
INTEGRATING RISK MANAGEMENT, QUALITY MANAGEMENT, AND PATIENT SAFETY INTO THE ORGANIZATION

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INTRODUCTION

Since the 2000 publication of the Institute of Medicine's report, "To Err Is Human: Building a Safer Health System,"¹ healthcare organizations have recognized the need for robust programs to manage risk and improve the safety and quality of patient care. Because of differences in the underlying culture and the availability of resources, strategies vary widely among institutions. Some organizations, especially larger academic medical centers, have assimilated risk management and quality into their patient safety program, while many others maintain distinct departments. Regardless of the organizational structure, successful institutions encourage close collaboration of all three programs.

Clinicians and administrators from all areas are turning to their quality and risk management departments for assistance in improving clinical practice and organizational systems. External pressures from regulators, payers, and the public are inducing organiza-

tions to broaden the scope and complexity of their quality and safety programs and are virtually requiring the incorporation of quality, risk, and safety analyses into all aspects of professional practice. In addition, many national organizations, such as the Agency for Healthcare Research and Quality (AHRQ), and the National Quality Forum (NQF), have specifically focused on projects that demonstrate continued focus on patient safety and quality. Since 2003, The Joint Commission (TJC) has endorsed many specific safe practices (such as use of patient identifiers, use of standardized abbreviations, and improving and standardizing handoff communications) as further defined under their National Patient Safety Goals program and have incorporated them into their accreditation process. TJC continues to expand its requirements related to quality and now also includes broader physician competency and credentialing criteria under its agenda.

Due to these external requirements and the continued threat of discoverability related

to peer-review analysis and quality improvement, risk and quality managers remain valuable assets within organizations. The integration and collaboration of risk and quality activities with various key departments will improve patient care and help guarantee implementation of external compliance requirements, while also shielding the institution from discovery requests related to protected documents and data. In addition, recent implementation of the Patient Safety and Quality Improvement Act of 2005² also allows for an extension of protection of information gathered in pursuit of patient safety. This act specifically addresses how an organization can utilize a federally qualified external patient safety organization (PSO) both to foster the advancement of knowledge related to patient safety and also to extend the protection of that information. Chapter 8 describes the current thinking regarding how to best use this law to further enhance protection of information gathered in the pursuit of patient safety.

RISK AND QUALITY: THE REQUIRED ALLIANCE AND THE PEER-REVIEW PRIVILEGE

The patient safety movement continues to strengthen the collaboration between risk and quality. Risk managers can ensure a steady flow of information between departments to improve patient care while protecting their institutions from exposure to liability by ensuring applicability of their state's peer-review-privilege statutes. Some states do not have statutes defining a peer-review privilege or refrain from applying existing statutes to medical-malpractice claims;³ however, if the privilege exists within a jurisdiction, its application to quality and safety analysis is critical to the success of a risk management and patient safety program. Protecting confidential, peer-review data allows an organization to foster a culture that embraces the open exchange of infor-

mation and analysis without fear of medical-malpractice litigation.

The rationale for states' peer-review privilege statutes is to improve healthcare systems and define best-practice recommendations for clinical providers by promoting and protecting candid review of patient care.⁴ In many jurisdictions, the documents associated with such a review are shielded from discovery if created, obtained, or used by an applicable committee under the statute, such as a medical-staff quality assurance committee.⁴ This review process is routinely recorded for the courts in the form of a privilege log or a signed affidavit, typically drafted by the author of the reports.³ The organization must also be able to show the date on which the peer-review or quality-assurance activities were initiated.³ By working closely with their colleagues in the quality department, risk managers can use this peer-review privilege to shield from discovery the results of the quality and safety reviews conducted as part of their investigations into adverse patient-care events.

The medical staff must also be familiar with the privilege statutes and conduct their morbidity and mortality conferences and intradepartmental peer-review analyses in a manner that is covered by the privilege. Specifically, they must understand that merely designating a document as "confidential" or "prepared for quality committee" does not afford protection.³

It is imperative that risk and quality managers maintain vigilance throughout the organization to guarantee that processes be conducted within the framework defined by their jurisdiction's peer-review statutes. For example, occurrence reports, intake forms, and patient-complaint letters may not be protected by the peer-review privilege, so the risk manager may want to limit the narrative section on occurrence reports and intake forms and design a parallel process for review and analysis of patient complaints.⁵

COLLABORATION WITH OTHER DEPARTMENTS FOR MONITORING PHYSICIAN COMPETENCY AND CREDENTIALING

Medical Staff and Quality Monitoring

TJC and other national quality and safety organizations have placed stricter requirements on hospitals to include a greater emphasis on physician competency, thereby ensuring safe, quality care. TJC recently expanded several standards governing medical-staff organization to help guide physician practice and credentialing procedures within healthcare organizations. Case law in certain states has reinforced this move and recently expanded the legal risk to a hospital charged with negligence in physician credentialing.⁶

TJC requires the medical staff to be active participants in an organization's quality-monitoring initiatives. Under certain performance-improvement standards, the medical-staff organization is charged with conducting ongoing professional-practice quality evaluations and actively participating in "the measurement, assessment, and improvement" of a variety of quality-care metrics.⁷ These metrics include blood utilization, surgical-case review, morbidity and mortality statistics, and operative-procedure outcomes.⁷ The specific data-collection requirements compel close coordination between the departments of risk, quality, and medical staff. In addition to these historic standards, TJC now requires a much more vigorous analysis of each provider's care at the time of credentialing and privileging. Organizations are charged with reviewing data and compiling reports specific to individual provider performance for the various credentialing and privileging committees.

Credentialing

To demonstrate that a physician is competent and should be granted certain privileges

during the credentialing process, hospitals are now required to collect a more robust set of data focusing on evidence-based guidelines and standards. TJC requires hospitals to demonstrate a physician's competency by looking at key core competencies coupled with requirements for ongoing and focused professional-practice review.⁸ To demonstrate general physician competency, TJC encourages accredited organizations to utilize current standards for competency measurement such as those promulgated by the Accreditation Council for Graduate Medical Education in its General Competency requirements (see Table 2-1).

To demonstrate competency, healthcare organizations should focus on common activities and utilize data already collected. Some examples of core-competency criteria are listed in Table 2-2.

According to the Centers for Medicare and Medicaid Services (CMS) and TJC, "core" or "bundled" privileges may be used by a medical-staff organization during the credentialing process; however, the core or bundled privilege must specifically define those activities considered part of the core versus those activities that fall outside of the bundle.⁹ The core activities must also reflect activities that are being performed by a majority of the clinicians at the specific organization. Criteria for what constitutes a more specialized privilege should also be defined.¹⁰ The core privilege must be tailored to an individual clinician if issues of competency arise.

To better understand the role that "core privileges" and "bundled privileges" can play in helping to streamline the demand for data now a necessary component of the privilege delineation and recredentialing process, consider the case of a family physician for whom the complicated multipage recredentialing process may be mostly irrelevant to his or her practice. In standard credentialing each item on the form requires a predefined criteria that establishes the qualifications for each item on the list. This process can be overly

Table 2-1 General Competencies

Core Competency	Definition
Patient care	Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health
Medical/clinical knowledge	Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and social-behavioral sciences, as well as the application of this knowledge to patient care.
Practice-based learning and improvement	<p>Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning. Residents are expected to develop skills and habits to be able to meet the following goals:</p> <ul style="list-style-type: none"> • identify strengths, deficiencies, and limits in one's knowledge and expertise; • set learning and improvement goals; • identify and perform appropriate learning activities; • systematically analyze practice using quality improvement methods, and implement changes with the goal of practice improvement; • incorporate formative evaluation feedback into daily practice; • locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems; • use information technology to optimize learning; and • participate in the education of patients, families, students, residents and other health professionals.
Interpersonal and communication skills	<p>Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. Residents are expected to:</p> <ul style="list-style-type: none"> • communicate effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds; • communicate effectively with physicians, other health professionals, and health-related agencies; • work effectively as a member or leader of a healthcare team or other professional group; • act in a consultative role to other physicians and health professionals; and • maintain comprehensive, timely, and legible medical records, if applicable.

(continues)

Table 2-1 (Continued)

Core Competency	Definition
Professionalism	<p>Residents must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. Residents are expected to demonstrate:</p> <ul style="list-style-type: none"> • compassion, integrity, and respect for others; • responsiveness to patient needs that supersedes self-interest; • respect for patient privacy and autonomy; • accountability to patients, society, and the profession; and • sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.
Systems-based practice	<p>Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care. Residents are expected to:</p> <ul style="list-style-type: none"> • work effectively in various healthcare delivery settings and systems relevant to their clinical specialty; • coordinate patient care within the healthcare system relevant to their clinical specialty; • incorporate considerations of cost awareness and risk-benefit analysis in patient and/or population-based care as appropriate; • advocate for quality patient care and optimal patient care systems; • work in interprofessional teams to enhance patient safety and improve patient care quality; and • participate in identifying system errors and implementing potential systems solutions.

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complicated and unduly burdensome. Furthermore it may fail to reflect the type of work being performed by the specific provider. In core privileging, the items on the recredentialing list are bundled to reflect those activities commonly performed by the family physician, which is reflective of how family physicians are trained in their accredited residency and more accurately describes what family physicians do. In the

case of a family medicine provider, the core privilege might be “to admit, diagnose, and treat children and adults for most injuries and illnesses and to promote health and wellness.” The specific activities would then be bundled under this competency. In addition the specific qualification to hold this core of privileges would be the completion of an approved family medicine residency. This would eliminate the need to identify the

Table 2-2 Core-Competency Criteria

Core Competency	Example
Patient care	Peer-review-analysis data
Medical/clinical knowledge	Continuing medical education
Practice-based learning and improvement	<p>Author a book chapter; analyze and report Physician Quality Reporting Initiative (PQRI) data (PQRI is a voluntary program that provides a financial incentive to physicians and other eligible professionals who successfully report quality data related to services provided under the Medicare Physician Fee Schedule [MPFS]).</p> <p>The eligible professional should gather three approved measures on at least 80% of appropriate patients and submit the specified quality-data codes for services paid under the MPFS and provided during the reporting period. (Eligible professionals may earn an incentive payment of up to 1.5% of their total allowed charges for MPFS covered professional services furnished during the reporting period.) Participate in teaching rounds. Demonstrate interpersonal and communication skills.</p> <p>Participate in Performance Improvement (PI) of a multidisciplinary institutional review board-approved study; serve on a clinical committee; lead a Failure Mode and Effects Analysis (FMEA) or PI project.</p>
Professionalism	Actively participate in a professional society.
Systems-based practice	Participate in annual safety rounds; comply with specific regulatory standards; complete mandatory training programs (e.g., electronic-medical-record training).

hundreds of specific procedures and treatments that might fall under this more general description.

TJC-accredited organizations are also required to complete ongoing and focused professional-practice evaluations to demonstrate that a requesting physician is competent to perform the privilege(s) requested. This requirement applies to new physicians and currently privileged physicians who are requesting new or expanded privileges.¹¹ The medical-staff organization must also define criteria that trigger further, focused monitoring when questions related to competency or quality of care arise.¹² Often these issues will be flagged by the risk management department conducting their adverse-event case reviews, or by the quality department working with various clinical sections on their

morbidity and mortality case conferences. The criteria for review should be well defined in the organization's bylaws, policies and procedures, or quality plan. Examples of such "focused privileging triggers" can include (1) the incidence of malpractice claims within a defined time period, (2) the required reporting to a state's department of professional regulations, (3) an involvement in a sentinel event, and/or (4) a high incidence of adverse events.

To mitigate the risk of the healthcare organization being sued for negligent credentialing because of these new standards, risk managers are encouraged to work with their medical staff office or entity responsible for granting privileges to providers to ensure that their credentialing and appointment processes meet these new regulatory requirements.

Doctrine of Corporate Negligence

Plaintiffs have put forth the doctrine of corporate negligence to argue their theory of liability against healthcare organizations. To prove this theory, plaintiffs must demonstrate the basic tenets of a negligence claim: duty, breach of duty, causation, and injury. Plaintiffs raising a negligent-credentialing allegation will likely suggest that a hospital failed to follow its credentialing and privileging procedures, defined in its bylaws or applicable policies and procedures, and/or negligently credentialed or granted privileges to an unqualified physician.¹³

Duty

According to the doctrine, a hospital and its medical staff have a duty to exercise reasonable care to confirm that physicians are qualified to perform the privileges requested at the time of hire, during the recredentialing process, and/or when new privileges are requested. If the hospital knew or should have known that a physician was not qualified, and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of the physician.¹⁴ To demonstrate that this duty has been met, hospitals should evaluate how their medical staff organization determines privileges and whether they are using core, rather than specialized, privileges.

Breach of Duty

Plaintiffs will argue that a hospital has breached its duty by failing to adopt state licensing requirements and/or accreditation standards, or by failing to follow its own medical-staff bylaws, rules and regulations, or policies and procedures.¹⁵ Examples include reappointing a physician without evaluating quality or performance data related to that physician's practice or the physician's failure to meet the criteria defined for specialized privilege requests. Hospitals also have a duty to review the past

malpractice and disciplinary-action data and to monitor more closely physicians who have a "dirty file." These types of files should be referred to the organization's peer-review committee. If the physician is permitted to practice, he or she should undergo a period of focused, professional-practice review.

Causation

Causation may be more difficult to demonstrate in a negligent-credentialing case than in a malpractice claim that asserts negligence. The plaintiff must still prove negligence and that the patient's injury was directly related to the negligence. The plaintiff must also demonstrate that if the hospital had met its duty to perform a proper credentialing review, the physician would not have been granted privileges to perform the type of care that led to the adverse outcome.

Unlike a medical-negligence case, it is difficult to defend against a corporate negligence claim when peer-review data cannot be used to demonstrate compliance with the peer-review analysis conducted as part of the credentialing process.¹⁶ The risk management and legal departments determine whether the jurisdiction's peer-review statutes allow an organization to waive the privilege and produce certain documents normally shielded from discovery in malpractice litigation.¹⁷ Risk managers may consider working jointly with the medical-staff office to develop credentialing documents that are completely transparent, accessible, and separate from for-cause peer-review analysis. Risk managers and attorneys may also consider developing a "red flag" system for use during the credentialing process. These criteria would alert the credentials committee that a physician has a high number of malpractice claims, criminal convictions, sanctions from the department of professional regulation, and/or patient or staff complaints.¹⁷ These "flags" should trigger higher scrutiny of the physician's practice and may appropriately result in a period of focused, professional-practice review. Legal counsel can help

hospitals decide whether to make this review process transparent to discovery or perform the type of peer-review analysis typically covered under peer-review privilege statutes.

To avoid a negligent-credentialing claim and demonstrate compliance with regulatory standards during accreditation surveys, it is imperative that an organization's risk and quality departments work closely with the medical-staff office to ensure that the current credentialing process meets these requirements.

EARLY WARNING SIGNS OF POSSIBLE LIABILITY

Patient and family dissatisfaction is often an early indicator of potential litigation or adverse media attention. Ongoing communication between certain departments within an organization may reveal a subtle problem that will prompt the review of a patient's care. A close, collaborative relationship between the risk and quality departments, as well as other departments, such as patient relations/advocacy, billing, the HIPAA office, and medical records, will provide opportunities for quick problem identification and allow for early interventions with patients and family members.

Patient Complaints

A proactive and responsive patient relations office can often intervene early during a patient's hospital stay to counter negative patient, friend, or family impressions of care. Many times, a simple explanation or help in quickly resolving a problem experienced by a patient may be all that is needed to change perceptions and resolve a negative patient experience. Patient-relations specialists are often instrumental in coordinating patient-family conferences with the healthcare team. Such conferences provide open lines of communication between a physician and the patient, helping to adjust unrealistic patient expectations and allay criticism related to patient care. Dissatisfaction can often be

resolved prior to a patient's discharge, but occasionally a patient's or family member's expectations will not be met. Patient or family dissatisfaction is an early indicator of potential liability, regardless of the presence or absence of evidence of negligence.¹⁸ Data sharing between the patient relations office and the risk manager is essential to early liability analysis and possible prevention of litigation.

An organization's billing office is another outlet for patients to voice their concerns related to patient care. Requests for bill adjustments are typically coupled with allegations of inadequate or substandard care. Such complaints should be referred to the risk or quality departments for quality and/or peer-review analysis to trigger the peer-review privilege. Final recommendations related to bill adjustments may be made, but an organization may wish to check with their legal counsel or compliance officer to determine if such recommendations are discoverable under their state peer-review statutes, or subject to different billing practices.

Many hospitals now track patient complaints and trend this data for each health-care provider. This tactic allows an organization to implement strategies to improve physician-patient relations and strengthen the communication skills of those providers who generate a high number of patient complaints. Early intervention and physician mentoring may help reduce the incidence of malpractice claims.¹⁸

Medical Records

One of the strongest allies of the risk management department is the medical records department. It supplies the raw material (i.e., the medical-record documentation), and risk and quality managers turn to this department regularly for support and services. Charts are routinely requested for case-review analysis and abstraction, with expedited requests made during times of accreditation surveys and on-site inspections.

The role of this department in identifying adverse events and quality-of-care concerns

increased exponentially with the implementation of the CMS “Never Events” legislation in October 2008, which focuses on many hospital-acquired conditions (HAC). Also known as “The Deficit Reduction Act of 2005,” it “authorized the Secretary of the Department of Health and Human Services to select conditions that are: (1) high cost, high volume, or both; (2) identified through ICD-9-CM coding for billing purposes as complicating conditions or major complicating conditions that, when present as secondary diagnoses on claims, result in a higher-paying reimbursement code and (3) reasonably preventable through the application of evidence-based guidelines,” and refuse to pay for the associated care.¹⁹ The specific conditions that have been identified as preventable and therefore are subject to reduced reimbursement are listed in Table 2–3.

These conditions must be acquired during a patient’s hospital stay for the rules related to condition of payment to apply. If an HAC is documented as having been present on admission, the healthcare facility may still apply the secondary billing code to that diagnosis, placing the admission into a higher category of reimbursement. The intent of the new rules is to advance the quality- and safety-improvement initiatives related to these conditions. Coders working in a medical-records department often identify these HACs and initiate a report to the risk and quality departments for peer review and quality analysis.

Another early indicator for a potential claim against an institution is a request for medical records, especially by an attorney. Medical-records staff should notify their risk management department upon receipt of such requests.

POST-EVENT MANAGEMENT AND MEDIA RELATIONS

Plaintiffs’ attorneys, patients, and family members use public media outlets to voice their dissatisfaction or anger toward individ-

Table 2–3 Selected Healthcare-Acquired Conditions

Foreign object retained after surgery
Air embolism
Blood incompatibility
Pressure ulcers (stages III and IV)
Falls and traumas
Fracture
Dislocation
Intracranial injury
Crushing injury
Burn
Electric shock
Catheter-associated urinary tract infection
Vascular catheter-associated infection
Manifestations of poor glycemic control

ual healthcare providers or institutions. If an institution is provided with an opportunity to respond to an article or media report, the time frame to submit a response can be limited to as little as 30 minutes, and some reporters may ask for an immediate comment. The healthcare organization must be ready to respond immediately. If a risk manager or clinical provider has reason to believe an adverse patient-care event may become a media event, the media relations team should review the details and consider drafting an appropriate response. The risk manager can assist the media relations team by ensuring that the response follows Health Insurance Portability and Accountability Act (HIPAA) rules and regulations. A well-drafted response based on in-depth knowledge of the event is critical.

CONCLUSION

Risk and quality professionals have been key drivers in the national patient safety

movement. They have witnessed and embraced the increasing emphasis on patient safety and provider accountability and have incorporated the tenets of this reform into their professional practice. They coordinate their organizations' endeavors to create a culture of safety and collaboration throughout

their institutions to implement safety-systems analysis, data collection, and proactive risk-reduction strategies. Through their efforts, organizations will achieve the best practices resulting in innovative and effective safety, quality, and risk management programs.

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