MEDICAL PRACTICE

Contemporary Themes

Medical Audit

Below we print a symposium on medical audit and recertification. Dr. P. J. Sanazaro, formerly of the United States Department of Health, Education, and Welfare, deals with experience in the U.S.A. which has led to official introduction of certain audit schemes. The remaining articles summarize five medical reactions to this and its implications for their own medical fields.

Experience in the U.S.A.

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British Medical Journal, 1974, 1, 271–282

In principle, the medical audit is an objective and systematic way of evaluating the quality of care provided by physicians. In reality, it is conducted mainly in the hospital, assesses only some technical aspects of medical care, and often falls short of its objectives. Yet our health policy in the United States (November 1973) is that some forms of medical auditing will be implemented nationally from January 1974. This paper reviews briefly audit as a form of peer review, describes the forces acting to extend its application, and offers a personal view on the prognosis of this unprecedented development.

Evolving Medical Audit

Some 20 years ago any auditing usually took the form of "chart review." This is now regarded as a highly inefficient and unproductive use of physicians' time, leading mainly to biased judgments. The form of medical audit which has since evolved uses explicit, written criteria for judging whether care provided meets the standards of the medical staff. The criteria are developed for specific diagnoses, conditions, or procedures by a committee of the medical staff and then are reviewed and approved formally by the entire staff.

The next step is that lay staff abstract from patients' records those items of information referred to in the criteria. The records which conform to the criteria are not examined any further; this initial screening is also carried out by lay staff. The records in which there is a discrepancy between the abstracted information and the criteria are reviewed by members of the medical audit committee. If, after their review, important discrepancies remain which cannot be satisfactorily explained, formal procedures are followed in bringing the results to the attention of the doctors concerned.

Generally, if many staff members are found to show a broad pattern of substandard performance in some aspect of care, this is interpreted as a deficiency of knowledge calling for a specific remedial education programme. When only a few doctors account for a large proportion of an observed shortcoming, the head of their department (in a large hospital) or the executive committee of the medical staff (in a smaller hospital) meet them to discuss the problem. After either alternative, the particular area of performance is subsequently re-audited to determine whether the criteria are now satisfactorily met.

Medical auditing is now well established as a formal activity of the medical staff in several hundred hospitals. The Veterans Administration—accounting for some 70,000 acute, general hospital beds—is beginning to install audit. The staffing requirements and the mechanics are becoming standardized. Despite these signs of progress, the question remains whether the medical audit can actually assess that aspect of the quality of care which is reflected in the medical record. The answer to this question turns on the nature of the criteria that are used.

Optimal-care v. "Essential" Criteria

The feasibility of the "criteria approach" to medical auditing was clearly shown in the mid-1960's.[1] Panels of doctors, mainly

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specialists, developed criteria for 51 different conditions covering 135 I.C.D.A. diagnoses. These specified the items of recommended performance consistent with optimal care in the history, physical examination, and laboratory, radiological, and special examinations of patients with the particular conditions. Modifications of these criteria—which are still based on the concept of defining optimal care—are now widely prevalent. Though this system is a major improvement on previous ones, the use of "optimal care" criteria still has serious limitations. Thus, because its emphasis is on improving practice through education, much textbook medicine finds its way into these criteria. These tend to include a wide range of items in the history and examination that may be necessary to assure correct diagnosis and proper treatment, but only a small proportion of these procedures or items may be necessary for any given patient. In this way, the items abstracted from one patient's record may match up with only a few of the criteria for optimal care.[2] The resulting rating of "low quality care," based on the low ratio of items recorded to total criteria, does not in itself support the conclusion that care for that patient was less than adequate. The process of care may in fact have been exemplary, despite the low score.

To overcome this problem, so-called "essential" criteria for medical auditing are being introduced. These are defined as those elements of diagnosis and treatment which are essential to the proper care of every patient with a specified condition. There are three main categories of information.

(1) Items in the history, physical examination, and laboratory and radiological procedures which confirm the diagnosis, influence the choice or application of treatment, and help establish prognosis.

(2) Specific treatment which is known to be efficacious.

(3) Procedures or treatments which are contraindicated.

For each diagnosis the total number of such essential criteria is much smaller than their counterpart optimal care criteria. Each essential criterion can be substantiated by reference to published work or well-documented experience.

The important observation has been made that items corresponding to these minimal essential criteria are apt to be recorded by most doctors even those who habitually do not keep thorough notes. Essential criteria can be developed and applied most effectively in those conditions which can be diagnosed definitively and which can be prevented, cured, or objectively improved. It is much easier to see whether the doctors' notes contain the required information. Moreover, because the criteria relate to the standards of care which all patients with a particular diagnosis should receive, any failure to meet them which is not adequately justified indicates clearly that corrective action is needed. Though this refined method for devising criteria has been introduced only recently, it seems likely to be adopted widely.

Medical Auditing in General Practice

The feasibility of conducting a medical audit of ambulatory care has been amply demonstrated.

Several experiments are now under way to determine whether the information contained on claims forms for ambulatory care is suitable for auditing, using the essential criteria method. These claims forms are required by Government agencies or insurance companies as a condition of reimbursement. For many years the San Joaquin Foundation for Medical Care has reviewed these forms from its 300 doctor members, primarily to control unnecessary services but also to oversee quality. The claim form identifies the doctor and patient and has to contain the diagnosis, treatment, or procedure, and the drug prescribed or injected. It should be designed so that the doctors can relate each procedure or service to a specific diagnosis or problem. Completed forms are then screened by a data-processing system that compares the content of each form with the criteria that have been established for the particular diagnosis. Those which do not pass this screen are then reviewed by a doctor. If he cannot resolve the inconsistency, the matter is referred to a duly appointed committee of peers.

Medical auditing based on information abstracted from surgery or clinic records is limited because doctors tend to keep incomplete records. Many doctors believe that if Weed's problem-oriented record system were widely adopted it would greatly improve surgery records and make audit much easier. More and more doctors are using standard forms which ease the burden of recording normal findings and serve as a checklist for recording the treatment and course. A national conference has recently recommended a minimum set of data that should be recorded at each consultation in general or outpatient practice.[3] Once agreement has been reached on standard classifications and definitions, these items will be promoted widely throughout the public and private sectors of medical care. When they have been adopted, auditing by abstracting doctors' records will become practicable on a large scale. Until then, claims forms which need equivalent standardized information are the only realistic source of information for auditing ambulatory care.

Of course, in primary medical care relatively few diagnoses or conditions lend themselves to rigorous auditing by essential criteria—but these few account for a surprising proportion of patients seen. Many more patients require a note written about their actual health, rather than any diagnosis and treatment. Here it is important to record the data base and its interpretation, and criteria for these depend more on opinion than sound evidence.

In a third category of patients—those with chronic disorders such as diabetes mellitus or arthritis—thorough records as well as essential criteria for diagnosis and treatment are needed for adequate auditing.

We must wait for the results of systematic studies of the adequacy of auditing for these three categories before we decide how they should be implemented nationally. Locally, on the other hand, audits of care in general practice can adequately define broad patterns of practice and identify performance by individual doctors that deviates importantly from locally established standards.

Criticisms of the Medical Audit

The audit is a tool designed for a particular purpose—that is, objective documentation by and to doctors of how far their care conforms to their own standards of adequacy or excellence. It is in relation to this purpose that the audit should be evaluated.

One criticism is that the medical audit simply describes what doctors are now doing without regard to the efficacy of their treatment. This is valid if the review is conducted without using criteria based on the best available scientific evidence of efficacy. Similarly, the audit technique cannot ascertain the accuracy of diagnosis beyond the point where doctors agree on the essential criteria for making it. In similar vein the criticism of the basic assumption in auditing—that recorded information reflects actual performance—is changing in that most doctors now agree that the absence of such information is itself no longer acceptable.

Many doctors have resisted the introduction of criteria, fearing that these would become rigid rules, be difficult to change, stifle judgement, and inhibit innovation. Such apprehensions have been considerably allayed because none of these things have happened where these criteria have been used for a long time. Moreover, doctors are becoming increasingly aware of the considerable educational benefits in the process of setting criteria—especially when opinions have to be substantiated by suitable references in the medical journals.

Process and Outcome

A widespread and justified criticism of the audit is that it focuses exclusively on the process of care—what the doctor does or orders—and pays inadequate attention to patient outcomes—that is, changes in his health. The outcome of care certainly does validate its process, but establishing the relation between the two is the task of clinical research—ideally through the randomized clinical trial. Arguments in support of emphasizing the process are straightforward. "Process" must be given major attention because it is the basis of medical education. Also only by modifying process can outcomes be improved. Moreover, outcome criteria can be clearly specified in only a relatively few conditions. Outcomes may be immediate, intermediate, or ultimate, and it is difficult and expensive to obtain such data for auditing.

The practical importance of assessing end results is readily apparent,[2-4] and nobody questions the technical feasibility of incorporating some degree of assessing immediate outcomes in the medical audit. In the hospital, complications of treatment or operations, unnecessary removal of tissue, failure to remedy identified disease states or physiological hazards, and failure to achieve the full benefit of efficacious treatment can all be recorded and included in the audit. The use of essential criteria for assessing treatment is an important middle ground between process and outcome: they specify the therapeutic endpoints shown by clinical research to produce predictable and desirable changes in a disorder. An obvious current example is lowering the diastolic blood pressure sufficiently in patients with high blood pressure. If this process criterion is met then there is a strong inference that the patient is receiving the full benefit of therapy—even though the eventual result cannot yet be known. It may be safely predicted that outcome assessment will assume increasing prominence in the medical audit.

Role of Hospital Data Systems

The growth and spread of medical auditing have been hastened by the emergence of non-profit organizations which for a set fee will relieve hospitals of the burden of summarizing clinical data on all their patients. The largest and oldest of these is the Professional Activity Study (P.A.S.), which offers its services nationally. Several smaller regional hospital data systems have recently appeared, prominent among these being the Hospital Utilization Plan of Western Pennsylvania. These organizations provide services to subscribing hospitals which include processing, analysing, and reporting standardized summaries of data provided by each hospital as an abstract of each discharged patient's medical record. These reports are used with varying diligence by utilization review and medical audit committees.

P.A.S. now has extensive national and regional data on the patterns of hospital care for many diagnoses, but these are not fully representative. Nonetheless, many hospital staffs use these empirical norms as their points of reference. But increasingly doctors recognize that to assess the quality of care they must compare any statistics with locally determined criteria.

Support by the Medical Profession

In 1960 the Board of Trustees of the American Medical Association adopted the position that the hospital medical staffs are responsible for evaluating "the quality of medical care on the basis of documented evidence to support diagnoses, treatment and justified utilization of hospital facilities." In 1970 the A.M.A. proposed that "peer review organizations" consisting of doctors should be established to review the quality of care and the use of medical services. The A.M.A. defines peer review as the "evaluation by practizing physicians of the quality and efficiency of services ordered by other practizing physicians."

Among other distinguished organizations, the American College of Physicians and the American College of Surgeons have made efforts to assess the quality of care. The American Society of Internal Medicine is conducting studies to improve methods of assessing doctors' performance in office practice. It has now embarked on a policy of improving doctors' record systems so that they will "document not only the 'what' but the 'why' of care . . . so that the quality of care can be more easily assessed."

In 1972 the American Hospital Association issued guidelines to help hospital staffs to organize and operate effective medical care review. This Quality Assurance Programme takes into explicit account the respective responsibilities of the medical staff, administrative staff, and the board of trustees.

In 1973 the Joint Commission on Accreditation of Hospitals began to enforce a requirement it had established in 1970—that, as a condition of accreditation, each hospital should have an ongoing medical audit which examines the outcomes as well as the process of care. Furthermore, the results of such an audit are to be used to upgrade the quality of care. The J.C.A.H. states that, "while this often will call for audit-specific continuing medical education programmes for the staff or counselling for individual physicians, corrective action may sometimes be found to require medical staff policy changes, administrative policy changes, or hospital board action." This strong stand has given a powerful impetus to the adoption of the medical audit. Though accreditation is voluntary, it is a sine-qua-non of recognition of a hospital's meeting today's professional standards as well as a condition of reimbursement from major insurance companies and the Federal Government.

Action by the Government

In 1970 the National Center for Health Services Research and Development, in the Department of Health, Education, and Welfare, anticipated that the United States Congress might well legislate for some form of mandatory review of the quality of medical care in Federal programmes. Since there was no existing operating model of area-wide organizations conducting such a review, the N.C.H.S.R.D. initiated and funded a programme entitled "experimental medical care review organizations" (E.M.C.R.O.)[5] The purpose of this was to help medical societies or associations in creating formal organizations and procedures for reviewing medical care in hospitals, nursing homes, and offices—in a geographical area up to a State in size. The use of explicit criteria and standard definitions were required of all E.M.C.R.O.'s but the particular approach to organizing the review was determined by the applicants. Initially 10 such review organizations were started. The results showed that sufficient commitment, leadership, and technical sophistication exist to create systems for the large-scale appraisal of regional medical care based on the medical audit. A formal, independent evaluation of the E.M.C.R.O.'s is now in progress.

In October 1972 Congress did enact such a law, in the form of "professional standards review organizations (P.S.R.O.s)." By 1 January 1974 P.S.R.O. areas are to be designated for the entire United States and medical organizations will then be eligible to apply for conditional recognition by the Department of Health, Education, and Welfare as the P.S.R.O. for that area. The conditional P.S.R.O. will have up to two years to show that it is discharging its requirements under the law. The latter stipulates that three basic functions must be carried out with respect to the medical services reimbursed by the Federal Government; for the elder-

ly and the categorically poor. Each P.S.R.O. must assure that such services are (1) medically necessary; (2) meet professionally recognized standards of quality; (3) are of the proper level of care (hospital or nursing home) and duration.

The primary purpose of the P.S.R.O. legislation is to help control the rapid increase in total expenditure by curbing unnecessary use of services in hospitals and nursing homes. Though some regard the provisions about quality as an afterthought, the medical profession has now been challenged to carry out the cost control effectively while simultaneously safeguarding (and if need be upgrading) the quality of care provided. There is justifiable concern that adoption of optimal criteria, rather than essential criteria, might lead instead to greater increase in expenditures without a commensurate one in quality, except by definition. If this were to happen, critics of the medical profession might well claim that it had defaulted in its responsibilities.

Many doctors and health scene observers believe that P.S.R.O. "cannot work," and several state medical societies are officially urging repeal of the measure. These efforts are not likely to have much effect, given the public's attitude toward medical care generally and the genuine concern of Congress over the frightening costs of the programmes it has enacted. Doctors' leaders almost uniformly recognize the practical necessity of accepting P.S.R.O. as a political gift (or fact) and the wisdom of converting it into an opportunity. That opportunity is to install an effective system of assessing and assuring the quality of care in the day-to-day practice of medicine, under the auspices of the medical profession.

Relicensure and Recertification

A clear indication of doctors' concern with ensuring the quality of care may also be seen in our current discussions and decisions on relicensure and recertification. The medical societies of the States of New Mexico and Maryland currently require participation in courses of continuing education as a condition of relicensure, while other societies are contemplating such a requirement.

In March 1973 the American Board of Medical Specialties adopted in principle "the policy that voluntary, periodic recertification of medical specialists become an integral part of all national medical specialty certifying programs . . . ." By September 21 of the 22 boards had endorsed this policy and 13 have appointed committees to develop implementing recommendations. The American Board of Family Practice is the only board committed to a mandatory recertification of its members, and this is already scheduled for 1976. This may take the form of an objective test of knowledge of recent advances coupled with some assessment of performance in practice. The American Board of Internal Medicine is offering its diplomates a strictly voluntary recertification procedure. In October 1974 a one-day written examination will be administered at official test centres. Physicians successful in the recertification examination will be so identified in an appropriate, as yet unspecified, manner.

At present there are no precedents for recertification and no traditions to overcome. A common recertification procedure for all boards would be highly desirable. Some boards favour a voluntary approach while others believe the procedure should be mandatory. Some appear to favour examinations, others endorse documented participation in continuing education, and still others a combination of the two. Implicit in much of these discussions is the recognition that a once-for all examination, (especially one which tests only knowledge) is a far from satisfactory basis for certifying that a specialist is practising competently.

Though continuing medical education is looked on as a rational means of maintaining competence, the evidence for its being effective in changing the habits of practising doctors is not available.[6] This widely-known fact has led many to explore critically the effectiveness of continuing education that is aimed precisely at deficiencies discovered through the medical audit. We have no evidence on this either yet, but the lack of this in itself suggests that many factors influence the results besides education. The American Society of Internal Medicine has officially opposed the principle that relicensure or recertification should be based on attendance at courses: instead, it has proposed that assessment of actual performance in practice should be made the basis. A high-level Committee on Goals and Priorities of the National Board of Medical Examiners stated in its report " . . . it is almost certain that evaluation of professional competence at the practice level will be required throughout a physician's career. This evaluation process will probably become a qualification for recertification."

The Likely Future

Implementation of the new P.S.R.O. law will bring with it almost universal adoption of the medical audit in the U.S.A. The initiative given to the medical profession has been eagerly seized. The A.M.A. Task Force on P.S.R.O. is producing guidelines which will help the creation and effective operation of P.S.R.O.'s for controlling costs and assuring quality. E.M.C.R.O.'s are being drawn on as sources of information, tested experience, and improved techniques. The regional and national data systems and private insurance companies are looking ahead, and (in enlightened self-interest) are making constructive proposals. A philanthropic foundation has just made a substantial grant to a major private initiative by four national organizations to demonstrate maximum feasible quality assurance and appropriate public participation in P.S.R.O. The net consequence of all this activity, public and private combined, can but augur well.

The hospital audit, encompassing outcomes, will permit increasingly reliable comparisons of the quality of care, but it will be some considerable time before we can speak of measurement as a reality. To improve auditing of ambulatory care (which is not an immediate requirement of P.S.R.O.), doctors will have to make a voluntary effort to upgrade the content of general practice records. Even within existing constraints, the monitoring of prescribing patterns will become feasible, directing attention to problems too long neglected.

In this remarkable period of shifting health-care policy, the organized profession has taken progressive, positive stands in its support of peer review; its promotion of experiments and demonstrations to improve our methods of assessing quality; and its emerging policies on relicensure and recertification. The last two will probably become mandatory and take into account actual competence in practice. In all this doctors are seeking to transform their historic implicit responsibility to assure good care into an explicit public accounting, within the limits of safeguarding the doctor-patient relationship. Peer review, through the medical audit, will be the fulcrum of this rededication to first principles.

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