# Special Series

# A Brief History of Health Care Quality Assessment and Improvement in the United States

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**We review the history and current efforts to assess and improve health care in the United States. This process has involved a host of government agencies and commissions, professional organizations, insurance underwriters, corporations, and more recently, market forces. Traditional approaches to quality control have stressed case-by-case analysis and identifying outliers. Newer approaches include creating practice guidelines and profiles of hospitals and physicians. The joint goals of quality improvement and cost control can best be realized if institutions and practitioners embrace these new approaches and use them to enhance their performances.**

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Defining the quality of health care requires knowing how much people benefit from health services, as measured by factors like the results of specific diagnostic and therapeutic procedures, patient satisfaction, and society's sense of well-being. Because it is difficult to maintain quality while decreasing costs, each is receiving equal attention in current debates on reform, particularly in the context of managed care and integrated health systems. As reform proceeds, one of the greatest challenges will be to contain costs and simultaneously improve quality without imposing external controls.

We outline the history and current state of health care quality assessment and improvement in the United States. We also review professional and governmental programs that regulate quality and assure physicians' qualifications, malpractice lawsuits and the demands of insurance companies, and changes in the organization and provision of health care services. We stress hospital and medical staff activities because regulatory agencies have in the past focused on them; other important arenas such as nursing homes are not discussed.

## Voluntary Professional Programs

### *Organized Medicine*

In the early 19th century, American medicine was disorganized and of poor quality, with the control of medical education in the hands of proprietary and for-profit institutions. Several organizations and individuals undertook to correct this. Founded in part for this reason in 1847 as a confederation of state and local societies, the American Medical Association (AMA) encouraged Abraham Flexner in research that by 1910 led to his *Report to the Carnegie Foundation,* which documented the deplorable state of the nation's medical schools and major hospitals.[1,2] In the same year Ernest Codman of Boston's Massachusetts General Hospital noted the need to improve hospital conditions and to track patients to verify that their care had been effective. Although few followed Codman's lead, his efforts contributed to the American College of Surgeons' establishing its Hospital Standardization Program in 1917.[3]

The first five standards focused almost entirely on care within hospitals. Known as the "minimum standards," they called for the following:

- Organizing hospital medical staffs;
- Limiting staff membership to well-educated, competent, and licensed physicians and surgeons;
- Framing rules and regulations to ensure regular staff meetings and clinical review;
- Keeping medical records that included the history, physical examination, and laboratory results; and
- Establishing supervised diagnostic and treatment facilities such as clinical laboratories and radiology departments.[3]

### *Joint Commission on Accreditation of Hospitals*

With the adoption of the minimum standards, representatives of the American College of Surgeons began surveying health care organizations to determine their ac-

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**ABBREVIATIONS USED IN TEXT**

AMA = American Medical Association
DRG = diagnosis-related group
HCFA = Health Care Financing Administration
PRO = peer review organization
PSRO = professional services review organization

ceptability for accreditation. Additional standards addressing physical plant issues, equipment, and administrative structure led to a broadening of the survey teams. By 1952 the American College of Physicians, the American Hospital Association, the AMA, and the Canadian Medical Association had joined the American College of Surgeons to form the Joint Commission on Accreditation of Hospitals.[3]

Although the Joint Commission initially followed the minimum standards, in 1966 it abandoned this approach in favor of so-called optimal achievable standards.[3] This change occurred primarily for three reasons:

- Most American hospitals were already meeting the minimum standards;
- Medicare set more rigorous guidelines, creating an obligation to respond; and
- The techniques used to assess and improve quality had grown more and more sophisticated.

Avedis Donabedian's classic 1966 article described ways to evaluate the quality of health care and reflected these refinements.[4] He offered a broad definition of quality and recommended that it be measured in three areas: structure—the physical and staffing characteristics of caring for patients; process—the method of delivery; and outcome—the results of care. The Joint Commission and other groups ultimately embraced the structure-process-outcome model, and it is still in use today.

*Measuring Quality*

For many years the American College of Surgeons and the Joint Commission reviewed medical records to assess quality.[5] From an unstructured and highly subjective form of peer review, these audits evolved in the 1970s into standardized outcome-oriented surveys that also included surgical cases, blood and antibiotic use, and medical support services. The Joint Commission asked that these results be used in credentialing physicians and delineating their clinical privileges.[3]

In 1979 the Joint Commission dropped some audit requirements and replaced them with hospital-wide quality assurance programs. Using a variety of new methods, nonphysicians examined medical records and referred questionable findings to physicians. One new technique was the prospective generic screen in which, for example, reviewers tracked readmissions occurring after a short designated interval or transfers to an intensive care unit as signs of possible problems with quality. Another, the clinical indicator, such as the percentage of women patients on whom pelvic examinations were done, allowed departments to monitor their own performance.[6-8]

*New Methods of Measurement*

The Joint Commission has recently sought to broaden the scope of "quality assessment and improvement" (formerly "quality assurance") programs. Practice guidelines may help physicians manage patients. Developed primarily by professional societies that use the results of clinical investigations and consensus conferences to recommend standards, the guidelines must cover a wide range of patients and be updated frequently to be effective.

Physician profiling compares practice patterns using epidemiologic data on patients.[9] Investigators have applied this method to cholecystectomy, for example, looking at the number of procedures performed, indications, and complications. Physicians whose profiles stray substantially from the norm might be induced to change their practice habits by their colleagues, the hospital, or governmental agencies.

Adapting a technique called continuous quality improvement developed primarily for industry, the Joint Commission advocated this multidisciplinary approach in its 1988 *Agenda for Change*. This method tries to improve the performance of an entire group rather than identify isolated poor performers.[10-12] All of the workers—administrators, physicians, nurses, housekeepers, clerks—in an emergency department, for instance, might form a task force that would continually analyze and improve care.

Although it concentrates on acute general hospital care, the Joint Commission's mission has grown to include other health care settings—long-term care in 1965, community mental health in 1973, ambulatory care in 1975, and hospices in 1983. Recognizing this expanded role, it changed its name in 1987 to the Joint Commission on Accreditation of Healthcare Organizations. In that year it accredited approximately 5,000 of the 6,500 acute-care general hospitals and 2,800 other health care organizations.[3]

Less than 10% of hospitals gain full accreditation after their first survey; most receive conditional approval based on the need to make prescribed changes. Only 1% or 2% fail to meet requirements that also allow them to participate in Medicare, but even these hospitals usually appeal and ultimately satisfy the Joint Commission's guidelines. Although the value of this approach has not been proved by prospective studies, this regular review seems desirable for internal improvement and to meet the demands of regulators.

## Governmental Regulatory Programs

*Regulating Health Care*

State licensing programs, established toward the end of the 1800s, preceded federal rules; in 1906 national regulation of medication was undertaken by the Food and Drug Administration.[13,14] It was not until 1935 when the Social Security Act set standards for maternal and children's services that health care itself fell under federal supervision. Beginning in 1946 the Hospital Survey and Construction (Hill-Burton) Act required the states to apply minimum codes for new structures built with federal financial assistance. Several years later amendments to the Social Secu-

rity Act directed further state regulatory control over health facilities in return for federal matching funds.[15]

With the passage of Title XVIII of the Social Security Act in 1965 (Medicare), Americans 65 years of age and older received compulsory hospital insurance (part A) and voluntary supplementary medical insurance (part B). To monitor the care of Medicare patients, Congress enacted in the same law a set of rules called Conditions of Participation, which mandated certain principles central to operating a hospital, such as medical staff credentials and 24-hour nursing services, as well as utilization review, which evaluated the appropriateness of admissions.[15] This process established a new level of physician fiscal responsibility.

Under the Social Security Act amendments of 1965, acute-care general hospitals that were accredited by the Joint Commission or the American Osteopathic Association were deemed to have met all the regulatory requirements specified in the Act, with the main exception of utilization review. All hospitals also had to be licensed by their respective states. Hospitals that were not accredited could seek to meet the Medicare Conditions of Participation by electing to undergo a state certification process. Most of these nonaccredited but certified hospitals were then and are still small rural facilities, usually containing fewer than 50 beds.[15]

### *Professional Standards Review Organizations*

The Social Security Act amendments of 1972 also established the Professional Standards Review Organization (PSRO) program to promote efficiency and to try to eliminate unnecessary hospital utilization. The PSRO legislation created a network of physician-run organizations that could grant or deny payment for services provided under both Medicare and Medicaid and that would collect and store basic information on all Medicare and Medicaid patients to create profiles of institutions and individual physicians.[16]

By 1981 PSROs were established in 187 of 195 designated areas in the United States. They never met governmental expectations and were resisted by the AMA, state medical societies, and the states themselves. Finally, it could not be demonstrated that the PSROs actually saved money, and physicians and nonphysicians alike were concerned that the organizations emphasized cost containment over quality.[15,16]

### *Peer Review Organizations*

This disappointment led in the early 1980s to the replacement of PSROs by utilization and quality control peer review organizations or PROs.[15,17] Almost simultaneously, hospitals began to be paid prospectively on a cost-per-case rather than a cost-per-service basis. Peer review organizations are responsible for validating assignments to these diagnosis-related groups (DRGs), reviewing readmissions, reducing unnecessary hospital admissions and operations, and lowering death and complication rates. Reviewers look at a random selection of records of admitted patients and evaluate treatment based on six criteria, known as generic screens:

- The adequacy of discharge planning,
- Medical stability at discharge,
- Unexpected deaths,
- Nosocomial infections,
- Unscheduled returns to surgery, and
- Trauma suffered in the hospital.[15,17]

When PROs identify problems, they may choose a variety of remedies. These include formally notifying an institution or practitioner, requiring continuing medical education, preadmission or more thorough retrospective reviews, referral to medical staff committees, informing licensing and accrediting bodies, and sanctions, imposed only by the Inspector General, such as the loss of Medicare billing privileges.[15,17]

From the start of the program through early 1989, the PROs conducted approximately 6.6 million reviews and denied payment in more than 4% of cases. Practitioners or institutions requested reconsideration of about a third of the denials; denials were reversed some 40% of the time. The PROs identified more than 87,000 physicians with problems with the quality of their care during the same period. Almost all of these problems were resolved through the first few interventions and by the threat of sanctions, so that only 109 physicians were actually referred to the Office of the Inspector General. Although some might regard this small number of referrals as a sign that the PROs are ineffective, it more likely reflects the success of less severe measures in improving the quality of care.[15]

The PROs clearly emphasize quality and focus more on outcome as opposed to structure and process than did the PSROs, but they have not been immune to criticism. Some see the criteria they use to identify problems in quality as too insensitive, and others complain that intrusive PRO bureaucracies generate more paperwork than actual improvement in a flawed system.[18]

Responding to these criticisms, Congress asked the Health Care Financing Administration (HCFA) in the late 1980s to sponsor a study by the Institute of Medicine of the National Academy of Sciences on quality assurance for Medicare.[15,19] The study concurred that PROs were limited in scope and called for restructuring them and implementing yet another program, the Medicare Program to Assure Quality. Charged with updating the conditions of participation and encouraging the Joint Commission to modernize its quality improvement methods, this effort would continue to use existing PROs, but would direct them to look even more closely at outcome in evaluating institutions and practitioners.[19]

### *Recent Legislation*

The most important law in recent years to address quality was the Omnibus Budget Reconciliation Act of 1989, which instituted physician payment reform in the Medicare program.[20] This grew out of a study of new payment methods authorized in 1985, leading one year later to the Physician Payment Review Commission. The Com-

mission recommended that Medicare's "customary, prevailing, and reasonable" reimbursement schedule be replaced by one based primarily on resource costs related to a relative value scale. Undoubtedly this will change practice patterns and thus affect both cost and quality of care.[21-25] At the same time, new efforts in utilization review and quality assessment will be needed. These efforts will be aided by new data about individual and institutional practices that will help physician and hospital profiling to an extent not previously possible.[21]

The Omnibus Budget Reconciliation Act also authorized greater federal support for health services research and set up the Agency for Health Care Policy and Research. This agency replaced an existing office and highlights the government's interest in improving the outcome of medical treatment by supporting studies of health services and practice guidelines.[26]

*Quality Improvement Initiative*

Practice guidelines may have their first major effect as a result of the Health Care Quality Improvement Initiative proposed by the HCFA in 1992. This will attempt to steer PROs away from generic screens that have led to conflicts with physicians toward a cooperative approach based on the principles of continuous quality improvement. It will have three elements: a national history claims file made up of all claims paid by Medicare; a uniform clinical data set, which will provide information on 10% of discharged patients; and a patient care algorithm system based on clinical guidelines.[27]

The aim of the Quality Improvement Initiative is to apply the patient care algorithm to information provided by the claims history and data set. This will allow the PROs to both screen cases and describe how well the care conforms to published guidelines. They will then inform physicians and hospitals of these profiles, work with them to analyze areas of possible improvement, and assess changes as they occur.[27] This approach is still in its infancy, with only six PROs currently active in a pilot test of the uniform clinical data set and an algorithm system that has few guidelines written. The initiative will need more funding, and it is not certain whether physicians or hospitals will embrace it.[28]

## Methods of Enhancing Physician Qualification

While the federal government has tried to influence physicians indirectly through cost containment and quality improvement programs, the states generally regulate more directly by licensure, relying on standards set by professional organizations. Developed with the support of the AMA, the National Conference of State Medical and Licensing Boards was formed in 1891 and the National Board of Medical Examiners in 1915.[1]

All states require applicants for a license to have graduated from an accredited medical or osteopathic school with special provisions for graduates of foreign schools. About two thirds also insist on a one-year internship; a passing grade must also be achieved on a standardized examination. To renew a medical license, physicians in 24 states now must complete a prescribed number of hours in continuing education.[29]

Once licensed, physicians are not limited to any specific field of medicine and thus can practice in areas for which they have little or no training. Many physicians, however, have completed residencies and become certified by one of 23 specialty boards after passing an examination in that discipline.[30] Although certification was once permanent, 15 of the 23 boards have adopted or will soon adopt time-limited certification and a recertification process.

Because state hospital licensure holds institutions responsible for the care provided under their authority, hospitals must be assured that physicians who practice within them are qualified. At one time hospitals' only obligation was to make certain that physicians had valid medical licenses, but other criteria are increasingly being used to judge their qualifications. Among these are board certification and recertification, complaints made to state boards of medical examiners, and reports from the National Practitioner Data Bank.[31]

Created by the Health Care Quality Improvement Act of 1986, the National Practitioner Data Bank contains information on payments made by malpractice carriers to settle claims against physicians, as well as actions taken against physicians by hospitals and other health care organizations. Since 1990 medical staffs have had to provide to and solicit information for the data bank to obtain credentials and grant privileges.[32] The bank registered nearly 800,000 queries in its first year. Nearly 20,000 adverse actions and malpractice payments made were reported to the bank during the same period. The actual number of adverse actions is uncertain. It is not known if or how the required queries to the data bank were used,[33] nor if physicians regard this and other methods of enhancing their qualifications useful or necessary.

## Liability Litigation and Underwriter Demands

Physicians in the United States once had few fears about malpractice suits and paid little for malpractice insurance. After World War II, however, the number of suits and the cost of premiums rose dramatically. Responding to this in 1971, President Nixon ordered a study that found that the increase in claims had led insurers in many states to boost charges for policies to an unaffordable level or to refuse altogether to write malpractice insurance.

Equally striking was the influence commercial carriers were beginning to exert over quality of care. A number of insurance companies in California dropped hospitals and forced them into a group contract with a single firm, under which hospitals had to report incidents that might adversely affect the care of patients. The system, a forerunner of today's risk management programs, detected many problems and prompted many innovations, including wrist bands to identify patients in hospital and bed rails to prevent falls.[34]

Concerned about rising malpractice claims and premiums and wishing to find an alternative to tort law, the Cal-

ifornia Medical Association and the California Hospital Association commissioned a study to explore the extent of disability and death caused by adverse events. One type of event was an untoward drug reaction. Having identified such an occurrence, the investigators tried to determine its cause. Among the records studied, they found adverse events in approximately 5% of the total, of which 82% was attributed to treatments or procedures, 15% to incomplete diagnoses or treatment, and 2% to inadequate preventive measures.[35]

Extrapolating data from about 20,000 reviewed charts to the state's total number of patients admitted to hospital in 1974 suggested that 140,000 adverse events had occurred. From the standpoint of liability, it was possible to fix blame for only 17% of these episodes on medical or surgical fault, implying that the disabilities or deaths in the remaining 83% would not be compensated under the tort system. And there are doubts about whether even those patients injured by physician negligence would receive restitution because only one in ten such persons sued and was eventually compensated in California in 1974.[35]

Other studies also have shown that malpractice litigation is an insensitive way of uncovering deficiencies in quality.[36-38] Less clear is the extent to which the real or perceived threat of malpractice suits deters health care professionals from negligent behavior, even though it has prompted many to practice defensive medicine.[39-41] Could following practice guidelines simultaneously reduce negligence and open the way for a reduction in the money spent on malpractice insurance, estimated to be 15% of the total expended on physicians' services? That remains to be seen.[42-45]

## Changes in the Organization of Medical Practice

Medical practice was once dominated by solo general practitioners who operated as independent businesses and expected limited financial return. That physicians had relatively few interventions to offer justified the leanness of this return. They dealt with most patients face-to-face and usually at the bedside, consulted other physicians infrequently, and were responsible primarily to themselves. Such practitioners formed a majority of the AMA, and its political stance opposing governmental intrusion reflected the professional and economic autonomy of its members.[46]

The landscape of American medicine has changed dramatically. Specialists working in groups dominate solo general practitioners. Financial rewards from both fee-for-service billing of third-party payers, including federal and state governments, and from employment by large medical corporations are more generous.[47] Given practice arrangements and fiscal concerns, it is not surprising that practice habits and treatment results are being scrutinized far more often.

The trend toward corporations has led to a decrease in physician autonomy and an increase in competition. Hospitals and other health care institutions vie in public by comparing costs and styles of providing care. In the future, it is likely that they and their practitioners will compete increasingly on the basis of outcome. This will further encourage the federal government and the Joint Commission to create profiles of physicians.

One can also see the role competition will play by the interest in managed care.[48,49] Regardless of the form they take, managed care plans compete with one another to provide care that is appropriate, cost-effective, and appealing. Presumably quality, measured primarily in terms of clinical outcomes and patient satisfaction, will be an important, if not the most important, element in this appeal. Thus, quality and cost must be continuously assessed and improved if the plans are to remain competitive.

## Future Prospects

Greater concern for cost than for quality has marked many of the older regulatory efforts described here. This focus may lead to undesirable results. For example, the use of copayments and deductibles to decrease utilization and thereby lower costs may worsen health if both needed and unneeded services are reduced. To have a positive effect, policies should provide the following:

- Limit services that are of little or no benefit to patients,
- Encourage less costly and more effective care,
- Ensure access to that care, and
- Foster integrated health care systems that can provide beneficial services more efficiently.

Profiles and practice guidelines will supplement if not replace utilization review, case-by-case analysis, and the identification of outliers in efforts to control quality and help physicians improve their practices. This will be accomplished only with a large federal investment in outcomes research, user-friendly data services, and education. Medicine is quickly approaching a crossroads at which physicians must choose between accepting these new approaches and submitting to even more external control from which neither they nor society is likely to benefit.

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