Risk Management: Event Reporting

What's the Risk?

Event reporting is essential for risk identification and patient safety. It provides information to drive patient safety improvements that will help to protect others from similar risks and to protect the practice from liability claims associated with adverse events.

Without the implementation of a formal event reporting policy and procedures, the office runs the risk of unreported errors, event reports being found or referenced in patient medical records, reports containing inappropriate subjective speculation or statements as to the event's cause, and important process or system changes not being implemented.

Practices that have implemented a culture of safety have an event reporting process that encourages communicating openly and sharing safety concerns. Barriers to reporting come from fear of reprisal and disciplinary action, fear of reporting on a coworker, an unclear reporting policy, and a lack of understanding regarding the purpose of event reporting.

When Is This Risk an Issue?

The primary function of event reporting is to assist in improving the quality of care delivered to patients, reduce morbidity and mortality, and enhance patient safety through performance improvement.

Defining a Reportable Event

Risk management professionals often use three terms interchangeably: occurrence, event, and incident. Coverys has chosen to use the word event. An event is typically defined as a happening that is inconsistent with the routine operation of the healthcare organization/office practice or the routine care of a particular patient. The event may or may not result in an injury or harm to a patient or visitor. If no harm occurred, the event is considered a near miss. Near misses are important in event reporting because the potential for harm is present and needs to be addressed before causing actual harm to a patient.

Without clearly defining what and why to report and educating staff and practitioners on same, you run the risk of underreporting and can miss opportunities for improvement. Be sure to include examples of the types of reportable events, such as falls, medication errors, equipment failures, specimen labeling errors, tardy communication of critical results, lack of adequate follow-up (such as failure to notify a patient of abnormal results), surgical or procedural events, missed or delayed diagnosis, patient complaints, and complications.

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Capture important information by reporting visitor events, such as falls, immediately after they occur. Such information includes the location, condition of the area, and extent of harm, if any, to the visitor. If an injury occurred, the event may trigger a potential general liability claim that will need to be reported to your insurance company.

Injuries to employees impact the practice in lost work time for the injured employee, overtime for other employees, and potential workers' compensation claims. By having an active employee reporting system, events can be identified and corrected to avoid recurrence. Showing concern for employee safety and implementing an employee program help to avoid lost work time and aid in staff retention.

Reporting Events – Just Culture

A successful reporting system requires establishing a culture of safety that recognizes patient safety as the top priority and encourages staff to report errors and near misses. If staff members fear reprisal and punishment, they will not report. A risk identification process focusing on both a systems view and practitioner performance is recommended.

In a "just culture," staff is not reprimanded or punished for systems issues or human error. These issues are instead addressed through systems improvements, revised processes, and/or increased education. Staff members are still held accountable for reckless behavior, conscious disregard of policies and procedures, and causing intentional harm. Managers should ensure that staff members understand what a just culture entails, when they will be held accountable, and when disciplinary/correction action(s) will be taken. Such a process will enable the practice/organization to more fully promote a supportive learning environment and identify opportunities to enhance patient safety and reduce risk.

Verbal, Informal, or Anonymous Reporting

Verbal reporting is preferred when there is a concern regarding event report processing. A practitioner or employee may verbally report an event directly to the risk manager/office practice manager. 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 the risk manager/office practice manager received the report via a telephone call, personal contact, or anonymously.

Pay special attention when a patient or third party directs verbal (or written) complaints to a risk manager/office practice manager, clinic director, or specific practitioner. The party may believe these individuals will promptly consider their concern, especially if there is a potential for litigation. Consulting with caregivers and reviewing the medical record will help the risk manager/office practice manager analyze the litigation risk presented by the complaint, as well as a potential need for disclosure.

Reporting Forms, Design, and Process
Reporting can be done by using a paper form or a computerized event reporting system. One form or template may be used to report all types of events (patient, employee, and visitor) to help small office practices streamline the process. However, having different forms or templates for patient, employee, and visitor allows for more customization to ensure data is captured that is unique to the different types of events. The reporting form can be a barrier to reporting if staff cannot easily access and complete it. See the sample ***Patient or Visitor Event Report***.

Reporting by Staff
Event reporting should be completed by the most knowledgeable person, usually the witness or the one who first becomes aware of the event. It should then be given to the office manager or supervisor to review and obtain any additional necessary information. If the patient requires additional medical support, document this in the medical record. Instruct staff not to reference the actual event report in the medical record or to include the report or its copy in the medical record. Noting or including the report in the medical record may render it unprotected from the discovery process.

Reporting by Practitioners
Practitioners should notify their medical professional liability (MPL) insurer when an adverse event results in harm or injury to a patient. Reporting guidelines may also require practitioners to report events to the risk management professional at the affiliated healthcare organization if the event occurred at that organization. Practitioners should support a culture of safety within their practice by participating in and supporting event reporting. Common barriers to staff reporting are a lack of practitioner support and fear of how a practitioner may react.

Medical Record Audits
Another method to identify events is the practice's regular, concurrent quality and coding reviews of medical records. These reviews develop criteria, such as lack of documented informed consent for an office procedure, review of all unexpected deaths, etc. While this method will detect only those matters that may be identified by medical record review, the timeliness of reporting will encourage early investigation and resolution of identified problems.

Investigation, Tracking, and Analysis
Proper event investigation is critical to understanding the cause(s) and identifying areas for improvement. It begins with the report, which contains factual information around the event. It should not include a subjective narrative or attach blame to others.

Root Cause Analysis
Perform a root cause analysis (RCA) of serious events that cause injury, harm, or additional medical intervention and treatment. This process allows involved parties and others to analyze the event, what led up to it, and the aftermath.

RCA is a process that retrospectively reviews a high-severity event or near miss. Its purpose is to identify and understand the underlying causes and variations that contributed to the event. This identification assists in effectively determining risk reduction and treatment methods to avoid event recurrence. An RCA focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in an organization's processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events occurring in the future.

RCA methodology is based on the philosophy that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms. Directing corrective measures at root causes is expected to minimize the likelihood of event recurrence. However, absolute prevention of a recurrence by a single intervention is not always possible. Thus, RCA is often considered an iterative process and is frequently viewed as a tool of continuous improvement.

RCA is not a single, sharply defined methodology. There are many different tools, processes, and philosophies associated with RCAs. One technique uses the five whys process, an iterative question-asking technique used to explore the cause-and-effect relationships underlying a particular problem. The technique's primary goal is to determine the root cause, which typically requires asking why five times. This allows one to drill down and peel off all the layers of the symptoms to discover the root cause of a problem. It is important to note that although this technique suggests there is just one root cause, this is rarely, if ever, true. Most events involve multiple contributing factors. During this brainstorming session, consider factors that might have been involved, such as human issues, environment/place, equipment, material/supplies, method/procedure, orientation/training, etc.

If a thorough analysis is bypassed without drilling down to uncover potential hidden causes or a conclusion is prematurely made, the opportunity for correcting the real cause(s) of the event may be lost, and the potential for the event to recur remains. Once the causes have been uncovered, actions to correct and prevent the event from recurring can take place. See the sample ***Root Cause Analysis Worksheet***.

Interventions

After conducting an RCA, it is equally important to determine interventions to prevent recurring events. The types of interventions can vary in their strength and effectiveness.
Examples of low-level interventions, which are the least effective, include:

- Increasing training.
- Requiring attention to detail.
- Changing policy.
- Providing audible alarms or caution labels.
- Instituting double-checks.[1]

Examples of intermediate interventions include:

- Redundancy.
- Increase in staffing/decrease in workload.
- Software enhancements.
- Eliminate/reduce distractions.
- Education using simulation-based training.
- Creating a checklist.
- Enhancing communication, such as enforcing a read-back policy.
- Eliminating look-alike and/or sound-alike medications.
- Enhanced documentation to electronic medical records (EMR) software.[1]

Examples of high-level interventions, which are the most effective, include:

- Making physical changes to the environment (for example, changing examination rooms or procedure rooms; adding equipment).
- Using new devices with usability testing.
- Engineering control (forcing function).
- Standardizing equipment or processes.
- Engineering control (forcing function).
- Simplifying procedures or processes.
- Tangible involvement by leadership.[1]

Tracking and Trending

Tracking and trending reported information will assist the risk, quality, or office practice manager and practice quality committee to evaluate patterns and treatment for loss potential and loss prevention strategies. See the sample ***Patient or Visitor Event Report***, which contains an area to document general types of events and allows them to be categorized to facilitate tracking and trending.

Staff Education

Educate staff members on your event reporting policy and procedures. They should understand that reporting is important for the safety of patients, visitors, and fellow staff members. Include education on just culture. In addition, provide education on the staff's role in patient safety, expectations, and when and how to implement the corrective action process. Giving your staff members feedback on improvements that are made in response to reported events will remind them of their responsibility to report, reinforce the importance of the process, and avoid having them feel that reporting is of no value.

Discoverability

Patient and Personnel Files

There is a potential for risk exposure if the event forms and processes are not designed to protect the confidentiality afforded under state statutes. Send the reports (along with any additional forms or documents used in the investigation) to the risk manager/office practice manager upon completion. Do not make copies of the reports or include them in the patient's medical record or in personnel files. While a hospital-owned or large practice may have a designated risk management professional and/or risk management department, smaller practices often do not, so it is important to address who will receive the report. In small offices, reports are typically sent to the office practice manager.

Protection

Performing event reporting under the auspices of a quality improvement or peer review program may help protect the report from discovery and/or admissibility in a court of law, but state laws vary and may not include a practitioner in a small, private practice. Make every effort to protect the information, such as treating the document as a peer review and/or quality improvement document.

Work with legal counsel to review applicable state laws regarding the protection of event reports from discovery and ensure that the event reporting form includes any required statutory citations.

Even when statutes protecting this type of information are in place, protection cannot be guaranteed. Therefore, it is important that only the facts be recorded in the event report.

General Liability Occurrences

General liability information, such as visitor falls, is generally not considered peer/professional/quality review information and is not statutorily protected from discovery. Such a report may be subject to a work product privilege if completed in anticipation of litigation.

Medical Record Requests

Requests for patient records may have risk management significance. It is recommended that a key staff person in the practice be assigned to receive and process such requests after the practitioner has had an opportunity to review the request and pertinent medical records.

Disclosure of Adverse Events, Errors, and Unanticipated Outcomes

Regulatory standards require that patients and, when appropriate, their families be informed about the outcomes of care, including unanticipated outcomes. Paying attention and using care in the disclosure process as to what information is shared with patients and families is important in maintaining protections for peer review, event investigation, and performance improvement actions. See ***Disclosure*** for additional information.

How Can I Reduce Risk?

The following risk management recommendations are offered to assist in implementing and maintaining an effective event reporting program and policy.

Develop a Reportable Event Policy

Have a written policy on reporting an event

- Develop and implement a policy that includes:
  - The purpose for reporting.
  - Definition and examples of a reportable event.
  - Management and staff responsibilities.
  - How the reports are submitted.
  - How the information will be used.

Define "reportable event"

- Recognize that a reportable event is typically defined as a happening that is inconsistent with the routine operation of the healthcare organization or the routine care of a particular patient. Recognize that the event may or may not result in an injury to a patient or visitor. Provide staff and new practitioners a list of reportable events, such as:
  - Falls.
  - Medication errors.
  - Equipment failures.
  - Failure to follow up on critical results, patient complaints, and complications.

Ensure That Events Are Reported

Encourage staff to report all events

- Advise staff to report all events, whether or not they result in injury or represent a potential claim. Prepare the report as completely, accurately, and quickly as possible after the event. Tell staff who should receive the completed report and prohibit copying.

Train and educate employees

- Train employees how to identify reportable events and appropriately complete the required form. Educate medical staff to only document medical assessments and treatment rationale in the medical record.

Ensure That Events Are Reported

Encourage supervisors to complete reports	• Encourage supervisors to complete an event report if they become aware of an issue and to assist staff in appropriately completing reports.
Encourage reporting by medical record reviewers	• Encourage medical record reviewers to report promptly to the risk manager/office practice manager any unusual events identified during the course of conducting regular, concurrent quality and coding reviews of medical records.
Have practitioner support and participation	• Advise practitioners to take an active role in supporting a culture of safety that encourages open communication and event reporting. • Request practitioner participation in RCAs for sentinel events.
Implement ongoing education	• Implement ongoing staff education (at orientation and at least annually thereafter) on what and how to report. Be sure to include temporary and contract employees and students. • Provide feedback at staff meetings on identified issues and implemented improvements.
Sequester devices	• Whenever a device-related event occurs, save the device, including all parts and any attachments. Collect all packaging and supporting information, if possible. Do NOT change the settings. Sequester the product, device, or equipment. Notify the insurance company prior to repair. See the ***Medical Device Event Flow Chart***.

Report Sentinel Events Immediately

Report events immediately	• Immediately report the sentinel event to the risk manager/office practice manager so that the investigation and interventions may be initiated quickly. Some examples of sentinel events are:
	  ○ Unexpected patient death.
	  ○ Significant, adverse outcomes and/or patient injury.
	  ○ Equipment and medical device-related occurrences (e.g., malfunction or electric shock).

Report Sentinel Events Immediately	
	○ Significant procedural or sedation occurrence. ○ Significant medication error.
Instruct practitioners on reporting guidelines	• Instruct practitioners to verbally report all potential claims and unexpected adverse events to their insurance provider. Be aware that the hospital may require a practitioner to promptly notify the hospital's risk manager when an adverse event occurs on hospital premises.
Encourage medical staff to contact the appropriate individual in the healthcare organization	• Encourage practitioners, supervisors, and staff to contact the appropriate individual in the healthcare organization directly following high-risk events, even though a formal report will follow. This provides an opportunity for an immediate investigation.

Protect Event Reports	
Maintain statutory confidentiality	• To assist in maintaining statutory confidentiality, ensure that documents reach the risk manager/office practice manager as soon as possible and are confidentially secured (within 24-48 hours, unless immediate notification is indicated).
Include statutory citations on the form and in the policy	• Print the statutory citations under which the document is protected on the form to reinforce the importance of confidentially handling the document. Address this in a policy.
Do NOT make copies of event reporting documents	• Do NOT make copies of event reporting documents.
Do NOT store event documents in the medical record	• Do NOT store event reporting documents in the patient's medical record. Do NOT provide copies of the report to the patient or third parties.
Do NOT place copies in personnel files	• Do NOT place copies of event reports pertaining to patient incidents in personnel files as a means to document employee errors, mistakes, or issues.
Save event reports and related documents	• Retain event reports and other related documents (for example, investigation documentation and RCA) for 10 years.

Record Events Appropriately

Design the event report form appropriately	• Design the event form so that it does not require a physician to document the patient's physical condition following an accident or adverse event.
Include required information	• Include the following information on the occurrence form: ○ Patient/visitor identification and demographics. ○ Date and time of the event. ○ Date and time of discovery of the event. ○ Date of report and name of reporter. ○ Specific location of event. ○ Type of event. ○ Observable contributing factors. ○ Brief factual narrative entry noting relevant quotes by the patient and/or family after the event. ○ Any observed injury, as directly related to the event, and if needed, additional care provided. ○ Names and contact information of witnesses.
Report appropriate observed clinical information	• Instruct staff to record appropriate observed clinical information regarding the event and any intervention(s) provided in the medical record. Educate staff and physicians to use terms that objectively reflect what happened. Include information related to patient condition, care, treatment plan, and response. Record measures taken after an event to minimize patient injury, such as treatment provided or care plan modifications.
Use check-off system for forms	• Use check-off systems for forms whenever possible.
Limit narrative entries	• Limit narrative entries to brief, objective data, facts, or measurements, except when recording the injured party's actual description of the event. Include relevant quotes, as first-hand information is especially important for visitor or third-party injuries when there is no medical record.

Record Events Appropriately

Record investigative information in risk management file	• In order to maintain applicable statutory confidentiality protection, record other information relevant to the event or to the event investigation in the risk management file.

Assign a Key Staff Person to Medical Record Requests

Assign an appropriately trained staff member	• Assign an appropriately trained staff member to receive and process medical record requests. Train the staff member to identify those records with potential risk management implications and forward them to the practitioner for review. Ensure the staff member is thoroughly acquainted with principles of confidentiality and the policy on release of information.

Implement a Culture of Safety

Promote a culture of safety	• Have patient safety as the core focus for all office procedures and activities. • Encourage open communication, critical thinking, and identification of errors and/or problems.
Implement a just culture approach	• Implement an approach that embraces a just culture. Remember that event reporting is not intended to place blame. Investigate events to identify system areas that need improvement and/or knowledge deficits that require additional education or training. Ensure that staff members are held accountable when they display reckless behavior, take risks, or intentionally disregard policies and procedures.

Perform RCAs for High-Severity Events or Near Misses

Perform a thorough investigation	• Have the risk manager/office manager perform a thorough investigation and gather all information related to the event.
Organize a multidisciplinary team	• Organize a multidisciplinary team, including those involved in the event and others; for example, facilitator, practitioner, supervisor/manager, and other staff members. Have the facilitator set ground rules. Explain the meaning and purpose of an RCA.

Perform RCAs for High-Severity Events or Near Misses	
Describe the event	• Describe the event in detail to facilitate a complete analysis. Include the steps leading up to the event, the event itself, and the aftermath. Proceed in chronological order to help identify the cause and effect.
Identify root causes	• Identify root causes by utilizing the five whys technique described in the section titled ***Root Cause Analysis Worksheet***.
Determine interventions based on an RCA	• Determine interventions to prevent the events from recurring.
Develop an action plan	• Develop an action plan for implementing the identified interventions. Create a timeline and determine ownership. Modify the action plan as necessary.
Evaluate results	• Evaluate the action plan to determine whether the interventions have successfully prevented additional events. Modify, eliminate, or add interventions as necessary.
Share lessons learned	• Share lessons learned with staff and elicit feedback.

References:

1. National Patient Safety Foundation. *RCA^2 Improving Root Cause Analyses and Actions to Prevent Harm*; 2015. https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx.