Quality of care and peer review: A delicate balance

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This is the seventh in a series of articles by Foley & Lardner LLP published in **Compliance Today** *designed to address the compliance risks associated with quality of care in the hospital setting. This article explores the how the quality-of-care movement may impact traditional, practitioner-focused peer review.*

Quality-of-care measurement and reporting presents new, serious challenges for the peer review process. The Centers for Medicare and Medicaid Services (CMS) and many private payers require reporting on quality measures and may refuse payment for certain "never events."[1] Many medical errors are a result of a system failure: multiple problems cascade and result in a final error that harms or potentially harms the patient. The traditional approach of evaluating individual incidents can be focused, like a surgeon, on an individual, not allowing the facility or its medical staff to see greater "system" patterns of quality failures. Quality improvement processes should instead focus on problems that affect a facility as a whole and should be prospective; they should seek to address problematic patterns before they lead to bad outcomes.[2]

The traditional peer review process in the hospital setting is the evaluation by other physicians of the appropriateness and quality of care provided by an individual physician, generally by other physicians on the same hospital medical staff as the physician being evaluated. It focuses on the errors of individual practitioners and it is often reactive. It responds to incidents which involve individual physicians, and thus, is ill-suited for prospective investigations to broadly improve systemic quality within an organization.

Unfortunately, facilities fear the valuable confidentiality and immunity protections or privileges provided by many states might be waived if the information is used outside the peer review process (e.g., broader efforts to improve quality). Some physicians may resist the move toward standardized guidelines, and others may state that they are merely advocating for quality patient care, when in reality they are engaging in disruptive behavior. The push toward proactive quality assessments in peer review will require careful navigation of the practical, day-to-day tension between hospitals, physicians, the medical staff, and government regulators. This article explores some of the issues that may arise in the difficult and complex attempt to create safer facilities with high quality of care and maintain peer review processes.

Peer review is an incident-driven process

Medical errors are, in many cases, a failure of systems rather than individual physicians. The Institutes of Medicine (IOM) suggests that evaluating and correcting systems can achieve greater results than focusing solely on the errors of individuals.[3] Mistakes should be seen in the context in which they occur. For cases of individual incompetence, impairment, or willful abuse of patients, "traditional" peer review remains an effective, useful, and necessary solution, because there is clear individual responsibility for patient harm. But in many cases, harmful errors are the result of multiple failures by many persons involved in a patient's care. This is also known as the "Swiss cheese model," based on a metaphor of individual mistakes as holes in care which align in multiple layers across different systems and ultimately allow harmful or potentially harmful errors to pass through to affect a patient.[4]

Despite IOM's and others' belief that a systems approach to evaluating error may have more and sometimes far-reaching results than a result which focuses primarily on individuals, it has been difficult to change the way errors are evaluated and corrected within hospitals.[5] Peer review remains a process that assigns responsibility to individual practitioners and aims to evaluate and correct the behavior of particular practitioners. The need to evaluate systems does not mean personal responsibility is eliminated or even downplayed. Hospitals and medical staffs must have a way to correct and control the behavior of disruptive physicians. Nevertheless, when a facility evaluates individual incidents, reviewers should begin to think about how the holes may align to allow a continuing threat to patient safety to occur.

Reviewers should consider whether "fail-safes" could be designed in the hospital's systems, or if education of all staff involved could help prevent future similar harms.

This must be carefully done. If blame is placed on a system only, and not on an individual practitioner, it may become more difficult to prevail in justified and necessary individual corrective action. The practitioner might point to findings to claim he or she is not at fault for the error. It can also be difficult to maintain the peer review confidentiality protections when the analysis and discussion extends beyond the organized peer review committee. However, if a medical staff included quality councils and other committees as "medical staff committees," their proceedings may well still be protected. Organizational difficulties may present challenges to a systems-based approach to examining quality. The IOM recognized this problem, and recommended stronger federal laws to protect data related to health care quality improvement.[6] The Patient Safety and Quality Improvement Act of 2005 (PSQIA) and its recently passed implementing regulations defined a privilege for "patient safety work product" prepared for production to a patient safety organization.[7]

Potential loss of peer review confidentiality

Most states have enacted peer review privileges or protections, which preserve the confidentiality of the medical staff peer review process. These laws are rooted in the notion that keeping quality improvement processes confidential improves open and honest communication by peers about errors. Ideally, this results in a free exchange of ideas and thorough evaluations of problems.

However, recent studies have shown that physicians are not likely to report medical errors by their peers.[8] Moreover, confidentiality protections tend to be limited to the activities of well-defined peer review or patient quality committees. For example, in California, records generated by a medical staff committee, such as an infection control committee, qualifies for peer review protection, but purely administrative records fall outside the protection.[9] Some states may protect disclosure to administrators in some cases, but it is always advisable to discuss with legal counsel the contours of what likely will and will not be protected.[10]

Hospitals face a nuanced task when seeking to maintain state peer medical staff review protections when multiple departments become involved in quality review. This creates a dilemma for hospitals that want to look at quality in a broader facility-wide way. There are avenues to protect this information, particularly addressing broader quality issues in the medical staff bylaws. Hospitals which seek to expand the use of information gathered in peer review to a broader facility-wide analysis should work closely with legal counsel to take maximum advantage of all available state and federal protections.

Resistance by physicians to "cookbook" medicine

Generally, physicians agree that patients deserve safe, high-quality care, but these same practitioners disagree on how to ensure care is safe and of high-quality. Standardization of quality measures and use of evidence-based practice guidelines is seen by many physicians as a step toward consistent, quality care. Other physicians, however, reject standardization as "cookbook" medicine. Medicine has a strong tradition of autonomy for individual physicians' practice styles and clinical decision making. Many physicians resist any infringement on that autonomy and view practice guidelines and evidence-based medicine as motivated by financial or other administrative concerns, rather than a concern for quality patient care.[11]

Certainly, patients are different and some respond to treatment in unexpected ways. Quality measures, done poorly, might punish physicians who treat a more complicated patient mix or patients of low socioeconomic status (who often have a more difficult time complying with treatment) and patients who are in more progressed disease states when seen.[12] These difficulties add to the resentment some physicians feel toward the infringement on their autonomy by groups that promote standardization, such as medical staffs, medical groups, or specialty societies.

Effective guidelines are truly evidence-based, and derived through solid scientific study. Most physicians respond positively when they can understand how these guidelines assist them to improve their patient care.[13] It is important, when a facility (e.g., a hospital) implements guidelines, to verify that physicians are fully educated in how the guidelines will result in better outcomes for patients. It is also important to involve physicians in the establishment of guidelines. Physician leadership should communicate with other physicians about quality guidelines, because physicians accept information more readily when they hear it from their peers. Even where guidelines are in place, it is important to continue full investigation into the nuances of bettering the guidelines. And of course, guidelines are an important factor to consider, but they should not be the only issue considered.

Disruption or advocacy for quality care?

In some cases, disruptive physicians, who are abusive to co-workers or dangerous to patients, may assert that they are advocates for patient care. If a physician can understand

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that what he or she perceives as advocacy is seen by others as disruptive, he or she may be willing to change behavior. These physicians may simply need to be educated about appropriate feedback to colleagues and how their behavior may harm patients by eroding team dynamics.[14]

Other physicians may attempt to use complaints about quality as a shield against being subject to peer review. Physicians who make quality complaints to avoid peer review may attempt to protect themselves under whistleblower statutes. For example, under California law, medical staff members who make quality complaints are protected from retaliation.[15] Actions taken against the medical staff member within 120 days of a complaint are presumed to be discriminatory. These actions are broadly defined, and may include virtually all negative action taken against a medical staff member, including any reduction or suspension of privileges.[16] Although the presumption is rebuttable, violation of the law is a misdemeanor with a monetary fine. This may chill peer review proceedings against a physician during the presumed discriminatory period, even if the proceeding is well-justified.

A need for greater governing board oversight of quality

Strong leadership can make a difference in changing the culture of a hospital to refocus on quality and patient safety. It is important to have physicians involved at every step in developing a quality program, but governing boards must also take responsibility and become involved. Governing boards should make themselves accountable for patient safety. They can create specific, achievable patient safety aims and establish clear system-level measurements within the hospital, and require reporting on whether the hospital is meeting the aims established.[17] Gathering data is a critical step in developing solutions. One facility found that some steps necessary to create a sterile environment for central line placement were sometimes missed, because it was difficult to quickly locate all needed supplies. The solution was to simply create a bundle of all the needed supplies that could be grabbed.[18] By avoiding specific harms, this solution has also likely avoided the need for peer review of individuals related to these kinds of incidents.

Other facilities have found benefits from creating interdisciplinary teams to improve quality. The entire hospital staff supports the medical staff. For example, if a facilities department understands how important hand washing is to patient safety, they may change their own systems to prioritize repair of sinks and sanitizer dispensers.[19]

In many facilities, quality issues may vary between units. Some facilities may benefit from an "Adopt-a-Unit" program where senior leadership focuses on individual units to evaluate and improve them, rather than attempting to make sweeping changes of the entire facility at once.[20] This has the advantage of allowing sharper focus on the selected units, and allows a facility to examine if changes are successful on a smaller scale. It is often easier and more effective to implement small, incremental changes in health care settings.[21] Small changes generally face less resistance, and are easier to manage. However, in implementing changes in individual units, hospitals should be careful to apply the same peer review standards across the entire facility.

Conclusion

In an environment that increasingly demands that hospitals account for quality, it is important to consider the delicate balance between holding individuals responsible for bad actions through peer review and examining the systems in which errors occur. Hospitals must work with legal counsel to evaluate the subtleties of how to protect information used to examine quality. Examining quality more broadly creates the possibility of making more dramatic improvements. Hospitals should work with medical staff leaders to get their medical staffs on board with implementation of quality measures. Governing boards will need to take greater control of oversight for their facilities, and make decisions for their facility based on the information they receive, from the governing board to administration to the medical staff.[22] Working together, all of hospital leadership can make gains in improving quality. ■

1 "Promoting Patient Safety: CIGNA to Stop Reimbursing Hospitals for Never Events and Avoidable Hospital Conditions," Business Wire (April 17, 2008); Nadra Kareem, "Anthem Says it Won't Pay for Hospital Errors," San Fernando Valley Business Journal (May 12, 2008).
2 Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, eds., *To Err is Human: Building a Safer Health System* (2000).
3 See note 2.
4 Robert M. Wachter: Understanding Patient Safety, "Basic Principles of Patient Safety," p. 17-25 (2008).
5 See notes 2 and 4.
6 Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, eds., *To Err is Human: Building a Safer Health System*, "Protecting Voluntary Reporting Systems from Legal Discovery," p. 109-131 (2000).
7 42 United States Code §§ 299b-21, 299b-22; 42 Code of Federal Regulations §§ 3.20, 3.204-3.212.
8 Institute of Medicine as a Profession, "Survey on Medical Professionalism," *Annals of Internal Medicine* (December 4, 2007).
9 California Evidence Code § 1157; *Santa Rosa Memorial Hospital v. Superior Court*, 220 Cal.Rptr. 236 (1985); Willits v. Superior Court, 24 Cal.Rptr.2d 348 (1993).
10 For example, Kansas Statutes § 65-4915(e) allows, "[a] peer review committee or officer may report to and discuss its activities, information and findings to other peer review committees or officers or to a board of directors or an administrative officer of a health care provider without waiver of the privilege provided by [Kansas Statues § 65-4915](b) and the records of all such committees or officers relating to such report shall be privileged by [Kansas Statutes § 65-4915](b)."
11 Lucian L. Leape, Donald M. Berwick: "Five Years After To Err is Human: What Have We Learned?," *JAMA* 293(19), 2384-2390 (May 18, 2005).
12 Rodney A. Hayward, David M. Kent: "6 EZ Steps to Improving Your Performance: (or how to make P4P Pay 4U!)" *JAMA*, 300(3), 255-256 (July 16, 2008).
13 See e.g., William G. Wilkoff: "Cookbook medicine (Letters from Maine)" *Pediatric News*, 42(5), 25 (May 2008).
14 Nina Youngstrom: "Disruptive Physicians Heighten Hospital Risks at a Time When Collaboration is Key to Effective Compliance," Health Business Daily, May 6, 2008.
15 California Health & Safety Code § 1278.5(d).
16 California Health & Safety Code § 1278.5(d)-(g); California Business & Professions Code § 2056.
17 James Conway: "Getting Boards on Board: Engaging Governing Boards in Quality and Safety," *The Joint Commission Journal on Quality and Patient Safety*, 34(4) p. 214-220 (April 2008).
18 Martha Nolan McKenzie: "Cookbook Medicine," Emory Momentum (2007), available online at: http://www.whsc.emory.edu/_pubs/momentum/2007summer/pf_cookbook_med.html.
19 "Award winner involves entire staff in quality improvement initiatives: hospital culture changes following leadership crisis," *Healthcare Benchmarks and Quality Improvement*, 14(10) p. 109-113 (October 2007).
20 Robert M. Wachter: *Understanding Patient Safety*, "Organizing a Safety Program," p. 237-253 (2008).
21 Preston Gee: "A Quality Opportunity: Engaging Physicians in Outcomes Improvement," *Spectrum*, p. 8-9 (November-December 2005).
22 The Joint Commission, 2009 Hospital Accreditation Standards, Standards LD.02.01.01, LD.02.03.01.