Oversight of Medical Care Quality: Origins and Evolution

Richard E. Burney, MD

ABSTRACT: Not long after physicians began to gather in organized groups and form professional societies in the 19th century, it became clear that education, training and practices were highly variable and that oversight to prevent outright quackery was needed. Although the situation is quite different today, experience has shown that continued oversight of medical care is still necessary. Some modern physicians may allow their knowledge, skills, and practices to become out of date, resulting in ineffective, unnecessary and expensive care. They may engage in any number of unprofessional behaviors, ranging from substance abuse to billing and insurance fraud, leading to disciplinary actions by external agencies. That said, providing oversight in today’s highly complex health care delivery system is not a simple task to accomplish. Many rules, regulations, structures and processes have been put into place, all trying to ensure that medical care is safe, affordable and of high quality. This essay briefly describes the history and evolution of medical oversight—from its relatively simple beginnings in licensing and accreditation initiated over a century ago to the multiplex of oversight programs currently in place—including a look at some of the new, innovative and data-driven approaches being used today.

Introduction

Consider for a moment this question: how can members of the public know that the physicians they are seeing are good physicians? How can patients know that their physicians have the requisite knowledge and the skills to care for them competently, using up-to-date, effective methods? How can they be assured that their physicians are of “good moral character” and practice in a professional manner? These are important questions, because not all physicians live up to expected standards. Physicians can and do fall behind in their knowledge and skills, practicing in an outdated fashion. They may abuse drugs, become alcoholic, act dishonestly, fail to abide by agreements, abuse employees, engage in sexual improprieties, sell drugs illegally, commit billing and insurance fraud, invent dangerous and ineffective treatments, dishonor their profession by cheating, stealing and lying, and go to jail.

I have been engaged in the oversight of medical care quality for more than 35 years in hospitals, in a Professional Standards Review Organization, in a Medicare Quality Improvement Organization, and for the past seven years as a member of the Michigan Board of Medicine. I have seen all of these failings occur and understand that oversight of medical care is necessary. But if oversight of quality is necessary, who should be responsible for it? How should it be accomplished—fairly and consistently? What follows is an attempt to summarize efforts past and present to achieve the goal of affordable, high quality health care.

The Definition of “Quality”

The father of quality in health care, the late Avedis Donabedian, defined the essential attributes or domains of quality in terms of structure, process and outcome in a groundbreaking 1989 essay, which remains the foundation document for all studies of health care quality. The term “health outcome” was defined by Donabedian as “the end results of medical care measures by health status and patient satisfaction.” This definition was advanced further by Paul Ellwood, who introduced the concept of the patient-reported health outcome, while at about the same time, John Ware and others at the Rand Corporation—under government contract—developed the SF-36, the first valid, reliable and functional health-status measurement tool. The Institute of Medicine, merging these ideas, has defined “medical quality” as “the degree to which health services for individuals and populations increase the likelihood of desired...
Basic Quality Oversight: Education and Certification

At the national level, three levels of professional achievement are required and accepted that offer the public assurance of competence. The first level of assurance is provided by successful graduation from medical school, which requires the student to have completed a high level of education, training and testing. Medical school graduation also implies that graduates are of good moral character and that as professionals they embody a desire to care for people. Further proof of students’ abilities is provided by having successfully completed Steps I and II of the United States Medical Licensing Examination (USMLE), which medical graduates are required to pass before entering post-graduate training.

The next level of assurance is provided by successful completion of residency training in an area of medical specialization. One year of internship may have sufficed many years ago, but it is no longer considered even remotely sufficient to ensure competence in patient care. All medical graduates must now enter a post-graduate training health outcomes and are consistent with current professional knowledge. The purpose of oversight should be to ensure that proper structures in health care delivery are in place, as well as processes that ensure good quality and measure patient outcomes in ways that enhance improvement efforts. Table 1 shows how present oversight practices relate to structure and process.

### Table 1
Some structure and process elements in quality oversight

<table>
<thead>
<tr>
<th>Structural Elements</th>
<th>Applicable Attribute</th>
<th>Relevant Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical school graduation</td>
<td>Proof of education, character</td>
<td>Graduation</td>
</tr>
<tr>
<td>Post-graduate education (residency)</td>
<td>Core Competencies: patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, system-based practice</td>
<td>Completion of program Verification of core competencies</td>
</tr>
<tr>
<td>Specialty board certification</td>
<td>Knowledge, skills, training</td>
<td>Maintenance of Certification Continuous Professional Development</td>
</tr>
<tr>
<td>State licensing</td>
<td>Minimum level of education and training</td>
<td>Investigation of complaints Verification of CME</td>
</tr>
<tr>
<td>Fellowship in national organization</td>
<td>Character, safe practice</td>
<td>Verification of practice Educational programs Data bases: NSQIP NTDB</td>
</tr>
<tr>
<td>Hospital staff or medical care organization membership and oversight</td>
<td>Education, training, scope of practice; competence</td>
<td>Credentialing delineation of privileges Joint Commission requirements: OPPE, FPPE* Health Information Technology-based evaluation</td>
</tr>
<tr>
<td>Legal system</td>
<td>Competence</td>
<td>Malpractice litigation</td>
</tr>
<tr>
<td>National Practitioner Data Bank</td>
<td>Competence</td>
<td>Reporting of malpractice, change in privileges</td>
</tr>
<tr>
<td>Online resources</td>
<td>Practice pattern</td>
<td>Analysis of administrative data</td>
</tr>
<tr>
<td>Insurer/payer oversight</td>
<td>Cost, effectiveness</td>
<td>Approval of procedures, devices, treatments, and medications for payment Analysis of Electronic Health Record information</td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td>Medicare Quality Improvement Organizations PQRI** SCIP**</td>
</tr>
<tr>
<td>Commercial insurers</td>
<td></td>
<td>Utilization Review</td>
</tr>
</tbody>
</table>

* OPPE: ongoing professional practice evaluation; FPPE: focused professional practice evaluation
** PQRI: Practice Quality Reporting Initiative; SCIP: Surgical Care Improvement Program
program in either a direct patient care specialty, such as Internal Medicine, Pediatrics, or Family Medicine; or a supporting specialty, such as Radiology or Pathology/Laboratory Medicine.

Minimum training in any medical field generally takes three to five years. During that period, the Accreditation Council for Graduate Medical Education (ACGME) requires all trainees to be evaluated during their training in six “core competencies”: patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism and systems-based practice. Safeguards for the public are thus implied by completion of residency. Endorsement of successful residency program completion by the program director implies competence, professionalism, honesty and good moral character. Additional safeguards are offered by specialty board certification, which requires successful completion of stringent written and oral examinations and may involve practical testing as well.

A third level of assurance is offered by completion of post-residency fellowship training and certification, such as Cardiology, Gastroenterology, Cardiothoracic Surgery, or Neonatology. Successful achievement of subspecialty certification suggests a higher level of competence in a particular field and should provide additional assurance of competence.

Maintenance of Certification in a Medical or Surgical Specialty

Almost all specialties now award only time-limited certification, ranging from five to ten years. To maintain certification, physicians must demonstrate competence by passing an examination at prescribed intervals. The requirements for recertification (or “maintenance of certification”) vary by specialty, but in keeping with ACGME recommendations, usually include:

- Demonstration of active practice
- Skill and knowledge assessment
- Demonstration of professionalism
- Evidence of reflective self-assessment
- Proof of continuing education or life-long learning

These levels of assurance, which utilize education, specialty training and certification, should provide a foundation for quality, but as experience has shown, they are not always sufficient to achieve broad health care goals or to protect the public.

Fellowship in a national organization

Large national medical specialty organizations, such as the American College of Surgeons, the American College of Physicians, and the American College of Obstetrics and Gynecology, play important roles in setting standards for training and education for their members. The American College of Surgeons, for example, offers the Fellow, American College of Surgeons (FACS) certificate as emblematic of high quality practice and good moral character — but it cannot possibly oversee patient-level quality of care by those who have earned the FACS distinction.

Oversight by State Boards

Licensing of physicians and other professionals, as we now know it, began in the last half of the 19th century when the quality of medical education, in the absence of regulation, was highly variable, mostly unscientific, and often blatantly commercial.

These levels of assurance...should provide a foundation for quality, but as experience has shown, they are not always sufficient to achieve broad health care goals or to protect the public.

There were many “schools” of medicine at that time, ranging from homeopathic and eclectic to allopathic, Thompsonian, and dozens more. The threat to public health of widespread quackery led to the drive within the profession to improve medical training and to license physicians. Influenced by medical societies, which existed in almost every state, states began to pass legislation regulating medical practice in the early 19th century. Although quite weak, these laws nevertheless came under attack by physicians as an infringement on free enterprise and an illegal restriction of liberty. They were also seen as an effort by MDs, the largest group, to eliminate competition from alternative practitioners. This led to the repeal of all of these laws prior to the Civil War.

After the Civil War, states — once again encouraged by state medical societies — established medical oversight boards. These acts once again came under attack. This time, however, the right of states to
enact medical licensing laws was confirmed by the U.S. Supreme court in the 1889 decision, *Dent v. West Virginia.* The dispute leading to this case arose when Frank Dent, a graduate of the American Medical Eclectic College of Cincinnati, who had been in practice for six years, was denied a license by the West Virginia board for not having met state-licensing requirements, which included graduation from a reputable medical school or having passed a licensing examination. He sued and lost, which led to the appeal to the Supreme Court. In a separate case, the Supreme Court held that states could require physicians to be "of good moral character" in order to be licensed. In 1910 the court held it was reasonable for physicians to be required to register with the state in order to practice medicine. In these cases, the health of the public was found to have primacy over the individual rights of physicians (whether competent or incompetent) to practice.

**State Licensing Standards**

The requirements for obtaining a medical license do not raise the bar very high. Most depend almost entirely on the first two levels of assurance or competence described above — namely graduation from an accredited medical school and passage of the first two parts of the USMLE (or its counterpart osteopathic examination), followed by a period of post-graduate training and experience. USMLE Step 3 can be taken after six months of post-graduate training in an accredited program, and must be passed within five years. There is no requirement that an applicant have completed a residency program in an accredited hospital or institution. There is no limitation of practice by specialty. There is no special privilege for board certification.

**Oversight Functions of State Boards of Medicine**

Boards of medicine play an important role in regulation and oversight, even though the information they work with is limited to patient complaints, limited retrospective record review and interviews. Moreover, they have only blunt instruments at their disposal as remedies. They can take actions at the licensing level, such as limiting, revoking or suspending a license, or requiring treatment for alcoholism or drug addiction. Boards are effective in suspending, revoking, or limiting licenses and in refusing to grant or renew licenses of physicians who are obviously incompetent, convicted of fraud or other felony, alcoholic or impaired by substance abuse. Boards are also reasonably effective in limiting the practices of physicians who improperly prescribe or dispense opioid drugs, or inappropriately dispense medical marijuana certificates, and in disciplining physicians who have been found to have engaged in improper sexual conduct involving patients or trainees. Prescribing practices can be monitored, supervisor reports requested, and monitoring visits set up. State boards thus play an important role in protecting the public. But removing bad apples, although necessary, is not sufficient to ensure good quality medical care.

The effectiveness of any quality oversight program at the hospital or health care organization level depends on its leadership, structure and organization. Where there is formal organizational structure there is the possibility of effective quality oversight. By formal organizational structure, I mean a departmental structure of the type usually seen in teaching hospitals, in which real, tangible authority is vested in a director/service chief/department chair, whose income does not depend entirely on the goodwill of those he or she oversees. In the community hospital model, service chiefs elected by the medical staff to serve for a year or two voluntarily will have a difficult time if they wish to bring about change or impose discipline. In either structure, change or improvement will not occur without strong support from the leadership at the hospital board level.
Hospital Quality Processes

Historically, the mechanisms by which hospitals exercised quality oversight on medical practice fell under the general heading of “peer review.” The most familiar, time-honored ones are “death and complications,” “morbidity and mortality,” and “clinicopathologic conference,” which is based on autopsy findings. These have traditionally been regular occasions at which complications and errors in medical care are reported (or confessed) before one’s colleagues, and unusual or difficult medical problems can be presented for discussion. Optimally, they create an opportunity for physicians to set consensus standards of care, to be held accountable for their care, and to learn from the experience of others so that needed changes in practice are brought to light and errors are not repeated.

Traditional peer review was found wanting in the early 1970s when it became obvious that only a few years after Medicare’s implementation in 1965, its costs were increasing far more rapidly than anticipated. The government response was to try to reduce costs by paying only for care that was deemed “reasonable and necessary” as stipulated in Section 1862(a) of the Social Security Act.

This led to two initiatives, both endorsed by the medical profession. One was called quality assurance, or QA, which was intended to oversee and improve the quality of care. The other was Utilization Review (UR), which was intended to reduce costs by eliminating unnecessary hospital days and procedures. These initiatives were begun prior to the advent of the “diagnosis related groups” method of payment, in which a fixed rate for hospital admission was paid based on “diagnosis related group” or DRG. Quality assurance required chart review of samples of records and application of clinical judgments with regard to the appropriateness of care, compared to agreed-upon standards. Included within UR parameters that could be examined were such factors as length of stay, frequency of test ordering, admissions lasting less than 24 hours, and justification for admission based on parameters such as “severity of illness or intensity of service.” These assessments were unavoidably subjective and reviewers found that charts rarely recorded the necessary data on which to base judgments. In the end, neither QA nor UR programs had a discernible effect on cost. In spite of this, UR persists among many insurance companies, who use it to screen admissions, monitor length of stay and deny payment for hospital services.

The failure of the initial attempts at peer review made it clear that something better was needed, paving the way for both “patient outcome” measurements in the 1980s and “quality improvement” in the 1990s—an approach that was adapted from industry and focuses on improving inefficient and ineffective processes in patient care. These forms of peer-review based oversight remain important alternatives in improving health care quality.

Professional Practice Evaluation

There is today a demand for newer, more quantitative and objective metrics to assess competence. Advances in health information technology (HIT) have made these more available (if not always well understood). The Joint Commission now requires medical staffs to carry out Ongoing Professional Practice Evaluations (OPPEs) quarterly on all physicians on a hospital staff. If there is suspicion of a competence problem, a “focused” PPE (FPPE) is called for. Compiling meaningful data without burdensome chart review is not easy, and hospitals increasingly look to electronic health record (EHR)-derived data analysis and manipulation to do the bulk of this work. Statistical methods can also be applied to non-direct patient care, examining rates of correct radiographic interpretation, for example. Fully electronic health record systems are expected to expand this kind of medical care oversight more widely.

There is also new emphasis on looking at physician behavior, particularly disruptive, uncooperative or insensitive behavior toward patients, co-workers or employees, arising out of the recognition that these behaviors contribute to errors in patient care.

Oversight by Payers

Organizations that pay the bills for medical care provide oversight through economic credentialing. The rapid expansion of innovation in the medical marketplace in the past 30 years has led to an amazing explosion of new drugs, devices, procedures,
and treatments, some of which are useful and cost-effective, many of which are not. While FDA approval of a new device is evidence of safety, it says nothing about utility. Unopposed, the heavy marketing and aggressive pricing of these products could potentially lead to intolerable increases in medical costs. It has fallen to payers to be the countervailing force to prevent this from happening. Medicare, Medicaid, large managed care organizations and Blue Cross plans have all established mechanisms for reviewing and approving new devices, drugs, and treatments for reimbursement. Whenever possible, these decisions should be “evidence based” — that is, based on scientific evidence of improved patient outcome.

Oversight by the Legal Profession

Although physicians are rarely willing to acknowledge it, malpractice litigation plays a role both in compensating patients for medical injury and in maintaining and possibly improving the quality of medical care. Malpractice litigation is usually perceived as a threat and is blamed for excesses in testing, documentation, and cost of medical care. There is undoubtedly some truth underlying this perception, but at the same time physicians cannot reasonably disregard the potential for their errors and complications to cause harm. There is therefore a legitimate and proper role for litigation to compensate patients for injuries that have occurred as a result of negligence, thoughtlessness, ignorance, and failure of duty. Moreover, the malpractice system is able to discipline physicians and others who might otherwise fall between the cracks of other quality oversight processes, and who would otherwise not have to acknowledge their responsibility for poor practices nor be held accountable for them.

National Practitioner Data Bank

The National Practitioner Data Bank (NPDB) was established in Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986. The act was amended in 2013 to combine the National Practitioner Data Bank, which reported on physicians, and the Healthcare Integrity and Protection Data Bank, which provided reports on the rest of the health care system. The NPDB receives and compiles reports of any adverse actions taken on the credentials or license of a physician. These include both substantiated malpractice claims and adverse actions taken with regard to hospital privileges, such as dismissal from a hospital staff. If a malpractice claim is settled, the named physician is reported. If, however, a settlement is made prior to a claim being filed, no report is made.

There are gaps in the NPDB data. Most instances of medical error or negligence do not result in the filing of a claim. If a physician is dismissed from a hospital staff or his or her privileges are restricted, the action is reported. However, if a physician resigns under threat of loss of privileges, the action may not necessarily be reported. It is hard to know the extent to which listing in the NPDB actually offers useful information about the quality of a physician’s care. The actual data are sparse and don’t describe in detail what happened and why. Thus, even though it has been in existence for over 20 years, questions persist regarding the utility of the NPDB’s data.

Online Resources

Individuals can now seek out oversight-like information through online resources that compare hospitals (e.g., www.medicare.gov/hospital compare) and physicians (e.g., www.healthgrades.com). According to Wikipedia, “Healthgrades Inc. is a U.S. company that develops and markets quality and safety ratings of health care providers, including hospitals, nursing homes, physicians and dentists.” Large administrative data sets, primarily the Medicare data set, are used as the basis for comparison. Other websites offer the opportunity for patients to rate their doctors and health care experiences. The effectiveness of these on-line resources in assuring quality is unknown.

Continuous Professional Development

All good physicians know that in order to practice effectively in the rapidly changing environment of medical practice, they must continuously expand and refresh their knowledge and learn new skills. In the ideal, physicians regularly read the medical literature, attend conferences, and seek out courses that keep them current. The process of doing this comes under the general headings of continuous
professional development, life-long learning, or continuing medical education (CME). It is necessary, but not always sufficient, to ensure quality.

In 1968, the American Medical Association effectively mandated CME for physicians by advocating that all of its members engage in 150 hours of approved educational activities over a three-year period.17 State licensing boards soon followed suit, mandating the same or a similar amount of CME as a requirement for license renewal. This led to a rapid expansion of a CME industry, the offerings of which did not always meet the initial goals of the program. Attempts to reconfigure and redesign CME to be more effective began 30 years ago, when evidence emerged that traditional CME was not bringing about actual improvements in practice.18 Since then, newer methods have been proposed in which process is linked more closely to actual practice.19

**Newer Initiatives to Measure and Improve Quality**

The past two decades have seen the development of a variety of quality improvement entities and “lean” initiatives that are intended to make health care delivery more efficient or effective. This concept has been most visibly promoted nationwide by the Institute for Healthcare Improvement (IHI) and was adopted in the 1990s in the Medicare program, which made the transition from “quality assurance” to “quality improvement” when it had become clear that imposing punitive measures for errors and failures was not achieving the desired goals of improved quality and reduced cost.20 Other initiatives have been made possible by the ability to collect, aggregate, analyze and compare large amounts of health care data by provider. Regional comparisons using Medicare data began showing wide geographic variations in care in the early 1970s.21 Compliance with evidence-based protocols for treatment of common conditions linked with outcomes data, for example, can now be examined using analysis of the electronic health record. The hope is that sharing such data regarding adherence to evidence-based guidelines and sharing of best practices will be effective in improving health care delivery.

Medicare, through its network of state-based Quality Improvement Organizations, has promoted a number of evidence-based practices in the treatment of acute myocardial infarction and pneumonia, prevention of deep venous thrombosis and venous thromboembolism, reduction in urinary tract infections, prevention of central line-related sepsis, and reduction in surgical site infections, to name a few.

Other initiatives are contemplated or under way, using large amounts of data on health services that have become available through the National Center for Health Statistics, the National Cancer Institute (specifically, its Surveillance, Epidemiology and End Results database), Medicare, the National Trauma Data Bank and the National Surgical Quality Improvement Project (NSQIP). Some of these are based on administrative data sets, while others are based on survey data, hospital discharge data sets or actual case reviews. So far, none of these have been linked in a meaningful way to structure or process change and outcome improvement — but experiments are under way.

**The Physician Quality Reporting System (PQRS)**

PQRS is a Medicare program aimed at gathering and making available to the public data on quality of health care in a way that promotes comparison and competition. This process is described as “a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals (EPs).”22

In support of this approach, the American College of Surgeons offers a service that allows surgeons to record their cases and compare their outcomes to those of others in a way that meets the requirements of the American Board of Surgery for maintenance of certification — while also meeting federal requirements for the Physician Quality Reporting System (PQRS) demonstrating the “meaningful use” of electronic health records.

**Surgical Care Improvement Program (SCIP)**

The SCIP has been one of the first attempts to enforce evidence-based practices in surgery. Started by Medicare, the SCIP calls for proper antimicrobial selection prior to surgery, proper dosage and timing of antimicrobial administration, and the discontinuation of prophylactic antimicrobials. It has been adopted by insurers, such as Blue Cross/Blue Shield of Michigan, which imposed monetary penalties for imperfect...
adherence. This initiative has been a major test of whether findings in clinical research studies can be transferred to community practice that results in improvements in outcomes. The program has led to a number of changes in care-processes having to do with the ordering, administration and documentation of antibiotic administration in the operating room, possibly with some improvement in infection rates.23

The National Surgical Quality Improvement Project (NSQIP)
The NSQIP began in the Veterans Administration (VA) system as a way to measure and improve quality across the all VA hospitals. Nurses abstract data taken from a sample of surgical charts, which allows comparison of surgical results among hospitals. This project shined a bright light on wide variations in rates of complications and deaths after surgery in VA hospitals, and led to major changes in both structure and process among them. The American College of Surgeons adopted the model and has made it available on a voluntary basis to hospitals across the country.

Conclusion

In an ideal world, the character, motivation and personal desire of the caring physician to provide the best patient care possible would ensure quality. If all physicians had sufficient levels of these attributes, oversight might be superfluous. Unfortunately, this is not the case. Regulation and oversight are necessary and in our highly complex health care delivery system there is no simple way to do it. As a result, external agents, including state and national government, insurers, professional organizations, and the Joint Commission, have put many structures and processes into place with the intent of ensuring and improving medical care quality. Today, oversight of medical care is now carried out at many levels, by many different entities. Most, if not all, of these levels of oversight appear to be necessary, but all have their weaknesses and limitations. None is sufficient on its own. Oversight is, and will continue to be, necessary; and we should hope for continued innovation in how to accomplish it. Done wisely, it has the potential to improve health care quality. ■

References

1. Donabedian A. Evaluating the Quality of Medical Care. Milbank Memorial Fund Quarterly 1966; 144 (#3): 166-203.
2. Donabedian A. The Quality of Care: How it can be assessed. JAMA 1988; 260:1743-1748.

About the Author

Richard E. Burney, MD, is Professor Emeritus of Surgery at the University of Michigan, Ann Arbor. He served as Chair of the Michigan Board of Medicine from 2012 to 2015.

Copyright 2015 Federation of State Medical Boards. All Rights Reserved.