Quality Assurance in Medicine

Experience in the Public Sector

Kathleen N. Lohr, Robert H. Brook
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Rand
1700 MAIN STREET
P.O. BOX 2138
SANTA MONICA, CA 90406-2138
PREFACE

This report is an updated and extended version of a commissioned article by the authors that appeared in the May/June, 1984 issue (Vol. 27, pp. 583–607) of the periodical American Behavioral Scientist. It formed part of an entire issue given over to describing and critiquing quality-assurance efforts in medicine, mental health, and education for an audience whose expertise lies in other disciplines and fields. The current work updates details of the Utilization and Quality Control Peer Review Organization program (better known as the PRO program) to the present; it also gives additional information on legislation and regulations that have played a significant role in the history of federally sponsored professional peer review efforts since the early 1970s.

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SUMMARY

INTRODUCTION

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 interpersonal; processes and outcomes of care. Donabedian (1980) offered one “unifying” definition of quality of care: “... 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.” Operationally, quality of care of care can be formulated as:

\[
\text{Quality of Care} = f \left( \text{Technical Care, Art of Technical and } \right) \\
\text{Care, Art Interaction} \]

“High” quality of care should be reflected in good patient outcomes, such as full emotional well-being, adequate physical capacities for carrying out ordinary tasks, or at least a reduction in the rate of decline in health status.

Quality assessment is, for practical purposes, the measurement of the technical and interpersonal aspects of care. Quality assurance is the formal and systematic exercise of identifying problems in medical care delivery, designing activities to overcome the problems, and following up to ensure that no new problems have been introduced and that corrective actions have been effective. The largest and most influential public sector quality-assurance enterprises have been those mounted by the federal government; they are of special interest because they exemplify some fundamental tensions between cost control and quality assurance. This report, therefore, deals mainly with three programs: Experimental Medical Care Review Organizations (EMCROs), Professional Standards Review Organizations (PSROs), and Utilization and Quality Control Peer Review Organizations (PROs).
A SHORT HISTORY OF QUALITY ASSURANCE

Concern with the quality of medical care is as old as the healing art itself. Modern quality assessment and assurance dates to Florence Nightingale's efforts to improve conditions of care delivered to British soldiers in the last century. In the United States, several activities related to improving the organization or delivery of medical care, such as medical education reform and professional accreditation, antedate World War I. Little progress was seen between the wars, but the mid-to-late 1950s brought greater activity in the area: empirical quality-of-care assessments, growth of medical care foundations, and implementation of minimum standards by the Joint Commission on the Accreditation of Hospitals. The 1960s saw a significant leap forward in more formal quality-assurance enterprises, such as efforts by the Health Insurance Association of America to encourage commercial insurance carriers to embrace utilization review and quality assurance.

The pace quickened in the 1970s, with the PSRO program mandated to review utilization and quality of care for the Medicare and Medicaid programs. Academic research into quality-of-care issues gave particular attention to the inevitable "cost/quality tradeoff." Moreover, as quality-assurance efforts spread, interest in evaluating them began to rise as well.

By the 1980s, a variety of factors combined to replace the PSRO program with a new approach: the PRO program. Implementation of this program coincided with the emergence of the prospective payment system (PPS) for financing the hospital portion of Medicare, and this has had significant implications for the types of tasks that this quality-assurance program must now undertake.

PEER REVIEW AND QUALITY ASSURANCE

Experimental Medical Care Review Organizations

EMCROs, which operated from 1970 to 1975, 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. Although rigorous evaluation was not possible, various assessments suggest that at least some EMCROs improved existing quality-assurance methodologies and identified and successfully attacked problems in quality of care. More
important, perhaps, they fostered much greater participation in quality-assurance efforts by physicians in private practice. The 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 PSRO program, established by the Social Security Amendments of 1972 (P.L. 92–603). PSROs were to assure that services provided and paid for by Medicare, Medicaid, and Maternal and Child Health 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. At the height of the program, PSRO areas numbered 195; on average, each covered about one million people, about 35 hospitals, and 2000 to 3000 physicians. They were explicitly physician-dominated organizations; by the end of the program physician membership included more than half of the practicing physicians in areas of the country with a PSRO.

Statutory language and legislative history make clear that Congress intended the PSRO program to lower inappropriate or unnecessary use of services reimbursed through public programs. Early on, 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.

Program-wide evaluations focused mainly on whether PSROs had produced desired reductions in hospital stays and costs of federal health programs. Taken together, the evaluations are somewhat contradictory and incomplete but suggest that the program probably saved about as many resources as it consumed. These savings fell short of expectations, however, and additional efforts to lower medical sector costs were needed.

During the early PSRO years, their effect on quality assurance went largely unexamined, but by about 1979 the quality dimension began to attract more attention. Conclusions about the quality-assurance efforts of the PSRO program can never be definitive, but individual PSROs and one program-wide evaluation did document many accomplishments in curtailing improper or inappropriate practices and increasing provision of needed services. Certainly a significant achievement of the PSRO program was the dramatic and positive change in attitude of the medical community toward the whole principle of peer review.
By 1981, the program’s budgets were rising, the milieu in which the PSRO program operated had changed, and disappointment about the program’s achievements was increasingly voiced. Coupled with enthusiasm for stringent fiscal restraint in the public sector, these factors spelled the end for the PSRO program. In its place, the historic Tax Equity and Fiscal Responsibility Act (“TEFRA”) of 1982 established the PRO program.

Utilization and Quality Control Peer Review Organizations

TEFRA instituted marked changes in the peer review and quality-assurance efforts of the federal government, including: (a) expanded eligibility for for-profit groups and fiscal intermediaries to be PROs, (b) reduction of the number of PRO areas to 54 (mainly state-wide), (c) funding through contracts rather than grants (which made termination easier), and (d) requirements that the organizations specify objectives to be achieved over the two-year contract period against which the organization’s performance could be assessed.

The major changes arose from the Social Security Amendments of 1983 (P.L. 98–21), which established a prospective payment system (PPS) for Medicare. Beginning October 1983, hospital payments were to be based on the costs of treating Medicare patients classified into 468 diagnosis-related groups (DRGs); this essentially forces hospitals 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. As noted by Iglehart (1983, p. 1428), P.L. 98–21 was “... 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.”

The PRO program is an integral part of the PPS approach; hospitals paid under PPS were to have a signed contract with the state PRO by October 1984 as a condition of further payment. Consequently, PROs acquired some tasks not hitherto considered explicitly related to quality assurance. For instance, they must review the validity of diagnostic and procedure information provided by hospitals.

More important, PPS gives hospitals a clear incentive to underserve patients; thus, PROs are to review the completeness, adequacy, and quality of care rendered to Medicare beneficiaries. Every PRO must pursue five specific quality objectives: (a) reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission; (b) assure provision of medical services that, if not performed, have a “significant potential” for causing “serious patient complications”; (c) reduce avoidable deaths; (d) reduce unnecessary surgery
or other invasive procedures; and (e) reduce avoidable postoperative or other complications. Nonetheless, the major concerns for PROs will be to reduce inappropriate admissions and strenuously monitor hospital-specific admission patterns, decrease inappropriate surgical and invasive procedures (or acceptable ones done in-hospital that could be performed on an outpatient basis), and review admissions that are outliers in terms of either length of stay or expenditures (“day” or “cost” outliers).

CONCLUDING REMARKS

As the nation continues to grapple with high costs of medical care and the threatened bankruptcy of the Medicare Hospital Insurance Trust Fund, quality assurance is unlikely to grow in prominence or funding, at least in the public sector. Except for concern with under-service, quality assurance will probably not be a significant effort of the PRO program, at least in its early period. “Local peer review,” as practiced in the EMCRH and PSRO programs, may also diminish, in part because organizational changes associated with the new PROs may dilute some of the favorable attitude toward formal quality-assurance mechanisms that the earlier programs had fostered.

Nonetheless, the legacy of the federal programs for quality assurance is a very positive one. Methods in the field improved greatly, as did the techniques for systematically evaluating quality-assurance organizations. Physicians, it was shown, could be motivated to band together in the interest of improving quality of medical care; they could, through these agencies, identify and solve quality-of-care problems. Such progress, moreover, took place in an environment almost wholly concentrated on controlling the costs of medical care. If, in the coming decade, the nation brings its medical expenditures into line, then perhaps before the turn of the century it can look forward to the re-emergence of quality assurance as a significant national priority in its own right.
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I. INTRODUCTION

"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; defining assurance of the quality of medical care is even more problematic.

Our purpose here 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 report describes three initiatives in quality assurance sponsored by the federal government: Experimental Medical Care Review Organizations (EMCROs), Professional Standards Review Organizations (PSROs), and Utilization and Quality Control Peer Review Organizations (PROs). They are of interest partly because they constitute the largest and most influential public sector quality-assurance enterprises yet mounted in this nation, and partly because they exemplify some fundamental tensions between cost control and quality assurance.

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 interpersonal, 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" definition 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, pp. 5-6).

To suggest the complexity of the concept of quality, it might be "operationally" defined as the following function:
Quality of Care = f(Technical Care, Art of Care, Technical and Art Interaction)

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 delivering care to and communicating with the patient. The interactive term emphasizes . . . that the two terms are not just additive" (Brook and Williams, 1975, p. 134). Under some circumstances, as in much of primary medical care that is sought for reassurance as well as accurate diagnosis and relief of symptoms, one might postulate that this interaction term must be "positive and significant" (i.e., that both the technical and humanistic elements be positive) if quality of care is to be high. We show this as a functional construct rather than an additive equation because the exact relationships among these variables have never been quantified.

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. It would also be seen in the prevention or reduction of a decline in health status that would otherwise have occurred.

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: articulating a usable definition of quality, establishing mechanisms to set professionally acceptable standards and criteria against which quality might 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 and Associates, 1982) describe quality assurance as a health care discipline and define 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 tend 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 representatives, 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—i.e., what 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 might 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 impending on implementation must be anticipated. Goals and objectives for the program must be set, and these may not coincide with the goals of persons or institutions to be evaluated. New institutional arrangements must be established or old ones 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 art itself. 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.

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 Egda(h (1973), Harrington (1973), Lewis (1974), Brook and Williams (1976), Egda(h and Gertman (1976), Christoffel and Loewenthal (1977), Williamson (1977), Williams and Brook (1978), Sanazaro (1980), Young (1982), Palmer and Nelson (1982), Williamson and Associates (1982), and Fine and Meyer (1983). Lohr and her colleagues (1981) traced the past and future course of FSROs 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 and Associates (1982) provide a useful guide for incorporating quality assurance and cost containment into the medical curriculum. The summer and fall (1982) issues of Health Services Research were devoted entirely to the "organization/behavior interface" in quality assurance (see Luke, 1982, for an overview). Finally, the most elegant and conceptually sophisticated treatment of quality assessment remains the work of Donabedian (1980, 1982).
INTRODUCTION

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 delivered 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, although 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 every-day medical practices. Second, individual hospitals and clinics started grass roots 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 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 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 quality-assurance research and practice 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 ranged widely: documenting deficiencies in both inpatient and ambulatory care relating to, say, care for specific clinical problems such as urinary tract infection or to misuse of prescription medications and laboratory tests; improving quality assessment by, for instance, 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, questions 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 tradeoff—and how the direct and indirect costs and benefits of quality assurance might best be estimated. The (rather stormy) marriage of cost and

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3 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).
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 Fig. 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 or health status (presumably owing to iatrogenesis and undue sick role behavior).

Inevitably, as quality-assurance efforts became widespread, interest in evaluating these mechanisms grew. Evaluation research has a

![Fig. 1—The quality/resources curve](image-url)

For a recent overview of the Medicare and Medicaid programs and the concerns with rising costs in those programs, see Lohr and Marquis (1984).
lengthy history, of course, although evaluation of health services programs per se has been a distinct field of endeavor only since the late 1960s. 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.

As with costs of care, the literature on program evaluation is robust. Classic works include volumes by Weiss, Suchman, Wholey, Abt, and Riecken and Boruch (see citations). 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 Evaluation edited by Wortman (1981). Little, however, has appeared on concepts or methods for evaluating quality-assurance programs (apart from the publications cited below on the federal peer review programs). One large project was sponsored by the Bureau then responsible for PSRO implementation. Called the Ambulatory Care Quality Assurance Project (ACQAP), it sought to develop a generic model for designing and assessing quality-assurance programs aimed at ambulatory care and to assess and document such activities in over 25 health delivery settings before the time PSROs would try to undertake ambulatory care review (White et al., 1977). Another effort is the work of Williamson and his colleagues in evaluating the “health accounting” approach to quality assurance (Williamson, 1978; Williamson et al., n.d.).
II. PEER REVIEW AND QUALITY ASSURANCE

The largest programs of quality assurance in the United States have, not surprisingly, been sponsored by the federal 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)\(^1\) sponsored a demonstration program in utilization review and quality assurance built around several area-wide Experimental Medical Care Review Organizations. 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 (i.e., 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\(^2\) suggest that at least some EMCROs were able to improve existing

\(^1\)For simplicity, the present names of agencies are used. Until 1981, DHHS was the Department of Health, Education, and Welfare.

\(^2\)Program-wide descriptions or evaluations of the EMCROs can be found in publications of the National Center for Health Services Research (see A. D. Little, Inc., 1973, or Magliott 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
quality-assurance methodologies and to identify and successfully attack problems in quality of care. More important, perhaps, they fostered the participation in quality-assurance efforts by physicians in private practice to a degree not previously seen.

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 start-up, 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 payment for services rendered (for which reimbursement the physician could not subsequently have recourse to the patient). The timing of reductions in injectable drug use 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 assurance. (It should probably be noted that in the area of cost containment and reductions in use of hospital days, the EMCRO’s 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.
with those whose medical practice one wants to change. In short, theory, empirical work in unrelated fields, and some EMCR experience reinforced the view that quality assurance can best be achieved through "local" peer review.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Elements of the PSRO Program

Local peer review was at the heart of the Professional Standards Review Organization, or PSRO, program. This program was established in 1972 (Social Security Amendments of 1972, P.L. 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. Table 1 briefly outlines selected laws and regulations of the last 12 years that shaped (and then replaced) the PSRO program.

PSROs consisted of area-wide groupings of practicing physicians that were separate, independent, and nonprofit organizations. At the height of the program, the areas numbered 195 and were as big as a state or as little as a subdivision of a city. On average, each PSRO covered about one million people, about 35 hospitals, and 2000 to 3000 physicians (although the range was large). They were explicitly physician-dominated organizations; by the end of the program, physician membership included more than half of the practicing physicians in areas of the country with a PSRO.

Statutory language and legislative history make it clear that the Congress primarily intended the PSRO program to lower inappropriate or unnecessary use of services reimbursed through public programs. In designing and implementing PSROs, however, legislators were surely aware of the potential role PSROs would have in quality assurance. In the early years, the federal executive branch and the medical profession itself emphasized the quality-of-care aspect of the program. Certainly, the physician leadership stressed the capability of these peer review organizations to achieve quality-assurance goals so as to gain local acceptance of them. Nonetheless, all were acutely sensitive to the UR priorities of the program. The inevitable result would be conflict between the implementers who stressed quality assurance and the instigators who sought cost containment, especially as the PSRO
Table 1

PRINCIPAL LEGISLATION OR INSTRUCTIONS REGARDING THE PSRO AND PRO PROGRAMS

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
<th>Description</th>
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<tr>
<td>1972</td>
<td>P.L. 92–603: Social Security Amendments</td>
<td>Created the original PSRO program by which area-wide nonprofit groupings of physicians would review services reimbursed by federal beneficiary programs (Medicare, Medicaid, and Maternal and Child Health), the costs of which were to be borne entirely by the federal government.</td>
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<td>PSROs on behalf of hospitals were to carry out utilization review and profile analyses and to do Medical Care Evaluation studies.</td>
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<td>Hospitals that were willing to perform review functions “in house” and were capable of doing so effectively were to be delegated the responsibility by the PSRO.</td>
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<td>Allowed hospitals to invoke a “waiver of liability” for Medicare patients (and in some cases for Medicaid patients under a different “without fault” formulation), such that unless the hospital knew or could reasonably have been expected to know that the care it was providing was unnecessary, the costs of that care would be reimbursed regardless of the recommendation of the PSRO.</td>
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<td>Created an ambiguously phrased, multiple-source funding system of grants that seemed to allow for review reimbursement from Medicare, Medicaid, and direct appropriations. (The provisions were in fact sufficiently open to interpretation that all program funding came from appropriations for FY 1973–1976.)</td>
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<td>Established state and national PSRO Councils.</td>
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<td>1975</td>
<td>P.L. 94–182: Amendments to Title XVIII of the Social Security Act</td>
<td>Established mechanisms to designate an entire state as a PSRO area when previously the state had had two or more PSRO areas.</td>
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<td>Specified more directly how activities were to be funded. It subsequently developed that hospital review was financed separately and directly from the Hospital Insurance Trust Fund (Medicare), overhead was covered by a transfer from the Fund to general revenues, Medicaid review was covered by a transfer to the Fund, and the remainder of the PSRO costs (e.g., for operations and other line items) were covered by annual budget appropriations. Delegated hospitals were paid directly, not through the PSRO.</td>
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<tr>
<td>1977</td>
<td>P.L. 95–142: Medicare-Medicaid Anti-Fraud and Abuse Amendments</td>
<td>Required that PSROs take on long-term care review as a prerequisite to becoming “fully designated.”</td>
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Table 1 (continued)

Required that, within two years of becoming “fully designated,” PSROs take on ambulatory care review

Required the Secretary of DHHS to produce an annual evaluation report to Congress.

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<tr>
<td>Title IX, Subpart III: Provisions Relating to PSROs</td>
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<tr>
<td>Reversed the long-term care and ambulatory care review requirements specified in P.L. 95-142.</td>
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</table>

Allowed PSROs to offer membership to “nonphysician professionals with hospital admitting privileges.”

Required Secretary of DHHS to establish a program to evaluate cost-effectiveness of review of particular services and to demonstrate either cost-effectiveness or the finding that such review yields other significant benefits before it shall be required of PSROs.

Expanded membership of state and national PSRO councils to nonphysicians.

<table>
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<th>1980. PSRO Transmittal No. 100</th>
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<tr>
<td>Ordered that Quality Review Studies supersede Medical Care Evaluation studies and that more emphasis be placed on improving quality of care, that a broader set of topics be considered, and that methods other than medical record audit be developed.</td>
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<tr>
<td>Title XXI, Chapter 3: PSROs</td>
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<tr>
<td>Made delegated review optional by allowing the PSRO to select which hospitals would be delegated review functions.</td>
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</table>

Required the Secretary of DHHS to specify PSRO requirements relative to assuring quality of care, lowering unnecessary utilization, and managing activities efficiently and to evaluate them on those grounds. Eased the mechanisms by which PSROs could be terminated.

Required PSROs to review only Medicare services and made allowance to support only 75 percent of a state’s costs attributable to review of Medicaid services.
Table 1 (continued)

Title I, Part III, Subtitle C: Peer Review Improvement Act
Modified the entire PSRO program by establishing the Utilization and Quality Control Peer Review Organization (PRO) program in its place. Major differences from the original program include:
(a) allowed eligible organizations to be proprietary and to have only a “sufficient” number of physicians to perform review;
(b) disallowed facilities and facility associations from participating, but allowed payor organizations (e.g., insurance companies or fiscal intermediaries), also referred to as physician-access organizations, to participate after 12 months (from enactment); physician-sponsored organizations are to have priority over physician-access organizations;
(c) eliminated the old system of federal funding by grants and replaced it with a system in which the Secretary of DHHS enters into biennial contracts with PROs;
(d) made it easier to terminate such contracts than it was to terminate PSRO grants;
(e) consolidated PSRO areas, such that the UQCPRO area would generally be a state unless the volume of activities (e.g., number of Medicaid plus Medicare admissions) or other factors warranted otherwise;
(f) improved the peer review organization’s ability to sanction physicians or hospitals that do not comply with the obligation to provide services economically, and only when such services are medically necessary, and only of a quality that meets professional standards;
(g) effectively eliminated state and national PSRO councils.

Ordered the Secretary of DHHS to disregard PSRO evaluations for the first two quarters of FY82 as a means of allowing PSROs to compete for PRO contracts on an equal footing with other bidders in the area.

Established prospective payment system (PPS) for Medicare hospitalizations based on diagnosis-related groups (DRGs), thereby replacing the retrospective cost reimbursement system and other funding provisions enacted under TEFRA.
Required that by October 1983 PPS hospitals must contract for review services with a PRO if one exists in the area and that by October 1984 hospitals must have such a contract as a condition for continued Medicare reimbursement.
Table 1 (continued)

Specified that PRO functions shall include reviewing:
(a) validity of diagnostic information provided by hospitals;
(b) completeness, adequacy, and quality of care provided;
(c) appropriateness of admissions and discharges;
(d) appropriateness of care for which "outlier" (essentially, out-of-DRG-range) payments are made.

Provided that the PRO be paid directly for review on the basis of a rate per review determined by the Secretary; all funding is to come from the Trust Funds (and none from direct appropriations).

1983. PSRO Transmittal No. 105

Provided detailed instructions on performing Admission Pattern Monitoring (APM). This included requirements for designating hospitals as anomalies (hospitals that appear to have abnormal patterns or numbers of discharges or average lengths of stay relative to a rolling baseline period), according to specific formulas and a test statistic that gives the probability that a given observation (i.e., hospital discharge rate) is not an "outlier" relative to previous observations.

Also specified were steps PSROs would take to carry out and report on APM activities (Level I and Level II analyses).

1984. PSRO Transmittal No. 107

Provided detailed instructions on how PSROs were to conduct various types of admission review, validate DRG assignments, select samples of cases for review, report in detail on medical review activities, etc.

Specifically required reviews include the following:
(a) admission review for all cases under review for any other reason, for a random 5 percent sample of admissions, and for any cases with certain principal diagnoses believed not to be indicative of a justified admission. Usually, if 2.5 percent of all admissions reviewed or three cases (in a calendar quarter) are found to be unnecessary, 100 percent of admissions are to be reviewed the following quarter.
(b) all transfers from PPS hospitals to various PPS-exempt units in acute hospitals (psychiatric, rehabilitation, alcohol/drug treatment, and swing beds) and all transfers from PPS hospitals to any other (PPS or non-PPS) hospital.
(c) all cases involving subsequent admissions to any acute hospital within 7 days of discharge from a PPS hospital, with more intensive review of those cases where the two confinements are related (medical record review to determine if the patient was prematurely discharged and institution of quality-review studies in hospitals where a problem is identified).
program evaluations came to rest almost exclusively on quantitative cost-control measures.

Over the years, PSROs took on a variety of activities: direct UR of hospital admissions and lengths of stay, Medical Care Evaluation (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 state-wide 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.

Eventually, 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., Part A of 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.3

Evaluations of the PSRO Program

A number of program-wide evaluations were conducted over the years.4 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 hospital stays and costs of federal health programs.

The evaluations are, in the aggregate, somewhat contradictory and incomplete. Both the HCFA and CBO evaluations agreed that PSROs saved about 2 to 2.5 percent of days of care per 1000 Medicare beneficiaries. They disagreed over how to value these days in benefit/cost calculations. When viewed from the perspective of just the Medicare program, the program clearly saved more money than it cost to run; when viewed from the perspective of society as a whole, the cost savings were more questionable (Dr. Mark Chassin, personal communication). In general, one can conclude 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. In contrast, the 1979 PSRO Program Evaluation, conducted "in-house" by the Health Care Financing Administration (HCFA, 1980) was a landmark effort that went considerably beyond

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3In 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 (see Table 1)), although whether such program oscillations delayed full implementation remains an open question.


Evaluations of individual PSROs for refunding of grants were 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 program-wide evaluation for any particular year or funding cycle.
earlier efforts to assess quality-of-care programs. It was the first attempt to summarize quality-assurance efforts across the nation in a wide variety of clinical areas into a quantifiable impact measure (Dr. Mark Chassin, personal communication).

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-$1000, 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) also 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 patients 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 1981–82 survey documented similar accomplishments. These included lowering the complication rate from primary Cesarean 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 5100 patients) be considered for elimination from the Medicare and Medicaid program because "quality of care did not meet professionally recognized standards." Reductions in inappropriate laboratory (or "routine") tests and use of single-unit blood transfusions affected tens of thousands of patients.

Despite these cited improvements, it is difficult to conclude anything definitive 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, until the 1979 HCFA evaluation, federal agencies paid little attention to evaluating the quality-assurance functions of PSROs, so the body of evidence is slim.

On the other hand, no evidence suggests the PSRO program was harmful, and as noted above both anecdotal reports and positive conclusions of the 1979 evaluation tend to confirm that various individual efforts were effective. What remains poorly understood is whether the benefits generated by the program in the quality area outweighed the costs.

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 (see Table 1) 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.
III. THE MOVEMENT TO PEER REVIEW ORGANIZATIONS

CONTRACTION OF THE PSRO PROGRAM

Political Environment

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 Medicare Trust Fund) was climbing. Simultaneously, enthusiasm for stringent fiscal restraint burst upon the nation. By mid-year 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. In the interregnum between PSROs and PROs, Medicare fiscal intermediaries would perform medical review in areas not covered by a PSRO.

In the spring of 1981, HCFA had 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.

Performance Evaluations

The 1981 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): (a) organization and program management (300); (b) process of review (850); (c) and impact or potential impact of review (1200). 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 in any full PSRO evaluation. The components of this evaluation tool are important, however, for two reasons: First, they reflect a growing sophistication in the thinking behind evaluating any such public program. Second, they figure in procedures for evaluating and awarding PRO contracts (see below).

Essentially the same three areas as in the 1981 ranking were considered, but the weights given to the three areas changed. More emphasis was placed on impact, less on organization and review operations (percentage of total possible points in parentheses): (a) organization and program management (8 vs. 13 percent); (b) compliance and process of review (24 vs. 36 percent); and (c) impact and potential impact (68 vs. 51 percent). About 10 percent of the new score for compliance and process dealt with quality-review studies; about 33 percent of the new impact score dealt with “resolution of important patient care problems.”

Regarding the quality-assurance “compliance and process” dimension, the evaluation was to indicate whether the PSRO had met or not met a series of specifications relating to 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. This was eventually codified into a “Severity Index” for PRO quality activities with the following numerical ratings: loss of life, 10; permanent loss of a major physical function, 7; unnecessary surgery or other invasive procedures or postoperative or other complications that do not cause death or permanent loss of function, 5; underutilization of services with significant potential for causing serious patient complications, 3; and other problems, 0.

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 went rather beyond both the “variation rate” approach of the earlier
HCFA evaluation and the "minimum achievements" of the first national ranking.

THE NEW LEGISLATIVE DIRECTIONS

Starting in 1980, a series of legislative bills with major provisions that would reshape PSROs began to be enacted (see Table 1). Although some have not yet taken complete effect (as of summer 1984), they will fundamentally change the nature, scope, and duties of peer review organizations. The impact on the quality-assurance aspect of their mission is likely to be considerable.

The Budget Reconciliation Act and TEFRA

The Omnibus Budget Reconciliation Act of 1981 (P.L. 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, or TEFRA (P.L. 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 (see Table 1).

For one, TEFRA markedly expanded eligibility for participation in PROs by for-profit groups and fiscal intermediaries. This diluted the influence of practicing physicians in the operation of the new organizations, although in the first years physician organizations were to be given priority over nonphysician ones in PRO competitions. For another, it created different funding arrangements (PRO contracts rather than PSRO grants) that made it even easier to terminate inefficient organizations. For a third, to be awarded such contracts, potential PROs must specify objectives to be achieved over the contract period (two years), and the organization’s performance will be assessed in terms of those objectives. These points are elaborated below in the description of the PRO program.
Prospective Payment in the Social Security Amendments of 1983

As a response to continued escalation of medical service costs in the public sector, especially Medicare, Title VI of P.L. 98–21 (the Social Security Amendments of 1983) established a prospective payment system (PPS) for Medicare that went into effect October 1983. Hospital payments were hereafter to be based on the costs of treating patients classified into 468 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. PPS applies to all Medicare participating hospitals except special ones such as psychiatric, rehabilitation, and long-term-care hospitals (or similar units in acute care hospitals), except those in so-called waiver states (New Jersey, New York, Maryland, and Massachusetts) or exempted areas (Virgin Islands, Puerto Rico, Guam, American Samoa), and certain other hospitals designated by the Secretary of DHHS.

P.L. 98–21 was historic legislation. Iglehart (1983, p. 1428) 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." Lohr and Marquis (1984) cite a number of articles and documents that explore problems and options for Medicare in the PPS age.

The PRO Program

The PRO program, which is assigned the peer review responsibilities for Medicare, acquired some tasks not hitherto considered as explicit parts of a peer review or quality-assurance effort. Required activities are outlined in Table 2, but the main departures from the PSRO program occur in two areas.

First, the PRO is to review the validity of diagnostic and procedure information provided by the hospitals in its area. This may prove to be a critical, yet very difficult, assignment: critical because accurate designation of hospital case mix by DRGs is crucial for adequate, but not excessive, prospective funding, and difficult because of the problems associated with validating "true" diagnoses on a broad range of patients in other than a sparse sampling framework.¹

¹Diagnostic accuracy had always been a concern as regards data submitted by PSROs to the federal government through the PSRO 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, p. 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.
Table 2
SELECTED ACTIVITIES REQUIRED OF PROS

I. Selected Admission Objectives and Required Activitiesa

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<td>A.</td>
<td>Reduce admissions for procedures that could be performed effectively and safely in an ambulatory surgical setting or on an outpatient basis.</td>
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<td>B.</td>
<td>Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific DRGs.</td>
</tr>
<tr>
<td>C.</td>
<td>Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.</td>
</tr>
<tr>
<td>D.</td>
<td>Review (before admission or before procedure) every elective case for five procedure-related DRGs (from a state-specific list of the top 20 procedures or procedure-specific DRGs for 1982).</td>
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<tr>
<td>E.</td>
<td>Review admissions occurring within seven days of a discharge and deny all claims for inappropriate admissions.</td>
</tr>
<tr>
<td>F.</td>
<td>Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary.</td>
</tr>
<tr>
<td>G.</td>
<td>Review transfers from a PPS hospital to other hospitals or to specific PPS-exempt special units or swing beds.</td>
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<td>H.</td>
<td>Perform Admission Pattern Monitoring.</td>
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II. Quality Objectives

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<tr>
<td>A.</td>
<td>Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission.</td>
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<tr>
<td>B.</td>
<td>Assure the provision of medical services which, when not performed, have &quot;significant potential&quot; (occurrence in 5 percent or more of cases) for causing &quot;serious patient complications&quot; (as in the PSRO evaluation criteria noted earlier).</td>
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<tr>
<td>C.</td>
<td>Reduce avoidable deaths.</td>
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<tr>
<td>D.</td>
<td>Reduce unnecessary surgery or other invasive procedures.</td>
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<td>E.</td>
<td>Reduce avoidable postoperative or other complications.</td>
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III. Other Required Activities

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<td>A.</td>
<td>DRG validation.</td>
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<tr>
<td>B.</td>
<td>Review every case involving day and/or cost outliers for necessity and appropriateness of admission and subsequent care.</td>
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aSee Table 1 for details on the PSRO Transmittals related to these PRO activities.
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. 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 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 reducing such overuse and lowering medical care expenditures. Coupling quality assurance with protection against underservice may thus prove to be a significant development of the PRO program.2

The PRO program has not been speedily implemented, given that it was brought into being by TEFRA in 1982. A number of persons testifying before the Senate Subcommittee on Health in February, 1984 (see Committee on Finance, 1984) alluded to delays already experienced and expressed concern that the October 1984 deadline for hospitals to have PRO contracts in force could not be met. Final regulations to specify area designations and define eligible organizations were published in the February 27, 1984, Federal Register; this followed a good deal of public comment about certain provisions. For example, the regulations came to specify that a “physician-sponsored” organization must be composed of at least 10 percent of the physicians in the area; if it is composed of 20 percent, it will be considered “representative.”

2The concern with underservice had been put early on (and forcefully) 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 underserve 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 1985 or 1984 if he completely dismantles them in 1981” (p. 258). Her fears have been echoed by many observers since that time. For instance, in commenting on the draft PRO Scope of Work, the American Hospital Association asserted that PRO objectives would be based on dollar targets, not medical needs of beneficiaries, resulting in “. . . a rationing of care . . . [and] thereby increasing the probability that medically appropriate cases will be denied by the PRO and jeopardizing essential services for Medicare beneficiaries . . .” (Committee on Finance, 1984, p. 119). That HCFA gave some recognition to the problem is evidenced by the requirement that PROs pursue one quality objective focused on “. . . assuring the provision of medical services which, when not performed, have significant potential for causing serious patient complications.”
The Request for Proposal (RFP No. HCFA-84-015) for the program appeared February 29, and proposals were due April 30, 1984. Negotiations and resubmissions continued throughout the summer, and of this writing about 32 of 47 contracts had been signed. Meanwhile, the deadline by which hospitals must have a signed PRO contract was extended to mid-November 1984.

How PROs are to be evaluated is not entirely clear in public documents. The draft Scope of Work for PRO contracts specified (in September, 1983) that the evaluation involve a "cost-benefit" calculation based on accomplishments in admissions review, DRG validation, and review of "outliers" (cases that go beyond pre-established lengths of stay or costs). In addition, the cost-benefit evaluation was to include an "admissions factor." This was 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 how achievements in this arena were to be incorporated into the overall evaluation methodology remained unspecified. Some of these evaluation provisions were sharply criticized in Senate hearings (Committee on Finance, 1984), because they appeared to downplay the quality-assurance component significantly.

The final performance evaluation provisions (RFP No. HCFA-84-015) call simply for (a) a cost-benefit calculation for areas where actual dollar benefits can be calculated (namely, admission review, DRG validation, and outlier review), (b) measures of changes in behavior (basically those related to hospital admissions), and (c) meeting objectives or responsibilities in quality of care, sanctions, fraud, and abuse, and other areas for which no monetary benefit can be applied. Quality impact is to be measured as "the reduction between baseline period and contract evaluation in the product of the number of patients affected by the problem times the severity of the problem" (as severity was defined above). HCFA's methods for making the before/after comparisons in admissions rates were to be made available to the contractors at a later time.

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3Designated PRO areas number 54: all 50 states, the District of Columbia, Puerto Rico, Virgin Islands, and a combined area of Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands (see Federal Register, 1984). As noted above, however, seven of these areas are not covered directly by the PPS Medicare legislation; they were not included in the main PRO solicitation but rather were given a separate solicitation somewhat later in the spring of 1984.
IV. 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 report will grow in prominence or funding, at least not in the public sector. Greater attention to quality of medical care may arise as concerns with underservice increase, but except in this guise, quality assurance is not likely to be a prominent effort of the PRO program. This may reflect, as much as anything, a shift in public sector programs toward finding a floor beneath which quality of care to beneficiaries should not fall, and away from attempting to ensure the highest possible quality of care.

PROs will have more immediate tasks than quality assurance. They must focus on investigating the validity of diagnostic and procedure 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. Moreover, it seems 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. Cutbacks in federal funding for Medicaid review would have the same constraining effect on quality-assurance activities for that program.

"Local peer review," as practiced in the EMCHO 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. Local physician leaders may be reluctant 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. Conversely, physicians may increase their participation in (or at least support of) PROs to preserve what control and influence they have left to prevent nonphysician entities from becoming PROs in the future (a point stressed to us by Dr. Mark Chassin).

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 earlier peer review organizations. Requirements about the proportion of physicians in an area that must belong to the PRO for it to be accepted for a federal contract were considerably relaxed relative to the PSRO program. For example, it was originally proposed that a physician-sponsored PRO need be composed of no more than 5 percent of the licensed physicians practicing in the PRO area; public comment was sufficiently negative that the final regulations raised the figure to 10 percent (Federal Register, 1984). Moreover, possible competition for PRO contracts from for-profit groups and fiscal intermediaries, which have different (lower) requirements for physician participation, may further dampen enthusiasm for and dedication to peer review among those of the medical community who have spent years in the quality-assurance arena.

Finally, 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 some members of the medical community because they are seen as infringing on physicians' response to local needs and objectives. The utility or desirability of national standards has come to be viewed less negatively, however, in some quarters.

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. For instance, the methods for doing quality assessment and assurance improved greatly, as did the techniques for systematically evaluating quality-assurance organizations.

Perhaps the most significant achievement was a dramatic change in the attitudes of the medical community during the 1970s. We saw 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. By the 1980s, the average physician had come to accept the idea that length of stay review, medical record audit, and other peer review activities were here to stay. 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 re-emergence of quality assurance as a significant national priority in its own right.
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