieve the desired aim.
2) 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 alliances 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 an old solution or 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 labels 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 hours a day. But 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 Mode 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 patient 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 a 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 technology 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 coupled 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.

- Hierarchical 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.”

Lucien L. Leape, M.D., Harvard School of Public Health

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 **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. These 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 together in explaining how errors occur 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.

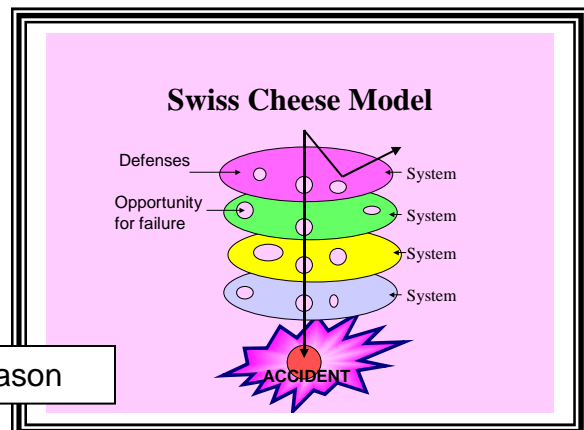
Adapted from Reason

Why people make mistakes:

- Fatigue
- Inattention / Distraction
- Unfamiliar situations / new problems
- Using past solutions
- Equipment design flaws
- Illegible printing
- Communications errors
- Mislabeling / instructions

Why processes / systems fail:

- Variable input (ex: patient personalities)
- Inconsistency
- Complexity
- Too many / complicated steps
- Human intervention
- Tight time constraints
- Hierarchical culture



There are many types of defenses that organizations have to deflect failures and keep 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 care 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.

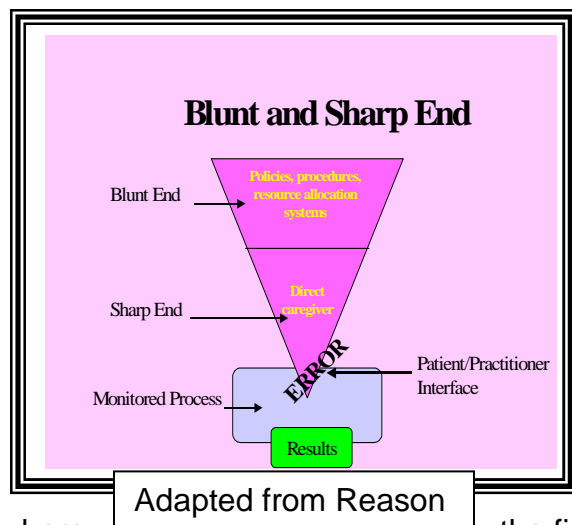
Blunt and Sharp End

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

For example, if a medication error occurs it may be easy to blame the single nurse. What is not readily apparent are factors that may have contributed to the error such as the medication delivery being late; or delivered to the wrong unit; or a policy that required purchase of medications that were cheaper but look alike. These other “blunt ends” contribute to potential errors but are only noticed when made at the “sharp end”.

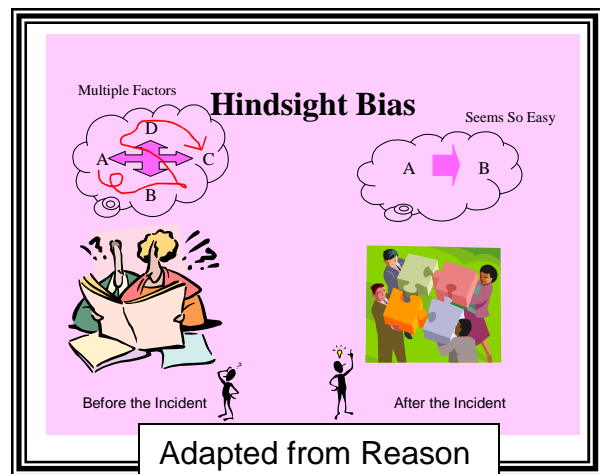
Hindsight Bias

Hindsight bias is the phenomenon where it seems obvious how an error happened after the fact. However, before the error occurred, it wasn’t obvious that the



Adapted from Reason

blunt and work are with see the final error



Adapted from Reason

process or system was error prone. Because health care professionals do not readily identify a problem with 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 an 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, 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 an 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 diagnostic 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 go 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 of the failure **X** severity of the failure **X** detectability if the failure occurs). (See Appendix F for example with numbers)
- ❖ 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 serious. 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 (Pharmacy & Therapeutics) Committee; review of vendor products and labels; storage/dispensing practices; and alerts to those who administer medications. Then the organization must test the design, 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:

1. Define the problem / gather the facts
2. Assemble an interdisciplinary team.
3. Determine the sequence of events
4. Identify contributing factors
5. Select root causes

6. Develop corrective action & follow-up plan.

Through continued reporting of incidents or near misses 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 record arriving 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 past 24 hours with 4 emergency procedures
- *The assistant in the OR is a new employee.

It is possible that all of 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 result of weaknesses in a system.

Study / Examination vs. Investigation

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

Accountable vs. Blame

Health care professionals are accountable for their knowledge, competence and work. Blame is used to find and excuse for failure not 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 blame.

VI. Creating Change and Improving Safety

The goal of a patient safety program is to create a nonpunitive / 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 or 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 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 noninterchangeable connections to “force” the right route to be used).
- Eliminate look alike and sound alike
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 to errors and modify or correct them.

Frontline health care workers, those having direct patient contact, are the last line of defense between the patient and an 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 are 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 using “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 in 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 errors.

VII. Special Topics

Medication Safety

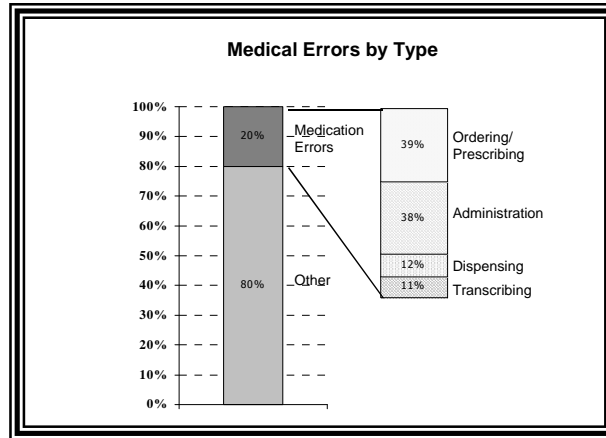
The IOM study estimates that as many as 7,000 patients die each year as a result of medication errors, with an estimated additional hospital cost of \$4,700 for each preventable medication error. These figures don't take into account the intangible costs - the physical and emotional effects, of medication 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 Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) has a more comprehensive definition:

"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care 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 errors. This provides a procedure 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 in providing guidance, direction and priorities for initiatives related to patient safety, focusing on medical errors. They have developed four practice model guidelines in medication safety. These guidelines be used to assist healthcare organizations develop their own processes to ensure safe medication administration. (www.fha.org/quality.html)



role
can

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 medication 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:

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

- Development of special procedures or protocols for the use of “high risk” medications such as heparin, insulin, chemotherapy, concentrated electrolyte solutions etc., can help to 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 the 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. 0.2 mg. *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.



Phase 2: Dispensing

The pharmacy staff also needs access to key information about the patient prior to the 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 have minimal distractions and interruptions, appropriate lighting, air conditioning/air flow, safe noise levels, and should include ergonomic consideration of equipment, fixtures, and technology.

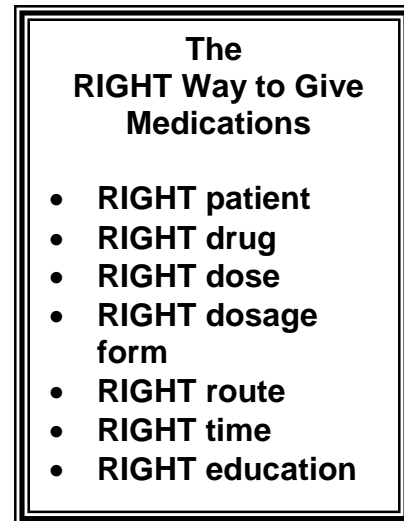
Use of technologies designed to ensure consistency and ease of administration should be considered such as prefilled syringes, premixed IV solutions, etc. Ensure that prefilled syringes have appropriate route noted and, if possible, use non-interchangeable connections to prevent the inadvertent administration by another route. Consider using automated dispensing devices such as Pyxis®, 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 texts and/or online resources should be readily available to nurses. It is also important that essential patient information is double-checked prior to giving the medication. Orders that are incomplete, illegible or otherwise questionable should be clarified using an 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 have been fully labeled with medication name, dose to be administered, dosage form, route, special storage requirements, 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.

Phase 4: Monitoring

Development of nonpunitive processes for reporting medication errors, 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 the 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 or 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 Joint Commission Board of Commissioners originally approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery in July 2003, and it became effective July 1, 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol was created to address the continuing occurrence of wrong site, wrong procedure and wrong person surgery and other procedures in Joint Commission accredited organizations. The Universal Protocol drew upon, and expanded and integrated, a series of requirements under The Joint Commission's 2003 and 2004 National Patient Safety Goals. The three principal components of the Universal Protocol include a preprocedure verification, site marking, and a time out.

The surgeon plays an important role in identifying the correct site for surgery. It begins with the 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.



Consider the use of a **body diagram** in documentation, clearly marking the

Remember, an informed patient is a safe patient. Next is marking the site for the surgery. Clearly mark either the correct side 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 or 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 anesthetist/anesthesiologist, 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 procedures.

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 support

- 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

Assistive devices

Potential for falls, improper use



Radiology/Nuclear Medicine

Monitoring during procedures

- Falls
- Inadequate shielding
- Allergies/reactions (contrast media)
- Wrong side 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



TABLE 1
OTHER HIGH RISK AREAS WITH POTENTIAL FOR MEDICAL ERRORS

Lab

Venipuncture

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

Lab specimens

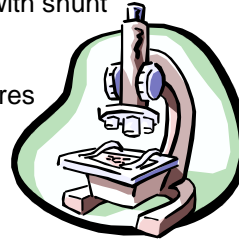
- Mislabeled specimens
- Contamination of specimen such as cultures
- Improper preparation of specimen

Performing tests

- Equipment calibration/control problems
- Interpretation of results

Results reporting

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



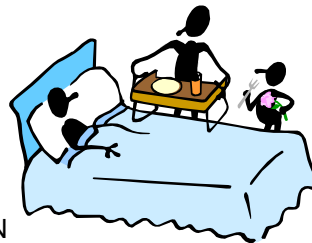
Dietary

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

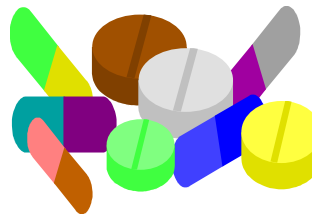
Vital sign monitoring



Pharmacy

Storing medications

Dispensing medications



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 accidents. Falls 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 caused by environmental factors (clutter, wet floors, rugs), physiological factors (vertigo, CNS impairment, muscular weakness, broken bones) or 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 eight 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 patients reach and always ensuring the call bell is within reach. Patient/ family education should include information on safety concerns and risks, how to fall safely, wearing nonskid footwear and rising slowly. Answering patient call lights immediately to encourage asking for assistance and checking high-risk patients 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 maybe considered a form of restraint.

Siderails

Thought for decades to be standard devices used to protect patients, siderails 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 of 2000, the FDA brochures, "A Guide to Bed Safety: Bed Rails in Hospitals" and "Nursing Homes and Home Health Care: The Facts," became available. (1)

Alternatives to siderails

That pose less serious physical & psychological threat:

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

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

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 as well as near misses or potential 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 commitment.

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.

IOM Report

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 potential 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 of both internal and external reporting. As defined by 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 (AHCA) 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 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 organizations 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, organizations need a system of reporting incidents in a timely and confidential manner. AHCA requires that the incident report must be received in the Risk Management Department within three (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 in injury, or has caused injury, or that is not consistent with the expected operation of the hospital.

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 incidents/injuries are reported to the employee health office. An

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)

Barriers to reporting

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



established line of communication, through the manager or 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.

Disclosure

ASHRM (American Society for Healthcare Risk Management) defines disclosure as communication of information regarding the results 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 families have come to the forefront. All agree, that patients/families or their representative are entitled 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 rapport with the physician and ongoing communication with the health care team.

Risk managers must encourage and develop institutional policies and/or position statements on disclosure of unanticipated 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 policies 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 well 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 insure 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 to 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 patient to ask questions – of caregivers, in the hospital, in physician's office, and at 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 health, 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 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 these mistakes.

Dr. Lucien Leape, Harvard School of Public Health

The most comprehensive approach to patient safety will include consideration of the following:

Structure

- Facilities
- Equipment
- Supplies
- Policies and Procedures

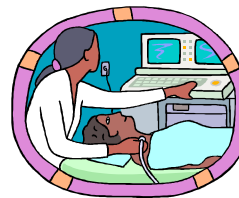
Work Environment

- Communication channels
- Personnel management and policies
- Staffing
- Ergonomics
- Culture of reporting

People

- Attitude and motivation
- Training
- Physical health/alertness/fatigue
- Emotional health

(Spath, 1999)



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 and 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 reactive approach. Continuous reporting of not only errors but of near misses will enable organizations to conduct both failure mode as well as root cause analysis to change systems. Together we can reduce medical errors and improve patient safety.

Thank you for your participation in this program.

Glossary of Terms

Accreditation Watch An attribute of an organization's Joint Commission accreditation status. A health care organization is placed on Accreditation Watch when a reviewable sentinel event has occurred and has come to the Joint Commission's attention, and a thorough and credible root cause analysis of the sentinel event and action plan have not been completed within a specified time frame.

Action Plan The product of the root cause analysis which identifies the strategies that an organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

Adverse Drug Event (adverse drug error) Any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (for example, dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.

Adverse Drug Reaction (ADR) An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.

Adverse Event An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.

Causation The act by which an effect is produced. In epidemiology, the doctrine of causation is used to relate certain factors (predisposing, enabling, precipitating, or reinforcing factors) to disease occurrence. The doctrine of causation is also important in the fields of negligence and criminal law. *Synonym:* causality.

Disclosure Communication of information regarding the results of a diagnostic test, medical treatment or surgical intervention.

Error of Commission An error which occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched for another patient.

Glossary of Terms

Error of Omission An error which occurs as a result of an action not taken, for example, when a delay in performing an indicated cesarean section results in a fetal death, when a nurse omits a dose of a medication that should be administered, or when a patient suicide is associated with a lapse in carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes.

Flow Chart/Diagram A pictorial summary that shows with symbols and words the steps, sequence, and relationship of the various operations involved in the performance of a function or a process.

FMECA (failure mode, effect, and criticality analysis) A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur.

Incident Report The documentation for any unusual problem, incident, or other situation that is likely to lead to undesirable effects or that varies from established policies and procedures or practices.

Malpractice Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position; often applied to physicians, dentists, lawyers, and public officers to denote negligent or unskillful performance of duties when professional skills are obligatory. Malpractice is a cause of action for which damages are allowed.

Negligence Failure to use such care as a reasonably prudent and careful person would use under similar circumstances.

Plan-Do-Study-act (PDSA) cycle A four-part method for discovering and correcting assignable causes to improve the quality of processes. *Synonyms:* Deming cycle; Shewhart cycle.

Process A goal-directed, interrelated series of actions, events, mechanisms, or steps.

Proximate Cause/Factors An act or omission that naturally and directly produces a consequence. It is the superficial or obvious cause for an occurrence. Treating only the "symptoms," or the proximate special cause, may lead to some short-term improvements, but will not prevent the variation from recurring.

Risk Containment Immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices.

Glossary of Terms

Risk Management Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

Root Cause The most fundamental reason for the failure or inefficiency of a process.

Root Cause Analysis A process for identifying the basic or causal factor(s) that underlie variation in performance, including the 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. Such events are called "sentinel" because they signal the need for immediate investigation and response.

Sentinel Event 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 risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

Unanticipated Outcome A result that differs significantly from what was anticipated to be the result of a treatment or procedure.

Variation The differences in results obtained in measuring the same phenomenon more than once. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes. Excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. *Common-cause variation*, also called endogenous cause variation or systemic cause variation, in a process is due to the process itself and is produced by interactions of variables of that process is inherent in all processes, not a disturbance in the process. It can be removed only by making basic changes in the process. *Special-cause variation*, also called exogenous-cause variation or extra-systemic cause variation, in performance results from assignable causes. Special-cause variation is intermittent, unpredictable, and unstable. It is not inherently present in a system; rather, it arises from causes that are not part of the system as designed occurrence or possible occurrence of a sentinel event.

References

Patient Safety

(2004). Near-Miss Analysis. In P. Aspden, J. M. Corrigan, J. Wolcott, & S. M. Erickson, *Patient Safety: Achieving a new standard for care* (pp. 226-247). Washington DC: The National Academies Press.

Facts about Patient Safety. (2012, January 19). Retrieved August 1, 2012, from The Joint Commission:
http://www.jointcommission.org/about_us/patient_safety_fact_sheets.aspx

OxenFLA. (2005, June 13). *Duke Univ. surgical tools contaminated [washed in hydraulic fluid]*. Retrieved August 1, 2012, from Free Republic:
<http://www.freerepublic.com/focus/f-news/1421779/posts>

Patient Safety. (n.d.). Retrieved August 1, 2012, from ACHA Section 395.1012:
http://www.leg.state.fl.us/statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=395.1012&URL=0300-0399/0395/Sections/0395.1012.html

Patient Safety and Quality Improvement Act of 2005 Statute and Rule. (2005, July 29). Retrieved August 2, 2012, from AHRQ:
<http://www.pso.ahrq.gov/statute/pl109-41.pdf>

Patient Safety Rule 42 C.F.R. Part 3. (2008, November 21). Retrieved August 2, 2012, from Federal Register (73 FR 70732):
<http://www.gpo.gov/fdsys/pkg/FR-2008-11-21/pdf/E8-27475.pdf>

Preventing Death and Injury From Medical Errors. (1999, November 29). Retrieved February 6, 2012, from The National Academies:
<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=9728>

Protecting 500 Million Lives from Harm. (n.d.). Retrieved August 1, 2012, from Institute for Healthcare Improvement:
<http://www.ihl.org/offerings/Initiatives/PastStrategicInitiatives/5MillionLivesCampaign/Pages/default.aspx>

The 2012 Florida Statutes. (2012). Retrieved August 3, 2012, from Online Sunshine:
http://www.leg.state.fl.us/statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=395.0197&URL=0300-0399/0395/Sections/0395.0197.htm

Human Factors Engineering. (n.d.). Retrieved August 1, 2012, from AHRQ: Patient Safety Network: <http://psnet.ahrq.gov/primer.aspx?primerID=20>

Root Cause Analysis (local Copy) - NASA. (n.d.). Retrieved August 1, 2012, from Airforce University:
http://www.au.af.mil/au/awc/awcgate/nasa/root_cause_analysis.pdf

Swiss Cheese Model. (n.d.). Retrieved Aug 1, 2012, from Patient Safety - Quality Improvement: Anatomy of an Error:
http://patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html

The Institute Of Medicine (IOM). (2001). *Crossing the Quality Chasm: A New Health Sytem for the 21st Century*. Washington, DC.

The Institute of Medicine (IOM). (1999). *To Err is Human: Building a Safer Health System*. Washington , DC.

The New Look at Error, Safety, and Failure:A Primer for Health Care. (1999, September 16). Retrieved August 1, 2012, from GAPS Center: PEXIS:
<http://csei.eng.ohio state.edu/ productions /pexis /readings/submod1/NewLookPrimer.pdf>

Shreve, J., Van Den Bos, J., Gray, T., Halford, M., Rustagi, K. & Ziemkiewicz, E. (2010). *The Economic Measurement of Medical Errors*. Society of Actuaries: Milliman.

Ward, W. A. (n.d.). *Thinkexist.com*. Retrieved Aug 2, 2012, from William Arthur Ward Quotes: http://thinkexist.com/quotation/if_you_can_imagine_it-you_can_achieve_it-if_you/15190.html

Just Culture

Brad Brugger, Pete Sirucek. (2011, September). *Just Policy - AeroSafety World*. Retrieved August 1, 2012, from The Just Culture Community:
http://www.justculture.org/downloads/aerosafety_world_1.pdf

Clarke, N. (2005.) Workplace learning environment and its relationship with learning outcomes in healthcare organizations. *Human Resource Development International*, 8, (2), 185-205.

Developing a Just Culture. (2012, August 1). Retrieved August 1, 2012, from Health Leaders Media: <http://www.healthleadersmedia.com/page-2/NRS-251182/Developing-a-Just-Culture>

Employee Discipline: Preserving "At-Will" Employment Status & Terminating Employees with Confidence. (2005, October). Retrieved Aug 2, 2012, from PHYL Loss Control Services: <https://www.phly.com/ebrochure/LossControl/Flyer10-05.htm>

Gordon, S. (2012, August 2). *Toxic Hierarchy in Health Care*. Retrieved August 2, 2012, from Nursetogether: <http://www.nursetogether.com/tabid/102/itemid/1800/Toxic-Hierarchy-in-Health-Care.aspx>

Just Culture. (n.d.). Retrieved August 1, 2012, from California Hospital Patient Safety Organization: <http://www.chpso.org/just/index.php>

Just Culture and its critical link to patient safety (Part I). (2012, May 17). Retrieved August 2, 2012, from ISMP Medication Safety Alert: <http://www.ismp.org/newsletters/acutecare/showarticle.asp?id=22>

Marx, D. (2001). *Patient Safety and the "Just Culture"*. New York: Columbia University.

Morris, S. (2011). *Just culture-changing the environment of healthcare delivery*. US: American Society for Clinical Laboratory Science.

Surveys on Patient Safety Culture. (2012, July). Retrieved August 3, 2012, from AHRQ: <http://www.ahrq.gov/qual/patientsafetyculture/>

Wachter, R. M., & Pronovost, P. J. (October 2009). Balancing "no blame" with accountability in patient safety. *New England Journal of medicine*, 1401-1406.

Patient- and Family- Centered Care

Center for Advancing Health (2010). *A new definition of patient engagement: What is engagement and why is it important?* Washington, DC: Author

Gruman, J., Rovner, M.H., French, M.E., Feffress, D., Sofaer, S. Shaller, D. & Prager, D. J. (2010). *From patient education to patient engagement: Implications for the field of patient education*. *Patient Education and Counseling*. 78, 350-356.

Hibbard, J. H. & Mahoney, E. (2010). *Toward a theory of patient and consumer activation*. *Patient Education & Counseling*. 78, 377-81.

Maurer M, Dardess P, Carman, KL, et al. Guide to Patient and Family Engagement: Environmental Scan Report. (Prepared by American Institutes for Research under contract HHS 290-200-600019). AHRQ Publication No. 12-0042-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2012.

Roizen, M. (2006). *YOU the Smart Patient*. New York: Free Press.

Kaneski, T., & Blevins, D. (2007). Implementing a Pediatric Rapid Response Team. *Focus on Patient Safety*, pp. 2-3.

Rapid Response Teams. (n.d.). Retrieved August 3, 2012, from AHRQ:
<http://psnet.ahrq.gov/primer.aspx?primerID=4>

Rob Graham. (2012, April 29). *Boston Children's Hospital*. Retrieved June 1, 2012, from Newsroom:
<http://childrenshospital.org/newsroom/Site1339/mainpageS1339P878.html>

Spath, P. (2004). *Partnering with Patients to Reduce Medical Errors*. Chicago: AHA Press.

What is patient and family centered care? (2011, December 14). Retrieved July 31, 2012, from Institute for patient-andfamily-centered care:
<http://www.ipfcc.org/about/index.html>

Patient Safety Organization

Frequently asked questions. (2009). Retrieved August 2, 2012, from Patient Safety Organization of Florida: <http://www.psoflorida.org/faq.html>

Patient Safety Organizations. (n.d.). Retrieved Aug 2, 2012, from AHRQ:
<http://www.pso.ahrq.gov/psos/fastfacts.htm>

PSO Monthly Brief. (2010, November). Retrieved June 1, 2012, from ECRI Institute:
https://www.ecri.org/EmailResources/PSO_Monthly_Brief/PSO_Brief_Nov10.pdf

Handoff communication

Hardwired Results. (2005, Spring). Retrieved June 28, 2012, from Studer Group:
http://www.studergroup.com/newsletter/Vol1_Issue3/vol1_i3_sec7.htm

Nurse.com News. (2012, May 28). Retrieved June 1, 2012, from Effective communication means better patient safety:
<http://news.nurse.com/apps/pbcs.dll/article?AID=/20120528/NATIONAL02/105280025&t>

Pocket Guide:TeamSTEPPS. (2008, March). Retrieved June 1, 2012, from Agency for Healthcare Research and Quality:
<http://www.ahrq.gov/teamstepstools/instructor/essentials/pocketguide.pdf>

Robert Wood Johnson Foundation (n.d.). *Transforming Care at the Bedside toolkit*. Retrieved from
<http://www.rwjf.org/qualityequality/product.jsp?id=30057>

National Patient Safety Goals

Facts about the Universal Protocol. (2012, January 9). Retrieved November 30, 2012, from The Joint Commission:
http://www.jointcommission.org/facts_about_the_universal_protocol/

Morbidity and Mortality Weekly Report: Guideline for Hand Hygiene in Health-Care Settings. (2002, October 25). Retrieved August 6, 2012, from CDC (Centers for Disease control and Infection):
<http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

National Patient Safety Goals (NPSGs). (2003, January 1). Retrieved August 1, 2012, from The Joint Commission:
http://www.jointcommission.org/standards_information/npsgs.aspx

Institute of Medicine (IOM). (2006). *Preventing Medication Errors*. Washington DC: The National Academies Press.

Sentinel Event Alert: High-Alert Medications and Patient Safety. (1999, November 19). Retrieved August 6, 2012, from The Joint Commission:
http://www.jointcommission.org/assets/1/18/SEA_11.pdf

Sentinel Event Alert: Medication errors related to potentially dangerous abbreviations. (2001, September 1). Retrieved August 6, 2012, from The Joint Commission:
http://www.jointcommission.org/assets/1/18/SEA_23.pdf

The Cancer Cure Foundation. (n.d.). Retrieved February 6, 2012, from Medical Errors - A Leading Cause of Death:
http://www.cancure.org/medical_errors.htm

Performance Improvement

Facts about the Tracer Methodology. (2010, September 1). Retrieved August 2012, 2012, from The Joint Commission:
http://www.jointcommission.org/facts_about_the_tracer_methodology/

Jimmerson, C. (2010). *Value Stream Mapping for Healthcare Made Easy*. New York: Taylor & Francis Group.

Model for Improvement. (2011). Retrieved August 3, 2012, from NICHQ:
http://www.nichq.org/how_we_work/model_for_improvement.html

Nolan, K. (1999). ASQ's Accelerating Change Collaborative Series: A Challenge for industry. *Quality Progress* , 55-59.

Kowalczyk, L. (2007, November 19). *Tele-treatment: Monitoring from afar, 'eICUs' fill medical gap*. Retrieved August 3, 2012, from Boston.com:
http://www.boston.com/business/globe/articles/2007/11/19/tele_treatment/?page=full

Tran, T. H., Schimmel, G., & Sullivan, E. (2008). Trim-Lean on the front line. *Building Quality in Health Care* , 16-18.

Using Simulation To Improve Safety, Quality And Education in Healthcare. (2009). Retrieved August 3, 2012, from The Center for Medical Simulation:
<http://www.harvardmedsim.org/>

Summary of Major Initiatives Related to Patient Safety

The recommendations contained in the IOM report lay out a four-tiered approach:

- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- Identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

RECOMMENDATION 4.1 Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality. This center should

- Set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
- Develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

RECOMMENDATION 5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should

- Designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to

be used by states, including a nomenclature and taxonomy for reporting;

- Require all health care organizations to report standardized information on a defined list of adverse events;
- Provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and designate the Center for Patient Safety to:
 - Convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and
 - Receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

RECOMMENDATION 5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:

- Describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
- Convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
- Periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
- Fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

RECOMMENDATION 6.1 Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

RECOMMENDATION 7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety.

- Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.
- Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

RECOMMENDATION 7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.

Health professional licensing bodies should:

- (1) Implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
- (2) Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should

- (1) Develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
- (2) Disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
- (3) Recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;

- (4) Work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and
- (5) Collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

RECOMMENDATION 7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:

- Develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
- Require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
- Work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.

RECOMMENDATION 8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should:

- Provide strong, clear and visible attention to safety;
- Implement non-punitive systems for reporting and analyzing errors within their organizations;
- Incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and
- establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.

RECOMMENDATION 8.2 Health care organizations should implement proven medication safety practices.

Presidential / Congressional Involvement

In 1997 the President established the Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. This commission created the Quality of Healthcare in America Project. The output of this project was the IOM reports *To Err is Human* & *2001 Crossing the Quality Chasm*. Congress requested that the IOM draft strategies for national reporting, and as a result the IOM is producing 2001 *Envisioning the National Health Care Quality Report*.

Important Elements of the Executive Summary of Crossing the Quality Chasm

The second report on America's health care system written by the Institute of Medicine as commissioned by the Committee on the Quality of Health Care in America.

The committee proposes six aims for improvement to address key dimensions in which today's health care system functions at far lower levels than it can and should. Health care should be:

- *Safe* – avoiding injuries to patients from the care that is intended to help them.
- *Effective* – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoid underuse and overuse, respectively).
- *Patient-centered* – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely* – reducing waits and sometimes harmful delays for both those who receive and those who give care.
- *Efficient* – avoiding waste, including waste of equipment, supplies, ideas, and energy.
- *Equitable* – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

Recommendation 1: All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States.

Recommendation 2: All health care organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable.

Recommendation 3: Congress should continue to authorize and appropriate funds for, and the Department of Health and Human Services should move forward expeditiously with the establishment of, monitoring and tracking processes for use in evaluating the progress of the health system in pursuit of the above-cited aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The Secretary of the Department of Health and Human Services should report annually to Congress and the President on the quality of care provided to the American People.

Recommendation 4: Private and public purchasers, health care organizations, clinicians, and patients should work together to redesign health care processes in accordance with the following rules:

- *Care based on continuous healing relationships.* Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This rule implies that the health care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits.
- *Customization based on patient needs and values.* The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.
- *The patient as the source of control.* Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision making.
- *Shared knowledge and the free flow of information.* Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
- *Evidence-based decision making.* Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician or from place to place.

- *Safety as a system property.* Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.
- *The need for transparency.* The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.
- *Anticipation of needs.* The health system should anticipate patient needs, rather than simply reacting to events.
- *Continuous decrease in waste.* The health system should not waste resources or patient time.
- *Cooperation among clinicians.* Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Recommendation 5: The Agency for Healthcare Research and Quality should identify not fewer than 15 priority conditions, taking into account frequency of occurrence, health burden and resource use. In collaboration with the National Quality Forum, the agency should convene stakeholders, including purchasers, consumers, health care organizations, professional groups, and others, to develop strategies, goals, and action plans for achieving substantial improvements in quality in the next 5 years for each of the priority conditions.

Recommendation 6: Congress should establish a Health Care Quality Innovation Fund to support projects targeted at (1) achieving the six aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity; and/or (2) producing substantial improvements in quality for the priority conditions. The fund's resources should be invested in projects that will produce a public-domain portfolio of programs, tools, and technologies of widespread applicability.

Recommendation 7: The Agency for Healthcare Research and Quality and private foundations should convene a series of workshops involving representatives from health care and other industries and the research community to identify, adapt, and implement state-of-the-art approaches to addressing the following challenges:

- Redesign of care processes based on best practices

- Use of information technologies to improve access to clinical information and support clinical decision making
- Knowledge and skills management
- Development of effective teams
- Coordination of care across patient conditions, services, and settings over time
- Incorporation of performance and outcome measurements for improvement and accountability

Recommendation 8: The Secretary of the Department of Health and Human Services should be given the responsibility and necessary resources to establish and maintain a comprehensive program aimed at making scientific evidence more useful and accessible to clinicians and patients. In developing this program, the Secretary should work with federal agencies and in collaboration with professional and health care associations, the academic and research communities, and the National Quality Forum and other organizations involved in quality measurement and accountability.

Recommendation 9: Congress, the executive branch, leaders of health care organizations, public and private purchasers, and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.

Recommendation 10: Private and public purchasers should examine their current payment methods to remove barriers that currently impede quality improvement and to build in stronger incentives for quality enhancement.

Recommendation 11: The Health Care Financing Administration and the Agency for Healthcare Research and Quality, with input from private payers, health care organizations, and clinicians, should develop a research agenda to identify, pilot test, and evaluate various options for better aligning current payment methods with quality improvement goals.

Recommendation 12: A multidisciplinary summit of leaders within the health professions should be held to discuss and develop strategies for (1)

restructuring clinical education to be consistent with the principles of the 21st-century health system throughout the continuum of undergraduate, graduate, and continuing education for medical, nursing, and other professional training programs; and (2) assessing the implications of these changes for provider credentialing programs, funding, and sponsorship of education programs for health professionals.

Recommendation 13: The Agency for Healthcare Research and Quality should fund research to evaluate how the current regulatory and legal systems (1) facilitate or inhibit the changes needed for the 21st-century health care delivery system, and (2) can be modified to support health care professionals and organizations that seek to accomplish the six aims set forth in Chapter 2.

(Full text of the report is available at www.nationalacademies.org.)

Joint Commission on Accreditation of Healthcare Organizations

Established in 1951, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is an international accreditation agency whose accreditation reflects an adherence to guidelines and standards. Because accreditation is by its nature a risk-reduction activity, the Joint commission has played a vital role in promoting patient safety and quality health care for the American public. In 2000, the JCAHO made explicit its formal commitment to patient safety by revising its mission “to continuously improve the safety and quality of care provided to the public.” Additionally, patient safety standards became effective July 2001 (www.jcaho.org).

Reportable Events

Agency for Health Care Administration Code 15

- Death of the patient;
- Brain or spinal damage;
- Performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- Surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process;
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Agency for Health Care Administration

Annual Reportable Events

- Permanent disfigurement;
- Fracture or dislocation of bones or joints; or
- Any condition requiring definitive or specialized medical attention which is not consistent with the routine management of the patient's case or patient's pre-existing physical condition; or
- Any condition requiring surgical intervention to correct or control; or
- Any condition resulting in transfer of the patient within or outside the facility, to a unit providing a higher level of care; or
- Any condition that extends the length of stay; or

- Any condition that results in the limitation of neurological, physical, or sensory function which continues after discharge from the facility.

Joint Commission Reportable Sentinel Events

Event results in the

- Unanticipated death of the patient, not related to the natural course of illness or underlying condition;
- Major, permanent loss of function, including sensory, motor, psychological or intellectual impairment;
- Patient Suicide;
- Infant abduction or discharged to the wrong family;
- Rape of a patient, not to include allegations of rape;
- Hemolytic transfusion reaction resulting in death or loss of function;
- Surgery performed on the wrong patient or body part

A Framework for a Root Cause Analysis and Action Plan

This three page template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities should be fully considered in our quest for “root causes” and risk reduction.

As an aid to avoiding “loose ends,” the three columns on the right are provided to be checked off for later reference:

“Root Cause?” should be answered “yes” or “no” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.

“Ask ‘Why?’” should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn’t occur when it should have)—in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not identified as root causes will have checkmarks in this column. Also, items that are identified as root causes will often be checked in this column, since many root causes themselves have “roots.”

“Take action?” should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the “Take action?” column for each of the Findings that requires an action.

**A Framework for a Root Cause Analysis and Action Plan
In Response to a Sentinel Event**

<u>Level Of Analysis</u>		<u>Questions</u>	<u>Findings</u>	Root	Ask	Take Action?
What Happened?	Sentinel Event	What are the details of the event? (Brief)				
↓		When did the event occur?				
		What area/service was impacted?				
Why did it happen?	The process or activity in which the event	What are the steps in the process, as designed? (a flow diagram may				
		What steps were involved in (contributed to) the				
What were the most proximate factors? (typically "special cause" variations)	Human Factors	What human factors were relevant to the outcome?				
	Equipment Factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors	What factors directly affected the outcome?				
	Uncontrollable environmental factors	Are they truly beyond the organizations control?				
	Other	Are there any other factors that have directly influenced this outcome?				
		What other areas or services are impacted?				

**A Framework for a Root Cause Analysis and Action Plan
In Response to a Sentinel Event**

Level Of Analysis	Questions	Findings	Root	Ask	Take Action?
<p>Why did that happen? What systems and processes underlie those proximate factors?</p> <p>(Common cause variation here may lead to special cause variation in dependent processes.)</p>	Human resource issues	To what degree are staff properly qualified and currently competent for their responsibilities?			
		How did actual staffing compare with ideal levels?			
		What are the plans for dealing with contingencies that would tend to reduce effective staffing?			
		To what degree is staff performance in the operant process(es) addressed?			
Information management issues		How can orientation & inservice training be improved?			
		To what degree is all necessary information available when needed? accurate? complete? unambiguous?			
Environmental management issues		To what degree is communication among participants adequate?			
		To what degree was the physical environment appropriate for the processes being carried out?			
		What systems are in place to identify environmental risks?			
Leadership issues: corporate culture		What emergency and failure mode responses have been planned and tested?			
Encouragement of communication		To what degree is the culture conducive to risk identification and potential risk factors?			
Clear communication of priorities		To what degree is the prevention of adverse outcomes communicated as a high priority? How?			
Uncontrollable factors		What can be done to protect against the effects of these uncontrollable factors?			

Framework for an Action Plan in Response to a Sentinel Event

	<u>Risk reduction Strategies</u>	<u>Measures of Effectiveness</u>
	Action item #1:	Measure:
	Action item #2	Measure:
	Action item #3	Measure:
	Action item #4	Measure:
	Action item #5	Measure:
	Action item #6	Measure:
	Action item #7	Measure:
<p>For each of the findings identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness, OR...</p> <p>If, after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.</p> <p>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</p> <p>Consider whether pilot testing of a planned improvement should be considered.</p> <p>Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.</p> <p>Cite any books or journal articles that were considered in developing this analysis and action plan:</p>		

