Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improvement Act

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Abstract

The Patient Safety and Quality Improvement Act, passed in 2005, has been heralded as an important advance in patient safety. Numerous questions have been raised regarding details of the implementation of the legislation. Recent concern has been expressed that progress in implementing the legislation has been slow, and important issues have not been addressed to transform the legislative intent into a viable patient safety system. To date, no model has yet been offered on how the information exchange between the Patient Safety Organization (PSO) contemplated by the Act and client health care organizations can be completed and acted upon. In this article, we propose a Care Enhancement Model, based on our experience in aviation and health care safety, which describes how information can be prioritized, acted upon, and used for improvement. We present the thematic tenets of the "Care Enhancement Model" as a blueprint to connect the PSO with a provider setting and a national Network of Patient Safety Databases (NPSD) as created by the Act. We then provide detailed roles and responsibilities of each of these components that might provide guidance for an effective tripartite safety system.

Introduction

The Patient Safety and Quality Improvement Act of 2005 (the Act) has been heralded as an important advance in patient safety. Several reviews of the Act outline its main features.[1, 2, 3, 4] The Act reflects the need for voluntary reporting of error and system weakness information for organizational and industry learning. The Act provides for legal privilege for reports and information regarding safety between any health care provider and a Patient Safety Organization (PSO). Furthermore, the Act provides for a national Network of Patient Safety Databases (NPSD) of voluntary incident reports submitted by PSOs and others for broad dissemination and learning. Therefore, the Act has the potential to create an event reporting system that provides feedback for developing safer practices associated with preventing, identifying, and mitigating harm to patients associated with the processes of care.[5]

Due to the complexity of the regulatory process,[6] the limited guidance available for providers, and the uncertainty about the role PSOs should play, progress in implementing the Act has been slow.[7, 8, 9, 10] Moreover, it is recognized that the detection, by itself, of an event or error is not sufficient to improve patient safety.[11] Detecting and reporting of harm and near misses as they occur in health care settings are essential, but they are only part of the full complement of

components of patient safety improvement and error management programs.[12] Clearly, the control of safe operations is a continual process.

No model has yet been offered that describes how the information exchange between the PSO and client health care organization can be completed and acted upon. This article presents a model to describe how voluntarily reported information can be prioritized, acted upon, and used for improvement among providers and PSOs. Specifically, we propose a "Care Enhancement Model" as a blueprint that connects the PSO and health care organization in the context of the national database network. We then discuss the roles and responsibilities of each part of the triumvirate of health care organization, PSO, and national database network. In this description, we outline the manner by which health care organizations would interface with the PSO and the national NPSD to improve safety.

In addition to the ability to respond rapidly and effectively to changes in the safety realm, the prerequisites for adequate safety control require a sensitive multichannel feedback system.[13] While a more proactive approach to risk assessment is desirable,[10] no construct has yet provided guidance as to how providers and PSOs can and should work together to effectively improve safety.

Care Enhancement Model

The Act provides a basic framework for the structure and function of the PSO and how it relates to health care organizations that are the source of error reporting.[4, 5] There are three main components in a national voluntary reporting system: the PSO, the client health care provider organization, and the national database network. The Act suggests specific roles for each of these three components: (1) the PSO provides a defined list of services that are legislatively described; (2) the health care provider organization is a client to the PSO and uses its services to improve patient safety within the service setting; and (3) the national NPSD acts as an archive and resource for safety information. Figure 1 shows the three components of the Care Enhancement Model for the national voluntary reporting system and how they can relate to each other.

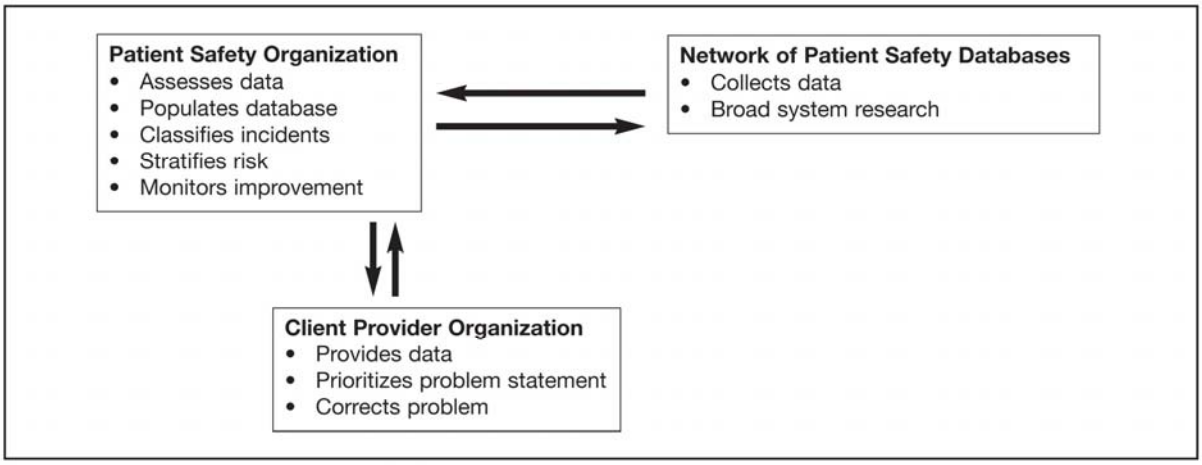

Figure 1. Three components of a national Care Enhancement Model for a voluntary patient reporting system.

The broad relationships noted in the Care Enhancement Model are thematic. Hence, some details with respect to the roles and responsibilities of these three components may be helpful to guide implementation by each entity to maximize safety improvement in the health care delivery system. Through this model, reports are analyzed for local purposes, used for national assessments, and archived for future use. They are provided internally to the provider organization and externally for global application and alerts. This circular flow of information provides a continually improving safety effort while consistently adding data to allow for additional work for care enhancement in ways not contemplated at the time they are reported or analyzed.

The Health Care Organization

The central focus in the voluntary reporting system is the health care organization, which serves as both the source of error reporting and the location where safety management and improvement programs provide feedback meant to improve care. As such, the health care organization must participate in error reporting for its own benefit and to benefit the industry as well. The health care provider organization also represents the "sharp end," and hence, is responsible for in-depth event investigation to assess associated event or incident causal factors. Tight coupling of this information with appropriate system change and redesign,[14]—through use of Problem Statements to focus efforts—will help to improve system functionality and safety.

Problem Statements describe and quantify identified risks the institution faces. The health care organization transmits the Problem Statement to the PSO and concretely defines the core performance issue to be addressed. The health care organization is responsible in the Care Enhancement Model to assign priority for Problem Statements and to implement corrective measures. Figure 2 illustrates the application of the patient safety information received from the PSO and describes how the Problem Statements are used for improvement. This structure is patterned after the air carrier risk-management model and positions the health care organization

Figure 2. Use of problem statements in health care organizations.

as both the source of near miss reporting and user of the products from the PSO to improve its systems and safety practices.

We identify four distinct components inside the health care organization. First, the Patient Safety Department (PSD) serves as the interface between the PSO and the organization. The data are reduced to the format agreed upon by the PSO and transmitted to the PSO. The key questions asked of each Problem Statement are:

- What is the frequency of occurrence?
- Was this a one-time event or a point on a trend line?
- What are the ramifications of the Problem Statement's recurrence?

The second component in this model is senior management, which holds ultimate accountability for the Problem Statements. Senior management must take several critical steps for care enhancement including:

- Determine priorities for correction, as reflected by allocation of resources to problem correction.
- Assign responsibility to appropriate line departments to design and implement corrective strategies.
- Create a timeline for process improvement.

Managing the Problem Statement involves management's determination of priorities and resources to be committed to correction; assignment of responsibility for correction; and development of processes to track the accomplishment of corrective measures and changes in system performance.

The Problem Statements would be presented to senior medical center management in regularly scheduled periodic meetings. In conference with PSD staff, this leadership group receives the information contained in the Problem Statements, the assessed risk of which has been determined by PSD staff. As appropriate, leadership directs further inquiry and then deliberates on the implications of the information. Senior leadership then assigns priority for corrective measures, including budgetary and policy alignments, as necessary, based on a management determination of the best interests of the institution. In making these decisions, the senior leadership could ask the following questions to assist in prioritizing the Problem Statements:

- Could the Problem Statement issue directly cause a medical accident?
- Could the Problem Statement issue result in death or serious injuries to individuals?
- Does the Problem Statement issue have a significant impact on patient care?
- Does the Problem Statement issue have a serious impact on cost, reliability, or compliance?

The third component in this model is the Clinical Unit Leadership (CUL). Once senior management has prioritized the Problem Statements, it must identify the accountable line department responsible for corrective action. Unresolved Problem Statements then become Prioritized Problem Statements and are assigned to the CUL. The accountable department within the institution that is responsible for corrective action receives the statement as a directive to develop relevant and effective solutions. The CUL should be able to draw on other resources

within the organization—such as engineering, patient safety, and quality improvement departments—as needed. For example, if senior management has prioritized a Problem Statement for surgical care, the perioperative division would be the accountable department within the institution that is responsible for corrective action and would receive support from other departments. Key to this system is the fact that, rather than having a support department assume the primary responsibility, management of the operational department is itself accountable for the correction with the assistance of a support department.

The accountable department that is responsible for corrective action receives the Problem Statement as a directive to develop an intervention or solution in conjunction with PSD staff and whatever additional resources are required. The solutions are crafted by the line organization designated responsible by senior management. Both the accountable department and senior management should look to external support to implement appropriate changes. The PSO, as well as other sources of guidance, should be available to the accountable department to create positive changes that address the Problem Statement. In this manner, all available resources are utilized to engage the process of system safety improvement.

The health care organization cannot simply stop at accepting a Problem Statement and assigning it to an accountable group. Organizational management is also responsible for monitoring the progress of potential corrective actions. As measures are implemented responding to the various Problem Statements of the organization, senior management should receive routine updates to chart the organization's performance and any issues created by the safety interventions. Should an intended improvement not produce the expected results, that fact should be identified and the cycle repeated. In this manner, proactive interventions are developed, and the embedded regularly scheduled reviews by senior management assure continual understanding of the organization's performance improvement and mitigation of risk. This methodology helps enhance the culture of safety and provides a real-time understanding of system function, both critical goals of the Act and in the safety improvement enterprise.

The fourth component in our model is the Safety Dashboard (SD), a graphic depiction similar to a Gantt chart on which PSD staff record the progress of corrective actions accomplished by the responsible organization. The chart depicts timelines for implementing the various corrective measures, and assignments are color-coded, tracked, and displayed to give a rapid overview of the progress of all prioritized Problem Statements. The Safety Dashboard is the core means to communicate the Problem Statement and risk assignment, the organization unit accountable for the Problem Statement, the interventions, and the timeline for completion.

The Safety Dashboard is reviewed at the regular PSD meetings with senior management to assure that remedial measures are being implemented as agreed, thereby assuring that senior management has complete information to meet its accountability obligations. In addition, once the interventions have been applied, the SD serves as a link to the safety databases to monitor performance improvement. As corrective measures are implemented, the PSD continues to chart the organization's performance. If an improvement does not produce better results, that fact would be identified and the process begun again.

Three points are important to emphasize. First, the PSD is a staff organization that supports both senior management in its requirement to account for the organization's performance and the

CUL for practical and technical assistance in meeting the responsibilities assigned to them. At no time does the PSD assume an active role as designer or implementer of corrections. This separation is essential for assuring that the PSD remains unbiased in its assessments of performance. By virtue of its position outside daily operations, the PSD is able to serve an objective measurement and reporting function.

Second, management of the Problem Statement includes management's determination of priorities for correction, as reflected by allocation of resources to problem correction. Management simultaneously assigns responsibility to appropriate line departments to design and implement corrective strategies.

Third, the near misses encountered by practitioners in the workplace can be reported in the health care organization without fear of punishment or retribution. Personnel within the organization are the sources of the reports, which are transferred through the PSO to the organizational entity's administration. The entity's administration can then provide the reports to the PSO using its patient safety evaluation system as defined by the Act.

The PSO

The second component of the model in Figure 1, the PSO, creates and populates the performance database from various data sources, identifies trends and stratifies risk, and develops Problem Statements. The PSO receives information from two sources: the client organizations and the Network of Patient Safety Databases. The PSO assesses the information from these sources and feeds back lessons learned to those health care organizations with whom it has contracted, as well as to the broader health care industry. In addition, the PSO is responsible for tracking corrective measures and measuring summative changes in system performance.

The PSO classifies, analyzes, and warehouses the reported data and returns a Problem Statement to the PSD. The PSO applies hierarchical linear modeling, determines best methods to analyze data that reside at multiple levels of analysis, analyzes trends, reduces data, and assigns the report to existing Problem Statements or creates a new Problem Statement. The risk assessment assignment of the Problem Statement is a statistical calculation that considers the probability the hazard will be encountered and the severity and ramifications of a hazard encounter.

Note that the PSO can be a freestanding organization, or it can be associated with an existing organization. In the latter case, this "component organization" would be required to have sufficient protections to isolate the PSO functions from the other operating functions of the larger organizations.[15] However, this should not affect its ability to function effectively within the Care Enhancement Model. The PSO will receive reports from client organizations and assess these data. Using these reports and lessons learned, the PSO will populate its own database, as well as a national network of databases.

On a local level, the PSO will classify and stratify risk on the basis of reports and analysis, provide avenues and pathways for potential improvement, and monitor whether improvement has in fact been accomplished. As noted above, one of its most important roles is to prepare and disseminate Problem Statements to client provider organizations and perform a clearinghouse function for the associated potential benefits from this activity on the local and national levels.

Reports distributed by the PSO would include not merely adverse events, but also information derived from the several sources. These include near miss and hazard reports, *in situ* simulations, sentinel events, security reports, and any other lens through which reliable insights into the organization can be obtained. This PSO role is essential for health care organizations to benefit from a near-miss reporting and analysis system.

The aviation experience with the Aviation Safety Reporting System (ASRS) suggests a near-miss reporting and analysis system can provide: (1) modeling, to gain insight into near misses that can become an adverse event; (2) trending, to gain insight into the distribution of failure and recovery factors; and (3) mindfulness, to maintain a level of alertness in the work environment.[16]

A key underlying assumption of the Act is that voluntary reporting of near misses will improve patient safety. This assumption is based on the success of the voluntary reporting system developed in commercial aviation, which has shown that analysis of near-miss data provides an opportunity to design systems that can prevent catastrophic events. The ASRS system—as it has matured into the Aviation Safety Action Program (ASAP)—is an effective model for health care hazard/near-miss reporting. Similar to aviation, the PSO will require an effective patient safety taxonomy (classification) system to gather, classify, analyze, and retrieve information about near misses, hazards, and adverse events. Following this pattern, a PSO will direct the development of a taxonomy by which system deficiencies are classified for entry into a secure database. The near miss/hazard reports will become a uniquely rich source of system intelligence.

A standardized taxonomy is needed because many organizations and agencies collect safety data, yet there are few common frameworks to classify such data.[14] The Patient Safety Event Taxonomy (PSET), developed by the Joint Commission, is a standardized terminology and patient classification scheme for near misses and adverse events.[17] The PSET taxonomy is a key prototype for a PSO system because it can link to other patient safety taxonomies and to local reporting systems and specific areas of clinical care.[18] Appropriately qualified personnel will continually evaluate these data for improvement opportunities. Developed information will be transmitted regularly and systematically to accountable management in provider organizations that participate with the PSO.

The structure of these reports may vary, depending on the health care organization and the PSO assisting the organization due to differences within the local environment. For example, acute care hospitals in urban environments will require different data reporting formats from those needed by outpatient surgical centers in rural settings. The PSO within the Care Enhancement Model would assign data to taxonomies, determine best methods for analyzing specific data at multiple levels, perform trend analysis and data reduction, and identify issues as they relate to existing Problem Statements or create new Problem Statements for the health care organization.

PSO Problem Statements can be developed and articulated based on the answers to several key questions derived from errors or incidents. These include:

- What is the frequency of occurrence?
- Was this a one-time event or a point on a trend line?

- What is the risk assessment of hazards associated with the event and potential severity of a negative outcome?
- What are the ramifications of the Problem Statement issue recurrence?

The answers to these questions are a function of the particular events or incidents, the locale of care, the providers and management involved, and other factors reflecting the fact that all health care is local. This is an important benefit of creating these Problem Statements and a reason why they are of primary importance in the Care Enhancement Model presented here. The Problem Statements developed by the PSO are transmitted to the health care organization and acted upon based on prioritization by management in the client facility. To complete the feedback loop, the health care organization should also submit periodic reports to the PSO. In this way, improvements can be monitored and shared with other organizations, the health care system generally, and the national database network.

The airline industry has shown that analysis of near-miss data provides an opportunity to design systems that can prevent adverse events. However, near-miss data for the health care domain require more extensive analysis than is currently done and must be acted upon at the level where system weaknesses are found.[14]

The incident causation model developed by Van der Schaaf[19] has four components: (1) initial failure, (2) dangerous situation, (3) inadequate defenses, and (4) recovery. In this incident causation model, near misses are precursors to possible adverse events. Examining near misses provides two types of information relevant for patient safety: weaknesses of the health care organization processes (errors, failures, and inadequate system defenses) and strengths of the organization —such as unplanned recovery—which compensate for those weaknesses. These informal recovery systems are characteristic strengths of high-reliability organizations.[20]

National Database Network

The third component, the national Network of Patient Safety Databases (NPSD), will collect data from PSOs and other information. However, it is clear that the national database network is not a "national PSO."[15] The Act directs that the national NPSD be authorized to accumulate and analyze voluntarily reported, nonidentifiable patient safety data; develop common reporting formats for the reporting to and among the network's patient safety databases; and analyze national and regional statistics, including patterns of health care errors.[2] We propose that the NPSD be patterned after the ASRS,[21] which allows for voluntary reports regarding safety issues across the aviation system for broad research and learning purposes.

The Patient Safety and Quality Improvement Act calls for a national, voluntary patient safety reporting system based on a network of regional PSOs that contract with local health care organizations.[4] One primary responsibility of the national NPSD is to collect data from PSOs throughout the country. However, it is very important that the network make such information easily available for providers and researchers in health care system safety. We emphasize that the full benefits of such a database can be realized only by making the information accessible.

In addition, like the ASRS,[22] the network database should be used by government researchers and agencies—such as the Centers for Medicare & Medicaid Services—to ensure that care is

being enhanced. Incentives such as reporting to PSOs, whose reports are certified as being placed with the network, might be the basis of hospital and other provider reimbursement increases. This is currently the procedure used in the Physician Quality Reporting Initiative and the Reporting Hospital Quality Data initiative.[23, 24] Also, like the ASRS, newsletters and other means of disseminating NPSD findings should be a fundamental part of the national database network's scope of responsibility. This would allow the NPSD to maximize its potential for safety promotion.

Conclusion

In this article, we have described a Care Enhancement Model to implement the components of the Patient Safety and Quality Improvement Act. We have drawn upon principles garnered from the aviation and health care safety systems to create what we believe is a practical approach with the capability to fulfill the potential of the Act. To be useful as a management tool, patient safety data must be voluntarily reported and reduced to meaningful information. The risk management process—accomplished through the Problem Statement, Prioritized Problem Statement, and Safety Dashboard methodologies—creates a transparent sequence to ensure that the organization is aware of the risks and challenges it faces. Proactive interventions are developed, and regularly scheduled reviews by senior management assure continual understanding of the organization's performance improvement and mitigation of risk.

Using the Care Enhancement Model approach, which is patterned after the air carrier risk management model,[21] the PSO can create and populate the performance database from these and other data sources in order to develop trends and risk stratification for the health care organization's experience. This structure can also provide health care managers with an important safety tool based on learning from the commercial aviation industry: concrete Problem Statements that describe and quantify identified risks confronting the institution.

Using Problem Statements, the health care organization, the PSO, and the national database network are integrated. They provide the health care manager with a focus on the areas of safety and system weakness that are important to improve care, reflecting the local nature of all health care system performance. The Problem Statement also allows the PSO to focus on assisting and engaging health care providers with information and lessons learned from safety experience within and outside local health care organizations' geographic and professional locales. Moreover, lessons from efforts focused on the Problem Statement can then be fed to other health care entities and used to populate the national database network.

As we have emphasized throughout this article, all health care is local. An effective voluntary reporting system can only be developed by extensive accountability at the provider organization that acts on near miss and incident reporting data. These data are not currently available and will not be available without a national system as is contemplated by the Patient Safety and Quality Improvement Act. By building on the basic infrastructure represented by the three components of a national voluntary reporting system (the health care organization, the PSO, and the national database network), the Care Enhancement Model should be adaptable and flexible enough to address system issues across a wide spectrum of health care delivery settings.

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