1977). The survey was done by private firms for the Social Security Administration.
3. *Theodosian Code*, C. Pharr, translator (Princeton Univ. Press, Princeton, N.J., 1952) 13.3.1–19, pp. 387–390. In late Roman law, some physicians and certain other professionals were exempt from public obligations, including paying taxes and military service. See also *Justinian's Digest* (Central Trust Co., Cincinnati, 1932), 27.6.2, vol. 3, p. 123; and 50.6.6, vol. 5, p. 235.
4. *Nottingham Eyre* (1329), folio 218 (Egerton manuscript No. 2811, British Museum). Also A. K. R. Kiralfy, *A Source Book of English Law* (Sweet and Maxwell, London, 1957), p. 184.
5. Stratton *v.* Swanlond, Year Book Hilary, 48 Edward III, plea 11, folio 6 (Hilary, 1374). Two related cases are Year Book Michelmas, 43 Edward III, plea 38, folio 33; and Year Book Trinity, 46 Edward III, plea 19, folio 19. All three are in C. H. S. Fifoot, *History and Sources of the Common Law, Tort and Contract* (Stevens, London, 1949), pp. 81–83. The corresponding plea roll is in A. K. R. Kiralfy, *A Source Book of English Law* (Sweet and Maxwell, London, 1957), pp. 187–188.
6. G. Clark, *History of the Royal College of Physicians of London* (Clarendon, Oxford, 1964), vol. 1, pp. 14–18. See also S. W. P. Holloway, *History* **49**, 299 (1964).
7. Privileges and Authority of Physicians in London, 4 Statutes at Large, 14 Henry VIII, chap. V, p. 155 (1522–23); An Act Touching the Corporation of the Physicians in London, 6 Statutes at Large, 1 Mary, chap. VI, pp. 15–17 (1553).
8. Dr. Bonham's Case, 8 Coke Rep. 114–121 (1610); College of Physicians Case, 2 Brownlow and Goldes. 256–266 (1609). See also 2 Brownlow 255–267 (1675); 128 Engl. Rep. 928–934 (1609). Bonham was sent to prison on 7 November 1606, but was out within a week. There was a second action against him in late 1608. For the Royal College's view, see G. Clark, *History of the Royal College of Physicians of London* (Clarendon, Oxford, 1964), vol. 1, pp. 208–214.
9. 8 Coke Rep. 119–120.
10. 8 Coke Rep. 118.
11. See generally S. E. Thorne, *Law Q. Rev.* **14**, 543 (1938); T. F. T. Plucknett, *Harvard Law Rev.* **40**, 30 (1926–27); J. W. Gough, *Fundamental Law in English Constitutional History* (Clarendon, Oxford, 1953), pp. 30–47.
12. An Act to Regulate the Quality of Practitioners in Medicine and Surgery, Statutes of United Kingdom, Great Britain, and Ireland, 22 Victoria, chap. XC, pp. 299–312 (1858); An Act to Amend the Medical Act (1858), Statutes of United Kingdom, Great Britain, and Ireland, 23 Victoria, chap. LXVI, pp. 259–262 (1860).
13. See generally R. H. Shyrock, *Medical Licensing in the United States, 1650–1965* (Johns Hopkins Press, Baltimore, 1969); R. C. Derbyshire, *Medical Licensure and Discipline in the United States* (Johns Hopkins Press, Baltimore, 1969), pp. 13–45.
14. T. M. Logan, *Trans. Am. Med. Assoc.* **23**, 46 (9 May 1872).
15. Minutes of House of Delegates, *J. Am. Med. Assoc.* **74**, 1319 (8 May 1920). See generally C. B. Chapman and J. M. Talmadge, *Pharos* **34**, 30 (1971).
16. Pratt *et al. v.* British Medical Association *et al.*, British Ruling Cases **9**, 982–1021 (1915).
17. United States *v.* American Medical Association *et al.*, 110 Fed. Rep. 2nd ser. 703–716 (1940). See also M. Fishbein, *A History of the American Medical Association* (Saunders, Philadelphia, 1947), pp. 534–550.
18. The AMA is today often severely criticized on the ground that its interest was not in improving the training of doctors, but was rather in preserving monopoly and discouraging competition by limiting the size and number of American medical schools. The criticism is easy to lodge, difficult to refute, and impossible to substantiate.
19. Plato, *The Statesman*, H. N. Fowler, Transl. (Heineman, London, 1967), pp. 147–157.
20. E. Freidson, *Profession of Medicine* (Harper & Row, New York, 1970), pp. 42–45.
21. Dissatisfaction with professional performance is inherent in a number of studies, many done by members of the profession: R. H. Brook, M. H. Berg, P. A. Schechter, *Ann. Int. Med.* **78**, 333 (1973); C. W. Eisele, V. N. Slee, R. G. Hoffmann, *ibid.* **44**, 144 (1956); H. M. Somers, *Milbank Mem. Fund Q.* **55**, 193 (1977); B. C. Payne, *J. Am. Med. Assoc.* **201**, 126 (1967); J. P. Bunker, B. A. Barnes, F. Mosteller, *Costs, Risks and Benefits of Surgery* (Oxford Univ. Press, New York, 1977); R. Stevens, *American Medicine and the Public Interest* (Yale Univ. Press, New Haven, Conn., 1971); O. L. Peterson, *J. Med. Educ.* **31**, 1 (1956); D. G. Warren, *J. Leg. Med.* **21**, 23 (1974).
22. E. W. H. Groves, *Br. Med. J.* **2**, 1008 (1908); E. A. Codman, *Surg. Gynecol. Obstet.* **18**, 491 (1914); H. R. Kuehn, *Bull. Am. Coll. Surg.* **58**, 7 (1973).
23. C. C. Havighurst, *Duke Law J.* (1975), pp. 1256–1263; J. O'Connell, *Ending Insult to Injury* (Univ. of Illinois Press, Urbana, 1975), pp. 97–111; American Bar Association, *1977 Report of the Commission on Medical Professional Liability* (American Bar Association, Chicago, 1977), pp. 99–100.
24. O. W. Holmes, *Common Law* (1881) (Harvard Univ. Press, Cambridge, Mass., 1963), p. 89.
25. The American Surgical Association took an important step in this direction in its "Statement on professional liability" [*N. Engl. J. Med.* **295**, 1292 (1976)].
26. J. D. Blum, P. M. Gertman, J. Rubinow, *PSROs and the Law* (Aspen Systems, Germantown, Pa., 1977), pp. 1–17.
27. 42 U.S. Code Annotated, No. 501, chap. 7, subchap. xi, 1301–1320, pp. 309–333 (public law 92-603) (1972); see also *Fed. Reg.* **38** (part 2), 34944–34951 (20 December 1973).
28. P. Caper, *N. Engl. J. Med.* **291**, 1136 (1974).
29. H. E. Simmons and J. R. Ball, *Univ. Toledo Law Rev.* **6**, 739 (1974), p. 763.
30. E. J. Levit, M. Sabshin, C. B. Mueller, *N. Engl. J. Med.* **290**, 529 (1974), p. 545.
31. The incidence of compensable injury is probably higher than it should be. Pocincki *et al.* estimated that such injury (due to negligence) occurs in about 2 percent of all hospital admissions, but that only 1 in 17 of those injured file claims {L. S. Pocinki, S. J. Dogger, B. P. Schwartz, in *Report of Secretary's Commission on Medical Malpractice* [DHEW (OS) report No. 73-89, Department of Health, Education, and Welfare, Washington, D.C., 1973], appendix, p. 50}. In a more recent study it was found that "potentially compensable events" occurred in 4.7 percent of admissions to the hospitals they studied, but that in only about a fifth of such events would claims have been successful [D. H. Mills, Ed., *Medical Insurance Feasability Study* (Sutter, San Francisco, 1977), pp. 96–105].
32. B. Bledstein, *The Culture of Professionalism* (Norton, New York, 1976), p. 334.
33. J. L. Berlant, *Professionalism and Monopoly* (Univ. of California Press, Berkeley, 1975), p. 307.
34. E. Freidson, *Doctoring Together* (Elsevier, New York, 1975), p. 249.

The Quality of Medical Care

Methods for assessing and monitoring the quality of care for research and for quality assurance programs.

Avedis Donabedian

We have granted the health professions access to the most secret and sensitive places in ourselves, and entrusted to them matters that touch on our well-being, happiness, and survival. In return, we have expected the professions to govern themselves so strictly that we need have no fear of exploitation or incompetence. The object of quality assessment is to determine how successful they have been in doing so; and the purpose of quality monitoring is to exercise constant surveillance so that departure from standards can be detected early and corrected. But, first, we must specify what it is that is being assessed and monitored.

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Definition of Criteria and Standards

For this article I shall assume that the object of assessment and monitoring is medical care itself, which is the interaction between the physician and his (or her) client. This interaction is itself divisible into two domains. One is that of technical performance. Here, the heart of the matter is the application of medical knowledge and technology in a manner that maximizes its benefits and minimizes its risks, taking account of the preferences of each patient. The other domain is the management of the personal relationship with the patient in a manner that conforms to ethical requirements, social conventions, and the legitimate expectations and needs of the patient.

For purposes of assessment the definition of quality must be made precise and operative in the form of specific criteria and standards. Here one encounters a fundamental problem. If quality consists in a precise adjustment of care to the particular requirements of each case, is it possible to formulate detailed specifica-

0036-8075/78/0526-0856$02.00/0

Summary. This article classifies the major approaches to the assessment of the process and outcomes of medical care. The apparent need to safeguard and enhance the quality of care has led to the institution of mechanisms that subject care to constant review so that deficiencies may be found and corrected. The article reviews the developments that led to the involvement of the federal government in this activity through its sponsorship of professional standards review organizations (PSRO's). The major features of the PSRO's are described and their possible effects discussed. It is too early to say how the PSRO's will fare, but should they fail to accomplish their objectives the pressure for more radical solutions will be difficult to resist.

tions of what constitutes quality that apply to groups of cases? Most physicians would answer in the negative. They would insist that a definitive assessment of quality must be based on a knowledge of all the particulars in a case, so that an assessor recognized to have superior skill can reconstruct in his own mind the conduct of care that he would have recommended under the circumstances. Such assessments, which use what are called "implicit" criteria, are, of course, time-consuming and costly. They also tend to be unreliable unless performed by extremely competent and motivated physicians who are also skilled in doing assessments. Besides, the qualifications of any assessor may be challenged. For these reasons, those who propose to keep medical care under constant supervision have resorted to the formulation of "explicit criteria" that are supposed to represent at least acceptable practice (*1*). At one extreme, these criteria and standards represent what leading experts, using the best scientific evidence, consider to be the best practice. At the other extreme they may be derived from the average practice of physicians in a community. Obviously, the stringency and presumed validity of these two formulations would be expected to be very different and, in practice, an attempt may be made to accept something intermediate.

The issue of validity is particularly vexing, no matter what kind of criteria is used, because not everything in medical practice is universally accepted or fully substantiated by "scientific" evidence. This means that there is a wide margin of doubt about some of the criteria and standards in almost any formulation, and provides another reason why physicians resist being judged by criteria and standards other than their own. With preformulated explicit criteria there is the additional difficulty that the criteria cannot easily take account of the variability among different cases. This is handled by subclassifying cases into reasonably homogeneous classes and by dividing the criteria into two types that one might call "categorical" and "contingent." The categorical criteria are lists of procedures that must be performed in every case belonging to a class, or never performed in such cases (*2*). The contingent criteria are lists of procedures that should be performed, or may be performed, in some cases but not in others, depending on the nature and circumstances of the cases. A further refinement is to specify for each procedure the frequency with which it is expected to be performed in a "representative" sample of the cases in any given class (*3*).

Most students of the subject would agree that explicit criteria formulated in this manner are useful for identifying cases that are suspect because of noncompliance, and that the degree of compliance is a rough measure of quality. However, most physicians will insist that a definitive judgment in any given case cannot rest on compliance with criteria that are meant to apply to the "average case." It is still necessary to subject each case of questionable care to a judgment by expert physicians who are given all the relevant facts and expected to use not only the explicit criteria but also the much larger set of internalized implicit criteria which governs the care of individuals in all their complexity.

It follows that most systems for monitoring the quality of care employ a two-stage approach: one that identifies cases that do not conform to explicit criteria and another that submits these cases to detailed review by colleagues, that is, "peer review." Reviewers from outside may be used in addition to or instead of colleagues when the initial judgment is contested, when an outside agency has initial or supervisory responsibility, or when research is being done. This combination of initial screening followed by detailed review, either internal or external to the organization that provides care, meets the objectives of monitoring whenever there is the will and the ability to use it properly. It does not, however, fully meet the more rigorous requirements of a valid and reliable judgment on the quality of care. For that it is necessary to specify in detail the appropriate strategies of care as judged by their benefits, risks, and costs.

Approaches to Assessment

It may be inferred from the above that quality assessment is a judgment on the process of care provided by practitioners either individually or as a group. When direct information concerning the process of care is not available, or is incomplete, inferences may be drawn concerning "process" by examining either "structure" or "outcome" (*4*). By "structure" I mean the material and social instrumentalities that are used to provide care. These include the number, mix, and qualifications of the staff; the manner in which the staff is organized and governed; space, equipment, and other physical facilities; and so on. The assessment of structure is a judgment on whether care is being provided under conditions that are either conducive or inimical to the provision of good care. Since the relation between structure and process is poorly understood, inferences drawn from the former can be seriously challenged. There are stronger grounds for using "outcome" to indicate the quality of antecedent care.

The outcomes of care are primarily changes in health status that can be attributed to that care. A broader view includes changes in the health-related knowledge, attitudes, and behavior of the client (*5*). Health status can itself be viewed rather narrowly as physical or physiological function or, more broadly, to include psychological function and social performance (*6*). In fact, there is much current research into ways of combining all these elements into a single measure that not only reflects survival but also gives an indication of the quality of life (*7*). If successful, such measures would express the quality of care in terms of its contribution to the duration and quality of life. More precisely, the quality of care is proportional to the extent to which possible improvements in the quality of life are attained as a result of that care, with the assumption that cost is no object.

In recent years this formulation has gained a large following, and it has intensified the controversy between those who emphasize the assessment of process and those who swear by outcome. In my opinion this controversy arises from a misconception. Quality assessment is not clinical research which is designed to establish the relations between process and outcome. It is a judgment on the

process of care that uses what is already known about those relations, given the limits of current medical science. It is true that process elements can be used as indicators of quality only if there is a valid relation between these elements and desired outcomes. It is equally true that specific outcomes can be used as indicators of the quality of care only to the extent that there is a valid relation between the two. Thus, validity resides not in the choice of elements of process or outcome but in what is known about their relationship. If a valid relation exists, either may be used, depending on which can be more easily and accurately measured; it not, neither can be used.

Studies of the Quality of Care

Each study of quality can be categorized in so many ways, and the clusterings of attributes are so indistinct that it has been impossible to devise a satisfactory simple classification. In this article I ignore studies that rely mainly on evaluations of structure and use the classification given in Table 1 for the remainder. A brief review of selected studies drawn from this classification can illustrate and raise questions about specific methods of assessment, as well as provide information about some factors that influence performance. But, because some of these studies are old, and almost all have examined highly circumscribed situations, the only conclusion that can be drawn about levels of quality in general is that whenever the quality of care has been examined, serious and widespread deficiencies have been found. This may be a characteristic of all human endeavor—that is, if sufficiently strict standards are used we shall all be found to have failed in some degree. It is certainly so for the performance of physicians.

As to the prevailing levels of quality in the United States or elsewhere, we have to rely on gross measures of longevity, mortality, morbidity, the use and distribution of services, the frequency of surgical operations, and the like. But these phenomena, though important, are influenced by so many unexamined variables that it would be foolhardy to use them for confident assertions.

Studies of the Process of Care

The reputations of physicians among their colleagues arise to a large extent from the opportunities that they have to observe each other at work. The openness of practice to such observation is, in fact, a major safeguard, and a cogent argument in favor of organized forms of practice. It is interesting, therefore, to find the first important use of direct, formal observation with a view to assessing the quality of care in a study of rural general practice, that most isolated and secret corner of medicine-land (*8*). The method used was to have a qualified physician, with the permission of his host, observe the latter as he cared for patients who were making the first visit for a new illness. In this way it was possible for the observer to make a judgment about the completeness of the examination, the appropriateness of further investigation, and the suitability of treatment. As a result, 25 percent of practitioners were rated superior or good, whereas 44 percent were judged to be below an "average" or acceptable level. The better practitioners were more likely to be younger, to see patients by appointment, and to have access to laboratory services; but, above all, they were more likely to have had a period of training in internal medicine subsequent to graduation from medical school. All these are structural characteristics conducive to better care, though they do not assure it. Other studies using the same approach suggest that general practice in other countries may suffer from similar characteristics and handicaps (*9*).

That the observation of practice is a method with wider applicability is shown by a study of the interaction between nursing personnel and randomly sampled patients in selected hospitals in the Detroit area (*10*). More interesting than the levels of performance revealed were the findings suggestive of differences related to the characteristics of patients. Aspects of nursing care tended to be less satisfactory for nonwhites, for patients in wards with many beds, for those who had cancer with a poor prognosis, for younger females and for older males. Because of the nature of this study these findings cannot be accepted as conclusive, but they do illustrate a problem of great social significance: The extent to which the quality of care may differ according to the social or economic characteristics of clients either because the sources of care are different or because the same sources are guilty of discriminatory behavior.

The direct observation of practice is, of course, costly and time-consuming. It may also alter the behavior being observed, except that those who have used it say that very soon the presence of the observer is forgotten and the subject lapses into his usual routine. The analysis of medical records is less obtrusive and more easily subject to checking by several judges, but it suffers from the limitations in the completeness and veracity of the record, especially in office practice. This has led to criticism of this method for being an assessment of recording rather than of care. This has been countered by the argument that recording is an important element in care and that there is an association between the quality of recording and the quality of care (*11*).

The analysis of the record of care varies greatly in breadth and detail. At one extreme all that is sought is information about a small number of critical elements that are important in themselves and which may also be taken as representative of aspects of care that are not directly observed. These critical elements or indexes can be formulated so that they are applicable to all patients or to subgroups of patients characterized by age, sex, diagnosis, and the like. For example, in the records of office care one can look for the frequency with which blood pressures are measured; rectal and vaginal examinations are done; the eyegrounds and ears examined with the appropriate instruments; infants are immunized; children with sore throats have a throat culture for streptococci; pregnant women have their urine tested; sedatives, tranquilizers, and antibiotics are prescribed; and injections are given when the drugs could have been taken by mouth (*12*). Hospital records offer opportunities for the construction of much larger lists of such indicators with greater assurance that the necessary information is in the record (*13*). A favorite type of sleuthing is to locate reports of abnormal laboratory findings which physicians agree require attention, and to determine how often these go unnoticed, are ignored, or are dealt with inadequately. For example, in the general clinic of one university hospital about a fifth of such abnormalities were not followed up (*14*); and in one community hospital more than half of the abnormal findings were either ignored or inadequately handled (*15*). In general, when the results of investigations that attempt to characterize critical elements of practice are assembled, it is astounding how variable practice is found to be, and how often it seems to depart from standards of supposedly good care.

Developments in data acquisition and processing have stimulated the use of this approach to assessment and monitoring, and greatly amplified its usefulness. Data from records of ambulatory care, abstracts of hospital charts, and the

claims for payment that are submitted to insurance companies and government programs can all be fed into the computer to be rapidly processed and collated with other, prestored information about the patient, the practitioner, or the hospital and its subdivisions. In this way aberrations in practice can be identified, located, and subjected to more detailed scrutiny if their frequency or importance justifies it.

Besides being an instrument that may expose and embarrass the physician, the computer can also be a friend and ally. It is possible to develop a system of information that alerts the physician when some predetermined critical events have occurred so that he may intervene if he sees fit. Since inattention rather than ignorance appears to account for many "errors" in care, computer-aided management could be a major safeguard of the quality of care (*16*).

One step up in the progression from presumptive indicators of quality to more inclusive and definitive assessments of the quality of care is the justification of surgical intervention and of other major procedures. The justification of surgery can itself be arranged into a progression. Even before surgery occurs, the initial recommendation can be subjected to verification by one or more consultants, a procedure that is now required by several insurance plans (*16a*).

As to those already operated upon, two steps are available in the progression to more rigorous justification. The first is to determine whether the tissue removed is sufficiently diseased to justify its having been removed. The simplicity and usefulness of this procedure has made it standard practice in any well-run hospital. In part, its validity depends on the skill and integrity of the pathologist, who serves as the conscience of the hospital, holding as he does the mirror that reveals its failures. But no matter how expertly the tissue removed is judged, the justification of surgery cannot rest on this alone. The decision to operate depends on weighing the risks of operating unnecessarily against those of not operating when necessary; and the best judgment is likely to be attended by the removal of some normal tissue. Therefore, a definitive judgment on any operation must go an important step beyond the condition of the tissue removed and include additional circumstances of the case. Several of these issues are well illustrated in a comparison of appendectomies in the teaching and community hospitals of Baltimore (*17*). In the teaching hospitals, which presumably typify the best practice, about a third of the tissue removed was normal or not clearly diseased; and this proportion was the same whether the patients were on welfare or were private patients who paid for their own care either directly or through an insurance plan. In the community hospitals, the proportion of appendectomies with normal or near-normal tissue was higher, and it varied according to how the patient paid the hospital and physician. It was 40 percent for welfare patients, 42 percent for patients who paid for their own care, 50 percent for those who had insurance other than Blue Cross and 55 percent for those who had Blue Cross.

A more complete assessment of surgical and medical care is obtained by an elaboration of the critical indicators of care so that they blend into the longer diagnosis-specific lists of explicit criteria to which I have already referred. The percentage of compliance with these criteria, with equal or different weights attached to component items, can be used as a summary measure of the quality of care. A study of a sample of hospital cases in Hawaii which used this method is particularly notable since it provides a rare view of an important segment of care in a large population in its natural habitat. The overall performance score was 71 percent of what would have indicated perfect compliance with the criteria. Unfortunately, a frequency distribution of scores is not given, nor can we judge whether 71 percent is good, bad, or indifferent. An application of the same method to an admittedly biased sample of office care in Hawaii yielded a distinctly dismal score of 41 percent of full compliance, judging by the information in the record (*18*).

Table 1. A classification system for use in quality assessment.

I. Studies mainly of structure
II. Studies mainly of process
  A. Direct observation of practice
  B. Studies based on the medical record
    1. The presence or absence of selected critical elements of care
    2. Justification of surgery and other major procedures
    3. Audits using explicit criteria
    4. Audits using implicit criteria
III. Studies mainly of outcome
  A. Morbidity, disability, mortality, and longevity in communities and populations
  B. More refined measures of morbidity, disability, mortality, and longevity
    1. Preventable adverse events
    2. Preventable progression of disease
    3. Diagnosis-specific outcomes
    4. Postoperative mortality and morbidity
  C. Assignment of responsibility for adverse events
    1. With prior specification of expected outcomes
    2. Without prior specification of expected outcomes
IV. Studies that combine process and outcome to show system effects
  A. "Trajectories"
  B. "Tracers"
V. Evaluation of strategies
  A. Criteria maps
  B. Testing of strategies
    1. By modeling
    2. By clinical trials

In my opinion, a final judgment of the quality of care in each case cannot rest on compliance with explicit criteria alone. It must be based on a review of all the known facts by one or more experts who use the entire range of their own knowledge and experience to arrive at a judgment. An example in this tradition was the study of the quality of hospital care received by members of the Teamster's Union in New York City. Each of two eminent physicians was given the entire record of each case and asked to rate it using as a criterion how he himself would have managed the case. As a result, 43 percent of cases were judged to have received less than "optimal" medical care (*19*).

In both the Hawaii and the Teamster's studies some attention was given to finding out what factors are associated with the quality of care. By taking some liberties a composite picture may be drawn (*20*). The most important single factor associated with the quality of hospital care is the nature of the hospital itself. Care is best in large, urban, university-affiliated hospitals and worst in proprietary urban hospitals and other small hospitals, whether urban or rural. Physician specialization is also a factor, although its salutary influence is weaker, and is felt only when practice is confined to the area in which the physician has specialized. Once he steps outside his domain the specialist may do worse than the generalist. The importance of the hospital in safeguarding quality is most important for the generalist, while outside the best hospitals the specialization of the physicians is the important safeguard. Physicians in the larger group practices provide better hospital care, but this appears to be mainly due to the use of specialists by the groups. In office care, group practice has a small edge over solo practice, but the data are not reliable. Perhaps more important than all these associations is the observation that a large part of the variation in performance remains unexplained, which suggests that our measurements may be faulty and that there is much about the determinants of performance that we do not understand.

Studies of the Outcome of Care

The incidence and prevalence of illness and disability, the incidence of mortality, and measures of longevity are obvious indicators of the health of a population. But medical care makes only one rather small contribution among the many social and biological factors that determine such outcomes. Considerable refinement is needed to reveal the effects of the quality of care.

Outcomes can be made more sensitive and specific measures of the quality of care by careful selection so that they pertain to specific categories of patients, are preventable or attainable by good medical care, and are measured only after corrections are made for characteristics that influence the degree of success that even the best medical care can be expected to achieve. Recently, a large list of measures considered to be responsive to medical care have been offered as indicators of the quality of care in communities (*21*). It has also been suggested that the stage at which diseases first come under attention, or patients are admitted to the hospital for the first time, tells us something about how easy it is to gain access to care and how good that care is (*22*). It is also possible to specify for selected diagnoses and conditions the most useful outcomes to measure, when to measure these outcomes, and what patient characteristics to take into account so as to isolate the contribution of medical care to the selected outcomes. It is much more difficult to specify the extent to which variations in the quality of care will be reflected in these outcomes (*23*).

The study of postoperative mortality and morbidity can be taken to represent the class of more specific and refined studies of outcome. It has long been known that there are large differences in postoperative mortality among hospitals. In one notable instance a 25-fold difference was observed among 34 medical centers. Corrections for differences among medical centers in factors such as type of operation and the patients' age and physical status reduced the spread to a sevenfold difference in some operations and a threefold difference in others (*24*). So disturbing were these large and unexplained differences that another study was conducted in which every attempt was made to correct for patient characteristics that might have accounted for the differences observed. Real and significant differences remained, suggesting that the chances of experiencing serious complications or death following the same operations, in similar patients, can be two or three times as high in some hospitals as in others (*25*). I suspect that even these large differences do not tell the full story because it is not certain that in situations of high risk the benefits of operating are always higher than the risks.

When outcomes are used to monitor care in an institution or program, every major adverse event and a sampling of other "critical incidents" require careful analysis so that future performance can be improved (*26*). Physicians may become more aware of the consequences of their actions if they can be persuaded to specify ahead of time precisely what improvements in health they expect for patients in specified categories, so that their achievements can be compared with their expectations (*27*). But whether the expected outcomes are specified in advance or not there is no escape from the responsibility to review and assess the care itself. Such "retrospective" assessments can also be a primary research tool. Notable exemplars are the early studies of maternal and newborn mortality by the New York Academy of Medicine. In 1930 to 1932, 66 percent of deaths of women in childbirth were judged by a "conservative" estimate to be preventable, and of these 61 percent were ascribed to the physician because of errors in judgment or in technique (*28*). In 1950 to 1951, 42 percent of deaths in the newborn who were not premature were judged to be preventable; and in about 80 percent of preventable deaths there were errors of medical judgment or technique (*29*). In both studies the type of hospital and the qualifications of the attending physicians had an important bearing on outcome, which was life itself. These deeply disturbing findings resulted in the introduction of many controls, including regular reviews of all maternal and infant deaths, that have been credited with at least some of the remarkable improvements that have occurred since. But a recent review of trends in maternal mortality in Michigan from 1950 to 1970 shows that, in spite of spectacular declines in mortality, the percentage of deaths judged "preventable" has increased markedly from about 60 percent to about 80 percent (*30*). As standards of care are raised, perfection seems to become even more difficult to achieve.

Process and Outcome Combined

Two methods of assessing the quality of care can be put in a separate category because they are designed to dissect elements of a system that delivers care by means of a combination of process and outcome measures. The first, which may be called the "trajectory" method, selects one or more diseases or conditions, and follows patients from the time they come for care to some time after their care presumably ends. In this way it is possible to examine the successive steps in a progression that is, too often, a tragic odyssey of accumulated failures, and to document the final effect of this experience on the health of the patient. In one such study the originators of this approach found that of a group of patients who came to the emergency room of a city hospital with gastrointestinal symptoms 33 percent did not show for all recommended examinations, the examination was not adequately done in 12 percent, and in 15 percent there were abnormal findings that were not treated appropriately—all of which adds up to a failure rate of 60 percent. When the effects of treatment were taken into account, the patients' encounters with this particular institution were judged to have had a salutary effect in only 27 percent of cases (*31*).

If one begins with a mental map of the medical care system that subdivides the system into domains of function and responsibility, it is possible to select a number of diagnoses or conditions as indicators of the quality of care in each subpart. Each diagnosis or condition functions as a "tracer"; and the set of tracers can be considered to provide what is analogous to a set of carefully selected soundings of an unexplored terrain (*32*). This attractive notion has been tested partially by using as tracers the occurrence and the management of anemia, ear infection, hearing loss, and visual defects to assess medical care for children from 6 months to 11 years old in selected areas of Washington, D.C. From this exploration a dismal picture emerged of much unrecognized, preventable, and improperly treated pathology. For example, 12 percent of 4- to 11-year-old children need glasses but do not have them. Of those who have glasses 31 percent do not need them, 37 percent do not have adequate correction, and in 5 percent the glasses make vision worse rather than better (*33*).

Evaluation of Strategies of Care

Patient care is a planned activity that involves the choice of specific elements from a potentially large pool of such elements, and the proper sequencing of these elements in order to achieve specified diagnostic and treatment objectives.

A plan of action, as well as the pattern of actions that result, can be called a strategy. In my opinion, the essence of quality or, in other words, "clinical judgment," is in the choice of the most appropriate strategy for the management of any given situation. The alternative strategies that a physician might reasonably consider can be specified in the form of a decision tree which indicates alternative courses and their consequences. To each of these a probability can be assigned based, preferably, on demonstrated fact but, when this is not available, on expert opinion. The balance of expected benefits, risks, and monetary costs, as evaluated jointly by the physician and his patient, is the criterion for selecting the optimal strategy for that patient (*34*). The construction and use of models that incorporate existing knowledge can be very helpful in arriving at a more definitive specification of quality because the best course of action suggested by intuition may not be the best indicated by more formal decision analysis. Moreover, such models, by revealing critical deficiencies in existing knowledge, stimulate research so that, in the end, the specification of optimal management may be firmly established.

The results of such developments are beginning to be felt in the field of quality assessment. Perhaps the first step has been the construction of "criteria maps" as a substitute for the more usual lists of explicit criteria. Mapping represents a stepwise scheme of actions taken to make a diagnosis, search for complications, and select a mode of treatment and implement it. It recognizes that there are alternative acceptable ways of meeting each requirement (for example, of a valid diagnosis), and that succeeding actions are conditional on prior findings. Such criteria maps are now being used in quality assessment on a trial basis (*35*). The next step will be a linkup with the work that is now going on, independently of the activities of quality assessment, in modeling and testing strategies of care (*36*). The empirical testing of such strategies with careful clinical trials will, of course, provide the bedrock on which all quality assessment, in fact all of clinical medicine, must ultimately rest (*37*).

The Context for Monitoring

That the content of medical practice must be subjected to constant surveillance is an idea that has finally emerged as a principle supported by law. The ostensible purpose is "quality assurance," although this is perhaps too ambitious a goal, since "assistance" or "enhancement" is the most that can be hoped for. Of course, the quality of care depends on many factors, including the selection of students and their education, training, and socialization into young professionals; opportunities for continuing education and renewal; the availability of the instrumentalities and financing that permit the application of the full potential of medical science; and the professional and financial incentives that influence the behavior of physicians. The monitoring of the physician's work is meant to generate one additional incentive to appropriate performance.

Traditionally, the professions have been largely responsible for regulating their own conduct in the interest of higher standards, with government assuming a supportive and reinforcing role. In general, medicine has a proud record of achievement in this respect. But, in recent years, the feeling has grown that it should either do more or relinquish some of its prerogatives by accepting supervision from the outside. Many factors have contributed to this state of affairs. Most important has been the far-reaching change from individual to collective financing of health care through private health insurance programs. For many years, the private health insurance companies and organizations, as well as the representatives of the larger groups of purchasers of insurance, have been unhappy about the increase in the costs of care without assurance of the needfulness and the quality of the services received. However, there was little that they could do, or wished to do, beyond questioning the most obvious abuses. But when the federal government itself became the largest payer of all by instituting Medicaid and Medicare, there was the means and eventually the will to assert that he who pays the piper can call the tune. The sharpest goad to action was no doubt the enormous drain on the federal treasury; but there was also concern for the quality of care, and a need to establish accountability of the programs to Congress and of Congress to the electorate. And the electorate was now better informed and more demanding.

Antecedent to and parallel with these developments there were several others. First was the gradual concentration of a critical section of care in the hospital which emerged as a dominant center of organized practice. Second was the increasing recognition of the hospital's responsibility for the supervision of its physicians by the public, by hospital trustees, and by the courts (*38*). Third was the development, piece by piece, of the conceptual apparatus, the methods, and the technology of quality assessment and monitoring and their incorporation in several prototypes in actual practice (*39*). All these, working together, set the stage and provided the instruments and opportunity for a bold legislative initiative which was part of the 1972 amendments of the Social Security Act (*40*).

Professional Standards Review Organizations

The legislation provides for dividing the country into areas which may be states or parts of states in each of which a Professional Standards Review Organization (PSRO) must be set up. This is envisaged as a new organization endorsed by a majority of physicians in the area and open to all of them. Only when the local physicians are unable or unwilling to respond may other arrangements be approved. In addition, the legislation provides for statewide professional standards review councils and a National Professional Standards Review Council, with the Secretary of Health, Education, and Welfare at the apex of this organizational pyramid.

It is the responsibility of the local PSRO to begin by monitoring hospital and nursing home care provided under specified government programs, primarily Medicare and Medicaid; but later it must enlarge its scope to include ambulatory care as well. Such surveillance may be exercised directly by the PSRO, but it may also be delegated to individual hospitals who assume responsibility to review their own care, provided they are found capable of doing so. As a basis for these review activities the PSRO must formulate explicit criteria, norms, and standards that cannot differ significantly from their more widely applicable regional counterparts which are promulgated by the National Council, unless the differences can be justified.

A wide range of monitoring activities is envisaged for and required of the PSRO when it is fully operational. For example, either before admission or within a day of admission to the hospital a "coordinator" to whom this function is assigned, usually a nurse, must review the particulars of each case and determine whether the admission is justified or possibly not justified according to the criteria in force. If the latter is the case, a physician "adviser" must reassess the situation. If admission is found to be justified, the patient is assigned a specified number of days in the hospital based on approved standards that vary according

to diagnosis. If at the end of this period the patient is still in the hospital, the process of review is repeated and an extension approved or denied. At first, every admission must be subjected to such detailed review, but later, based on evidence of prior performance, some categories of cases may be exempted while attention focuses on others which are considered less likely to conform.

Besides watching over the appropriateness of admission and length of stay, the nurse and physician in charge of monitoring in each hospital are expected to review a sample of the records of hospital patients in order to determine whether the content of care conforms to the criteria and standards of the PSRO. In addition to these activities, the hospital or the PSRO must, at intervals, conduct detailed studies of important segments of care, for example of certain diseases or procedures, in order to detect and correct prevalent or localized weaknesses. Furthermore, the PSRO is charged with maintaining a statistical system for collecting information about aspects of the care of all patients under its jurisdiction and to compile tabulations (called "profiles") by patient, by physician, and by hospital so as to identify situations that deviate from usual or expected practice.

The legislation recognizes the vulnerability of practicing physicians to erroneous actions by the PSRO and makes provision to redress the balance. No observed deviation in practice is assumed to be an error, nor is any decision by a functionary of the PSRO considered to be final. In each instance, the physician may appeal to a committee of his peers that will hear him and examine all the details of a case before it passes a judgment. Even when it rules against the physician, the PSRO has no authority to prevent admission to the hospital or to compel the patient to leave. All it does is to refuse to certify the appropriateness of care, which usually means that the government will not pay for the care, or that the physician may have to return payment that has already been made. In unusual circumstances, for example if the physician is found to be repeatedly at fault, the PSRO may recommend temporary or permanent exclusion from reimbursement for the care of patients under its jurisdiction. But, depending in part on the nature of the ruling or penalty, the physician is protected against ill-considered or arbitrary actions by a variety of safeguards including due notice, hearings by the local PSRO, the statewide council and the Secretary of Health, Education, and Welfare and, ultimately, by an appeal to the courts. Besides, the jurisdiction of the PSRO is at present confined to inpatient care, and only to beneficiaries of specified government programs. Beyond these limits the physician may practice in the ordinary manner, except that the standards of the PSRO are likely to be adopted by other insurance programs to apply to their clients, and by the hospital to apply to all its patients. Under such conditions the physician could not escape their reach.

Implications of PSRO Legislation

Although bold in concept and awesome in scope, the PSRO legislation follows a traditional pattern in delegating the supervision of medical practice to the physicians themselves, with legitimacy and support provided by the government. It is also traditional in decentralizing the actual supervision of care so that it rests primarily with the local PSRO, with further delegation of many functions to the individual hospitals. Moreover, it accepts the system of medical care as it is, merely adding to it a mantle of surveillance, which is itself a consolidation of many preexisting elements, most of which were devised and put into operation by physicians and their professional organizations. But in spite of these familiar features, the PSRO's appear to have risen as Leviathan from the depths, casting a shadow across the medical landscape in whose darkness each may nurse his private fears.

Those who fear government control point out that never before has the federal government, or any government, set out to influence and control so pervasively and in such minute detail the most intimate operations of medical practice in this country. Their alarm is intensified by what they consider the unseemly haste with which the federal bureaucracy has begun implementing the legislation through grants, contracts, and instructions which appear to bypass the orderly process of formulating regulations. Nor are their fears assuaged by decentralization and delegation, for they see the reins ultimately gathered in the hands of the Secretary of Health, Education, and Welfare, who only has to pull them to impose his will (*41*).

Paradoxically, there are others who dream a different nightmare. According to these, the federal government has weakened the influence of state agencies on programs which they formerly controlled, and has handed over its own powers and responsibilities to an organization of local physicians that is bound to be controlled by the local medical societies, in spite of legislative provisions meant to avoid that outcome (*42*). Health professionals other than physicians are equally outraged by the all-physician membership of the PSRO and its seeming hegemony over all practice, including that of nonphysicians. And others, who distrust professionals of any stripe, vehemently protest the fact that consumers have virtually no influence over the PSRO, which they regard as one more instrument of professional dominance in the market for medical care (*43*). In fact, it is difficult to find anyone who has something good to say about the PSRO, least of all the practicing physician who must work under its unblinking eye.

The fear of being found wanting by the PSRO is only the beginning of the physician's woe. By law, the patient must be notified when a determination that affects him is made, and the physician is left with the task of placating a disgruntled patient who may be asked to pay the bill. Besides the irritation and embarrassment caused by such encounters, it is feared that they will contribute to the already high tide of malpractice suits (*44*). The vulnerability of the physician to being sued may be further increased if the criteria and standards used by the PSRO become generally known or if the PSRO is forced to divulge the performance profiles of physicians and hospitals under its sway. Against these fearsome eventualities it is small comfort that the legislation protects the physician against liability arising from his adherence to PSRO standards, provided in all else he has been blameless.

Knowing that the PSRO would stand up to every attack if it were to show promise of improving quality and containing costs, its critics have been most insistent in discounting these expectations (*45*). As to quality, the lists of explicit criteria that the PSRO's use to define quality have been attacked as dubiously valid in that they pay no attention to aspects of care beyond those that are purely technical, are insufficiently adaptable to variations among individual patients, are conducive to a stereotyped, unthinking form of "cookbook" medicine, inhibit innovation and progress, and divert attention from the outcomes of care in favor of emphasis on process. The PSRO's are, of course, aware of these criticisms which, they believe, do not reflect the more recent refinements in their criteria or the judicious flexibility with which they are applied. Nevertheless, some critics have argued that the university medical centers be excluded

from the jurisdiction of the PSRO in the interests of teaching, learning, and research (*46*). Others have asked that the health maintenance organizations be also excluded lest they be handicapped in their attempts to provide effective care at lower cost by the dead weight of insufficiently proven criteria (*47*). Unless we are very careful, it is also argued, the local norms of the PSRO will eventually conform to the regional norms, and the regional norms to the national norm, so that a deadly and mediocre sameness will settle across the land.

To others this outcome would be desirable since it could mean that at least minimum standards would be enforced everywhere. What is feared, on the contrary, is not that the PSRO will be overly confining but that it will not be effective enough; or, worst of all, that it will succeed in its weaknesses and fail in its strengths. There are many justifications for holding such views. Physicians are a highly privileged group and each one of them is vulnerable to error that may have disastrous consequences. As a result, physicians are united in their mutual defense and reluctant to criticize each other, especially if this is seen to be in the service of outside interests or professionally dubious goals. This tendency is reinforced by the need that physicians have for the respect and goodwill of colleagues in order to establish a practice, gain admission to hospital privileges, engage in consultations, and exchange referrals. Add to this the cement of personal friendships, of a similarity in social origins and experiences, of a shared ideology, and of a common threat, and the result is a social organism not easy to manipulate. In this light, it is easy to understand why the system of monitoring has delegated responsibility for review to local physicians and even to individual hospitals; if the enterprise were seen to be indigenous, it might accomplish through persuasion what it could not through external pressure. But this strategy could also fail, if the shared interests of local physicians united them in efforts to subvert and emasculate the PSRO by going through the motions of compliance while its actual intent is nullified (*48*). The system of medical care as it now exists has built-in incentives that work against many of the purposes of the PSRO. Should education and persuasion fail to bring about the desired effects the PSRO can resort to policing; but policing is precisely what the local fraternity of physicians is least likely to impose upon itself. If this is so, the PSRO's will have imposed an onerous and costly burden with little to show in benefits.

The likely effect of the PSRO on costs is hard to predict. The certification of admission and length of stay if properly done is bound to reduce charges for inpatient care, but there is reason to believe that the savings will be small and that they will be offset by the cost of the certification procedure itself (*49*). One should also be aware of the problems that patients will face if the hospital stay is not approved for payment, or if the alternative services mean a financial drain because they are not fully covered by insurance. PSRO activities that are meant to improve the content of care have an even more ambiguous effect on cost. To the extent that unnecessary procedures are discouraged costs will be reduced. But many believe that the line of least resistance will be to do for all patients everything that the PSRO criteria require or allow, markedly increasing cost without commensurate benefit to health. The picture becomes gloomier when the dubious prospects for savings is compared to the certainty of the costs of institution and running the PSRO program itself, which has been estimated to require a yearly expenditure of $1.25 billion if it were expanded to cover all inpatient and ambulatory care (*50*). Although the federal programs are obligated for their share of this cost, ultimately the added burden will fall on all taxpayers and consumers.

Much of this assessment is, of course, pure speculation. It is too early to know how the PSRO's will perform in actual practice. The experience of the much more limited programs that preceded the PSRO has been very mixed, showing success in some cases and failure in others, with the reasons for either not clearly understood (*39*, pp. 122–151; *51*). A recent reassessment, which included information about the early experience of the PSRO's that are already in operation, suggests that the utilization control programs of hospitals do occasionally report savings, but that these tend to be overestimated because of improper accounting assumptions. It is still not clear what audits of the quality of hospital care have accomplished. The review of claims for ambulatory care has been found to be cost-effective, but this is mainly or entirely due to the administrative component as distinct from professional peer review. All these "savings" when they do occur are to the financial intermediaries. The social costs and savings could be different because of the various ways in which costs can be shifted. As to the effect on the health of people almost nothing can be said (*52*).

Let me emphasize that these assessments are only provisional, since the evidence concerning the accomplishments of the PSRO's is in the process of being assembled. In my opinion, if the PSRO's conscientiously implement their mandate there is bound to be an improvement in quality, in cost, or in both. Should they fail to do so there could be pressure for more vigorous policing by agencies outside the medical establishment including the insurance carriers, the state health department, or an agency of the federal government itself. Alternatively, it may be concluded that what is needed is a radical change in how services are organized and physicians employed and paid, so that the incentives to professionally appropriate behavior are strengthened. The reliance would then be primarily on creating the proper conditions for good practice rather than on the fear that unsatisfactory practice will be discovered and disapproved. However, even under the best conditions, constant monitoring will have to be maintained, for without it medicine cannot see itself, nor know where it is going.

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National Health Insurance: Comments on Selected Issues

Robert M. Ball

National health insurance has been debated for so long now, and there has been so much talk about the politics of national health insurance and the details of one plan versus another, that it seems to me it might be helpful to go back to fundamentals—to review the bidding. What is national health insurance all about?

1) The most important objective of national health insurance is to make sure that everyone can get good medical care at a price he or she can afford. This may seem obvious but it needs to be repeated because in recent years other important, but nevertheless subsidiary, objectives have almost stolen the show. In discussing national health insurance today we hear almost as much about the objectives of cost control, the improvement of the quality of care, and changing the system to make it more responsive to patients' needs as we do about removing the economic barriers to the receipt of care and the protection of the patient's pocketbook. The subsidiary objectives are of great importance, but I doubt if we should be talking about a national health insurance program unless we are concerned principally about protecting the individual against the cost of care and the equity question of making adequate medical services available to all.

2) In spite of the current intellectual fashion of arguing the contrary, national health insurance assumes that medical care is worth having. Although it is useful to examine how effective some personal medical services are—and, indeed, whether some of them do more harm than good—the desirability of having medical services available is not open to serious question. By and large, even the most skeptical critics of American medicine seek medical services for themselves and their families and so confirm the widely held belief that such services are useful in the prevention of disability and premature death, the relief of pain, the reassurance of those who are ill, and the promotion and restoration of health. Overall, genetic and environmental factors and personal habits may have more effect on health than medical care services, but that is not inconsistent with the conclusion that medical care frequently does make the difference between sickness and health and life and death. And it is this conclusion that makes ability to pay an unacceptable way to ration medical care in a democratic society and leads to

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0036-8075/78/0526-0864$01.50/0