# Risk Identification

## What Are the Risk Exposures?

Reliable and efficient data gathering is essential to risk identification and analysis. Risk identification and analysis provide the foundation of the risk management process.[1] Due to the complexity of the healthcare delivery system, limited resources, and the variety of loss exposures, no one data source will provide the risk management professional with all the information that is needed. Several data collection processes will be addressed in this section. Certain reporting processes, such as incident/occurrence/event reporting, are "reactive" and are triggered by single events. Others, such as occurrence screening and the use of clinical quality indicators through the quality review process, are "proactive" and allow for prospective loss prevention. It stands to reason that the earlier a real or potential risk exposure is identified, the greater the opportunity will be to mitigate the risk.

Please see the chapter titled ***Patient Relations*** available in the Risk Management Policyholder Resources Portal. This chapter addresses further risk identification, the loss reduction implications of a sound patient relations program, methods for acting on the results of patient satisfaction surveys, and the implementation of cultural competence and language access service plans.

## When Is This a Risk Issue?

Data are gathered through the formal and informal mechanisms. Incident, event, or occurrence reporting has traditionally been the backbone of a healthcare organization's formal data gathering system. For the purposes of this chapter, we will refer to these acts as "event reporting." Event reporting can be effective in identifying clear-cut events such as falls, medication errors, and biotechnology issues. A model event reporting system is described later in this chapter.

Patient care events that result from delays in diagnosis or treatment and/or errors in medical or nursing judgment are more difficult to capture through the event reporting system. The integration of risk and quality management data is critical if the healthcare organization hopes to target risk reduction activities on areas or practices with the most significant losses or greatest potential for loss. Occurrence screening and the use of "trigger tools" as a proactive process to reduce risk and improve quality of care are addressed later in this chapter.

The risk management professional also relies on less formal reporting mechanisms, including verbal reporting of events by employees or members of the medical staff, referrals or reports of concern, patient or visitor complaints, and certain requests for medical records. These types of informal reports will be addressed in detail in the sections that follow.

Finally, many healthcare organizations have developed additional data gathering tools, such as patient satisfaction surveys. Review of survey results may provide the risk management professional with valuable information regarding single events and potentially troublesome trends.

Reliance on a single source, such as event reports, for data is likely to give the risk management professional only a one-dimensional view of the organization. While addressing problems identified through event reporting will benefit the healthcare organization, integrating the event report data into the overall risk management information data pool can help ensure that efforts are prioritized and result in the greatest benefit to the organization and its patients. A comprehensive process of assessing risk exposures across the entire organization has evolved into the term "enterprise risk management" or ERM.[2] This is a collaborative methodology that requires the engagement of leaders, managers, healthcare practitioners, and others in working together with the risk management professional to better identify and analyze risk, to evaluate risk treatment opportunities, and to implement those that will best address the institution's needs.[3] Establishing and maintaining trusting relationships with key individuals in various clinical, non-clinical, leadership, and support positions are essential to building a viable risk management program.

Once identified, risk exposures should be measured on a scheduled basis (e.g., monthly, quarterly) by analyzing patterns and trends identified through the formal and informal event reporting systems, as well as an ERM approach. Analyses of patterns and trends should consider both the frequency and severity of the injury classifications and financial and reputational risks.

The risk management professional typically prepares quarterly and annual reports that summarize patterns and trends identified through the event reporting system and include an analysis, a treatment plan, and an evaluation of the treatment of all types of events. The reports are communicated to the quality/risk, safety, P&T, and other appropriate committees, individuals, and the governing body.

**Patient Safety Culture**

Any data system is only as robust and valuable as the information it contains. Accordingly, it is imperative that the risk management professional and facility leaders create a patient safety culture that encourages employees and medical staff members to step forward and report patient safety events and near misses in a timely manner. Supportive and effective interventions that respond to individual performance issues, knowledge and skill deficits, oversight, and negligence, as well as the rare reckless behavior, are essential. For a thorough discussion of patient safety culture, please see the chapter titled ***Culture of Safety***, available in the Risk Management Policyholder Resources Portal.

*Risk Management Professional*

The risk management professional provides educational activities concerning current risk and patient safety issues, risk management procedures, and best practices in hospital and healthcare settings. The role of the risk management professional in identifying potential claims and

variations should be stressed. The risk management professional is the champion for advocating risk identification as a duty and responsibility of all medical and clinical staff members, employees, and volunteers and empowering individuals to contribute to and participate in valuable and sustainable solutions.[4]

It is important for the risk management professional to be a knowledgeable and reliable resource. Remaining current in the field enables the person in that position to maintain credibility with physicians, administrators, governing body members, and other clinical and non-clinical employees of the organization.

Perhaps most importantly, it is imperative that the risk management professional maintain a consistent posture of professionalism and confidentiality. Lack of trust will hinder the reporting of sensitive information. A breach in confidentiality may well destroy the integrity of the entire reporting system.

## Event Reporting Policy and Procedures

The event reporting process is an early warning system designed to provide the information necessary to alert the risk management professional to events that require immediate investigation, damage control, and/or quality/safety review.[5] Event reporting has been the traditional method for a healthcare organization to identify risk.[6] Historically, event reporting has been most effective in identifying clear-cut events such as falls, medication errors, and IV problems, although under-reporting has now emerged as an issue. While these events present the organization with loss exposure, the resulting indemnity payments are often not the most significant losses. Event reports have also not been optimally effective in identifying the risks associated with complications of patient care or unexpected adverse outcomes. A lack of understanding as to the purpose of the report and what constitutes an event may contribute to under-reporting of events. In addition, there are many behavioral, emotional, cultural, and perception-based barriers to reporting. These will be addressed later in this chapter. The risk management professional's role in educating staff members, colleagues, peers, and leaders is crucial and one pillar upon which the event reporting system's success rests.

### *Essential Components*

A written policy and procedures on an event reporting system should provide a clear definition of a reportable event. The definition of event, as defined by the American Society of Healthcare Risk Management (ASHRM), is "an occurrence that is not part of the routine care of a particular patient or the routine operation of the healthcare entity."[7] The event may or may not result in an injury to a patient or visitor. While this is a valid and acceptable definition, it is very broad. Staff members will benefit not only from a definition, but also from a listing of examples and categories of reportable events (e.g., falls, medication errors, equipment failures, diagnosis, treatment- or procedure-related events, surgically-related events, blood-related events).

The Joint Commission's list of reportable sentinel events and the National Quality Forum's (NQF) list of Serious Reportable Events (SREs) (formerly known as "never events") may also be used

to select good examples. These lists are available on the websites of both organizations. Many states are standardizing their list based on the NQF-endorsed event types and The Joint Commission's reviewable sentinel events, which closely mirror the SREs.

*Responsibility*
Unit or department managers should be accountable for ensuring that events on their unit are reported, though everyone in the institution has a duty and responsibility to report events and near misses.

*Verbal Reporting*
A physician or employee may make a verbal report of an event or near miss directly to the risk management professional. Reports may also come from an injured party in the form of a complaint. An event report form is used to track these reports, noting that it was received by the risk management professional and including the mode of communication (e.g., telephone call, personal contact, anonymous).

Special attention is given to verbal (or written) complaints directed to the risk management professional or unit manager by patients or third parties. The individual may believe the risk management professional will give prompt consideration to his/her concern, especially if there is a potential for litigation. Consultation with caregivers and a review of the medical record will assist the risk management professional in analyzing the matter and determining the need for disclosure.

*Medical Staff Reporting*
Physicians should not complete an event report, since discoverability issues may result if the event reporting forms/data entry screen require a physician to document the patient's physical conditions following an accident or adverse event. Such documentation may be interpreted to be part of the patient's care and part of the medical record. Physicians should **verbally** report an event to the risk management professional, who will ensure that an event report is completed by an appropriate staff member.

*Employee Reporting*
Administrators, department managers, and staff members are encouraged to contact the risk management professional directly following high-risk events, even though a written event report will follow. This will provide an opportunity for an immediate investigation.

Verbal reporting is also preferred when there is concern regarding the processing of an event report, such as when the reporter wishes to remain anonymous. For a reporting system to be successful, it is important that the risk management professional be perceived as an ally, not an adversary.

*Narrative Entries*
Caution should be used with narrative entries on event reports. Narrative recitations can be a problem for the facility if they include opinions, conjecture, speculation, or rationalization.

*General Liability Information*
General liability information (e.g., pertaining to a visitor falls) is generally not considered peer, professional, or quality review information and may therefore not be protected from discovery. Such a report may, however, be subject to work product privilege if completed in anticipation of litigation.

*Documentation*
It is never appropriate to document in the medical record that an event report has been completed or that the risk management professional has been contacted. Doing so could threaten the confidentiality protections afforded event reports. Under the laws of most states, a patient has a right of access to and control over release of his/her medical records. By placing or referencing an event report in the medical record, control of the document arguably resides with the patient.

*Event Report Handling*
Pursuant to the risk management plan, the risk management professional should receive reports on behalf of the risk/quality oversight committee in order to ensure protection of the investigation and reporting documents under state law. Unless otherwise required by state law or a voluntary reporting program, the event should be reported within 24 hours of the event or when the event became known, unless immediate notification is indicated due to its severity.

Discoverability should be prevented by not making copies of the event report, either for the patient's medical record or for the personnel file for the purpose of documenting employee errors or issues. Using the event report to initiate disciplinary action will certainly discourage the reporting of errors, events, and near misses.

*Contributing Factors*
Factual, objective descriptions of obvious contributing factors included in an event report will assist in initiating prompt patient safety measures, in performing subsequent risk analysis, and in implementing risk treatment strategies. The event report is not, however, an appropriate document in which to engage in subjective speculation or conclusive statements as to the cause of the event.

*Accountability Approach*
An accountability approach will provide for an organization-wide systems analysis of opportunities for improvement, enable review of knowledge and skill deficits, and help in determining the need for increased oversight and awareness of negligence and reckless behaviors. Event reporting is not intended to place blame, but rather to identify system areas for improvement and staff member areas for accountability.

*Severity Coding*
When used in the context of risk financing programs, the term "severity" refers to the financial impact of a potential loss.[8] When it is used in the context of event coding, the term "severity" refers to the seriousness of the harm to the patient.[9]

Severity indices have been developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC/MERP) and the Institute for Healthcare Improvement (IHI). The NCC/MERP coding index includes near miss categories. The IHI index was developed as an adaptation; it eliminated near miss categories, as the purpose of IHI's coding index is to specifically measure the severity of adverse events. One purpose of severity coding is to differentiate areas of potential and actual patient harm. This identification assists organizations in determining high-risk events with the most significant potential of resulting in severe injury and financial loss, as well as topics for root cause analysis or failure mode effects analysis.

*Medical Record Requests*
Requests for patient records may have risk management significance, as they may be used to identify potential claims. The risk management professional should be instrumental in educating staff about medical records requests, as well as serve as an accessible resource to assist with questions and provide ongoing consultation.

*Medical Devices*
The Safe Medical Device Act comes into play whenever an event involves equipment or medical devices. Events involving medical devices may include, among other situations, equipment malfunctions, electric shocks, or human error in the operation of the device.

*Leadership Overview*
Leaders are directly involved in the management and resolution of events. Action and follow up may depend on the severity and type of event and trending information.

**The Event Report Process**
From a risk management perspective, an event reporting program is considered a risk identification notification system. From a compliance standpoint, most hospital facilities have implemented event reporting programs in order to comply with the CMS Conditions of Participation (COP) for Hospitals, Quality Assessment and Performance Improvement (QAPI) Program. Section 482.21(a)(2) requires that the hospital "measure, analyze, and track quality indicators, including adverse patient events and other aspects of performance that assess processes of care, hospital service, and operations."[10] Section 482.21(c)(2) requires that the hospital analyze the causes of the events and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.[11] Apart from the regulatory motivation, an event reporting system should contribute to an organization's ability to quickly respond to the notification of an adverse event or a near miss.

An "adverse event" is generally defined as "any happening that is not consistent with the routine care of a particular patient or an event that is not consistent with the normal operations of a particular organization."[12] The following is an expanded version of an adverse event:

> Any occurrence not consistent with the routine operations of the facility of routine care of a particular patient; an unexpected event; an experience that leaves a

> patient, visitor, or other person feeling, rightly or wrongly, that he or she has been mistreated, neglected, or injured in some way.[13]

For our purposes, events also include situations considered to be "near misses." The National Patient Safety Foundation defines a near miss as follows:

> (1) The American Society for Healthcare Risk Management (ASHRM) succinctly defines a near miss as, "Any variation in a procedure that did not affect the outcome but might have produced a serious adverse outcome. Also called a 'good catch.'"[14]

Event reporting is designed to assist in improving the quality of care delivered to patients, to reduce morbidity and mortality (consistent with state statutes), to enhance patient safety through performance improvement, and to protect the organization from exposures that threaten or contribute to financial loss.

*Effective Event Reporting Systems*

According to the Agency for Healthcare Research and Quality (AHRQ), an effective event reporting system has four key attributes:

- A supportive environment (i.e., a culture of safety) exists and protects the privacy of individuals reporting an event or near miss.
- A broad range of individuals are reporting (not just nurses).
- Reported events are summarized and reported within the organization in a timely manner.
- A structured process is in place for reviewing and analyzing reports and developing action plans.[15]

**Barriers to Event/Risk Reporting**

Despite the critical value that a sound event reporting system has in supporting the risk management program, there are still lingering barriers that impair individuals from executing their duty and responsibility to facilitate the organization's risk identification process. In fact, the AHRQ reported that fewer than 10 percent of the errors and adverse events that take place in hospital settings are captured through the event reporting system.[16]

The risk management professional must be poised to repeatedly and consistently extol the virtues of timely reporting and the value it gives to problem resolution, patient safety, and the health of the organization.

Recent studies revealed that nurses complete the lion's share on event reports.[17] Physicians are less likely to report adverse events, due primarily to the following:

- No feedback or event follow-up.
- Form too long; lack of time.
- Event seemed "trivial."
- Unit was busy; forgot to report.

- Not sure who is responsible for making the report.[18]

Under-reporting and negative perceptions regarding event reports remain as two of the greatest challenges to risk management professionals. More likely than not, these factors are directly associated with a punitive culture or perceived punitive culture. The paradigm shift from a punitive environment to an open and supportive reporting environment is a transition that requires a tenacious advocate and change agent.

**Risk Management Information System (RMIS)**

With the rapid and ongoing emergence of technologies to streamline healthcare operations across all types of patient care settings, it is important to note that the risk management program will benefit significantly from an automated risk management information system (RMIS). In this context, "automated" means electronic server-based or web-based platforms hosted by a vendor or information technology (IT) with applications that include computerized event reporting forms and the capability to easily and quickly extract data for individual and aggregate event analysis and produce meaningful RMIS documents for internal and mandatory external reporting purposes.[19]

The value of an RMIS cannot be overstated. Such automation permits more effective allocation of risk management resources to promote patient safety and loss prevention. Virtual real-time access to event data facilitates the ability to intervene and act in a very timely manner. Moreover, the RMIS assists the risk management professional to better identify and select risk treatment strategies that best accommodate the organization's mission, vision, and strategic plan and will yield the most significant impact.[20]

The disadvantages of a paper-based system are numerous and widely recognized. For instance, consider the time it takes to complete a paper event report form and the time that passes before the paper form is seen by the risk management professional. Consider also the risk of security and confidentiality breaches if the form is lost, misplaced, or copied. Consider that the handwriting on the paper form may be difficult to read or illegible, requiring additional time just to obtain the facts. The ability to analyze data, identify trends, track interventions, benchmark performance improvements, and generate reports is significantly impaired in a paper-based environment.[21]

The implementation of a viable and reliable RMIS should provide the risk management professional with the necessary tools to advance the risk management program to the next level in order to best protect the organization's assets, and satisfy internal and external reporting and regulatory requirements while maintaining patient safety at the highest possible level.

**Event Report Design and Analysis Tips**

A user-friendly event reporting format is one essential element of success for the event reporting system and risk identification process. Although the structure and content of event reports vary widely across acute care institutions, certain fundamental data are critical to understanding the particular adverse event and conducting analyses of individual events and aggregated information.

Basic data should be included in every event report. Although the structure and content of event reporting may vary widely across acute care institutions, certain fundamental data are critical to understanding the particular adverse event as well as for conducting analyses of individual events and aggregated information.

The risk management professional is responsible for leading the loss prevention and risk reduction activities at the facility. Timely event reporting, prompt investigation of events, and skilled analysis of distinct and aggregated data will complement the risk identification component of the risk management program. Reporting risk exposures and risk treatment undertakings to leaders is an imperative of the organization.

*Demographic Information*
Patient information should include the patient's name, home address, telephone number, and medical record number. (Note that the medical record number assigned to a patient does not change, while a patient account/business number is newly assigned with each admission or visit date). Patient demographic data are frequently imprinted on a paper form using the patient's ID plate. In an electronic environment, demographic information may be automatically imported onto the screen if there is an interface with the automated patient care management system. Visitor and employee information includes the person's name and contact information. The information is useful in identifying witnesses or claimants in the event of litigation.

*Socioeconomic Information*
Gender, age, marital status, insurance, and employment status can help the risk management professional evaluate potential financial loss and estimate economic damages in the event of a lawsuit.

*Visit or Admission Information*
This includes data such as visit or admissions date, room number, time of the event, date and time of report, and diagnosis or chief complaint. The analysis of aggregated data could reveal problem-prone units or potential issues with a particular work shift, as well as identify event frequencies over time. These types of findings demonstrate the need for department- or unit-specific reports and recommendations for risk intervention activities.

Comparing the date and time of events to the date and time of the event reports can serve to evaluate the effectiveness of the event reporting process as an early warning risk identification system. Failure to report events and near misses in a timely fashion impairs the ability to exercise risk interventions in a timely manner. Findings of untimely reporting should compel the risk management professional to review policies, procedures, and process functions to determine the reasons for delay and to institute measures to correct any problems.

*Factual Event Description*
An individual analysis of an event can guide the investigation process, but certain information, such as location, type of event, level of injury, physical examination results, and an environmental assessment, should be included. Aggregate analysis of event type can yield trends in frequency

and severity of events, motivating an assessment of systemic problems. This will assist the risk management professional in prioritizing loss prevention strategies.

*Contributing Factors*
Contributing factors, which are generally system or critical process failures, are known at the time of the event or discovered during the course of the investigation. Individual analysis of contributing factors can lead to swift intervention. Aggregate analysis of contributing factors will likely reveal a pattern of system or process failures that require institutional risk control activities.[22]

**Event Reporting Oversight**
Data gleaned from event reports are used as a vehicle to notify leaders, including managers, administrators, and risk management professionals, that something unusual has happened or could have happened. Risk treatment interventions may then be engaged to manage actual and potential risks and loss control measures may be implemented, as applicable. As discussed previously, an RMIS database can generate reports for individual and aggregate analysis tracking and trending and assist in satisfying external reporting requirements.

Whether required as a condition of state licensure, as a requirement for participation in the Medicare or Medicaid programs, or to satisfy accreditations standard, a healthcare organization should have an oversight framework in place. This oversight framework is charged with risk identification and mitigation, helping to ensure the safety of patients, visitors, and employees. A formally organized committee typically assumes these functions. In order to take advantage of the statutory protections, the data, reports, and information must be generated by and for a professional/peer review committee.

**Confidentiality**
Most states afford some degree of statutory protection to peer, professional, and/or quality review data. Event reports and associated documents and data are treated confidentially to help protect them from discovery in the event of litigation. Although some courts have ruled such information is discoverable, it is essential that the policies and procedures guiding the event reporting program clearly address the confidential handling of event reports and data and that actual practices reflect compliance with the policies and procedures.[23]

**Occurrence Screening or Clinical/Quality Indicator Screening and Triggers**
There are other risk identification opportunities apart from the traditional event reporting systems used at facilities. These methods involve focused medical record review using occurrence screen, the IHI Global Trigger Tool, or other triggers or trending analyses and interventions based on administrative data sets as established by the Agency for Healthcare Research and Quality and other professional organizations.

Generically speaking, occurrence or clinical/quality indicator screening is a medical record-based quality improvement system designed to identify adverse patient outcomes (APOs) and patient care variations.[24] If a comprehensive electronic information system is in place, indicators can be

captured concurrently and automatically routed into data stratification, analysis, graphing, and trending for further performance improvement and patient safety initiatives.[25]

Indicator screening uses objective, outcome-based criteria, selected and approved by the medical staff, to identify records for quality review.[26] Screening can be concurrent, retrospective, or both[27] and is generally performed by quality improvement, utilization management, or health information management personnel. Screening through record review is much more effective than event reporting in identifying APOs, especially those related to misdiagnosis, inappropriate treatment patterns, and variations from acceptable standards of care.

Indicator screening may detect events also reported by other means, particularly adverse patient outcomes which have already been identified as potential claims. However, "reactive" identification of single events which may result in litigation is but a secondary purpose of screening. Its primary risk management value is its ability to identify patterns of care which impact loss exposure and necessitate proactive risk treatment. Screening is also effective in identifying high-risk diagnoses, interventions, and circumstances, as well as high-risk practitioners.

### AHRQ Indicators

AHRQ provides quality indicators to assist hospitals to (1) identify potential adverse events that might need further study; and (2) provide the opportunity to assess the incidence of adverse events and complications using administrative data found in the typical discharge record. AHRQ includes indicators for complications that may represent patient safety events. AHRQ provides software that hospitals may use to mine readily available and inpatient administrative data to monitor the indicators.

### Adverse Event Triggers

When relying on members of the healthcare team to report medication errors, fewer errors may be captured for a variety of reasons. Most notably, there are differing views on what constitutes a reportable error. Using triggers (or clues) is a strategy that may be employed to identify a harmful event before it occurs. "Triggers have become a widely used way to retrospectively analyze medical records in order to identify errors and adverse events, measure the frequency with which such events occur, and track the progress of safety initiatives over time."[28] Additionally, "Triggers alert patient safety personnel to possible adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred."[29] Computerized methods of detecting and reporting trigger screens have proven very efficient and reliable. A great initial investment in electronic record capability is required to implement a trigger-based system, but it can yield significant savings in the time required by professional auditors, such as nurses and pharmacists. Another benefit is the value of concurrent review, which provides opportunities for more rapid action before harm reaches the patient.

When an adverse event is verified, interventions can be implemented and tracked longitudinally for effectiveness. This is true from both a retrospective review, such as is the process with the IHI Global Trigger Tool, as well as with concurrent trigger reviews. When a trigger identifies an actual

adverse event, interventions can be formulated and implemented to decrease the frequency of highly common causative factors associated with adverse events. One community hospital identified 1,000 triggers over a six-month period and generated physician intervention action in approximately 25 percent of trigger cases. Without the trigger, these adverse events would not have been discovered.[30]

The *IHI Global Trigger Tool for Measuring Adverse Events* and training resources are available from IHI.

**Occurrence Screen Selection**

Sample organization-wide and service-specific screens are available from a variety of quality improvement and risk management publications and professional organizations. Joyce Craddick's Medical Management Analysis International system is one of the most comprehensive and well-known systems, originating in the late 1980s.[31] This system not only identifies screens, but also provides mechanisms for peer review and data analysis. A provision for physician profiling, which is useful for evaluating clinical competence of individual members of the medical staff at the time of reappointment, is also included.

It is recommended that healthcare organizations evaluate their internal screens to verify that they are at least as valid and capable of identifying variations in care as those used by external review organizations, such as CMS and The Joint Commission. CMS requires organizations to report quality data for Medicare payment reimbursement (quality indicators) and payment exclusion purposes (hospital-acquired conditions [HACs]). The Joint Commission requires accredited organizations to conduct a comprehensive systemic analysis (e.g., a root cause analysis) for sentinel events. Quality indicators, HACs, and sentinel events are important event screening indicators. The quality measures change each year. A listing of the current measures is available at Quality Net.

The Joint Commissions' reviewable sentinel events are as follows:

> The Joint Commission – Reviewable Sentinel Events
> A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:
> - Death
> - Permanent harm
> - Severe temporary harm*
>
> An event is also considered sentinel if it is one of the following:
> - Unanticipated death of a full-term infant
> - Discharge of an infant to the wrong family

- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staff around-the-clock setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital**
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure***
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery****
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat or flashes occurring during an episode of patient care*****
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm******

*Severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

**Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s)

by another individual's hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:

- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact as described above, occurred on the premises
- Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact

***Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

**** "After surgery" is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

*****_Fire_ is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association.

******Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hours), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk—and timely implementation of clinical interventions consistent with evidence-based guidelines—are important steps in the ongoing provision of safe and reliable care.

> Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings. For additional details, *see* "Update: Revised Definition of *Severe Maternal Morbidity* in Sentinel Event Policy," June 2015 *Perspectives.*[32]

Another important source for occurrence screens is the National Quality Forum's *List of SREs* (Serious Reportable Events), which were (previously referred to as "Never Events".

**Informal Reporting Processes**

Reporting mechanisms that are less formal than an event report may also provide the risk management professional with valuable information. These include verbal reports by members of the medical staff or employees of the organization, referrals or reports of concern, and patient or visitor complains.

It is important that the method for getting such a report to the risk management professional is tracked (e.g., telephone, personal contact, anonymous). The purpose of tracking the method of notice is to direct education and process improvement efforts. For instance, if the risk management professional receives a number of telephone calls directly from angry family members, it may be an indication that the patient relations program needs to be reviewed.

***Risk Management Referral Form – SAMPLE*** is available in the Coverys Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

*Verbal Reporting*

A verbal report of an adverse event may come directly to the risk management professional from a physician or employee. It may also come from an injured party in the form of a complaint. Verbal reporting is discussed in other sections of this chapter as well.

Give special attention to verbal (or written) complaints directed to the risk management professional by patients or third parties. Seeking out the risk management professional may indicate that a claim is being considered. The party may also feel the risk management professional will give prompt consideration to his/her concern in order to avert litigation. Consultation with caregivers and a review of the medical record will assist the risk management professional in analyzing the risk that is represented by the complaint.

*Medical Staff Reporting*

Physicians are expected to **verbally** report all potentially compensable events (PCEs) which occur within the healthcare organization to the risk management professional, who will ensure that an event report is completed by an appropriate staff member. Physicians are not to complete an event report themselves. This will help avoid the potential for discovery, as his/her completion of an event report could be construed as a document which may meet the definition of a medical record, particularly if it included changes to the patient's clinical condition and medical treatment plan as a result of the PCE. Under the laws of most states, the patient is

entitled to access and control the release of information contained in his/her record.

*Reporting by Employees*
Administrators, department managers, and staff members should be encouraged to contact the risk management professional directly following serious events, even though a written report will follow. This facilitates prompt investigation and review.

Verbal reporting is also acceptable when the reporter wishes to remain anonymous. For a direct, informal reporting system to be successful, it is important that the risk management professional is perceived as an ally, not an adversary. As with physician reporting, an event report may be initiated by the risk management professional.

## How Can I Reduce Risk?

| Create a Proactive Culture of Patient Safety | |
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| **Create culture** | • Understand that the risk management professional and facility leaders need to create a patient safety culture that encourages employees and medical staff members to come forward and report patient safety events and near misses in a timely and proactive manner.<br>• Recognize that success for a data system that relies upon voluntary self-reporting depends on a nurturing, open environment that promotes collaborative problem-solving, organization-wide learning, and a systems-focused view of error causation.<br>• Approach errors methodically and consistently using a process such as David Marx's *The Just Culture Algorithm*™, which evaluates behaviors, duties, choices, and consequences of the behavior.<br>• Ensure that accountability is addressed in a fair and rational manner. |
| **Remain visible** | • Keep the lines of communication open, starting with the risk management professional being visible, credible, and readily available.<br>• Ensure that the risk management professional:<br>  ○ Is available by telephone during working hours and by voicemail while attending to other business.<br>  ○ Provides for immediate, around-the-clock notification of high-risk events. |

## Create a Proactive Culture of Patient Safety

- Designates off-hour support for risk management functions (e.g., house supervisor, rotating risk management on-call support).
- Conducts walking rounds in both clinical and non-clinical areas.
- Understands the organization's mission, vision, strategy, culture, structure, and operational processes.
- Participates in medical staff and a multitude of institutional committees (e.g., pharmacy and therapeutics, surgical services, infection prevention and control, patient safety).
- Nurtures collaborative relationships and provides expert consulting support to the medical staff, other healthcare providers, and to leaders and members of the governing body.
- Demonstrates effective negotiation skills.
- Actively leads risk management educational activities, as these will establish recognition among the staff.
- Quickly acknowledges staff member participation in the risk identification process and appropriately communicates outcomes of patient safety enhancements and the organization's loss control improvements resulting from the event reporting system.[33]

## Include Essential Components in a Written Event Reporting Policy and Procedures

**Include essentials**

- Include a clear and not overly broad definition of a reportable event.
  - Include the event types/categories that the state requires if the state has a mandatory adverse event reporting program.
- Ensure that providers and staff members know to report all events and near misses, whether or not they result in injury or pose the risk of a potential claim, to assist in tracking and trending patterns for loss potential and loss prevention strategies.

## Include Essential Components in a Written Event Reporting Policy and Procedures

- Ensure that providers and staff members know that events with catastrophic outcomes should be reported immediately to the risk management professional so that an investigation and any needed intervention can be initiated rapidly.
  - Some examples include, but are not limited to:
    - Unexpected patient death.
    - Severe brain or spinal cord damage.
    - Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.[34]
    - Abduction of a patient of any age.[35]
    - Significant, adverse outcomes and/or patient injury.
    - Equipment and medical device-related occurrences.
    - Hemolytic transfusion reaction.
    - Rape.
    - Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting.[36]
    - Death or serious injury of a patient or staff associated with the introduction of a metallic object in the MRI area.
    - Suicide.
- Ensure that event reports are prepared as completely and accurately as possible.
- Complete a visitor event report for all visitor events.

**Sample tools**

- ***Event Reporting Form - SAMPLE*** and ***Visitor Incident Report Form – SAMPLE*** are available in the Coverys Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

**Maintain responsibility**

- Make unit managers accountable for ensuring that events of their unit are reported.
- Educate employees and medical staff members on identifying reportable events and appropriately completing the required form or documenting in the RMIS.

| Include Essential Components in a Written Event Reporting Policy and Procedures | |
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| | • Encourage supervisors to complete an event report should they become aware of an issue and assist others in the appropriate completion of reports.<br>• Provide initial education during the orientation process and ongoing teaching regarding what and how to report.<br>• Ensure that all employees know their responsibilities and duties when it comes to reporting events and near misses.<br>• Report unusual events promptly to the risk management professional (if the organization conducts concurrent quality and utilization review of clinical records).<br>• Understand that the timeliness of reporting will facilitate earlier investigation and resolution of identified problems. |
| **Include reporting requirements** | • Understand that a physician or employee may make a verbal report of an event or a near miss directly to the risk management professional.<br>• Be aware that physicians are expected to verbally report all potential claims, unexpected adverse events, and compensable events to their insurance provider.<br>• Understand that physicians are also expected to promptly notify the hospital risk management professional that a potentially compensable event has occurred on the hospital premises.<br>• Have the reporting guidelines state that the observable facts of all adverse events reported by the physician to his/his medical professional liability insurer should also be reported to the risk management professional of the healthcare organization.<br>• Provide the event reporting policy and procedures, including examples of reportable events, to physicians at the time they join the medical staff.<br>• Provide guidelines for reporting in the medical staff rules and regulations and/or orientation materials.<br>• Include periodic review of reporting procedures as an agenda item for medical staff meetings.<br>• Design event report forms/data entry screens so that they do not require a physician to document the patient's physical condition following an accident or adverse |

## Include Essential Components in a Written Event Reporting Policy and Procedures

event, as such documentation may be interpreted to be part of the medical record.

- Educate members of the medical staff to document medical assessments and treatment rationale only in the medical record.

**Include required information**

- Ensure that the following information is included on the event report:
  - Patient/visitor identification data.
  - Date of admission and date of event.
  - Date and time of discovery.
  - Date of report.
  - Name of reporter.
  - Specific location of the adverse event.
  - Type of adverse event.
  - Observable contributing factors.
  - Patient condition prior to the adverse event.
  - Brief narrative entry noting relevant quotes by patient and/or family member after the adverse event.
  - Names of witnesses and where they can be reached.
  - Names of those notified of the adverse event and the time of the notification.
  - Injury observed that is directly related to the adverse event.
  - Treatment intervention and/or modification to the care plan.
  - A summary of the physician's diagnostic or treatment orders.
- Consider implementing a separate medication event report, as there are many variables that may factor into a medication event or near miss.
- Use a check-off system for paper forms when possible, as they can be completed quickly, facilitate computer data entry, and prompt the reporter to make and record appropriate observations and necessary information.
- Limit narrative entries to brief, objective data, facts, and/or measurements.

| Include Essential Components in a Written Event Reporting Policy and Procedures | |
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| **Develop documentation guidelines** | • Record appropriate observed clinical information and interventions regarding the event in the medical record, as well as interventions provided.<br>• Educate staff members and physicians to use terms that objectively reflect what happened and that represent the facts involved.<br>• Ensure that information included in the clinical record is related to the patient's condition, care, treatment, and response.<br>• Record measures taken after an event to minimize patient injury, such as treatment provided or modifications to the care plan.<br>  ○ For instance, data that should be recorded in the clinical record regarding a medication event should include, but not be limited to:<br>  ▪ Medication given to the patient (name, dose, and route).<br>  ▪ Time of medication event.<br>  ▪ Patient reaction.<br>  ▪ Physician and patient notification, as appropriate.<br>  ▪ Intervention(s).<br>  ▪ Patient monitoring and response.<br>  ▪ Conversations with patient and family members.<br>• Do not document in the medical record than an event report has been completed or that the risk management professional has been contacted. |
| **Include handling guidelines** | • Ensure that documents reach the risk management professional as soon as possible.<br>• Ensure that the risk management professional confidentially secures the completed event report.<br>• Be certain that no one copies event reporting documents and that the report is not stored or referenced in the medical record.<br>• Be sure that copies of event reports are never placed in personnel files as a means for documenting employee errors, mistakes, or issues. |

| Include Essential Components in a Written Event Reporting Policy and Procedures | |
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| **Include contributing factors** | • Include a factual, objective description of obvious contributing factors related to the event. |
| **Educate staff members** | • Ensure that staff members are trained to maintain an effective and efficient event reporting system.<br>• Provide education to staff members, including new employees, temporary and contract employees, medical staff members, volunteers, and students, at regular intervals (at least annually).<br>• Provide learning objectives to the audience to clarify the purpose of the training, including understanding the event reporting policy and procedures and demonstrating competency in completing the form. |
| **Use accountability approach** | • Identify and implement an approach consistent with the organization's culture and directions from leaders.<br>• Focus the risk identification process on both a systems view and provider performance in order to more fully promote a supportive learning environment and identify opportunities to enhance patient safety and reduce risk. |
| **Sample tool** | • ***Accountability Structure for Event Response - SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal. |
| **Employ severity coding** | • Implement a method of categorizing and classifying the severity of each event.<br>• Understand that the purpose of severity coding is to differentiate areas of potential and actual patient harm. |
| **Sample tool** | • ***Severity Coding Tool - SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal. |
| **Include record requests** | • Assign a key staff person in the health information management (or medical record) department the responsibility to receive and process requests for patient medical records.<br>• Train this individual on how to identify those with potential risk management implications.<br>• Ensure that this individual is thoroughly acquainted with the principles of confidentiality. |

| Include Essential Components in a Written Event Reporting Policy and Procedures | |
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| **Preserve devices** | • Preserve any device, including all parts and attachments, whenever a device-related event occurs.<br>• Collect all packaging and supporting information, if possible.<br>• Never adjust the settings after an event.<br>• Sequester the product, device, or equipment. |
| **Sample tool** | • ***Medical Device Event Management Flow Chart – SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal. |

| Recognize the Purposes and Key Attributes of an Effective Event Reporting System | |
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| **Recognize attributes** | • Understand that the event reporting process may be used in multiple types of healthcare settings for the following purposes:<br>○ **Loss control**: Reporting adverse events provides notification to risk management of a potential claim or lawsuit so that prompt and appropriate loss control action may be undertaken.<br>○ **Aggregate data analysis**: Performing trend analysis of event report data using various criteria or categories (e.g., by type, location) assists in identifying areas and specific patient care components which require intensified review and/or action.<br>○ **Focus on systems and provider performance**: Analyzing the contributing factors that led to an event frequently shows that these factors are deeply rooted in the complexity of the healthcare system. It is not uncommon to find the same error occurring in a number of facilities, because it is related to a common underlying problem.<br>○ **Event analysis**: Determining the root causes of an issue and implementing immediate interventions will reduce the risk of recurrence. It is imperative not to just look at patient outcomes or injury associated with an adverse event but to explore the events that led up to or allowed the issue to happen. This includes the analysis of near misses. Analyzing the |

| Recognize the Purposes and Key Attributes of an Effective Event Reporting System | |
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| | event frequently reveals that human error, as evidenced through aberrant provider performance, is a causative factor. This must be addressed through systems solutions, along with remediation of knowledge and skill deficits and increased provider awareness to avoid oversight and negligence. The disciplinary process should be invoked when reckless behavior is involved.<br>○ **Patient safety and quality improvement**: Providing patient safety officers, quality management staff members, and administrators with the means for identifying opportunities for improvement in processes and systems helps to continuously enhance patient safety. |
| **Recognize limitations** | • Recognize that event reports alone are likely ineffective for identifying a wide range of patient safety threats.[38]<br>• Complete and analyze event reports in concert with active surveillance mechanisms such as trigger tools, direct observations, and chart audits.[38] |
| **Make program simple** | • Develop a simple and user-friendly event reporting system.[39]<br>• Favor electronic or web-based systems that facilitate data input and aggregation, provide feedback to the event reporter, and document process improvements that result from the event analysis.[40] |
| **Understand and Address Barriers to Event/Risk Reporting** | |
| **Understand barriers** | • Understand the most common barriers to event reporting, such as:<br>○ Perception that reporting only applies to nursing staff.<br>○ Non-physicians uncomfortable reporting on physician performance or behavior.<br>○ Individual does not want to be considered an informant.<br>○ Fear of punishment or disciplinary action.<br>○ Lack of clear policies and procedures for event reporting, including definitions of reportable event and what constitutes patient harm. |

## Understand and Address Barriers to Event/Risk Reporting

- Reporting must not be necessary or valuable due to the lack of follow-up or feedback.
- Anonymous reporting is not permitted and confidentiality is compromised.
- Lack of education regarding the importance of event reporting.
- Not enough time to complete the event report.
- Fear of having to go to court, testifying, or putting the facility at risk.[41]

**Address barriers**

- Provide organization-wide (including medical staff) educational programs and training on event reporting (initially at orientation, annual programs, special focus topics, and refresher programs).
  - Training should stress that adverse event reports must be factual accounts of what transpired in the event or near miss incident.
  - Accusations, hearsay, and finger-pointing must be avoided.
  - Event reports should be completely documented on the paper or electronic form, immediately or as soon as possible following the event, by the person with the most knowledge of the event.
  - Clinical facts associated with an event must be appropriately documented in the medical record, without reference to the completion of an event report.[42]
- Document clear, concise, and comprehensive policies, procedures, and definitions (with examples) to support the event reporting.[43]
- Develop user-friendly paper event reporting forms or use an electronic or web-based, user-friendly reporting system.[44]
- Implement a structured plan to provide feedback to demonstrate the patient safety value and quality improvement associated with event reporting.[45]
- Replace a punitive culture with an open and supportive culture of event reporting that will facilitate organization-wide learning, improved patient outcomes, and reduced loss exposures.[46]

| Use Risk Management Information Systems (RMIS) | |
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| **Use an RMIS** | • Understand the efficiency that automation brings to risk identification, risk analysis, and risk mitigation. |
| **Evaluate risks** | • Evaluate the common following issues prior to selecting and implementing an RMIS:<br>o Appropriate security levels and data access (i.e., breach protections).<br>o Ease of data entry by event reporter (i.e., user-friendly screens).<br>o Compatibility or integration with existing data systems such as patient information and electronic medical records.<br>o System back-up provisions.<br>o Vendor capabilities for data import/export, software upgrades, training, and system maintenance.<br>o Report generation for multiple internal audiences and external submission requirements.<br>• The RMIS should satisfy the AHRQ's technical specifications and "Common Formats" for reporting to patient safety organizations (PSOs).<br>• Reports should be robust to promote internal statistical analysis and trending.<br>• The ability to customize reporting capabilities to remain current with patient safety nuances and regulatory/accreditation requirements.<br>• Data reports must provide clear and meaningful information.[47] |

| Include Critical Event Data in Event Reports | |
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| **Include data** | • Ensure that the following basic data is included in an event report:<br>o Demographic information related to the patient, visitor, or employee involved in the event, including name, home address, telephone number, and medical record number.<br>o Socioeconomic information regarding the individual involved in the vent, such as gender, age, marital status, insurance, and employment status.<br>o Information related to the visit or admission, including data such as the visit or admissions date, |

## Include Critical Event Data in Event Reports

room number, time of event, date and time of report, and diagnosis or chief complaint.

- Factual description of the event by location and type of event (such as medication event, including name of medication, diagnostic error, treatment error, wrong site/wrong procedure/wrong patient/wrong surgery, elopement, patient fall, visitor slip and fall, lost property), level of injury and results of physical examination by a clinician and findings of an environmental assessment (such as equipment defect, restraint in/not in use, condition of floor).
- Contributing factors known at the time of the event or discovered during the investigation, such as a lack of informed consent, use of unapproved abbreviations, failure to perform a surgical time-out, failure to deliver/receive critical test values in a timely manner, failure to verify a verbal order, and others unique to a particular event.

## Develop Oversight Framework for Risk Identification and Mitigation

**Develop framework**

- Ensure that the healthcare organization has an oversight framework that is charged with risk identification and mitigation and that ensures the safety of patients, visitors, and employees.
- Task a formally organized professional committee with responsibility for monitoring and evaluating the event reporting system.
- Ensure that the committee regularly receives event report data and directs action based upon a review of the data.
- Be certain that the risk management professional, as a member of the committee, receives and processes event reports on behalf of the committee.
- Ensure that the risk management professional consults with the committee chair as needed and prepares individual and aggregate reports for committee consideration.
- Ensure that the risk management professional (on behalf of and under the direction of the committee) understands that they are responsible for sharing relevant information

## Develop Oversight Framework for Risk Identification and Mitigation

with the appropriate organizational leaders and/or medical staff departments upon receiving an event report of concern.

- Be certain that the risk management professional understands that s/he is responsible for making recommendations, as well as facilitating considerations and implementation of the recommended interventions.
- Document actions taken to resolve issues in the form of meeting minutes, memos to staff members, and/or newly developed or revised protocols, policies, or procedures.
- Have a follow-up mechanism in place to evaluate the effectiveness of actions taken.

## Maintain Confidentiality of Event Reporting Documents

**Maintain confidentiality**

- Handle all documentation and communication related to the investigation of an event in a confidential manner.
- Implement a process for timely legal counsel review of event reports if attorney-client privilege is used when litigation is anticipated.
  - House documents in confidential files identified for this purpose.[48]
- Affix a confidentiality statement to the paper event report form and any follow-up forms used if confidentiality protection is pursued using peer, professional, and/or quality review statutes.
- Ensure that documents gathered from the RMIS include a header or footer on every page that includes a confidentiality statement.
- Consult with the organization's attorney for recommendations regarding state laws on the content of the statement of confidentiality and for best practice.
- Do not photocopy an event report or follow-up form or generate multiple copies of an event report from the RMIS.
- Explain to unit managers or other staff members, if they are participating in an investigation, that the original event documentation may be reviewed online or in the risk management professional's office.

## Maintain Confidentiality of Event Reporting Documents

- Ensure that event data are reviewed through an established peer, professional, and/or quality review program; that a policy and procedures clearly addresses this linkage; and that program documents include an appropriate statement of confidentiality.
  - Understand that if this linkage and review process are not operationalized or are inconsistently managed, the statutory privilege may be compromised.[49]

## Develop Relevant Generalized and Specialty Occurrence Screens

**Develop screens**

- Design occurrence screens in consultation with both risk management and quality improvement.
- Develop screens for organization-wide application.
- Develop specialty screens for high-risk areas, such as obstetrics, emergency services, and surgery/anesthesia services.
- Have the occurrence screens approved by medical staff to ensure that the screens are relevant to actual clinical services.
- Direct usage of the screens by having a written protocol that includes assignment of responsibility for screening, as well as a description or outline of how the process is to be followed and how reports are to be prepared and submitted to peer review committees.

**Sample tools**

- ***Generic Screening – Clinical Indicators Policy – SAMPLE*** and
- ***Medical Staff Generic Occurrence Screening Worksheet - SAMPLE*** are available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

**Note significance**

- Take note of the following examples of organization-wide screens with risk management significance, including:
  - Unplanned admission following outpatient treatment.
  - Unplanned readmissions.
  - Unplanned transfers to other healthcare facilities.
  - Neurological impairment not present on admission.
  - Unexpected excessive or multiple transfusions.

## Develop Relevant Generalized and Specialty Occurrence Screens

- Transfusion reaction resulting in compromise/death.
- Significant adverse drug reactions.
- Medication errors resulting in compromise/death.
- Healthcare-associated infections.
- Hospital-incurred trauma.
- Failure to recognized and treat abnormal diagnostic findings.
- All cases of unexpected cardiac/respiratory arrest.
- Equipment failures resulting in injury.
- Unexpected death or disabilities.

- Note the following examples of emergency department-specific screens, including:
  - Failure to diagnose or a misdiagnosis.
  - Inappropriate or ineffective patient hand-off to another area, unit, or staff member.
  - Inappropriate EMTALA transfer.
  - Any patient who leaves against medical advice (AMA) or who left without being seen (LWBS).
  - Patient misidentification.
  - Radiological discrepancies from wet read to final read.
  - Long wait time that affected initiation of treatment in a timely manner.
  - Incidents of violence or assault.
  - Incomplete, missing, or inadequate discharge instructions.[50]
- Direct the reporting of such events to the risk management professional for investigation and follow-up.

## Develop Processes for Informal Reporting

**Develop processes**

- Adopt a standard form for the healthcare organization to document informal reports.
- Clearly identify the form as a referral form which is used by the risk management professional on behalf of the risk/quality management committee for the purpose of

## Develop Processes for Informal Reporting

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| | obtaining information to assist in reducing morbidity and mortality and for improving the quality of patient care.<br>• Be certain that a notation is included that details how the report was received by risk management (e.g., telephone, personal contact, anonymous), whether a response is requested, and comments as to follow-up or referral of the concern.<br>• Include information gathered through informal reporting mechanisms in the centralized database used for the event reporting system.<br>• Enter all data received by the risk management professional so that reports generated for the governing body, administration, medical staff, and/or healthcare organization departments and committees will reflect comprehensive tracking and trending of events in the facility.<br>• Provide examples of reportable events to physicians at the time they join the medical staff.<br>• Have the guidelines for reporting require that all events reported by the physician to his/her medical professional liability insurer be reported to the risk management professional of the healthcare organization.<br>• Include the guidelines for reporting in medical staff rules and regulations to ensure that they are periodically reviewed and approved by the medical staff.<br>• Have the risk management professional initiate an event report or an informal report upon receipt of verbal notification from a physician or another party. |
| **Sample tool** | • ***Quality Assurance/Risk Management Referral Form - SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal. |
| **Encourage employees** | • Encourage administrators, department managers, and staff members to contact the risk management professional directly following serious events even though a written event report will follow. |
| **Notify risk management professional** | • Notify the risk management professional upon receipt of a request for direct release of records to a patient or member of his/her family when a satisfactory statement of purpose or “need to know” information is lacking. |

## Develop Processes for Informal Reporting

- Inform the risk management professional upon receiving a request from a known plaintiff attorney.
- Ensure the risk management professional performs a comprehensive review upon receipt of a request for records known to be associated with an adverse outcome, injury, or other unexpected event.

## Recognize Other Informal Methods for Evaluating Organizational Risk

**Recognize methods**

- Understand that other sources for identifying actual and potential risks to the institution should be routinely considered and addressed by the risk management professional, such as:
  - Committee minutes.
  - Patient safety rounding.
  - Direct observation.
  - Regulatory/accreditation survey reports and private assessments.
  - Patient satisfaction survey results.

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