



System Safety in Healthcare

by Dev Raheja and Maria C. Escano, M.D.

Reporting Patient Safety Incidents to Prevent Risk of Harm

“Incident reporting” is frequently used as a general term for all voluntary patient safety event reporting systems which rely on those involved in patient care. Initial reports often come from frontline personnel directly involved in an event or the actions leading up to it (e.g., the nurse, pharmacist or physician caring for a patient when an error occurred). Voluntary event reporting is therefore a special form of surveillance for near misses or unsafe conditions that are unlikely to show up in formal surveys [Ref. 1]. The purpose of incident reports is to help identify potential and actual risks and, thus, mitigate hazards. Incident reports also alert risk managers to potential lawsuits. They are generated for at least five types of medical errors: near misses, adverse events, intentional unsafe acts, never events and sentinel events. These events may affect any person on the premises, including patients, employees, physicians, visitors, students or volunteers. Incident reporting serves to describe incidents that are unexpected, unusual or out of the ordinary routine of a health care facility’s operations, whether or not they cause injury. The reports can include a variety of things: patients unable to tolerate side effects of medication, family members failing to use a caregiver’s instructions or family members becoming upset at the quality of healthcare.

Requirements of an Effective Reporting

According to the Agency for Healthcare Research and Quality (AHRQ) [Ref. 1], an effective event reporting system should have four key attributes:

- The institution must have a supportive environment for event reporting that protects the privacy of staff who report occurrences.
- Reports should be received from a broad range of personnel.
- Summaries of reported events must be disseminated in a timely fashion.
- A structured mechanism must be in place for reviewing reports and developing action plans.

“The purpose of incident reports is to help identify potential and actual risks and, thus, mitigate hazards. Incident reports also alert risk managers to potential lawsuits. They are generated for at least five types of medical errors: near misses, adverse events, intentional unsafe acts, never events and sentinel events. These events may affect any person on the premises, including patients, employees, physicians, visitors, students or volunteers.”

While traditional event reporting systems have been paper based, this reference suggests web-based systems that can also receive information from electronic medical records (EMRs). Special systems have also been developed, such as the Intensive Care Unit Reporting System and the Surgical and Anesthesia-Related Errors. The reference also states: “Voluntary event reporting systems are generally confidential, in that the identity of the reporter is known, but legal protection is provided unless professional misconduct or criminal acts took place. Some systems, such as the ICU Safety Reporting System, are entirely anonymous — neither the patient nor the reporter can be identified.”

The reference points out a 2008 study of more than 1,600 U.S. hospitals that evaluated their event reporting systems using these criteria and concluded that “according to these standards, most hospitals do not maintain effective event reporting systems. In addition to lack of physician reporting, most hospitals surveyed did not have robust processes for analyzing and acting upon aggregated event reports. Failure to receive feedback after report-

ing an event is a commonly cited barrier to event reporting by both physicians and allied health professionals.”

Major Limitations

The reports supply the number of events of a particular type, but do not supply the number of patients vulnerable to such an event for calculating the percentage of patients at risk. Therefore, the Incidence Reporting System (IRS) has the following limitations, according to a National Institute of Health (NIH) report [Ref. 2]. They are:

- IRS can't be used to measure safety (error rates)
- IRS can't be used to compare organizations
- IRS can't be used to measure changes over time
- IRS generate too many reports
- IRS often don't generate in-depth analyses or result in strong interventions to reduce risk
- IRS are associated with costs

IRSs do offer significant value. The report points out that while IRS are relatively new in healthcare, similar systems in the nuclear, railway, fire and aviation industries have had tremendous success.

System-Wide Progress

According to the NIH, [Ref. 2], The Institute of Medicine (IOM) advocates for the development and use of IRS. The IOM recommended the following:

- **Recommendation 5.1:** *A nationwide mandatory reporting system should be established that provides for the collection of standardized information by governments about adverse events that result in death or serious harm.*
- **Recommendation 5.2:** *The development of voluntary reporting efforts should be encouraged.*

The Joint Commission now requires that all hospitals have and use IRS. In order to be a valid measure of the rate of adverse events, a measure requires three things. There should be a clear definition of the event (numerator); few adverse events in healthcare are well defined. There should be a clear definition of the population at risk (denominator); the population in healthcare is usually not defined. Finally, there should be a consistent surveillance system for detection of both the event and the population at risk. IRSs have a problem in all three of these areas.

The Office of Health and Human Services (HHS) reports more progress by the government agencies [Ref. 3]. It provides procedures and examples of incident reports, in addition to the following updates:

- Hospitals must track and analyze instances of patient harm as a condition of participation in the Medicare program. In a 2010 report, the Office of the Inspector General found that 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays that resulted in prolonged hospitalization, required life-sustaining intervention, caused permanent disability or resulted in death. An additional 13.5 percent experienced temporary harm events that required treatment.
- Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. We defined “adverse events” as “significant harm experienced by patients as a result of medical care.” We defined “temporary harm events” as “harm that required medical intervention but did not cause lasting harm.”
- Hospitals use incident reporting systems to monitor adverse events and other patient safety issues. Reports include adverse events, “near-misses” or situations with the potential to harm patients.
- Hospital administrators we interviewed explained that they rely heavily on incident reporting systems to identify safety problems. Administrators from all 34 hospitals indicated that they rely on incident reporting systems to capture much of the information used to conduct patient safety improvement activities.

The Agency for Healthcare Research and Quality (AHRQ) Primer includes so-called “never events” [Ref. 4]. According to this primer, the term “never event” was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability) and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into seven categories: surgical, product or device, patient protection, care management, environmental, radiologic and criminal. A 2013 study estimated that more than 4,000 surgical “never events” occur yearly in the United States.

The Joint Commission has also included a “sentinel events” requirement in the incidence reports [Ref. 5]. A “sentinel event” is defined by The Joint Commis-

Table 1 — Reporting of Sentinel Events.

Main Sentinel Events Reported to the Joint Commission in 2015	
Type of Event	Number of Events
Unintended Retention of a Foreign Body	123 (13.14%)
Wrong-patient, wrong-site, wrong-procedure	121 (12.93%)
Suicide	98 (10.47%)
Fall	95 (10.15%)
Delay In Treatment	82 (8.76%)
Op/Post-op Complication	82 (8.76%)

sion as “any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient’s illness.”

“Sentinel events” include “unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof” and all of the following, even if the outcome was not death or major permanent loss of function:

- Infant abduction, or discharge to the wrong family
- Unexpected death of a full-term infant
- Severe neonatal jaundice (bilirubin over 30 milligrams/deciliter)
- Surgery on the wrong individual or wrong body part

- Instrument or object left in a patient after surgery or other procedure.
- Rape in an acute-care setting
- Suicide in an acute-care setting, or within 72 hours of discharge
- Hemolytic transfusion reaction due to blood group incompatibilities [Ref. 1]
- Radiation therapy to the wrong body region or 25 percent above the planned dose

Incident reporting has much potential to improve patient care, especially when instituted in an environment motivated by learning and collaboration, while promoting transparency and effective proactive solutions. ●

References

1. Agency for Healthcare Research and Quality. “Reporting Patient Safety Events,” <https://psnet.ahrq.gov/primers/primer/13/voluntary-patient-safety-event-reporting-incident-reporting>, June 2017.
2. National Institute of Health. “What to do With Healthcare Incident Reporting Systems,” *Journal of Public Health Research*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147750/>, December 1, 2013.
3. Department of Health and Human services. “Hospital Incident Reporting Systems Do Not Capture Patient Harm,” <https://www.oig.hhs.gov/oei/reports/oei-06-09-00091.pdf>, accessed July 7, 2018.
4. Agency for Healthcare Research and Quality. “Never Events,” <https://psnet.ahrq.gov/primers/primer/3>.
5. Wikipedia. “Sentinel Event,” https://en.wikipedia.org/wiki/Sentinel_event, accessed July 7, 2018.