

# ADVERSE EVENTS

*"Virtually every course of medical action is associated with some adverse risk to the patient."* <sup>(1)</sup>  
The presence of these adverse risks, combined with the error-prone nature of complex systems, creates an ever present potential for harm.<sup>(2)</sup> The objective of an organization's safety mission is to minimize the risks and errors within its systems and processes by *"..making it easy to do things right and hard to do them wrong."* <sup>(3)</sup> This entails understanding the causes of risks and errors, and how they contribute to preventable adverse events in healthcare, as well as having a good working knowledge of safety principles and strategies to learn from adverse events so as to minimize their recurrence. *"Safety and its associated design principles, are the very marrow of the organization, and rather than treating each error and hazard as a unique, surprising, separate, and sometimes tragic event, people [should] view the entire organization as a system, and the search for improved safety as a lifelong, shared journey."* <sup>(4)</sup>

## KEY ISSUES

### ◆ Definitions

In the Harvard Medical Practice Study, which formed the basis for the Institute of Medicine report *"To Err is Human: Building a Safer Health System"*, an **adverse event** is defined as *"An unintended injury caused by medical management rather than the underlying disease or condition of the patient."* <sup>(5)</sup> One can find many variations of this definition across the healthcare industry, such as: *"Any unexpected injury or potential for injury that occurs during the care of the patient, caused by care processes (rather than the underlying condition) which can and frequently does adversely affect the health of the patient."* <sup>(6)</sup> A **near-miss** or **close call** is defined as *"Any event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention",* <sup>(7)</sup> and is used to describe *"Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious event."* <sup>(8)</sup> Most adverse events and near-misses are the result of errors or hazardous conditions. The definition for **error** is *"An unintended act, either of omission or commission, or an act that does not achieve its intended outcome."* <sup>(8)</sup> A **hazardous condition** is *"Any set of circumstances, exclusive of the disease or condition for which the patient is being treated which significantly increases the likelihood of a serious adverse outcome."* <sup>(8)</sup>

There is a subset of adverse events that are more serious in nature and rise to the level of a **sentinel event**. Such an event is defined by The Joint Commission (TJC) as *"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" refers to any process variation for which a recurrence would carry a significant chance of a serious adverse outcome."* <sup>(9)</sup> Each organization must develop its own definition of a sentinel event, which may specify parameters for *"unexpected"*, *"serious"*, and *"the risk thereof"*, and which

must at a minimum include adverse events that are subject to review by TJC that meet any of the following criteria:

- ◆ The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
- ◆ The event is one of the following, regardless of whether or not the outcome was death or major permanent loss of function: (a) Suicide of a patient in a setting where the patient receives around-the-clock care; (b) Infant abduction or discharge to the wrong family; (c) Rape; (d) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; and (e) Surgery on the wrong patient or wrong body part <sup>(9)</sup>

### ◆ **External Requirements**

#### **Accreditation Standards**

TJC standards speak to the need for organizations to create "...an environment in which patients, their families, and organization staff and leaders can identify and manage actual and potential risks to patient safety." <sup>(8)</sup> Issues related to patient safety are integrated across several standards and can be somewhat prescriptive, as with an organization's response to sentinel events, or less so, as with how an organization structures its safety program. Despite any latitude that is permitted within the standards, the expectation is clear: organizations are to establish whatever mechanisms are needed to actively seek to understand the causes of adverse events and to learn from them in order to systematically design safety into healthcare operations. <sup>(10)</sup> As such, the Joint Commission expects that organizations proactively identify and manage any potential risks to patient safety and that they also respond appropriately to events when they actually occur. Both proactive and reactive mechanisms are to be integrated in such a way as to promote organizational learning, involving all segments of an organization. <sup>(8)</sup>

#### **Regulatory Requirements**

There are regulatory agencies that oversee the safety of products and activities within healthcare. For example, the Food and Drug Administration regulates products such as medicines, medical devices, blood products, vaccines, and radiation emitting electronic devices. The Occupational Safety and Health Administration is concerned with blood borne pathogens and the handling of hazardous materials. Adherence to these and other requirements is intended to minimize the risk of adverse events and enhance the overall safety of the healthcare organization.

### ◆ **Understanding Error Causation**

"Every adverse event has causal factors that could have been avoided." <sup>(11)</sup> Since errors are at the root of most avoidable adverse events, in order to prevent them, one must have an understanding of the underlying causes of error within the healthcare domain. Below is a discussion of the most significant causes.

#### **Human Factors**

"Demanding perfect human performance in a complex system without providing appropriate support is expecting people to work at a level beyond human capability." <sup>(12)</sup> Human factors looks at ways to enhance human performance by examining shortcomings that arise from the interface between humans and other elements in the workplace such as equipment, technology, and the work environment. This approach, used in other high-risk industries, focuses on looking for the causes of these shortcomings in the design of systems that may not be tailored to account for human strengths and weaknesses. <sup>(13)(14)</sup> Historically, systems design has relied far too much on

human vigilance, memory, and calculation abilities; all of which are human functions that are known to deteriorate with fatigue and other distractions.<sup>(15)(16)</sup> Equipment is often designed without taking into account human thought processes, assumptions, and weaknesses; lacking built in mechanisms to counter predictable human errors.<sup>(17)</sup> In fact, most healthcare processes and technologies were not designed with human limitations in mind.<sup>(18)</sup>

*"Human error is the byproduct of the same mental processes used in normal day-to-day thinking."*<sup>(13)</sup> In the course of any given day, the human mind is called upon to perform numerous perceptual functions (detecting, identifying, and recognizing sensory input) and cognitive functions (using rules and strategies, memory, information processing, hypothesis formation, and problem solving) while at the same time being required to perform these tasks with a high level of accuracy and speed. The human mind, in its effort to be efficient at managing this information, seeks the most expedient and familiar modes of functioning. Yet, it is this attempt at efficiency that allows errors to emerge, since the mind may select modes of functioning that are not necessarily the best ones for a specific situation. Human performance can also be compromised by internal (fatigue, illness, boredom) and external (workload, temperature changes, noise) conditions.<sup>(13)(14)</sup> Research shows that when under pressure, people tend to regress to their most familiar ways of responding.<sup>(19)</sup> This is an involuntary human response. However, people can also choose to override their automatic response mechanisms and intentionally deviate from expected norms in situations where they see that an organization's operating procedures are not amenable to their work situations. This is important to keep in mind when looking for causes of errors, in that workplace factors can alter human response both involuntarily and voluntarily.<sup>(14)</sup>

Since the conditions under which people work can directly contribute to human performance and errors, it is far better and easier to work on improving situational factors in the workplace than it is to change human behavior. Likewise, since humans are by nature fallible, a person-centered approach would be ineffective and could do more harm than good.<sup>(14)</sup> Consequently, the guiding principle of human factors theory is: *"We cannot change the human condition, but we can change the conditions under which humans work."*<sup>(20)</sup> The relevance of human factors theory to patient safety translates into three principles that guide system design: (a) Preventing errors by designing systems to compensate for predictable human weaknesses, making it more difficult at every hand off in the system to make mistakes; (b) Making errors visible so that they can be intercepted; (c) Developing strategies to mitigate the effects of errors once they occur.<sup>(13)(14)(21)</sup> Organizations achieving reliable systems design are ones that *"...are preoccupied with the possibility of failure. They expect to make errors and train their workforce to recognize and recover them. They continually rehearse scenarios of failure and strive to imagine novel ones. Instead of isolating failures, they generalize them. Instead of making local repairs, they look for system reforms."*<sup>(20)</sup>

### **Systems Theory – An Organizational Model**

Current understanding of error causation supports the notion that most medical errors do not stem from negligence or incompetence, but from underlying flaws in systems that create an error-prone work environment. Within a systems paradigm, human error is viewed not as a cause but as a consequence or symptom of latent conditions that originate at a level of an organization that is more removed from its front line operations. These latent conditions typically stem from deficiencies in organizational functions such as budgeting, staffing, developing policies and procedures, maintaining equipment, and managing processes, which can create work conditions that exacerbate human fallibility and stress the limits of human performance. In fact, the evolution of latent conditions can originate even further upstream, beyond the sphere of the individual organizations, to include the activities of external entities such as drug/device manufacturers and healthcare payers.<sup>(14)(22)(23)(24)</sup>

Systems theory contends that errors result from the convergence of these latent conditions with unsafe acts that occur at the point of interaction between the patient and the clinician. *"For each unsafe act it's important to ask what local conditions shaped it."* <sup>(14)</sup> Historically, error investigation would begin at the point of interface, scrutinizing those actions that were known to immediately precede an incident, and conclude with the indictment of the person who performed the final task in a long sequence of causal events that led to the error. <sup>(14)</sup> *"All mishaps have both a context in which they occur and a chain of events from which they appear to have arisen."* <sup>(25)</sup> It is suggested that error investigation should first involve asking the question *"What does this tell us about our system?"* and only then *"What does this tell us about this individual?"* <sup>(4)</sup> Since latent conditions can exist concealed within a system for a long period of time, they are not easily recognizable as the true contributory factors. <sup>(14)(16)(25)</sup>

Organizations with an awareness of the risks inherent in their systems, develop defense strategies to guard against the possibility of these risks actually causing errors. Examples of defenses are the development of standardized work processes, installation of alarms and automatic shutdowns in devices, training in methods of teamwork and communication, and building forcing functions into work processes. Defenses lessen the likelihood of error by placing barriers at the point where the risk of error is greatest. Since research shows that most errors are not due to a single cause, one method of proactively identifying and eliminating latent conditions is to construct multiple layers of defense barriers. Adverse events occur when these defenses are breached both by the creation of latent conditions and by human actions. <sup>(14)</sup> The investigation of incidents with complex causes must involve looking at various components of a system, their interrelationships, and any weak links. <sup>(26)</sup> The causal links may be so layered that it requires an iterative approach of asking "why" an error occurred enough times until you arrive at the systemic root causes. <sup>(16)</sup> *"The reality is that most errors are made by good people with good training, skills, and intentions who inadvertently commit errors despite their best efforts because of an unfortunate confluence of individual, workplace, communication, technologic, psychological, and organizational factors."* <sup>(24)</sup>

### **Systems Complexity**

*"While quality health care depends heavily on the building of strong relationships between patients and those who care for them, the systems of care that surround those relationships are becoming increasingly complex and difficult to manage."* <sup>(27)</sup> Most errors are multifactorial in nature and can be directly attributed to the complexity of the healthcare system itself. <sup>(24)(26)</sup> Considered to be the most complex sector of our economy, modern healthcare *"...is characterized by more to know, more to do, more to manage, more to watch, and more people involved than ever before."* <sup>(28)</sup> The delivery of healthcare involves the interaction of numerous members of the healthcare system, each with their own unique roles and specialized skills, and each intercepting the continuum of care at varying points in the delivery process. <sup>(29)</sup> Greater patient acuity and shorter lengths of stay create additional pressures to coordinate care efficiently within a more condensed time frame. These factors, added to changes in healthcare delivery and reduced resources due to economic pressures, can create a need for work-arounds in the interest of time and cost savings. <sup>(23)(30)</sup> Advances in medical science and technology have also increased at a furious pace in recent decades. Clinicians must manage this new information, including new pharmaceuticals and devices, ever changing therapies and disease protocols, and increasing use of technology. <sup>(31)(14)</sup> Changing technology places a new set of cognitive demands on the user by requiring new skills and judgment abilities, and greater human interface with technology shifts the risk points in work processes. <sup>(17)(32)</sup> Overall, complexity raises the level of risk by increasing the interdependency of healthcare activity, thus introducing a greater potential for systems weaknesses at each link. <sup>(28)</sup>

Navigating such a complex network increases the potential for error because of the need for multiple and expedient hand-offs throughout the system.<sup>(23)(28)</sup> It is at the point of the hand-off where the greatest vulnerability exists because of critical systems breakdowns or gaps that can occur between the multiple task sequences that take place along the care continuum. The greater the complexity, the more room there is for error because of the need to have properly functioning systems of communication, coordination, and cooperation.<sup>(33)</sup> Each member of the health care team must have access to timely and pertinent information about patients. Since most communication involves one-to-one exchanges, the effective transfer of information can be impeded.<sup>(34)(35)(36)</sup> Errors are sometimes averted because discontinuities come to be anticipated by those working within the system and informal processes are devised to bridge these gaps by adapting ones work processes. Ironically, it is the complexity of systems that both contributes to and limits the success of adaptations created by individuals, teams, and organizations to guard against known threats.<sup>(28)(32)(35)(37)</sup>

The challenge for organizations is that it is difficult to determine in which way their susceptibility to errors will manifest by increases or changes in systems complexity, because the hazards and work trade-offs are often so well hidden, subtle, and diffuse, that it masks its detectability.<sup>(38)</sup> Even though the exact effect may be unknown, one thing is certain, "*as the number of elements in a system increases, the probability that each element will operate successfully diminishes.*"<sup>(22)</sup> These added elements compound the already complex practice of medicine, which by its nature tends to be uncertain. Clinicians encounter uncertainty around how to manage an increasing knowledge base, the need to often work with unknowns and probabilities because of the limits of scientific knowledge, the complexities of human physiology and disease, the uniqueness of individual patient characteristics, interface with technology, and ones own human limitations.<sup>(39)</sup> The difficulty of medical work is that uncertainty is ever present, but fluid, and thus difficult to harness. Ultimately, the best is done in the face of uncertainty even though the specific outcome of an action cannot be predicted.<sup>(40)</sup>

#### ◆ **Proactive Approaches to Risk and Error**

Effective July 1, 2002, TJC expects that "*...an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.*"<sup>(8)</sup>

#### **Failure Mode and Effects Analysis (FMEA)**

At least annually, Joint Commission accredited organizations are expected to select one high-risk process for proactive risk assessment.<sup>(8)</sup> Though not mandated, FMEA is a common technique for conducting such an analysis. FMEA was developed by the United States Military in the 1940's to determine the effect of system and equipment failure.<sup>(41)</sup> The aerospace industry used FMEA in the 1960's to look at safety issues.<sup>(42)</sup> In the late 1980's, FMEA was adapted by the automotive industry for use as a quality improvement tool.<sup>(41,42)</sup>

The objective of FMEA is to look at all ways a process or product can fail, prioritize where to focus effort, and then measure the outcomes of process or system change. While there are variations in how FMEAs are conducted the following are brief descriptions of the steps to the FMEA process.

Step 1: Select a topic for review. There are many ways to identify which topic to review, however, the topic should be a high-risk or high-vulnerability area to merit the time and resources for review. At UMHHC, topics were brainstormed, and a Risk Priority Number (RPN) was calculated for each topic. To calculate the RPN, each topic was assigned a score for probability of occurrence, risk or severity of effect, and ability to detect prior to occurrence. Probability is

scored on a 0-3 scale where 0 is no probability and 3 is high probability. Risk is scored on a 1-5 scale where 1 is minimal clinical/financial impact and 5 is loss of life/limb/function. Ability to detect is scored on 1-3 where 1 is good and 3 is poor. Each of these scores is multiplied for each topic to calculate the RPN. Hence the RPN scores can range from 0-45, the higher the score, the higher the priority.

Once the topic is identified, the scope and the process must be clearly defined. If the scope is too narrow, FMEA may not be the best process to use. If the scope is very broad, perhaps one aspect of the process could be examined. For example rather than examining the admitting process, only examine the process of admitting patients from the Emergency Department.

Step 2: Assemble the team. A multidisciplinary team, including a content expert, facilitator, and a team leader should be formed. A multidisciplinary team ensures that various viewpoints are considered. The content expert will provide insights into how the process is actually carried out. However, having people who do not know the process may promote critical review of the process. The team leader should be someone who has experience in group dynamics and has the role of ensuring that the team functions effectively. The facilitator acts as a consultant, assisting the team leader with accomplishing necessary tasks and stepping in when necessary to keep the team on target.

Step 3: Graphically describe the process using a flowchart. It is imperative that all process and subprocess steps are identified. To aid in the discussion of the flowchart, consecutively number each process step (1, 2, 3. . .). If there are subprocesses within processes, consecutively letter these steps (1a, 1b. . . 3a)

Step 4: Identify potential failure modes for each step. Brainstorming is a good method for identifying the failure modes. Synergy from the group process generates ideas and aids in the identification of failure modes.

Step 5: Calculate a risk priority number (RPN) for each failure mode. Each failure mode is assigned a numerical rating based on risk severity, a probability of occurrence, and ability to detect. These scores are multiplied to calculate the RPN. Work is then focused on the failure modes with the highest risk based on RPN. This is the same process used by UMHHC in step 1.

Step 6: Take action to eliminate or reduce the failure modes. Using an organized problem-solving process such as root cause analysis, action plans can be identified to eliminate or reduce the failure modes.

Step 7: Implement the new process and measure outcomes. Clearly describe the action plan for each failure mode. Identify the outcome measures and identify the person responsible for completing or ensuring completion of each action. Outcome measures can be outcomes of specific implementation steps such as the provision of chlorhexidine skin prep for CVC insertions or patient outcomes such as a decrease BSI. Once implemented, measure the outcomes to determine success. <sup>(42,43,44)</sup>

Some organizations have divided some of the steps into more than one step, while others have combined some of these steps. For example the Veteran's Affairs National Center for Patient Safety (VA NCPS) has combined steps 4 and 5. <sup>(43)</sup> Where as the American Society of Healthcare Risk Management has broken down step 6 into two specific steps. <sup>(44)</sup> The VA NCPS has much experience with FMEA. For more information on the Veteran's Affairs National Center for Patient Safety and their HFMEA™, visit [www.patientsafety.gov](http://www.patientsafety.gov)

### **Sentinel Event Alerts/National Patient Safety Goals**

*“Most error management efforts are piecemeal rather than planned, reactive rather than proactive, event-driven rather than principle-driven.”* <sup>(14)</sup> In 1996, The Joint Commission implemented the Sentinel Event Policy. This policy is designed to help organizations identify sentinel events and take action to prevent recurrence. <sup>(45)</sup> The current definition of a sentinel event was made in November, 1997 <sup>(45)</sup> and 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, “the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.”<sup>(45)</sup> Any time a sentinel event occurs, the organization is expected to complete a thorough root cause analysis, implement actions to reduce risk and monitor the effectiveness of the actions. The policy furthermore encourages the organization to report the sentinel event to the TJC, so that they can learn more about the underlying causes of sentinel events, share “lessons learned” with other health care organizations, and reduce the risk of future recurrences.<sup>(45)</sup>

Beginning in 1998, TJC has published the “Sentinel Event Alert”. The “Sentinel Event Alert” is a mechanism for the TJC to share the most important “lessons learned” from the reported sentinel events. The information that is published includes information relating to the occurrence and recommendations for prevention of recurrences. It can be used by healthcare organizations as a means of identifying issues for a proactive patient safety program.<sup>(45)</sup> For more information on “Sentinel Event Alert”, visit [www.jcaho.org](http://www.jcaho.org) .

In April, 2002, the TJC formed the Sentinel Event Alert Advisory Group. This group conducts thorough reviews of all Alert recommendations. Based on these reviews, the Sentinel Event Alert Advisory Group offers recommended goals for approval by the TJC’s Board of Commissioners as annual National Patient Safety Goals.<sup>(45)</sup>

The current National Patient Safety Goals can be referenced at <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>

Each year, new recommendations from the Sentinel Event Alert Advisory Group will be added to the pool of potential National Patient Safety Goals. It is anticipated that TJC will limit the goals to six with no more than 12 recommendations.<sup>(45)</sup>

### **Seeking input on matters of patient safety**

Under The Joint Commission’s standards, organizations are to monitor their performance related to processes and outcomes that are critical to accomplishing the goals contained in their corporate missions. Through the monitoring of certain data, organizations can gauge their success in accomplishing these goals, including that of achieving patient safety. To this end, Standard PI.3.1 suggests that organizations consider collecting data that includes *“Patient, family, and staff opinions, needs, perceptions of risks to patients, and suggestions for improving patient safety.”*<sup>(8)</sup> Organizations can employ creative means of obtaining honest and open feedback from staff around patient safety concerns, including discussion during patient safety orientation and educational sessions, conducting institutional patient safety rounds (discussed in the Safety Culture chapter) and other forms of informal walk-arounds. These can also be conducted independently by various departments, including risk management, pharmacy, etc... Culture surveys can reveal staff perceptions around the organizational climate of safety. Staff involvement in root cause analyses of adverse events and in quality improvement projects addressing safety issues are other means of gaining staff feedback. Patient and family input can be obtained through formal patient relations functions provided by organizations, focus groups or through patient satisfaction surveys and comment cards that prompt responses to safety related

questions, such as *"Did you have any concerns about your safety during your hospital stay?"* Other venues for receiving patient/family feedback are discussed further in the section below. All feedback can then be integrated on an institutional level.

### **Patients and families as partners in safety**

Patients and families are considered active partners in the safety mission, playing a vital role in enhancing safety. As a second set of eyes to observe if something goes awry in the care process, they can help identify potential errors. For instance, if given medication that is different in appearance from prior doses, they can alert clinicians to this inconsistency. They can also help mitigate the effects of errors that have occurred by informing clinicians of adverse outcomes so that prompt action can be taken. Research shows that both the incidence of errors and patient non-compliance with treatment plans decrease if patients and families are given pertinent information. Patients who are educated on the purpose of medications and their effects are more likely to take them as recommended and to notify clinicians if adverse side effects emerge. Greater patient and family involvement in the informed consent process also has a positive impact on safety. Those who are well informed about the prognosis and treatment options (including benefits, harms, and side effects) and who are involved in dialogue around the best treatment strategy are less likely to agree to less effective or risky procedures and are more likely to adhere to treatment plans. This decreases the odds of adverse events occurring and leads to better health outcomes. While the degree to which patients and families can be involved will vary depending on the medical situation (its urgency and the degree of technical knowledge required to understand the treatment process), as a general rule, the greater the involvement of patients and families, the less likely is the occurrence of error.<sup>(46)</sup>

Some patients may not be comfortable speaking up about their care. They may be reticent about asking clinicians if they are being given the correct medication or test for fear of appearing to challenge professional expertise, or they may hesitate to ask if clinicians have washed their hands before beginning an examination or procedure. Yet, in the interest of patient safety, it is crucial that organizations encourage them to overcome these barriers. Though this will bring healthcare activity under greater scrutiny, the benefits of this level of openness are multifold. It serves to increase everyone's level of accountability for safe healthcare delivery, including that of clinicians, patients, and families alike, by placing a renewed emphasis on the rights and responsibilities of all.<sup>(47)</sup> In addition to playing a greater role in error surveillance, patients and families will be required to take more responsibility for their own healthcare. For instance, by giving complete information about their medical history and adhering to treatment plans. Clinicians likewise must do their part in providing pertinent information to patients and families and in obtaining vital information from them as well. For example, failure on the part of clinicians to take into account the cultural practices of certain patients may result in decisions that are inappropriate to their needs and sometimes even be harmful. For instance, alternative therapies used without the clinician's knowledge, could result in adverse interactions when combined with conventional medicine<sup>(46)</sup>.

Another vital role that patients and families can play is to offer valuable insights and suggestions on how to make health care safer. As recipients and observers of care, patients and families see the healthcare delivery process through a different lens, and may challenge clinicians to see things from a new perspective.<sup>(48)</sup> It has been suggested that patients and families participate actively in a variety of patient safety initiatives, such as root cause analyses of adverse events, patient safety rounds, and safety advisory committees. Instead of fearing this type of partnership, organizations should view it as an untapped resource that can bring about the creation of innovative solutions to patient safety issue.<sup>(47)</sup>

### ◆ **Reactive Approaches to Risk and Error**

*"A mistake is an event, the full benefit of which has not yet been turned to your advantage."* <sup>(49)</sup>  
The primary purpose of capturing information around hazard or incidents is to learn from them and to eliminate the hazards or prevent future occurrences.

#### **Categorizing incidents for follow-up**

When an incident occurs, whether it is an actual adverse event, a near-miss, or the discovery of some hazardous or latent condition, it must be assessed by the organization to determine the appropriate course of action. As appropriate, the clinical situation is stabilized and preliminary fact-finding and an evaluation of the situation by Risk Management or other designated staff begins. The next step is to assess the incident and determine what level of analysis and action is required. Incidents at a certain level of seriousness that are sentinel in scale (see definitions) are channeled in an expedited fashion to the executive level of an organization for determination of status and formal review. If determined to meet the criteria for such an event, an institutional sentinel event review process is formally initiated. Under TJC standards, when a sentinel event occurs, organizations must conduct a thorough and credible RCA that involves detailed inquiry into all root cause categories that may have potentially contributed to the incident. Both the RCA and an action plan must be completed within a mandated time frame of 45 days.

Some institutions approach the categorization of hazards or incidents based on the Veteran's Affairs National Center for Patient Safety (VA NCPS) prioritizing scoring methodology known as the Safety Assessment Code (SAC). This scoring methodology uses numerical measures for severity and probability that then drives the level of analysis required. Assessing severity includes criteria such as the extent of injury, length of stay, and level of care required for remedy. For incidents that result in adverse events, the assessment reflects the actual condition of the patient. For near-misses or hazards, the score represents the worst outcome that could have potentially occurred. Assessment of the "worst case scenario" should trigger a more in-depth analysis. Assessing probability involves estimating the potential risk of a hazard or incident in terms of the frequency of its occurrence. This may not be a precise assessment since it necessitates having knowledge of the organization's high-risk points. In some cases, this information may already be available if the organization has been tracking certain incidents. Otherwise, those performing the assessment must call upon their own experiential knowledge, or they may solicit the informal expert opinions of staff with the best working knowledge on the subject matter. Each hazard or incident is assigned a score from 1- 3 based on the severity and probability of occurrence. Scores of 3 are considered the highest risk and automatically require root cause analysis of the incident. For more information on the Veteran's Affairs National Center for Patient Safety visit [www.patientsafety.gov](http://www.patientsafety.gov)

Since the prevalence of near-misses is far greater than actual events, their inclusion in the investigative process provides a rich opportunity to examine systems weaknesses without first having to experience any adverse outcomes. They also offer unique information on how recoveries from near-misses were made, which can be valuable when determining safety interventions. By virtue of their sheer numbers, near-misses also lend themselves to statistical analysis. <sup>(50)(51)(52)</sup>

#### **Determining appropriate course of action**

Once the parameters for severity and probability are assessed, the organization must determine a course of action. The purpose of categorizing incidents and establishing their priority is based on the objective of improving care balanced with the need to prioritize the time and resources needed

to respond to reported issues. Potential responses may range from a formal review including a Root Cause Analysis (RCA), an Aggregated RCA Review (described below), department review, existing committee review or tracking and trending with continued monitoring.

The Aggregated RCA Review concept also comes from the Veteran's Affairs National Center for Patient Safety model. Rather than using scarce resources to perform separate analyses for incidents that may be of lower severity or frequency, aggregation makes possible the examination of patterns and trends over time that may not be detectable in individual case analysis. With larger numbers, these patterns and trends may become more apparent, enabling organizations to perform more meaningful analyses. Examples of such incidents are falls and medication errors. This format aligns well with the performance improvement processes already in place within hospitals. <sup>(50)(51)</sup>

Departmental level review is appropriate for those incidents or concerns that are primarily isolated to a particular area. If the decision is made to delegate the review and analysis to an existing committee or to the departmental level the organization must be certain that there are sufficient resources, leadership, expertise, and initiative within the committee or department to perform this function adequately. If no committee exists or the departmental route is not appropriate, a special Adverse Event Review Team can be designated to address the issue. <sup>(50)(51)</sup>

### **Root Cause Analysis**

Root Cause Analysis is a methodology for identifying the contributing factors that underlie variations in performance associated with adverse events and near-misses. It is a structured approach to an investigation that retrospectively examines and dissects the genesis and evolution of incidents in order to discover why they occurred and to uncover their causes. A tool that has been used for years in other industries for the investigation of accidents, Root Cause Analysis is based in human factors engineering and therefore focuses on weaknesses in systems and processes that may have diminished human performance. The primary objective of the analysis is to find ways of redesigning systems and processes in order to reduce the likelihood of error and to enhance human performance. <sup>(18)(51)(53)</sup>

#### **◆ Assembling the RCA team**

Some believe that the prime source for solutions to patient safety issues lies within the experience of the team and that tapping into this process can be as or more fruitful than the mass collection of data and the analysis of statistics. <sup>(51)(54)</sup> Assembling the right people to form an effective team is a critical first step in the RCA process. The team should have multidisciplinary representation in order to bring differing perspectives and expertise to the analysis. The team must include content experts who can speak to the specific details of the situation under investigation, whether it is the clinical care process, proper operation of a piece of equipment, the intricacies of a task, or how a process should occur. There must also be front-line staff present that are familiar with how things really are or how things work in the real world, including any hazards and hidden barriers that might not be evident to others. They are often the best at seeing new emerging threats to safety, particularly as a result of changes in processes and systems within organizations. <sup>(32)</sup> Leadership and managers should also be included both for their operational knowledge during the RCA as well as for resource allocation and assistance in implementation of the action plan that follows the RCA. Representation from Risk Management and Quality Improvement is also critical as experts in the RCA process and managing group dynamics. The University of Michigan Hospitals and Health Centers have approached RCA team formation by using "fixed team members" and "content experts." The fixed team members that are always present include representation from: Chief of Staff, Chief of Nursing, Chief Operating Officer, Quality Improvement and Risk Management. The "content experts" are then selected based on the

analysis to be performed. Representation often includes medical staff, nursing staff, nurse managers, biomedical engineering, and pharmacy.

◆ **Setting the tone**

How does one set the proper tone for a meeting of this nature? It is suggested that the meeting be initiated with an opening statement from the team leader who is in a senior leadership position, in order to create an atmosphere that is conducive to open discussion. It should be emphasized that the objective of the meeting is to discover systems issues and not to establish individual culpability. The statement should reinforce that all matters to be discussed will be held in confidence and that everyone is encouraged to speak up and offer honest feedback without fear of repercussion. Such declarations at the outset of a meeting serve to create an atmosphere of trust and respect, and a sense that this is a safe place to talk. Other members of the team who are involved in overseeing the RCA process, such as those from Quality Improvement and Risk Management, will also have a role in maintaining this tone throughout the meeting. Tone can also be set through written communication used to convey information about the RCA process.

◆ **Protecting interests and maintaining objectivity**

It is important to understand that team members may bring to the table their own special interests and concerns that affect them and/or their work areas directly. It is the role of the facilitator to be cognizant of this and to manage this dynamic as the RCA process plays out. Depending on the situation, these variables may need to be acknowledged openly. When looking for causes of an incident, there may be some resistance to probing deeper into an issue for fear of it reflecting badly on one's work area or management abilities. Group dynamics will also bring into the equation the issue of people with varying degrees of power within the organization sitting at the table together. It will be necessary to pay attention to the level of participation and ensure that all team members are drawn into the discussion. When negotiating solutions to patient safety issues, there will likely be reaction around the impact of these interventions on such matters as budgeting, staffing, and clinical practice, particularly if it necessitates changes in behavior and work culture, or shifts in responsibility and authoritative control. It is the role of the leader and facilitator to keep these competing interests and concerns in balance and to know when it is appropriate to challenge them. The team may need to be encouraged to explore innovative solutions and to strategize ways to put these ideas into a sustainable effort. It is essential that as much objectivity as possible be maintained so that personal biases are not allowed to dominate the process.

◆ **Ensuring "Through and Credible" Root Cause Analysis**

While there may be some variation in how a Root Cause Analysis is actually conducted, the Joint Commission does set some basic parameters. In order for it to be acceptable, the analysis must focus on systems and processes, rather than on individual performance. It must identify proximate or special causes of variations in clinical processes, then drill down to the root or common causes in organizational processes. To do so, the probing must continue until all possible root causes are uncovered through the repeated asking of the question "why?" The goal of the analysis must be to identify improvements in systems and processes that would reduce the risk of recurrence. Finally, the RCA must be thorough and credible.

To be "thorough" it must include:

- A determination of the human and other factors most directly associated with the incident and the processes and systems related to its occurrence;
- Analysis of the underlying systems and processes through a series of "why?" questions to determine where redesign might reduce risk;
- Inquiry into all areas appropriate to the specific type of incident;

- Identification of risk points and their potential contributions to this type of event; and
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be "credible" a Root Cause Analysis must:

- Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review
- Be internally consistent (i.e. Not contradict itself or leave obvious questions unanswered)
- Provide an explanation for all findings of "not applicable" or "no Problem"
- Include consideration of any relevant literature <sup>(9)</sup>

#### ◆ **Beginning the investigative process**

When a serious incident occurs, clinicians involved in the incident may experience emotional responses complicated by a sense of responsibility for what happened. Throughout the process, support should be made available for all clinicians, regardless of discipline or position in the organization. Recognizing the impact that such events may have on clinicians, TJC Standard LD.5 requires that there be "...*defined mechanisms for support of staff who have been involved in a sentinel event*" as part of the organization's patient safety program.<sup>(8)</sup> Supportive services include employee assistance programs, critical incident debriefings, and other internal or external support mechanisms. It is suggested that these supportive mechanisms be offered immediately upon the identification of the event, reinforced as the investigative process is in progress, and thereafter as appropriate based on the needs of the staff involved. Since some events will become part of the legal system, staff may also need supportive services as the events are re-discussed at a later time and in a different context.

Generally, the first step in the investigative process involves fact-finding to establish the exact details and chronology of the incident, including time frames. This phase of the analysis entails querying those directly involved in the incident by asking "*what happened?*" Most organizations have defined mechanisms by which they gather data once an event has occurred. Often these mechanisms involve risk management or other designated staff interviewing employees, reviewing documentation and summarizing the events. The information gathered is then presented to the appropriate review body for analysis and action planning. The University of Michigan Hospitals and Health Centers (UMHHC) utilizes this methodology and adds a significant step in order to validate the data in a multidisciplinary fashion. The factual information as obtained by Risk Management from the staff and medical record is flowcharted capturing the sequence of events, variations in processes, handoffs and the context that led up to the incident. All staff involved in the event are then brought together to review the flowcharts for accuracy and additional context. This meeting is led by the Chief of Staff or designee and participants are invited to offer suggestions for improvement. Participants are then thanked for their participation and the approach to the remaining root cause analysis process is explained. In general, participants in the event do not participate in the RCA unless they are the only content experts available. This approach lends itself to increased objectivity and critique during the RCA. Event participants are then invited to a "wrap-up" meeting to review the RCA and action plan.

#### ◆ **Scope of the review**

The scope of the review may vary, depending on the nature of the incident and its severity. For sentinel events, the analysis must encompass at least the minimum scope of possible causes related to the incident as outlined in the TJC Root Cause Analysis Matrix. For example, for incidents involving procedural complications, the scope includes such items as: (a) availability of information; (b) competency assessment; and (c) staffing levels.<sup>(55)</sup> A credible RCA considers all

factors before rejecting any as being non-contributory.<sup>(53)</sup> For non-sentinel events, in some cases, the RCA may be more limited in its scope, focusing on factors that are known to directly contribute to a particular incident. At times, other categories may need to be brought in, such as “patient observation procedures”, which relates to recovery from an incident and mitigation of its effects. Other suggested categories include analysis of the tools that people use since research shows that even the simplest of tasks can be error-prone when using poorly designed tools.<sup>(32)</sup>

#### ◆ The Analysis

With the chronology determined and the scope outlined, begins the iterative process of asking “why?” enough times until all aspects of the investigation are analyzed and all causal factors identified. Research shows it is seldom a single cause, but instead a convergence of multiple causes that bring about an incident. Furthermore, while it is usually the proximate cause that points to human error, those factors that most contribute to the human error are often beyond the individual's control.<sup>(56)</sup> One of the rules of causation is: “*For every human error in your causal chain, you must have a corresponding cause.*”<sup>(57)</sup> For this reason, the RCA approach seeks first to identify direct causes of failures in processes and then drills down to establish the root causes in organizational processes that are usually due to latent conditions. Root causes most often point to organizational processes that create the resources, constraints, incentives, and demands that shape the work environment and influence behavior.<sup>(32)</sup> For example, an injury incident related to a medical device may reveal a direct cause that implicates user error and skill level. However, further investigation reveals multiple issues, including: (a) Failure on the part of the device manufacturer to provide appropriate instructional materials; (b) Variability in modes of training between departments; (d) Failure to include all clinicians who may use this device into the competency assessment/ privileging scope; and (e) Poor mechanisms for maintaining clinical competency for a device-related procedure that is low frequency, high risk. Further inquiry into the issue may reveal not only inadequate systems for integrating this particular new piece of equipment into use but for all new equipment, shifting the analysis from “proximal” issues to “common” issues within the organization. A consequence of this discovery may lead to improvement of educational interventions around new devices and the implementation of guidelines and clear institutional expectations around the device training process. Often a brainstorming exercise that involves all team members in a free flowing process of idea generation structured around the “why?” question is the first step in moving toward common causes. As part of this exercise, it may be helpful to pose “triggering” questions that facilitate the thought process around certain categories or utilize quality improvement techniques such as the Ishikawa diagram to visually display root causes.

While engaging in this process, experts caution that focusing only on sources of systems failures loses the rich insight that one can reap from gaining an understanding of how people anticipate, prevent, detect, mitigate, and recover from incidents before their consequences impact the patient. “*Often humans are not the cause but the active agents that regularly contribute to success. They resolve conflicts, anticipate hazards, accommodate variation and change, cope with surprise, work around obstacles, close gaps between plans and real situations, detect and recover from miscommunications and misassessments.*”<sup>(32)</sup> Developing an understanding of how clinicians manage uncertainty, risk, and hazard; and how they use these skills to forestall or deflect incident trajectories and to bridge gaps in systems within the context of actual practice sheds light on where systems vulnerabilities are and how one might to respond to them. The flip side to this is that human adaptability may be so commonplace that an organization comes to rely on it and then cannot perceive true systems weaknesses and the way in which elements converge to create a path toward failure.<sup>(24)(32)</sup> Both conditions must be considered in the course of the analysis.

As the analysis process progresses, numerous methods of obtaining fuller insight into causes of an incident may be employed. If additional information needs to be obtained, more data can be collected, including more document review. The team may choose to conduct a walkthrough of a case that involves role-playing and observation of processes, problem-solving simulations in the work environment, and examining the tools used. If relevant, a literature search accompanies this process. Benchmarking to examine what other organizations are doing to address this issue is also helpful in this process.<sup>(35)</sup> The conclusion of this phase of the RCA process involves summarizing findings based on a conglomeration of the questions and answers that surfaced. The team then narrows down from this information what they believe to be the primary root causes of the incident and arrive at a consensus. An action plan is developed that addresses the root cause identified in the analysis.

#### ◆ **Action Planning**

Once the team identifies underlying causes, the next step is to develop an action plan. For it to be acceptable by TJC, the plan must (a) identify changes that can be implemented to reduce risk, or formulate a rationale for not undertaking such changes; and (b) where improvement actions are planned, identify who is responsible for implementation, when the action will be implemented, including any pilot testing, and how the effectiveness of the actions will be evaluated.<sup>(9)</sup> If it is discovered that a proximate cause or special cause variation is not unique to just this incident, but has a common cause applicable to other segments of the organization, then strategies may need to be applied more broadly. Other strategies may emerge as self-evident through the process of identifying causes. Readily apparent systems deficits may point to obvious solutions. However, just as there are multiple causes of failure there are also multiple avenues for improvement and no set way to approach a solution. Strategy selection should involve determining what the most reasonable and prudent actions are to address the issue. Examples of some of these are discussed below:

Reducing reliance on memory: (a) Checklists and protocols are good for processes that involve many steps or where the exact sequencing of steps is critical. However, they should only be used as tools to minimize variables and ensure consistent outcomes, not to hinder human judgment in those instances when it is called for. (b) Standardization minimizes unnecessary variation in drugs, equipment, supplies, and rules, which increases consistency of performance. (c) Color-matching prevents using the wrong items together, as with IV, TPN, and drainage tubing. (d) Pre-packaging ensures that all essential items are ready and tasks aren't interrupted in order to obtain additional items. (e) Automated reminders aid in supplying key information at critical points in processes.

Reducing reliance on vigilance: (a) Bar-coding reduces cumbersome identification procedures. (b) Constraining functions, such as removing concentrated potassium chloride solutions from units, distances one from the opportunity for error. Forcing functions are design features that force the correct use of a device or process. (c) Natural mapping uses intuitive logic in design, as with knobs that turn clockwise with increasing intensity, or the color red to indicate danger.

Simplifying tasks and processes: Probability of error increases with complexity. Simplifying reduces the number of steps, the number and timing of choices, and the duration of tasks.

Reducing hand-offs: The more people involved, the greater are the communication challenges. The less people involved in a task or process, the fewer are the hand-offs and chances of error.

Reducing the need for calculation: Performing mental calculations is error-prone. Preprinted charts, calculators, double blind checks, and automated calculations are risk reduction strategies.

Providing for reversibility or automatic correction: Creating mechanisms to promptly detect and correct potential errors stops the trajectory of errors and blocks their full manifestation.

Recovering when prevention fails: Planning and rehearsing proper responses to error enhances the chances of prompt recovery and limits the impact of consequences on the patient.

Providing adequate training: There is a correlation between low level or lack of training and increased incidence of errors. Training should be provided at appropriate intervals and should include the most effective venues and modalities for learning.

Managing fatigue: Since fatigue affects ones response time and accuracy, strategies should be used to reduce the opportunities for fatigue occurring or compensating for the effects of fatigue.

Providing adequate informational resources: Accurate and readily accessible information can reduce error. This necessitates regular review of access to and relevance of information. <sup>(21)(58)(59)</sup>

Once the risk reduction strategies are determined they should be stated in terms that are clear and specific and have direct relevance to the root causes identified. An unaffected reader should be able to understand and follow the statement. (VA article in Journal of QI) The final step in action planning is then developing appropriate measurements. The goal is to have outcome measures that determine whether or not the strategy had the intended impact and was effective in reducing the incidence of similar errors. These measures should include a numerator and denominator and targets for performance. In cases where outcome is difficult to measure, process measures may need to be utilized. Measurement and monitoring should not only look at the effectiveness of improvements over time, but it should also ascertain that there were no unintended consequences as a result of these actions. <sup>(50)</sup> It is a known characteristic of complex systems that if a change occurs in one area it will likely have an effect on some other aspect of the system. Organizations must be cognizant of this phenomenon and ensure that the resulting counter effect will not create new systems vulnerabilities.

#### ◆ **Conclusion of the Root Cause Analysis**

##### **Lessons learned**

Once the action plan has been developed, it is critical to internally disseminate the lessons learned and the plan for correcting necessary systems and processes. A particular group for which this follow through is important are the clinicians involved in the original incident. Presenting the action plan and getting their reaction to the proposed risk reduction strategies provides important feedback to the RCA team and serves a secondary purpose of bringing closure to a very difficult situation in a constructive, purposeful fashion. While internal dissemination of information is critical, it is also important for organizations to consider sharing their learning through publications, presentations, reporting to accrediting agencies and professional groups.

##### **Informing the family of the results**

Though not mandatory , some organizations are providing the opportunity for the patient's family to be informed about what interventions have been put into place to prevent this type of incident in the future. This may help bring closure for the family and some sense that their loss or experience was a catalyst for positive change within the organization.

## **CHALLENGES**

#### ◆ **Is This a Systems Issue or a Performance Issue?**

*"Clearly, punishment for all errors or blanket immunity from sanctions for all actions are both unacceptable extremes, particularly in a high-risk domain."* <sup>(14)</sup> Organizations must take care to differentiate between errors that occur at the hands of employees because systems' flaws set them up for failure and those errors that are caused by unprofessional, unethical or irresponsible human behavior. <sup>(23)</sup> The challenge for organizations is to strike the proper balance between these two extremes. *"Clinical providers need to have an environment in which it is okay to recognize and*

*talk about errors. But, at the same time, patients need to trust that the system has sufficient systems of accountability."*<sup>(10)</sup> The question becomes one of how to determine when it is a systems issue or a performance issue. Organizations must develop guidelines to help draw the line between acceptable and unacceptable behavior of its membership relative to their involvement in adverse events. Reason cautions organizations that the degree to which someone is at fault for causing an incident is not always as clear as one may think since culpability can be confounded by other variables, such as the person's intentions, actions, and the consequences of those actions. In an attempt to walk organizations through this thought process, Reason constructed a decision tree prototype as a tool designed to gauge human culpability. The decision tree takes one through several levels of inquiry, including questions about whether there were any medical conditions that the clinician had for which he/she required medication, or whether safe operating procedures were knowingly violated, and if so, if it was because the procedures were not workable. Guided by a series of questions, organizations are able to determine if it can be presumed that the person involved in the incident was culpable, blameless, or if it falls into a gray area that needs further discernment and investigation. When faced with the task of having to differentiate between systems and performance issues, it is the gray area that will prove the most challenging for organizations. The tool helps to bring into the equation any systems issues that may have factored into the cause of the incident, hopefully narrowing down the gray area somewhat.<sup>(14)</sup> The Veterans Health Administration in its Patient Safety Handbook has defined that they will only focus on the individual when there is commission of *intentional unsafe acts*. These acts, as they pertain to patients, are considered to be "*any events that result from a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse; an impaired provider/staff; or events involving alleged or suspected patient abuse of any kind.*"<sup>(60)</sup>

#### ◆ When Outcomes Can't Be Adequately Measured

One of the purposes of measurement in healthcare is to assess if a particular intervention was successful, if the presumed cause of the problem being addressed is in fact the true cause, and if the problem is being impacted in a positive way through the intervention. Many adverse events in healthcare occur with reasonable enough frequency to be able to measure them by quantitative means. Typically, certain types of incidents occur and their frequency is measured. Interventions are then put into place to reduce their recurrence, and outcomes are subsequently measured to gauge the success of the intervention. In this way, correlations can be made between the intervention and the outcome. However, organizations will encounter challenges when facing the dilemma of how to measure the success of interventions for low frequency events that do not lend themselves to outcome measures, such as infant abductions, blood mistransfusions, and patient suicides. Because of the rarity of such events, organizations may be tempted to measure success by the absence of adverse outcomes. However, this is not a reliable measurement criterion. Yet, how will an organization truly know that an intervention leads to improved patient safety if outcomes cannot be measured? In these cases, organizations must look to process-based measures. Process indicators can be derived from analyzing processes related to low frequency incidents via Root Cause Analysis or other quantitative methods. The presumption is that by identifying the high-risk points in certain processes, and then putting into place defense strategies to lessen the level of risk, the likelihood of incidents related to these processes will be decreased. Since there is often no evidence base to draw from and process changes cannot be measured by outcomes, the challenge is one of not knowing for certain if the process mechanism that has been selected is the right one to impact change. The most reliable way of gauging success of these interventions is to establish measures that would give a good indication of whether or not defense strategies are functioning as they should. <sup>(4)(27)(53)(61)</sup>

#### ◆ **Limitations of Root Cause Analysis (RCA)**

Two of the defining characteristics of organizational errors are that they tend to have multiple causes and that these causal factors can continuously reconfigure themselves to create new and unique error-prone situations. Thus, it is argued that analysis of any one incident may not reap root causes that are necessarily predictive of the chain of events of future incidents. Likewise, it is never certain that the factors determined to be the root causes of a specific incident are in fact the actual ones that contributed to the incident. Furthermore, because the RCA process is retrospective and somewhat speculative in nature, it is prone to hindsight bias, a well-documented phenomenon in psychological research. When humans have knowledge of the outcome of an incident after the fact, during post-incident investigation, they are inclined to skew their memory of what happened before the fact. There is a tendency to oversimplify the complexity of the circumstances and events that actually transpired. Hindsight bias minimizes one's appreciation for the level of risk and uncertainty that clinicians confront on a daily basis. The RCA process may also be slanted towards those issues that are of greatest concern to the organization at the time; hence, the focus of investigation may be to probe more intensely those select issues. Organizations are also cautioned that if a Root Cause Analysis is not conducted properly or if inappropriate remedial actions are taken as a direct result of the analysis, it can create a whole new set of problem-prone situations and serve to discourage participation and trust in the process itself. <sup>(53)(32)</sup>

#### ◆ **Quality Assurance Protection under the Law**

*Perspective:* Patient safety analyses by design uncover reasons for unintended patient outcomes mainly to improve future care. The analyses benefit from strategies like aggressively gathering facts, intentionally fostering a non-punitive environment within a culture of responsibility, examining problems from new and different perspectives, and encouraging free expression of opinion, exploration of alternatives and consideration of significant change. The culture of litigation is the spectral opposite. Litigation is adversarial. Its culture is one of blame, of judgment. Patient safety endeavors are inherently forward-looking; litigation's purpose is to look backward and judge. The risk that knowledge gained in a patient safety analysis will be misused in a lawsuit is real.

Sentinel or adverse events warn of risk to other patients. The risk is immediate. The risk compels immediate analysis and immediate operational changes if indicated. Studies also reveal that a very small percentage of hospital errors result in litigation. <sup>(62)</sup> Invariably, suits are filed long after the event and can take years to resolve. Understanding error causation cannot wait for litigation to run its course. Most states have enacted legislation offering protection from disclosure "to records, data, and knowledge" collected in a patient safety analysis. The protections are not absolute. The laws are subject to interpretation by individual judges. The facts of each analysis will be subject to judicial scrutiny. Observing certain precautions during the process can increase the likelihood of protecting accumulated information later in a courtroom. There is no guarantee.

Concern is often overblown. Experience shows that where patient safety analysis documents a breakdown in systems or performance, litigation frequently reveals the same information and those cases usually are settled. Where the examination suggests performance was reasonable and identifies other reasons for the unanticipated outcome, hospitals are tempted to divulge the results of the analysis anyway.

*Legal Protection:* Michigan law imposes responsibility on “the owner, operator, and governing body of a hospital” for “all phases of the operation of the hospital, selection of the medical staff, and quality of care rendered in the hospital.”<sup>(63)</sup> Hospitals are obligated to insure that health care providers are granted privileges consistent with their training, experience and qualifications.<sup>(64)</sup> They are obligated to ensure that the staff is organized to be able to review hospital practices to reduce the morbidity and mortality, improve the care rendered, and to review the quality and necessity of care provided and preventability of complications and deaths.<sup>(65)</sup>

Legislatures also recognize that in order to fulfill oversight responsibilities and stimulate open dissection of events, hospitals need some assurance that the information they gather will not be used against them. Thus, statutes support the oversight duties with the following protection:

“The records, data, and knowledge collected for or by individuals or committees assigned a review function described in this article are confidential and shall be used only for the purposes provided in this article, shall not be public records, and shall not be available for court subpoena.”<sup>(66)</sup>

Key phrases shed light on the boundaries of this protection. Only information collected for or by “individuals or committees assigned a review function” is covered. The information is covered only if it is used “for the purposes provided in this article;” namely, peer review, activities aimed at improving care, reducing morbidity and mortality, reviewing necessity and quality of care and preventability of complications and death. It is also important to understand that when this information is requested in the course of litigation, Michigan trial courts simply do not accept the hospital’s assertion that the material falls within the statutory boundaries; instead, the court is empowered to hold evidentiary hearings to determine the charge of the individual or committee that conducted the examination and the use to which the information was put.<sup>(67)</sup> Investigation of adverse events by an individual or committee assigned to investigate those events should clearly fall within these protections. The challenge is making sure not to compromise those protections.

Michigan courts, like courts across the country, also prohibit the use at trial of subsequent remedial measures to prove negligence.<sup>(68)</sup> Unfortunately, this evidentiary protection is frequently useless at trial. Courts allow such evidence admitted for other purposes: to show feasibility, for instance.

*Risks to Legal Protection:* The boundaries of statutory protection define the risks to that protection. It is, therefore, critical that the information obtained in the investigation be obtained for, or by individuals assigned the review function. Information obtained by or for others outside that review function does not qualify for the statutory protection. So, for instance, an independent investigation of an adverse event undertaken personally by the supervisor of an involved nurse independent of a committee organized to look at the incident is probably not covered. Reports by involved personnel to the hospital administrator are likely not covered, or information gathered and used for on-going patient care.<sup>(69)</sup>

The most likely focus for a court considering a request for production of information gathered in an adverse event investigation is the way the collected information was used once it was collected. Courts will carefully track how the information was routed and examine the purpose of that routing. If at any time the information is not used for the review purpose assigned the individual or committee collecting it, a court will likely order the information produced for opposing counsel. So, for instance information collected in an adverse event review but given to a defense attorney to prepare for litigation may sacrifice the protections under this statute. Information shared with outside vendors could also fall outside the limits of this protection.

*Recommendations:* To increase the likelihood that information collected in a review remains protected in a subsequent lawsuit, consider:

- Carefully creating a paper trail establishing the purpose for the review;
- Delineating the individual or committee members assigned that review function;
- Documenting the process chronologically;
- Carefully restricting access to the information gathered only to those involved in the review function;
- Limiting use of the information purely to the review function and overarching purposes of the statutes;
- When the nature of the analysis requires involving outsiders in the process, making sure their involvement is essential to the review purpose, documenting the deliberation to reach that conclusion, and making sure the individuals restrict their participation solely to the review purposes;
- When it is advisable to share information or conclusions with outsiders, (such as working with a medical device manufacturer to inform it of information necessary to make corrections), doing it completely independent of the adverse event review process and without reference to the individual case. Focus on the defect or human factors issue alone. Intermingling purposes could sacrifice the protections entirely;
- Clearly distinguish between findings of deficiencies or breakdown in existing systems from discovery of new and better ways of rendering that care;
- Mark all materials created and accumulated in the review process with a statement that they are privileged under the applicable statute and carefully segregate those materials;
- Should a lawsuit arise, insist on aggressive efforts to enforce statutory protections and resist temptations to use information where the conclusions were helpful. Because trial lawyers are advocates, the hospital defense lawyer may be insensitive to the importance of maintaining the protections to institutional efforts toward patient safety globally. Hospitals should educate their trial lawyers to the process that was followed and to the precautions the hospital took to preserve the protections.

Patient safety advances require critical analyses of adverse events. Protecting institutional fiscal health is important, but discouraging or inhibiting patient safety analyses for fear of complicating potential future litigation requires an institutional priority check. And where the claims management philosophy is principle-driven, we have found that patient safety analyses generally do not adversely affect the litigation result.

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**References**

- (1) Bogdarus S et al. Perils, Pitfalls, and Possibilities in Talking About Medical Risk. *JAMA*. 1999;28: 1037-1041.
- (2) Shelton J. The Harm of First, Do No Harm. *JAMA*. 2000;284: 2687-2688.
- (3) Kohn LT, Corrigan JM, Donaldson MS (eds) *To Err Is Human: Building a Safer Health System*. Washington, DC: Committee on Quality of Health Care in America, Institute of Medicine. National Academy Press. 1999.
- (4) Berwick D. Taking Action to Improve Safety: How to Increase the Odds of Success. In: Proceedings of the 1998 Annenberg Center for Health Sciences Conference: *Enhancing Patient Safety and Reducing Errors in Health Care: Conference Proceedings*. Annenberg Center for Health Sciences.
- (5) Brennan T, Leape L, Laird N. The nature of adverse events in hospitalized patients: results from the Harvard medical practice study. *New England Journal of Medicine*. 1991;324: 2377-2384.
- (6) University of Michigan Hospitals and Health Centers. *Peer Review Process Policy 04-06-042*. October 2001.
- (7) University of Michigan Hospitals and Health Centers. *Patient Safety Reporting and Analysis System*. 2002.
- (8) Joint Commission on Accreditation of Healthcare Organizations. *Revisions to Joint Commission Standards in Support of Patient Safety and Medical / Health Care Error Reduction*. Oakbrook Terrace, IL: JCAHO; 2002.
- (9) Joint Commission on Accreditation of Healthcare Organizations Standards. *Sentinel Events*. Oakbrook Terrace, IL: JCAHO; 2002.
- (10) Loeb J. To Err is Human: An Interview with the Institute of Medicine's Linda Kohn. *Journal on Quality Improvement*. 2000;26: 227-234.

- (11) Spath P. Developing an effective patient safety policy. *Hospital Peer Review*. 2000: 108-110.
- (12) Wolff A, Bourke J. Reducing medical errors: a practical guide. *Medical Journal of Australia*. 2000;173:247-251.
- (13) Reason J. *Human Error*. Cambridge: Cambridge University Press; 1990.
- (14) Reason J. *Managing the Risks of Organizational Accidents*. Aldershof, UK: Ashgate Publishing Limited; 1997.
- (15) Berwick D. A User's Manual For The IOM's 'Quality Chasm' Report. *Health Affairs*. 2002.
- (16) Wears R et al. Human Error in Medicine: Promise and Pitfalls, Part 2. *Annals of Emergency Medicine*. 2000;36:142-144.
- (17) Eisenberg J et al. Does a Healthy Health Care Workplace Produce Higher Quality Care? 2000;27:444-457.
- (18) Bates D, Gawande A. Error in Medicine: What Have We Learned? *Minnesota Medicine*. 2000;83: 18-23.
- (19) Weick K. The Collapse of Sensemaking in Organizations: The Mann Gulch Disaster. *Administrative Science Quarterly*. 1993;38: 628-652.
- (20) Reasons J. Human Error: Models and Management. *BMJ*. 2000;320:725-726
- (21) Porto G. Safety By Design: Ten Lessons Form Human Factors Research. *American Society for Healthcare Risk Management*. 2001.
- (22) Philips D. New Look Reflects Changing Style of Patient Safety Enhancement. *JAMA*. 1999;281.
- (23) Kizer K. Ten steps you can take to immediately improve patient safety in your facility. *Briefings on Patient Safety*. 2000;1.
- (24) Wears R et al. Human error in medicine: Promise and pitfalls, part 1. *Annals of Emergency Medicine*. 2000;36.
- (25) President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. *Chapter 12: Adapting Organizations for Change*. In: *Building the Capacity to Improve Quality*. July 19, 1998. Accessed at [www.hcqualitycommission.gov/final/chap12.html](http://www.hcqualitycommission.gov/final/chap12.html)
- (26) Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*. Washington, DC: National Academy Press. 2001.
- (27) Leape L. Error in Medicine. *JAMA*. 1994;272: 1851-1857.
- (28) Schiff G, Rucker T. Beyond Structure-Process-Outcome: Donabedian's Seven Pillars and Eleven Buttresses of Quality. *Journal on Quality Improvement*. 2001;27: 169-174.
- (29) Kosnik L. The New Paradigm of Crew Resource Management: Just What Is Needed to reengage the Stalled Collaborative Movement? *Journal on Quality Improvement*. 2002;28: 235-241.

- (30) O'Leary D. Reducing Medical Errors: A Review of Innovative strategies to Improve Patient Safety. In: Testimony before the House Committee on Energy and Commerce Subcommittee on Health. 2002.
- (31) Shine K. Health Care Quality and How to Achieve It. *AAMC Paper - Academic Medicine*. 2002;77: 91-99.
- (32) Cook R, Woods D, Miller C. *A Tale of Two Stories: Contrasting Views of Patient Safety*. In: Report from a workshop on assembling the scientific basis for progress on patient safety. National Health Care Safety Council of the National Patient Safety Foundation at the AMA. 1998.
- (33) West E. Organisational sources of safety and danger: sociological contributions to the study of adverse events. *Quality in Health Care*. 1000;9:120-126.
- (34) Zwarenstein M, Reeves S. Working Together but Apart: Barriers and Routes to Nurse-Physician Collaboration. *Journal on Quality Improvement*. 2002;28: 242-247.
- (35) Larson L. Ending the Culture of Blame: A look at why medical errors happen and what needs to change. *Trustee*. 2000;53: 6-10.
- (36) Kosnik L. The New Paradigm of Crew Resource Management: Just What Is Needed To Reengage the Stalled Collaborative Movement? *Journal on Quality Improvement*. 2002;28: 235-241.
- (37) Cook R et al. Gaps in the continuity of care and progress on patient safety. *BMJ*. 2000;320: 791-794.
- (38) Sharit J. A Modeling Framework for Exposing Risks in Complex Systems. *Risk Analysis*. 2000;20: 469-482.
- (39) Lester H, Tritter J. Medical error: a discussion of the medical construction of error and suggestions for reforms of medical education to decrease error. *Medical Education*. 2001;35: 855-861.
- (40) Paget M. *The Unity of Mistakes*. Philadelphia: Temple University Press; 1988.
- (41) *FMEA History*. FMEA Methodology. Accessed at [www.fmeca.com/ffmethod.htm](http://www.fmeca.com/ffmethod.htm). November 30, 1999.
- (42) McDermott RE, Mikulak RJ, Beauregard MR. *The Basics of FMEA*. Portland, OR: Resource Engineering, Inc. 1996.
- (43) DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using Health Care Failure Mode and Effect Analysis TM: The VA National Center for Patient Safety's Prospective Risk Analysis System. *Journal on Quality Improvement*. 2002;27: 248-267.
- (44) *Strategies and Tips for Maximizing Failure Mode Effect Analysis in your Organization*. In: White Paper prepared by the American Society for Healthcare Risk Management. 2002.
- (45) Joint Commission on Accreditation of Healthcare Organizations. Accessed at [www.jcaho.org](http://www.jcaho.org). 2002.

- (46) Vincent C, Coulter A. Patient Safety: What about the patient? *Quality and Safety in Health Care*. 2002;11: 76-80.
- (47) Grol R. Improving the Quality of Medical Care: Building Bridges Among Professional Pride, Payer Profit, and Patient Satisfaction. *JAMA*. 2001;286: 2578.
- (48) Classen D. Patient Safety, Thy Name is Quality. *Trustee*. 2000;53:13-15.
- (49) Senge P. *The Fifth Discipline: The Art & Practice of the The Learning Organization*; Doubleday & Company, Inc. 1994.
- (50) Bagian J et al. Developing and Deploying a Patient Safety Program in a Large Health Care Delivery System. *Journal on Quality Improvement*. 2001;27: 522-532.
- (51) University of Michigan Hospitals and Health Centers. *Patient Safety Reporting and Analysis System*. 2002.
- (52) Berman S. Reporting Outcomes and Other Issues in Patient Safety: An Interview with Albert Wu. *Journal on Quality Improvement*. 2002;28: 197-204.
- (53) Agency for Healthcare Research and Quality. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment Number 43. AHRQ Publication 01-E058. (July 20, 2001).
- (54) Building a team is key to a "thorough and credible" root-cause analysis. *Briefings on Patient Safety*. 2000;1: 1-5.
- (55) Patient Safety in 2001: The JCAHO Standard. *Briefings on Patient Safety supplement*. Opus Communications, Inc. 2001.
- (56) Leape L. Error in Medicine. *JAMA*. 1994;272: 1851-1857.
- (57) *Using the Five Rules of Causation*. Adapted from Marx D. Developed by The Department of Veterans Affairs National Center for Patient Safety.
- (58) Crane M. How good doctors can avoid bad errors. *Medical Economics*. 1997.
- (59) Rex J et al. Systematic Root Cause Analysis of Adverse Drug Events in a Tertiary Referral Hospital. *Journal on Quality Improvement*. 2000;26: 563-575.
- (60) The Department of Veterans Affairs. *VHA National Patient Safety Improvement Handbook*. Washington, DC: Veterans Health Administration. 2002.
- (61) Spencer FC. Human Error in Hospitals and Industrial Accidents: Current Concepts. *J Am Coll Surg*. 2000; 191: 410-418.
- (62) Meyers, A.R. "Lumping it." The hidden denominator of the medical crisis. *Am J Public Health* 1987; 77: 1544-1548
- (63) MCL 333.21513(a)
- (64) MCL 333.21513(c)
- (65) MCL 333.21513(d)

- (66) MCL 333.21515; see also MCL 333.20175(8) and MCL 331.533
- (67) *Monty v. Warren Hosp. Corp.*, 422 Mich 138 (1985); *Gallagher v. Detroit – Macomb Hospital Association*, 171 Mich App 761 (1988)
- (68) Michigan Rule of Evidence 407
- (69) *Marchand v. Henry Ford Hospital*, 398 Mich 163 (1976); *Gallagher*, supra

## **PRIMERS – Recommended Reading**

- ❑ Chassin MR, Becher EC. The Wrong Patient. *Annals of Internal Medicine*. 2002;136: 826-833.
- ❑ Porto GG. Safety By Design: Ten Lessons From Human Factors Research. *American Society for Healthcare Risk Management*. 2001.
- ❑ Leape L. The Role of Human Factors Research in Reducing Medical Errors: A Conversation with Dr. Lucian Leape. *Forum*. 1997;17:5-6.
- ❑ Wears RL, Perry SJ. Human Factors and Ergonomics in the Emergency Department. *Annals of Emergency Medicine*. 2002;40: 206-212.
- ❑ Leape L. Lucian Leape on the Causes and Prevention of Errors and Adverse Events in Health Care. *Journal on Nursing Scholarship*. 1999;31: 281-290.
- ❑ Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM.. The Veterans Affairs Root Cause Analysis System in Action. *Journal on Quality Improvement*. 2002;28: 531-545.
- ❑ DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using Health Care Failure Mode and Effect Analysis. *Journal on Quality Improvement*. 2002;28: 248-267.