Improving the Value of Patient Safety Reporting Systems

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Abstract

Use of patient safety reporting systems (PSRS) to identify and mitigate risks to patients who are harmed by medical care has been a national priority for nearly a decade. Yet, most reporting systems are still new and focus on reporting events. To improve the value of PSRS, we must use the data to identify safety hazards, prioritize where to focus resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm. We developed and implemented a Web-based PSRS and discuss in this paper the benefits, limitations, and challenges we encountered. First, we discuss the benefits of PSRS as part of a patient safety learning community. The remainder of the paper focuses on the challenges we faced that still need to be resolved to improve the value of reporting systems. We address these challenges as follows: what to report, how to minimize reporting burden and costs, how to conduct expert reviews and prioritize safety efforts, how to place incidents into taxonomies, how to know that the reporting system actually improved patient safety, and who should be responsible for attempting risk mitigation.

Introduction

The Institute of Medicine (IOM) recommended using patient safety reporting systems (PSRS) to evaluate why patients are harmed by medical care.[1, 2, 3] In response, 22 States have legislation requiring reporting systems, The Joint Commission requires that hospitals report mistakes (www.jointcommission.org), and a law including incident reporting was enacted in 2005.[4] Under the auspices of the Agency for Healthcare Research and Quality (AHRQ), the United States will launch a national error reporting system.

Despite diligent efforts, most reporting systems are relatively new and focus on collecting events. In addition, stakeholders disagree about the goal of reporting. Should the goal be to improve patient safety or to ensure individual and institutional accountability?[5, 6] Little attention has centered on analyzing reports and assessing how to use the data to improve patient safety.[7, 8, 9] Thus, health care organizations struggle to prioritize improvement efforts and evaluate whether patient safety has improved.

Our efforts to develop and implement a Web-based patient safety reporting system, called the Intensive Care Unit Safety Reporting System (ICUSRS), revealed various potential benefits and challenges.[10, 11, 12, 13] The purpose of this paper is to discuss the strengths, limitations, current challenges, and future directions in using patient safety reporting systems to improve safety.

Potential Benefits of Patient Safety Reporting Systems

Web-based patient safety reporting systems (PSRS), such as the ICUSRS, provide a means to efficiently identify and, hopefully, mitigate hazards.[14] Many participating sites in the ICUSRS project stated how this reporting mechanism helped them improve patient safety. For example, one hospital identified insufficient staff knowledge as the main cause of events related to the use of intracranial pressure monitoring devices. This recognition led to an improved staff training program. Nevertheless, most of the evidence regarding the benefits of PSRS is anecdotal. While health care has traditionally relied on quantitative methods to understand the epidemiology of diseases and other health-related issues, anecdotal stories provide the context in which an incident occurred.[5, 15] The information pulled from these stories can help shape future interventions to mitigate harm.

A well-functioning PSRS should collect events (incidents) that could or did lead to patient harm. While there is wide variation relative to how harm is classified,[16, 17] we believe harm can be biological, physiological, or psychological in nature. An event that causes harm is typically called an adverse event (e.g., retained surgical instrument); an event without ensuing harm is called either a near miss or a close call (e.g., wrong medication identified before administration). Ideally, a patient safety learning community would use PSRS data to identify safety hazards, prioritize where to focus their resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm.

In this community, learning should occur on multiple levels. A local patient care area can reduce risks that are unique to it; a hospital can reduce risks that span multiple units; and the broader health care community can learn from risks that span multiple health care organizations. Recently, AHRQ solicited proposals for a Patient Safety Organization (PSO) Network and national patient safety database (NPSD), which could provide the structure for this learning community.

Nevertheless, current approaches to mitigating risks are probably neither efficient nor effective. Local hospitals develop interventions to mitigate risks that have a low probability of achieving success. For example, errors involving devices are common, and the local intervention is generally staff re-education. The collective costs of re-education across the United States would be substantial. A more effective and efficient approach would be to redesign the devices. Yet, individual hospitals and health care systems cannot do this alone. A collaborative effort is needed.

Limitations of PSRS

In a previous commentary, we discussed the dilemma of using PSRS as a means to evaluate progress in patient safety.[9] Selection bias and other uncertainties preclude the feasibility of interpreting PSRS data as rates or trends in rates. To calculate a valid rate, you need a reasonably accurate numerator (event) and denominator (population at risk of the event). However,

definitions of events vary widely, and determining a population at risk for most events is opaque at best. Also, many in health care debate the issue of preventable harm vs. inevitable complications. In addition, PSRS suffer an unknown degree of underreporting, given that reporting is voluntary and spontaneous, and a systematic surveillance system is not feasible. Yet many, particularly those using reporting systems for accountability, wrongly interpret PSRS data as valid rates of errors or as a valid measure of patient safety. The inferences from these interpretations will project an inaccurate or incomplete picture of patient safety.

Because reporting bias varies over time, amongst hospitals and clinical areas, by event type, and by perceived harm, the noise (measurement error) generated inevitably drowns out any signal. Due to these biases, reports from PSRS should be interpreted as a nonrandom sample of identified hazards from a larger unknown universe of hazards that can focus our efforts on improving patient safety. In essence, incidents should be used as golden nuggets of data to address and fix a specific hazard in a clinical area or hospital. PSRS data cannot be used to measure rates or monitor progress in improving patient safety.

Challenges Facing PSRS

The focal point of most reporting systems is submission of events. Consequently, many health care organizations suffer from data overload. For example, The Johns Hopkins Hospital implemented a PSRS and received about 11,000 reports in year 1 and about 14,000 in year 2.[a] Much of our comprehension from PSRS thus far has come from individual case review, not aggregate data analysis. This is because individual cases are readily understood, and learning methods are better established.[18] Yet, our ability to use aggregate data to prioritize improvement efforts across the institution and to evaluate whether these efforts improved patient safety are limited.

We must decide how to use data from reporting systems to prioritize and mitigate hazards. Below we discuss several fundamental, yet unanswered, questions that must be addressed to enhance the efficiency and effectiveness of PSRS to help improve safety.[19]

What to report? What should be reported is an important and fundamental question. Our decisions likely drive the amount and level of detail reported about an incident, the time required to report, and ultimately the usefulness of the data. In the ICUSRS project, there was variability in the volume and content of incidents submitted from the 18 intensive care units participating in the first year.[10] Text descriptions ranged from meticulous in detail to telegraphic facts. In addition, discrepancies were sometimes found between text descriptions and structured data for the same incident. For example, the text description from one event reported that the patient died, but “no harm” was checked in the harm classification section. This was one of many cases found when the ICUSRS team reviewed incidents to evaluate underreporting of harm and contributing factors. In fact, over 30 percent of cases had additional contributing factors evident in the free text that were not checked in the structured response categories.

[a] Personal communication, Lori Paine, RN, MS, June 12, 2008.

Previous studies have shown that visibility of the event and/or its outcome, the reporter's comprehension of the definitions of harm and contributing factors, a culture that is cognizant of safety, and discernible followup actions all influenced reporting activities.[2, 20, 21, 22] A clearer definition of reportable events is needed. For example, double-checking insulin doses is a standard process of care. If the second nurse finds an error, is this a reportable event? While safety culture influences a clinician's willingness to report events, there is still uncertainty about the relative value of text vs. structured data and of reporting any event vs. specified events.

A second but related question is, What type of events should be reported? In addition, given that health care organizations generally take action only on harmful events, the relative value of reporting a large number of near misses should be explored. While it is generally agreed that no-harm events contain identifiable hazards, reporting these incidents increases the burden on reporters and subsequent investigators. As the IOM noted, the value of "near miss" reporting needs to be demonstrated in health care.[3] We must identify which events will facilitate improvements in patient safety. For example, if harm is a condition for action, the value of near miss reporting is questionable. Given the limited resources for patient safety, few near misses are investigated and even fewer are used to institute improvement efforts.

How can reporting burden and costs be minimized? Incident reporting incurs costs for those reporting, analyzing incidents, resolving hazards, and evaluating the impact of hazard reduction efforts. As reporting systems proliferate nationwide, so will the costs of incident reporting. Most hospitals (87 percent) participating in the ICUSRS used multiple reporting systems, and integrating these systems did pose challenges.[13] However, the ICUs submitting the highest volume of reports used the ICUSRS as their primary mechanism for reporting incidents to their unit manager and/or risk manager. To avoid duplicate efforts and wasted resources within and among hospitals, organizations should consider coordinating reporting systems. The AHRQ-sponsored PSO Network to establish a national patient safety database (NPSD) is a good example of coordinating efforts. This PSO Network will develop a national database to collect and analyze events and then report information and provide resources that can be used to improve patient safety. Ideally, hospitals should have a single reporting system that would route events to multiple stakeholders.

How to conduct expert reviews and prioritize safety efforts? Conducting expert reviews presents multiple challenges. Expert reviews are costly, and gaining consensus regarding preventability of an incident is a challenge.[23] In addition, experts must be able to comprehend the nascent field of patient safety in the context of their clinical disciplines. They must also commit sufficient time to review each incident, understand what happened and why, and formulate a plan to prevent a recurrence. Reporting systems that collect all types of incidents will face challenges in recruiting multiple experts to review all incident types. In addition, while PSRS may contain information about events and contributing factors, acquiring more detailed information about events requires a more thorough investigation, such as a root cause analysis (RCA). Events submitted to a reporting system often trigger or initiate an RCA. Thus, linking a reporting system to professional societies or a national agency might increase its strength and probability of success. As patient safety develops and uses a standardized taxonomy to code incidents, the ability to use and interpret data in PSRS will increase.

Because of the accumulation of a large number of events, health care tends to investigate many events superficially and few thoroughly. As the volume of reports increases, health care organizations must learn to analyze aggregate data and also develop strategies to prioritize improvement efforts.[22] Strategies to prioritize patient safety efforts using aggregate data are underdeveloped. Severity scoring (i.e., severity of patient injury and frequency of occurrence) is one approach to prioritizing efforts.[22] However, we do not know how reporting bias influences what event types are reported, how harm varies among event types, and whether severity scoring to prioritize interventions will result in fewer harmful events. Also, scant data exist regarding the most useful format to report findings to caregivers and risk managers.

One promising approach to prioritize risks identified by PSRS data is the Harm Susceptibility Ratio (HSR), which is informed by the Risk Resiliency Ratio developed by Carl Macrae.[24] The HSR is intended to prioritize events that have a low probability of being "trapped" or defended. That is, the odds that an event will result in harm. Mathematically, it models the odds of harm in a specific work area or event type, divided by the odds of harm averaged among all work areas or event types. The HSR can be interpreted as an odds ratio with vulnerability indicated by any number >1. In addition, we can look at the distribution or dispersion of events among organizations. If events are distributed among many organizations, the solution might be more effective and efficient to occur at a regional, State, or county level, depending on the clustering of events. More research is needed to help develop methods to prioritize data in reporting systems and to determine the appropriate level for interventions.

How to place incidents into taxonomies? Understanding incidents in the aggregate requires a classification of those incidents. However, what is comprised by a meaningful taxonomy for medical incidents is debatable.[25] In addition, many taxonomies have been developed independent of each other and range from broad to specific. The Applied Strategies for Improving Patient Safety (ASIPS) Victoroff taxonomy, for example, targets the primary care setting,[26] while the ICUSRS was developed for critical care.

In the United Kingdom, the National Reporting and Learning System (NRLS) collects and categorizes events in both inpatient and outpatient settings. Though it is far from perfect, the NRLS is perhaps the most mature, country-level PSRS in existence. This national effort has one reporting system and taxonomic classification that could be emulated in the United States. However, the NRLS is currently faced with an unwieldy volume of reports and an unclear mechanism for prioritizing events, designing interventions, and evaluating their impact. The United States could learn much from the successes and shortcomings of the NRLS. In particular, they could make better use of professional societies in analyzing events and designing interventions.

Nevertheless, three types of taxonomies have been applied to incident reporting: conditional risk, classifying event types and contributing factors, and process maps.[3] All three taxonomies have challenges. Few health care researchers have judged the conditional risk of incidents because it has low inter-rater reliability and introduces bias.[27] Moreover, the type of events and contributing factors coded can significantly influence the results obtained. For example, most taxonomies include mistakes (e.g., prescribing errors) and the outcome of mistakes (e.g., patient falls, decubitus ulcers) as event types. However, falls and decubitus ulcers are visible harms (outcomes) that might have resulted from failure to monitor patients or an inaccessible bedpan

(process) that occurred earlier in the delivery of care. When examining the proportion of incidents in the ICUSRS with harm identified, it is not surprising that falls and decubitus ulcers were among the highest.

Lack of clear process maps is one reason why some event types are classified by the outcome, not the underlying process or mistake. For example, the process map for medication errors is clear and understood—prescribing, documenting, dispensing, administering, and monitoring. When a patient receives the wrong medication, the steps upstream from the drug administration are visible to staff.[19] Without lenses to see process maps and the factors (e.g., teamwork, supervision) that contribute to mistakes at each step in the process, caregiver reports would likely be incomplete and biased. A generic process map could include three steps: diagnose, treat, and monitor. Within each step would be three parts: the decision to do something, the process of doing it, and interpreting the results. Clear process maps would help prioritize patient safety improvement efforts.

How do we know that the reporting system actually improved patient safety? As mentioned previously, health care has struggled to answer whether patients are safer.[8] The number of events reported to patient safety reporting systems will not provide the answer.[28] One measure of safety could be whether we learned from the mistake, intervened, and reduced the probability that another patient would be harmed from a similar event. A tool was developed to investigate individual incidents and then plan and carryout a strategy to prevent the mistake from recurring.[29] This tool is being used at The Johns Hopkins Hospital in clinical areas and as part of morbidity and mortality conferences.

To better understand the impact of interventions, we can classify them from strongest (most likely to reduce future harm) to weakest (least likely to reduce harm). Strong interventions include strategies to eliminate or prevent a mistake. For example, the field of anesthesiology redesigned their equipment to prevent the connection of oxygen tubing to nitrous oxide canisters. Unfortunately, such strong interventions are rare in health care. A mediocre intervention would make a mistake visible. For example, clinicians could place an ‘epidural only’ sticker on epidural tubing to prevent inadvertent connection to an intravenous catheter. A weaker intervention would mitigate harm. For example, The Joint Commission recommended removing “concentrated” potassium from care areas.[30] While we can still overdose a patient with potassium, the risk for harm is reduced. The weakest but most common intervention would be to create a policy or procedure or to educate staff. Although multiple interventions are often used, a strong intervention is clearly the most desirable.

Evaluating the effectiveness of an intervention is inversely related to the intervention’s strength; strong interventions need limited evaluation, while weak interventions need rigorous evaluation. In general, there are three methods to evaluate whether the risk for harm is reduced. We can measure the presence of a policy or program (the most common method), the staff’s knowledge of the policy or program, or the appropriate use of the policy or program.[8] If the policy or program involves communication among caregivers, the most valid method to measure the intervention’s effectiveness is to observe team behavior. For example, if a preprocedure briefing is recommended to improve teamwork, it would be more reliable to observe the effectiveness of the discussion than to review a chart documenting the briefing. Additional research is needed to

learn how to effectively and efficiently evaluate whether interventions generated by PSRS data have reduced a patient's risk for harm.

Who should be responsible for attempting risk mitigation? What level(s) of the health care industry should be responsible for addressing a safety issue? For example, should the local nursing unit, the department, the hospital, the health care system, or a medical manufacturer be responsible for mitigating hazards? The most effective interventions eliminate or prevent the mistake; the least effective interventions encourage vigilance, educate staff, or institute a policy. The highest level possible should attempt to mitigate the risk. For example, if an equipment design flaw caused an event, it is more efficient and effective to have the manufacturer fix the flaw than to try to educate staff at every hospital about the design flaw.

Health care lacks a process for determining what level or levels should attempt mitigation of hazards. Nevertheless, some degree of centralization would be cost effective. For example, mistakes involving central line placement are common, costly, and distributed among multiple specialties.[31, 32] While individual departments within health care organizations may lack the resources to develop training programs for proper placement of central catheters, a centralized program with input from clinical and educational experts would be effective and efficient. Many types of mistakes commonly occur across institutions that would benefit from a central method for addressing common hazards. In light of these issues, a national organization capable of exercising national policy and working with manufacturers to implement broad-based interventions might be more effective and efficient than current approaches in which individual hospitals design their own solutions and which have a low probability of reducing risks to future patients.

Health care could create an organization similar to the aviation industry's Commercial Aviation Safety Team (CAST).[33] CAST is a public-private partnership made up of three core teams: a joint safety analysis team, a joint safety implementation team, and a joint implementation measurement data analysis team. Operators, manufacturers, labor organizations, and the government appoint members to support these teams. The strength of CAST lies in its extensive membership, its proactive commitment to safety, and its ability to design and broadly implement strong system changes. They have been credited with reducing fatal airline crashes by 65 percent over the past 10 years.

Future Directions

Until these challenges can be addressed, regulators and accreditors could standardize methods of evaluating whether specific types of events recur. For example, hospitals could determine whether they have a behavior-specific policy for preventing wrong site surgery, assess staff knowledge about this policy, and use an audit tool to evaluate whether the policy is implemented appropriately. Until the science of PSRS advances, its value will derive from surfacing and reducing hazards. The challenge is to migrate from investigations that go a mile wide and an inch deep, to an inch wide and a mile deep.

A research agenda to advance this science could include understanding the bias in reporting, developing tools to use information in PSRS to prioritize patient safety efforts, and developing

measures to evaluate whether safety actually improved. Health care must spend its resources more efficiently. The need to improve patient safety is too great and the resources too scarce not to evaluate what works and at what cost.

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