THE INTEGRATION OF RISK MANAGEMENT AND PATIENT SAFETY

Risk Management and Patient Safety: The Synergy and the Tension

Judith Napier, MSN, BSN
Barbara J. Youngberg, JD, MSW, BSN, FASHRM

INTRODUCTION

There is a great deal of confusion about both the differences and the similarities between risk management and patient safety. Many healthcare organizations and providers have sought to demonstrate their support for patient safety merely by changing the name of either the risk management or quality department to the patient safety department, often without changing the nature or focus of the work. It is important as a risk manager to not only understand the distinction but also to recognize how it might impact the manner in which risk is addressed in one's organization.

Historically, risk management in health care evolved from programs that existed in other industries and were focused primarily on the transferring of risk through the purchase of insurance. Risk managers, even those in health care, often came out of the insurance industry and reported to the finance department. Their job was to buy the best coverage,

the correct limits, and to make certain that claims, once they appeared, were reported to the appropriate carrier who would then assume responsibility for them. This complete transfer of risk became more difficult as medical malpractice cases became more frequent and more costly. The risk manager then required additional knowledge and skill to understand a more complex transaction instead of merely transferring all of the risk to a carrier. The role evolved to allow for the risk manager to assess the organization's total potential risk, determine the organization's risk appetite (or ability to fund and finance some of their own risk), and then select partners to assist them in structuring a program that would combine self-insurance, co-insurance, and excess insurance. This process is described in detail in the chapters in this book specifically associated with risk financing.

The second aspect of the risk manager's role, claims management, generally revolved around the management and defense of

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malpractice claims. Physicians, hospital employees, and the hospital itself historically became familiar with the risk manager after a patient had sustained an injury or when a lawsuit was filed requiring defense. The risk manager's job description often included protecting the assets of the organization as well as supporting and defending providers who were named in these suits. The relationship with the patient was secondary to protecting the assets of the organization or the provider's malpractice carrier, so resolving a claim by paying as little as possible was the goal.

The injury or suit historically triggered a detailed investigation of the factors that gave rise to the claim. The focus of this investigation was often on developing a strategy for defending the organization or the care provider. Due to the fact that the legal system is by nature adversarial, those named in suits often felt shame, anger, a sense of punishment, and often a sense of isolation, all of which limited the amount of discussion surrounding the claim and tended to put the focus on the individual who had provided care rather than on the system that might have contributed to the harm. Seldom were claims viewed as learning opportunities, and generally each claim was viewed as an isolated case, even though factors similar to those of other cases might have been present. The initial response to a claim was to "hunker down," sequester the information, prepare to aggressively defend and/or contain the loss, admit to nothing, and leave it to the attorneys to resolve. Resolution of claims often involved the hiring of outside counsel, who learned many things about the claim but seldom were asked to share that information with the organization or the provider. By the time one claim ended, the organization, the providers involved, and the risk manager had moved on to other claims and new issues.

The third component of a risk manager's role prior to the introduction of patient safety was loss control. This aspect of the job was not initially part of the risk manager's job but

emerged as malpractice costs rose and as individuals became aware of specific clinical issues that often were giving rise to increasingly costly claims. At that point many nurses entered the field of risk management because they were familiar with the nuances of clinical care and were better able to work effectively with clinicians. This more proactive and clinically focused approach actually was encouraged initially in the specialties of obstetrics, anesthesia, and emergency medicine where losses were increasing in frequency and were often catastrophic in severity. Risk managers began to identify both patterns of behavior that gave rise to claims and changes to make in practice that could allow the practitioner to avoid costly lawsuits. The motivation for much of the activity was the injury or loss suffered by a patient, so in many cases it still did not serve to prevent an injury but rather to contain or prevent future injuries.

In 1998, the Institute of Medicine (IOM) report[1] contained information that surprised the public. The information about the alarming numbers of preventable medical errors was not a surprise to most risk managers or to clinicians who continued to face rising malpractice premiums due to continued catastrophic injuries sustained by patients. Many people recognized that current activities had been unsuccessful in preventing harm to patients, and that the approach of blaming individuals who were involved in harmful events suppressed any potential for learning. The challenge to healthcare providers and administrators was to develop a culture of learning, to become more transparent and open in hopes of advancing knowledge, and to create systemic mindfulness that focused more on the situations and conditions in which individuals work rather than on the individuals themselves. This new approach served to challenge risk managers to think differently about the work they were doing, which, given the number of preventable errors that continued to be reported, suggested that the approaches being taken were having only

limited success in actually preventing harm to patients.

The changes can be described best by revisiting the functions of risk management. As related to the function of risk financing, the underlying job responsibilities remain the same, though perhaps they are more complex given the cyclical nature of the insurance industry and the desire for insurance providers to move further away from the risk, forcing the organization and often individual providers or groups of providers to either pay more or assume a deductible. (See Chapter 11, which covers enterprise risk management and details the new levels of sophistication now required to not only better understand the true nature of risk but also to design a program that protects the organization from catastrophic financial loss while creating incentives for aggressive loss control.)

The second function of risk management, which is claims management, changes when principles of patient safety are applied. Though a risk manager still will work hard to defend their organization or a provider from frivolous lawsuits or claims where there has been no negligence, when preventable errors or errors caused by negligence are identified a different approach is generally taken. Under principles that are at the core of patient safety, transparency becomes imperative and involves providers being honest with patients about the cause of their injury. In addition, the investigation and resolution process is viewed as a learning experience, and sharing what is learned with all stakeholders in a manner that maintains privacy and confidentiality of patient and provider occurs so that the underlying issues can be fully understood and resolved. Though risk management can do little to change the adversarial nature of the legal process under principles of patient safety, risk managers can reorient their investigation to be more about understanding the systemic vulnerabilities that caused the event, as opposed to merely looking at the behaviors of the caregiver. In addition, under principles of patient

safety every attempt is made to preserve the patient–provider relationship. When errors are made and injuries result, both parties can speak about them freely, discuss how to compensate the patient for their loss, share the learning that was extracted, and if desired, maintain the relationship into the future. Other chapters in this book (e.g., Chapter 19) deal with disclosure and early-offer programs and describe in great detail not only how these programs should be structured but the benefits that organizations are already seeing from this approach.

What has changed most dramatically following the IOM report is the manner in which the third aspect of risk management, loss control, is influenced by applying principles of patient safety. Whereas in the past a patient injury or sentinel event was often the trigger for a risk management investigation, now, under a concept known as "systemic mindfulness," risk managers, guided by patient safety principles, continually assess the environment in which care is given to identify potentially harmful practices, processes, or failure modes, and then modify them before an injury can occur. The focus is less on the error operator (or the individual involved in the error) and more on the myriad factors that endangered the individual and caused or contributed to the error. In addition, focus is not only given to actual events but also to near-miss events, the latter being an attempt to better understand how errors get intercepted due to caregiver vigilance, technology, or improved processes. As an organization attempts to create an overarching culture of safety, the risk manager's role changes from being the person responsible for investigation and problem resolution to the aggregator of information that allows for the identification of trends and patterns as well as for improved prioritization. This information comes from everyone in the organization who are encouraged and empowered to speak up when they notice a potential problem or weakness in the system. Achieving the goal of systemic mindfulness, as this increased awareness is termed in patient

safety parlance, requires that everyone in the organization (including physicians) become a risk manager or, at the very least, a risk identifier. Their knowledge of what is required of them relative to the care they provide, as well as how best to achieve an appropriate and sustainable solution once problems are identified, improves the likelihood of success relative to the solution applied to the problem. Furthermore, this knowledge, coupled with the widespread dissemination of what is learned, improves the likelihood that all of the goals of risk management, decreased insurance costs, fewer liability claims, and safer systems resulting in fewer injured patients will be achieved. Because this aspect of the risk manager's job has changed dramatically, the remainder of this chapter addresses how a risk manager perceives the synergy between their role and that of others in the organization who also contribute to patient–provider safety.

Figure 1–1 shows business-strategy decisions with regard to redesigning a healthcare system in order to expand a clinical service line such as obstetrics. This may be done to meet a changing demand in the community and to increase revenue and market share.

The finances are devised with appropriate budgets, only to later see erosion due to adverse outcomes and claims. This occurs when the strategic decision is not reached with a full understanding of the necessary clinical and professional demands that will be needed to meet the standard of care.

THE RISK-INTELLIGENT ENTERPRISE

Figure 1-1 also illustrates the direction of risk management beyond clinical risk. Moving beyond insurance and the obvious clinical risks associated with professional liability in the day-to-day delivery of health care, the expanding risk management model highlights what some people call risk intelligence.[1] The risk-intelligent enterprise develops a full-spectrum vision of risk. It entails developing an enlightened approach to risk management that spans the entire organization, with a leader who is capable of applying the following four functions of risk management to current and future organizational risks:[2]

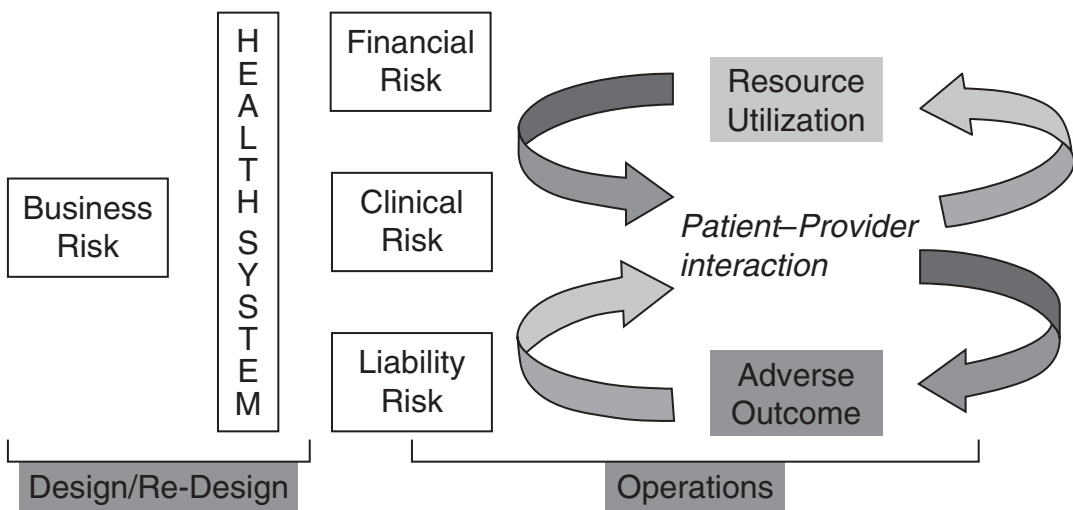- Oversight of the organization's ability to meet the regulatory requirements

Figure 1–1 *Managing Interrelated Risks in the Healthcare Setting*
By permission of Anna Marie Hajek.

- Working with business units to assist the leaders in understanding risk in business transactions
- Advising staff and leaders on the best approach to manage the new or emerging risk for the organization
- Providing leadership to maintain an understanding of the organization's mission and goals, and defining who is able to provide direction

It is important to have expertise that includes a deep understanding of the various components of risk, whether it is billing and compliance relative to a Recovery Audit Contractors (RAC) audit, risk associated with regulatory compliance with Stark laws, or professional liability exposure with clinical care. No one person can cover the level of detail required in all areas; however, the risk-intelligent enterprise builds bridges between risk "silos" to open lines of communication and share information. Having someone who is able to work across these lines and have a broad understanding of the full portfolio of risks that the organization faces, and an ability to influence direction of the management of the risks, is critical for value-added risk management rather than risk avoidance or risk transfer.

Risk is defined as the chance of loss. Risk analysis is the process used by the person or the person's assigned risk management functions to determine the potential severity of the loss from an identified risk, the probability that the loss will happen, and alternatives for dealing with the risk.[3] The key here is the alternatives for managing the risk. The decision to retain the risk, transfer the risk to the organization, or attempt to modify the risk is part of the responsibility of the "enlightened" risk manager. Using multiple avenues to understand the degree of the risk, and then using knowledge and experience to modify that risk, is part of the responsibility. A person can only do this with a complete understanding of the risk.

VALUE PROTECTION OR VALUE CREATION

Unrewarded risk is defined as the prerequisites: Occupational Safety and Health Administration (OSHA) requirements with health and safety standards, Joint Commission standards, Centers for Medicare and Medicaid Services (CMS) requirements, etc. We could perform all of the regulatory requirements in a timely and competent manner and might still have a bad outcome that results in a claim or legal filing. These activities just meet the baseline expectations. The primary reason to address these risks is for value protection, not value creation. We must meet the baseline in order to secure accreditation with Joint Commission survey or CMS standards of participation. The standards have indeed been developed to improve patient care, but that will not move us up the innovation scale or assist us in developing new models of care delivery until we build the processes into the daily lexicon, practices, and culture of our organization.

Rewarded risks, on the other hand, are those that you undertake to spur value creation.[4] New business acquisitions, new models of care, new clinical services—all are designed to add value, not to sustain the status quo. In a risk-intelligent enterprise, assuming risk is part of the equation for growth; how that risk is assumed and managed is up to the organization, which must determine the direction and level of analysis, the risk appetite for the organization, and how the leaders will choose to offset or manage the risk beyond the obvious exposure.

The American Society of Healthcare Risk Managers (ASHRM) defines domains that highlight the interconnectedness of risk in health care.[3] These domains include:

- Strategic
- Operational
- Financial
- Human capital

- Legal and regulatory
- Technology

Risks do not exist or behave in "isolation" but instead can be identified, grouped, and catalogued in risk domains. These domains assist organizations to not only identify risk across the spectrum but also to develop mitigating strategies that interface across business lines. Risk management continues to evolve as a process to identify practice concerns from quality data, clinical indicators, and outcomes, and to develop various strategies to mitigate the risk (reduce or eliminate) through risk management techniques such as practice modification, insurance transfer, or risk avoidance such as when we eliminate the risk by closing of an obstetrics unit or mental health services or reducing the privileges of a specific provider who may not have the requisite skill to safely perform a specific procedure. Risk management expands beyond the clinical setting to the organization at large as health care begins to look at risk in the broader context for the organization.

PATIENT SAFETY

Some people would argue that risk management and patient safety are one in the same discipline. Risk management has always had an element of prevention; however, due to the day-to-day risks, management of the prevention has often gone unattended. In 1999, with the advent of the IOM report, which stated that 48,000–98,000 people are injured or die each year at the hands of health professionals, the focus on prevention became targeted. This launched work from professionals outside of the healthcare industry who began to look beyond the individual-practice issues and analyze why the injuries and deaths were occurring. What in the system was allowing the repeated problems to happen, and how could we analyze in a systematic manner the practices, behaviors, and outcomes that were causing these problems?

James Reason introduced his book, "Managing the Risks of Organizational Accidents," which focuses on the risks of hazardous technologies, to the healthcare community.[5] This book prompted the healthcare industry to begin looking at errors and accidents differently, and led healthcare leaders to begin to understand how accidents occurred and, more importantly, to look at accidents and patient events from a systems perspective rather than a case-by-case perspective. The "swiss cheese" model as defined by Reason[5] is a dynamic process with moving "holes" that break down the defenses established to maintain a safety net in the organization. The holes allow the "risk" to penetrate and at times reach the patient. These holes are failures in the system. Because the conditions are ever changing, the system has built-in defenses that do not allow the holes in the system to line up and create an avenue for the error to reach a patient; instead, the defenses, both active and latent, are designed to:[5]

- Create understanding and awareness of the local hazards
- Provide clear guidelines on how to operate safely
- Provide alarms and warnings when danger is imminent
- Restore the system to a safe state in an abnormal situation
- Interpose safety barriers between the hazards and the potential losses
- Contain and eliminate the hazards should they escape this barrier
- Provide the means to escape and rescue should hazard containment fail

The purpose of patient safety is to provide a safe environment, to explore the possibility of failure, and to create "defenses" that will change the current system of operation in order to reduce the potential for failure. One of the fundamental differences between risk management and patient safety is the difference between fixing problems and driving change toward creating a safer environment.

Risk Management	Patient Safety
It's about the organizational tactics to fix problems.	*It's about the culture of the organization that will drive change.*
• Focus is on *individual case*	• Focus is on *system failures*
• Post-event investigation	• Recovering from error to reduce harm
• Implement *tactics* to address the event rather than the system failures	• Relationship with human factors that impact failures in system
• Relationship with legal standard of care	• System *themes and patterns* identified
• Unexpected outcomes drive the process	• Good Catches and AWTH focus the efforts
• *Reactive*	• *Proactive*

Figure 1–2 Risk Management Versus Patient Safety

Change management includes a host of processes that may or may not come to light in one case but will, over time, shine through from patterns, themes, and archetypes that resonate in many events (Figure 1–2).

Patient safety is more about changing the work culture than about the problem itself. Developing a resilient organization that is able to respond to the changing environment, rather than developing individual policies and procedures to solve all of what may come up in the course of a work day, is the goal of patient safety. The latter task is impossible and would result in failure over time. The point is to use knowledge learned in other high-risk industries where they have come to understand system failure in their environment, and to apply this knowledge to the health care delivery system. Such organizations are termed highly reliable organizations (HROs) because of the success rates that they are able to achieve repeatedly under pressure. Karlene Roberts[6] studied these organizations to understand the processes and practices that have impacted their ability to respond to unexpected problems and to overcome those problems without significant failure. The HROs have some common characteristics. They typically do the following:[6]

• Track small failures
• Resist oversimplification
• Remain sensitive to operations
• Maintain capability for resilience
• Take advantage of shifting locations of expertise

As previously stated, risk managers tend to rely on lessons learned from past mistakes, which they apply to the case at hand in order to "defend" the actions of those involved. Because of the continued volume of events, risk management has not been able to evolve quickly enough in terms of developing prevention models. Risk managers have relied on legal findings, large claim settlements, as well as verdicts and legal theories to implement change through fear rather than attacking the problem at the root–the culture and environment.

Patient safety has the ability to support the risk management efforts through new ways of understanding how things go wrong and applying new models to the problems. Defining teamwork and communication in ways that address how individuals communicate across disciplines, departments, and organizational expectations relative to the caregivers' role in this work begins to anchor the safety agenda for an organization. Developing a better understanding of situational awareness and applying knowledge learned through human-factors theories, to gain a broader

understanding of why the failures occur, has been the progress in safety that risk management has not yet been able to reach.

Patient safety is designed to create an environment whereby everyone operates from the same set of principles and the organizational design conforms with what Weick and Sutcliffe refer to as the seven properties of sense making.[7,8] Think of the questions that address the seven principles relative to the time-out process with universal protocol in the operating suite:

- *Social context:* Does the process encourage conversation? Is it open and does it allow for questions and clarification?
- *Identification:* Does the process give people a distinct, stable sense of who they are and what they represent? In other words, what is their role?
- *Retrospect:* Does the process preserve elapsed data and legitimate use of the data? Do we study our flaws and work toward performance and process improvement?
- *Salient cues:* Does the process enhance the visibility of cues? Do we rely on memory or do we use human-factors knowledge to trigger with visual cues and forcing functions?
- *Ongoing projects:* Does the process enable people to be resilient in the face of interruptions? In health care, do we teach situational awareness and how to recognize when colleagues have lost situational awareness?
- *Plausibility:* Does the process encourage people to accumulate and exchange plausible accounts? Do we allow staff time to brief and debrief following critical exchange of information and/or actions such as surgery or a cardiac-arrest response?
- *Enactment:* Does the process encourage action or hesitation? Do we recognize the behavior we want versus reprimanding the behavior we do not want?

CONCLUSION

Patient safety and comprehension of the science of safety are not only expectations in the healthcare industry but also a cause for continual struggle internally with regard to who is responsible for patient safety and what patient safety strives to do. Is it designed to establish a culture that is responsive to safety issues? Is it designed to monitor and measure outcomes of core policies, national patient safety goals, or other regulatory requirements that address safety? Is patient safety designed to understand the system failures that are impacting the outcomes and design models of care in order to support the caregivers and providers in a more reliable way? Is the purpose of patient safety to redesign the system of care in a way that is more responsive to new technologies, accounts for human factors that impact outcomes and create system failures, and makes it possible to reduce harm to patients and staff through the new models?

The reality is that patient safety is all of the above. The work of patient safety spans the entire system and begins to embrace much of the risk-intelligent-enterprise model. The work crosses multiple "silos" and needs to be addressed from a systems approach. It needs to be embedded throughout all that we do in health care beyond the regulatory requirements and the individual sentinel events, and it must begin to penetrate to the most fundamental levels in the organization: how we think and act toward each other; how we include patients and families in decision making relative to care and treatment; and when a failure occurs, how we respond. All of these factors influence the organization's effectiveness in implementing a patient safety culture.

Patient safety is the outcome. The work is in designing a system of care that applies the principles learned from highly reliable organizations, and the properties of sense making, in an environment that is highly

complex, rapidly changing with technology, and dependent on people and staff to adhere to the appropriate principles and rules in the face of production pressures. Designing a culture that recognizes these flaws and, more importantly, begins to piece together in a systems approach the principles outlined in this chapter, for both risk management and patient safety, will move us closer to understanding these two worlds.

ADDITIONAL RESOURCES

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