

Data for safety: Turning lessons learned into actionable knowledge

FOREWORD

This is the third in a series of three monographs exploring the interrelated concepts of patient safety taxonomy, development of adverse event reporting systems and actionable knowledge prepared by the American Society for Healthcare Risk Management (ASHRM).

The concept of Data for Safety originated in 2006 when ASHRM's Board of Directors identified the challenge facing risk management in using the myriad sources of data available to "tell the stories" and make the case for patient safety initiatives. At the heart of this discussion was the recognition that risk management professionals know a lot about risks and opportunities in their organizations but they need the framework to mine their data, link their findings to organizational efforts to improve safety, and deploy their knowledge on behalf of the organization. They need to make their knowledge "actionable."

The following monograph explores the historical and current context of safety efforts, sources of data for mining, and tips for risk management professionals in organizing their efforts internally and spreading their knowledge throughout the organization.

INTRODUCTION

Any effort to improve patient safety needs a systematic approach to data collection, analysis and solution development (National Initiative for Children's Health Care Quality Project Advisory Committee, 2001). Patient safety data can lead to actionable knowledge that ultimately improves the quality of patient care and lessens the likelihood of adverse events. However, there must be meaningful data analysis and solution development to ensure that lessons learned are converted into action. A 2004 report examined prominent scientific methodologies and tools for improving quality and preventing harm, finding that each approach had its unique attributes and advantages (McDonough, Solomon & Petosa, 2004).

Aggregating data both internally and externally enhances learning and identifies trends that may expose common problems and tracks improvement (Aspden, Corrigan, Wolcott & Erickson, 2004). Ultimately, data analysis should support systems redesign to prevent errors based on a balanced utilization of evidence-based technology, training, ongoing education, and consensus standard operating procedures and "best practices," keeping in mind each human's inherent cognitive (e.g., memory recall) and physical (e.g., fatigue) limitations. (McDonough, Solomon & Petosa, 2004).

BACKGROUND

Analysis of adverse events and other patient safety data may significantly enhance understanding of the underlying causes of risks and hazards in the delivery of healthcare but, to date, the sharing of adverse event information has been hampered by a lack of openness out of concern for risk. Hospitals have also shied away from standards of practice comparisons fearing an increase in liability and loss of market share.

In reality, the reluctance to share patient safety data has done little to prevent providers, consumers, regulatory bodies and legislators from realizing the danger present within healthcare systems and has significantly impeded the opportunity to share improvement stories and establish best patient safety practices.

Unlike hospital quality measures, sources of risk management data have not undergone greater transparency because most of the valuable data comes from untoward events and therefore is treated with greater legal protection. Historically, much information has been withheld for fear of potential or actual litigation or exposing medical staff peer review information.

LEADERSHIP COMMITMENT

Forward-thinking leaders must support processes that support the anticipation, identification and avoidance of failures. Leaders must make the commitment to better understand organizational vulnerability and conditions that lead to errors, thus minimizing risk.

Making patient safety a reality requires leaders to develop comprehensive patient safety systems that promote both a culture of safety and safe practices. A safe patient care system encourages healthcare providers, patients and others to be vigilant in identifying potential or actual adverse events. When these events or near misses occur, appropriate steps must be taken to prevent and mitigate harm.

Additionally, the disclosure of appropriate information on adverse events facilitates learning and redesign of care processes.

An adequate information infrastructure is necessary to provide stakeholders with immediate access to information. Trained professionals with expertise in patient safety and well-designed incident reporting systems for near misses and actual adverse events are critical.

Leadership should focus on these key areas:

- Expansion of the type of events that are analyzed, including both near misses and adverse events.
- Increased use of automated surveillance, which can provide leaders a more accurate picture of patient safety within the organization.
- Increased attention to performance data that can be converted to actionable knowledge, leading to better design of systems that prevent errors.

GETTING TO THE ROOT OF PATIENT SAFETY DATA

Learning and growing are natural processes in an organization. Data gathering, analysis and resultant knowledge are critical for these to successfully occur (Mireles, 2008). However, most healthcare safety assessments today are retrospective in nature and lack proactive approaches (Riley, Liang, Rutherford & Hamman, 2008).

Adverse events are complications or injuries a patient experiences as a result of the delivery of care and are not part of the natural changes involved in the evolution of the patient's illness. Today, most patient safety focus on the analysis of actual adverse events, which by definition occur after the error has reached the patient. Less attention has focused on the detection and analysis of near misses, which translates to missed opportunities.

Near misses occur more frequently so monitoring and analyzing these events

provides quantitative insight into the factors that contribute to a higher level of risk within the organization. This increased awareness leads to more proactive efforts and process changes that increase patient safety.

Additionally, since many failures often contribute to an adverse event, the early detection (i.e., at the first failure point in the chain of events) provides an opportunity to intervene and stop the failures that lead to a serious adverse event (Aspden, Corrigan, Wolcott & Erickson, 2004).

Traditional efforts detect adverse events through incident reports, chart review, document review (e.g., death certificates) and monitoring of patient progress (Blais, Bruno, Bartlett & Tamblyn, 2008). Chart reviews, voluntary reporting of events, claims data and other automated administrative data can provide valuable patient safety data. While private-sector reporting systems are more likely to capture information on near misses than mandated reporting systems, few organizations focus efforts on collecting and analyzing this data (Aspden, Corrigan, Wolcott, et al., 2004).

Minimum datasets

Regardless of how near miss and adverse event information is detected, the process for gathering and analyzing the information should essentially be the same. The Institute of Medicine (IOM) recommended a combination of narrative and coded elements, to include:

- The Discovery
 - Who and how it was discovered
 - The Event
 - Type of near miss/adverse event
 - Where, when and who was involved
 - Severity and preventability of the event
 - Likelihood of recurrence
 - Ancillary Information
 - Patient information
 - Product information, as applicable
 - Detailed Analysis
- (Aspden, Corrigan, Wolcott, et al., 2004).

Methodologies for gathering data

Historically, chart reviews by nursing and medical experts were generally considered the gold standard for assessing adverse events (Kohn, Corrigan & Donaldson, 1999). Most chart reviews are restricted to specific time-limited studies and are expensive and time-consuming to acquire. Chart reviews alone cannot effectively monitor patient safety and lack a proactive approach to safety (Blais, Bruno, Bartlett & Tamblyn, 2008; Aspden, Corrigan, Wolcott, et al., 2004).

An alternative to chart review used widely in organizations for years has been the voluntary reporting system, or incident reports. The reports are routinely filled out by healthcare providers (mostly nurses) to report events or accidents experienced by patients. One study compared the number of adverse events measured via chart reviews with those captured by incident reports in adult medical/surgical units. Incident reports had been submitted in only 15.5 percent of charts with adverse events and 4.4 percent of charts without adverse events. The presence of an incident report varied according to the type and consequence of the adverse events. Overall, the conclusion was that incident reports were not very useful in detecting hospital adverse events and that any voluntary reporting system should be expanded to cover a wider range of adverse events (Blais, Bruno, Bartlett & Tamblyn, 2008).

In the *To Err is Human* report, the IOM identified voluntary patient safety reporting systems as a key to reducing medical errors (Kohn, Corrigan & Donaldson, 2000). While voluntary reporting has been considered a critical component of any patient safety program, a number of studies have shown the rates of reporting to be disappointingly low. Identified reporting barriers include time required to report the event, lack of feedback, confusion or lack of knowledge about what type of events should be reported and confidentiality of the reporter or fear of retribution (Bahl, Thompson, Commisky, Anderson & Campbell, 2008; Schectman &

Plews-Ogan, 2006; Milch, Salem, Pauker, Lundquist, Kumar & Chen, 2006).

Claims data have also been used to detect adverse events. In one study this approach was effective in detecting adverse events for surgical patients, yet did not work well for medical patients (Aspden, Corrigan, Wolcott, et al., 2004; Lezonne, Daley, Herren, Foley, Fisher, Duncan, Hughes & Coffman, 1994). Organizations such as the Physician Insurers Association of America (PIAA) have collected and analyzed claims data. Such data have served as a rich source of information for risk managers who want to focus on specific vulnerabilities.

Some organizations are focusing on increasing the rate of voluntary reporting and supplementing that information with pharmacy and laboratory data, electronic discharge records, billing information and other administrative data (Bahl, Thompson, & Commisky, et al., 2008; Longo, Hewett, Bin & Schubert, 2005; Melton & Hripcsak, 2005). One study suggested the use of an automated surveillance program could effectively detect adverse drug events (ADEs) at a significantly higher rate than voluntary reporting systems (Cullen, Bates, Small, Cooper, Nemeskal & Leape, 1995).

The University of Michigan Health System (UMHS) recently conducted a pilot study to test the efficacy of using administrative data to identify adverse events. Based on the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicators, the system used a diagnosis timing variable to ensure only conditions acquired after hospital admission were identified and referred for further investigation by clinicians. By using the administrative data, several previously unreported adverse events were identified, including some that were deemed to be preventable (Bahl, Thompson, & Commisky, et al., 2008).

The federal government and other third-party payers are poised to utilize administrative data to identify and reduce reimbursement for hospital-acquired conditions. It is hoped that

the augmentation of administrative data will help systems identify and investigate adverse events and better prepare for the new federal laws that will reduce reimbursement for hospital-acquired conditions (Bahl, Thompson, & Commisky, et al., 2008).

Another potential source of patient safety data is through the electronic health record (EHR) as systems become more sophisticated. One aspect that seems feasible is to have the EHR prompt a provider with certain information when it appears that an adverse event might have occurred (Aspden, Corrigan, Wolcott, et al., 2004).

SPREADING LESSONS LEARNED

Reporting systems alone do not bring change. Neither does the completion of a root cause analysis (RCA), even one that is exceedingly well-done. Chances are high that valuable RCA lessons are not routinely shared across managers and front line staff within the relevant specialty area let alone across an institution or to a broader group. For example, responses to the Agency for Healthcare Research and Quality's (AHRQ) Culture of Safety Survey showed that only 52 percent of respondents reported any feedback about changes put into place based on event reports. (Agency for Healthcare Research and Quality, 2008).

To be successful in patient safety, risk managers must find ways to spread lessons learned across their organizations. This is no small task. In complex organizations like hospitals, spreading lessons learned demands focus, planning and exceptional execution in order to overcome organizational and cultural resistance.

What exactly is a *lesson learned*? The National Aeronautic and Space Administration (NASA) define a lesson learned as knowledge or understanding gained by experience. The experience may be positive, such as a successful test or mission, or negative, such as a mishap or failure. A lesson must be significant in that it has a real or assumed impact on operations; valid in that it is

factually correct; and applicable in that it identifies a specific design, process, or decision that reduces or eliminates the potential for failures and mishaps, or reinforces a positive result. (General Accounting Office, 2002).

Hospital processes, procedures, and systems often lack effective mechanisms to capture and share lessons learned and, therefore, they have no assurance that lessons are being applied. As champions for enterprise-wide culture of safety, risk managers must support a culture that creates an expectation for the spread of lessons learned by encouraging open communication about safety issues, educating staff about patient safety concepts and practices, promoting safety as everyone's responsibility, and identifying resource needs.

Tips to enhance the risk management contributions to safety and learning processes include:

- **Involve multidisciplinary perspectives.** Relationship building is essential because successful patient safety initiatives require cooperation from staff and physicians. Gaining interest and commitment is something that risk managers must work hard at. Involving a multi-disciplinary group in choosing opportunities for improvement and ensuring that they are well-researched will help to create a high probability of success. For example, specialists or sub-specialists can help decide whether a lesson is relevant across clinical service lines or is unique to a particular specialty or service.
- **Use credible external sources for case studies and recommendations.** An effective risk manager aims to prevent the fire rather than fight it after it starts. Likewise, learning from others' mistakes or mishaps improves error prevention. Risk managers should seek out credible external sources of patient safety case studies and improvement strategies. For example, the *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare

systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. (www.ecri.org/PatientSafety/SafetyAdvisories/Pages/default.aspx).

- **Explore Patient Safety Organizations.** Participating with or as a patient safety organization (PSO) may accelerate the spread of lessons. The Patient Safety and Quality Improvement Act of 2005 establishes a framework for federally certified PSOs to receive and provide guidance on reports of medical errors, near misses, and other patient safety events to with assurance that the information will be protected from legal discovery and kept confidential. PSOs will become operational upon the issuance of final regulations from the Department of Health and Human Services.
- **Disseminate information effectively.** Lessons are lost if they are not disseminated in a timely fashion to and used by those who will benefit from them. Offering continuing medical education (CME) and continuing education (CE) credits to physicians and others who participate in RCA efforts, proactive systems analysis, patient safety rounds, patient safety committee meetings, focused education and other efforts may be a good way to spread lessons. Dissemination encompasses policy and procedure review and revision, and training on same.
- **Provide incentives.** Incentive programs may provide leverage and commitment to the spread of lessons learned. For example, basing compensation on achieving patient safety goals (e.g., medication error rate, fall rate, infection rate) is getting attention, both for senior executives as well as patient safety officers and department managers. Performance evaluations and reward programs tied to patient safety metrics may help to align goals.
- **Celebrate successes.** Lessons learned can be based upon successes, not just failures. For example, a near-miss event may provide positive lessons on how to

avert an actual harm event. By focusing solely on failures, the hospital's lessons learned program will miss valuable improvement opportunities.

- **Support a culture of safety.** It is human nature to reluctantly share negative lessons, whether for fear of personal failure, litigation, or lack of time. One needs to acknowledge these barriers and identify ways to overcome them. Patient safety experts cite “storytelling” as one effective approach. While detailed investigations and analysis will remain under the patient safety officer/risk manager’s domain, the detection of near misses and adverse events would be much more efficient if front-line staff became more involved in the preventive measure, early detection and reporting of events. (Aspden, Corrigan, Wolcott, et al., 2004)

Stop by Rehab and congratulate your colleagues”;

- Develop screen savers displaying success in graphs or tables, “before and after” pilot project (e.g., reduction of central venous catheter infections);
- Take advantage of restroom “stall stories,” (e.g., place attractive signs in staff and visitor restrooms highlighting effectiveness of hand hygiene in reducing healthcare associated infections);
- Place posters outlining “how we did it” on unit bulletin boards, e.g., implementation of a rapid response team to reduce cardiac arrests outside the ICU;
- Publish patient safety culture survey results in hospital newsletters;
- Involve executive leaders by scheduling periodic visits to units for support and encouragement.

COMMUNICATING SUCCESSES AND LESSONS LEARNED

To make data actionable, risk managers need to communicate successes and lessons of the projects to employees and clinicians, especially those involved in the project. This step can be harder than it sounds. After all, employees are bombarded everyday with e-mails, journals, newsletters and other information. These techniques from ECRI Institute can help break through the noise:

- Use word-of-mouth feedback during multidisciplinary patient care rounds;
- Incorporate outcome data into quarterly report to medical staff departments and hospital departments;
- Report results of quality benchmarks for the improvement project to the quality improvement committee;
- Create an Intranet-circulating banner displaying positive results, e.g., “Falls Reduction Project a Success! Rehab unit reduced incidence of falls by 50 percent.

ECRI Institute (2006). “Healthcare risk control. Keys to successful patient safety projects.” www.ecri.org. Reprinted with permission.

GETTING THE BOARD ON BOARD

Patients entering into the care of healthcare providers should expect that their care will not result in harm. Attention to patient safety, including all risks or exposures and not just sentinel events, starts at the top. Boards of Directors in healthcare organizations have both a moral and fiduciary responsibility for patient safety. Setting the tone in the boardroom in favor of patient safety means more than just reviewing data at each meeting. It means being aware of patient safety metrics, requiring accountability and expecting improved performance without placing blame (Krause, Balkcom & Dunn, 2006). High-performing boards communicate clearly, often and aren’t afraid to challenge the status quo.

ANALYZING AND AGGREGATING PATIENT SAFETY DATA

Opportunities and challenges

The collection, aggregation and analysis of patient safety data are vital to healthcare organizations, providers, purchasers, oversight bodies and the public. It is through patient safety data that healthcare organizations and healthcare providers can determine priority areas for improvement, track progress and give accrediting and regulatory bodies information on performance.

Patient safety and risk analysis generates information to guide the organization through their safety and risk profile. In healthcare, areas of risk revolve around providing care and include clinical facts, malpractice costs, revenue exposure, regulations and public perception. The ability to share or merge data could lead to better use of system resources and better ensure an accurate portrayal of patient safety information (The Joint Commission, 2008).

Adverse event reports by themselves do not provide actionable data. Rather, to be actionable, the data must be analyzed, best practices gleaned from the evidence, and strategies for implementation developed.

Numbers by themselves do not provide actionable data. For example, the number of incorrect medications administered is not meaningful without knowing the total number (known as the “denominator”) of all medications administered. In other words, ten incorrect medications out of a total of 50 administered doses are much different than ten incorrect medications out of 10,000 administered doses.

Benchmarking reports by themselves do not provide actionable data. Many factors influence the number of reports submitted by an organization, such as size, volume, patient case mix, severity of illness, and differences in the reporting culture. Remember the risk management conundrum: A higher number

of reports does not necessarily signify more harm or less safety, rather it might signify better systems in place for detecting and reporting actual adverse and near misses.

Innovation in data benchmarking and analysis

Innovation in patient safety benchmarking is occurring in localities across the country. Creative initiatives in Minnesota and Wisconsin exemplify state efforts that have evolved based on the needs of their communities for specific healthcare information (The Joint Commission, 2008). The University Health System Consortium (UHC) created a reporting network within its member organizations (Morath & Turnbull, 2005).

The Pennsylvania Patient Safety Reporting System (PA-PSRS) collects nearly 20,000 events and near misses each month. The mandatory reporting system established an independent, non-regulatory state agency that collects reports for the purpose of learning, not enforcement. The agency regularly publishes patient safety guidance based on its original analysis of the reports, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes (Hanlon & Rosenhal, 2007).

The NASA/Veterans Administration’s Patient Safety Reporting System (PSRS) emphasizes close calls and has served as a prototype for a blameless reporting system since 2000. Reports are voluntary, confidential and contain de-identified data. Reports are submitted to NASA, which oversees all PSRS functions. Since its inception, reporting has increased 900 percent for close calls and is providing previously undetected patient safety issues as opportunities for improvement. (Morath & Turnbull, 2005).

REPORTING DATA TO EXTERNAL ORGANIZATIONS

There are two kinds of patient safety reporting. Mandatory reporting that focuses on holding providers and organizations accountable for the safety and quality of care they provide. These entities tend to focus on identifying the most serious adverse events and issues related to gross negligence or professional misconduct. Voluntary reporting, as it suggests, is valuable for organizations wishing to build a learning culture and engage front line caretakers (Morath & Turnbull, 2005).

External organizations tend to focus on macro-level analysis and communication of general patient safety trends rather than the detailed data found within an organization. The objectives of these reporting systems vary, but generally allow for data reporting that supports aggregation, comparative analysis, trend identification and analysis, performance improvement, and research.

State agencies

A number of states currently have some mandatory reporting requirements as part of their oversight for healthcare organizations (Aspden, Corrigan, Wolcott, et al., 2004). State level reporting of medical events is most often the result of a state mandate for the collection and analysis of event data to create accountability and transparency with regard to medical events. Most of these reporting systems focus only on adverse events with only two states, Pennsylvania and Kansas, collecting information on near misses. The number of states that have some form of mandatory reporting has increased from 15 in 2000 to 26 states plus the District of Columbia in 2007 (Additional information is available at http://www.nashp.org/docdisp_page.cfm?LID=B20C4AF8-3BFF-43EA-A02A83A4D15BB06E; search for “2007 Guide to State Adverse Event Reporting Systems”).

Federal agencies

The federal government operates many reporting systems in order to carry out its public health, regulatory responsibility and its caregiver role. Actions taken at the federal level are driving the push for transparency of health-related information. Increased recognition of the importance of patient safety data has stimulated the development of major performance measurement initiatives across various organizations and associations (The Joint Commission, 2008).

In 2005, the Patient Safety and Quality Improvement Act laid the groundwork for the first-ever national system for providers to voluntarily report medical errors, near misses, and other patient safety events to designated organizations called Patient Safety Organizations (PSOs) while having some assurance that the information will be protected from legal discovery and kept confidential.

Proposed regulations, issued in February 2008, reiterate the law’s intent to encourage PSOs to aggregate data from multiple providers. By amassing a larger volume of data, a PSO may be able to detect event patterns that would not be apparent with data from just one provider. More than just a reporting system, the program allows providers to seek expert help in understanding these patient safety events and in preventing their recurrence. The program covers more than event data, extending to all “patient safety work product,” a term defined in the law.

A PSO is a public or private organization with expertise to analyze the risks and hazards in patient care and to make recommendations to improve healthcare quality and patient safety. PSOs must meet several criteria and be certified as such by the U.S. Department of Health and Human Services. For example, PSOs must follow security requirements when handling providers’ confidential patient safety data.

There is no requirement that providers work with PSOs; the entire reporting system is voluntary. (ECRI Institute Special Advisory, March 2008, Patient Safety Organization “Proposed Rule Lays Groundwork for Patient Safety Improvements.” Available at www.ecri.org/PatientSafety/psa/Pages/advis0308.aspx.)

Others

Some other related initiatives include those of the American Medical Association, The Joint Commission and others. Many of these organizations also maintain performance measure databases, as do third-payer plans, payers and professional disciplines (The Joint Commission, 2008).

CONCLUSION

The patient safety officer/risk manager needs to be fluent in the various ways to collect and analyze patient safety performance data within the organization.

Defining, measuring, and tracking specific indicators provides a framework for valuable benchmarking. By utilizing benchmarks in the patient safety arena, there is much to be shared between healthcare entities to further the journey toward preventable patient injury or death. Patient safety data can provide a wealth of information about patient safety and quality of care within an organization. This data can turn into “actionable knowledge” that can be used to improve clinical practice, patient safety, and reduce risk.

PATIENT SAFETY DATA WEB SITE RESOURCES

- Agency for Healthcare Research and Quality/Medical Errors and Patient Safety
<http://www.ahrq.gov/qual/errorsix.htm>
info@ahrq.gov
- American Hospital Association (AHA)
<http://www.aha.org>
- American Hospital Association
Quest for Quality Prize
<http://www.aha.org/questforquality>
questforquality@aha.org
- ASQ's Six Sigma Forum
<http://www.sixsigmaforum.com>
- Aviation Safety Reporting System (ASRS)
<http://asrs.arc.nasa.gov>
- Center for Patient Safety
www.ASHP.org
patientsafety@ashp.org
- ECRI Institute
www.ecri.org
- ECRI Institute Patient Safety Center
<https://www.ecri.org/PatientSafety/Pages/default.aspx>
- Facts about Patient Safety
<http://www.jcaho.org/accredited+organizations/patient+safety/index.htm>

- FMEA Information Centre
<http://www.fmeainforcentre.com>
postmaster@femainforcentre.com
 - Institute for Healthcare Improvement
www.ihl.org
info@ihl.org
 - Institute for Safe Medication Practices (ISMP)
<http://www.ismp.org>
info@ismp.org
 - Josie King Pediatric Safety Program
<http://www.josieking.org>
sking6137@comcast.net
 - Leapfrog Group
www.leapfroggroup.org
 - Massachusetts Coalition for the Prevention of Medical Error
<http://www.macoalition.org>
 - National Academy for State Health Policy (NASHP)
<http://www.nashp.org>
info@nashp.org
 - National Center for Patient Safety
www.patientsafety.gov
NCPS@med.va.gov
 - National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP)
<http://www.nccmerp.org>
 - National Patient Safety Foundation (NPSF)
www.npsf.org
info@npsf.org
 - National Quality Forum
www.qualityforum.org
info@qualityforum.org
 - Patient Safety Reporting System (PSRS)
<http://psrs.arc.nasa.gov>
 - PULSE (Persons United Limiting Substandards and Errors in Healthcare)
<http://www.pulseamerica.org>
pulse516@aol.com
 - QualityHealthCare.org
<http://www.qualityhealthcare.org>
 - Speak Up for Patient Safety Program
<http://www.jcaho.org/accredited+organizations/speak+up/index.htm>
 - Stand Up for Patient Safety Program
<http://www.npsf.org/html/StandUp/standup.html>
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