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The 19th anniversary meeting will take place in San Francisco, March 21–23.

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CORRECTION

Book Review of *Neurologic Disorders of Ambulatory Patients: Diagnosis and management* (January 25, 1990; 322:277). The name of the book's author was given incorrectly. The correct name is John H. Wagner, Jr. We regret the error.

SPECIAL REPORT

A STRATEGY FOR QUALITY ASSURANCE IN MEDICARE

THE Institute of Medicine of the National Academy of Sciences has just released a report on quality assurance for the Medicare program.[1] The legislation authorizing the study called for an ambitious and far-reaching strategic plan for assessing and ensuring the quality of medical care for elderly people during the next decade. The deliberations and fact finding of the study's 17-member committee included the review of commissioned and staff-produced papers, public hearings, panels, site visits, focus groups, and many meetings.

The resulting report indicates that although the current quality of medical care for Medicare enrollees is not bad, it could be improved; that the current system to assess and ensure quality is in general not very effective and may have serious unintended consequences; and that exciting opportunities are now emerging to set in place a comprehensive system of quality assurance that can address itself to improving the health of elderly people.

MAJOR FINDINGS AND CONCLUSIONS OF THE STUDY

What does it mean to say that one will ensure the quality of care? Believing that any quality-assurance program for Medicare should be guided, first of all, by a clear definition of quality of care, the study committee defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition is similar to those offered by groups as diverse as the Joint Commission on Accreditation of Healthcare Organizations[2] and the congressional Office of Technology Assessment.[3] However, it refers broadly to health services, not just to patient or medical care, and it focuses on both individual patients and larger groups comprising those who seek and use health services and those who do not. A critical aspect of the definition is its emphasis on outcomes of care that are desired by patients, with a crucial assumption that patients will be informed and will share appropriately with their physicians in decision making about their care. Finally, with its emphasis on health services that are consistent with current professional knowledge, this definition highlights traditional notions of continuous professional growth and evaluation for physicians and other clinical practitioners.

What important factors about elderly people should a quality-assurance program take into account? It is not news, of course, that the population of elderly people in this nation is growing (both in absolute numbers and as a proportion of the entire population) and graying (as the average number of years lived after the age of 65 rises). An increasing number of elderly people live with chronic illness and disabling conditions. All these factors suggest that demands for well-coordinated, highly technical, and compassionate supportive care will increase in the next decade. What is not clear is whether the nation and the professional communities will be able to provide it.

Near-universal coverage by the Medicare program gives elderly people better access to health care than any other age group. Nevertheless, gaps in coverage and financial barriers do exist and affect quality adversely, as many of those giving testimony to the com-

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mittee attested. Furthermore, health care costs continue to rise independently of increasing demand or the per capita use of services.[4,5] With the spiraling expenditures come ever-stronger pressures for cost containment and calls for the rationing of health care,[6] perhaps on the basis of age.[7] The reform of physician-payment mechanisms[8] may presage considerable shifts in the types of care available to elderly people, even as the use of inpatient hospital care remains at lower levels than a decade ago and as the use of other sites of care, such as outpatient and long-term care facilities and home settings, continues to expand. These financial and organizational factors, whose directions over the coming decade are not entirely predictable, pose threats to the quality of health care. In our judgment, a successful quality-assurance program for Medicare will have to be able to respond flexibly to them.

What are the problems a quality-assurance program should address? Poor quality of care can be categorized in terms of the overuse of health services, the underuse of services, and poor technical or interpersonal performance. Evidence of overuse, especially of procedures and certain types of medications, such as psychotropic drugs, is substantial. For example, in a review of almost 5000 hospital records of Medicare patients, 17 percent of coronary-angiography procedures and 32 percent of carotid endarterectomies were judged to be inappropriate, and an additional 9 and 32 percent, respectively, were judged to have been performed for indications that were equivocal.[9,10] Many physicians with whom the Institute of Medicine committee spoke recognized overuse as a prevalent problem.

Underuse is harder to detect under existing surveillance systems but is widely believed to be considerable, especially for certain groups of elderly people (for instance, those who are poor or whose access to care is poor because of geography) and for certain poorly covered services, especially long-term care. Background papers for the Institute of Medicine study[1] reported the substantial underdiagnosis of conditions such as treatable incontinence, curable infections, gait disorders, metabolic disorders, and psychiatric problems, especially depression. Examples of underuse included the underprovision of rehabilitation services and of home care nursing services.

Many diverse examples of poor performance have been documented and were mentioned to the study committee and staff during extensive site visits. For instance, one study of hospital mortality found that 14 percent of deaths were probably or definitely preventable, and explanations included errors in diagnosis and management.[11] Antibiotics were also widely misused according to one community-hospital study, in which only 72 percent of therapeutic uses and 36 percent of prophylactic uses were found to be appropriate.[12]

We cannot say that any one of these three aspects of poor quality of care is most important. Different problems are evidently more or less important according to the setting in which care is rendered and whether reimbursement is through a fee-for-service system or a prepaid system of capitation. Again, quality-assurance programs must be able to detect and respond appropriately to very different types of problems, in many different settings of care, and for various types of practitioners.

Various pieces of evidence suggest that a small number of outlier (very poor or aberrant) practitioners and providers account for a large proportion of the very serious problems in quality; they occupy what can be called the tail of the quality distribution. For example, at a public hearing a representative of the Medicare peer-review organization (PRO) in California estimated that perhaps 6 to 8 percent of the state's 50,000 physicians had serious, recurring problems in quality. The medical director of a PRO in another state reported that about 5 percent of the practicing physicians in that state accounted for 95 percent of the identified problems in quality. More than a decade ago, the California Medical Insurance Feasibility Study reported an "injury rate" of 4.65 per 100 hospitalizations, of which 17 percent were due to negligence.[13]

Average, everyday practice — the large central portion of that quality distribution — is not, however, immune from deficiencies in quality. A successful quality-assurance program cannot focus on only one part of this distribution. It must be able to detect and correct, if not prevent, problems in quality among outliers at the same time as it seeks to improve average practice — a task some refer to as shifting the curve upward to better performance. External regulatory mechanisms may be needed to address the outlier problems; educational efforts based on better data about peer practices and patient outcomes may be preferable in shifting the curve. The Medicare quality-assurance program must be able to support both regulatory and educational efforts.

Instances of truly superior care make up the other tail of the quality distribution. In the rush to attend to deficiencies, quality-assurance programs often ignore the exemplary practitioners and institutions, thereby losing an important opportunity to highlight and reward outstanding models of high-quality care.

What is Medicare doing now to ensure the quality of care for elderly people, and how successful are those activities? The PRO program is Medicare's existing effort to address many potential or real problems in the care of elderly people. Congress created the program in 1982, essentially as a replacement for the professional standards review organizations (PSROs).[14] The PROs have had major responsibilities for monitoring the implementation of the Medicare prospective-payment system since its inception in 1983, and Congress has added many other assignments to the PRO agenda in the intervening years.

The statewide PROs, which are overwhelmingly nonprofit, physician-based organizations, constitute a

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potentially valuable infrastructure for quality assurance. Many have an institutional history dating to the PSRO program and earlier. They have a committed and experienced cadre of physicians, nurses, administrators, and technicians with considerable understanding of the tasks that need to be accomplished in quality assurance. They are also gaining an experience in the use of computers and data analysis that did not exist a decade ago.

The present configuration of the PRO program, however, has several limitations, evidenced in published reports and in many comments heard by committee members during public testimony and site visits. An important drawback is that the PROs still appear to give primary attention to control of utilization and to aspects of the implementation of prospective payment rather than to quality of care. Whether this is true is a matter of debate, but the belief that it is continues to prejudice the acceptance of PROs by physicians and hospitals. Many commentators perceive the PROs to be adversarial and punitive and to impose excessive burdens on providers. Others believe that despite their intrusive and regulatory characteristics the PROs have little real influence on quality of care.

The focus of the PROs is on individual events and, often, outliers rather than on episodes of care or average practice, and their attention remains mostly on hospital care. Although the PROs require many programs of corrective action for physicians and hospitals with poor records, the sanctioning process for more serious problems seems to be largely ineffective. The PROs are constrained (sometimes in counterproductive ways) by regulatory and legal systems, and they have no ability to spotlight exemplary performance.

Debate over the sanctioning process has been acrimonious. Among the issues are whether PROs have to demonstrate that physicians are "unwilling and unable" to correct unacceptable practices, the wording and timing of so-called "quality denials" for substandard care and the notification of patients about such denials, and the use of monetary penalties instead of exclusions from the Medicare program. Some of these issues (such as matters concerning the quality denials) appear to have been settled by the recent Omnibus Budget Reconciliation Act of 1989, but others linger as irritants to both practicing providers and the PROs.

It was the committee's strong impression that interventions attempted by the PROs to remedy severe problems in quality were for the most part unsuccessful. Although the PROs institute many thousands of lesser interventions — such as notifying physicians or hospitals of possible problems or requiring various forms of continuing medical education or mandatory consultation with specialists — they have recommended relatively few full-sanction proceedings. The Health Care Financing Administration reports having forwarded little more than 100 recommendations for sanctions to the Office of Inspector General in recent years; more telling is that by one count only 8 of 18 sanction cases that reached the level of an administrative-law judge were upheld in favor of the Medicare PRO program.

Some observers criticize the low level of public oversight and accountability of the PRO program. The program does not appear to follow recommended procedures of public administration (e.g., certain formal procedures for rule making) as much as some experts think desirable,[15] and there is little opportunity for patient or provider groups to have a useful and systematic role in program planning. The highly detailed contract specifications through which the program supports the statewide PROs seem to render them relatively inflexible and unable to address local or changing problems in quality, and individual PROs are evaluated on the basis of how well they meet rigid contract requirements, not how well they improve the quality of care. Finally, no one can say what effect the PROs have had on the quality of care in the nation as a whole because the program (unlike the PSRO program) has not been formally evaluated in that or any other area.

What concepts and practical tools might best serve a quality-assurance effort for Medicare? The complex factors outlined above imply that no single approach or conceptual framework is likely to suit all purposes. The classic model of structure, process, and outcome expounded by Donabedian has guided quality-assurance efforts for almost a quarter-century.[16,17] It is a robust basis for the Medicare quality-assurance effort, but it has often been applied in ways that make quality assurance seem reactive, punitive, and excessively regulatory. For better than a decade, proponents of process-of-care measurement and advocates of outcomes measurement have engaged in a rather unproductive debate about the merits of their approaches. The consensus appears to be that successful quality assurance will always have to concern itself with both the processes of care and patient outcomes.

Newer models of continuous quality improvement emphasize internal, organization-based, professionally led efforts to improve many small processes of care in a ceaseless cycle of examination and change.[18,19] These approaches emphasize ongoing, prospective self-examination and professionalism, often focus on problems in systems of health care delivery rather than the problems of individual patients, and target average, everyday performance much more than the identification of outliers. Little experience is yet available, however, to indicate whether this will be a viable approach to tackling clinical quality-of-care problems. Nevertheless, different approaches to quality assurance may be necessary for different sites of care (e.g., the hospital, the home, or ambulatory care settings) and for different organizational structures, such as health maintenance organizations and fee-for-service practices. The continuous-improvement models deserve careful testing and experimentation.

What methods exist to detect problems in quality of care? Problems in quality can be detected through many

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mechanisms. For instance, large administrative or insurance-claims data bases may be used to create indicators of potentially poor outcomes (or sentinel events) and the provision of inappropriate services; small-area-variation analysis to determine differences in the use of services per person is another approach that uses such large data bases. At an institutional level, hospitals or large group practices may adopt systems that track indicators such as patterns of nosocomial infections or unusual occurrences according to physician, unit, shift, or service. In addition, physician and nurse reviewers can examine medical records retrospectively, against either explicit written criteria or implicit professional norms, to judge the quality of the process of care. Cases of problems in quality can also be uncovered by applying generic quality screens to patient records.

The criteria according to which quality of care can be judged or improved belong to at least three different classes. One type of criteria comprises guidelines for clinical practice, which are now a major focus of concern in the public and private sectors and among physicians.[20] A second type of criteria includes those that lay out ways to manage patient problems or to evaluate care that has been given for specific patient problems. These criteria can be fairly simple descriptions of good (or not so good) clinical care, or they can be very elaborate criteria maps and decision trees that attempt to cover many possible clinical factors.[21,22] A third type involves criteria used to find cases that appear to warrant further professional review. These different types of quality-of-care criteria have very different characteristics, and the study proposes some properties they should have if they are to be used as guidelines or yardsticks for acceptable quality of care.[1]

What methods exist to remedy problems in quality once they are detected? Approaches to correcting problems in quality can emphasize a considerable array of professional and educational activities, regulatory mechanisms (financial penalties or program exclusions, for instance) such as those employed by the Medicare PRO program, and indirect methods based on beliefs about competition and the forces of health care markets. No quality-assurance program can be successful without a mix of approaches, yet most programs to date lack a full spectrum of proven techniques for correcting identified problems in quality.

What broad problems challenge the nation's ability to make progress in quality of care? The present structure of our health care system does not have the capacity to achieve a comprehensive and maximally effective quality-assurance program, either for Medicare or for the nation more generally. Research is needed in several areas: basic methods of quality review and assurance, the application of techniques of quality assurance and continuous quality improvement, and the dissemination of information necessary for improving the performance of health care professionals. It will also be necessary to train professionals in research skills and in techniques of quality assurance and continuous improvement. In addition, patients and their families must be enabled to share more fully in decision making about their own health care.

Major Recommendations of the Study Committee

The committee recommended a number of steps for a strategy of quality review and assurance for Medicare. One called on Congress to expand the mission of Medicare to include an explicit responsibility for ensuring the quality of care of Medicare enrollees. Thus, any new Medicare quality-assurance program must give more attention to the processes of patient–practitioner interaction and decision making, to broad health and quality-of-life outcomes, and to patient satisfaction and well-being. Three goals for a Medicare quality-assurance program were stated: continuously improving the quality of health care for Medicare enrollees, strengthening the ability of health care organizations and practitioners to assess and improve their own performance, and identifying and overcoming systemic and policy barriers to good quality of care.

The committee's central recommendation was that Congress restructure the existing PRO program, redefine its functions, and implement a new program — the Medicare Program to Assure Quality, or MPAQ. Regardless of the criticisms that can be raised about the PROs, the committee generally believed that an abrupt end to or shift away from the complex existing program, with its historical ties to earlier Medicare peer-review efforts, was neither desirable nor feasible; the MPAQ would therefore build on the present structures. It would, for instance, continue to use local (but not necessarily statewide) organizations like the PROs (now to be called Medicare Quality Review Organizations) for more systematic data collection, analysis, and feedback to providers and practitioners.

More important, the MPAQ would be explicitly oriented to quality of care, not to utilization or cost control. It would be charged to facilitate programs of quality improvement within provider organizations and physician practices through the dissemination of useful data, technical assistance, and other tactics. It would also attempt to make the Medicare Conditions of Participation for hospitals more consistent with and supportive of the overall federal quality-assurance effort.

The aim is a system of quality assurance that focuses on health care decision making and the health outcomes of Medicare beneficiaries, that enhances professional responsibility and capacity for improving care, that uses clinical practice as a source of information to improve quality, and that can be shown to improve the health of elderly people by attending to problems of overuse and underuse of services as well as poor technical quality. A more basic goal is to have a fully functioning program in place by the year 2000 (with many of its parts operating successfully well before then) that can respond flexibly to changing health care needs, health care delivery and financing mechanisms, and social realities. The committee's report describes in some detail potential approaches the

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MPAQ and its Medicare Quality Review Organizations may take, but it calls for implementation of the new program over a 10-year period, during which appropriate methods can be tested for all major settings and systems in which elderly patients receive care.

To address the concern about lack of public accountability and oversight, the committee advised that Congress establish two new advisory groups. The first is a quality-program advisory commission similar to the congressional commissions for Medicare prospective payment for hospitals and physician payment; it would oversee the activities of the MPAQ and report to Congress on them. The second, a national council on Medicare quality assurance, would advise the Department of Health and Human Services and would assist in the implementation, operation, and evaluation of the MPAQ. The committee also recommended that Congress authorize and appropriate the funds needed to implement its other recommendations — an amount roughly estimated to be twice the present investment in the PRO program. Then, to make the program more answerable to the public for the expenditure of public monies, the committee called for a periodic (e.g., every two years) report to Congress from the Secretary of the Department of Health and Human Services on the quality of care for Medicare beneficiaries and on the effectiveness of the MPAQ in meeting the program goals.

Issues for the Future

Many issues about quality of care and quality assurance remain to be considered. For instance, how good is the United States at delivering health care to its citizens and ensuring the quality of that care? Many in policy-making and professional circles severely criticize this nation's health care system and point to other countries, often Canada, as models for reform. These points are likely to be debated for some time, and they may accurately reflect the reality that we provide adequate health care for some but by no means all of our citizens. The criticism of quality assurance is not valid, however, because the United States (and its medical community) is the world leader. Although other countries have quality-assurance mechanisms in place, often imported from the United States, none approach the degree of sophistication or the acceptance and leadership by physicians that is apparent here.

The ambiguity of the relation of quality of care to access, costs, and use of services persists, and the appropriate relation between the review and management of utilization (on the one hand) and quality review and assurance (on the other) remains clouded. It is very difficult to distinguish between utilization review and management as mainly cost-cutting measures and as useful tools for quality assurance (for instance, if procedures requiring previous authorization curtail manifestly unnecessary surgery), and it is therefore difficult to determine what sorts of agencies should carry them out. We share the concern that assigning a quality-assurance program responsibility for controlling use and costs will undermine goals of quality of care, and we reiterate the committee's strong preference for making the major goals of the MPAQ those of quality assurance and improvement.

Assuming that the criticism of the PRO program has substance and that its difficulties are real, what is the threat to the success of the MPAQ in bottling new wine in old wineskins? In other words, is it sensible to start a new program with agents who are viewed today with a mixture of hostility and disdain, and is the committee's decision to emphasize transition rather than starting over a mistake? The MPAQ will be a far-reaching and complex program, and successful implementation will require every possible advantage. Our reading of the practical and political climate is that building on the history and strengths of the peer-review community, of which the PROs are the most visible manifestation, is a far more attractive proposition than trying to invent new entities to carry out the MPAQ mandate.

How can society know it is getting value for its investment in quality of care? In general, this country does not subject major social programs to much public oversight and accountability or systematic, quantitative evaluation. Should this public program be accountable to the public and be required to justify itself by demonstrating an effect on things as difficult to pin down as health outcomes and quality? We believe the answer to that question is yes; public oversight and accountability and rigorous evaluation are critical aspects of this effort.

What are the critical problems in quality the MPAQ should address? Despite considerable effort, the Institute of Medicine study was not able to say that particular problems, such as the overuse of procedures or hospital inpatient care, were more or less important than the underuse of, say, home health care, or that they were more or less important than, for example, poor diagnostic or therapeutic decision making on the part of office-based physicians. It seems clear that problems of all three sorts can be found, with differing degrees of frequency and severity, in all settings of care. This means that the nation must develop a better epidemiology of quality of care to guide the allocation of resources in quality assurance. The MPAQ is intended to capture information about clinical practice that can be used to develop this picture more fully, but efforts beyond Medicare and elderly people will be needed.

The growing enthusiasm for the models of continuous quality improvement should be of special interest and appeal to the community of practitioners. Their emphasis on self-examination and self-correction is in accord with traditional views about the learned professions, and their focus on systems of care made up of many small processes reflects a practitioner's daily activities more than do patient outcomes, which may be remote in time and place. Nevertheless, information about successful applications is scant; these approaches have yet to be shown capable of coping ade-

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quately with problems of the overuse of services, underuse of services, or poor technical or interpersonal skills. Moreover, the continuous-improvement programs are difficult and time-consuming to implement. They are very much oriented to complex organizations such as hospitals and prepaid group practices, and they do not lend themselves to quality assurance in the office of the average private practitioner.

What is the proper role of outcomes in measuring and improving quality of care? Little empirical research, let alone practical experience, gives confidence that patient outcomes can be the primary basis of a quality-assurance or continuous-improvement effort. Yet outcomes and outcomes management became the watchwords of the 1980s,[23,24] and they are likely to remain a dominant refrain in the 1990s. In short, outcomes are not a completely proved approach to quality assessment and assurance, but as the committee's definition of quality makes clear, they cannot and must not be ignored. We concur with the committee's effort to temper unbridled enthusiasm for outcomes with the practical appreciation that, for many aspects of monitoring and improving health care, the process of care is the key.

Regardless of the weight accorded processes or outcomes in quality assurance, it will be important to understand and acknowledge that patients differ in their preferences for types of health care and for the results they may reasonably expect from that care. The landmark work of Wennberg and his colleagues comparing surgery with watchful waiting in men with benign prostatic hypertrophy[25,26] is only the opening chapter, and many questions remain: How should physicians elicit patient preferences and take account of them in health care decision making? When the values and preferences of individual patients conflict with broader social values and preferences, which take precedence, and what is the role of the physician in this regard? Physicians face difficult choices in balancing their traditional obligations of beneficence (the duty to do good) and nonmaleficence (the duty to do no harm) with the more recently espoused rights of patient autonomy (the duty to respect the rights of patients to independent self-determination) and concerns about equity and distributive justice (the combined duty not to discriminate among people or groups on the basis of irrelevant characteristics and to distribute resources fairly, not capriciously or arbitrarily). We hope that these issues can be more fully addressed during the implementation of the MPAQ.

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