CHAPTER FIVE

How to Ensure Quality Care

MONITORING QUALITY OF HEALTHCARE
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Board Responsibility for Quality and Performance

“Isn’t that what the doctors and nurses are supposed to be doing?” is a common first thought when new hospital board members are told that patient safety and the quality of care are ultimately the board’s legal responsibility. While physicians and nurses are critical to the quality process, and having well-trained and appropriately credentialed professionals on the staff is important, considerably more is required for boards to carry out their legal and fiduciary responsibilities for quality. Boards must have a broad view and understanding of quality to ensure that patient care is safe, effective, and reliable.

For many years, graduate programs in healthcare administration taught a model of hospital organization using the metaphor of a three-legged stool, with the administration, the board, and the medical staff as the legs of the stool supporting a platform for patient care delivery. The board was responsible for fundraising and gathering community input, the administration for staffing and operating the hospital, and the medical staff for bringing patients to the hospital and providing care. Board members assumed the quality was high if the hospital had well-trained doctors, state-of-the-art technology and facilities, low staff turnover, satisfied patients, and generally clean reports from auditors, regulators, and accreditation agencies. While these proxies for describing good quality are important and contribute to high-quality patient care and experiences, simply equating quality to facilities, doctors, or reputation does not fulfill the board’s responsibility for ensuring that patient
care is safe and every patient gets exactly the right care, every time.

For more than 200 years, the “three-legged stool” description, sometimes called the Franklin Model (based on the hospital concept used by Benjamin Franklin when he founded The Pennsylvania Hospital in the late 1700s), paralleled the basic legal responsibilities of doctors and hospitals. But beginning in the 1960s a series of legal decisions, most notably Darling v. Charleston Community Memorial Hospital (211 N.E.2d 253, 1965), established the hospital board was ultimately responsible for the outcomes of patient care.

**Credentialing.** During the 1970s and 1980s, the primary tool for ensuring quality was the medical staff appointment and reappointment process. Sometimes referred to as credentialing, this process established the level of care and procedures that individual physicians were allowed to perform based on their training and experience. Physicians would apply for membership to the medical staff, and the hospital board would rely on a recommendation from the existing medical staff to allow physicians to admit patients to the hospital. The underlying hospital quality theory in the 1970s and 1980s: Keep the “bad” physicians off the medical staff.

**Peer review.** As an extension of the credentialing process, hospitals and medical staffs established peer review and other mechanisms to investigate and monitor individual physician performance; these efforts focused on the mistakes or errors a physician might have made in the care of patients. Recommendations to the governing board for corrective action might range from no action to relatively

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**Brief History of Quality in Hospitals**

I am called eccentric for saying in public that hospitals, if they wish to be sure of improvement,

- Must find out what their results are.
- Must analyze their results to find their strong and weak points.
- Must compare their results with those of other hospitals.
- Must care for what cases they can care for well, and avoid attempting to care for cases which they are not qualified to care for well.
- Must welcome publicity not only for their successes, but for their errors, so that the public may give them their help when it is needed.
- Must promote members of the medical staff on the basis which gives due consideration to what they can and do accomplish for their patients.

Such opinions will not be eccentric a few years hence.

*Source: Codman (1916).*
benign corrective actions, such as a letter to reprimand a physician or requirements for additional training. In some cases, recommendations might involve limiting privileges to perform certain procedures, or in extreme cases, terminating all care privileges and expulsion from the medical staff. The more punitive the potential board action, the greater the risk the board, hospital, or physicians involved in the peer review might be sued for violating the due process standards in the medical staff bylaws, which are meant to ensure fairness and impartiality in the review process.

In most states, the deliberations and investigations surrounding peer review have some measure of confidentiality and protection from legal discovery. But that is cold comfort for most physicians asked to be involved in the process. While the intent of peer review is good, the process is sometimes difficult and potentially flawed. Fear of lawsuits, potential conflicts of interest, variations in the professional knowledge of the reviewers, social relationships, closed sessions without nurses or others with a perspective present, and an unspoken but inherent reluctance among physicians to criticize their colleagues tend to diminish the potential impact and benefit of peer review on overall quality. Occasionally, suggestions do come out of the peer review process that might improve the care for all patients, but such suggestions are a byproduct of the process and not the focus of the effort.

**Quality assurance.** In the 1970s and 1980s, a quality control process known as quality assurance (QA) also emerged. In the QA process, patient charts were pulled after the patient was discharged and reviewed for the appropriateness and quality of care. The charts selected for review might have been pulled because of a patient complaint or known problem with the care, were sometimes selected for a routine review of specific types of admissions or might have been a random selection of charts. In some hospitals, but not all, efforts were made to ensure that every physician on the active medical staff had at least a few charts reviewed each year. Generally, the criteria for chart selection was determined by a committee of the medical staff and the charts were prescreened by a registered nurse (RN) employed by the hospital looking for specific issues, usually related to compliance with Medicare and Medicaid regulations. If the nurse noted a problem or gap in care, the chart was referred to a physician reviewer. If the physician reviewer felt the physician care was inadequate, the chart might be referred to a peer review committee that would investigate further. If the care by the hospital staff was poor or something bad had happened such as a fall, but it was not a physician mistake, the chart might be sent to risk management or referred to someone in management. Because Medicare and Medicaid reimbursement was often at stake, efforts were usually focused on improving documentation and payment issues. While some useful information was occasionally gleaned, leading to overall improvements in
care, for the most part QA used the same quality theory as peer review: Find and eliminate the bad apples.

However, removing the bad apple from the barrel does nothing to improve the quality of the rest of the apples in the barrel. Credentialing, peer review, and QA remain important and necessary, but these efforts generally do not result in quality improvement for all patients, and they are not processes that completely fulfill the board’s ultimate responsibility for quality care.

A Different View of Hospital Quality

In the late 1980s, the theories and methods to improve quality and reduce manufacturing defects began to be understood and adapted in healthcare. The key breakthrough in thinking about quality in healthcare was the realization that poor quality outcomes were most often the result of system or process failure rather than individual physician or staff failure or just bad luck. Quality became a process problem, not a people problem. Physicians are a critical part of the process, but not the entire care process—a lot of other people are involved.

As an example, surgeons are sometimes compared or judged by their surgical-site infection rate. However, the surgeon rarely cleans the equipment, cleans the operating room, maintains the ventilation system, shaves the patient, prepares the surgical site, starts the prescribed antibiotic in the effective window prior to surgery, or controls the glycogen levels of the patient during surgery. How well these tasks are carried out is known to decrease the probability of a surgical site infection by as much as 90 percent, but they are out of the effective control or direct influence of the surgeon. So while surgical technique and maintaining a sterile field during surgery are clearly important, are surgical site infections a doctor problem or a hospital system problem? The answer is likely some unknown and unknowable combination. However, across the country, the rigorous adherence to a set of simple basic operating room tasks—such as hand washing, proper preparation of the surgical site, and the timely administration of antibiotics—has been shown to dramatically reduce the overall incidence of surgical-site infections.

Dr. Paul Batalden, a cofounder and the first chair of the board of the Institute for Healthcare Improvement (IHI), said it best: “Every system is perfectly designed to produce the results it gets” (McInnis 2006). Batalden’s observation is grounded in statistical process control theory, which postulates that any stable process produces variation in outputs—some will be good and some will be bad. The required management action is not to chase the bad results but to change the process so it consistently produces the desired results. While perfectly logical, the
idea that processes, rather than doctors, are the root of many of the poor outcomes in healthcare has been slow to take root.

System and process thinking got a major boost in 2000 when the government-sponsored Institute of Medicine (IOM) published *To Err Is Human* and in 2002 followed up with a second report, *Crossing the Quality Chasm*. The first report highlighted how error and poor quality were rampant in healthcare and reported that between 98,000 and 140,000 patients died unnecessarily each year in US hospitals, making hospital deaths the eighth leading cause of death, ahead of motor vehicle fatalities. As expected, there were fierce attacks on the report and challenges to the estimated number of preventable deaths and the ideas presented. However, since the original publication, other studies and estimates suggest the IOM understated the enormity of the problem.

The second report advocated healthcare redesign along the principles of safe, effective, efficient, patient-centered, cost-efficient, and equitable care for all. While initially controversial, the IOM reports served as a wake-up call for hospitals to begin thinking about quality and patient outcomes much differently. In the decade since the IOM reports, awareness has developed that many of the things we used to consider complications in the treatment of patients are actually avoidable patient-harm events. Potentially fatal hospital-acquired conditions—such as ventilator-associated pneumonia, sepsis, infections associated with venous catheters, and medication errors—can effectively be eliminated by strict adherence to simple care and procedure protocols.

Dr. Donald Berwick (2003), the founder and former president of IHI and now administrator of the Centers for Medicare & Medicaid Services (CMS), has said when you strip everything else away, what patients are really saying is

1. Don’t hurt me.
2. Help me.
3. Be nice to me.

These three patient-centered elements, in the order of priority listed, redefine how we think about quality in healthcare. “First, do no harm” is part of the Hippocratic Oath all physicians take upon graduation—an old idea. But for healthcare organizations, “Don’t hurt me” is a relatively new foundation to organizational quality improvement efforts. Unfortunately, as reported by the IOM, patient harm is widespread and insidious. In 2006, IHI launched its 5 Million Lives Campaign, aimed at encouraging hospitals to take steps to significantly reduce harm to patients. As part of that campaign, IHI (2006) adopted and published a broad and inclusive definition of patient harm:
Unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment or hospitalization, or that results in death. Such injury is considered harm whether or not it is considered preventable, resulted from a medical error, or occurred within a hospital.

Hospitals and other healthcare organizations typically keep track of the number of falls, infections, medication errors, wrong-site surgeries, delayed treatments, bed sores, procedural mishaps, and other potential patient-harm events. However, this information may be gathered by different people for disparate purposes and is rarely compiled on an organization-wide basis. Reports on falls are separate from reports on infections, which are separate from reports on medication errors and so on. To further muddy the waters, harm is often reported as a rate per 1,000 patient days or some other denominator that tends to diminish the impact of the data. Board members, management, and medical staff leadership are routinely shocked the first time the aggregate actual number of harm events is presented—almost always much higher than expected. Boards need to ask to see the actual number of harm events and then set aggressive targets for reduction.

The second plea, “Help me,” is typically why most individuals choose healthcare as a career—they want to help other people. “Help me” does not mean “cure me.” Most patients are realistic in their expectations of what medicine can and cannot do. What they really want is for the healthcare system to reliably deliver everything that is known to help. Hospitals face two problems in meeting this need. The first is defining what is known to help. Numerous studies over the past decade have shown tremendous geographic variation in the treatment for almost all medical conditions and wide disparities in healthcare costs (Dartmouth 2011). The second problem is, after defining what is known to help based on clinical evidence, building the processes and systems to ensure that the “right care” is always delivered.

The IOM has estimated 30 percent of what is spent on healthcare in the United States adds no clinical value. Other studies suggest only about 50 percent of all care delivered is actually evidence-based, meaning there is hard, replicable science linking the treatment and the outcome.

The practical application of evidence-based medicine had its roots in an obstetrics malpractice insurance crisis in the late 1970s and early 1980s. In response, the American College of Obstetrics and Gynecology began publishing guidelines to help practicing physicians who agreed to practice according to the guidelines to obtain or maintain malpractice insurance. Next, in 2004, Medicare began measuring the quality of care in hospitals with a set of core measures that tracked whether the common evidence-based clinical treatment elements were delivered for the conditions of heart attack, pneumonia, congestive heart failure, and stroke.
Medicare’s action helped hospitals and physicians begin to think differently about the use of protocols and standardized care plans and spurred the concept of the “right care”—delivering evidence-based care every time for every patient.

Many hospitals have fallen into the trap of looking at the percentage of time individual care elements were delivered rather than how often patients receive all of the required care elements. If a patient qualifies for six elements in an evidence-based care plan, but the hospital only delivers four, did the patient get the right care? Numerous studies have shown hospitals that can reliably deliver all of the care according to the evidence have lower mortality and complication rates (Mukherjee et al. 2004; Eagle et al. 2005).

The third patient desire—“Be nice to me”—is reflected in patient satisfaction data. During the 1990s, almost all hospitals began focusing on patient satisfaction, conducting surveys and adapting service techniques from other industries to improve the patient experience. In 2009, Medicare began publishing comparative patient satisfaction statistics for all hospitals, available on the CMS website. Service quality and amenities are important, but a smiling nurse and valet parking will not likely offset the experience from a hospital-acquired infection, a wrong-site surgery, or a medication error resulting in harm.

**Board Strategies for Measuring and Improving Quality**

The board is ultimately responsible for everything happening in the hospital, including reducing harm and ensuring care is delivered appropriately and according to the evidence. There are four common challenges with which boards and new board members may struggle:

1. **Getting comfortable with the board’s responsibility for the care and safety of patients.** Getting comfortable requires boards to have good processes in place for credentialing, discussing difficult issues, and resolving conflicts. There is no ambiguity about a board’s legal responsibility for care and outcomes. But it takes a strong management and medical staff team and good board relations to be transparent and openly discuss patient harm and poor quality outcomes—topics that in most hospital environments have not traditionally engendered trust between the board, management, and physician leadership. As the nursing staff plays such an important role in the delivery of quality patient care on a 24-hour-a-day, 7-day-a-week basis, the board must be willing to appropriately involve nursing leadership in these discussions as well. Most CEOs did not get to be the CEO by delivering bad news. Boards have a responsibility to create a board meeting environment in which difficult issues can be discussed without fear of punishment.
The way to begin to build the right board environment is by asking inquiry questions, not attack questions. Board members should feel comfortable asking governance questions about quality, such as

- How many patients were harmed last month?
- How does that compare to the previous six months?
- Are we trending downward?
- What are the plans for the next wave of efforts to reduce patient falls, medication errors, hospital-acquired infections?
- What percentage of the care delivered in our cardiac program was “right care”?

These questions are no different from the types of questions the finance committee asks about financial issues: Where are we, are we getting better, what is your strategy for improvement?

2. **Setting the right expectations for the organization’s leadership and medical and nursing staffs.** Setting the right quality expectations and having a good process to monitor progress are the two most important things a board can do in exercising its responsibility for quality patient care and preventing harm. Recent studies have shown that better outcomes are associated with hospitals in which:

- The board spends more than 25 percent of its time on quality issues.
- The board receives a formal quality performance measurement report.
- There is a high level of interaction between the board and the medical staff on quality strategy.
- The senior executives’ compensation is based in part on quality improvement (QI) performance.
- The CEO is identified as the person with the greatest impact on QI, especially when so identified by the QI executive (usually a physician on the hospital payroll who has responsibility for implementing QI programs).

The key is setting the right governance aims. Hospital boards should set aggressive aims seeking to dramatically reduce levels of harm to patients. External comparative data are not necessary and, in fact, counterproductive when it comes to harm—there is no appropriate level of harm, especially if you are the patient. All that is required is a simple monthly or quarterly count of the number of patients who experienced harm. Some organizations have developed composite indicators that measure not only patient harm but also the number of serious safety events whether the patient was harmed or not,
on the theory that the focus should be on preventing any event that could lead to harm.

The board must also set “what by when” targets (e.g., reduce all harm events by 50 percent by December 2013), which will create the expectation that significant process change is required to reach the targets, not an incremental or marginal approach to improvement.

3. **Getting useful information and monitoring performance.** The board should also focus on what is important—high-level outcomes rather than detail. For far too long, hospital boards have suffered from an excess of data and a dearth of information from quality reports. Instead, the board should focus its review and discussion on a few high-level outcome measures that can be presented in a fairly simple scorecard or report format. The scorecard should include measures and targets for the following:

- Hospital mortality tracked over time (run chart)
- Number of patient safety and harm events, tracked over time
- Unplanned hospital readmission rate
- Percentage of time care is provided according to the evidence (right care)
- Patient satisfaction

Measures on the board’s quality scorecard should be limited to the most important areas to provide governance and not management oversight. The organization’s quality and operating strategies should be linked and should drive the measures in the desired direction.

In some organizations, boards may need to add a few other measures specific to the mission of the organization or challenges faced by the organization. Those types of measures might include the following:

- A measure that represents access or waiting time in clinics or emergency facilities
- A measure representing culture or staff satisfaction
- A measure representing cost efficiency or value
- A measure representing equity in care across demographics

The most effective boards have active quality committees that begin their meetings with a brief story of a patient experience, effectively putting a face on the data. The committee typically reviews the board’s quality aims and targets and progress toward achieving those quality aims. It also reviews the execution and quality improvement plans the medical staff and management propose for
the next month or quarter. Further, the committee should review sentinel events and reports of harm and review regulatory dashboards for compliance exceptions; it may also periodically receive reports from risk management. Finally, the committee should consider any policy change recommendations which may require full board approval. Some boards use the quality committee to review medical staff credentialing recommendations prior to a vote by the full board. The chair of the quality committee, not the management team, should make the committee report to the full board.

Dr. James Reinertsen (2011), a senior fellow at IHI, advocates including patients on the quality committee of the board. Board members may occasionally be patients, but their experiences, because of their access and status in the organization, often do not represent the experiences of other patients. More importantly, a board member’s fiduciary duty is to the organization. Patients in the boardroom tend to reduce self-serving conversations and add a perspective no one else in the room is free to deliver.

4. **Creating accountability for quality results.** The final challenge is to create accountability for quality results. Many hospitals are beginning to tie CEO and senior leader compensation to the achievement of strategic and quality goals. When structured correctly, compensation can align management actions with the board’s goals and expectations. Organization-wide accountability is also created through transparency of aims, targets, and progress. Boards that spend as much time discussing quality issues at their meetings as they do financial and operating issues send a clear message to the organization, which can drive cultural change and foster accountability.

**The Business Case for Quality**

Whether or not there is a financial case supporting a specific improvement strategy, there is always a business case for improving quality in healthcare. Poor quality represents waste in the hospital and healthcare system. Across the country, hospitals are learning that when they eliminate or dramatically reduce ventilator-associated pneumonias, central line infections, medication errors, and patient falls, operating costs go down, not up. Quality in healthcare does cost less when waste in the form of patient harm is reduced.

In 2008, Medicare began eliminating payment when any “never events” occur and reducing payment for complications that occur in the hospital. Depending on state regulations the event may be reportable to a public agency or to The Joint Commission.
Other payers have followed with even more restrictive policies. Under the 2009 healthcare reform legislation, the pressures ratchet up on hospitals with increasing payment reductions if the hospital has a higher-than-expected rate of readmissions, and expands those quality penalties to the Medicaid program. Not many carrots, but lots of sticks. Healthcare reform also envisions value purchasing—forcing hospitals to reduce costs to show greater value. Improving quality and reducing harm may be the most powerful value strategy on the board’s strategy scorecard.

### Never-Event CMS Regulatory Categories

1. Air embolisms
2. Mediastinitis—surgical site infection after coronary artery bypass graft
3. Catheter-associated urinary tract infections
4. Vascular catheter-associated infections
5. Blood incompatibility
6. Objects left in the patient during surgery
7. Falls, trauma
8. Pressure ulcers
9. Poorly controlled blood sugar
10. Infections after elective orthopedic and bariatric surgery
11. Deep vein thrombosis or pulmonary embolisms following total hip and knee replacement

### The Board and Healthcare Quality

New board members generally face a steep learning curve for ensuring quality in healthcare. But that curve can be flattened if they keep a few things in mind and in perspective:

1. Ultimately the board is legally responsible for the quality of care and service provided.
2. Medical staff credentialing and peer review are important but alone are insufficient to ensure good quality. Having good doctors does not automatically equate to decreased harm and better outcomes.
3. Every system is perfectly designed to produce the results it gets. Poor quality and patient harm are generally the results of flawed systems and processes.
4. Patients have three requirements: Don’t hurt me, help me, and be nice to me. Quality in healthcare is about delivering on all three.
5. The board should track a few key quality metrics and set aggressive targets to set expectations and create organizational and strategic focus.
6. The quality committee of the board is the primary mechanism for monitoring quality performance and improvement efforts.
7. There is a strong business case for improving quality and reducing harm.
8. Ask lots of questions. The only dumb question is the one not asked.