

SAFETY PLAN

A safety plan is designed to support and promote the mission, vision, and values of an organization, with a special focus on the continuous enhancement of safety for all patients. It defines institutional safety priorities and delineates the mechanisms for effectively responding to patient safety concerns in both a proactive and reactive fashion, with the goal of reducing risk, errors, and other adverse events. A safety plan constructs the foundation for a systematic and coordinated approach to integrating patient safety priorities into the design and redesign of all relevant organizational processes, functions, and services. Bringing the plan to fruition requires an organizational safety infrastructure that operationalizes mechanisms and mobilizes resources for effectively addressing patient safety concerns. This chapter examines some of the issues around organizational patient safety planning.

KEY ISSUES

◆ Accreditation Standards

The Joint Commission (TJC) Patient Safety Standards require that “...leaders ensure implementation of an integrated patient safety program throughout the organization.” (JCAHO Standard LD.5)⁽¹⁾ At a minimum, the program must include the following:

- ◆ *"Designation of one or more qualified individuals or an interdisciplinary group to manage the organization-wide patient safety program."*
- ◆ *"Definition of the scope of the program activities, that is the types of occurrences to be addressed - typically ranging from 'no harm' frequently occurring 'slips' to sentinel events with serious adverse outcomes."*
- ◆ *"Description of mechanisms to ensure that all components of the health care organization are integrated into and participate in the organization-wide program."*
- ◆ *"Procedures for immediate response to medical/health care errors, including care of the affected patient(s), containment of risk to others, and preservation of factual information for subsequent analysis."*
- ◆ *"Clear systems for internal and external reporting of information relating to medical/health care errors."*
- ◆ *"Defined mechanisms for responding to the various types of occurrences, e.g. root cause analysis in response to a sentinel event, or for conducting proactive risk reduction activities."*
- ◆ *"Defined mechanisms for support of staff who have been involved in a sentinel event."*
- ◆ *"At least annually, a report to the governing body on the occurrences of medical/health care errors and actions taken to improve patient safety, both in response to actual occurrences and proactively." ⁽¹⁾*

◆ **Determining the Scope of a Patient Safety Program**

According to The Joint Commission, "scope" refers to the types of incidents that will be addressed by an organization's patient safety program. Incidents can range from near-misses that cause no harm to sentinel events that are very serious in nature.⁽¹⁾ The organization's response to patient safety concerns will, to a large degree, be determined by the scope of its patient safety plan. The plan's scope will influence the selection and prioritization of institutional safety activities, including the mechanisms necessary to appropriately report and respond to incidents. In essence, establishing the scope of a safety plan is the starting point – the blue print for mapping out the policies and procedures that will put into place a systematic mechanism for achieving patient safety. When setting out to formulate an organizational patient safety strategy, one must be mindful of the breadth of the population that is affected by an organization's healthcare activities. A truly comprehensive approach to patient safety goes beyond the realm of the patients themselves. Recognizing this fact, TJC reminds healthcare organizations that *“Although the standards focus on patient safety, it would be difficult to create an organization-wide safety initiative that excludes staff and visitors. Many of the activities taken to improve patient safety (eg. Security, equipment safety, infection control) encompass staff and visitors as well as patients.”*⁽¹⁾ Organizations will therefore need to give thoughtful consideration to the mechanisms they establish to ensure that safety activities are effectively designed and coordinated to achieve safety for patients, staff, and visitors alike.

◆ **Creating a Safety Oversight and Management Structure**

The Joint Commission requires that safety activities are *“...integrated into the new design and redesign of relevant organizational processes, functions, and services across the organization”*.⁽¹⁾ However, they do not prescribe what the specific organizational structure of a patient safety program should look like. What they do suggest is the following: *“The standards do not require the creation of new structures or ‘offices’ within the organization; rather the standards emphasize the need to integrate all patient-safety activities, both existing and newly created, with an identified focus of accountability within the organization’s leadership.”*⁽¹⁾ While there is an expectation that the entire membership of an organization shares ownership for patient safety, the overriding mandate is clear: the primary responsibility for ensuring the successful implementation and monitoring of compliance with safety standards rests with the leaders.⁽²⁾ Accountability is expected to go up the chain of command to senior line executives, who in turn must be positioned to support all of the functional operations within the organization. For it to be successful, an organization's patient safety program must have well defined executive responsibility and the various safety functions should report regularly to the highest authorities within the organization. At a minimum, this involves review, at the executive level, of error occurrence reports and action plans to address proactive and reactive responses by the organization to actual occurrences and potential risks.⁽³⁾⁽⁴⁾ In addition to reviewing data, executives in both the clinical and non-clinical arenas should be involved in actively monitoring the organization’s safety systems, including such activities as walk-throughs and safety rounds. This level of monitoring provides a first-hand opportunity to observe high-risk settings, evaluate hazardous conditions, and to interact openly with front-line staff about their safety concerns.⁽⁵⁾

Over and above the role of executive leadership, the day-to-day oversight and management of an organization's patient safety program should rest with either one or more qualified individuals or with an interdisciplinary group.⁽¹⁾ The advantage of having one or more dedicated positions for this role is that it enables a more focused coordination of all of the mandatory components of the safety plan and monitoring of program implementation.⁽²⁾ Otherwise, an interdisciplinary

collaborative, such as a Patient Safety Committee consisting of members representing a spectrum of clinical and non-clinical groups, may be charged with the patient safety oversight and management function. Some experts suggest merging existing departments together, such as the Quality Improvement and Risk Management departments, collapsing them into one functional entity. Another approach taken by some organizations is to shift the primary responsibility for oversight and management of the patient safety program to an existing department or committee by broadening its scope and function, with defined linkages and lines of accountability between entities. Since The Joint Commission requires that an organization's planning process take into account performance improvement priorities that respond to high-risk, high volume, or problem-prone processes, many organizations incorporate patient safety into their existing performance improvement structure.⁽¹⁾ Using a combined approach, an organization may decide, for example, that the patient safety oversight and management function would be best accomplished with the designation of a Patient Safety Officer who works in conjunction with a Patient Safety Committee and a Quality Improvement department, all of whom report up to an oversight entity such as a Performance Improvement Committee.

In addition to having a direct line to executive leadership and a well-defined oversight function, an organization's formal safety structure must lend itself to the successful integration of all newly created and existing safety functions for patients, staff, and visitors. In some cases, this might entail substantial redesign of an organization's traditional approach to safety management.⁽²⁾ Historically, safety has been addressed by hospitals in a somewhat disconnected manner, with separate entities each responsible for individual aspects of organizational safety. For example, Risk Management would handle issues related to legal liability, risk reduction, and loss prevention; Quality Improvement would focus their efforts on improving healthcare processes and outcomes; Safety Management would oversee the safety of the environment of care; Infection Control worked to reduce nosocomial infection rates, and so on. In order to achieve total excellence in safety, it requires the full integration of an organization's individual structures into a comprehensive safety program so that they function in a collaborative fashion to effectively achieve the goals and objectives set forth in the institutional safety plan.⁽⁴⁾

Another facet of the patient safety program that must be taken into consideration in the planning phase is the role of the existing institutional environment of care function in the oversight and management of patient safety activities. Before the advent of the patient safety movement, hospitals accredited by the Joint Commission were required to develop a safety structure, most often under the leadership of a Safety Officer, that addressed seven formal management plans encompassing essential elements of the environment of care. These comprise the management plans around the specific issues of safety, security, life safety (fire safety), emergency, hazardous materials and waste management, equipment, and utilities. With the new patient safety requirements, healthcare organizations are urged to integrate the environment of care function into the patient safety structure, through the involvement of the Safety Officer in the organization-wide patient safety program.⁽¹⁾ Organizations will need to consider whether to structurally merge environment of care with patient safety or to make the connection in some other manner. One option would be to coordinate institutional safety efforts through membership representation on the Patient Safety Committee by environment of care leadership.

Ultimately, each individual organization must decide what the best structure is for oversight and management of its own patient safety program to ensure that it fulfills the scope of the safety plan and that it facilitates implementation of the plan's goals and objectives.⁽²⁾ Simply put, it is a matter of structuring the organization in such a way as to optimize its ability to perform its safety functions effectively. Regardless of how the patient safety program is actually configured, each organization should ensure that they have in place a safety structure that creates a functional

linkage between an organization's governing body, its oversight/management arm, specific functional entities, and the rest of the membership.

◆ **Implementing Patient Safety at the Departmental Level**

Safety initiatives stand a far better chance of being successfully implemented if all members of an organization are actively engaged and committed to the safety mission. This requires all members having a good understanding of the intent of the institutional safety plan and of how they play a part in meeting the goals and objectives of the plan. This connection can be best made at the departmental level. The first step that most organizations take is to establish their institutional safety priorities and to incorporate them into the goals and objectives of their high level strategic plans. What follows is the development of performance measures that will be used to measure overall institutional and individual departments' progress in meeting these safety goals and objectives. The selected measurements should reflect those institutional safety concerns that are high risk, high volume, or highly problem-prone in nature, which have the greatest potential for harm. In collaboration with organizational leaders, each clinical and non-clinical department, as part of its departmental performance improvement plan, then devises its own specific strategies to meet the institutional goals and objectives. These specific strategies outline how the department will contribute to the organizational safety effort and help to achieve positive performance outcomes. Departments may already be engaging in some quality improvement initiatives that could be aligned with institutional patient safety priorities. Otherwise, new initiatives will need to be devised that are linked to the organization's strategic plan. The performance improvement methodology that is used on the organizational level can then be applied at the departmental level for ongoing assessment of performance related to departmental safety activities.

CHALLENGES

◆ **Organizational Role Structures**

Organizations and the members working within them can become accustomed to their established internal role structures, so much so, that when they are faced with circumstances that require them to respond differently, adapting to new role structures can create confusion. Experience shows that there is a greater likelihood of conflict and confusion within an organization if changes to role structures do not keep pace with the changing demands of the environment in which the organization exists. At this point in time, healthcare organizations are being urged to reconfigure their role structures to effectively address the issue of medical risk and error. During the transitional stage, there is always a risk of developing a hastily designed and ill-structured response, which will have an adverse effect on the behavior of an organization. To ensure that the organization remains resilient through the change process, great care needs to be given to properly orient members to their new roles, to avoid creating ambiguous tasks, to ensure that key roles are in place within the organization, and to legitimize the new role system.⁽⁶⁾

◆ **Multilevel Strategies for Achieving Safety**

A safety plan influences the establishment of safety priorities and the mobilizing of resources for addressing safety concerns in both a proactive and reactive manner. This is not a simple process since it is well known that to achieve safety in complex systems it requires the use of multilevel

strategies. No one strategy can be effective in addressing the broad spectrum of risk factors that emerge from the dynamic interface of the many elements present within a system. Below are some of the organizational strategies that can be used as part of the safety plan implementation. Based on the factors that are known to contribute to each patient safety concern being addressed, organizations will need to evaluate what they are trying to accomplish and which strategies will be the best fit for achieving desired outcomes. For example, because of the many factors that contribute to problems of error in the patient identification process, it may necessitate employing multiple error prevention strategies. These may include interventions involving engineering (instituting barcoding technology), cultural change (addressing the acceptability of work-around processes), safety management (clarifying whose job it is to replace patient ID bands), performance leadership (replacing a punitive style of management with one that is more participative), education and training (assessing competency evaluation), and enforcement (conducting audits of blood transfusion forms).⁽⁴⁾

◆ **Engineering**

Designing for safety in order to safeguard against incidents is the primary emphasis of an engineering strategy. This includes altering features of the work environment through the use of automation, ergonomics, workflow redesign, analysis of man/machine interface, and other process safeguard and design methods.

◆ **Cultural Change**

A cultural change strategy recognizes the potency of the “unwritten rules” that guide behaviors of an organization’s members and understands how these assumptions can affect the degree to which safety is embraced. Strategic initiatives include clarifying an organization’s mission, vision, and values and demonstrating a visible commitment to safety by leadership.

◆ **Safety Management**

This strategy attempts to improve the management systems and structures of an organization’s safety operations. Based on the premise that good management fosters a positive relationship between structure, process, and outcomes, initiatives focus on organizational design by defining job responsibilities, measuring accountability, goal setting, action planning, etc...

◆ **Performance Leadership**

The focus is on a participative style of management that empowers employees, encourages teamwork, and reinforces safe work practices through reward and recognition. Management is encouraged to model desired attitudes and behaviors, as opposed to using a “command-and-control” style of management that focuses on punishment.

◆ **Education and Training**

This strategy attempts to influence the attitudes of an organization’s members through the creation and implementation of safety policies, procedures, manuals, and programs for orientation, training, and remediation.

◆ **Enforcement**

The focus of enforcement is to improve an organization’s compliance with external requirements. Monitoring compliance involves activities such as facility inspections, audits, walk-throughs, and other interventions that are intended to minimize risk of external sanction.⁽⁴⁾

◆ **Finding the Best Solutions**

"The widespread publicity surrounding patient safety...results in tremendous political pressure to do something."⁽⁷⁾ In this current climate, it is tempting to look for "quick fixes" to the problem of patient safety. Yet, it is imperative not to jump to premature solutions just to appease those demanding change, but to pause and thoughtfully evaluate the effectiveness and impact of any patient safety initiatives before they are implemented. The greatest risk is that, in an

organization's haste to adopt safety initiatives, numerous unforeseen consequences could be unintentionally created and introduced into systems that may present even greater risks than the ones being mitigated. There is a danger in narrowing the focus of possible solutions too quickly, to the exclusion of others that may potentially produce far better patient safety outcomes. Even if an intervention proves to be successful in one setting, it may not necessarily work as effectively in another setting. Each organization has its own unique set of variables that can influence the success or failure of an intervention, which makes the transferability of interventions to some degree unpredictable. There is further risk in thinking that if one initiative is adopted, no other substantive efforts need to be made towards achieving the goal of safety. For example, concern has been expressed that some organizations may focus predominantly on instituting mandatory reporting as the "magic answer" to patient safety, without putting any effort into examining other factors that are also known to contribute to medical errors, such as organizational culture and work processes, or the role of leadership in downplaying safety issues. Some organizations may also believe that the best solutions to patient safety are complex and must come with a hefty price tag. Yet, at times, the best solutions are discovered to be the ones that are relatively simple and cost-effective. ⁽³⁾⁽⁷⁾

Some organizations may also have the mistaken impression that technology is the ultimate answer to patient safety. While technology has a lot to offer, in the quest for patient safety, incorporating technology into the workplace can also be a "double-edged sword" in that it alters work processes and shifts the risk points for error. Technology can also create unforeseen complications by introducing variables that add to the complexity of healthcare delivery due to greater interface between humans and machinery. For example, infusion pump programming errors by practitioners have been known to contribute to patient fatalities. Another danger lies in the human tendency to become overly reliant on technology and to acquire a false sense of security about its reliability - so much so that one's guard comes down and human involvement in monitoring and double checking potential systems weaknesses is diminished. Ideally, human expertise should be used in conjunction with, and not replaced by technology. Technological interventions should be approached judiciously and when implemented, they should be done so in the context of a monitoring system that is capable of detecting and correcting unintended consequences in order to negate the potential for harm before it reaches the patient. This necessitates maintaining an appropriate level of human involvement. ⁽³⁾⁽⁸⁾⁽⁹⁾ Another issue around the use of technological solutions is that organizations may intentionally or unintentionally use technology as a surrogate for doing the difficult work of changing the cultural mindset and behavior of an organization. *"It is easier to buy technology than to change organizational culture and human behavior."* ⁽³⁾ Bringing about the organizational changes necessary for safety in healthcare may require as much of an effort to change its culture as to change its technological infrastructure. ⁽¹⁰⁾

In order to lessen the potential for falling into the "quick fix" trap, organizations should apply a systems approach to the investigation of safety initiatives, as a way of trying to anticipate the impact of these initiatives on multiple aspects of organizational life. More questions need to be asked, such as, "What are the downstream impacts of changes?", "What safety nets are built in if processes don't go as planned?" or "How is human behavior adversely affected by the behavior of machinery and technology?" It would also be advisable to incorporate into the decision making process a thorough analysis of the effectiveness of any proposed initiatives compared against any scientific evidence available that may support or refute an organization's own initial assessment. ⁽³⁾⁽⁷⁾⁽⁹⁾

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PRIMERS – Recommended Reading

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