

The assurance of quality

by C. Rollins Hanlon, MD, FACS, Chicago

Seventy-five years ago, Dr. Franklin H. Martin and his associates formally incorporated a visionary venture in education and standard-setting directed at ensuring both competence and ethical integrity in the care of surgical patients. Assurance of high quality of surgical care was always implicit in the aims of the early American College of Surgeons; that assurance continues to permeate the objectives and programs of this College as it enters the last quarter of its first century. How can that objective be realized in today's turbulent environment?

Our College's record in pursuit of quality is a distinguished one, exemplified by successful educational and voluntary regulatory efforts, such as the programs in cancer, trauma, and hospital accreditation. In addition to these three programs, the College has launched a host of other initiatives in education and voluntary standard-setting aimed at ensuring the provision of high-quality, ethical surgical care. These College efforts have brought immense benefits to patients and to the community.

Many of the College's programs reach back to simpler times, before the evolution of those events that Paul Starr has chronicled in his book, *The Social Transformation of American Medicine*. Clearly we now face new and more complex challenges than those that confronted Franklin Martin. But for the thousands of surgeons who have pledged to follow Martin's principles, the basic motivation is grounded in the straightforward, albeit difficult rule that the welfare of the patient comes first. Martin and his followers were exemplars of that rule.

There is a relevant story about Mahatma Gandhi that portrays accurately the attitude that Gandhi exemplified in his life. A woman brought her daughter to him, asking that the Mahatma counsel the young girl against an obsessive addiction to sweets. Gandhi sat quietly for a long time and then asked the woman to bring her daughter back in three weeks. At the appointed time the two returned, and Gandhi took the girl aside for kindly but vigorous advice about her eating habits. The child's mother was immensely grateful but could not refrain from asking, "But why, Gandhiji, didn't you tell this to my daughter three weeks ago?"

"Ah, madam," said Gandhi quietly, "three weeks ago I was still addicted to sweets."

Two millennia ago another great leader gave us the familiar story of the good Samaritan. His admonition to go and do likewise is firmly imbedded in the minds, if not always in the hearts, of myriad physicians whose primary goal must continue to be the compassionate care of the sick. We have made an exciting technological passage from the days when the Samaritan poured oil and wine into the wounds of the man on the road to Jericho,

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but the ideal of selfless service has remained the same throughout medicine's long evolution to the scientific triumphs and the social dilemmas of today. Can the observance of that ideal no longer be entrusted to the profession because a segment of our company has yielded to the commercialism that has profoundly altered the milieu of our practice? Each of us has the opportunity to exemplify a negative answer to that question and to demonstrate that we have not personally adopted the attitude that has transformed our society.

Health care costs

The general outline of that transformation in economics and in science is well known. We have moved through an explosive expansion in biologic knowledge as a result of massive research support from governmental and private sources. As the accompanying technology has proliferated and become more complex, the cost of medical diagnosis and treatment has risen sharply, placing heavy stress on funding from the public and private sectors. The health care fraction of our gross national product (GNP) has increased steadily, giving rise to doleful but unwarranted cries that we are

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spending too much on health, either in contrast to previous expenditures or by comparison with other industrialized nations. I agree with those economists who say that we have not reached a critical point in the percentage of the GNP devoted to health care. How we should apportion those health care resources is the critical issue.

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Much of the rise in health care costs can be traced to our national and local funding of care for elderly and disadvantaged citizens. These entitlement programs have strikingly improved access to care, despite the gloomy reality that health insurance for many millions of our people is still not provided by private or public funds. Looking ahead, it seems unlikely that any legislator will risk blocking the imminent increase of Medicare premiums, which will be the largest in the program's history. This rise is currently scheduled to affect more than 30 million people at the start of 1988.

Health care is often formulated as a triangle consisting of access, quality, and cost. These interlocking variables tend to rise and fall in public consciousness, and the public interest is reflected in our national media and our legislative chambers. During the decades when discoveries at the laboratory bench were rapidly being brought to the bedside, and the fascination of the media with “scientific breakthroughs” contributed to the steady escalation of public support for biologic research, the thrust of private and federal efforts was directed at expanding access to these marvelous new therapies.

But as the staggering bills for applying our new knowledge and skills were placed alongside other desiderata in a constricted federal budget, the previous free-spending attitude toward health care became a mania for cost cutting. I will not itemize

all the acronymic federal initiatives to cut costs; however, one recent initiative has targeted hospital costs through application of funding by diagnosis-related groups, or DRGs. Now the legislators are directing their attention to physician costs by imposing arbitrary cuts of certain physicians' fees under the rubric of “inherent reasonableness.” It is easy to see the federal strategy of firing away at one cost salient after another, thereby dividing what was once a unified opposition by all of the health care establishment to national health insurance.

Social transformation

Mention of national health insurance reminds us of Paul Starr's view that the fixation of organized medicine on this federal threat diverted physicians' attention from the risks inherent in private, business-sponsored alternatives. As health care took on the trappings and attitudes of big business, a corresponding entrepreneurial mentality developed in medical practitioners, while the distinction between for-profit and not-for-profit institutions became quite blurred. Other factors too numerous to list facilitated the transformation of medical practice from a pattern of care dominated by individual practitioners to a pattern of organized systems by which practice groups provided contract medical care for huge aggregations of individuals in unions, industry, or government. In all of these group contracts, the chief emphasis was on access and on cost.

It is clear that greater use of medical services will increase overall costs unless the system is made more efficient. For years, various cost-containment strategies have been directed at eliminating unnecessary services, cutting unit costs, and pushing for healthier habits to lessen demands on the system. Recognizing that each physician generates a certain quota of health care services with a calculable cost, planners have also looked to cutting services by lowering the number of doctors. Unfortunately, the same planners had previously subsidized the production of more doctors, and these proliferating medical chickens have now come home to roost. The inability to reduce abruptly the

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Dr. Haulon is the newly installed President of the College and an Executive Consultant. He delivered this Presidential Address during Convocation ceremonies at the 1987 Clinical Congress.



number of doctors entering the system has driven planners to work toward a selective use of services, more crudely known as rationing of care.

Rationing has many forms, one being cuts in so-called unnecessary or nonessential services. As our population grows, especially among the elderly who require more services per patient, major cuts in service become obvious to the public, which complains over delay in access to care and over early discharge from the hospital—the so-called “quicker and sicker” syndrome. This approach may save money for one part of the system, but it leaves the patient unhappy, a fact that, by one definition, denotes an unsatisfactory quality of care.

Quality assessment

The patient's definition of quality in health care is usually outcome-oriented. When experts are enlisted to assess the quality of care, they generally divide it into structure, process, and outcome. Structure concerns the physical plant of a health care facility. The early hospital accreditation program of the American College of Surgeons began from the premise that the best surgeon in the world could not provide a high quality of care if the hospital surroundings were unsafe or unsanitary. Our College's hospital accreditation program evolved after 35 years into the Joint Commission on Accreditation of Hospitals (JCAH). Recently under the JCAH's “Agenda for Change,” the name has been changed to the Joint Commission on Accreditation of *Healthcare Organizations* to reflect its expanded approach to systems of care, and outcome has been stressed rather than process (see page 40).

Process addresses the keeping of records, the safeguards against medication errors, and similar protocols. Outcome in its bare essentials concerns mortality and morbidity, but the interpretation of these indicators of quality must be modified by data on how ill the patient was on entry and by other severity-of-illness measures, such as the patient's age and the presence of diseases other than the presenting reason for treatment. Neglect of

severity-of-illness factors blighted the credibility of last year's federal statistics on hospital mortality, and the second public release of such data this month may suffer from a similar flaw.

Whether one assesses quality in terms of structure, process, or outcome, most agree that accurate, objective measurements are hard to come by. But the issue is important, current interest is intense, and many complex studies have attempted to assess quality. Such studies have been going on for decades, but the pace and intensity have increased in recent years under the stimulus of cost concerns and more sophisticated demands by industrial health care systems or by agents of consumer coalitions, such as the American Association of Retired Persons, which is clearly a powerful political force.

National meetings

To indicate the level of interest in quality of care, I will list several large meetings during this year alone. This listing skips over many other efforts in quality assessment by health care organizations, including those of the College. The recently completed project coordinated by the American Medical Association, entitled “The Health Policy Agenda for the American People,” had substantial segments on the quality of health care and on quality assurance, along with recommendations and pertinent references for many aspects of this diversified issue.

Anyone who has followed these recent meetings and the massive amount of published material on quality assessment realizes how impractical it is even to outline here the multiplicity of approaches to the subject. These efforts have covered the qualifications of health care professionals, the mechanisms of medical decision-making, and the definitions of quality in health care from the viewpoints of the physician, the patient, and any third party in the encounter. If we can complete the immensely complex task of defining quality, we are faced with the much more difficult job of ensuring that an individual patient's encounter with the health care system will be an experience of high

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quality. It is easy to become so bemused by the analytical techniques we apply to vast amounts of data from large numbers of patients that we lose sight of the simple truism expressed by the chairman of a recent National Health Council conference on quality of care: "Patients come to the doctor one at a time."

That conference in March 1987 was entitled "Preserving the Quality of Health Care in a Changing Environment." A copyrighted summary of that meeting provides readers with a concise account of the field as viewed by many of its research leaders. It also contains a number of opinions and suggestions from representatives of public interest groups for modifying the practice of medicine in accord with their perception of faults in the system. These comments are not solidly based in experience and investigation, nor are they capable of ready translation into reasonable courses of action.

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Another relevant meeting was held in May 1987 under the auspices of the Institute of Medicine of the National Academy of Sciences. That meeting focused on the interrelations of technology assessment and quality of care, and on the differences between assessing the quality present in systems of care and the quality of performance by individual physicians. These are critical distinctions because some expert managers of health maintenance organizations seem to assume that the exacting controls in their system can be widely replicated in all similar organizations and that such tightly controlled, high-quality organizations will probably come to dominate the field of health care. This is an exciting prospect, but one is reminded of com-

parable expectations for the coalescence of medical care into a dozen great agglomerations to be known as "supermeds" that would sweep other systems away. These rosy predictions for supermeds, whether in size or in excellence, are still a long way from realization.

Reliable data

At the Institute of Medicine meeting, the need for reliable data was also thoughtfully addressed together with cautionary views as to the impairment of confidentiality and the added risk of professional liability. The enforced data-gathering for hospitals and practitioners in New York State under the Malpractice Crisis Reform Bill of 1985 is a prime example of a simplistic, meat-ax approach to deal with one serious crisis by generating another. Nonetheless, the collection by the federal government of performance data for hospitals and the accumulation of detailed physician practice profiles by large business firms are inexorable developments. The medical profession needs to work actively in the shaping and interpretation of such information in order to participate in fashioning constructive solutions to the problems these data delineate.

Ultimately, such dispersion of information is designed to assist the public in making a wise approach to treatment alternatives, whether such decisions concern the selection of a physician or the choice of a hospital. It seems clear that the action of the federal government in publishing raw data on hospital mortality rates last year was a disservice to the public and an unfair attack on those hospitals whose statistics were displayed without the opportunity for effective public explanation. A repeat, "confidential" distribution of similar data by the government in September had the advantage of allowing hospitals to study and prepare critiques of their own statistics before public release in December. But the published information cannot contain adequate detail on severity-of-illness factors. These factors are highly relevant to interpreting mortality and morbidity data but are not applied because the state of the art is inadequate in this important area.

The Institute of Medicine (IOM) will publish the

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record of these important deliberations, and is continuing its investigation of such matters by various approaches. The dispersion of these IOM reports may help educate the profession and the public, including special interest groups, so that we can move toward more reasoned solutions.

A third national meeting was held in late September 1987 under the title of "Standards of Quality in Patient Care: The Importance and Risks of Standard Setting." Conducted by the Council of Medical Specialty Societies, the conference reviewed standards developed by various specialty societies, touching lightly on the question of overlap between specialties and the so-called turf battles that for years have defied final resolution either by the disputing specialties or by multispecialty organizations attempting to act as arbitrators in these destructive emotional confrontations.

The issue of disputes and litigation between physicians and non-physician practitioners was addressed only obliquely in the review of legal liability in setting clinical standards. Despite my respect for expert legal practitioners in the arcane science of antitrust law, I am less than reassured by the assertion that a carefully crafted caveat preceding a published standard of practice will minimize legal risk. However, if we must publish standards, I am an enthusiastic proponent of caveats, created with all the obfuscatory language that our legal brethren can muster. Unfortunately, there is no shield against the filing of a lawsuit; winning such a suit can be a Pyrrhic victory, for even the ideal eventuality of a summary judgment is dismayingly prolonged and expensive.

Clinical policy-making

The problem of expense applies as well to one of the leading methods of standard-setting by physician panels—the Health Services Utilization Study originated some years ago by analysts at the Rand Corporation in conjunction with interested academic physicians. This method adjudicates the propriety of indications for a particular procedure rather than assessing only process and outcome. A critical part of the standard-setting is a Delphi method in which the second set of opinions terminates the decision-making process.

My mathematical credentials are insufficient to impugn with any cogency the reliability of the Delphi technique. However, I record a deep personal concern over sponsorship of a debatable process that carries the potential for labeling certain widely used operations as rarely or never indicated. I have often said that one unnecessary operation is too many, but we need to approach with great caution a consensus that discounts the credibility and reliability of individual clinical judgment in favor of a tenuous common opinion arrived at by data manipulations in which I have an abiding lack of confidence.

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I would not want these comments to be misinterpreted as a generic objection to organizational clinical policies. The College, from its origin, has been in the forefront of policy-making on general clinical behavior, but the current activity concerns prescriptions and proscriptions on highly specific procedures. This College was in the forefront of cooperation with third-party payors for more than a decade in the so-called medical necessity project of the Blue Cross, Blue Shield plans. That effort was entered into after long and careful study by the College's Board of Regents and was abandoned because of problems in controlling a policy dominated by cost considerations rather than clinical judgment. Dealing with various third-party payors is a necessity in today's practice environment, but I would recall for you the old maxim that one who sups with the devil had better have a very long spoon.

Clinical policy is a complex and important tool, especially in the hands of large purchasers of medical services, such as the automobile industry. For example, the General Motors philosophy of purchasing steel is equated by one of its benefit managers with the way it purchases health care ser-

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vices for over two million employees, which is to contract selectively with those that they consider to be efficient providers. Industry's data bank on physician and hospital profiles is remarkably complete, and it is clearly industry's plan to use it in selecting individuals and institutions whose services will be economically most desirable. The federal government is similarly disposed, as indicated by its recently proposed regulations on dealing with preferred providers. Other large purchasers will adopt similar strategies, and big business has begun a national center for the accumulation and dissemination of data on quality of care.

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As for assuring quality by punitive steps against erring members of organizations, the Health Care Quality Improvement Act of 1987 (P.L. 99-660) provides limited immunity for professional societies and others who have taken action against a physician based on deficiency in competence or professional conduct. This qualified immunity, which has many exceptions, will be applicable if organizations adhere to a number of restrictive clauses, one of which is the obligation to report to a central clearinghouse whatever disciplinary actions have been taken against a staff physician. It would seem that freedom from liability for peer review, if purchased in this way, entails an extremely high cost.

In addition to intense national interest in the subject, there has been international cooperative effort, as exemplified by a May 1987 invitational meeting cosponsored by the Joint Commission on Accreditation of Healthcare Organizations, the International Society of Quality Assurance, the Hospital Research and Education Trust of the American Hospital Association, and the World Health Organization. We do not lack for formulaic approaches to assessment of quality, especially the newer approaches that address the indications for various kinds of treatment.

Lessons learned

What lessons may we derive from this desultory review of the vast and rapidly growing field of quality assurance? If we as a nation decide to limit health care services to reduce costs, for example, by forbidding a given therapy for individuals over a certain age, such exclusion is a debatably acceptable social policy. A more politically attractive policy for politicians is to impugn the qualifications of practitioners by separating them into preferred and nonpreferred categories, thereby implying that the public will be better served by those who fit the fiscal constraints of our paymasters. Herein lies the great danger of allowing the determination of quality to escape from the hands of the physicians who are best qualified to assess it.

Has the medical profession developed standards of quality in the *structure* of its institutions and in the *process* of educating its practitioners? Indeed it has, as evidenced by the distinguished record of the Joint Commission on Accreditation of Healthcare Organizations and by our elaborate system of residency education and certification. Our College has fought for the correlation of these two systems by maintaining the benchmark concept of specialty board certification and strongly defending it against those who would remove or dilute from JCAH standards the use of board certification as a factor in delineation of clinical privileges.

The concept of recertification, spontaneously introduced by the profession itself has made widespread progress since it was firmly advocated by the American Board of Medical Specialties in 1973. The discriminating and closely reasoned fashion in

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which individual specialty boards have adopted or rejected this policy has been challenged by recently proposed legislation to make certification and recertification mandatory, along with the usual heavy-handed regulations to assure compliance. Here is another example of an attempt to take over by law a professional system of quality assurance. Such actions start from the faulty premise that virtue can be achieved by ukase. All experience demonstrates that this is not so, nor can such legislation be reliably enforced even by a vast system of regulators and enforcers. Nothing succeeds like genuine voluntary control by one's peers.

I have reviewed some of the proposals for outside control of professional people, physicians with high intelligence, strong motivation, and a lifetime of disciplined conduct. These professionals have adopted such a way of life in order to achieve the capacity and the right to minister, independently, to the afflicted of the world. Are we to accept the assumptions of our paymasters that we are like mice in a maze, expected to act according to our instinctive drives? Are we to assume that surgeons exist like Pavlovian dogs, salivating when the fee signal goes off, or worse yet, that we are incapable of being motivated, trained if you will, to a higher level of conduct?

Let me close with another story, this one told to Kenneth Adelman, director of the U.S. Arms Control and Disarmament Agency, by one of his Russian counterparts in Geneva. A tourist visited Leningrad and went to the zoo where he saw an arresting sight. There in the lion's cage sat a lion, resting quietly alongside a lamb. The tourist was astounded and hurried on his way feeling happy and uplifted. Returning to the zoo the next day, he saw the same sight, so he rushed off to the head zookeeper's office and said, "I've seen the most marvelous thing in the lion's cage. Tell me, how do you train the lion to do that?" And the zookeeper replied, "We don't train him, we just give him a different lamb every day."

There is a large body of health care economists, planners, business benefits managers, lawyers, legislators, and Washington apparatchiks of every stripe who believe with the Leningrad zookeeper that the way to deal with our profession is to give us

a different rule every day because we are incapable of exercising professional control over what they view as an innate appetite for exploiting our patients. I maintain an opposing view—that we are a select company of women and men with dedication to our profession and to our patients.

For 75 years, the Fellows of this College have given testimony to their moral fiber. It would be absurd to assert that there is no selfishness and greed in our ranks masquerading at times under the thin cloak of itinerant surgery, for example, performed by surgeons eager to provide service at a distance until the fee is paid, after which the obligation of service seems to devolve on other partners in a financial scheme. And there are other buccaneers in our profession, spending six-figure sums on advertising their wares and taking home seven- or even eight-figure yields from their surgical factories. Still others are not content with princely earnings but seem driven to the criminal behavior of evading their tax responsibility to the republic that still provides more personal freedom than any system of government I know.

We must remind ourselves that we will get the kind of government that we deserve, and in our personal conduct comport ourselves so as to merit the freedom accorded to responsible professionals. Our Central Judiciary Committee is busy ensuring compliance with the norms of conduct that thousands of surgeons gladly and voluntarily embraced. The College does this work of assuring quality despite the ever-present threat of reactive litigation by the offender under the rubric of antitrust law.

Quality of care cannot be assured by federal law, by governmental agency regulations, or by the elaborate scientific formulations of health care economists and sociologists. The vital factor in quality assurance lies in the hearts of those who voluntarily subscribe to the precepts of the Golden Rule. Those whose names are officially carried on the rolls as Fellows of the American College of Surgeons must look to faithful observance of the Fellowship pledge. Let us not be counted as animals in a regulated health care zoo, but rather let us follow the example of the good Samaritan in our dedication to the patients we are privileged to serve.