Medical Audit in General Practice

THE topic of audit has become one of the main growth areas in the medical literature over the last decade. There are now thousands of articles in the world's medical journals either describing audits, arguing for or against them, discussing ways and means of carrying them out, and even defining and debating the meaning of the word itself. There is now a danger that the number of articles on audit will smother any worthwhile ideas which are struggling to reach the light.

Many articles on audit have confused the 'average general practitioner driving his Mini-Metro down Clapham High Street,' and the main aim of this paper is to illuminate the important issues raised by the introduction of medical audit to general practice.

Aims

My objectives are as follows:

1. To define medical audit as now practised in the United Kingdom.
2. To outline the essential characteristics of medical audit in general practice.
3. To review the literature in order to detect those trends likely to be most fruitful in general practice.
4. To describe my personal experiences with audit and enumerate those lessons learned from carrying out medical audit in practice.
5. To propose a blueprint for medical audit in primary care to facilitate its adoption as a routine activity in any practice.

In assessing the value of medical audit three main questions must be asked:

1. Is effective medical audit possible in general practice?
2. Does it produce any beneficial effects for the patient, the doctor, and the community?
3. How can we ensure that the activity is practised by all doctors and not just a keen band of innovators?

Definitions

> *If you will take this audit, take this life and cancel these cold bonds.*
>
> (Shakespeare, 1623)

Wittgenstein (1921) has said:

> "Language disguises thought. So much so, that from the outward form of the clothing it is impossible to infer the form of the thought beneath it."

In considering audit the first task, therefore, is to strip off the outward clothing of the word to reveal the form of the thoughts and principles hidden beneath.

The word audit comes from the Latin and literally means "he hears". It has been used for centuries in accountancy and business and it is in this connection that the *Oxford English Dictionary* defines it: "Audit is the making of an official systematic examination—usually referring to accounts" (Onions, 1933).

In earlier times, Samuel Johnson (1770) defined audit as "taking a final account", and Shakespeare uses the word to represent a final reckoning. An auditor in Johnson's day was a "king's officer who yearly examines the accounts of all under officers accountable", and today the title is almost synonymous with a professional accountant.

The *Encyclopaedia Brittanica* (1973) defines audit as "an investigation of an activity, by someone not connected with it, to determine whether it is being carried out in conformance with its objectives." The *Encyclopaedia* goes on to distinguish between professional auditing, which involves the examining of activities and records by an external accountant, and internal auditing which has come to represent a form of managerial control which operates by assessing the efficiency and effectiveness of an activity by those responsible for it.

These definitions of audit describe a process which at first sight seems far removed from medicine, and it is surprising that such a word was ever chosen to represent an enquiry into the provision of medical care. Some of the earliest references to audit are found in the reports of the American College of Surgeons in the 1930s; and thus, like many other things which both fascinate and infuriate, audit is yet another import from our transatlantic cousins.

However, whether we approve or not, the word 'audit' has now become firmly entrenched in our vocabulary, and perhaps it is time to agree finally upon its meaning and the meaning of numerous related phrases which have sprung up under its umbrella.

Most authors writing on audit have provided their own definition of audit; for example:

> "The evaluation of the quality of medical care as reflected in medical records."
>
> (Slee, 1967)

> "A process of critical analysis."
>
> (Williamson, 1973)

> "Medical care review."
>
> (Marson *et al.*, 1973)

> "A process of enumeration and evaluation."
>
> (Mourin, 1976)

> "The process of data collection."
>
> (Harris, *et al.*, 1977)

The definition of audit by the Joint Commission on Accreditation of Hospitals in the USA is:

> "The evaluation of the quality of patient care based on explicit and measurable outcome criteria that can be applied to significant numbers of patients' records for the purpose of documenting and improving provider performance and overall quality of care."
>
> (Jacobs *et al.*, 1975)

In a recent article, Shaw (1980a) presented all of the terms related to audit and pointed out that suitable combinations could produce up to 96 phrases which either have been or could be used to describe auditing

activities. These include such phrases as 'quality care review,' 'medical process evaluation,' and 'quality assurance'. Shaw goes on to say:

> "If medical audit was understood to refer only to self-audit and peer review, much confusion would be avoided."

It seems, therefore, that audit must be seen as an umbrella term which covers several very different activities (Figure 1).

In my view the term 'external audit' should be used to describe any such assessment carried out by any person or body not personally involved in the activity under scrutiny. This will include DHSS officials, local administrators, retired general practitioners, academics, college representatives or any other group of professional or lay people.

Before considering peer review it is necessary to agree what constitutes a peer. For example, the Alment Committee Report on Competence to Practise (1976) interpreted medical audit as:

> "The sharing by a group of peers of information gained from personal experience and/or medical records, in order to assess the care provided to their patients, to improve their own learning and to contribute to medical knowledge."

The Report then goes on to define peers as:

> "Doctors who practise in the same specialty and in broadly similar conditions of practice."

Similarly, the GMSC for Wales working party on medical audit (1975) defines peers as:

> "Clinicians, all practising in a comparable situation."

However, in my opinion any review by other practitioners, even of similar background, is really an external form of assessment. Thus, not only should the term 'medical audit' be reserved solely for self-audit and peer review (*British Medical Journal*, 1980; Shaw, 1980a), but I would add that a peer group should consist only of those doctors whose activity is being currently assessed. Although some may argue that there is a place for external assessment of general practitioners, much of the antagonism towards medical audit has surely been generated by the fear that a doctor's clinical activity and facilities are to be scrutinized and criticized by 'outsiders,' even if they are well meaning academics or colleagues.

I should therefore like to put forward the following definition of medical audit:

> **Medical audit is a study of some part of the structure, process and outcome of medical care, carried out by those personally engaged in the activity concerned, to measure whether set objectives have been attained, and thus assess the quality of care delivered.**

SETTING STANDARDS AND OBJECTIVES

One of the main features which distinguishes audit from research or any other investigation of a doctor's activities is the evaluation of the findings when compared with a set of previously agreed objectives. Creating these objectives is far from easy even for the most straightforward clinical conditions (Watkins, 1981). The objectives should attempt to answer the two questions:

1. What am I trying to achieve?
2. How should I go about doing it?

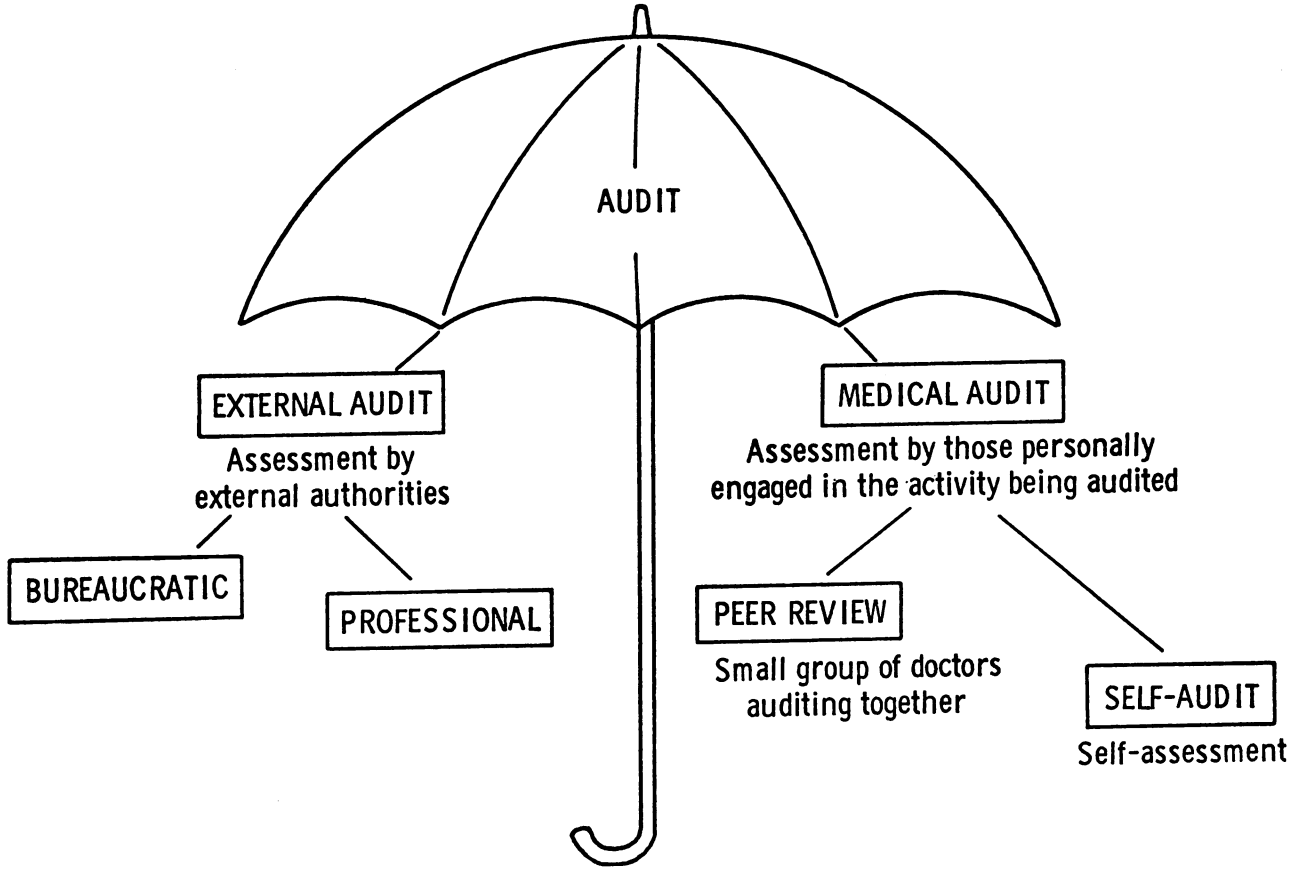


Figure 1. The umbrella of audit.

The first question will lead to a set of outcome objectives which must include such items as pain, discomfort, and inconvenience to the patient, cost and efficiency, effective use of medical resources, avoidance of iatrogenic disease, residual disability, and long-term complications.

The second question will lead to a consideration of the facilities and process of care which are required to achieve the outcome objectives. Classically, there are two kinds of such objectives (Donabedian, 1966):

Empirical Where the objectives are based on criteria derived from many studies where the 'statistical average' is obtained after evaluating the habits of many different doctors (i.e. the 'average' level of care).

Normative Where the objectives are based on criteria derived from the standard textbooks and the work of experts who are usually hospital specialists or academics (i.e. the 'best' level of care).

The value of both these approaches is open to question, first because the average will not necessarily be appropriate for every patient or doctor, and secondly because the opinons of experts in one area of medical care may be invalid when transferred to another (Brotherston, 1962).

Perhaps the preferred approach is for every doctor, or group of doctors, to derive their own objectives and criteria of quality after reference to other sources and consideration of their own capabilities and resources (Watkins, 1981). In this way the doctor's own criteria set a standard against which his performance may be measured.

Self-selected criteria

Thus, self-selected criteria should be the starting point of any medical audit in general practice for several reasons. First, the task of agreeing the criteria or objectives of care is itself a major part of the educational process of medical audit (Fifer, 1978a). It leads the doctor to review the relevant literature and to discuss the problem with other general practitioners and specialists. An understanding of other doctors' criteria is therefore obtained, which can be modified according to his own capabilities and the facilities available to him.

Secondly, one of the main aims of audit is to effect desired behavioural changes in the doctor where indicated and there is increasing evidence that this change occurs only if the doctor himself plays an active part in the initial process of selecting the criteria against which his performance is to be measured (Ryan *et al.*, 1979). The criteria of any one practitioner may, of course, be quite unsuitable for another with differing interests, capabilities and facilities.

For instance, one general practitioner may have a special interest in orthopaedics and so feel competent to diagnose and provide non-surgical treatment himself without referral to a specialist, whereas another, with little expertise in the subject, may need to refer most cases to a specialist for diagnosis and treatment.

There are, therefore, many pathways to 'good' clinical care, each depending on the knowledge and skill of the individual doctor and some of which are more cost-effective than others (Figure 2). The ideal situation would

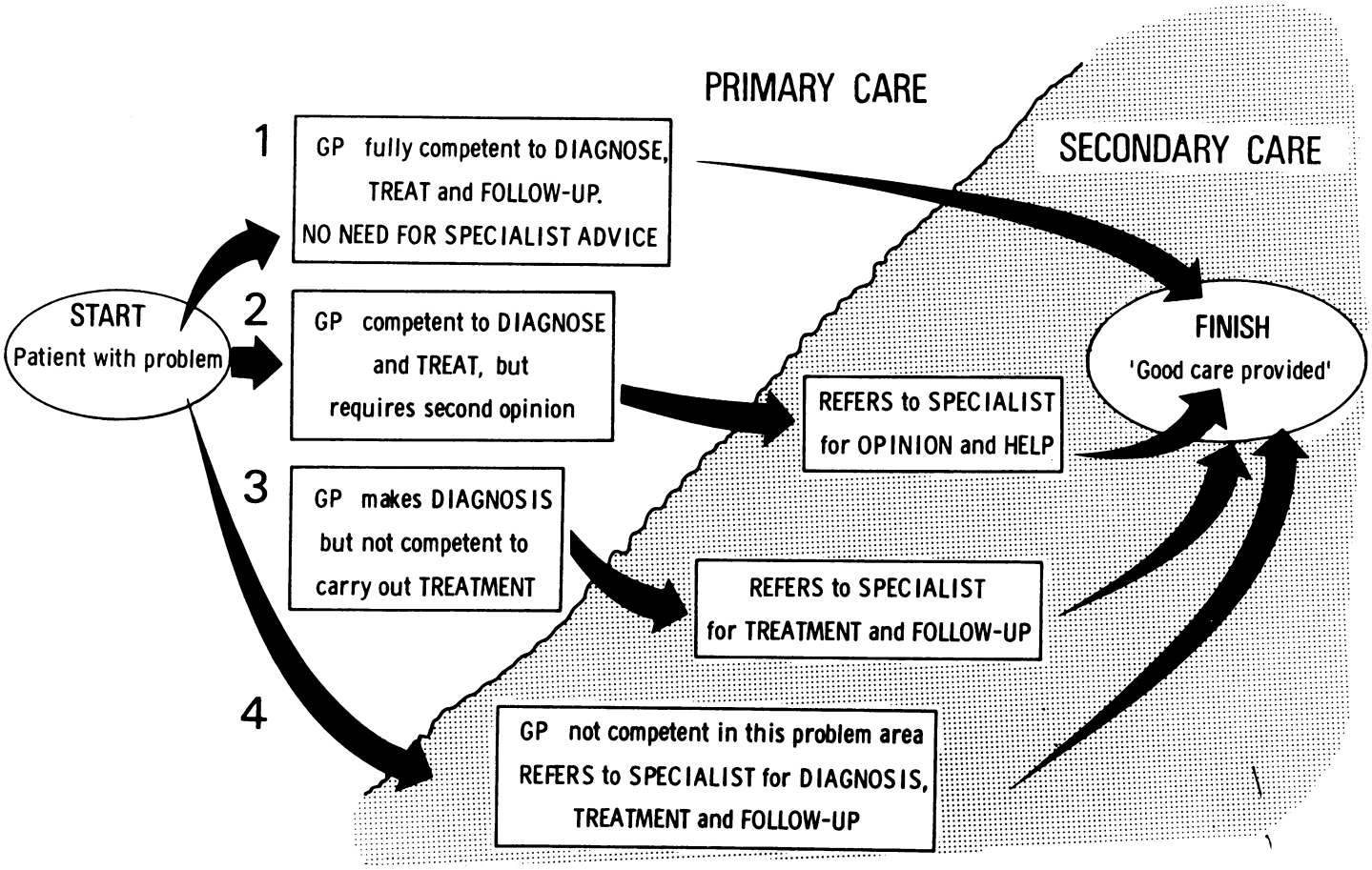


Figure 2. Pathways to 'good' clinical care, assuming that the general practitioner has facilities for diagnosis and treatment.

be for each general practitioner to reach a certain minimum level of competence in every subject whilst having special expertise in a small number of areas. The task of defining what is the minimal acceptable level of care is exceedingly difficult, but it is a task which must be tackled, particularly informally by local groups of trainees and doctors. However, these problems are more concerned with competence to practise than with medical audit, and it is important to keep the two issues separate, as the educational objectives of medical audit will almost certainly be frustrated if it ever becomes compulsory.

I feel strongly that medical audit is not concerned with setting standards to judge between 'good' and 'bad' doctors. If it is wished to detect and punish bad doctors then other methods will have to be found. Medical audit must always be constructive and as such must be as confidential to the participants as are the confidences of our patients.

Assessing quality of care

'Quality' is one of those words the meaning of which everyone knows but few can easily define. Indeed it has been suggested that we abandon the word altogether as its use may hinder rather than help thinking (Brotherston, 1962). The *Oxford English Dictionary* (Onions, 1933) defines quality as the "nature, kind or character of something: the degree or grade of excellence." This immediately points us to the biggest problem of all—what is a measure of excellence?

Donabedian (1966) states:

> ". . . Criteria of quality are nothing more than value judgments that are applied to aspects, properties, ingredients or dimensions of the process called medical care. As such it may be almost anything anyone wishes it to be—although it is usually a reflection of the values and goals currently in the medical care system and in society as a whole."

For medical care to be excellent it must satisfy all the needs of the patient in the most effective and efficient manner (McCormick, 1976). These needs will include:

1. Protection from preventable disease,
2. Early and accurate diagnosis,
3. Effective treatment of physical, social and emotional disorders,
4. Advice and help to live with the condition and adapt to the environment,
5. Confirmation of the sick role in order to deal with society at large.

All of these needs require a personal physician with the full availability of secondary care, other primary care health workers, and preventive services. Some will be

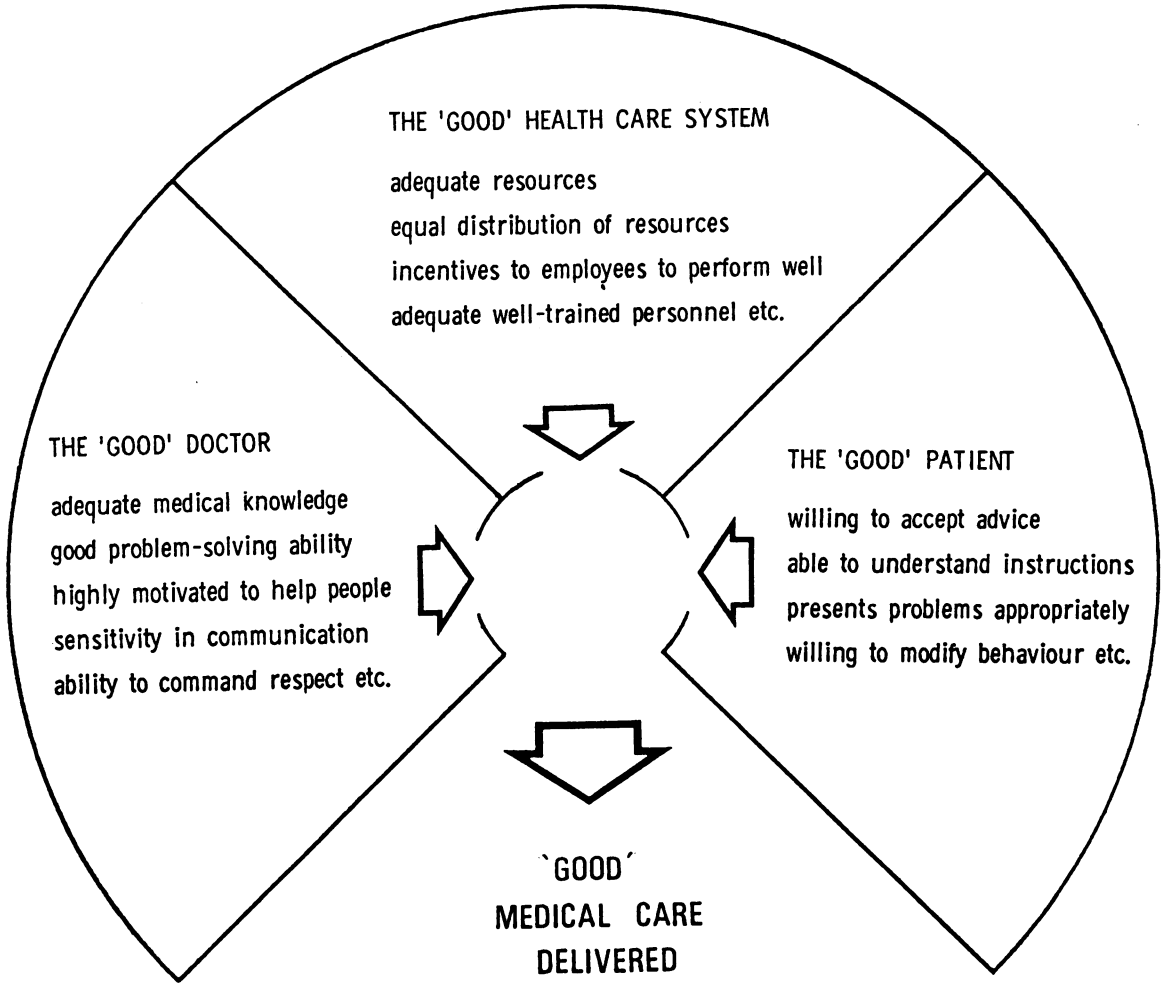


Figure 3. 'Good' medical care requires a 'good' doctor, a 'good' health care system, and a 'good' patient.

perceived by the patient and expressed as wants or demands, but others are perceived only by a physician or society at large (Clark and Forbes, 1979). Thus, in assessing the quality of health care provided, it is necessary to take into account the doctor, the patient, and the health services provided by society, as all will influence the final outcome (Figure 3).

The 'good' doctor cannot function efficiently if society does not provide the facilities and environment for both doctor and patient to function effectively. The doctor is therefore always constrained by the patient and the community, and his value judgments will always reflect those of the society in which he practises.

Medicine demands of the doctor a balance between the technical components of the discipline and the interpersonal components of care (Donabedian, 1979). The quality of technical management largely depends on the balance of its expected benefits and risks, and the quality of the interpersonal process is balanced between legitimate patient expectations and contemporary social and professional norms (Figure 4).

Trying to measure the quality of general practice as a whole may well be exceedingly difficult (Marson *et al.*, 1973), but what of defining the criteria required for good care in specific clinical conditions? Workers in this area have pointed out the difficulties encountered and the fact that it is nearly always impossible to get two doctors to agree on criteria for even simple clinical conditions (Watkins, 1981). However, Forsyth and Logan (1962) argue that virtually all doctors will agree on basic criteria of quality for many conditions, and that these can be used as a starting point. Thus, no doctor would disagree with the statement that a child presenting with earache should have the ears examined with an auroscope, and that the outcome of any intervention should be the rapid relief of symptoms without long-term complications or disability. Although at first sight outcome objectives seem to be easier to determine than process objectives, it must be pointed out that there are major difficulties in correlating the process of care with its outcome.

A REVIEW OF AUDIT IN MEDICINE

Evaluation of medical care is as old as medicine itself, and it is only in the last few years that the activity has been called audit. For example, in the 1860s Florence Nightingale proposed a uniform format for the collection and presentation of sickness statistics to evaluate the care provided (Nadolny, 1979), and at the beginning of this century Codman proposed an 'end-result analysis' to compare the results obtained by different staff members of the Massachusetts General Hospital. In 1912 the Clinical Congress of Surgeons in American set up a committee under Dr Codman's chairmanship to develop a programme of hospital standardization (Christoffel, 1976). From its early beginnings in American hospitals the ideas of audit have now spread into all branches of health care in most countries in the world.

Until recently most audit studies in the USA have centred on hospital practice, and it has generally been accepted that general practice presents quite a different

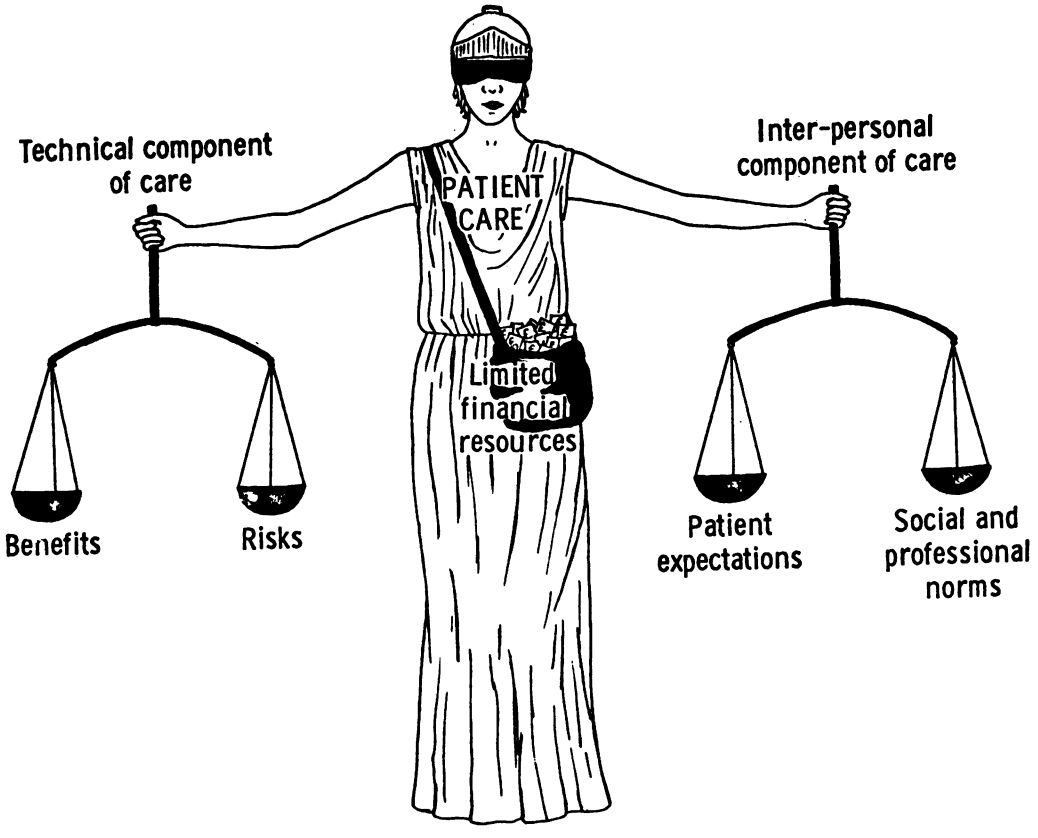


Figure 4. The requirement for a 'balanced' approach to patient care.

challenge (Mushlin *et al.*, 1978). As Shaw (1980b) aptly describes:

> "General practice does not lend itself easily to objective measurement, being concerned less with diagnostic processes and acute events, but rather with people, relationships and a continuity of care leading eventually to death. If it is difficult to audit diseases, will it ever be possible to audit the care of patients?"

I therefore wish to review some of the auditing techniques employed in general practice (or family medicine in North America) over the last decade in order to evaluate their usefulness and applicability to British general practice today. Most workers have divided audit of medical care into the three areas suggested by Donabedian (1966), namely: structure, process and outcome. Although it may be argued that the usefulness of this classification has been exaggerated and may even now be detrimental to the progress of medical audit, it is a convenient starting point for the purposes of review.

Audit of structure

The structure of general practice consists of the attributes of the doctor himself, the facilities available to him, and the administrative methods employed to avail patients of the medical services required.

Many workers have looked at the doctor's qualifications, equipment, administrative arrangements and ancillary support, with the apparent assumption that a good doctor can be determined by the surroundings in which he works (Irvine, 1972).

Although there is an overwhelming belief that a good doctor can be identified by such attributes as his environment and the attitude of his staff, there has been a distinct lack of evidence that any particular item of the structure of general practice actually affects the outcome of care (Shaw, 1980a). Does a health centre lead to better patient care, does an appointment system, or secretarial help?

The list of changes in the structure of general practice over the past 25 years is vast, but there has been little attempt to examine the effects of such changes on the health or satisfaction of patients.

For the doctor, it seems obvious, but not proven, that pleasant surroundings and co-operative helpers enable him to concentrate more on his patients, and the abolition of distractions leads to subtle improvements in the doctor/patient relationship. Whilst this is undoubtedly true—at what price are these improvements obtained? They may, perhaps, lead to the withdrawal of local facilities for the patient in order to concentrate them in an often remote central health centre. Doctors seem reluctant to ask their patients to audit their activities in this field, and ignore opinions quoted in the press as unrepresentative—"After all, *my* patients are quite satisfied!"

Extensive investigations and studies have been mounted in general practice over the last two decades which have examined such areas as the doctor's attributes (Peterson *et al.*, 1956), his equipment (Irvine, 1972), his administrative arrangements in the surgery (Stott and Davies, 1975), his activities during the consultation (Buchan, 1978; Floyd and Livesey, 1975), and the availability of supporting services (Marsh, 1969). The whole subject has been well reviewed on several occasions (Peterson *et al.*, 1956; Forsyth and Logan, 1962; Stott and Davis, 1975; Mourin, 1976; Stevens, 1977; Alderson, 1978) and still more ideas for audit of the structure of general practice are forthcoming (Fry, 1981). However, it may be more appropriate in the future to combine these structural aspects of audit with the process of care and relate them both to outcome, particularly in certain tracer conditions.

Audit of process

Most audit studies published during the last decade have been primarily concerned with examining the process of care. Cynics have argued that process is of little importance, as there are many different ways of arriving at good care, and several studies have supported the view that process itself does not affect the outcome (Cargill, 1979; Hall, 1979). However, the process of care will inevitably affect outcome in all but self-limiting conditions, but only in conjunction with other factors such as the patient's willingness to accept change, or his cultural and social environment (Figure 3). If audit studies have not shown a correlation between process and outcome, perhaps it is because the wrong parts of the process were being studied, or because the measurements were not sensitive enough to detect changes. Unfortunately, it is a human failing to collect those facts which are easiest to collect, regardless of whether or not they will provide the answer. There have been very few studies to determine which parts of the doctor/patient interaction are the most important for a successful outcome. It is also very difficult to study the diagnostic process in primary care as the data used in decision making are poorly understood and the probabilities of disease have not been fully investigated (Marson *et al.*, 1973).

Once the patient presents to his physician with a set of symptoms, a process of diagnosis and interaction is begun which will eventually lead to a final outcome, after passing through many intermediary outcome stages. It is difficult to measure the final outcome in chronic diseases, as death may occur many decades after the critical process of intervention. However, the general practitioner is ideally placed to audit chronic diseases if the auditing process is continuous, for in time all diseases reach their conclusion and the general practitioner should be in possession of most of the relevant data about a specific patient's management.

As Donabedian has pointed out, it is probably false to try to separate the process of care from its outcome, particularly in general practice. One should think rather of an unbroken chain of antecedent reasons followed by intermediate ends which are themselves the means to still further ends. He goes on to say that auditing the process of care requires that a great deal of attention be given to specifying the relevant dimensions, values and standards to be used in assessment, but it may be better to admit that we are really studying whether medicine is being practised according to the norms and standards presently accepted by the profession and society (Donabedian, 1966).

In auditing the process of care, the doctor can choose to examine medical records; to make direct (or indirect)

observations of the consultation; or to use sociometric methods where the attitudes and opinions of doctors are studied (Donabedian, 1966).

Criterion audit

The most popular form of audit in the USA has been 'criterion' or 'chart audit,' whereby the participating doctors agree on a limited number of tangible elements which they consider to be critical to the process and the outcome of care. These criteria are explicitly formulated so that lay staff can examine the records to determine whether they are present or absent.

Correlation between process and outcome

Much has been made by critics of audit of the fact that several studies have not shown a correlation between process and outcome. The study by Dickinson and Gehlbach (1978) on patients with hypertension in a group family practice in North Carolina is often quoted in this context. However, as the authors themselves point out, the unproved assumption of any audit process looking at medical records is that the physician who demonstrates a high adherence to an established set of criteria is also the best at intervening in the illness process to the benefit of the patient. The criteria used in this study were derived by a panel of experts so that the doctor was being measured according to the acceptability of the process by his peers. It was noted that many doctors did not adhere to the protocols, which suggests that the original criteria were inappropriate. This has been found by other workers when the criteria against which the process was to be compared have been set by external experts (Watkins, 1981).

Nobrega and colleagues (1977) also studied hypertensive patients, and after evaluating process and outcome they failed to produce a statistically significant association between them. However, this was a retrospective study of patients' records whereby they were looking for a 'laundry list' of items which experts thought should be in the record. Again it seems surprising that anyone should have expected there to be a correlation between the doctor's entries in the medical record and the final outcome for the patient. Perhaps the good doctor does keep good records, but they serve mainly as tools of communication rather than as sources of data on those parts of the process which have an effect on the outcome of intervention.

Romm and Hulka (1980) studied diabetes and hypertension as tracer conditions in hospital and also failed to demonstrate that adherence to their process criteria was associated with improved outcome measures.

One study which has shown a correlation between the process as recorded in the records and the outcome as determined by the patient was reported by Mushlin and colleagues (1978). They studied patients with sore throats, upper respiratory tract infections, and urinary tract infections by giving them a questionnaire to determine their residual symptoms, activity limitations, and anxiety. They were able to correlate poor outcomes with important deficiencies of care as recorded in the records.

It is surely obvious to any practising general practitioner that the most important transactions in a consultation are rarely recorded in the notes and it is these which are most likely to influence outcome.

Studies on patient compliance have suggested that communication is important, and this is one aspect rarely measured in process audit, with the exception of studies using video-recording of the consultation (Verby *et al.*, 1979). These workers felt that as communication is so important to the process of care, it may be used as a reflection of the overall quality of care.

Tracer conditions

As it is impossible to audit the process of care for all illness at the same time, the principle of studying tracer conditions has been investigated. Some conditions are more amenable to study than others, so it seemed sensible to start auditing those conditions which could be audited, the assumption being that the provision of good care for one illness would represent good care in all illnesses.

Some conditions are particularly suitable for audit in general practice (Shaw, 1980b). These include hypertension, diabetes, thyroid disease, leg ulcers, otitis media, pyrexia of unknown origin, surveillance of the elderly, backache, urinary tract infections and depression.

Any tracer conditions used in audit should satisfy the following criteria (Kessner *et al.*, 1973):

1. There must be a definite functional improvement.
2. The condition must be well defined and easy to diagnose.
3. The prevalence rates must be high to provide adequate numbers.
4. The natural condition must be suitable to change by intervention.
5. The management process must be well defined.
6. The effects of the non-medical factors should be understood.

The range of illnesses audited is impressive. Some of those studied over the last few years include: obstetric care in family medicine (Phillips *et al.*, 1978), peptic ulcer disease (Derschewitz *et al.*, 1979), osteoarthritis (Greenfield *et al.*, 1978), obesity (Binnie, 1977), diabetes (Doney, 1976), acute abdominal pain (Gruer *et al.*, 1977), fungal skin infections (Sheldon, 1979), urinary tract infections (Ryan *et al.*, 1979), and gastro-intestinal cancer (Macadam, 1979).

With experience and persistence it is conceivable that nearly every condition brought to the general practitioner will eventually be amenable in some way or other to an audit of the process of care.

Outcome audit

At first sight the outcome of an illness must appear to be the final arbiter of the quality of care. This outcome may be death, as in surveys such as the Perinatal Mortality Survey and the Maternal Mortality Study, or some other measure of the health or satisfaction of the patient. However, there are serious difficulties to be overcome before the outcome of care can be used to assess whether the process of care is appropriate or 'good.' For example:

1. Many other factors apart from medical care will influence the final outcome, such as the patient's financial, social and cultural environment as well as his behaviour when seeking care.

2. Some aspects of outcome, such as the degree of social disability suffered, will be very difficult to measure.
3. Long periods of time may elapse between the intervention and the final manifestations of outcome.
4. The face values of quality are not absolute. How can one set the prolongation of life against the costs in terms of suffering? How can happiness and good health be evaluated? If, for example, 10,000 women have to be made very unhappy in labour with 10 per cent of them suffering greater degrees of puerperal depression to the long-term detriment of their children, is this an acceptable price to pay to avoid one maternal death? Such value judgments are exceedingly difficult to make—and anyway, who should make them?
5. If patients' opinions are used it must be remembered that their expectations are largely conditioned by the doctors who provide the care (Marson *et al.*, 1973).

Thus, Donabedian (1966) urges caution in using outcomes whilst accepting that they remain the ultimate validators of the effectiveness and quality of medical care.

Brook and colleagues (1977) chose eight disease conditions or surgical procedures in order to study outcome, including asthma, breast lump, osteoarthritis, otitis media, and removal of tonsils and adenoids. The chief factors affecting the choice of conditions was the extent to which medical intervention determined the outcome, and the ability to produce disease specific outcome criteria against which performance could be measured.

Mushlin and colleagues (1978) defined what they termed deficient outcomes as the occurrence of preventable, undesirable events. They showed that patients with what they termed deficient outcome were more likely to have omissions in the record than those with a satisfactory outcome.

In order to expand the outcome measures, several studies in the last few years have attempted to measure mobility, social impairment, and patients' satisfaction as indicators of the outcome of health care (Hunt *et al.*, 1980).

As previously suggested, outcome measures may be more successful if each doctor first sets out his own objectives for care, and then compares the outcome of treatment with these objectives (Watkins, 1981).

A list of suggested outcome measures for clinical audit in general practice is given below. They should apply to almost any condition in general practice and can be modified to suit each doctor's needs. An example of the use of these measures in audit is given in the appendix.

1. Primary prevention of disease whenever possible.
2. Complete elimination of any pathogenic organism without damage to the host tissues.
3. Secondary prevention of the consequences of the disease process.
4. Relief of the patient's symptoms, distress, and anxiety in as short a time as possible.
5. Avoidance of iatrogenic symptoms or disease.
6. Prolongation of life to its maximum, thus avoiding premature deaths.
7. Minimizing the cost of the disease to the patient, the doctor, and society.
8. Producing a satisfied patient.
9. Clarifying and relieving the patient's interpersonal problems.
10. Not compromising the patient's integrity from the ethical point of view.
11. Preservation of, or improvement to, the patient's level of functioning at home, work, and in society.
12. Producing the desired outcome in the shortest period of time.

EXTERNAL, PEER OR SELF-AUDIT?

Many of the arguments about medical audit seem to centre upon who is to perform the evaluation part of the procedure.

External review

Some workers have argued for external assessment as a means of ensuring that certain minimum standards of care are being maintained (Dollery, 1971; McWhinney, 1972). Darnell and Fitch (1980) have defined 'external review' as:

> "The process of gathering data and making recommendations about one or more institutionally defined topics directly or indirectly related to patient care which is carried out by professional peers external to the therapeutic environment in which the review occurs."

The advantages of an external form of medical audit are few. It could be argued that a more objective view would be obtained and both good points and bad points are more likely to be highlighted than if a self (or internal) review is made. Parallels may be drawn with investigations into police activity where an internal review may be termed a 'white wash' or 'cover up.' It could also be argued that the public to whom the doctor is accountable would be more satisfied by an independent evaluation of medical care. This attitude has flourished in the USA where audit and review have become mandatory. There is a real fear that this could happen in the United Kingdom, with certain authorities being employed by the state to investigate the doctor's clinical activity.

Several writers have argued that external audit must always fail, even if other forms of external assessment may be required and successful (RCGP Birmingham Research Unit, 1977). Some of their reasons are as follows:

1. It is difficult, if not impossible, to make available to an external assessor the most important components of clinical performance and judgment without completely destroying the consultation.
2. The quality of care, however measured, is always relative. There are very few measures of quality which are universally agreed and applicable.
3. Individuals learn best by discovering their own mistakes and the natural reaction to external criticism is to adopt defensive postures.
4. Rigidly applied criteria of the prevailing fashionable standards of care stultify innovation and research.

Even using external sources just to set standards by which care can be evaluated is undesirable (Watkins, 1981), since it has been stressed that setting the objectives

is the first and one of the most important parts of the auditing process, and should be done by the doctors being audited.

I therefore maintain that external audit should not be considered further.

Peer review

"As then the physician ought to be called to account by physicians, so ought men in general be called to account by their peers."

Aristotle

Ryan and colleagues (1979) used the group of doctors working within the same practice to set standards and evaluate their findings, and Verby (1979) similarly used a small group of doctors (all being subjected to the same reviewing process) to arrive at a consensus view.

Small groups of peers carrying out an audit has the advantage of providing a forum to obtain realistic objectives and to point out flaws in methodology or analysis which the individual doctor may not notice. However, there are also drawbacks. Some small groups become either very destructive by insensitive handling of criticism so that little behavioural change takes place, or they avoid really challenging situations because of a fear of exposure before their colleagues. Shaw (1980c) has argued that clinical freedom may be jeopardized if small local groups of doctors set standards to which all the participants then feel obliged to adhere.

Self-audit

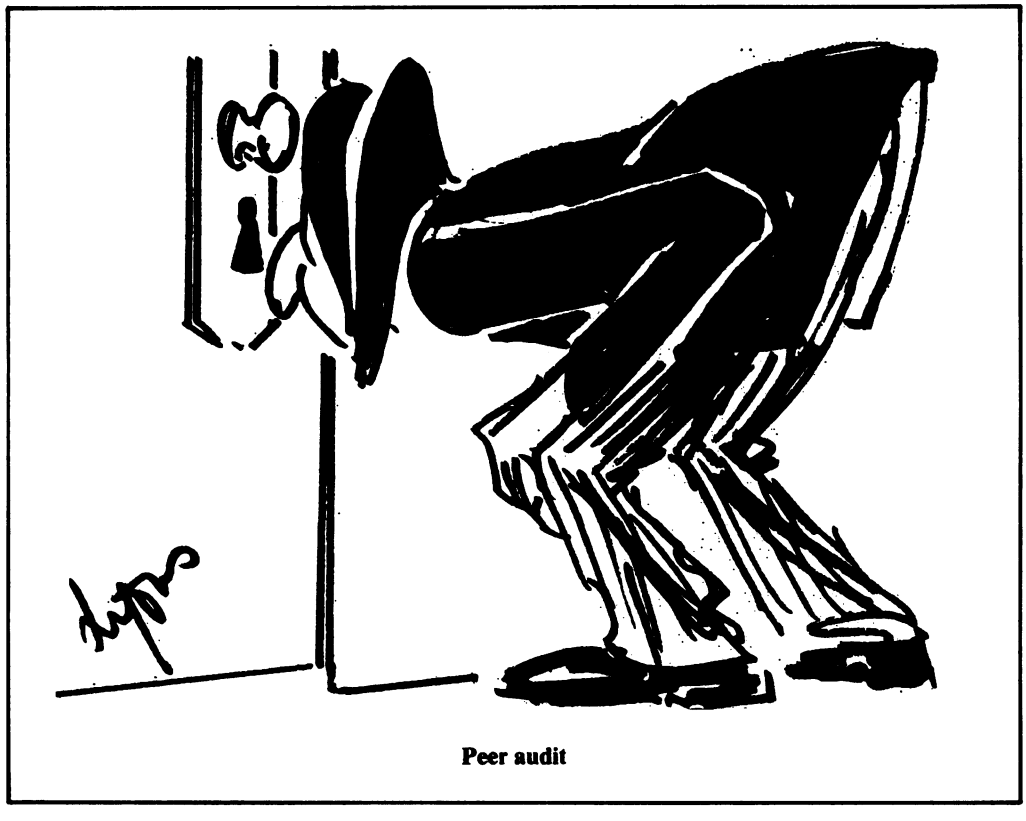
"And how his audit stands—who knows save heaven?"

Shakespeare (Hamlet)

Self-audit has much to recommend it and it is being practised increasingly (*Journal of the Royal College of General Practitioners*, 1979). When carried out properly, it can be the most rewarding from the viewpoint of making desirable changes in behaviour. General practitioners who have audited themselves are often astonished to find that they have not been performing clinically in the ways they had imagined. Thus an objective view can be obtained without involving other doctors which enables changes to be made from the highest motives—a desire to perform well and do the best for patients—rather than from baser motives such as a desire to appear well before colleagues, to avoid reprimand from authorities, or to receive extra remuneration from paymasters.

My own view is that peer review and self-audit should be regarded as two components of the same process, since the final common pathway of all medical audit is for the individual doctor to be confronted with his own behaviour when compared with his own criteria whether or not he agreed these criteria in a peer group, or compares his findings within a peer group. If the essential learning experience of audit is to lead to behavioural changes then the individual doctor must be intimately concerned in all stages of the audit (Shaw, 1980c).

Perhaps successful medical audit will always be a marriage between self-analysis and peer group discussions, as both are necessary to achieve different ends. No pressure should be brought to bear upon any doctor to conform to the professional norms as these norms will always be ridiculous within a short space of time as knowledge advances. Yet any doctor who practises outside these norms should first be aware of the fact, and



Peer audit

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secondly, be encouraged to monitor continuously the effects of his activity in order to challenge and modify both his own beliefs and those of his colleagues. That is the mark of a professional medical man and all society needs to do is to provide both the encouragement and the facilities to enable every doctor who wishes to incorporate medical audit into his everyday activities.

IS MEDICAL AUDIT NECESSARY?

"It is one thing to show a man that he is in error, and another to put him in possession of the truth."

John Locke

Many doctors will argue that there are already sufficient safeguards of the quality of medical care in the United Kingdom. These include open appointment procedures with independent assessors, numerous complaints procedures for the patient (including the full weight of the law), postgraduate sessions, discussions with colleagues, and a free press which usually sides with the patient in any confrontation.

What is so different and special about medical audit? What has changed over the last decade to produce such a torrent of support for audit from official reports? The Royal College of General Practitioners (1977) in its evidence to the Royal Commission, the BMA's Central Committee for Hospital Medical Services (*British Medical Journal*, 1978), and the Royal Commission on the National Health Service (Merrison, 1979), have all given support to medical audit either enthusiastically or else with few reservations.

I would suggest that some of the reasons for this pressure are as follows:

1. In all branches of medicine there has been a decline in the continuing relationship between a patient and a single doctor, with a consequent rapid increase in team care and the use of deputies. The larger the health care team, the more need there is for some formal process of review to ensure an acceptable level of continuous care.
2. Patients are becoming better educated in medical matters and therefore have higher expectations which lead them to be more critical of the quality of medical care provided.
3. The media are increasing their coverage of medical mistakes with 'shock horror' stories.
4. Many doctors, politicians and lay people believe that nationalized medicine protects the bad doctor and that not enough is done to encourage the improvement of standards of medical care within the National Health Service.
5. More health statistics are now widely published and regional inequalities brought home to the public.
6. Some members of the public are aware that audit has become mandatory in the USA and Canada and demand that similar measures are instituted here.

ARGUMENTS AGAINST AUDIT

Medical audit has many critics who have argued that the dangers and disadvantages of audit far outweigh any potential benefits. They argue as follows:

1. American experience has shown that audit is difficult, time consuming, and expensive (Markus, 1980; Meyers, 1980). Greer and Dobson (1979) estimated that implementing the PSRO program in the USA in 1976 cost $81·3 million and showed no significant change in either hospital utilization or associated government expenditure.
2. There is little evidence that the standard of patient care has been improved by audits. Fifer (1978b) reviews the possible explanations for this widespread belief in the USA and suggests that the unproductiveness of medical audit there is directly related to the essentially non-substantive content of the topics chosen for evaluation. He notes that the audit requirements have come from innately antagonistic quarters—if hospitals do not appear to satisfy those requirements, they might lose accreditation—and he believes that physicians perceive the purpose of medical audit to be inherently nihilistic and punitive.
3. There is a deep-rooted suspicion of external assessment of the doctor's clinical judgment, based to a great extent on experience in North America. For example, in Canada 'working papers in medical audit' have now been formalized and made available for scrutiny within each hospital by the Canadian Council on Hospital Accreditation (Surridge, 1979). These consist of comparisons between abstractions from the patients' records and criteria obtained from the medical literature; they are sent to the administrative staff of the hospital, or the chairman of the medical audit committee, for action. This process has naturally created anxiety amongst both English and Canadian doctors.
4. If voluntary audit is successful, then there will be pressures for it to be taken over by the Royal College or other bodies and made obligatory (Hall, 1979). This appears to have happened in America and Canada, which has led to fears of it happening in the UK.
5. The items which we can measure are not necessarily those which are the essential clinical skills and humanitarian qualities at the centre of good general practice (*Lancet*, 1980). Others have argued that assessing the quality of a doctor is very difficult, and should therefore not be attempted (Cargill, 1979). Cargill also points out that medical audit based on a review of the medical records is likely to be non-productive in view of the generally poor standard of record keeping.
6. Audit in general practice is particularly difficult since so many illnesses improve spontaneously. It is likely to be more difficult than hospital audit as it is much harder to audit a patient than it is to audit a disease (Stott and Davis, 1975; Mushlin *et al.*, 1978).
7. The results of audit will be made available for litigation purposes (Surridge, 1979).
8. Some medical writers in the popular press see audit as an unnecessary activity foisted onto the profession by élitist doctors. Peck (1980) argues that patient satisfaction is the only real kind of audit and views as

idiocy the statement that if we do not audit ourselves, it will be foisted onto us by bureaucrats.

At a recent conference on audit organized jointly by the British Medical Association and the Royal College of General Practitioners, a doctor from Wigan was reported as saying:

> "My local medical committee sent me here to say we want nothing to do with it. We're quite happy the way we are. Our patients are satisfied, we are satisfied, and I don't see any point in the whole business."
>
> (Laurance, 1980)

ARGUMENTS FOR AUDIT

It is important at this stage to weigh the benefits of audit against the time, cost, and potential disadvantages. The advantages fall into four broad groups:

1. *Educational value*

Most doctors who have undertaken a peer review or self-audit maintain that the results provided a powerful incentive to remedy deficiencies uncovered. Before a doctor can satisfactorily embark on self-evaluation, he has to be aware of his own deficiencies (Wood and Byrne, 1980). This can be done by other assessment programmes, but nothing makes deficiencies so clear as revealing them in everyday practice (Acheson, 1975; Erviti *et al.*, 1977; Horder, 1980). Audit-based approaches which concentrate on identifying criteria that clearly constitute 'deficiences' have been shown to be feasible and practicable (Williamson, 1978).

Sherman (1980) has pointed out that most instances of substandard medical care do not necessarily reflect a lack of knowledge, but rather a failure to use what the doctor already knows. Making the doctor aware of his own shortcomings should, therefore, provide motivation to improve care in this direction.

2. *Improvement of efficiency of practice*

A review of the process of care will reveal many activities which are inappropriate and inconsistent when compared with the original criteria set by the doctor. Remedying these produces a more effective process which must be more economical to the doctor (in terms of less time spent on repeat consultations), to the patient, and to society as a whole (Sheldon, 1979).

Block (1978) points out that the rocketing costs of health care in the USA have produced the demand to audit medical care; the profession there missed the opportunity to do it themselves, and so it was forced on them from above. Other workers point out that audit carried out as a routine part of daily clinical activity need not necessarily be a costly exercise (Ireland, 1980).

3. *Improvements in effectiveness of care*

This must be the greatest benefit of audit and the final common pathway of all studies—to show that the care received by the patients has improved. To measure changes in outcome is far from easy and is the greatest challenge facing those wishing to undertake medical audit in general practice.

4. *Reassurance to the public*

There has been increasing pressure for the medical profession to improve overall standards (Duncan, 1980). Gingerich (1979) points out that evaluation of clinical intervention, if done properly, will not only satisfy the demands of third party funders and consumers, but will also provide the clinician with first-hand information about his own practice.

PERSONAL EXPERIENCE

Eight years ago the facilities of the local Regional Health Authority computer were made available to our practice, thus providing us with the opportunity to collect certain items of information on every doctor/patient encounter in the practice. We decided to do this in order to examine the process of care for one or two clinical conditions which interested us.

For the three-year period from March 1975 to February 1978, a carbon copy was taken of every prescription issued by the practice, and the disease or problem for which each drug was given was added to the form. All the doctor/patient contacts were recorded, as were prescriptions issued after telephone consultations or repeat prescriptions without the patient being seen.

Throughout the study, details of all prescriptions issued were tabulated either using the computer or by hand, and from these tabulations we were able to study the drug treatment of any problem or condition. The accuracy of our recording methods was checked by obtaining photocopies of the prescriptions dispensed from the Prescription Pricing Authority.

The study is described more fully elsewhere (Sheldon, 1979).

Analysis of prescribing habits

During the first 12-month period a total of 7,748 prescriptions were entered on the computer file. Our checks had shown that five per cent of all prescriptions were not included because a carbon copy had not been taken, so the estimated total of prescriptions issued during the year was 8,135. Assuming that the average patient list was 1,550 (it rose at a constant rate from 1,350 at the beginning to 1,750 at the end of the first year), the prescription rate for medicines was 5·25 items per patient per year.

The number of different drug preparations used during this first year was 472, but this included prescriptions from one full-time doctor, a part-time assistant, and three occasional locum doctors.

During the third 12-month period, when all prescriptions were again monitored, a total of 10,110 items were prescribed. The average list size for this year was 2,213. Again, assuming that five per cent of prescriptions were not included, this gives a prescription rate of 4·79 items per patient per year.

Audit of clinical care

The main purpose of the study was to use the information obtained about prescribing habits to audit the care given in certain clinical situations. This was done for several conditions commonly encountered in general practice and a brief description of the audit of one of these is presented here. Fungal skin infections were chosen because it was felt that they were difficult to treat effectively in general practice and were often referred unnecessarily for consultant dermatological advice.

Table 1. Comparison of the number of consultations and items prescribed for fungal skin infections during a 12-month period before and after the audit in 1976.

	1975	1977
Patients treated	29	31
Illness episodes	33	33
Consultations	44	33
Repeated prescriptions	9	6
Items prescribed	60	39
Number of prescriptions for each agent		
'Tri-Adcortyl' cream	29	0
Griseofulvin tablets	12	5
'Tineafax' preparations	6	4
'Mycil' preparations	6	4
'Jadit' preparations	3	0
'Canesten' cream (clotrimazole)	2	14
Whitfield's ointment	0	7
Others	2	4
Total	60	39

Fungal skin infections

All the drugs used in fungal skin infections during the first year were listed (Table 1) and it was noted that no prescriptions had been issued for Whitfield's ointment (which is the standard treatment for fungal skin infections and is relatively cheap), whilst there were a large number of prescriptions for 'Tri-Adcortyl' cream, which is a combination proprietary preparation with no specific activity against ringworm.

Treatment protocols were produced for all the common fungal skin conditions and during the third year of the study we monitored the changes which occurred in our prescribing habits as a result of the auditing process. Table 1 shows that in 1977, after the audit, we stopped prescribing 'Tri-Adcortyl' cream and started prescribing Whitfield's ointment. We also noted that many fewer prescriptions for griseofulvin tablets were needed. Comparing the findings for 1975 and 1977, we found that although exactly the same number of illness episodes were treated in both years, the total number of items prescribed had fallen by a third from 60 to 39 and the number of consultations required had also fallen from 44 to 33.

Lessons learned

> "*If we respect truth, we must search for it by persistently searching for our errors, by indefatigable rational criticism and self-criticism.*"
>
> Karl Popper

The overwhelming impression on all those who took part in this audit was the tremendous impetus it provided to our continuing education. From the very beginning, when we tried to set the objectives for the care we provided, through to the continued monitoring of our activity after the audit, there was a constant stimulation to rethink, check with the literature, discuss with other practitioners and generally challenge the accepted norms of both our peers and specialists. I am certain that this would not have been so if someone outside the practice had been examining our work and comparing it with some other 'norm'. The greatest stimulus to behavioural change will always be self-discovery, and medical audit must remain an activity of individual doctors, or small groups of doctors, if it is to achieve its aim of improving the quality of medical care by altering patterns of behaviour.

Many commentators have argued against audit on the grounds that the data collection is too time consuming and expensive. We can refute these arguments, at least in so far as the use of an encounter form if concerned. The forms used were extremely simple in design, consisting of a space for a carbon copy of the prescription, and room to add the diagnosis or problem for which each drug was given. Additional information can be added to an encounter form if desired, although a few basic details about investigations performed and referrals to others is probably sufficient.

We were determined not to impose on the doctor, so the method of data collection had to be fitted into our normal routine without lengthening or altering the consultation. The receptionist therefore prepared the encounter form, entered the patient's name and address on the prescription, and clipped the prescription and carbon paper to the form. Not having to write the patient's details on the prescription saved about 15 seconds, which exactly matched the time needed to enter the diagnostic details. We found that approximately one hour per day of ancillary time per 2,500 patients was taken up first by preparing the forms, and then by collecting and sorting them afterwards. The doctor therefore had no extra work and the data collection continued for nearly four years without difficulty or interruption.

Most of the data analysis can also be delegated to practice staff. For the first year of our study the computer was used, but in the final year the analyses were done by hand by our secretary. If two or three clinical conditions are chosen for study, it is a simple task to collect the forms relating to these conditions to carry out simple analyses, and to examine the medical records to find out the outcome of the consultation. Altogether we estimated that a total of seven hours per week of ancillary staff time was expended on this audit (for two doctors with a small list size). Minimal effort was required on the part of the doctor, apart from at the beginning and end of each audit when the objectives were agreed or re-examined.

Above all, this simple exercise in medical audit confirmed the overriding importance of audit to the professional ethos of the doctor. For the first time we began to feel 'on top' of some of our problems. We did not know all the answers, but then neither did anyone else. But now we had a tool with which to follow up our decisions, to test our theories, and to chide us when we slackened.

ESSENTIALS OF MEDICAL AUDIT

In nearly all studies of medical audit, even those with widely differing methods and results, there are common underlying basic principles which may be taken as basic requirements. They are:

1. A systematic examination of some aspect (either administrative or clinical) of the activity of providing health care.

2. A comparison of the results of this examination with a set of criteria or standards derived either internally or externally.
3. A desire to assess the quality of care (as described by its effectiveness and efficiency), with a view to highlighting deficiencies which can then be remedied.

The structure of medical audit needed to meet these basic requirements therefore consists of the following five steps (see Figure 5).

1. *Setting objectives*

First, a topic or area of activity must be chosen. This can vary from a simple clinical problem, such as the treatment of vaginal discharge, to a complicated team activity, such as the routine care of the elderly at risk.

Objectives are set both for the outcomes of care and for the process and structure believed necessary to reach those outcomes. As previously discussed, ideally these objectives are determined internally by each doctor or group of doctors. However, advice should also be sought from other general practitioners and specialists, and also

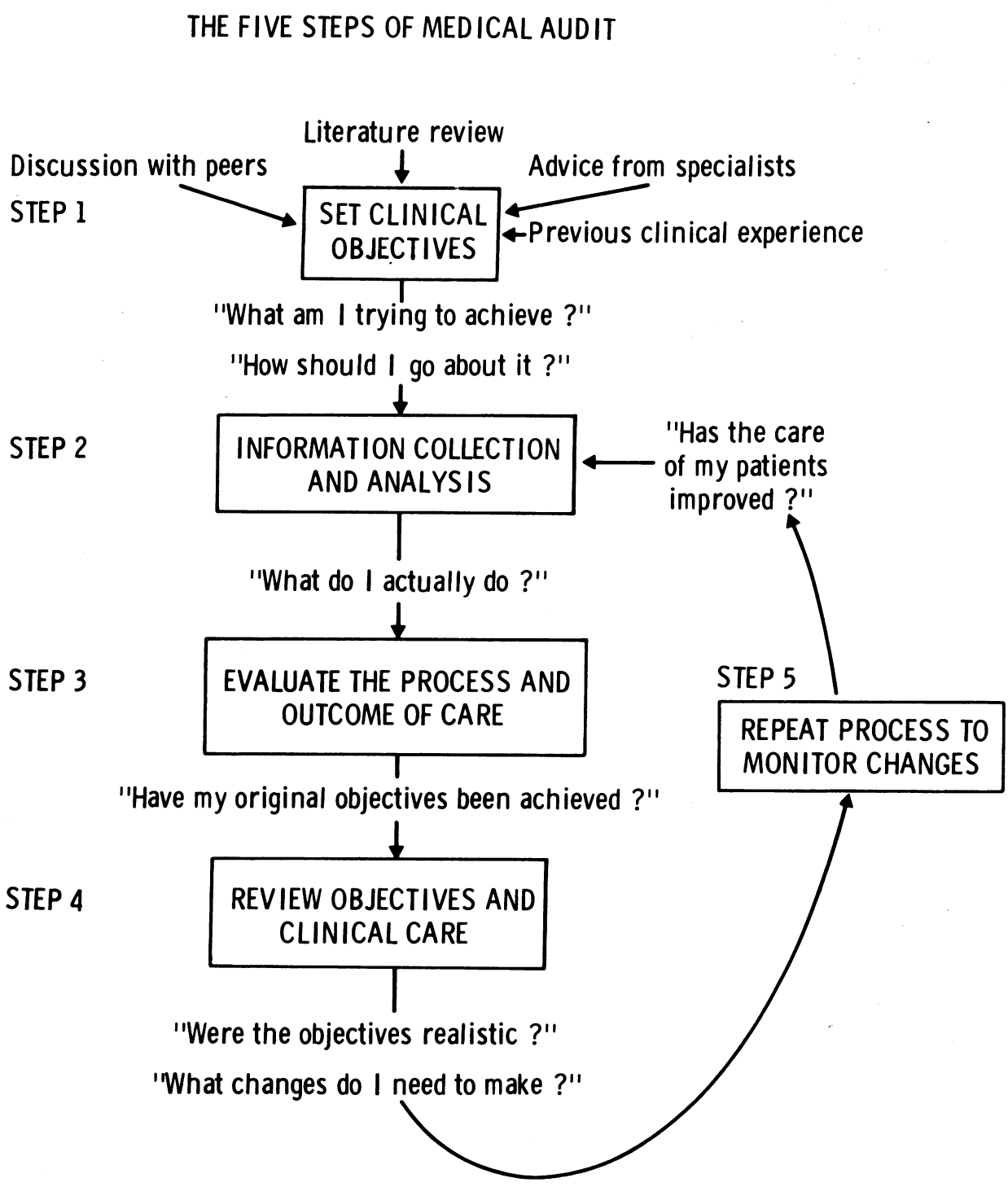

Figure 5. The five steps of medical audit.

by reference to published works. These objectives set a standard against which the participating doctors will then be able to judge their own performance.

2. *Information collection and analysis*

Data must now be collected on the everyday care of the topic to be studied. This brings us to the problem of what information must be collected, and how. If possible, attempts should always be made to collect details of the outcome of interventions: for example: How quickly did patients return to their previous state of health? Was there any residual disability? How long were patients off work? How much did patients suffer?

Such data collection often proves difficult, but reviewing the records of patients will provide some of the answers, and enquiry from patients still more. As the outcome is hard to assess, it is sometimes possible to collect only details of the process of care: How many repeat consultations were needed? How many drugs were prescribed? What investigations were done? What referrals to specialists were made?

It is accepted that a 'good' process of care does not necessarily lead to a satisfactory outcome, and more research needs to be done in general practice to determine how process affects outcome in each condition. In the meantime, intermediate measures of outcome may be used which are generally accepted as being beneficial. Thus, a high uptake of immunization is considered 'good,' and attainment of this objective can be measured, whereas to monitor the morbidity and mortality from the relevant infectious diseases in any one practice would be extremely difficult.

When decisions have been made about the type of information to be collected, methods of information collection can be devised. These methods will include reviewing the medical records; use of registers of diagnoses, investigations and referrals; and the use of encounter forms recording the therapy given and the problems identified at each consultation.

The data collection process must continue for some time, so it should be designed to cause as little disruption as possible to daily activities. The doctor's daily involvement must be minimal, and the best results are obtained where the practice ancillary staff are given the task of data collection as part of their normal duties.

Analysis of the information can be tackled by hand, by feature cards, or by computer. Assuming that most practices do not yet have access to a computer, quite satisfactory analyses can be done the hard way, by hand.

3. *Evaluation of the process and outcome of care*

The initial analysis of the information usually consists of numbers and percentages (for example, 40 per cent of the women with vaginal discharge had a swab taken; 60 per cent received Flagyl). These figures need to be interpreted by reference to the medical records of all, or a sample of the patients. Reference to the records may also help to indicate the outcome by comparing such factors as return consultation rates, relapses, amount of medication needed, or time off work.

Other more sophisticated techniques of investigating outcome may also be used if desired. These usually consist of direct enquiries to a sample of the patients through questionnaires or interview.

4. *Review of objectives*

The analysis of the collected information will thus answer the question: "What did I actually do?" and so should indicate, at least in part, how well the patients were cared for. When this information is compared with the

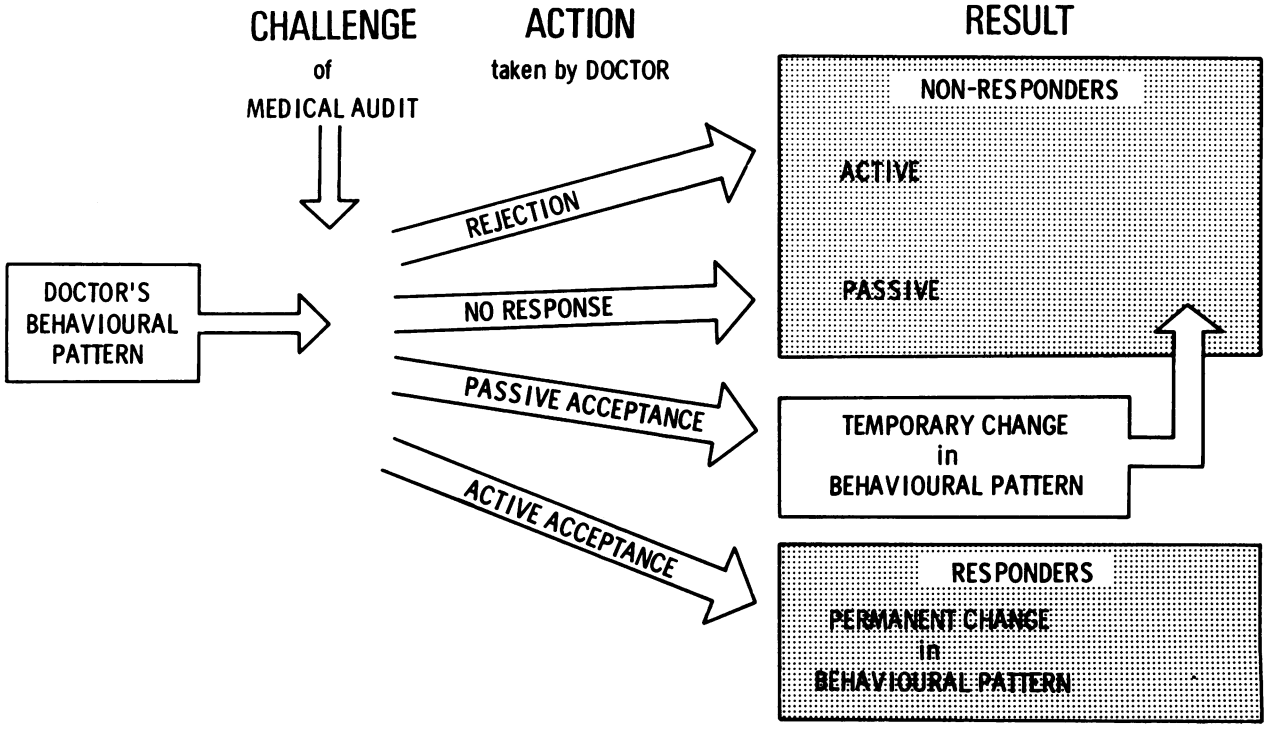

Figure 6. The possible behavioural changes following the challenge of audit.

original objectives, the processes and outcomes of care are often found not to live up to the doctor's expectations.

Two possibilities are now evident: either the original objectives were not realistic and need to be modified in the light of experience; or the original objectives were correct, but the standard of care was inadequate.

Changes in the objectives, or projected changes in behaviour, should now be made. This can be done either by the general practitioner alone or by reference to a peer group.

5. *Monitor changes made*

A repeat of the steps involving information collection and analysis are needed to monitor any changes made. It has been suggested that behavioural changes following an audit are only temporary and that doctors soon fall back into their previous bad habits. However, if deficiencies have been discovered by doctors themselves and they are well motivated to improve the standard of care, then the resultant change is more likely to be permanent (Figure 6).

Many workers have stressed the importance of this final stage of audit, as no audit is complete until desirable change can be demonstrated to have occurred (*British Medical Journal*, 1976; Batalden, 1977; Beezley and Heil, 1978; Mushlin *et al.*, 1978; Stern, 1978).

Most medical audit studies now employ these five stages and it is suggested that they are all essential components of any successful audit (Gingerich, 1979).

An outline of how such a medical audit might be conducted in general practice is given in the appendix.

CONCLUSIONS

Medical audit has progressed rapidly over the last decade, although much developmental work remains to be done before it can become a routine activity in service practices. Most audit studies so far published have been imperfect and should be considered as research activities rather than examples to copy. Much more experimentation is required in general practice to develop medical audit into a routine practice activity which demonstrably improves the provision of primary health care.

Effectiveness

Enough studies have now been carried out to indicate that it is possible to organize medical audit in general practice. However, nearly every study so far reported has described short-term studies and evidence is still lacking that medical audit can be carried out continuously or at least regularly in order to monitor care on a continuing basis.

Is such audit effective? That is, does it demonstrate to the doctor the deficiencies in his practice and consultation technique? Does it then enable him to make the required changes, and finally monitor those changes to ensure that they are permanent? As yet, there are no clear answers and future studies in medical audit must attempt to answer these questions.

Benefits

For the patient

A few studies have described changes in the process of care given to the patient with the assumption that better care leads to better health. As yet there is no direct evidence that the patient has benefited from audit and the early development of measurable outcomes of our intervention is of importance. To put this statement into perspective, it is fair to say that virtually no other aspect of health care in which major changes have been instituted over the last few decades has attempted to show that the patient has actually benefited from such change.

For the doctor

I have been impressed with the effect of medical audit on the participating doctors who have undertaken it. The first reaction is nearly always one of astonishment at how different their actions are in practice, when measured objectively, from their rose-tinted expectations. This tends to be true particularly with regard to prescriptions. I now believe that it is fair to say that no general practitioner has any real idea of his prescription activity until this has been audited.

It has also impressed me how valuable this information is when gathered and contemplated by the doctor himself. None of us likes to be criticized by others and I am doubtful if either peer pressure or external exhortation will produce permanent and beneficial changes in a doctor's behaviour patterns. It is my belief that we should encourage self-review of clinical activities, although it will always be helpful to share experiences and results with groups of like-minded peers. However, this activity should probably be supplementary to self-audit rather than a substitute for it.

For the community

It has been suggested that any activity which demonstrates a reduction in certain measurable costs (such as referrals to hospital or number of prescriptions issued) is of value to the Health Service as a whole and therefore to be encouraged. We should not be satisfied with this simplistic view, but try to discover the ways in which altering one aspect of care influences other aspects. An example from my own experience concerned the percentage of all consultations which ended with a prescription. As a result of constantly examining the reasons why I was prescribing, the number of prescriptions issued fell until my prescribing costs, as measured by the Prescription Pricing Authorities, were well below the local and national averages. What I failed to study was the consequent changes engendered by my actions. There was a suggestion that I was performing more routine investigations, perhaps as a substitute for prescribing. No effort was made to measure whether patients returned to work more quickly or whether more referrals were made. It is surely important that any attempt to audit our activities must bear in mind the ripple effect of our actions and so attempt to put medical audit on a firmer footing in the future.

Compulsory audit

Medical audit will be beneficial only if it is a voluntary activity initiated by the desire to study and improve personal clinical actions. We can do much to encourage doctors to audit with the provision of expertise and facilities, but any attempt at coercion will fail. We must educate all new entrants to general practice on the benefits of audit, but accept that some will not wish to participate.

I am convinced that medical audit will be a complete waste of time, effort and money *unless* it is undertaken enthusiastically by general practitioners willing to examine critically their own activities.

Standards in medicine have usually been created by conventional wisdom, so *ipso facto* the standards are always changing. Traditionally, the controlled clinical trial has been the mainstay of establishing such standards, but in general practice it is audit, which links structure, process and outcome, which will be invaluable in constantly testing current standards and modifying them in the light of new knowledge and practical experience.

Measuring the quality of care in general practice has been likened to attempting to measure the quality of life (Stott and Davis, 1975), and whilst accepting that we must start by measuring those things which are measurable (Acheson, 1975), we must be prepared to find little correlation at first between what we can measure and what is important in medical care. Rapid advances are now being made, and the audit of the 1980s should not be confused with the initial pilot studies in the 1970s.

A final word comes from Meyers (1980):

> "Those who enthuse prematurely about peer review should be prevented from playing a major role in its implementation. By all means let us have pilot studies of all forms of peer review, but let us insist on proper assessment of the value of various methods of such review to doctors and patients, together with a study of their cost-effectiveness, before the notion of infallibility of audit and its proponents becomes accepted by the profession as conventional wisdom."

Future reports of medical audit should attempt to answer this challenge.

APPENDIX

Suggested protocol for clinical audit in general practice

THERE are as many different ways of conducting medical audit as there are general practitioners, so the following suggestions are intended to stimulate ideas rather than present an ideal approach. As mentioned above (p. 6), I am sure that Donabedian's division of audit into structure, process and outcome should now be combined into an audit programme using all three aspects of care as applied to 'tracer' conditions commonly encountered in daily practice. The following is a brief description of how such an audit might be undertaken:

Aim

This audit will investigate the way our practice manages children under 15 years presenting with earache, in order to identify deficiencies in care and correct them where appropriate.

Objectives

1. *Structure*

We will audit the doctor's knowledge of all aspects of middle ear disease; the availability of help at all times of the week for such acute episodes of illness; and the availability and reliability of diagnostic equipment needed to cope with these conditions.

2. *Process*

We will audit the range of diagnoses made when children present with earache and the drug therapy used.

3. *Outcome*

A series of desirable outcome measures will be decided upon, and compared with the actual outcomes measured over one year in the practice.

Standard setting

This list is presented solely to indicate the range and use of standards in medical audit, *not* as a suggested set of standards nor as one which I would necessarily use myself.

1. *Structure*
   a) Each child presenting with earache will have a full examination of the ears and upper respiratory tract. Thus each doctor (and nurse) must have an effective auroscope with access to a sufficient supply of spare batteries.
   b) Children with more than one attack of middle ear infection in a year (or in other cases to be defined) will have their hearing tested. The practice audiometer will be available and in working order at all times.
   c) Children with earache presenting before 5 p.m. will be seen that day either in the surgery or at home, whichever is more appropriate. After surgery hours, emergency calls for this condition should normally be seen and examined by the doctor on call.

2. *Process*
   a) In each case the diagnostic label will be as accurate as possible with regard to both the site of the problem and the likely cause.
   b) If there is inflammation in the middle ear, the ear should be re-examined after treatment to assess recovery. If any doubt exists, a further examination will be made and hearing tested as appropriate.
   c) When there is evidence of infection in the middle ear which is not associated with viral infection in the upper respiratory tract, then a suitable antibiotic will be given.
   d) The antibiotic of choice is X in a dosage of Y. If sensitivity exists then the next best antibiotic is Z. A suitable quantity of emergency starter packs will be kept by all doctors to enable antibiotic therapy to start as soon as possible.
   e) Any child with more than two attacks in any six-month period will be fully examined with a view to finding causative factors which may respond to other treatment.

3. *Outcome*

A list of measures of a successful outcome for all conditions, with the corresponding measures for earache in children is given in Table 2. All patients presenting with earache over the next year will be questioned about the final outcome by a questionnaire.

Data collection and analysis

The 'tools' and procedures needed for this audit are as follows:

a) The practice secretary will check diagnostic equipment at regular intervals and keep a log of problems of deficiencies.
b) A suitable 'messages received' book will be kept so that the practice secretary can identify those patients presenting through the receptionists where the request for help was for earache in a child under 15 years of age.
c) A morbidity register will be kept to record all children with earache, or an encounter form used to collect data.
d) Good records will be kept, with the minimum entry for this condition being: date, duration of symptoms,

Table 2. Measures of successful outcome for all conditions with corresponding measures for children with earache.

General aspects of a successful outcome in any clinical condition	*Specific measures for children with earache*
1. Primary prevention of disease whenever possible.	Usually not possible, but give health education to parents regarding treatment of catarrh and upper respiratory tract infections.
2. Complete elimination of any pathogenic organism without damage to the host tissues.	Use appropriate antibiotic only when bacterial infection is present. (How do we know?—check with specialists. Do we need to investigate this area?)
3. Secondary prevention of the consequences of the disease process.	The complication of glue ear should not arise. (How do we ensure this?) No permanent hearing deficiency is produced.
4. Relief of the patient's symptoms, distress and anxiety in as short a time as possible.	Relief of severe pain should normally be achieved in eight hours. Parental anxiety should be relieved by prompt and effective attention to the child. Long-term hearing problems should be discussed. In recurrent cases, advice should be given to the parent as to how to act in the early stages of an attack.
5. Avoidance of iatrogenic symptoms or disease.	Patients sensitive to particular antibiotics should not be given those antibiotics. Drugs with possible side-effects or adverse reactions should be used only when strictly necessary.
6. Prolongation of life to its maximum, thus avoiding premature deaths.	Not normally applicable.
7. Minimizing the cost of the disease to the patient, the doctor, and society.	The indirect cost of time and effort on part of both parent and doctor should be minimized by appropriate, timely treatment and avoidance of complications. Any drug therapy will be the 'best buy' having regard to appropriateness, effectiveness, safety and cost. Referrals to specialists will be required only to cope with complications or associated pathology; and these should be minimised by appropriate care by the general practitioner.
8. Producing a satisfied patient.	In this case, the parent must be satisfied.
9. Clarifying and relieving the patient's interpersonal problems.	Not normally applicable, but the doctor should be aware of attention-seeking behaviour in some children who may complain of earache without demonstrable pathology.
10. Not compromising the patient's integrity from the ethical point of view.	Not normally applicable.
11. Preservation of, or improvement to, the patient's level of functioning at home, work, and in society.	The child should not be away from school for more than four days.
12. Producing the desired outcome in the shortest period of time.	Outcome measures listed above will apply.

1. These general outcome measures should apply to almost any clinical condition in general practice, and can be modified to suit any medical audit.

2. The specific outcome measures for children with earache are *not* standards to be applied to 'judge' any doctor, but should consist of personal suggested standards. It will be noted that some are incomplete and will demand further study or research on the part of the participating doctors.

results of examination, investigations performed, drug therapy given, diagnostic label.

e) Facilities for the ancillary staff will be available to review the records of all children with earache identified from message books, morbidity register, or encounter form.

f) A questionnaire will be sent to all or a sample of parents two weeks after the initial consultation to determine initial outcome and satisfaction. A second questionnaire may be used to test long-term outcome, but patients with complications should be seen again by the doctor and be identifiable from the medical record.

g) A referral register will be kept so that all referrals of children with earache can be identified.

At first sight, this list seems formidable, but in fact many of the activities described would normally be carried out anyway, and the additional items should all be within the capability of the practice ancillary staff. The doctor's involvement in the data collection process should be minimal.

The period of data collection will need to be at least six months, and since further periods of collection should be carried out at regular intervals in order to monitor changes, it is desirable to devise a continuous information collection process which does not interfere with the practice routine. Several conditions can be audited simultaneously making the initial outlay of effort and time more worthwhile.

Data analysis should be left to one member of the practice staff (preferably the most senior), who will collect and analyse the relevant information under the guidance of the medical staff.

Data evaluation

Evaluation should become a regular activity in the practice, with analyses being given to the doctors, enabling them to compare their activities with their own agreed standards. Any changes thought necessary should be written down for future reference alongside the original standards.

Monitoring changes

Further periods of data collection will be made without the general practitioner being aware which month's data will be used (because the collection process is continuous) in order to monitor the changes made following the auditing process.

Comment

I make no apology for making the audit of clinical conditions appear so complicated. To be effective, the process will involve most of the members of the practice and should be a continuous process. Entropy is a fact of life in practice and can only be prevented by incorporating medical audit into the everyday practice routine.

This structure should be adaptable to almost any clinical condition encountered in general practice. Although there will be an initial change in the general practitioner's behaviour because he knows that he is being audited, this cannot be maintained indefinitely, and after a month or so, 'normal behaviour' will be resumed. It is best to audit two or three conditions at the same time to prevent one topic from occupying too high a place in the doctor's thoughts.

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