Quality Assurance in Medicine

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"Quality" is a vague concept, not just in the field of medical practice. Hence, describing the assessment of this elusive property of medicine is difficult; and defining assurance of the quality of medical care is even more problematic.

Our purpose here, however, is not to unravel the conceptual underpinnings of quality and quality assurance in health care—a task that would take volumes in itself—but rather to describe and reflect upon some current activities in the field. First we briefly define the concepts of quality of care and quality assurance and recount the history of the quality assurance movement. Then, the major portion of the article describes three initiatives in quality assurance sponsored by the federal government. They are of interest partly because they constitute the largest and most influential public sector quality assurance enterprises yet mounted ir this nation, and partly because they exemplify some fundamental tensions between cost control and quality assurance.

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A BRIEF DEFINITION OF QUALITY OF CARE

Quality of medical care can be defined from several perspectives (the practitioner's, the patient's, society's) and with respect to several dimensions (technical and intrapersonal; processes of care and outcomes of care). The foremost thinker in this area, Avedis Donabedian, reflects that "the quality of technical care consists in the application of medical science and technology in a manner that maximizes its benefits to health without correspondingly increasing its risks. . . . [T]he quality . . . of the interpersonal relationship . . . is the extent of conformity" to socially defined values, norms, expectations, and aspirations governing interpersonal interactions. He arrives at a "unifying" defintion of the concept of quality of care as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" (Donabedian, 1980: 5-6). To capture the complexity of the concept of quality, Brook and Williams (1976) "operationally" defined it as follows:

$$\begin{array}{lcccccccc} \text{Quality} & & \text{Technical} & & \text{Art of} & & \text{Technical} & \text{Art of} & \\ \text{of Care} & = & \text{Care} & + & \text{of Care} & + & \text{Care} & \text{Care} & + \text{ (error)} \end{array}$$

In this formulation, "technical care includes the adequacy of the diagnostic and therapeutic processes. Art of care relates to the milieu, manner, and behavior of the provider in deliverying care to and communicating with the patient. The interactive term emphasizes . . . that the two terms are not just additive" (p. 134). Under some circumstances, as in much of primary medical care that is sought for reassurance as well as accurate diagnoses and relief of symptoms, one might postulate that this interaction term must be "positively significant" (i.e., that both the technical and humanistic elements be positive) if quality of care is to be high. The error term underscores that measurement of any construct such as quality of care is not free of error.

Much quality-of-care work proceeds by evaluating the technical processes of care or the interpersonal or humanistic elements of care. However, the underlying expectation is that "high" quality-of-care scores, as in the above formulation, would be reflected in good patient outcomes, such as full emotional well-being or adequate physical capacities for carrying out ordinary tasks.

In the medical arena, quality assessment is usefully distinguished from quality assurance. Quality assessment, for practical purposes, can be taken as the measurement of the technical and interpersonal aspects of care. Although evaluative judgments are of course implied by this definition, quality assessment is explicitly understood to exclude active steps to correct deficiencies in care.

Quality assurance, on the other hand, is seen as a formal and systematic exercise in identifying problems in medical care delivery, designing activities to overcome the problems, and carrying out follow-up monitoring to ensure that no new problems have been introduced and that corrective steps have been effective. As such, it necessitates the following: articulating a usable definition of quality; establishing mechanisms to set professionally acceptable standards and criteria against which quality may be judged; creating systems by which to collect and analyze relevant data; disseminating findings to practitioners and other concerned individuals or officials, and implementing methods to initiate and follow up corrective actions.

One set of experts (Williamson et al., 1982) describes quality assurance as a health care discipline and defines the activities in terms of improving the effectiveness *and* efficiency of health care delivery. By this they mean to underscore that true quality assurance encompasses both quality in the traditional sense and cost containment (i.e., efficient use of services). This duality—high effectiveness of care and appropriate use of health resources—has become a common theme of quality assurance activities in recent years.

Among the more basic conceptual building blocks of quality assurance are the types of criteria used to assess quality and the

sources of those criteria. At one end of the spectrum are *implicit* criteria; they tend to have little or no formal or written structure and to be based on the internalized expectations of an expert practitioner acting as evaluator. At the other end are highly detailed, specific, and written criteria; these *explicit* criteria typically have a well-developed structure and allow little or no room for the individual judgment of the evaluator. Donabedian (1982) proposed an intriguing conceptual framework for cataloging the sources of criteria: normatively versus empirically derived (respectively, based on participants' judgments or on observed behaviors); exogenously, endogenously, or autogenously derived (respectively, the circumstances in which one is judged by criteria established by another, one group is judged by criteria developed by its own respresentatives, and one person is judged by his or her own criteria); and representative versus elitist criteria (derived respectively, from the general body of practitioners and from those with a recognized claim to excellence).

Perhaps the best-known distinctions are among *structure, process*, and *outcome*. Structural variables are proxy measures of quality—characteristics of facilities (such as types of full-time staff or specialized services available) or of providers (such as medical specialty certification by a medical specialty board). Process refers to how the patient was moved into, through, and out of the health care system—that is, that which was done to or for a patient with respect to his or her particular disease or complaint. Outcome measures describe what happened to the patient with respect to palliation, improvement, stabilization, cure, rehabilitation, or whatever other eventualities may be applicable. The linkages between outcomes and process of care are not well developed theoretically or well verified empirically for medical practice today, and the linkages between processes and structural variables (and especially between outcomes and structural measures) are even less well articulated.

Quality assurance usually takes as its starting point one of two categories of health problems or conditions: provider's diagnosis, or patient's reason for visit. These are the "referents"

(Donabedian, 1982) of the quality-of-care criteria—the things to which the criteria apply. The difficulties of using an organizing framework—even as simple as "diagnosis" or "symptom"—are many. Among them are the array of diagnostic classification systems in use over time or in different places, the need to account for different levels of severity in the same illness or for the joint presence of two or more disorders, and the possible inaccuracy of the patient's self-description of his or her problem.

Finally, quality assurance should be thought of as a continuing *program*. In any setting, large or small, positive and negative factors impinging on implementation must be anticipated. Goals and objectives for the program must be set, and these may or may not coincide with goals of those to be evaluated. New institutional arrangements must be established, or old ones must be modified or abolished. Mechanisms for evaluating the success of the program itself must be initiated, together with procedures for instituting corrective measures when the program seems to be floundering. The conceptual issues inherent in these pragmatic concerns have not been fully explored with respect to the medical setting, although they are important topics in the organizational theory, implementation, and evaluation fields.

A BRIEF HISTORY OF QUALITY ASSESSMENT AND ASSURANCE

Concern with the quality of medical care is as old as the healing arts themselves.[1] Practitioners of two thousand years ago were held to stringent standards for positive outcomes of their care; a surgeon might lose a hand, for example, if his operations proved unsuccessful. A fundamental tenet of the Hippocratic oath—above all, do no harm—is as direct a statement about maintaining quality of care today as it was when first enunciated.

Active steps to assess and improve the quality of medical care have waxed and waned over the ensuing centuries. The modern movement of quality assessment and assurance is often said to date to the efforts of Florence Nightingale to

improve the conditions of care deliverd to British soldiers during the Crimean War. In the United States after the turn of the century, E. A. Codman gave life to concepts and practices that grew into assessment of patient care outcomes ("Was surgery successful or not?") and medical record audit. Reforms in medical education secondary to Abraham Flexner's report for the Carnegie Foundation for the Advancement of Teaching (about the dismal state of medical training in this country), movement toward professional accreditation, and the reorganization of the American Medical Association and Association of American Medical Colleges along modern lines all antedate World War I, but these activities do not constitute "quality assurance" as that concept is commonly understood today.

Little systematic effort at assuring the quality of medical care was carried out between the two world wars. One influential health work of that time, the classic Lee and Jones (1933) report for the Committee on the Costs of Medical Care, was at best only indirectly related to quality. At a more general level, the emergence of systems for certifying medical specialists in the 1930s heralded a concern with quality of care (but again not quality assurance in today's terms).

The mid- to late 1950s brought greater activity in the area. First was a set of empirical assessments of the quality of care delivered by physicians in various settings (general practitioners in North Carolina and Canada, physicians in early prepaid group practices in New York City). These tended to show deficiencies in the care given for a wide range of problems encountered in everyday medical practices. Second, individual hospitals and clinics started grassroots quality assurance activities within their own walls. Medical care foundations, pioneered in California, began review of ambulatory and inpatient care delivered by participating physicians as a prerequisite to reimbursement by fiscal intermediaries. The Joint Commission on the Accreditation of Hospitals (JCAH) undertook to establish and enforce a set of minimum standards (mainly regarding facilities and personnel) that would ensure satisfactory performance on the part of such facilities. More generally, medical schools began to assert more and more authority over hospital staff appointments, qualifications of

instructors, and other organizational factors that would impinge on the quality of medical care.

The 1960s saw a significant leap forward in more formal quality assurance enterprises. In creating Medicare in 1965, for example, Congress mandated that hospital-based utilization review committees be established, principally to guard against overuse of services; two years later, state Medicaid agencies were also required to create equivalent review procedures. The private sector expressed its concern with monitoring the quality of medical care in several ways. For example, the JCAH continued its work, especially in articulating requirements for internal quality assurance studies that would eventually include ambulatory services review. The Health Insurance Association of America encouraged its members (i.e., commercial insurance carriers) to embrace the concepts of utilization review and quality assurance. Finally, specialty associations and medical societies demonstrated increasing sensitivity to quality-of-care matters and to continuing education.

The pace of growth in research and practice in quality assurance quickened in the 1970s. The most ambitious effort was that embedded in the legislation establishing the Professional Standards Review Organizations, or PSROs (described below). Simultaneously, much academic research into quality-of-care issues began to appear in the professional literature.

By mid-decade, over one thousand reports in the literature dealt with various aspects of measuring or improving quality of care. The topics under consideration ranged widely: documenting deficiencies in both inpatient and ambulatory care relating to, say, unnecessary surgical procedures or misuse of prescription medications and laboratory tests; improving quality assessment by, for example, clarifying the dichotomy between the art of care and technical care and the distinctions among structural, process, and outcome variables; and developing new methods to measure quality ("tracers," health accounting, criteria mapping, staging, or sentinel events). Utilization review (or UR, an exercise more explicitly related to conserving medical resources and reducing unnecessary or inappropriate use of resources) came under greater scrutiny; for example,

problems such as whether prior, concurrent, or retrospective review was the most efficient UR approach were examined.

More explicit attention was also being given to the inevitable tension between quality and costs—the so-called cost/quality tradeoffs—and how the direct and indirect costs and benefits of quality assurance might best be estimated.[2] The (rather stormy) marriage of costs and quality issues is a particularly significant aspect of quality assurance in medicine; it would prove to have a marked impact on the mission of the federal quality assurance program.

The relationship can be depicted as in Figure 1 (Brook et al., 1976). The "quality-resources" curve ranges through four "regions"; in the first two regions, quality is low because not enough resources are devoted to maintaining high (or perhaps even adequate) care, although care in the second region approaches optimality. The flat of the curve in region three suggests that about the right amount of resources are being consumed; the downward sloping curve in region four indicates that too many resources may be going into health, with some attendant decrements in quality/health status (presumably owing to iatrogenesis and undue sick-role behavior).

Inevitably, as quality assurance efforts become widespread, interest in evaluating these mechanisms is growing. Evaluation research has a lengthy history, of course, although evaluation of health services programs per se had been a distinct field of endeavor only since the late 1960s.[3] Evaluation of quality assurance systems lagged evaluation in other areas of medical care, owing partly to conceptual and methodologic difficulties and partly to the relative newness of quality assurance itself. Nonetheless, by the early 1980s, a variety of evaluations of the federal quality assurance programs—focused, as we will see, more on cost containment than quality—had been performed.

PEER REVIEW AND QUALITY ASSURANCE

The largest programs of quality assurance in the United States have, not surprisingly, been sponsored by the federal

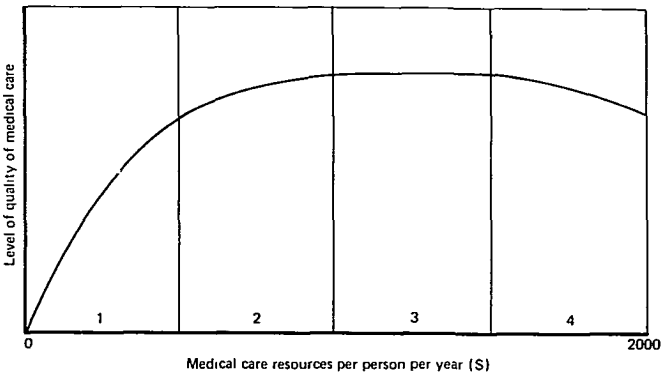

Figure 1: The Quality Resources Curve

government. As the overview that follows will show, the purposes, organizational accomplishments, and future directions of these programs are quite diverse, lending support to the earlier observation that quality assurance is a complex enterprise.

EXPERIMENTAL MEDICAL CARE REVIEW ORGANIZATIONS

Between 1970 and 1975, the National Center for Health Services Research of the Department of Health and Human Services (DHHS) sponsored a demonstration program in utilization review and quality assurance built around several areawide Experimental Medical Care Review Organizations (EMCROs).[4] EMCROs were voluntary associations of physicians that typically reviewed inpatient or ambulatory services paid for by Medicaid or Medicare. Their dual mission was to foster ways for physicians in relatively large geographic areas to come together in a quality assurance effort and to upgrade available methods for assessing and assuring quality of care.

Despite the emphasis many EMCRO proposals placed on quality, much initial activity centered on utilization review (e.g., cost control). The main reason was probably that UR was easier to do, for the same reasons that would arise in the later PSRO program: First, the methods were already available and, second, hospital days (dollars) were easier to "count" than more subjective judgments about quality of care.

EMCROs were not "experiments," and thus rigorous evaluation of the program was not possible. Descriptive and evaluative studies suggest that at least some EMCROs were able to improve existing quality assurance methodologies and to identify and successfully attack problems in quality of care.[5] More important, perhaps, they fostered the participation in quality assurance efforts by physicians in private practice to a degree not previously seen.

The New Mexico EMCRO

The EMCRO established for the New Mexico Medicaid program was one of the more successful efforts. This peer review system attempted both to control Medicaid expenditures and to improve the quality of care, concentrating principally on hospital review.

A major quality-of-care problem was overuse and misuse of injectable medications in outpatient settings. Within two years of its beginning, the EMCRO had had a major impact; for example, use of injections (about half of which were antibiotics) was reduced by more than 60 percent (from 41 to 16 injections per 100 ambulatory visits). When evaluated over time according to characteristics of physicians, diagnoses, ambulatory visits, and entire episodes of care, reductions in the use of injectable drugs were sustained among the classes of drugs targeted by the EMCRO. Quality of care improved most among those physicians with the poorest records initially.

The EMCRO developed a dual approach to quality assurance. The initial set of activities was educational: development and dissemination throughout the provider community of explicit guidelines for the use of injectable drugs within the Medicaid

program, and face-to-face meetings between reviewing physicians (virtually all of whom were in private practice in the state) and providers found to be delivering medically unnecessary care. Several months later came economic sanctions: retrospective denial of payments for services rendered (for which reimbursement the physician could not subsequently have recourse to the patient). The timing of reductions in the use of injectable drugs suggested that much of the EMCRO's effect could be attributed to the educational efforts.

This finding is consistent with beliefs about dissemination and adoption of medical innovations. (Innovation in this context could be any change in medical practice intended to improve the quality of care; see, e.g., Lohr et al., 1981, for citations to this research.) Since the 1950s, but especially in the late 1960s and 1970s, two factors have been seen as critical in legitimizing adoption of innovations by practicing physicians: leadership and involvement by colleagues of high professional standing ("peers"), and direct, perhaps face-to-face, communication with those whose medical practice one wants to change. In short, theory, empirical work in unrelated fields, and some EMCRO experience reinforced the view that quality assurance can best be achieved through "local" peer review.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Local peer review was at the heart of the Professional Standards Review Organization (PSRO) program. This program was established in 1972 (Social Security Amendments of 1972, PL 92-603). The legislation mandated that PSROs should assure that services provided and paid for by the Medicare, Medicaid, and Maternal and Child Health programs were medically necessary and of a quality that met locally determined professional standards, and that they were provided at the most economical level consistent with quality of care.

PSROs consisted of areawide groupings of practicing physicians that were separate, independent, and nonprofit organizations. At the height of the program, the areas num-

bered 195 and were as big as a state or as little as a subdivision of a city. On average, each PSRO covered about 1 million people, about 35 hospitals, and 2,000 to 3,000 physicians (although the range was large). They were explicitly physician-dominated organizations; by the end of the program, more than half of the practicing physicians in areas of the country with a PSRO were members.

Statutory language and legislative history make it clear that the Congress intended the PSRO program to lower inappropriate or unnecessary use of services reimbursed through public programs. In the early years, however, the federal executive branch (and the medical profession itself) emphasized the quality-of-care aspect of the program. The inevitable result was a conflict between the implementers who stressed quality assurance and the instigators who sought cost containment. Over the years, PSROs took on a variety of activities: direct utilization review of hosptial admissions and lengths of stay; Medical Care Evaluations (MCE) studies (i.e., quality assurance); long-term-care review; and "special initiatives" such as surgical review, ancillary services review, and ambulatory care review. (The program also supported statewide councils and a national council.) Hospital UR was the overriding effort, however, and PSROs were evaluated essentially according to how well they saved money; quality assurance activities were given only secondary attention.

Over the years, the total PSRO program became a sizable element of the federal health budget—most of it, of course, being expended on activities related to UR and control of medical care costs, not quality assurance. The level of program funding grew from $4.5 million in FY 1973 to $150 million in FY 1979, falling back to $144 million in FY 1980. Until FY 1977 all monies were directly appropriated; thereafter, the Hospital Insurance Trust Fund (i.e., Medicare) provided from 40 to 60 percent of the total program budget. In FY 1979, about 60 percent of the PSRO program budget went for hospital review, and another 30 percent for program management and support (HCFA, 1980).

In understanding the impact of the PSRO program (or lack of it), it is instructive to note that the program was in "full" existence for rather less time than suggested by the dates of the relevant legislation. Only a handful of PSROs were funded by 1974 and by 1977 only half of the PSRO areas ultimately funded to carry out review (i.e., classified as "conditional") were in place. In mid-1981, there were 182 funded PSROs, of which only about one-quarter were "fully designated" operations.[6]

A number of *programwide* evaluations were conducted over the years.[7] Of necessity, given the emphasis placed by PSROs on hospital review and decreasing unnecessary use of inpatient services, most of these evaluations focused on whether PSROs had been able to produce desired reductions in hospitals stays and costs of federal health programs. The evaluations are, in the aggregate, somewhat contradictory and incomplete. Nonetheless, they suggest that the PSRO program probably saved about as many resources as it consumed; these savings fell short of expectations, however, and additional efforts to lower costs in the medical sector were needed.

During the first years the effect of PSROs on quality assurance went largely unexamined. However, the 1979 PSRO Program Evaluation, conducted "in-house" by the Health Care Financing Administration (HCFA, 1980), was a notable effort that went considerably beyond earlier efforts to assess quality-of-care programs. The major outcome measure was change in a "variation rate" between an initial MCE audit and a reaudit, where variation rate is the proportion of patient records that did not meet a specific standard in some quality-of-care area. The evaluation found that MCE studies in certain PSROs improved care for a range of conditions such as pneumonia, asthma, and tonsillectomy and adenoidectomy, although the report noted that for some disorders (e.g., positive pathology reports in appendectomy) the variation rate did not improve between audit and reaudit. The greatest improvements were observed for problems involving higher levels of initial variation rates (rates greater than 10 percent). The study also

attempted to relate the benefits of MCE studies to the costs of conducting them plus the costs of changes in care secondary to the MCE studies. Measuring outcome as a weighted index of "health status months" ranging from 0 (death) to 1 (perfect well-being) and assuming that a health-month was worth $500-$1,000, the study suggested that the benefits could far surpass costs.

The American Association of Professional Standards Review Organizations (now the American Medical Peer Review Association) has sought to identify how much PSROs affected the quality of medical care. A narrative report (AAPSRO, 1981) on the impact of PSROs on quality of care cited a wide range of improvements in acute inpatient, ambulatory, and long-term care. Examples included decreasing services provided by "outlier" (very substandard) physicians (for, e.g., diagnosis, treatment, and medication of patient with cardiac, pulmonary, or renal failure); improving the diagnosis of acute myocardial infarction (heart attack); reducing the inappropriate use of intermittent positive-pressure breathing services and blood transfusions; and increasing the provision of needed services that were being underused (e.g., preoperative visits by anesthesiologists or better diagnostic testing for pulmonary disease).

A 1981-1982 survey documented similar accomplishments. These included lowering the complication rate from primary Caesarian sections and hysterectomies, improving the dosage and type of medications given during cardiopulmonary resuscitation, reducing the use of a powerful antimicrobial drug when not indicated, improving the practices for evaluating level of pain and need for pain medications after surgery, and raising the use of cultures and sensitivity testing in urinary tract infection. In one case, a PSRO proposed to the Secretary of DHHS that one facility (involving 66 physicians and 5,100 patients) be considered for elimination from the Medicare and Medicaid program because "quality of care did not meet professionally recognized standards." Other quality-related effects impacting on tens of thousands of patients involved reductions

in inappropriate laboratory (or "routine") tests and use of single-unit blood transfusions.

Despite these cited improvements, it is difficult to conclude much about the quality assurance effort of the PSRO program as a whole. First is the problem of aggregating the individual findings, interpreting them in a larger context, or doing more than rudimentary statistical analyses. Second is the conceptual and practical difficulty of relating benefits from quality assurance to the costs of achieving such benefits or to the savings in medical resources. Finally, except for the 1980 HCFA evaluation, federal agencies paid little attention to evaluating the quality assurance functions of PSROs so the body of evidence was slim.

By 1981-1982 PSRO evaluations were giving more explicit attention to "quality impact." Colliding with this trend, however, was the shift away from PSROs to Utilization and Quality Control Peer Review Organizations and to new responsibilities relating to *prospective* reimbursement of hospitals for Medicare admissions (see the next section). Thus, a full examination of the effects of the PSRO program on quality of care will probably never be done.

THE MOVEMENT TO "PEER REVIEW ORGANIZATIONS"

Contraction of the PSRO Program

By 1981, the milieu in which the PSRO program operated, at least at the national level, had changed. Various PSRO program evaluations had seemed to show that Congress's expectations (reduced federal health expenditures) had not been met, and the PSRO budget (or that part coming from the Trust Funds) was climbing. Simultaneously, enthusiasm for stringent fiscal restraint burst upon the nation.

In the spring of 1981, HCFA conducted a "national ranking" of PSROs in an expanded effort to defund poor PSROs, provide a priority ranking that could be used in subsequent program reductions and, implicitly, improve the program's

image at a time during which it was under severe congressional criticism. The agency initiated terminations of 46 PSROs at that time; some were eventually reinstated on appeal.

The ranking was based on a set of "performance evaluation criteria"; PSROs had to achieve a minimum score in at least two of three performance areas (possible points in parentheses): organization and program management (300); process of review (850); and impact or potential impact of review (1,200). Bonus points were allowed for the ranking (but not for the determination of minimum performance) for achievements outside the scope of minimum review responsibility. In early 1982, more complex and detailed criteria based on these performance areas were circulated, but they have not been used again (as of this writing) in any full evaluation.[8]

By mid-1982, only 145 areas had active PSROs; in 39 areas, PSROs had been terminated. The few remaining areas either were not covered by a PSRO at all or were covered by another area's PSRO.

The New Directions

Starting in 1980, a series of legislative bills with major provisions that would reshape PSROs began to be enacted.[9] Although some have not yet taken effect (as of October 1983), they will fundamentally change the nature, scope, and duties of peer review organizations. The impact of the quality assurance aspect of their mission is likely to be considerable.

The Omnibus Budget Reconciliation Act of 1981 (Title XXI, Chapter 3: Professional Standards Review Organizations, PL 97-35), the remarkable legislation that heralded the start of the present administration, required that the Secretary of DHHS evaluate PSROs more directly on the basis of what they accomplished in assuring quality of care, reducing unnecessary use of services, and running their operations effectively. It also made it easier for the Secretary to terminate PSRO grants. The impact of this bill was attenuated, however, by succeeding legislative events.

The Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Title I, Part III, Subtitle C: Peer Review Improvement Act of 1982, PL 97-248) effectively ended the PSRO program, replacing it with one that would come to be known as the PRO program (short for Utilization and Quality Control Peer Review Organization). The changes from the old program were considerable. For one, it markedly expanded eligibility for participation in PROs by for-profit groups and fiscal intermediaries; thus, it diluted the influence of practicing physicians in the operation of the new organizations. For another, it created different funding arrangements (PRO contracts rather than PSRO grants) that made it even easier to terminate inefficient organizations.

As a response to continued escalation of medical service costs in the public sector, especially Medicare, Title VI of PL 98-21 (the Social Security Admendments of 1983) established a prospective reimbursement mechanism for Medicare hospitalizations to go into effect October 1983. Payments were based on the costs of treating patients classified into one of over 460 diagnosis-related groups (DRGs). The crucial factor is that hospitals must attempt to live within a prospective budget determined by prices established in advance on a cost-per-case basis, rather than rely on retrospective reimbursement of such costs. This was historic legislation; Iglehart (1983) described it as "sweeping . . . legislation that reverses key economic incentives that have driven the behavior of hospitals since the federal program for the elderly began 18 years ago" (p. 1428).

The PRO program, which is assigned the peer review responsibilities for Medicare, has as a result acquired some tasks not hitherto considered as an explicit part of a peer review or quality assurance effort. First, the PRO is to review the validity of diagnostic information provided by the hospitals in its area. This may prove to be a critical, yet very difficult, assignment: critical because of the importance of accurate designation of hospital case mix by DRGs to adequate, but not excessive, prospective funding, and difficult because of the problems associated with attempting to validate "true" diagnoses on a

broad range of patients in other than a sparse sampling framework.[10]

Second, the prospective approach to payment, whatever it may do to reduce total social spending on medical care and redistribute payments from high-cost to low-cost hospitals, also provides hospitals with a clear incentive to underserve patients.[11] Thus, PROs are expected to review the completeness, adequacy, and quality of care (although the distinctions among the three concepts are not made explicit). Underservice had always been a concern of PSROs in their quality-assurance role (as evidenced by some of the quality-of-care achievements that increased the provision of services). Because such problems ran counter to the overriding concerns with overuse of services, however, it was an area of review that always took second place to efforts directed at reducing overuse of services and lowering medical care expenditures. The coupling of quality assurance with protection against underservice may thus prove to be a significant development of the PRO program.

CONCLUDING REMARKS

In the near future, as the nation continues to grapple with high costs of medical care and the threatened bankruptcy of the Medicare Hospital Insurance Trust Fund, it does not seem likely that quality assurance as defined at the outset of this article will come into its own, at least not in the public sector. Possibly, greater attention to quality of medical care will come in through the back door of concern with underservice. Except in this guise, however, quality assurance is not likely to be a prominent effort of the PRO program.

PROs will have more immediate tasks than quality assurance. They must focus on investigating the validity of diagnostic information relating to DRG-driven reimbursement, and they must attend sharply to activities that figure importantly in the cost-benefit evaluation envisioned for the program.[12] Moreover, it seems very improbable that the funding needed to mount a

significant quality assurance effort that deals with even a few of the major deficiencies of medical care in this country will be forthcoming from an entitlement program as heavily in debt as is Medicare, and cutbacks in federal funding for Medicaid review would have the same constraining effect on quality assurance activities for that program.

"Local peer review" in the quality-assurance arena, as practiced in the EMCRO and PSRO programs, may also diminish. Physicians, of course, favor improving quality of care in some abstract sense. As an organized profession, however, they did not embrace quality assurance as implemented through the PSRO program; only after some years' experience with the PSRO program could the medical community be said to have become more supportive of it than not. Organizational changes associated with the new PROs may dilute some of that favorable attitude toward formal quality assurance mechanisms.

Physicians will probably have less influence and control in PROs than in the earlier organizations because of the entrance of for-profit groups and the relaxation of requirements about the proportion of physicians in an area that must belong to the PRO for it to be accepted for a federal contract. For example, it is proposed that a physician-sponsored PSRO need be composed of no more than 5 percent of the licensed physicians practicing in the PRO area. Moreover, some observers speculate (see Hunt, 1982) that the PRO contracting system is a more powerful means for the federal government to enforce "national" standards of care (than had been available under the old PSRO grants). Such national standards have always been opposed by the medical community because they are seen as an infringement on physicians' response to local needs and objectives. Finally, there may arise some reluctance on the part of local physician leaders to continue to press for their colleagues' active participation in peer review activities precisely because past participation was (in some eyes) rewarded only by the unceremonious termination of the PSRO program.

Yet the legacy of the federal programs for quality assurance is a positive one. In more than a decade of federal involvement, we can trace several accomplishments. First, it was demonstrated

that physicians could be motivated to band together in the interests of improving quality of medical care, and that they could, through these agencies, identify quality-of-care problems and effect measures to overcome them. Furthermore, the methods for doing quality assessment and assurance improved greatly, as did the techniques for systematically evaluating quality-assurance organizations. Such progress, moreover, had taken place in an environment almost wholly concentrated on controlling the costs of medical care. If, in the coming decade, the nation can begin to bring its medical care expenditures into line, then perhaps before the turn of the century it can look forward to the reemergence of quality assurance as a significant national priority in its own right.

NOTES

1. There exists a notable body of literature on the history of the quality assessment/assurance movement, upon which this section is based. Developments in quality assessment and assurance are covered by Egdahl (1973), Harrington (1973), Lewis (1974), Brook and Williams (1976), Egdahl and Gertman (1976), Christoffel and Loewenthal (1977), Williamson (1977), Williams and Brook (1978), Sanazaro (1980), Young (1982), Palmer and Nelson (1982), and Williamson et al. (1982). Lohr and her colleagues (1981) traced the past and future course of PSROs with respect to technology assessment in medicine. Starr's (1982) survey of more than two centuries of American medicine provides fascinating historical background, although it does not touch on quality issues per se. Williamson et al. (1982) provide a useful resources guide for incorporating quality assurance and cost containment into the medical curriculum. The most elegant and conceptually sophisticated treatment of quality assessment remains the work of Donabedian (1980, 1982).

2. The literature on costs of care is so vast that we could not possibly do it justice here, even by severely restricting our citations to those most directly related to quality or quality assurance. For a quite comprehensive bibliography and discussion of cost-effectiveness in medical practice, we refer the reader to publications of the Office of Technology Assessment, most particularly to the OTA (1980) volume. Phelps (1976) dealt at length with the complexities of cost-benefit analysis of quality assurance programs. The treatise by Donabedian (1976) on benefits of medical care programs should not be overlooked. Finally, works by Havighurst and his colleagues on "the cost/quality tradeoff" are classics (Havighurst and Blumstein, 1975; Havighurst and Bovbjerg, 1975).

3. As with costs of care, the literature on program evaluation is robust. Classic works include volumes by Weiss (1972a, 1972b), Suchman (1967), Wholey et al. (1970), Abt (1976), and Reicken and Boruch (1974). More recently, special journals or compilations devoted just to evaluation (such as *Evaluation Research* or the

Evaluation Studies Review Annual volumes published by Sage Publications) have begun to appear; the latter typically include a section devoted to health and health programs, although quality issues per se are only very rarely covered. A variety of works have appeared devoted to evaluation of health services programs, including that by Shortell and Richardson (1978) and a recent volume of the Sage Research Progress Series in Evalution edited by Wortman (1981). Little, however, has appeared on concepts or methods for evaluating quality assurance programs per se (apart from the publications cited below on the federal peer review programs). One exception is the work of Williamson and his colleagues in evaluating the "health accounting" approach to quality assurance (Williamson, 1978; Williamson et al., n.d.).

4. For simplicity, the present names of agencies are used. Until 1981, DHHS was the Department of Health, Education and Welfare.

5. Programwide descriptions or evaluations of the EMCROs can be found in publications of the National Center for Health Services Research (see A. D. Little, 1973; Maglott et al., 1977), but in reality no full-scale evaluation of the entire program was ever completed. Among the EMCROs the one in New Mexico was perhaps the closest to being a "prototype" PSRO; the evaluations of its accomplishments (see, e.g., Brook and Williams, 1976; Lohr et al., 1980) suggest what, under the best circumstances of that day, a peer review organization might have been expected to achieve in the area of quality assurance. (It should probably be noted that in the area of cost containment and reductions in use of hospital days, the EMCROs' record was not encouraging.) By the time the EMCRO program was disbanded, the PSRO program had been underway for about two years, and federal and academic interest in evaluation of peer review programs had understandably turned toward the PSROs.

6. In mid-1981, almost three-quarters of the PSRO areas were in conditional status, and a handful were completely unfunded. The main difference between fully designated and conditional at that time was that a formal hearing was needed to terminate a fully designated, but not a conditional, PSRO. During the late 1970s, the requirements placed on PSROs for becoming fully designated fluctuated (e.g., the requirement for doing long-term-care or ambulatory-care review) although what effect such program expectations may have had in delaying full implementation of the program remains an open question.

7. Program evaluations include the following: OPEL (1977); Chassin (1978); Health Care Management Systems (1978); CBO (1979, 1981); GAO (1980); and HCFA (1980). Evaluations of *individual* PSROs for refunding of grants was done by the DHHS regional offices. These offices were responsible for markedly different numbers of PSROs (e.g., 13 in the Boston region, 42 in the Chicago region); some offices used objective and explicit scoring systems to evaluate their PSROs, others used site assessments and implicit evaluation criteria. Such evaluations were never really aggregated into a programwide evaluation for any particular year or funding cycle.

8. Essentially the same three areas were considered, but the weights given to the areas changed. More emphasis was placed on impact, less on organization and review operations (percentage of total possible points in parentheses): organization and program management (8 vs. 13 percent); performance of review operation—compliance and process (24 vs. 36 percent); and performance of review—impact and potential impact (68 vs. 51 percent). About 10 percent of the score related to compliance and process dealt with MCE (now quality review) studies; about 33 percent of the score related to impact dealt with "resolution of important patient care problems."

With respect to the quality assurance "compliance and process" dimension, the evaluation was to indicate whether the PSRO had or had not met a series of specifications relating to MCE (quality review) studies (e.g., number of studies, requirements that studies be based on written criteria and include thorough data analysis, peer review, complete documentation, and restudy). Key factors of the "impact on quality" dimension included the prevalence of the problem (number of patients affected), the severity of the problem, and the extent to which it was resolved. Severity was conceptualized as the degree of actual adverse effect on patient well-being, categorized as life-threatening, major loss of function, other adverse effects (e.g., complications or iatrogenic illness), and other patient care practices that may reflect or result in inappropriate patient care outcomes The degree of problem resolution was defined as the observed reduction in the problem (number of hospital discharges affected) adjusted to the rate of occurrence of the problem during a specific baseline period. Altogether, this level of complexity in the evaluation criteria goes beyond both the "variation rate" approach of the earlier HCFA evaluation and the "minimum achievements" of the first national ranking.

9. An outline of the laws and regulations of the last 10 years that shaped (and then replaced) the PSRO program can be obtained from the first author (publication P-6918).

10. Diagnostic accuracy had always been a concern as regards data submitted by PSROs to the federal government through the PRSO Hospital Discharge Data Set. Some observers, however, believed that those data, although perhaps not a full accounting of Medicare or Medicaid admissions, had better rates of diagnostic accuracy than did Medicare data available through the Medicare Provider Analysis and Review data set that is developed from claims submitted by fiscal intermediaries (see Lohr et al., 1981: 27). It is thus interesting that, as part of the DRG-based prospective reimbursement of Medicare hospitalizations, fiscal intermediaries will be allowed to be PROs after October 1984.

11. This problem was forcefully put by Smits (1981) during the PSRO "contraction" period:

> The proposed legislation [referring to "procompetitive" bills before Congress], which is intended to give hospitals and health-care plans a competitive incentive to cut costs, also provides a strong incentive to do so by delivering substandard services or by forcing patients to underuse services. There appears to be little question that such a system would require monitoring of the quality of care. . . . Mr. [David] Stockman [head of the Office of Management and Budget, which was spearheading the drive to extinguish the PSRO program] may wind up rediscovering PSROs in 1983 or 1984 if he completely dismantles them in 1981 [1981. 258].

12 Draft provisions of the Scope of Work that would be issued as a basis for PRO contracts specified (in September, 1983) a series of objectives related to admissions (reduction of inappropriate admissions, readmissions, and transfers to facilities or hospital units that are exempt from prospective reimbursement). In the quality area, PRO contractors would be required to show impact along one or more of the following lines: reduce unnecessary hospital readmissions resulting from poor care provided during prior admissions; assure provision of medical services that, when not performed, have "significant potential" for "causing serious patient complications"; reduce avoidable deaths and postoperative complications, reduce unnecessary

surgery or other invasive procedures with significant potential for causing serious patient complications. Significant potential was yet to be defined. One notable departure from the PSRO program was the prior articulation of a "cost-benefit" computation by which PROs (and the program more generally) would be evaluated. This cost-benefit calculation would be based on accomplishments in admissions review, DRG validation, and review of "outliers" (cases that go beyond preestablished lengths of stay or costs). In addition, the cost-benefit evaluation will include an "admissions factor." This is a complex measure based on how much impact a PRO had on changes in admissions rates, as compared to increases or decreases in admissions rates that the PRO area had had in the previous few years relative to the national average. The cost-benefit computation would not include quality-related activities, and the way in which achievements in this arena would be incorporated into the overall evaluation methodology remained unspecified.

REFERENCES

AAPSRO [American Association of Professional Standards Review Organizations Task Force] (1981) PSRO Impact on Medical Care Services: 1980, Vols. I and II. Report of the 1980 Ad Hoc Task Force on Impact. Potomac, MD: The Association.

ABT, C. C (1976) The Evaluation of Social Programs. Beverly Hills: Sage.

A. D. LITTLE, Inc. and National Center for Health Services Research and Development (1973) EMCRO Program. DHEW Publication (HSM) 73-3017. Rockville, MD: Department of Health, Education and Welfare.

BROOK, R. H. and K. N. WILLIAMS (1976) Evaluation of the New Mexico Peer Review System, 1971 to 1973. Medical Care 14 (Supplement). (Also available as R-2110-HEW/RC, Santa Monica, CA: The Rand Corporation, 1977.)

BROOK, R. H. and K. N. WILLIAMS (1975) "Quality of health care for the disadvantaged." J. of Community Health 1: 132-156.

BROOK, R. H , K. N. WILLIAMS, and A. D. AVERY (1976) "Quality assurance today and tomorrow: forecast for the future:" Annals of Internal Medicine 85: 809-817.

CBO [Congressional Budget Office] (1981) The Impact of PSROs on Health Care Costs: Update of CBO's 1979 Evaluation. Washington, DC: Congressional Budget Office, Congress of the United States.

———(1979) The effects of PSROs on Health Care Costs: Current Findings and Future Evaluations. Washington, DC: Congressional Budget Office, Congress of the United States.

CHASSIN, M. R. (1978) "The containment of hospital costs: a strategic assessment." Medical Care 16, 10 (Supplement).

CHRISTOFFEL, T. and M. LOEWENTHAL (1977) "Evaluating the quality of ambulatory health care: a review of emerging methods." Medical Care 16: 877-897.

DONABEDIAN, A. (1982) Explorations in Quality Assessment and Monitoring, Vol. II. The Criteria and Standards of Quality. Ann Arbor, MI: Health Administration Press.

———(1980) Explorations in Quality Assessment and Monitoring, Vol. I. The Definition of Quality and Approaches to its Assessment. Ann Arbor, MI: Health Administration Press.
———(1976) Benefits in Medical Care Programs. Cambridge, MA: Harvard University Press
EGDAHL, R. H (1973) "Foundations for medical care." New England J. of Medicine 288: 491-498.
EGDAHL, R. H. and P. M. GERTMAN [eds.](1976) Quality Assurance in Health Care Germantown, MD. Aspen Systems Corporation.
GAO [General Accounting Office] (1980) Department of Health and Human Services Should Improve Monitoring of Professional Standards Review Organizations, HRD-81-26. Report to the Subcommittee on Oversight, House Committee on Ways and Means. Washington, DC: Author.
HARRINGTON, D. C. (1973) "Ambulatory medical care data· 20. the San Joaquin Foundation peer review system " Medical Care 11 (Supplement): 185-189.
HAVIGHURST, C. C. and J. F BLUMSTEIN (1975) "Coping with quality/cost trade-offs in medical care: the role of PSROs." Northwestern Univ. Law Rev. 70. 6-68
HAVIGHURST, C. C. and R. BOVBJERG (1975) "Professional standards review organizations and health maintenance organizations. are they compatible?" Utah Law Rev. (Summer), 381-421
HCFA [Health Care Financing Administration] (1980) Professional Standards Review Organization 1979 Program Evaluation. Health Care Financing Research Report. HCFA Publication 03041. Baltimore, MD: Department of Health and Human Services
Health Care Management Systems, Inc (1978) Final Report: PSRO Ambulatory Care Quality Assurance Review. La Jolla, CA: Health Care Management Systems.
HUNT, K. (1982) "Are they taking the peer out of peer review?" Medical Economics 20 (December): 183-187
IGLEHART, J. K. (1983) "Medicare begins prospective payment of hospitals." New England J. of Medicine 308: 1428-1432.
LEE, R. I. and L W. JONES (1933) The Fundamentals of Good Medical Care Committee on the Costs of Medical Care, Publication 22. Chicago. Univ. of Chicago Press.
LEWIS, C. E. (1974) "State of the art of quality assessment." Medical Care 12: 799-806.
LOHR, K. N., R. H BROOK, and M. A. KAUFMAN (1980) Quality of Care in the New Mexico Medicaid Program (1971-1975). The Effect of the New Mexico Experimental Medical Care Review Organization on the Use of Antibiotics for Common Infectious Diseases. Medical Care 18 (Supplement). (Also available as R-2513-HEW. Santa Monica, CA: The Rand Corporation, 1980.)
LOHR, K. N., J. D. WINKLER, and R. H. BROOK (1981) Peer Review and Technology Assessment in Medicine (R-2820-OTA) Santa Monica, CA: The Rand Corporation.
MAGLOTT, D., B. D. ATELSEK, and F. D. HAIR (1977) "The Experimental Medical Care Review Organizations and PSRO: what we have learned so far," Proceedings: Conference on Professional Self-Regulation. DHEW Publication (HRA) 77-621. Hyattsville, MD: Department of Health, Education, and Welfare.
Office of Technology Assessment (1980) The Implications of Cost-Effectiveness

Analysis of Medical Technology. Washington, DC: Congress of the United States. Office of Technology Assessment (August).
OPEL [Office of Planning and Evaluation, and Legislation] (1977) PSRO. An Evaluation of the Professional Standards Review Organization. Executive Summary. Draft of DHEW Publication OPEL 77-12, Vol. 1. Washington, DC: Department of Health, Education and Welfare, Health Services Administration.
PALMER, R. H. and H. R. NELSON (1982) "A review of methods for ambulatory medical care evaluations." Medical Care 20: 758-781.
PHELPS, C E. (1976) "Benefit/cost analysis of quality assurance programs," in: R. H. Egdahl and P. M. Gertman (eds.) Quality Assurance in Health Care. Germantown, MD: Aspen Systems Corporation.
RIECKEN, H W. and R. E. BORUCH [eds.] (1974) Social Experimentation. A Method for Planning and Evaluating Social Intervention. New York: Academic Press.
SANAZARO, P. J. (1980) "Quality assessment and quality assurance in medical care." Annual Rev. of Public Health 1: 37-68.
SHORTELL, S. M. and W. C. RICHARDSON (1978) Health Program Evaluation St. Louis, MS: C. V. Mosby.
SMITS, H. L (1981) "The PSRO in perspective." New England J. of Medicine 305: 253-259.
STARR, P. (1982) The Social Transformation of American Medicine. New York: Basic Books.
SUCHMAN, E. A. (1967) Evaluative Research. Principles and Practice in Public Service and Social Action Programs. New York: Russell Sage Foundation.
WEISS, C. H. (ed.) (1972) Evaluating Action Programs: Readings in Social Action and Education. Boston: Allyn and Bacon.
WEISS, C. H. (1972) Evaluation Research. Methods of Assessing Program Effectiveness. Englewood Cliffs. NJ: Prentice-Hall.
WHOLEY, J. S., J. W. SCANLON, DUFFY, J. S. FUKUMOTO, and L. M. VOGT (1970) Federal Evaluation Policy. Analyzing the Effects of Public Programs. Washington, DC: The Urban Institute.
WILLIAMS, K N. and R. H. BROOK (1978) "Quality measurement and assurance." Health and Medical Care Services Rev. 1, 3: 1, 3-15.
WILLIAMSON, J. W. (1978) Assessing and Improving Health Care Outcomes. The Health Accounting Approach to Quality Assurance. Cambridge, MA: Ballinger.
———(1977) Improving Medical Practice and Health Care. A Bibliographic Guide to Information Management in Quality Assurance and Continuing Education. Cambridge, MA: Ballinger.
———S. D. HORN, T. CHOI, and P. E. WHITE (n.d.) "Evaluating an outcome-based quality assurance system." Executive Summary and Final Report prepared for the National Center for Health Services Research. Baltimore, MD: Johns Hopkins University School of Hygiene and Public Health. (mimeo)
WILLIAMSON, J. W., et al. (1982) Teaching Quality Assurance and Cost Containment in Health Care. A Publication of the Association of American Medical Colleges. San Francisco: Jossey-Bass.
WORTMAN, P. M. (1981) Methods for Evaluating Health Services. Sage Research Progress Series in Evaluation, Vol. 8. Beverly Hills: Sage.
YOUNG, H. H. (1982) "A brief history of quality assurance and peer review." Professional Psychology 13: 9-13.