ProAssurance
Treated Fairly

KEY considerations
For Healthcare Organizations

PROMOTING PATIENT SAFETY • PROVIDING SOUND ADVICE • PLEDGING TREATED FAIRLY

VOLUME 14 • SPRING 2021

Adverse Event Reporting

Have We Moved the Needle on Patient Safety?

Author: Lisa Hallman, Senior Risk Resource Advisor

The reports are key to the development of risk mitigation strategies designed to create a safer environment for patients, physicians, and staff.

The reporting of unusual occurrences and adverse events has been a staple of the risk management plan in hospitals and healthcare facilities for many years. Incident and event reports, whether written or oral, are a means of alerting hospital leaders to potential or actual patient harm. These reports are critical to the ongoing identification of risk and the investigation of the circumstances that led to an adverse event. The reports, too, are key to the development of risk mitigation strategies designed to create a safer environment for patients, physicians, and staff. Additionally, the incident report, and the information it contains, is a valuable alert to potentially compensable events and the need for disclosure discussions.

The Centers for Medicare and Medicaid Services (CMS) require hospitals to track adverse patient events through the Conditions of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI). The Joint Commission mandates all hospitals employ a voluntary error reporting system, and requires hospitals to conduct a root cause analysis (RCA) under certain circumstances, such as a sentinel event. The Joint Commission also requires hospitals to complete one prospective risk assessment every 18 months, typically through performing a Failure Mode and Effects Analysis (FEMA). This risk assessment seeks to identify all possible failures in a process by analyzing each step, thereby allowing corrective actions to be taken proactively before a patient is harmed.

Recognizing the value of incident and adverse event reporting, the process was elevated with the advent of the Patient Safety Quality Improvement Act of 2005 (PSQIA). The shift to value-based reimbursement of healthcare also enhanced the importance of adverse event reporting. Value-based reimbursement can increase the financial impact on an organization, and serves as an incentive for hospitals to rectify known conditions that contribute to patient harm. A recent American Health Law Association (AHLA) briefing noted the following: "Patient safety is not only a policy issue but also an economic one. Healthcare organizations face the high financial costs of patient harm on an annual basis. Based on recent studies, evidence suggests that 15% of hospital expenditure and activity can be attributed to treating safety failures."[1] The Florida-based Adventist Health System has hospitals in multiple states, and attributes a savings of $108 million over three years to their patient safety initiatives.[2]

While hospital-specific event reporting systems offer single organizations the ability to collect, track, and analyze their incidents, the Patient Safety Organization (PSO) program offers similar, and additional benefits, on a much larger scale.

Continued on page 2

Continued from page 1

Adverse Event Reporting

Created through the PSQIA of 2005, this program establishes a means of collecting, aggregating, and analyzing adverse event information submitted by providers of healthcare with additional confidentiality protections.[3] The PSO program elevates the importance of adverse event reporting through the collection and aggregation of large amounts of related information for de-identified analysis. The result is the ability to educate healthcare providers on ways to reduce the incidence of adverse events.

Participation in a PSO will not entirely replace the hospital-specific event reporting process. Less significant events and near misses will likely not be reported to a PSO but are important in managing organizational risk. Event reporting has evolved over the years from a hardcopy paper form or a hotline to an electronic format that allows immediate notification to the risk manager and unit leader. The electronic format has the added advantage of compiling and categorizing details for analysis in an easily reportable manner. A PSO may collect data in various formats, but the data needs to be converted to a Common Format for large-scale data aggregation and analysis. Not all PSOs use the Common Format, which prevents their data from being utilized in large scale data analysis.[4]

Incidents or adverse events are most often reported by frontline staff who discover an error, a near miss, or witness an incident. A near miss or close call is defined by the Joint Commission as "a patient safety event that did not reach the patient."[5] Near misses are extremely valuable in alerting staff and leaders to circumstances that could be harmful and putting risk reduction strategies in place to prevent that harm.

Factors that influence incident or adverse event reporting by staff include time, an understanding of what constitutes an incident and adverse event, the ease-of-use of the reporting tool, and feedback from the reports they make, with a culture of safety of critical importance within the organization. A culture of safety includes non-punitive reporting with the objective of reducing the incidence of harm—not individual staff punishment for a near miss or error. All errors are not blame-free, however, and staff should be held accountable for reckless or at-risk behaviors. Intentional deviation from established policies, procedures, and safety protocols require coaching or discipline of the employee.

Ease-of-use is one of the most important factors leading to the success of a reporting program. The multiple responsibilities of front-line staff require the reporting to be completed in a timely and efficient manner. Systems and processes must be intuitive and simple enough to use, even if not accessed frequently. Events are often easier to track when entered into a software program. Whatever method is chosen, a hospital should make sure it works for the stakeholders in the organization.

Near misses are extremely valuable in alerting staff and leaders to circumstances that could be harmful and putting risk reduction strategies in place to prevent that harm.

Feedback to staff following the reporting and investigation of an incident or adverse event is important to continued reporting. Factors tempering feedback include employee privacy, patient confidentiality, and professional peer review. Feedback that informs staff of process changes as a result of event reports is appropriate. Hospitals may have reward programs for staff and physicians who report events and near misses that contribute to patient safety.

In addition to the incident and adverse event reports, patient complaints may alert an organization to circumstances that contribute to patient harm. Investigation of patient complaints may lead to process changes that enhance patient safety.

Confidentiality and legal protections on a national scale are a significant benefit afforded by the PSQIA through the formation and voluntary participation in a PSO. An Office of Inspector General (OIG) report found that 97% of hospitals that participate in a PSO find it valuable.[6] To gain the full benefit of these protections, the information submitted to the PSO must comply with specific regulations, such as having a Patient Safety Evaluation System (PSES) in place to handle the Patient Safety Work Product (PSWP).[7] The legal protections have been tested in state courts across the country with mixed results.[8]

All states and the District of Columbia have enacted peer review privilege statutes. State laws vary in the specifics of their protections. Healthcare organizations should work with their legal team to understand and comply with the applicable state statutes. For example, one Indiana appellate court has opined, "the purpose of the peer review statute is to foster effective review of medical care."[9] Providing complete confidentiality in this process enables peer review members to speak "candidly, objectively, and conscientiously" without worrying about potential litigation. Like many other state peer review statutes, Indiana's peer review statute also prohibits anyone involved in the peer review process from revealing any information regarding the communications, records, or determinations of a peer review committee.

While Indiana state law protects the confidentiality of information discussed in the peer review committee, it does not protect the confidentiality of final actions taken concerning a particular provider. Final actions may include modification, restriction, or termination of physician privileges. Final actions are discoverable and may be used in litigation, while peer review discussions that led to the amendment of privilege remain protected.

Continued on page 3

Continued from page 2

Adverse Event Reporting

Tennessee enjoys one of the broadest protections of quality improvement and peer review information in the country. Its peer review statute allows an organization "to evaluate the safety, quality, processes, costs, appropriateness or necessity of healthcare services."[10] It is important to note that actions that are not for the purpose of an "evaluation" may not be privileged. Additional items not protected by the quality privilege include outside literature or guidelines to discern whether or not care delivered was appropriate. Peer review information may also be discoverable if it is removed from the quality context and placed in a provider's credentialing file.

Quality improvement committees may also have confidentiality protections. These protections generally extend to incident reports that relate specifically to patient care. In contrast, meetings to discuss adverse outcomes can be discoverable if they are not conducted through a peer review process or quality committee.

Healthcare organizations should consult with an experienced healthcare attorney to ensure their medical staff bylaws, rules and regulations, and committees designed to address patient safety align with state and federal statutes. If the organization participates in a PSO, a healthcare attorney can advise on how to obtain the greatest confidentiality protection from applicable federal regulations.

In addition to improving quality and patient safety, event reporting can play a critical role in loss reduction. By learning about incidents and adverse events early, an organization can begin investigating and implement risk mitigation activities.

Warning signs of a potential claim include the following:

- A serious adverse event
- Complications from care
- Staff concerns about care
- Patient complaints
- Notification of an investigation from a state licensing board

Contact ProAssurance Risk Resource or claims intake if you are presented with a legal action or suspect a claim may arise from an event.

Given the significant value of incident and adverse event reporting, what has been learned of the impact on patient safety and harm prevention? A 2015 study using England's National Reporting and

Learning System (NRLS) data found that hospitals where staff reported more incidents had fewer litigation claims.[11] Supportive learning environments and a shift away from a culture of blame to a culture of safety support a robust adverse event reporting system. The results of the OIG PSO report indicates that PSO participating hospitals highly value the resources and data analysis, and believe they have made measurable improvement in patient safety.[12] As former British Health and Human Services Secretary Jeremy Hunt said, "A thousand worries prevent the one thing that really should be happening, which is proper learning from that mistake and a proper attempt to make sure it can never be repeated."[13]

Endnotes

1 Beyond Quality and Safety: How Patient Safety Organizations Impact Business and Financial Outcomes. February 14, 2020. Janice Suchyta, American Health Law Association.

2 Adventist Review. March 27, 2015. Andrew McChesney. Accessed December 31, 2020 at https://www.adventistreview.org/church-news/story2476-adventist-health-system-saves-$108-million-by-improving-patient-safety.

3 Patient Safety Organizations: Hospital Participation, Value, and Challenges. September 2019. Murrin, Suzanne, Office of Inspector General (OIG), U.S. Department of Health and Human Services.

4 Patient Safety Organizations: Hospital Participation, Value, and Challenges. September 2019. Murrin, Suzanne, Office of Inspector General (OIG), U.S. Department of Health and Human Services.

5 Sentinel Events (SE). CAMH Update 2, January 2016. Accessed December 31,2020 at https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/assetmanager/camh_24_se_all_currentpdf.pdf.

6 Patient Safety Organizations: Hospital Participation, Value, and Challenges. September 2019. Murrin, Suzanne, Office of Inspector General (OIG), U.S. Department of Health and Human Services.

7 AHRQ. Patient Safety Organization (PSO) Program. September, 2019. https://www.pso.ahrq.gov/resources. Accessed on 1/3/2021.

8 Patient Safety Organizations: Hospital Participation, Value, and Challenges. September, 2019. Murrin, Suzanne, Office of Inspector General (OIG), U.S. Department of Health and Human Services.

9 Terre Haute Regional Hosp., Inc. v. Basden, 524 N.E.2d 1306 (Ind. Ct. App. 1988).

10 TN Code § 68-11-272 (2012)

11 Howell A-M, Burns EM, Bouras G, Donaldson LJ, Athanasiou T, Darzi A (2015) Can Patient Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National Reporting and Learning System Data. PLoS ONE 10(12): e0144107. https://doi.org/10.1371/journal.pone.0144107.

12 Patient Safety Organizations: Hospital Participation, Value, and Challenges. September 2019. Murrin, Suzanne, Office of Inspector General (OIG), U.S. Department of Health and Human Services.

13 How Hospitals Can Increase Patient Safety Event Reporting [Web log post]. (n.d.). Retrieved from https://www.origamirisk.com/resources/blog-post/how-hospitals-can-increase-patient-safety-event-reporting. Accessed September 2, 2020.

Key Considerations is published twice annually by ProAssurance's Risk Resource department

Phone: **844-223-9648**
Email: **RiskAdvisor@ProAssurance.com**

Policyholders may find Risk Resource articles and information archived on our website: ProAssurance.com/Newsletters.

PROASSURANCE. Treated Fairly

M5229