

The Patient Safety and Quality Improvement Act of 2005: Developing an Error Reporting System to Improve Patient Safety

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Abstract: The Patient Safety and Quality Improvement (PSQI) Act enacted in July 2005 constitutes the basis for significant opportunity to improve patient safety in the health care system by creating a voluntary error reporting system. The PSQI Act creates an unprecedented opening to prospectively prevent injury through analysis of mistakes and close calls that have been voluntarily reported by providers and ensures legal protection for providers who report information about errors and injury to a Patient Safety Organization. This paper provides an overview of the main features of the PSQI legislation, describes essential components of a national patient safety reporting system, discusses what events to report, and identifies what lessons can be learned from aviation safety reporting systems.

Key Words: Patient Safety and Quality Improvement Act, voluntary error reporting system, safety, quality, law, policy, medical error

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The Patient Safety and Quality Improvement Act (Act), (Pub. L. 109–41) creates significant opportunities to improve patient safety in the health care system by facilitating the voluntary reporting of medical errors and delivery system weaknesses and developing feedback processes that lead to improved patient care processes. When implemented, the Act may create an unprecedented opportunity to prospectively prevent injury through analysis of errors and close calls that have been voluntarily reported by providers, rather than retrospective study of injury after it occurs and harm sustained.

The Institute of Medicine (IOM) provided significant analysis on the need for specific changes in law and policy to promote patient safety in health delivery. In response, Congress passed the Act in an effort to provide that infrastructure to improve patient safety. Comprehensive overviews discuss the specific details of the legislation.^{1,2}

However, a number of important features of a voluntary patient safety reporting system remain to be developed through regulation and implementation of the Act's provisions. In this paper, we describe our view of the essential components of a national patient safety reporting system, including a foundation for these components and the kinds of events to report. In addition, we propose several recommendations for policy makers, sponsors of Patient Safety Organizations (PSOs), and health care organizations regarding what we believe is necessary in a national system to successfully fulfill the potential of the Act to promote patient safety.

THE IOM REPORTS

Reports from the IOM were instrumental in creating urgency for federal legislation to develop a standardized event reporting system and proposing the architecture for a national patient safety system. In 2001, the IOM concluded that the information infrastructure necessary to ensure and maintain safety did not exist in the health care industry.³ In 2 subsequent reports, the IOM recommended that Congress provide clear direction, enabling authority, and financial support for the establishment of national data system to support patient safety.^{4,5}

The most recent IOM report for developing a national patient safety reporting system, *Patient Safety: Achieving a New Standard of Care*, provided a blueprint for the essential features of such a system, including a voluntary error reporting system for health care.⁵ It emphasized that the major components for such a system should include the following: a national health information infrastructure, a comprehensive system of patient safety programs, and patient safety report streamlining to proactively address errors and system weaknesses.

This IOM report persuasively presented the need for a health information structure to capture patient safety information to create a system that both prevents errors and allows broad learning from them when they occur. It also recommended that the Department of Health and Human Services should be given a lead role in establishing and monitoring a public-private partnership for the promulgation of standards for data that support patient safety.

OVERVIEW OF THE ACT

The critical components identified by the IOM have been facilitated by the Patient Safety and Quality Improvement Act. The Act, which was signed into law in 2005, provides for the creation of a national patient safety database through voluntary reporting by health care providers and feedback by PSOs. Its

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intent is to promote safety activities and learning through legal protection of safety information reported by providers to PSOs and any analysis by both. The reports and information from providers and PSOs will form the national patient safety database managed by a public-provider partnership between the federal government and private organizations.^{1,2}

The 11-page Act contains a number of features promoting voluntary error reports. The 3 most prominent features include the following: providing privilege and confidentiality for “patient safety work product” from subpoena, discovery, and/or disclosure in a civil, criminal, or administrative proceeding (except under very limited circumstances or if authorized by the provider); defining important terms necessary to implement a national patient safety database; and requiring the Department of Health and Human Services to facilitate the creation and operation of databases for analysis of patient safety trends.^{6,7}

Experience from other high-hazard industries suggests that perhaps the most effective method by which analysis can be conducted to prospectively prevent error and injury is by creating a mechanism to submit and analyze data about near misses and incidents, rather than a retrospective focus on accidents.^{8,9,10} The Act would provide an infrastructure to allow this experience to be applied to health care.¹¹ Patient Safety Organizations would contract with providers to help identify trends and develop proposals to recognize and address system weaknesses prospectively and prevent future medical errors and/or mitigate harm associated with their occurrence.¹²

In addition, broad-based learning across entities is fostered by allowing system lessons to move across committee and entity borders. Under the Act, confidentiality and privilege protections travel with the information, rather than being associated with the forum in which it was discussed (e.g., peer review committees) and the inherent limits of such an approach.¹

ESSENTIAL FEATURES OF A NATIONAL ERROR REPORTING SYSTEM

The Act incorporates numerous components for an error reporting system recommended by the IOM. Five of these features are discussed below: voluntary reporting, legal protections, standardized terminology and formats, prospective prevention, and near-miss analysis.

Voluntary Reporting of Near Misses

Medical error reporting systems are either voluntary or mandatory. Important distinctions in purpose and participation are found between voluntary and mandatory reporting systems. According to an IOM report, voluntary reporting systems provide information to prevent patient injury before it occurs, whereas mandatory reporting systems provide information after injury occurs and analyze the cause. A critical feature of the Act is that it relies on voluntary reporting to proactively identify areas for safety focus.

Voluntary reporting systems can be particularly effective if they focus on near misses and close calls, as has been the experience within the aviation industry.¹³ According to the IOM, a near miss is an error that could have caused harm but did not because of prevention, mitigation, or chance.⁵ Conceptually, near misses have a higher frequency of occurrence

yet the same failure factors as adverse events. Although near misses and sentinel events are part of the same continuum, they are conceptually distinct entities that have different acceptance and usefulness for broad safety improvement.

Using voluntary reports of near misses, voluntary reporting systems have been effective in promoting safety, quality, and efficiency in high-risk/high-reliability organizations, including aviation, nuclear power, and the military.¹⁴ The use of voluntary reports of near misses and system weakness under the provisions of the Act would allow organizations to identify system failures and, importantly, also yield success stories in avoiding adverse events. This circumstance would provide greater acceptability of reporting and discussion of the system’s issues surrounding the report. Near misses are also more frequent, providing significantly more information for study and assessment, and allow for local factors as well as more broadly applicable issues to be identified in the delivery system.¹³ The benefits experienced by other industries from studying near misses using voluntary systems may thus be of great potential for medicine,¹⁵ and the Act facilitates the creation and use of such systems.

A reliance upon adverse event reports and reporting may be misguided because these events often go undetected in health care organizations.^{16,17} Indeed, regardless of whether adverse event reporting systems are voluntary or mandatory, both kinds of systems capture few of these events.^{17–19} Legal mandates have been passed in 22 states for mandatory reporting of adverse events.¹¹ A typical example would be Minnesota, where mandatory reporting is required by hospitals on 27 serious events, along with a summary of the corrections implemented by hospitals in response. In the State’s first annual report, a total of only 99 events were reported among all hospitals in the state.²⁰ It is extremely unlikely that this number accurately reflects the total number of reportable occurrences in Minnesota.²¹ Another example of the incompleteness of mandatory reporting includes a Health and Human Services Inspectors General report that of the 104 documented deaths from restraints and seclusion, 42% went unreported as required by regulation.²² As noted by aviation safety reporting leaders, all reporting systems, regardless of their mandatory or voluntary nature, are voluntary if they rely upon reporters to come forth without other means to detect safety issues.^{23,24}

These characteristics have not gone unnoticed. The IOM report observed that with respect to patient safety reporting, insufficient attention has been paid to patient safety strategies that prevent adverse events in the first place, and extant patient safety reporting systems neglect near misses and their value.⁵

Legal Protection for Voluntary Reporting

The foundation of effective voluntary reporting, and indeed, any system of safety reporting in high-risk/high-reliability organizations and industries, is protection from punishment for good faith reporting and safety analysis. For health care, such protections have been very limited, and safety materials such as root cause analyses have been deemed legally discoverable to support lawsuits.

As previously noted, voluntary reporting systems may be more effective at getting providers to report errors and weaknesses and improve safety.¹² However, beyond the

inherent advantages of voluntary reporting of near misses and disadvantages of mandatory reporting of adverse events, the focus of the Act on prospective voluntary reports protect safety information, so its use is limited to its intended purpose of promoting quality and safety.

Under the Act's provisions, safety and quality information reported to PSOs and communicated within the entity's patient safety evaluation system is protected from disclosure or legal discovery. This constitutes a major advancement in patient safety. The legal protection addresses the great reluctance that exists among providers to report errors and system weaknesses in the absence of legal protections for the reported information. Such a reluctance was justified because safety information had been deemed discoverable in patient injury lawsuits,^{13,25} which led to underreporting and serious limitations in accurately assessing the true nature of safety risks within the delivery system and emerging trends not apparent at the patient care level. Such protections may also be valuable to protect against use of safety information to support patient injury litigation that claims a pattern of near misses known by the organization as evidence of negligence.

Although legal protection for voluntary reporting is important, other factors beyond fear of litigation or punishment may be present that also limit reporting. Embarrassment, risk to reputation, and negative media attention may play a role. Legal protections of the Act may or may not mitigate some or any of these factors, although a cultural change encouraging and accepting reports and knowledge that there is security from discovery may facilitate reporting. Whereas legal protection of near-miss reports may at first blush seem to have limited effect, its impact may be felt in the improvement of the culture of safety through the encouragement of the reporting of mistakes in a blame-free environment.

Standardized Terminology and Format

An urgent need exists for a standardized set of definitions in error reporting and safety. Too many resources are spent on health care measures that are either duplicative or ineffective and provide little comparative information for use by health professionals.⁴ For example, a recent study of medication safety found 119 different terms used for patient safety purposes, including 21 different definitions of adverse events, 13 different definitions of medical error, and 8 different definitions of a near miss.²⁶ In addition, there are more than 150 terminology systems in use to describe various medical domains.²⁷ These terminology systems have been promulgated by the federal and state governments, professional associations, and private organizations.²⁸ This pluralistic approach to terminology led the IOM to conclude that there is no universal safety nomenclature in the health care sector.⁵

The Act provides direction to address the inconsistent terminology and a confusing array of error and safety reporting systems in the United States. By mandating standardized elements for data to be reported to the national patient safety database for promulgation by the Secretary, a unified system of definitions and reportable information can be created. Such standardization can then fulfill the purpose of medical error reporting—to accumulate information regarding the occurrence and causes of medical errors to determine trends and

identify areas that need attention. This would replace the current health care error reporting “chaotic nonsystem.”¹²

In addition, a number of format issues can be clarified by the standardization provisions of the Act. Foremost among these is a process to develop an error reporting format and taxonomy that can be used for multiple comparisons. There is currently no agreement on a common set of data elements for representing patient safety information. Users of the available measures are hindered by the lack of reporting standards and inconsistent methodologies.^{29,30} Numerous data requirements from various organizations at the state level (state health departments), certification organizations (such as The Joint Commission), federal level (such as Food and Drug Administration), and private organizations (such as health plans and National Committee for Quality Assurance) are imposed on provider organizations. Each entity individually determines the elements and content of its reports, creating overlapping, contradictory, and inconsistent reporting expectations.

The current lack of format standardization creates unrealistic demands on providers and prevents data comparability between and within organizations. As a result of this confusion, the IOM recommended common reporting format in domain areas, data elements, and terminologies that would serve as a common language for reporting, research, and analysis on patient safety.⁵ The standardization provisions contemplated by the Act may address this need for reporting and feeding back information to health care organizations in a standardized way to provide effective learning while reducing the burden of capturing and reporting data to the PSO and the national database.

Prospective Prevention

Most risk assessment in health care is retrospective in nature. Retrospective risk assessment happens after an adverse event occurs and patient injury results. However, the IOM has noted that near-miss reporting and analysis systems should be created because near misses are often precursors of adverse events.^{4,5} This conclusion echoes experience from other high-risk industries in improving safety through a focus on near misses.^{8–10,13} Prospective risk assessment allows an understanding of the real or potential risk and then the opportunity to design a process in response that improves patient safety. There is a growing awareness in health care that such a more proactive approach to risk assessment in health care is required to eliminate risks and hazards that may lead to patient injury.³¹

Although the science of proactive risk assessment is very immature in health care, there is a growing belief that the voluntary reporting of near-miss data can contribute significantly to prospective prevention as it has done in other industries. The provisions of the Act create a patient safety evaluation system infrastructure to encourage, promote, and protect voluntary near-miss reports. This information provides the opportunity to analyze trends and events before patient injury occurs, yielding significant advances in patient safety. Process mapping, failure mode effects analysis, and probabilistic risk assessment are increasingly used methods in health care that allow design of safer processes prospectively.^{32,33} These can be both supported and facilitated by data feedback from a PSO. The Act thus allows health care to move beyond

post-failure “accident investigation” to the design of health care processes that make failure less likely and safety more likely.

DISCUSSION

The Patient Safety and Quality Improvement Act represents a catalyst for health care organizations to promote what we believe is a necessary system to improve patient safety: a legally protected near-miss reporting and analysis system that uses standardized terminology and formats for prospective prevention of errors and system weakness that could lead to patient injury.

The Act thus makes possible a new patient safety paradigm that in recent history has been difficult to imagine. Many safety hazards remain, despite common knowledge of their existence. There are processes that do not work without extraordinary efforts. There are traps that only the experienced, wary, and vigilant can avoid. There are procedures that spawn varieties of workarounds that are a tribute to the inventiveness and talent of health care providers while also constituting an indictment of poor systems design. Indeed, much of the learning by students and trainees involves the practical folklore that enables poorly designed equipment, facilities, processes, and systems to struggle on. The Act has the potential to energize patient safety at the local level through a comprehensive set of information not presently available.

The Act provides reason for optimism to improve patient safety. The most effective tool available to address the many issues within our very complex human-dependent system is simple intellectual honesty. The Act invites and protects tellers of truth to tell their story in a forum that will use their knowledge appropriately. It opens many opportunities to explore the causes and prevalence of near misses as well as a format to improve systems at both the sharp end and blunt end of patient care processes to improve patient safety before injury occurs. The Act recognizes that it is these people who can provide the most information, and their encouragement is, in our view, an important advancement for the safety enterprise.

As a corollary to a focus on reporters, system transparency is also a critical component necessary for highly reliable safety performance in hazardous industries.³⁴ Transparency, the shared access of all players to knowledge of the system’s daily function and weakness, permits a culture that supports intellectual honesty—the ability and habit of openly acknowledging problems. Blame, shame, denial, cover-up, and shifting accountability are too common in systems such as health care that create ethics and mandate relying inappropriately upon individual accountability even when the reality is that systems should generally be the focus to improve outcomes.³⁵ With the Act’s passage, there is now the potential to focus on the reality of health care delivery and allow intellectual honesty and open reporting of system problems.

Of course, 1 piece of legislation cannot solve all of the health care delivery system’s issues. The best reporting system cannot provide learning from the data nor reduce the probability of recurrence if they are simply collected and placed in an administrator’s office.³⁴ Indeed, several criticisms of the Act have been leveled. They include the following: the Act does not guarantee that mistakes will be reported; there are no penalties for failing to report errors; there is no incentive to

report mistakes; and there is no definition of medical error within the statute itself.⁶ Other critics argue that, without mandatory public reporting, there is no gain for safety through this legislation.¹² In addition, there is concern that adequate funding will not be available to fund a PSO system.

Although these criticisms are valid, and the effectiveness of the statute will require the test of time, we do have some thoughts. First, as other industries and systems have noted, no law or mandate can ever guarantee that errors will be reported. Positive and negative incentives can be in place, but ultimately, all reporting systems are voluntary and depend on the people who are within these systems to provide the necessary information to promote their goals. Second, we note that voluntary reporting systems have indeed garnered some success. Commercial and general aviation, nuclear power, oil and gas, the military, and other large scale systems have used voluntary reporting strategies and learned lessons that have promoted safety. We would hope that the talents and creativity of those in the health delivery system would be at least equivalent to those in these other systems and organizations and provide similar results over time.

In addition, statutory definitions and funding remain important issues to address before implementation of the Act can occur. Forthcoming regulations, which have not yet been issued in interim or final form, may address these concerns, and consortium models to fund safety activities beyond available public funding may be a method to defray some of the costs associated with these efforts.¹³

Of course, there are substantive and important discussions that remain that must be addressed but are beyond the scope of this paper. For example, how can organizations learn from incidents that are voluntarily reported? How will PSOs achieve the greater goals of the statute without a substantial infusion of research funding? Will reductions in basic research in patient safety limit advancement in meaningful safety interventions?

How should health care organizations filter incident reports for effective analysis of systems issues with PSO? What metrics should be used to determine whether trends in self-reported events are informative or useful in improving safety?

These questions will require significant attention by policymakers and providers as the Act’s provisions are elucidated and implemented; substantial research will be necessary to help answer these questions. Under the terms of the Act, an unprecedented opportunity to improve safety is upon us. In our view, we need to take advantage of it and move forward so that the current generation of patients, and those that follow, obtain the benefits of a delivery system that continuously assesses itself to improve the safety of the services it provides.

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