Monograph

Different Roles, Same Goal: Risk and Quality Management Partnering for Patient Safety

**ASHRM
Monographs
Task Force**

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FOREWORD

When a patient is harmed as a result of a medical error, risk managers and quality managers have immediate interests in identifying the circumstances that led to the error. These interests, however, can be quite divergent.

Citing reasonable concerns over privilege and potential for future litigation, risk managers go to great lengths to protect information. They typically conduct an in-depth investigation to assess the liability exposure to the organization and help mitigate any future loss that may arise.

Quality managers often conduct a parallel investigation. They aim to design formal process improvement initiatives that target the underlying causes of the event. Their focus has not necessarily included concerns over litigation or financial loss. Rather, their primary goal has been to improve the quality of patient care.

Over the years, these separate paths have contributed to a silo mentality. In many organizations, information is too rarely exchanged between risk managers and quality managers and collaboration is too often minimal or nonexistent.

Although risk managers and quality managers have respected and viewed each other as the "experts" of their respective disciplines, there was no compelling reason to address and eliminate these silos. Now there is.

Today, as the patient safety movement continues to expand, there is growing recognition of a "common ground" upon which a collaborative model must be pursued. The irony is that risk managers and quality managers have always worked to enhance patient safety. But if patient safety is to remain a shared objective, there must be a willingness to re-evaluate their respective roles from a new vantage point.

This monograph is not intended to provide a national model for risk management and quality management collaboration within a healthcare organization. Rather, the intent is to encourage dialogue between the two disciplines in an effort to promote understanding, and encourage innovative thinking that will lead to a collaborative structure that benefits the organization.

Such collaboration will reveal that by working together, risk management and quality management can accomplish much more than the sum of their individual efforts.

INTRODUCTION

Organizational structures differ

No two healthcare organizations are alike, and this is notably true with respect to the risk management/quality management structure. The structure is often driven by the size of the organization or its facilities. For smaller facilities, there may be one individual responsible for both risk and quality management activities. This same individual may also serve as infection control officer, patient safety officer and compliance officer. This individual may or may not have had formal education and training to prepare for such a diverse role. A comprehensive risk management knowledge base may not be essential for this role, particularly if the organization outsources some risk operations, such as claims management.

In larger organizations, various models are employed to assure that risk is adequately managed. For some, risk management is administered from the legal department. Others employ an enterprise risk management model where responsibility for each of the enterprise "risk domains" is apportioned among multiple departments or individuals. There is less variety with respect to the quality management functions within a large organization largely because the organizational focus of quality management remains fairly stable even as new tools and measures are introduced.

New terminology created

Newer labels are being used to describe the various quality management, risk management and patient safety operations within healthcare organizations. Traditional labels are still widely accepted, such as risk management, quality management and patient safety, etc. But different permutations of these traditional labels/titles are arising.

For example, some quality management departments have been renamed departments of "clinical effectiveness." In organizations where the risk management and quality management functions are combined, a new "quality risk management" department might be created. As the healthcare industry continuously strives for safer care and better outcomes, even more creative labels to describe these operations can be expected.

SILOS AND HOW THEY DEVELOPED

Quality management evolution

The evolutionary tracks of risk management and quality management have been influenced by forces demanding more and more from healthcare organizations each year.

While risk managers need to keep abreast of regulations, responsibility for compliance has tended to fall upon the organization's quality management department. However, in some states where risk managers must be licensed (such as Florida), the law requires risk managers to assure compliance by overseeing these activities, and this is no small feat.

Whether responsibility for these activities falls upon the risk manager or the quality manager, the job can be daunting. The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) require new standards for performance and core quality measures each year. National Patient Safety Goals are imposed upon every organization that wishes to maintain its accreditation status. And, of course, there is general pressure to adopt best practices that arise from evidence-based medicine.

Mutual interest in sentinel events

In 1996, the Joint Commission established its Sentinel Event Policy and incorporated it into the accreditation process. It forced healthcare organizations to do much more than simply investigate adverse events – they had to analyze them more closely to identify root causes.

Because these events involve patient injury, risk managers recognized that malpractice claims were likely to arise from these events, and they viewed the sentinel event policy as an opportunity for earlier identification of risk. Healthcare organizations scrambled to establish their own sentinel event policies and procedures, but concerns arose over the confidentiality and privilege protection that resulted from those proceedings. In 1998, the Joint Commission responded to these concerns by revising the policy to promote self-reporting of these events.

Patient safety movement gains momentum

In 2001, the Joint Commission adopted patient safety standards and by 2002, a survey process was introduced using a patient tracer methodology. A change in the survey process followed: by 2006, surveys would no longer be announced. National Patient Safety Goals were introduced in 2005 and healthcare organizations came to rely on quality managers to design and implement processes that would assure compliance with these requirements.

While all of these accreditation requirements were being introduced by the Joint Commission, there was wider pressure to join safety and quality initiatives promoted by other agencies, such as the Institute for Healthcare Improvement and National Quality Forum.

Healthcare organizations also faced increasing pressure to publicly report quality data. State governments were confronted with both the consumer's desire to compare quality measures from one healthcare organization to another and to accrue, analyze and report on healthcare organizations' efforts in the patient safety arena. Quality management soon gained recognition and support by executive leaders within their organizations, since the success of their efforts would affect the financial strength of the organization and directly influence its ability to recruit talented practitioners as well as new patients.

Risk management evolution

As quality managers kept pace with all of these requirements, risk managers were confronted with their own set of challenges.

The healthcare industry confronted a malpractice crisis and professional liability insurance became unaffordable for many physicians and hospitals. Healthcare organizations tried to accommodate medical staffs either by lowering insurance limits or by forming captive insurance programs to provide adequate coverage. New risks were introduced as physicians opted to "go bare" and forgo professional liability coverage altogether. Risk managers were compelled to expand their knowledge of risk financing options as their organizations sought creative solutions to these issues. At the excess insurance level, healthcare organizations needed to demonstrate solid risk management and loss prevention programs to negotiate favorable renewal rates.

At the state and national level, tort reform was promoted as a solution for those states designated by the American Medical Association as "crisis states." As these reforms were enacted, risk managers were required to know and understand the specifics of their state legislation in order to competently manage claims and to evaluate liability. Excessive verdicts continued to plague those states with no damage caps, and risk managers sought new ways to understand and analyze their claims in order to prevent or reduce future losses.

Current perspectives

As stated previously, the focus of a quality manager can be different from that of a risk manager. Quality management professionals focus on best possible outcomes in patient care. In addition, the quality manager is usually responsible for assuring that the organization meets accreditation and other regulatory requirements and that outcome data are reported in an accurate and timely fashion. Through chart audits, peer reviews and other formal techniques, quality management professionals seek out instances of suboptimal care or errors that can be remedied through process improvement. (In some respects, these quality management activities can be viewed as proactive risk management.)

Risk managers are also certainly in favor of best possible outcomes, but this may not be obvious to their quality management colleagues who believe that risk managers are *only* focused on financial losses from medical malpractice claims and other forms of organizational liability. The financial focus is just *one* factor in the complex equation that constitutes the practice of risk management … an *important* factor. After all, an organization's ability to deliver safe, quality care depends in large part upon its financial strength. Every dollar spent on professional liability losses is a dollar that might be spent on patient care.

Lost productivity is costly to the organization, as well. Risk managers work diligently to keep healthcare workers out of the court room and at the patient bedside where they belong. By minimizing the frequency and severity of malpractice claims, the risk manager's loss prevention efforts can support quality and patient safety efforts.

This focus on financial resources is not to imply that patients should not be compensated when they have been injured as a direct result of negligent care. When a patient is injured by a medical error, it is often the risk manager who encourages early disclosure and assures that an apology is extended to the patient and/or family. The risk manager is also influential in mobilizing organizational leaders to approve early resolution and compensation to the patient when appropriate. Although these situations can be difficult for everyone involved, these efforts help to bring closure to the patient and/or family.

When a medical error occurs, the next steps are fairly straightforward for risk managers and quality managers alike. Corrective action plans can be readily designed and implemented once the underlying causes are identified. But important quality of care issues can also be extrapolated from formal claims and lawsuits. This information needs to be conveyed to quality managers to help direct process improvement efforts.

Lack of collaboration is risky

Not all liability losses are the result of substandard care; yet effective risk managers aim to minimize these losses. For example, a patient may experience an unexpected outcome even as the care delivered by the healthcare team fully meets the legal definition for "standard of care." The lawsuit itself might be prevented if the practitioner is more visible and communicative to the family during the patient's hospitalization. Or perhaps the informed consent process is rushed and results in unrealistic expectations by the patient or family. The organization may still be confronted with potentially significant financial losses if a lawsuit is subsequently filed by the patient. But even if the patient dismisses the case, the organization incurs legal fees defending the care to that point. If the case proceeds to trial, the defense costs can be staggering.

Many organizations are surprised by a multi-million dollar plaintiff's verdict in a case they felt was completely defensible on standard of care. A good risk manager is keenly aware of the significant issues that can contribute to this type of "unexpected outcome" in the courtroom, and this awareness may take years of risk management experience to fully develop. So it is not entirely surprising when quality managers do not fully comprehend risk management initiatives that seem to contradict efforts to increase the quality of care.

For example, some malpractice cases are lost because the jury believes the defendant failed to comply with one of the organization's own written policies. Because of a silo effect between risk management and quality management, a risk manager may not even be aware that a particular policy exists until that policy first appears during the discovery phase of litigation. (Worse still is when employees are not aware that the policy exists.)

Risk managers know that any policy, procedure or protocol can be admissible as evidence in a malpractice claim and can be used to help establish or disprove that the standard of care is met. These documents must be carefully scrutinized for language that places unrealistic expectations on practitioners in day to day practice. Sometimes in the author's zeal to promote the highest quality of care within the organization, these policies are written with such high standards that no employee could realistically comply 100 percent of the time under ordinary circumstances. A risk manager's recommended revisions to such a document are sometimes not well received by quality management colleagues. These colleagues simply do not understand why they shouldn't assume the ideal when drafting such document. Yet, a single word may mean the difference between a defense verdict and a plaintiff's verdict. In cases where the care is entirely appropriate, a poorly chosen word can signal just the opposite impression to a jury.

Risk managers need to educate their quality management colleagues about these issues so that their recommendations are well-received and the rationale is understood.

In similar fashion, a settlement must sometimes be negotiated only because critical documentation cannot be located – documentation that would eliminate doubts about the appropriateness of care. Although witnesses have a clear recollection of the documentation in question, jurors may be led to believe that the documentation was destroyed to "cover up" an error. Quality management and patient safety professionals do not necessarily have the resources to assure that every single record is appropriately filed or retained in its proper location. But when a lawsuit is lost merely because of a

missing document (e.g. electronic fetal monitoring strips), the corresponding settlement or verdict can be astronomical. This underscores the importance of process improvement in record-keeping. Risk managers may appreciate the expertise of their quality management colleagues to evaluate the process and design strategies for minimizing the risk that future documents might be misfiled or lost.

THE NEED FOR A COLLABORATIVE MODEL

Underlying causes of a medical error must be identified and understood to prevent errors in the future.

As risk managers aim to minimize professional liability losses for the organization, they must be adept at recognizing those events that are likely to result in expensive litigation, whether an error is involved or not. This particular malpractice risk is a moving target, however, because the majority of patients who suffer an injury due to medical negligence actually do not file a malpractice claim. In the interest of patient safety, a patient's likelihood of filing a malpractice claim makes no real difference, because the underlying causes of an actual or potential medical error must all be identified and eliminated if care is to be improved.

The ideal risk management and quality management collaborative model allows the exchange of event-related information in a way that does not jeopardize the defense of a potential malpractice claim. In preparing for a collaborative model, the organization's state privilege statutes and related case law should be carefully researched. With the help of an effective healthcare attorney, the organizational chart might be structured to maximize any protection afforded by those statutes while allowing the flow of information across both disciplines.

Sentinel events are most costly, both in terms of human life as well as in financial losses for the organization. Risk managers therefore may wish to assume responsibility for investigating these events and conducting root cause analysis (RCA). There are many advantages to this action. Typically, risk managers are skilled investigators; they take care to avoid any speculation or premature conclusions that could potentially bias the analysis. With additional training, the risk manager will be able to identify special causes and latent causes of the event under analysis. The risk manager also will have the opportunity to sequester evidence, provide early risk management advice to those involved in the event, and conduct a prompt liability assessment that may lead to early intervention and resolution.

The risk manager will have the opportunity to recognize other risk issues not directly related to process or quality of care, too. Once the root causes are identified, the risk manager can forward this information to quality management colleagues for design and implementation of the corresponding action plan.

Ideally, the risk manager will have already established a partnership with a quality manager so that communication is ongoing while the investigation and analysis are pending. In this way, the quality manager can make recommendations for stopgap measures that can be implemented immediately. He or she can also begin to mobilize appropriate process improvement (PI) teams as the risk manager's analysis begins to crystallize, exposing flawed systems that potentially caused the event. The quality manager may be aware of a PI initiative that is already underway and intended to address a similar process. The investigation may reveal new information that warrants a slight revision of this existing PI initiative. This can improve efficiency of quality management efforts and ultimately maximize their impact on patient safety.

In fact, even budgetary requests related to patient safety are more likely to be granted when both quality managers and risk managers unite to present compelling reasons for the expenditure.

Considerations for collaboration

The models presented here suggest interaction between risk management and quality management. Contingent on financial resources and/or any state regulations, either model can be modified to suit the organization's individual needs.

However, regardless of the model structure, both risk management and quality management need to share data and keep each other informed. At a minimum, information regarding adverse events, peer review issues and quality of care concerns should be regularly exchanged between the two disciplines. Collaborative efforts assist in minimizing redundancy between the departments, eliminating silo thinking and, more importantly, fostering a partnership in patient safety between risk management and quality management.

Some states dictate whether the point person for adverse event reporting within a facility/organization will be a risk manager or a quality manager. Florida's risk management statutes designate risk management as the reporting agent for all adverse incidents meeting certain criteria, while New York delegates the responsibility for state notification of adverse events to quality management. Regardless of which department alerts the state oversight agency, both risk management and quality management need to be aware of the same information. Each department should be notified of events that result in adverse outcomes to a patient as well as any near miss events that could have resulted in harm to a patient.

Although quality management may typically address peer review issues, risk management should be aware of these issues and may choose to monitor them for any developments.

In addition, it is optimal if both departments work together to conduct an event investigation, RCA and any associated corrective action plan.

Setting the groundwork

Foremost in importance is to establish a working relationship between the risk management and quality management departments. This may be easier said than done if quality management and risk management do not communicate on a daily basis. If there is no established protocol for sharing information, either manager ought to create such an opportunity.

Begin by informing your risk management or quality management peer the forms and types of information you can provide to them (e.g., return to OR, perforation data, unplanned admission, retained foreign object, wrong patient/site/procedure, medication variances, etc.). This can be the springboard for cooperation. The incident reporting process produces a plethora of data of interest to quality management, risk management and other departments. From falls to decubiti, surgical misadventures to medication errors, incident data can provide key information on process failures, areas of performance deterioration, staffing issues and more.

Incident reporting systems also serve as early warning systems for risk managers and allow earlier identification of potential claims.

Resultant to the incident reporting system and tracking/trending of same, risk management or quality management may be the first to discover physician, nursing or staff performance issues. Alternatively, quality management specialists often review medical records on a daily basis. They are therefore privy to a variety of potentially compensable events or other risk issues that may not find their way to an incident report for any number of reasons. If risk management and quality managers

remain cognizant of the importance of sharing information, it is less likely that important patient safety issues will be overlooked and left unaddressed.

A good place for both risk management and quality management to begin their collaboration is to develop a procedure for responding to adverse or sentinel events. This procedure should set forth the specific responsibilities for each department in a way that minimizes redundancy without sacrificing the exchange of important information.

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MODEL ONE

The following model of collaboration is based on a format created for a system comprising a 342-bed acute care hospital, 120-bed nursing home, 103-bed assisted living facility, health park, physicians practice, home health and ambulatory surgery center.

1. Upon identification of a possible adverse event, as defined by the organization, state and/or Joint Commission, staff will immediately notify risk management by phone or in person.
2. Risk management will secure the medical record, additional documentation, equipment, supplies, packaging, operating manuals, etc., associated with the event and assure chain of custody. Immediate risk management advice will be provided to practitioners as appropriate.
3. The risk manager/designee shall inform the quality manager of the event as soon as practical and together they will coordinate the investigation of the event. If it appears the incident meets reporting criteria as defined by the organization, state and/or Joint Commission:
   A. Risk management notifies an executive leader (or leadership committee) as designated by the organization.
   B. An incident report is completed by involved staff prior to end of the shift and forwarded to risk management.
   C. The administrator-on-call, risk manager or other designee and the attending physician coordinate communication with the patient and family regarding the incident.
   D. Risk management, quality management, chief of staff/designee, involved practitioners and the involved departments begin an investigation of the incident within 24 hours of notification of the incident.
   E. Quality management initiates a chart review and develops a timeline.
   F. Quality management requests a peer reviewer to examine the medical record. The risk management and quality management representatives discuss with the peer reviewer his/her findings, the quality/risk investigation and adverse event criteria to evaluate if the incident meets state/Joint Commission reporting requirements for reporting an adverse event. If it meets the criteria, the risk manager contacts the involved physician(s), practitioners and departments.
   G. A review team comprising the CEO/designee, chief of staff/designee, section chief, chief medical officer, nurse executive, risk management, quality management, involved physician(s)/department(s) and others, as appropriate, meets to review the incident and the preliminary investigation.
   H. If the review team declares the incident a sentinel event, the CEO/designee immediately notifies the chair of the board of directors.
   I. An RCA is conducted within regulatory guidelines.
   J. The involved practitioners and staff are afforded an opportunity to participate in the RCA. The appropriate quality management committee reviews the completed peer reviews and RCA.

K. The RCA is forwarded to the institution's performance improvement committee, medical executive committee and board quality management.

L. Corrective actions and risk-reduction strategies are implemented as appropriate and monitored for ongoing effectiveness with reports to the appropriate quality management committees.

M. Quality management, in conjunction with risk management, ensures that appropriate interventions are taken to prevent recurrence of the event.

N. Quality management develops a follow-up plan for continued evaluation of effectiveness in conjunction with the appropriate department/unit director.

O. The appropriate department/unit director keeps risk management informed regarding corrective actions taken.

3. All meetings held for review purposes are conducted and protected through quality management/peer review process and risk management. All documentation, notes, reports and/or minutes remain secured. Contingent on state statutes, counsel may need to be present at the RCA or review the RCA to secure attorney work product.

4. Once the risk manager/designee has determined that the incident is reportable, all persons identified on the report are notified.

5. The risk manager/designee refers all occurrences to the appropriate quality management committee.

MODEL TWO

This model may be particularly appealing to an organization that subscribes to the enterprise risk management philosophy. It is based on a major metropolitan healthcare institution's model. As such, it goes beyond risk management and quality management "silos" because patient safety is influenced by almost every other department within a healthcare organization.

(Although "department" is used in describing the areas of responsibility within this model, the term can be interchanged with "activities" or "responsibility areas" if they are more accurate for an organization.)

This model begins with the establishment of an "institute" dedicated to quality, risk and safety. Risk management and quality management departments naturally are positioned within an institute model. However, patient safety is a goal of employees throughout a healthcare organization so accreditation, infection control, patient relations, environmental safety and occupational health would also roll up under the quality, risk and safety institute. The organization may even add corporate compliance and credentialing/privileging departments. As representatives of these areas collaborate, opportunities are created for innovative approaches to safety.

Moreover, an organization's employees must be counted among its patient population, since most employees receive their own healthcare from the organization that employs them. Thus, the healthcare organization has the unique advantage of influencing patient safety through its efforts to protect its own workforce. Workers are more likely to appreciate the importance of patient safety processes when the healthcare organization values the safety and wellness of its own employees.

More than communication

To maximize the benefits of the institute model, the departments ideally are located in the same geographic area. Weekly team meetings for all department managers assure timely communication of topics that are mutually important to all. The following topics might be appropriate agenda items:

1. Accreditation updates, new Joint Commission standards, information discovered during readiness rounds, findings of actual or mock Joint Commission and/or state surveys.
2. Patient complaint data – patient-specific complaints and grievances or issues identified in aggregate trending analysis.
3. Claims data – either lessons learned from an individual case or issues identified through trending analysis.
4. Sentinel Events – potentially compensable events, opportunities for process improvement, etc.
5. Other regulatory issues – CMS developments, new reporting requirements, new legislation, compliance issues.
6. Strategic planning – aligning goals and coordinating efforts to maximize safety.

Unless specifically sought, there are few opportunities for risk managers and quality managers to correlate issues identified in professional liability claims, workers' compensation claims, incident reports, patient complaints and regulatory bulletins. Weekly team meetings offer the unique opportunity for leaders of these areas to identify common themes that might otherwise go unrecognized. From here, priority areas can be identified and strategies developed to reduce risk and increase safety in the most cost efficient manner.

Influencing the safety culture

Lastly, this model offers an opportunity to influence the overall safety culture of the organization. By aligning performance goals within a single area, risk management and quality management are better able to make a financial case for patient safety. This may require consultation with departments outside of the institute, such as finance and medical operations, but new opportunities for quantifying the financial benefits of improved patient safety can be created.

Patient safety is further strengthened by having all quality, risk and safety departments within the institute reporting to a single leader who is also a member of the executive management team of the organization. Ideally, this leader has professional risk management experience in addition to having a clinical background. Because many clinicians have a limited exposure to risk management (usually as expert witnesses or claims reviewers), they commonly make the mistake of assuming that risk management, quality management and patient safety are all the same. A professional risk management background will assure that the leader appreciates and understands risk management recommendations that seemingly conflict with other initiatives.

To further improve the organizational culture, dotted line relationships might be considered with the organization's finance and legal departments as well. In this manner, the quality, risk and safety institute's leader can serve as an influential champion for patient safety and risk management initiatives at the executive level.

In order to truly improve patient safety, risk and quality managers should encourage collaboration beyond their respective areas so all employees understand their roles in achieving the goal of improved patient safety.

Effort takes time – time well spent

With any model, it can take time to build a strong, trusting working relationship and to break down the walls built in some organizations. It may be harder in an environment where departments unnecessarily guard and conceal information. But, if risk management educates quality management on the similarities of their goals, provides information and analysis and assists quality management

with patient safety initiatives, they can be strong partners in achieving ASHRM's vision of safe and trusted healthcare.

Risk management education of staff, medical staff, volunteers, students, administration and the board of directors is vital to understanding its place within both the patient safety arena and the organization. It is also important for successful collaboration.

Education of all individuals working or volunteering for an organization should occur at the time of employment or affiliation with the organization and annually thereafter. These are the jump points for the new employee/staff physician/volunteer to understand the roles and responsibilities of each service and to remind seasoned employees of their roles as well. It also enables risk management and quality management to explain departmental roles, particularly where the two specialties intersect or overlap in duties, while still emphasizing the cooperative nature of their efforts.

The more those within the organization see cooperative efforts between risk management and quality management regarding patient safety endeavors, the better they will understand their roles in both risk management and quality management at their institution.

CONCLUSION

An effective collaborative model begins with communication between the organization's risk manager and quality manager.

Utilizing all available protections under the law, the exchange of information must take place if the organization wishes to maximize patient safety and reduce liability in the most cost-effective manner. With a spirit of mutual respect and appreciation, risk managers and quality managers can lead their organizations to success in this regard.

By forging a new path that is patient safety-focused, a risk-quality management partnership can contribute to the overall quality of healthcare and contribute to overall quality and personal satisfaction in our professional lives.

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