Reducing Risk

A Publication on Healthcare Risk Management from Princeton Insurance

Guide to Investigating Events in the Physician Practice

*Note: This **Reducing Risk Resource** article is directed to the physicians and management staff who have responsibility for risk management at office-based physician practices, ambulatory care centers, and radiology centers. For the sake of brevity, whenever the term "physician practice" is used throughout this article, it is intended to apply as well to ambulatory care and radiology centers. In the article, it is assumed that the physician practice has established procedures for reporting an incident or adverse event, and "near-misses" (collectively, "events"). Decisions about content and format of event reporting forms, types of events required to be reported, and by whom, as well as policies for analysis and dissemination of information obtained, are beyond the scope of this article and therefore not addressed.*

Introduction

This article presents practical guidelines for investigating unexpected events that happen during, or as a result of, care provided in the physician office practice setting. It also discusses some of the reasons for undertaking internal investigation of these events.

Surveys have shown that approximately 80 percent of ambulatory care in the U.S. is provided in office-based physician practices.[1] The number of annual patient visits to physicians has also been increasing. As the delivery of medical care and services has grown, so too has the need to introduce risk management and patient safety principles into the physician practice setting.

Event Reporting

Event reports have historically been, and continue to be, a basic risk management tool that can help to identify unexpected events, injuries, and potential claims. Such reports help give early notice of not only negative outcomes but also "near-misses" that may happen in the complex course of a patient's healthcare experience. *See downloadable PDFs of sample Event Report Form* and *Instructions for use in your office*:

Healthcare practitioners use a variety of terms to describe events that are or should be reported. The list includes, but is not limited to, the following: events, incidents, variances, occurrences, adverse events, errors, near-misses, and potentially compensable events ("PCEs"). In this article, we will use the term "event" to refer to instances/situations which typically warrant being reported for risk management purposes. However, many other definitions have been put forth, such as this broad description: "any circumstance that is unexpected within the normal operations of the institution or the anticipated disease/treatment process of a patient." Another approach states it as simply "injuries related to medical management."[2] A "near-miss" refers to an unplanned event that did not, but could have, resulted in personal injury or property damage. And finally, the Joint Commission uses yet another term - "sentinel event" - which it defines as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."[3]

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1 Cherry DK, Wood well DA. National Ambulatory Medical Care Survey: 2000 Summary [online] 2002 June 5. Available from Internet: http://www.cdc.gov/nchs/data/ad/ad328.pdf. [Also from ECRI-HRC-Out-Patient Settings 2, July 2003]

2 Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324(6):370-6.

3 The Joint Commission: Sentinel event policy and procedures [Online] 2006 October. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

An effective event reporting education program should give staff an understanding of the situations when a report should be completed and by whom. Event report forms are most effective when completed by the person who first becomes aware of or witnesses the event. The clinical facts surrounding an event should always be documented in the medical record. However, the actual reports should never be placed in or alluded to in the medical record.

Some physician practices may have experience with event reporting in general, or as a means of communicating adverse events to their insurance carriers. Many, however, have not routinely done so. Moreover, staff assigned the responsibility of trying to manage risks and patient safety in a physician practice, in contrast to a hospital environment, will encounter challenges arising from differences in office cultures, types of risk exposures and level of safety knowledge and interest among personnel. A survey commissioned by the Accreditation Association of Ambulatory Health Care's Institute for Quality Improvement revealed that only one-third of the respondents indicated that they report and collect information on adverse medical events, and most of these were not physician practices, but ambulatory surgery centers.[4]

We also note that many states, including New Jersey, have enacted laws that mandate reporting of specific types of medically related adverse events that occur in licensed health care facilities in the state to the governing authority for healthcare oversight. In general, state reporting requirements will apply to large surgical centers or ambulatory care facilities that are licensed by the state, but not to physician practices.

Conducting an Investigation

As part of implementing a risk management and patient safety program, each physician practice will need to implement its own policies and procedures for event reporting, investigation and analysis of data collected from events, and follow-up improvement and monitoring mechanisms. We offer the following suggestions to assist the practice manager or other designated individual responsible for investigating events.

- Policy should state and staff should be trained to notify the practice manager (or other designated individual) promptly of any injuries, loss of life, and/or criminal acts, and defer to appropriate people to contact law enforcement or regulatory agencies.
- Ensure that any injured patient(s) or visitor(s) get prompt medical attention. Safeguard other personnel in the area, if needed.
- Secure the area, and protect (under lock if possible) any physical evidence that could be important later.
- Collect as much information as possible about the area before, during, and after the event:
  - Inspect the incident site immediately, but do not disturb the site unless it presents a hazard.
  - Identify and interview key affected healthcare workers, patients, and witnesses. Identify the physician to whom the event was reported (if applicable) and that physician's response (orders given).
  - If the event was not witnessed, try to speak with others, such as your office staff, co-workers, or relatives, who might have interacted earlier with the person involved.
  - Take photographs and measurements; sketch key aspects of the site; secure surveillance videotape, if available.
  - Collect physical evidence and samples for laboratory analysis, if applicable. Physical evidence includes:
    - Position of injured patients or visitors.
    - For device/equipment related events, record pertinent serial numbers, manufacturer and model names, settings at time of event; safety or warning devices and/or personal protective equipment that was in use.
    - Materials being used at the scene, including medications/injections/anesthesia/chemicals (records of doses, etc.).
    - Condition of environment: lighting, temperature, smoke, dust, mist, fumes; housekeeping and sanitation conditions (e.g. spilled liquid on floor or other involved surfaces).

Additional Points to Remember

The person conducting the investigation (after an event has been reported) and preparing a follow-up report should try to look back over the entire sequence of events that led to the event (with or without injury), going as far back in time as the investigator feels is

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[4] American Health Consultants Ambulatory Care studies show room for concern and comfort. Healthcare Benchmarks 2001 Oct. 8(10): 109-11. [See FN 13 in ECRI-HRC Analysis; vol. 3, Out-Patient Settings 2 - "Overview: managing Risks in Physician Practices"; July 2003.]

relevant, rather than focusing only on the injury. This allows an organization to identify and implement a wider variety of potential actions to continually improve patient care.

Staff should treat any and all documents generated as part of the follow-up investigation as strictly confidential, to optimize opportunity for legal protection. All information obtained in the investigation should be maintained in a separate file, and never placed in the patient's medical record.

As with event reporting, persons with responsibility for preparing investigation follow-up reports should state facts only, not personal opinions, assumptions, or conclusions.

The practice manager or other designated individual should consider seeking advice and guidance from legal counsel about the design of follow-up reports and how to standardize follow-up procedures.

Collect background information after immediate investigation at the site (appropriate to event):
- Employee records: training information, licenses, certifications, and employment records
- Equipment records: maintenance logs, service reports, work orders, operating manuals, and manufacturer instructions
- Previous incident reports (involving same patient, device or equipment)
- Weather reports (as relevant to location of event)
- Review existing documents, including: material safety data sheets (MSDS), job safety analyses, safety audit results, safety committee minutes, product/equipment specifications, equipment maintenance records, policies and procedures, floor plans/mechanical drawings and blueprints.

Interviewing Tips
- Conduct interviews of staff, witnesses and others involved while details are still fresh to them.
- Be a good listener.
- Keep in mind that the focus is on prevention, so ask open-ended questions.
- Get the facts, without placing blame or expressing opinions.
- Pay attention to unsolicited comments.
- For important points, repeat back what you heard to clarify and confirm facts.

Timing
- Each investigation should be conducted as soon after the event as possible. A delay of only a few hours may permit important evidence to be destroyed or removed, intentionally or unintentionally.
- The designated investigator or committee should present the results of the inquiry as quickly as possible to all staff; this enhances the value of safety education for clinical and non-clinical staff.

After Investigation: Analyze and Learn
The ultimate objectives - and value - of investigating events are to:
- Identify the contributing factors and root cause(s) of the reported events;
- Learn lessons that will help prevent similar events or near-misses from re-occurring;
- Support efforts to eliminate and control those factors.

After a thorough investigation (as outlined above) has been completed, and the necessary reports have been written and submitted (per internal procedures and externally mandated requirements), the practice manager or other designated individual(s) should consider the following actions:
- Analyze the data collected in the investigation to determine possible causes.
- Use aggregate event data (types, numbers of events, locations, etc) to identify and uncover trends in organizational risks. Provide findings from aggregate data analysis to appropriate clinical and non-clinical management of the practice.
- Use findings to develop risk prevention and safety strategies. Develop a system to measure the effectiveness of corrective actions implemented and revise as needed.
- Give staff feedback on findings of data analysis and results of their risk-reduction efforts.

Follow-up Reports and Legal Protection

NJ law does not protect adverse event or follow-up reports from discovery during legal proceedings, with limited exceptions.[5] Nevertheless, fear of discovery of documents should not prevent the practice manager investigating events and recommending corrective action to improve patient care and overall safety. Moreover, not correcting a known hazardous condition can place staff and patients at risk. It can also make a subsequent claim against the practice more difficult to defend.

In the absence of statutory protection, practice managers or other designated individuals should consider the following actions:

- Consult with legal counsel on follow-up report design.
- Implement standardized investigation and documentation procedures.
- Educate all clinicians and staff on the importance of recording only objective, factual information.
- Discourage staff from making personal notes, or writing private recollections, opinions, or accusations that might later be used against the organization or provider in a lawsuit.
- Inform their legal counsel of staff members who have direct knowledge of an event.

Potential Benefits

In return for the time, effort, and costs expended in conducting a thorough event investigation, the physician practice may find there are benefits to be gained.

- Predict and Protect: Collecting information about the type and number of events in the practice will enhance the ability to predict future occurrences, and then enable the practice to take preventative actions that will better protect patients and visitors from similar risk. It can also help protect the practice from future claims and lawsuits, thus avoiding financial loss.
- Correct and Improve: The information allows the practice to make system improvements. It also demonstrates management's commitment to safety.
- Defend: Timely reporting allows the practice manager or other designated individual to do a thorough investigation. This in turn will allow a quick response to the event and provide valuable information that will support a defense in case of a future lawsuit.
- Educate: Knowledge of types, numbers, and severity of events will enable management to develop more effective, targeted educational programs. The staff's heightened awareness of events can also help to reduce or avoid recurrence.

In summary, effective event investigations can have a significant impact on both risk reduction and patient safety for the physician practice.

For more information about reducing risk at your practice, please view our risk management newsletter at www.RiskReviewOnline.com. To access additional Reducing Risk documents, visit our website at www.PrincetonInsurance.com and click on "Risk Management - Publications."

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5 Reports made in compliance with the NJ Patient Safety Act (N.J.S.A. 26:2H-12.23-12.25), enacted in April 2004, effective Oct. 2004, are protected from discovery. This law requires a health care facility to report to the Dept. of Health and Senior Services (DHSS) every "serious preventable adverse event" that occurs in the facility. The Act is applicable only to licensed health care facilities in NJ, including general, long term care and mental health hospitals, and their licensed ambulatory care and satellite facilities. Thus, most physician practices would not have to comply with, nor be protected by, this law.