How a System for Reporting Medical Errors Can, and Cannot, Improve Patient Safety

John R. Clarke, MD

From the Department of Surgery, Drexel University, Philadelphia, Pennsylvania; Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, Pennsylvania; and Pennsylvania Patient Safety Reporting System, Harrisburg, Pennsylvania

ABSTRACT

The Institute of Medicine (IOM) has recommended systems for reporting medical errors. This paper discusses necessary components of patient safety databases, steps for implementing patient safety reporting systems, what systems can do, what they cannot do, and motivations for physician participation. An ideal system captures both adverse events when care harms patients and near misses, when errors occur without any harm. Near misses signal system weaknesses and, because harm did not occur, may provide insight into solutions. With an integrated system, medical errors can be linked to patient and team characteristics. Confidentiality and ease of use are important incentives to reporting. Confidentiality is preferred to anonymity to allow follow-up. Analysis and feedback are critical. Reporting systems need to be linked to organizational leaders who can act on the conclusions of reports. The use of statistics is limited by the absence of reliable numerators and denominators. Solutions should focus on changing the cultural environment. Patient safety reporting systems can help bring to light, monitor, and correct systems of care that produces medical errors. They are useful components of the patient safety and quality improvement initiatives of healthcare systems and warrant involvement by physicians.

Medical errors became identified as a significant problem in the delivery of health care by the Institute of Medicine (IOM) with their report To Err is Human. Safe care, free from iatrogenic injury, has become a component of healthcare quality. To fix the problems causing iatrogenic injury, one must be aware of the nature of the problems, make systemic changes, and monitor the effects of the changes. The IOM has recommended the implementation of systems for reporting medical errors, aggregating them, analyzing them, and using analyses to drive improvement. These recommendations motivated the national Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). The act provides confidentiality for reports of medical errors to accredited patient safety organizations that provide feedback on how to improve healthcare delivery systems.

State legislators and public advocates have concurrently been motivated to require statewide reporting, aggregation, and analysis of medical errors. As of 2005, 23 states require some reporting of medical errors. Eight of these states have patient safety reporting systems that aggregate reports, analyze them, and provide some feedback. Many of the states specifically require reporting of sentinel or “never” events as defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF). Some have broader definitions of iatrogenic injury than events that “must” be caused by error. Pennsylvania requires reporting of near-miss medical errors, even though they did not result in patient harm.

In addition to the existing state patient safety reporting systems and the JCAHO sentinel event reporting system, some large healthcare organizations have their own reporting systems. Most notable are those for the Veterans Affairs (VA) medical centers and the University HealthSystem Consortium (UHC) Patient Safety Network (PSN).

This paper will discuss necessary components of a patient safety database, important steps for implementing a patient safety reporting system, what a system can do, what it cannot do, and motivations influencing physician participation. Patient safety is a component of quality care. The process of delivering quality care includes providing care associated with the best outcome, not providing care that is not associated with the best outcome, providing it within the optimal period of time, and successfully delivering it as intended. Succinctly, it is doing the right things—and only the right things at the right time and in the right way. At surgical Morbidity and Mortality conferences, transgressions in the process of delivering quality care are called errors of omission, errors of commission, errors of timing, and errors of technique.

The outcomes of errors can be described as preventable
adverse events, when the error harms the patient, and near misses, when the error does not harm the patient. Near-miss events may not harm patients because of barriers that prevent harm from the errors, identification and correction of the errors by healthcare providers (or patients) before the patients are harmed, mitigation of the effects of the errors, or chance.

Recommendations have been made to include all adverse events, or harm from medical care, rather than just preventable adverse events, harm from errors in the delivery of medical care in patient safety reporting systems. The rationales include the effort involved in determining if an adverse event is preventable and the ultimate goal of reducing all adverse events, not just those resulting from errors.

Safety experts advocate collecting near misses on the assumption that errors that do not harm patients are signals of weaknesses in the system that may ultimately result in harm. Because harm did not occur, near-miss events may provide insight into solutions to the problems. Near-miss events are more common than preventable adverse events. Although certain harmful events—such as wrong-site surgery—may be rare, near-miss reports increase awareness of the constant potential for disaster.

Within a single healthcare organization, it is possible to have a patient safety reporting system integrated with other clinical and administrative databases. With an integrated system, medical errors can be linked to patient characteristics and team characteristics to further expand the understanding of at-risk situations. For instance, retained foreign bodies are known to be more likely in emergency operations on obese patients. Nursing errors are known to be more likely with large patient loads and overtime. If the organization includes multiple facilities, errors can also be linked to facility characteristics, such as computerized provider order entry (CPOE).

Providers must be motivated to report medical errors and adverse events. Incentives include professionalism, interest in fixing system problems (rather than persisting with “work-arounds”), encouragement in the form of feedback or positive reinforcement to the reporter, dissemination of the results of any analysis, and improvements in the system of delivering care. An effective reporting system must not only capture system errors, it must use them to drive improvement in the system of healthcare delivery. Effective analysis is the other critical component of a patient safety reporting system. Effective analysis requires expertise in patient safety and a mechanism for creating a broad-based consensus for effecting the appropriate changes.

Clinicians are familiar with the concept of chief complaint, signs and symptoms and test results, diagnosis, treatment, and outcome. Patient safety reports can be approached in a similar way. First, the apparent system problem is identified. Then the contributing factors from the organizational infrastructure, the team of providers, and the patient are considered. The root causes are diagnosed, but a good analysis doesn’t stop there. A likely effective system solution must be developed and implemented, then the results of changing the system must be monitored.

There is a tendency to focus solutions on individual compliance with existing systems. Traditionally, this has been referred to as “blame and shame.” In the age of enlightenment, this has been referred to as “blame and train.” In the opinion of the author, reporting systems that result in identification of noncompliance with existing standards of care and attempts to improve compliance with those standards will produce short-lived improvements and will ultimately not be effective. Improvements in the delivery of healthcare come from improving the system, not individual performance (Table 1). Reporting systems need to be linked to organizational leaders who can act effectively on the conclusions of the reports.
Anecdotaly, an effective near-miss reporting system may generate one report per bed per month—about 12 reports per bed per year. For a large healthcare organization, the corresponding quality improvement efforts must realistically be prioritized. Reporting focuses the importance of the problem—its frequency and the severity of its consequence. Prioritization will also take into account the cost of implementing the change perceived necessary and the likelihood that the change will fix the problem (Table 2). Problems may remain within a healthcare organization not because the problem is minor or because the solution is elusive, but because the likelihood of solving the problem is judged not worth the effort. Such complacency requires leadership to establish a cost-benefit threshold favoring action and to increase the likelihood of successful implementation of a solution.

A reality of most patient safety reporting systems is that they communicate stories. Like other stories, these stories convey neither the complete picture nor the statistics. However, stories capture providers’ attention. They are powerful motivators for change. How many wrong-side operations need be reported to motivate change? Solutions to real problems are memorable. Such stories, when disseminated in de-identified form, are comparable to case reports or case series (Table 3).

The use of statistics, so typical of epidemiology, is limited with patient safety reporting systems. One cannot be confident that all possible events (of any one type) have been captured. Usually, the number of opportunities for error is unknown. Hence, both the numerator and denominator needed to calculate the incidence of a particular error are unreliable. Furthermore, for many problems, the incidence of an error is very low so that a prohibitive sample size would be needed to show that any change was significant. For example, an 80% chance of showing significance in the reduction of wrong-side surgery from 1/25,000 operations to 1/50,000 operations would require nearly one million patients in each group. My experience is that an accurate count of all the instances of a specific problem is not necessary. One needs only enough reports to know there is a problem.

There is a strong temptation to benchmark against others or against the past. Too frequently, this manifests as benchmarking against the average. All of the caveats cited above are relevant. Additionally, one only has to think of an acceptable benchmark for wrong-side surgery to conclude that benchmarking, if done at all, should only be done against best practice.

Systems that collect near-miss reports can produce one valuable statistic: the recovery rate. The recovery rate is the percentage of reports about a particular problem that indicate no harm (near misses). Recover rates increase either when the number of near-miss reports increases or when the number of adverse-event reports decreases. Both are desirable. Increases in near-miss reporting indicate greater vigilance. Concomitant decreases in adverse-event reporting suggest successful improvements.

My personal experience is that significant progress is not made by solving every type of problem reported, one at a time. In fact, problems noted only on aggregation of system-wide reports are—by definition—uncommon, and solving them will have little effect on the overall incidence of preventable adverse events. My premise is that for solutions to be successful, they should focus on changing the fundamental cultural deficiencies that keep an organization from being what is called a “high reliability organization” (Table 4). In medicine, these cultural deficiencies include individual rather than organizational responsibility, high workloads despite evidence about its risk, low tolerance of variability in the delivery of care, pride in “work-arounds,” and casual communication of information. Cultural characteristics of a high reliability organization include leadership committed to safety, adequate resources, standardization around best practice, extensive team training, accurate information, and structured communication.

Buchman et al. have nicely summarized the strategy needed to affect change toward the use of clinical guidelines. The same strategy should be valid to affect changes toward the safe practice of healthcare. The strategy for change is based on a foundation of three principles: the importance of the environmental culture, empirical evidence of cause and effect, and the perceptions of others. Change requires a change in

---

**Table 1. Priority Order for Solutions to Reported Patient Safety Problems (From the Institute for Safe Medication Practices)**

| 1. | Forcing functions |
| 2. | Automation |
| 3. | Standardization |
| 4. | Checklists |
| 5. | Rules |
| 6. | Education |
| 7. | Information |

---

**Table 2. Prioritization of Patient Safety Reports**

- Number of events
- Probability event will lead to adverse event
- Harm from the adverse event
- Cost of intervention program
- Probability intervention program will succeed

\[
\text{Cost intervention} \div \text{Probability of success} = \text{Number} \times \text{Probability of adverse event} \times \text{Harm}
\]
the environment, in our case to a culture of safety driven by leadership. Change requires awareness of cause and effect by providing educational material based on reports and analyses linking at-risk behavior with adverse outcomes. Change requires a change in expectations, such as transparency about the presence, causes, and correction of errors to the patient in concert with reporting, analysis, and implementation of system improvements.

A patient safety reporting system can help bring to light, monitor and correct a system of care that produces medical errors. It is a useful part of the patient safety and quality improvement initiatives of a healthcare system and warrants involvement by physicians.

Table 3. Patient Safety Reporting Reality

- People instinctively work around problems.
- Tradeoff between number and quality of reports.
- Reports do not give meaningful epidemiological information.
- Causes usually deeply rooted in the culture.
- People forget, therefore providing information not sufficient.
- Many problems persist not because solution is elusive, but because solution is judged not worth the effort.

Table 4. High Reliability Organizations

- Commitment
- Attention and Awareness
- Rehearsal and Resources
- Effective Communication
- Standardization

References