PART 1

Risk Management
Administrative Issues
CHAPTER 1

Risk Management: An Institutional Imperative

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THE EVOLUTION OF RISK MANAGEMENT

Following the insurance crisis of the 1970s, the Institute of Medicine issued a landmark report entitled To Err Is Human: Building a Safer Health Care System. Two large studies, conducted in Colorado and Utah and in New York, revealed that adverse events occurred in 2.9% and 3.7% of hospitalizations, respectively. It was also found that more than half of these events resulted from medical errors that could have been prevented.¹

When these data are extrapolated to the 35,527,377 admissions to U.S. hospitals, it appears that more than 1 million medical errors could occur in a year, implying that more than 140,000 Americans die each year from medical errors—more than from motor vehicle accidents. It is estimated that the national cost of preventable events ranges between $17 billion and $29 billion.

Although controversy swirls about the data presented in the report, many healthcare professionals would argue that the actual number is less important than the fact that no one needs to die needlessly or suffer from preventable medical errors (see Box 1-1).

Box 1-1  Deaths of Nine Alabama Patients²

Nine patients died at Alabama hospitals due to an intravenous supplement that was found to be contaminated by bacteria. Ten other patients who received the supplement were also sickened by the bacteria, Serratia marcescens, which is commonly found in water. State officials attribute the source to a pharmacy that compounded the solution.

A New York Times article dated January 6, 2012, indicated that hospital employees recognize and report only one out of seven errors, accidents, and other events that harm Medicare patients while they are hospitalized, according to a study conducted by the U.S. Department of Health and Human Services. Even after hospitals investigate preventable injuries and infections that have been reported, they rarely change their practices to prevent repetition of adverse events.³

According to the Agency for Healthcare Research and Quality (AHRQ), the number of people treated in U.S. hospitals for illnesses and injuries from taking medications jumped 52% between 2004 and 2008—from 1.2 million to 1.9 million. More than 53% of hospitalized patients are prescribed at least one medication that could cause an adverse event.⁴
patients treated for side effects and other medication-related injuries were 65 years and older.  
In a state that requires reporting of wrong-site surgery, statistics from June 2004 to 
December 2008 revealed there were 427 reports of near misses (253) or surgical interventions 
started (174) involving the wrong patient (34), wrong procedure (39), wrong side (298), and/or 
wrong part (60). Eighty-three patients had incorrect procedures done to completion. 
Actions involving surgeons contributed to 92 cases. Other factors cited in wrong-site surgeries were site markings, patient positioning, 
and unverified consents (see Box 1-2).  

**Box 1-2  Wrong Patient Got Kidney Transplant**

The University of Southern California Hospital halted kidney transplants in January 2011 after a 
kidney was accidentally transplanted in the wrong patient. The patient who received the wrong kidney 
escaped harm because the kidney happened to be an acceptable match. The hospital shut down its program after realizing the error.

The Joint Commission Center for 
Transforming Healthcare collaborated with 
eight hospitals that perform more than 130,000 
procedures annually to determine why wrong-site surgery continues to occur. They found the 
following root causes:  

- Lack of intraoperative site verification when multiple procedures are performed 
- Ineffective hand-off communication or briefing 
- Primary documentation not used to verify the patient procedure, site, and side 
- Site mark(s) removed during prep or covered by surgical draping 
- Time-out process occurs before all staff are ready 
- Time-out performed without full participation 
- Time-outs do not occur when multiple procedures are performed by multiple providers in a single operative case 

It is critical to monitor any adverse events 
from both a quality and a legal standpoint. The 
University of Michigan Health System developed a proactive risk management program based on “common sense” as defined by a group headed by a former trial lawyer. The program stressed improved patient safety, accountability, and communication. The University of Michigan Health System does not wait for litigation to happen, but rather follows these principles:  

- Quick and appropriate compensation where inappropriate care causes injury 
- Vigorous defense of medically appropriate care (see Box 1-3) 
- Reduction of patient injuries by learning from mistakes (see Box 1-4) 

These principles have improved patient 
safety, lowered liability costs, reduced the organization’s total number of claims, and improved patients’ experiences.

**Box 1-3  Alarm Fatigue**

Death attributed to “alarm fatigue” at the University 
of Massachusetts Memorial Medical Center has 
pushed the hospital to intensify efforts to prevent 
nurses from tuning out warning alarms. Nurses 
exposed to a cacophony of beeps may no longer hear them or begin to ignore them. A 60-year-old 
man died in the intensive care unit after alarms 
signaling a fast heart rate and potential breathing problems went unanswered for nearly an hour, 
according to state investigators.
Risk Management Defined

Box 1-4 Transplant Team Missed Hepatitis Alert

The positive hepatitis C test alert that was missed by as many as six people on the transplant team at University of Pittsburgh Medical Center led to a shutdown of the facility’s living donor kidney transplant program. This medical error led to a demotion of a surgeon and the suspension of a nurse for two weeks.

Stanford University Medical Center, in contrast, works with an outside contractor, and has its own captive liability company. The cornerstone of its safety initiatives comprises technology and online education that facilitates communication between patients and physicians.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO, now known as The Joint Commission) promulgated safety standards that took effect on July 2, 2001. The critical areas of these standards related to (1) providing leadership, (2) improving organizational performance, (3) information management, and (4) patients’ rights. The update of September 2011 once again stressed leadership in the safety and quality of care, to include the following:12

- A culture that fosters safety as a priority
- The planning and provision of services that meet the needs of patients
- The availability of resources for providing the care
- The existence of competent staff and other providers
- Ongoing evaluation and improvement of performance

The governing body is pinpointed as having the ultimate responsibility for this oversight. Notably, a proactive risk assessment can help correct problems, mitigate risks, and reduce the likelihood of experiencing adverse events.

In the Institute of Medicine report entitled Crossing the Quality Chasm, it is noted that the U.S. healthcare system does not provide consistent, high-quality care to all people, creating this so-called chasm.13 Given the growing complexity of healthcare delivery, the system has fallen short in its ability to apply the new technology into safe practices. As more advances occur, it may be even less prepared to respond to the challenges ahead. Variation affects almost every key performance measure of the Institute of Medicine’s six key dimensions of a good healthcare system: effectiveness, efficiency, safety, satisfaction, access, and equity.

A recent study indicated that 10% of physicians and nurses have taken dangerous shortcuts in providing care. That percentage represents roughly a threefold increase since the 2005 publication of the study entitled Silence Kills. Safety tools such as protocols, perioperative briefings, checklists, and SBAR (Situation, Background, Assessment, and Recommendation) are being implemented to counteract this risk. Systems thinking about safety has been the biggest reason for the success of hospitals in this regards, according to the National Science Foundation Center for Health Organization.14

RISK MANAGEMENT DEFINED

Risk management for healthcare entities can be defined as an organized effort to identify, assess, and reduce, where appropriate, risks to patients, visitors, staff, and organizational assets. Another definition states that risk management is a program designed to reduce the incidence of preventable accidents and injuries to minimize the financial loss to the institution should an injury or accident occur.15
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From a managed care viewpoint, the risk management definition can be expanded to encompass a comprehensive rationale:

Risk management is the process of assuring that covered persons (members) receive all of the healthcare services they need, to which they are entitled under the contract, no more and no less, at the most cost-effective level possible by reducing or eliminating untoward incidents (occurrences) that might lead to injury or illness of patients, visitors, or employees.16

Untoward or adverse outcomes tend to yield a broad spectrum of possible explanations. A research scientist argued that there was no such thing as a medical accident. As a caveat for the doctors, he quoted from Shakespeare’s Julius Caesar: “The fault...is not in our stars, but in ourselves.” He concluded that more precise medical terminology would help physicians reduce harm: “Accident conveys a sense that bad outcomes are to be explained in terms of fate and bad luck rather than a set of understandable, and possibly changeable, antecedents.”17

PROGRESSIVE STEPS IN THE RISK MANAGEMENT PROCESS

In straightforward terms, risk management is the protection of assets. Risk management personnel usually accomplish this goal by following four steps in progression or combination: risk identification, risk analysis, risk control/treatment, and risk financing.7 In slightly different wording, the risk management process can move from (1) identifying exposures to accidental loss that may interfere with an organization’s objectives, to (2) examining feasible alternative risk management techniques for dealing with these exposures, to (3) selecting the best risk management techniques, to (4) implementing the chosen risk management techniques, to (5) monitoring the results of the chosen techniques to determine effectiveness. Arguing that this risk management process needs refinement to reflect reality, Burlando18 opts for the 5i system, a measured application of five descriptors:

• Investigate: observe or study by close examination and systematic inquiry
• Inform: present in material form
• Influence: affect or alter by indirect or intangible means
• Interpret: explain or tell the meaning of; present in understandable terms
• Integrate: form or blend into a whole; unite with something else

Furthermore, Burlando declares that the mission of risk management “is to select, coordinate and efficiently apply interdisciplinary skills to harmful uncertainties which may diminish the future value of public, private or personal resources.”

Risk Identification

Risk identification involves the collection of information about current and past patient care occurrences and other events that represent potential losses to the institution. In alphabetical order, such risks can be identified as antitrust violations, breach of contract, casualty exposure, defamation, embezzlement, environmental damage, fraud and abuse, general liability, hazardous substance exposure, professional malpractice, securities violations, transportation liability, and worker’s compensation. It is vital to realize that risk identification is not a one-time static analysis. Instead, the identification of possible liability...
risks—such as unexpected treatment outcomes, patient complaints about care, and adverse events that did, or could, cause harm—must be an ongoing process. Early warning data can be obtained through security reports, quality assessment studies, accreditation and/or licensure surveys, and patient complaints. Risk managers should receive a steady stream of information from specific departments, such as when attorneys seek chart information from medical records in preparation for a suit; billing offices, following up on delinquent statements, hear aggravated complaints; volunteers hear complaints because patients do not regard them as employees; and quality assessment activities yield data connected with their screening and review procedures. Furthermore, statistical data from insurers can identify those high-risk individuals and services involved in the payment of claims.

Risk Analysis

Risk analysis entails the evaluation of past experience and current exposure to eliminate or limit substantially the impact of risk on cash flow, community image, and employee and medical staff morale. The seriousness of the risk must be considered in terms of the probable severity to the individual and to the organization, the number of people possibly harmed, and the likelihood and/or frequency of occurrence. Closed claims data are most helpful in gaining an insight into the evaluation of current risks. A priority of high-risk activities for the risk manager logically develops from risk analysis information.

Risk Control/Treatment

Risk control and/or treatment is the organization’s response to significant risk areas, as well as its rejoinder to limit the liability associated with incidents that have occurred. It is the most common function associated with risk management programs. Loss control activities within an institution should not be viewed as a single formal program, because of the varied interrelated and overlapping elements. Often, loss control activity is equated with safety management, as their basic objectives are similar. At times, the quality assessment functions also cloud the specifics of loss control. It is not unusual for a loss/ risk control program to be a collaborative effort involving risk management, quality assessment, and safety management. Ideally, a risk control/ loss management program should categorize the potential liability problems into four areas: bodily injury, liability losses, property loss, and consequential losses. Figure 1-1 illustrates some elements of risk exposure. Note that the healthcare organization’s governing board and the chief executive officer (CEO) are responsible for the overall risk control system. In the second circle surrounding the board and the CEO are the administrative personnel who implement the programs. Specific elements in the third and fourth circles illustrate bodily injury, liability losses, property loss, and consequential losses.

A variety of methods and a combination of techniques are used for controlling the risks: risk acceptance, exposure avoidance, loss prevention, loss reduction, exposure segregation, and contractual transfer.

Risk Acceptance

Essentially, risk acceptance means that the facility decides not to purchase insurance against specific adverse events because the risk cannot be avoided, reduced, or transferred. In addition, the probability of loss is not great and the potential fiscal consequences are within the institution’s capabilities to resolve.
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Exposure Avoidance
After he investigated a hospital’s major liability losses, a consultant advised: “Eliminate the emergency room!” In theory, exposure avoidance aims to rid the institution of the service, personnel, or equipment that may cause the loss, or to advise the institution never to be involved in providing the service or program at all.

Loss Prevention
Using early detection and investigation, risk managers examine medical records, incident reports, patient complaints, and patient billing to pinpoint loss prevention areas. Some losses in specific services can be prevented by the involvement of medical and ancillary staff in educational programs and preventive maintenance. Some sources even advise keeping the patient fully informed of all mishaps, thereby relying on the satisfied patient not to sue the institution.

Loss Reduction
Although loss prevention activities may be undertaken, loss reduction is also pursued in most institutions. It involves the management of claims and ensures that all records are preserved.
and that all personnel are prepared in the event of a loss. Settlements and releases conclude loss reduction efforts. Without abandoning high-risk services, loss reduction or minimization aims to control adverse events by focusing on activities such as staff education, revisions of policy, and procedures.

Exposure Segregation

Administrators can decide to separate out or to duplicate the specific offending services, personnel, or activities identified as exposure risks to the institution. Risk managers can suggest intensive control actions; for example, to reduce medication errors in a hospital, all pharmacists can be disbursed from a central location. If the problem appears to be the distance between medication source and delivery, satellite pharmacies can be established on selected floors.

Contractual Transfer

A facility can transfer or shift the risk to the organization that provides the service through insurance or contract. This practice allows the institution to provide a high-risk service while avoiding liability loss. If a contracted company operates the emergency room of a hospital, the facility avoids risk by ensuring that the contract includes the assumption of all risk by the contractor. Although private insurance premiums can be used to handle contractual liability coverage, the facility may still be responsible for selecting a qualified contractor.

Risk Financing

Appropriate indemnification of risk requires a comprehensive prospective and retrospective organizational analysis of the direct expenditures associated with quantifying and funding losses and risk management activities. Financing choices include self-insurance, commercial insurance coverage, insurance premiums, and funding for any related risk management activities and liability payouts. While risk financing may be the responsibility of the institution’s or agency’s financial office, risk managers can make a valuable contribution to the deliberations by communicating effectively with the finance department, using terminology that finance personnel can understand.

RISK MANAGEMENT ACTIVITIES

An examination of the eight minimal components of a risk management program, as defined by the American Society of Healthcare Risk Management (ASHRM), engenders a fuller understanding of a risk management program:

1. There must be a designated, trained, and experienced risk manager who must obtain at least eight hours of continuing risk management education annually.
2. Risk managers must have access to all necessary credentialing, management, and medical data.
3. Institutions must commit the necessary resources to risk management through a written policy statement that is adopted by the governing body, medical staff, and administration.
4. Facilities must have a system in place for the identification, review, and analysis of unanticipated adverse outcomes.
5. Organizations must have the means to centralize risk management data and to share and integrate data collection and analysis with other clinical and administrative departments.
6. Periodically—at least annually—risk managers must provide the organization’s governing body with a report that reviews and evaluates risk management program activity.
7. Risk managers must ensure that medical staff and new-employee educational programs on minimizing patients’ risks and addressing high-risk clinical areas are provided.

8. Risk managers must forward information on individual practitioners, such as malpractice claim history, knowledge of adverse outcomes, and incident reporting data, to the committees that evaluate the competency of medical staff.

Strictly from a business-oriented approach, risk management aims to accomplish three major functions:

- Reducing the organization’s risk of a malpractice suit by maintaining or improving the quality of care.
- Reducing the probability of a claim being filed after a potentially compensable event (PCE) has occurred.
- Preserving the institution’s assets once a claim has been filed.

Without doubt, risk management includes quality assessment and related activities, such as medical staff credentialing, occurrence screening, incident reporting, and peer review. In addition, it seeks to promote effective communication and a positive attitude between patients and staff, and to make patients less likely to sue for malpractice.

Physicians agree on three ideal attributes for a professional risk manager: the ability to present facts rather than feelings, the ability to be concise in writing about or stating the situation, and the wherewithal to understand the facts and to respond to critical questions. In contrast, nurses identify three common qualities of a good risk manager: a demonstrated willingness to listen, an understanding of the other person’s responsibilities and problems, and a team approach to problem solving that involves asking input from others in forming solutions. These responses lead to the conclusion that a risk manager’s basic skills must include the art of persuasion, the expertise to be a keen listener, and knowledge about team building. Importantly, risk managers must realize that the board of directors or governing body is part of the team, even though that directorate is not the immediate supervisor.

Legislative and regulatory mandates also guide risk management activities to focus on preventive maintenance of equipment and devices, on patient safety measures, and on enhancing the safety of employees and visitors. Examples of such measures include ensuring that equipment is clean, properly calibrated, and in good repair; that a nurse call system is functional; and that security personnel patrol well-lighted parking lots and hallways.

CLASSIFICATION OF RISK LIABILITIES

Risk events include a multitude of sins: untoward incidents occurring to patients (clients), employees, or visitors; use of inadequate equipment or procedures to perform a task; use of improperly trained or qualified individuals to perform a task; improper manufacture of a product; and contamination or pollution of the environment. Failure to perform a service may prevent the achievement of a desired outcome or lead to an undesired outcome, may cause harm or injury, and may result from an error of omission or commission. Some specific examples of risk events, classified by type, include the following:

- Property risks: structural damage, vehicular accidents, technological obsolescence, theft, sabotage, production breakdown, and consequential losses.
• **Casualty/liability risks**: professional negligence (PCEs and adverse patient occurrences), worker’s compensation, directors and officers liability, environmental liability, and product liability

• **Employee benefit risks**: cost of benefit plans, disability claims, and Employee Retirement and Income Security Act (ERISA) violations

Risks can be identified through the use of records and files, flowcharts, personal inspections, expert consultations, surveys, questionnaires, and financial statements. Risk analysis considers the frequency and severity of the loss as related to profit, stable earnings, growth, continuous operation, legal requirements, and humanitarian concerns. A comparative assessment combines cost–benefit analyses with frequency of risk events and with populations affected to yield a weighted risk analysis. Interestingly, people may accept a new technology with perceived injury risks or reject a technology because of a minimal risk of injury. Medical care generally may be devoted to problems that are relatively minor. Because the viability of the institution is at stake, efforts must be made to evaluate and weigh the risk to preserve assets and to restrict the loss.

### RISK RED FLAGS

One or more “red flags” in connection with a patient’s care should alert healthcare providers to take actions to remedy the situation. Appropriate care and treatment should be provided, and patient records should reflect that care. In addition, the risk management department should be notified. Some specific red flags are highlighted here:

• **Treatment conditions**: poor treatment results, repetition of the problem, lack of follow-up care, and equipment malfunction

• **Patient relations**: dissatisfied patient, antagonistic patient or family members, complaining relatives, patient discharged against medical advice, intimidated patient, poor physician–patient relationship, and poor staff–patient relationship

• **Practice management**: poorly maintained medical records, lack of critical policies and procedures, and excessive volume of patients

• **Conduct of staff**: acting outside the scope of training, lack of qualified supervision, performance of a procedure for the first time without supervision, outspoken or rude behavior, personality conflict, and poor physician–staff relationship

### RISK MANAGEMENT TOOLS

Prompt identification of injuries and accidents to patients, visitors, and staff members has been a primary concern of risk management programs since they were first implemented in hospitals. In this manner, institutions address potential problems and correct their causes before they can occur again. In addition, administrators can take immediate action to avoid or lessen the cost of a lawsuit. Three systems are used to accomplish prompt identification: incident reporting, occurrence reporting, and occurrence screening.

#### Incident Reporting

Incident reporting systems were developed to identify events that were not consistent with the routine operation of the hospital or the routine
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care of particular patients or visitors, such as malfunctioning equipment or medication errors. **Box 1-5** illustrates the use of an incident reporting system.

**Box 1-5**

Nurse Jones enters Mrs. Smith’s room and finds her sitting on the floor next to her bed. Mrs. Smith says she slipped and fell, but she thinks she is okay. Nurse Jones appraises her condition and helps her back into bed. Mrs. Smith’s doctor is notified, and Nurse Jones reports to her supervisor. She is told to fill out an incident report.21

More recently, Incident reporting systems have incorporated computer technology. Calgary General Hospital (Alberta, Canada) devised a computer program that identifies five major incident categories: falls, medication errors, treatment/procedure errors, assaults, and computer errors.22 Another computer system focuses on the early identification of patterns and trends in the “how” and “why” of untoward events. Coded vulnerability indicators include the following specific options: system failure (22 choices); diagnostic tests (12 choices); consultation (28 choices); documentation (37 choices); patient rapport (7 choices); clinical conduct (50 choices); human factors (14 choices); and a miscellaneous narrative section. Analysis of the adverse events yields an awareness of and a basis for improved clinical practice and professional risk avoidance.23

Reporting systems rely on facility personnel to recognize and report an incident to a risk manager, a quality assurance coordinator, or a member of the management team. The reports tend to focus on treatment procedures, medication, intravenous and blood errors, infections, birth injuries, falls, burns, and equipment problems that could result in claims against the organization. By themselves, the reports do not offer a complete picture of the number of incidents that occur in a facility. According to some estimates, incident reports identify only 5% to 30% of adverse patient occurrences at a hospital. Staff may not report incidents for several reasons: lack of understanding of what a reportable incident is, fear of punitive action, concern that incident reporting exposes them to personal liability, reluctance to report incidents involving physicians, lack of time for paperwork, and lack of knowledge about the results that an effective incident reporting system can achieve. Only the person who witnessed the incident, or first discovered it, should file and sign an incident report. Anyone else with first-hand knowledge of the event should file a separate report. Critically, anyone filling out an incident report should keep in mind that the written report will be available to lawyers, and any admissions or accusations could be damaging to the reporting individual as well as to the employer. Thus there are several dos and don’ts regarding the filing of an incident report:23

- **Do** record the details in objective terms, describing exactly what was seen and heard, and nothing else: Jones writes that she found Mrs. Smith on the floor beside the bed, not that she fell.
- **Do** describe which actions were taken at the scene, such as helping the patient back into bed, assessment findings, and any instructions to the patient.
- **Do** document the time of the incident, the name of the doctor notified, and the time notified, and have the supervisor review the report.
- **Don’t** include names and addresses of witnesses, even if the form requests such information. Such data make it easier for
attorneys to sue the institution. Check with the supervisor before supplying this information.

- Don’t file the incident report with the patient’s chart. Instead, send the incident report to the person designated by the organization to collect and review such matters.
- Don’t admit liability or blame or identify others as responsible. Obviously, this incrimination could be harmful to the agency if a lawsuit ensues.

Occurrence Reporting

Some states and insurers require or encourage institutions to develop lists of specific adverse patient events (APEs) or adverse patient occurrences (APOs) that must be reported by staff, physicians, or both—that is, occurrence reporting. APOs could include maternal or infant death, a surgical patient’s unplanned return to the unit, or an allergic reaction to medication. Although the lists vary at the discretion of the organization, the insurers, or the states, specifying the reportable events increases the APO identification process by 40% to 60%. Because this system depends on individuals for reporting, however, many incidents still may not be written up. To promote better reporting, some states grant immunity from legal action to persons who provide or evaluate risk management information. In addition, efforts have been made to protect against the possibility that documents generated by the risk management program will become public information.

Occurrence Screening

Occurrence screening systems identify deviations from normal procedures or expected treatment outcomes and may be used in both risk management and quality assessment. An occurrence screening system uses criteria to identify APOs but does not rely on staff members to report the adverse events. Typical examples of APOs that can be identified using such a system include transfer from a general care unit to a special care unit, nosocomial infection, and unplanned return to an operating room. Medical record analysts or trained data screeners systematically review patient records using the prespecified criteria to discover APOs. Peer reviewers then determine whether a deviation from acceptable standards of care actually occurred. Such screening can be conducted during or after the patient care, or at both times. An estimated 80% to 85% of APOs can be identified by occurrence screening—a much higher percentage than obtained through incident reporting systems. Furthermore, a risk management program that combines occurrence screening with review of other data sources, such as incident reporting, infection surveillance, antibiotics use review, and medical staff peer review, can identify 90% to 95% of APOs—a greater proportion than any individual method can identify.

RISK AND QUALITY OF CARE

Any risk management process may sound harsh and lead to the conclusion that the healthcare industry is adopting a businesslike, bottom-line approach without consideration for the humane aspects of providing care to people in need. This perception is not accurate, although even charitable and well-meaning organizations must, of course, maintain financial viability to continue their worthwhile endeavors. Significantly, governmental and voluntary nonprofit healthcare agencies must compete with proprietary healthcare providers in an open marketplace. That fact is a major stimulus that compels all healthcare providers to reduce their losses and to attract patients to the services being offered. For this reason, risk management by
healthcare institutions becomes an integral tool of sound management. It is possible, however, that some patients covered by different insurance programs may receive differential care (see Box 1-6).

**Box 1-6**

Of great concern is the fact that premature death directly resulted from confirmed quality problems in 53 (7.4%) of 706 Medicare patients and in 42 (27.2%) of 154 Medicaid patients. These deaths were avoidable and were directly due to departures from accepted standards of medical care. Also of concern is the fact that readmission occurred in 60 Medicare patients and 18 Medicaid patients, resulting from confirmed quality-of-care problems during the previous admission.24

These connections are affirmed by the accreditation standards of The Joint Commission (TJC). Every applicable institution that seeks TJC accreditation must show substantial compliance with several standards that apply only to the quality-of-care and patient safety aspects of risk management:

- A hospital’s governing body must provide resources and support for the quality assurance and risk management functions related to patient care and safety.
- A hospital’s chief executive officer, through the management and administrative staff, must ensure appropriate medical staff involvement in and support for the following:
  - The identification of areas of potential risk in patient care and safety.
  - The development of criteria for identifying cases with potential risk regarding patient care and safety, and evaluating these cases.
  - The correction of problems in patient care and safety identified by risk management activities.
- The design of programs to reduce risks related to patient care and safety.
- A hospital’s management must establish and maintain operational linkages between risk management functions related to patient care and safety, and quality assurance functions.
- A hospital’s management must ensure that existing information relative to the quality of patient care is readily accessible to both the quality assurance and the risk management functions.

**RISK MANAGEMENT/QUALITY ASSURANCE FUNCTIONS AND ACTIVITIES**

In 1980, the American Hospital Association (AHA) formed the Interdisciplinary Task Force on Quality Assurance and Risk Management to define the relationship between hospital risk management (RM) and quality assurance (QA). A causal connection exists between risk management, the quality of care, and quality assurance programs. A quality–risk continuum has been identified, and quality assurance and risk management programs must work together to achieve their own goals. Four dicta emerge from the quality–risk spectrum:

- Quality control is the process of assuring that standards are met. The objective is 100% met, or zero defects.
- Risk control ensures that losses due to property, casualty, or employee benefit risks are prevented, reduced in frequency and/or severity, or transferred.
- Quality control is doing what you want to do: meeting standards.
- Risk control is not doing what you do not want to do: preventing errors.
when changes are made. All federal, state, and local legislation and regulations should be complied with and documented. Incidents such as fires, equipment malfunction, poisoning, strikes, disasters, and termination of vital services should be reported to the proper authorities.

With the help of a risk management committee responsible to the Board of Directors, Mt. Sinai Hospital (Toronto, Canada) identified three objectives for its risk management program:

1. To reduce the frequency of preventable adverse occurrences that lead to liability claims
2. To reduce the probability of a claim being filed after an adverse event has occurred
3. To help control the costs of claims that do emerge

Initiatives integrated into this risk management program included acting on the risks identified in the recommendations of a coroner’s jury, in departmental reports, in incident analysis, in occurrence reporting, and in a claims summary database.

Responsibilities of a Risk Management Committee and Coordinator

Because a risk manager’s activities involve the entire institution and all its programs and services, the responsibilities can evolve into a long, overwhelming list of tasks. Many tasks overlap with other units and are cooperative in nature. Grouping the responsibilities delineates the descriptive scope of a risk manager’s job.
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Purpose, Accountability, and Authority Functions

- Coordinate and carry out risk management activities in line with the program objectives
- Secure written statements affirming the support of the governing body, the administration, and the medical staff for the risk management program
- Describe the organizational reporting lines and the relationships between the risk manager and the rest of the institution
- Prepare a written statement detailing the involvement of every department and service and its responsibilities in risk management activities
- Provide for the flow of information among quality assurance, credentialing, peer review, and any risk management committee
- Monitor all incidents related to patient care
- Define the responsibility to recommend and implement corrective actions
- Prepare a statement assuring the confidentiality of all data collected for the risk management program

Specific Functions

- Review the potentially compensable events (PCEs)
- Investigate the PCEs
- Analyze and pinpoint trends in PCEs
- Report appropriate PCEs to the insurance carrier
- Assist in the resolution of conflicts among patients, physicians, and institution to avoid claims
- Settle claims, obtaining liability releases, at the authority level approved by management
- Adjust or write off bills as necessary within authority approved by management
- Maintain files of all lawsuits
- Ensure protection of records and other evidence
- Prepare the necessary material and people for a legal defense under the guidance of the insurance company and defense counsel
- Represent the institution in legal proceedings within defined parameters
- Assist and monitor the activities and charges of the defense counsel
- Provide risk management support/input to appropriate medical staff and institutional committees
- Act as the institution’s resource for risk management topics
- Prepare reports to the board, the healthcare system, management, and other entities as directed
- Comply with applicable regulatory codes and professional standards
- Provide risk management education for institutional personnel, medical staff, and residents
- Maintain professional competence through participation in seminars, conferences, and so on, and through membership in appropriate professional societies
- Develop the annual risk management budget
- Determine general, short-term, and long-term objectives
- Evaluate the program regularly and update it as necessary

Functional Relationships

- Biomedical engineering in regard to new products, equipment involved in PCEs, record keeping, and risk management alerts
- Quality assurance in regard to PCEs, professional staff, and incidents
- Safety/fire/disaster committees
- Employee health services
Risk Management Committee

Programs should include a risk management committee to assist in prioritization of risk reduction activities and to act as a liaison to the various professional staffs in the hospital. A typical risk management committee has a physician chairman, as well as representation from the major medical and surgical services, the nursing department, the technical staff (biomedical engineering, radiology, respiratory services, clinical laboratory), and the quality assessment department, plus the risk manager. One or more members of the governing body and hospital counsel may be members. A risk management committee reviews key risk-exposure information: all claims; all state-reported incidents; internal incidents of concern because of either the extent of injury or the potential for injury; emerging trends in delivery of care that present new avenues of exposure; and any other issues or events that may occur, or be averted, that may have the actuality or potential of leading to a heavy loss of financial resources or good reputation. Having a mix of clinical and technical personnel on the committee provides for multifaceted examination of loss potential and risk exposure of any situation. This committee reports to the medical staff, governing body, and administration and frequently serves as the primary source of ongoing education on loss prevention in a facility.

The goals of the risk manager and the administration in working within this committee are to facilitate information flow among various departments and services and to provide a central focus for collaborative loss control and risk reduction actions.

Responsibility of the Governing Body

A commitment, including accountability, to an institution-wide risk management program must be adopted in a written governing board policy. Governing body bylaws should include mechanisms for the approval of medical staff bylaws, including the appointment and reappointment of physicians. A mechanism must be established for reporting risk management activities to the board. If possible, a governing body member should be appointed to any risk management advisory group or committee.

Under the guidance of the governing board, one risk manager suggested that “chaos theory” offers an opportunity to enhance risk management. Chaos theory is “based on the simple principle that order can be found in disorder.”29 This theory concentrates on events that do not adhere to established principles, are unpredictable, do not result in a rational aftermath, and appear to disregard a lucid explanation. At a minimum, chaos theory provides a few buzzwords for risk managers. At most, this theory presents a unique prototype that has direct application to the risk management process. Five chaos theory concepts forge links to risk management practices:

1. Predictable patterns exist in apparent random events, because the nature of risk is universal; only the scale changes. Risk managers change their perspectives to study the larger universe, examine parallel systems, and to avoid the isolation of increasing specialization.

2. A sensitive dependence on initial conditions may exist. Small initial events need to be studied and related to larger outcomes. Could the minuscule wind from a butterfly’s wings cause severe weather changes elsewhere in the world?

3. Risk managers usually deal with apparently discrete or chance events. Over time, specific patterns begin to materialize as the random repetitive behavior produces information. Risk managers need to know where
to look for this information and extract the relevant data to apply in their activities.

4. Risk managers must comprehend the intricate interconnected network of forces and external influences that determine the variability of eventual outcomes. Predictably, these forces include the institutional values, goals, and rules, such as a smoke-free workplace, a policy of hiring the handicapped, or a mandate to recycle waste products.

5. To move from the conspicuous and make connections to the improbable, risk managers must adopt new ways of looking for risks using a combination of intelligence and perspicacity.

**SPECIFIC RISK MANAGEMENT FUNCTIONS**

**Incident Identification, Reporting, and Tracking**

An identification and reporting process must exist to identify any circumstance or occurrence that may prove injurious to a patient or that may result in an adverse outcome to a patient. Mortality, morbidity, infections, complications, errors in diagnosis, transfusions, results of treatments, and unimproved cases other than those related to the natural course of disease or illness should be reviewed. Each institution must define and list what constitutes a reportable incident and transmit that information to all employees and all regulatory bodies. A management system should include these elements:

- A time frame within which incidents must be reported
- Designation of the individual to receive incident reports
- Requirement that any employee or medical staff appointee who is aware of an incident must report it to the appropriate person
- The sharing of information, at a minimum, between quality assurance and risk management

The success of the program depends on the risk management staff’s skill in obtaining relevant information. In any risk management program, the keystone to information gathering is the incident report. Originally designed by the insurance industry, this incident report is the mainstay tool for risk assessment in all risk management programs in all industries.

Incident report forms are usually custom-designed for a healthcare facility by the risk management department, taking into consideration the type of information and the amount of detail for any event that need to be collected for adequate computer tracking. To foster use of this form, most risk managers prefer to sacrifice detail in favor of quick notification of an incident. Incident report forms should be devised so that they are unlike any other forms used in the facility, and they should be easy to complete. User-friendly forms have frequently occurring incidents listed in alphabetical order, with a check-off box, allowing space for a brief description of any detail the reporter thinks may be relevant to the situation. Some facilities include a space for physician’s comments if the event required medical intervention. On prompt notification of a serious event or situation, risk management staff can conduct their own investigation immediately and institute any needed loss control measures simultaneously.

Routing of the incident report must be clearly defined. In some facilities, the report is sent immediately to the risk management office. In most hospitals, if a report is completed by
nursing staff, it is routed through nursing administration before being transmitted to the risk manager. An industry standard for transmitting the incident report is no later than 24 hours, with telephone notification to the risk manager as soon as possible after any serious injury or other significant event. A combination of user-friendly forms, staff education, and feedback through risk management trend reports will encourage information flow that meets or exceeds the standard of 4.5 incident reports per licensed bed per year.

Incident reports can be categorized by type of event and severity of situation for computer tracking purposes. A severity index or scale might be based on the type of injury or the type of breach of procedure. Using a scale of 0, 1, 2, or 3, the 0 represents “no injury” whereas 3 may be an injury requiring significant “therapeutic intervention,” or a significant “breach of procedure” such as giving medication to the wrong patient. This information can easily be developed into a graphic report to accompany the risk manager’s analysis and recommendations of loss exposures and risk activities as reported in monthly, quarterly, and annual reports to the safety committee, the quality assessment committee, and the CEO and finance officer.

State-Mandated Incident Reporting

Some states have recognized the utility of risk management programs for the identification of major areas of patient vulnerability within the healthcare system and mandate the reporting of “incidents” to a state regulatory agency, although details of such requirements vary considerably from state to state. New York mandates reporting of hospital staff strikes; disasters or emergency situations affecting hospital operations; termination of any vital services in the hospital, such as telephone, laundry services, and pest control; and poisoning occurring within a hospital. When the peer-review process finds that the standard of care was not met and a patient death or impairment of bodily function unrelated to the normal disease process occurred, the incident must also be reported to the state Health Department. In addition, events requiring police or other legal notification are reportable in New York. In contrast, Massachusetts mandates quarterly and annual reporting of adverse patient events to the Board of Registration in Medicine. Events that are reportable in Massachusetts are defined as incidents of patient harm or death as an outcome of medical intervention. Meeting the standard of care is implied, but not explicit, in the regulations, leaving facilities to make their own interpretations as to whether an incident is reportable. Both New York and Massachusetts reserve the right to conduct an on-site review of any incident, including examination of the credentials of any personnel involved in an event.

Other states have legislative mandates for risk management programs. These state regulations relate to the administration of a risk management program, investigation and analysis of identified risks, education programs, patient grievance procedures, and confidentiality of risk management data. Obviously, it is incumbent on risk managers to be aware of the specific legislation that applies in their own states. Risk managers and quality assessment professionals can use statewide statistical data to compare the type and severity of events by region or type of healthcare facility to “improve” modalities of care.
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Incident Review and Evaluation

The incident review and evaluation process must provide for the following responses:

- Investigation of all incidents, even if no injury results
- Identification of trends among incidents
- Referral of incidents and trend summaries to be evaluated to determine whether further action is necessary
- Referral of incidents requiring further action to the appropriate institutional individuals, departments, services, and committees

Actions to Prevent Recurrence of Incidents

Any actions taken by quality assessment, peer review, or medical staff committees regarding referred identified problems must be documented in a written record. These actions can be classified using the acronym PACED: preventive, administrative, corrective, educational, and documentary.30

- Preventive activities could include a patient relations program; an employee newsletter; a formal safety and security program; a community input effort; and ongoing planning, coordination, and review functions.
- Administrative actions relate to an active process, involvement of department heads, and a formal philosophy regarding administration.
- Corrective activities focus on the encouragement of problem identification, the monitoring of problem situations, the existence of internal audit functions, and the expeditious resolution of problems.
- Educational programs concentrate on creating an interdepartmental educational services unit, upgrading medical and technical skills, having a patient education program, and maintaining records of educational activities.
- Documentary activities include attention to personnel files, financial records, medical charts, regulatory requirements, and written policies and procedures.

The following examples identify a host of work area concerns that could be involved in risk management actions:

- Hazards at work
- Fire safety
- Disaster plans
- Electrical safety
- Central services safety
- Employee/patient safety
- Nursing safety
- Malpractice/legal liability
- Medical staff
- Anesthesia personnel
- Surgery personnel
- Surgical suite hazards
- Surgery and anesthesia
- Nursing treatment
- Dietary safety
- Housekeeping safety
- Pathology safety
- Respiratory safety
- Radiology/laser safety
- Nursing/pharmacy errors
- Nursing and law

Internal Documentation

Institutions must maintain complete files of all risk management documentation, along with
Specific Risk Management Functions

In terms of risk management, credentialing and privileging are critical because they represent the primary mechanism available to hospitals, agencies, managed care organizations, and other institutions to help ensure that only competent personnel are employed and that those providers perform only those clinical duties and procedures for which they are deemed clinically competent. This evaluation process, in turn, reduces the likelihood of the occurrence of any negligent acts that could result in a claim against the organization. A facility or agency with a nonexistent or ineffective credentialing or privileging process could find itself in an indefensible position if a malpractice claim were filed, as the absence of such a process might indicate that the institution was negligent in ensuring that it employed only competent healthcare providers.

Credentialed and Privileging

Professional staff credentialing aims to ensure that institutions are staffed only by qualified individuals and that those individuals’ performance is maintained at an acceptable level. Credentialing activities consist of a complete review of the licenses, education, and training of all applicants seeking appointment or employment. In addition, physicians must regularly have their privileges updated. This process of recredentialing involves an evaluation by the institution of the physician’s clinical experience, competence, ability, judgment, and demonstrated performance in specified functions, such as open heart surgery, before any reappointment. Specifically, a profile of each physician and dentist must be compiled from at least the

following data sources:

- Morbidity and mortality review
- Blood utilization review
- Safety committee review
- Peer review organization data
- Medical care evaluations
- Incident report review
- Liability claims data
- Continuing education programs and training
- Utilization review
- Infection control review
- Surgical case review
- Tissue review
- Medical record review
- Complaints
- Prescription review
- Medical case review

Specific Risk Management Functions

In addition, hospitals are mandated under the Healthcare Quality Improvement Act of 1986 to make inquiries to the National Practitioner Data Bank concerning each physician, dentist, and others. Queries directed to the Federation of State Medical Boards, individual state medical boards and societies, and the insured’s malpractice insurance carrier will provide additional information on adverse professional actions, discipline, and sanctions. The federal legislation also mandates reports to the National Practitioner Data Bank of disciplinary actions or dismissals of medical staff from hospitals and institutions based on peer-review activities and adverse situations.

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Patient Complaint Program

A copy of the “Patient’s Bill of Rights” should be given to each patient on admission and be available in the patient’s own language. These rights should be posted in conspicuous areas throughout the institution or agency. A formal written program for addressing patient complaints must be established, along with documentation of any action taken to resolve grievances. All complaints must be investigated promptly and thoroughly. Patients must be provided with the name and phone number of the representative designated to respond to such complaints. Representatives, in turn, must treat complaining patients with dignity, courtesy, and due regard for their privacy while providing information about the following:

- Whom the patient may contact regarding the complaint
- Whom the patient may contact if dissatisfied with the resolution
- Procedures for investigating the complaint
- When the patient can expect a verbal or written response or resolution to the complaint

Tracking patients’ complaints and identifying trends in those complaints should be routine and reported to the risk management and other committees as necessary.

Risk Management Education

Risk management education should be included in orientation and annual in-service training programs for all institutional employees and professional staff in the following areas:

- Organization and goals of the risk management program
- “Patient’s Bill of Rights”
- Patient relations and complaint program
- Incident-reporting program
- Reporting responsibilities for alleged professional misconduct
- Safety program and department-specific safety practices.

Several insurance companies sponsor risk management seminars for physicians and nurses, providing them with continuing medical or nursing education credits. Core educational units fall into four categories. Opening with the perceived reasons for the malpractice problem, the seminar first covers the public patient, plaintiff attorneys, laws, the standard of care, and the role of physicians in iatrogenic injuries and defensive medicine. Second, the seminar focuses on loss prevention strategies, including rapport between physician and patient, communications, satisfaction, informed consent, office staff strategies, relationships between physician and hospital, and medical record documentation. Third, the seminar highlights litigation awareness, emphasizing the dos and don’ts if physicians are sued. Finally, arbitration details the alternate dispute resolution forum, the binding legal resolution, and the advantages and disadvantages of each method. In theory, these seminars may prevent claims, conserve the institution’s financial resources, prevent patient injury, and improve the quality of patient care delivered.

Insurance Companies and Risk Management

Insurance companies offer their insured institutions a variety of risk management services, including consultation, educational programs, publications, closed-claim studies, and computer software packages. Consultations between insurance company representatives and institutional risk management personnel aim to
help the organization minimize the risk of malpractice claims. Services may include claims auditing, chart review, policy review, and evaluation of specific clinical areas. Individual insurance company personnel may spend time in loss prevention and loss control activities. In filling this role, these individuals keep up-to-date with changes in laws and standards of practice having implications for facility liability, including lessons learned from cases involving actual losses and case-law decisions. Sometimes, the problem is a misunderstanding of the insurance policy.

Educational services seek to help organizations minimize the frequency and severity of malpractice claims. Programs can be provided in several formats, including national, regional, local, and institutional seminars and individualized focused training workshops. Seminars allow representatives of all the insured organizations to meet and discuss clinical, administrative, and legal risk management issues. Focused workshops give individual risk managers a more in-depth examination of issues that directly affect their specific facility. Companies may offer formal certificate programs for risk managers in areas such as an overview of risk management, risk exposure identification and evaluation, or functions of risk management. Each course may consist of self-study, specified readings, study questions, and projects. At the end of each course, participants may be tested and evaluated by qualified faculty.

Publications are designed to aid the insured institution to manage and reduce its liability risk. This kind of material ranges from pamphlets on a single issue to workshop proceedings to multivolume books to a combination of mass-media approaches. Often, insurance companies publish and distribute regular newsletters, case alerts, and bulletins. Available videotapes, audiotapes, films, and slide presentations may deal with topics such as malpractice in the emergency department, mediation errors, and minimizing risks in surgery.

Claims are studied continuously by the insurance companies. A database of open and closed claims filed against their insured organizations and individuals is routinely analyzed to identify lessons learned, so that future claims can be avoided. Professional liability representatives periodically analyze claims to identify factors that may have caused their submission. These factors are evaluated jointly by insurance company representatives and institution officials in an effort to correct the situations that led to the claims. This process is facilitated by computer reports that pinpoint the frequency and severity of malpractice claims.

While insurance companies do not require a prescribed risk management program, the surveys of the agency or institutional program and the results of the data analysis may reflect the adequacy of this program and lead to variations in the premiums charged. Continuing professional liability coverage may be conditional on implementing corrective action based on recommendations for improvement in the program or in specific situations that can cause liability.

**Dos and Don’ts of Risk Management: A Claims Perspective**

Small things that hospital employees, departmental supervisors, and medical staff members do— and don’t do—can have a significant impact on the frequency and severity of claims made against a hospital. Risk management experts urge hospitals to enforce dos and don’ts relative to documentation, product malfunction, contracts, confidentiality, and conflicts (see Box 1-7).
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Box 1-7: Dos and Don’ts of Risk Management

**DOCUMENTATION**

- Do follow all policies and procedures pertaining to documentation.
- Do document any changes in the patient’s status, attempts to contact the patient’s physicians or family members, and other activities relevant to the patient’s care. The absence of such documentation makes defending a medical malpractice action against the hospital difficult. In the words of one plaintiff attorney, “If it’s not in the chart, it never happened.”
- Do complete documentation entries contemporaneously. If changes or updates are necessary, they should be documented in a timely manner, with the date, reason for the change or update, and the initials of the person making the change included.
- Don’t alter records out of fear of litigation or disciplinary action. Altered records discovered by a plaintiff attorney can make a case practically indefensible.
- Don’t make changes to documentation days after an event occurs. Outline in memo form the situation surrounding the need for a change and discuss it with the hospital risk manager.

**PRODUCT MALFUNCTION**

- Do contact the risk management department whenever a product malfunctions, regardless of the perceived consequences at the time of the malfunction.
- Do notify the manufacturer of the malfunctioning product as soon as possible.
- Don’t return the malfunctioning product to the manufacturer after it has caused an injury.
- Don’t discard the malfunctioning equipment, product, or disposable accessories. Instead, store it in a secure location until the hospital’s professional liability company can be notified. Without the product as evidence, securing a contribution from a manufacturer would be very difficult if the incident ultimately warranted settlement, and the hospital could be solely liable.
- Don’t attempt to recreate the malfunction to discover what or how something happened. A report from an independent third-party investigation will be less credible if the product has been altered in any way.

**CONTRACTS**

- Do review all vendor contracts to ensure that the hospital is not exposed to additional risks.
- Do have all contracts reviewed annually by the hospital attorney.
- Don’t sign a contract without reading it and understanding it first.

**CONFLICTS**

- Do keep conflicts involving physicians and the hospital out of the public arena.
- Do familiarize all hospital personnel with hospital policies and procedures that affect their daily jobs. Lack of knowledge of hospital policies is not a viable defense.
- Don’t allow or engage in open criticism of health professionals’ treatment of a patient. Any documented conflicts over patient care would not only make a case very difficult to defend, but could also raise the ultimate value of the judgment.
- Don’t enact policies or procedures that are unrealistic. The hospital will be held to its stated policies and procedures as standards of care.
Computer Use in Risk Management

Next to an involved risk management committee, the most valuable asset for any risk management program is a one-gigabyte computer and all the software the risk management department can afford.

Although smaller agencies and facilities (those with fewer than 200 beds) can manage data for trend analysis manually, the need for long-term trend analysis of incidents, claims, equipment problems, and internal disasters (for example, floods occurring from broken pipes only on weekends) cannot be overemphasized. While many software packages are available that provide for central entry of data and specialized modules for RM, QA, or utilization review, the purchase decision should be based on a thorough analysis of the risk management data needs. Standard database software can be selected and customized to a particular program's needs at a significant savings over the special risk management packages available. In selecting software, the type of information that the risk manager will be analyzing and the type of reports that will be generated from the analysis are the key factors in making the purchase decision.

Data that risk management most frequently analyzes for trends include events involving patient injury, events leading to financial loss to the institution (floods, fires, theft), malpractice suits naming the facility, dates and allegations of malpractice suits filed against medical staff members (obtained on appointment and reappointment), and “indicators”—specific events with potential for patient injury or financial loss, such as a missing surgical consent, an antibiotic given to the wrong patient, a missing patient chart, or narcotic cabinet keys missing from the pharmacy. It is common to track hospital incidents and events by date, time, and location. Malpractice claims are usually tracked by date, allegation, person(s) involved, and damages requested, and are followed through the entire defense process, listing information collected and individuals deposed for the defense, to judgment, settlement, or dismissal of the case. The amount of the judgment or settlement is tracked, as are the expenses incurred. Any one of the many risk management packages currently on the market or one of the database software packages would handle this type of information quite readily.

Toward the Future

Usually, risk managers aim to reduce preventable adverse events, and to minimize financial loss to their organizations should such events occur. In a rapidly changing business environment, risk managers must be able to accurately determine where their healthcare organization is headed and effectively plan methods and techniques to mitigate the risks to their institutions. Within these goals, risk managers, along with everyone else, from top management to the
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lowest-level employee, appear to be involved in almost every aspect of the healthcare delivery system. Healthcare organizations that survive the constant turmoil in the industry will be abetted by an effective, strategic risk management program.

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