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Medical Audit

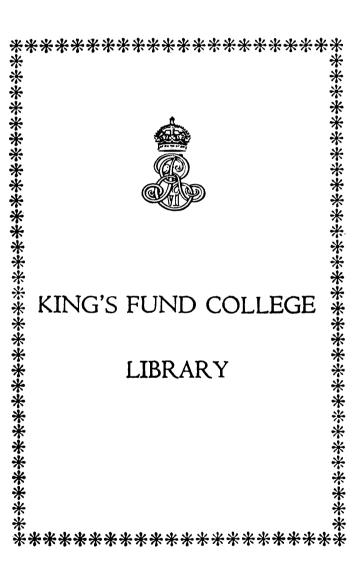
A HOSPITAL HANDBOOK



Charles Shaw

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Charles Shaw

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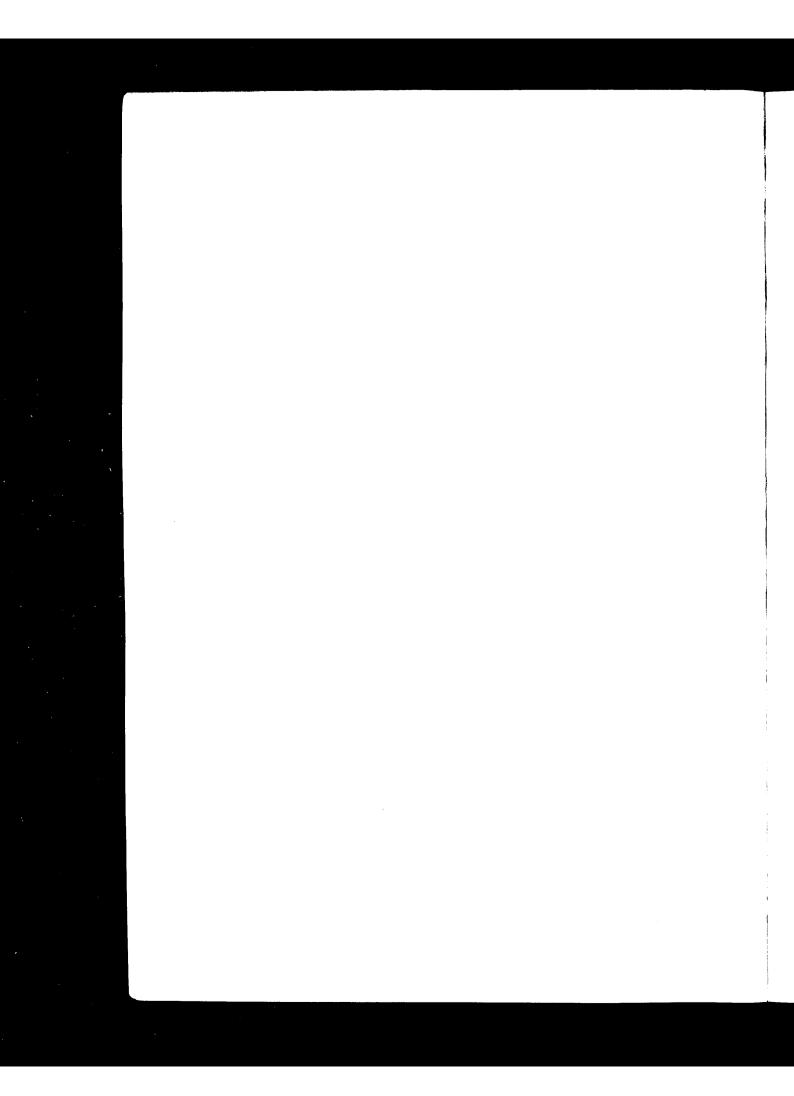
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CONTENTS

INTRODUCTION		page
1	The context of medical audit	1
	Quality assurance and medical audit	1
	Changing traditions	1
	Grounds for concern	2
	Indications for medical audit	8
	Attitudes of national bodies	9
2	Effective medical audit	12
	Does audit change anything?	12
	Mechanisms for change	13
	Characteristics of effective medical audit	14
	Existing review mechanisms	15
3	Getting started	18
	Who should begin?	18
	Who should be included?	18
	When to arrange meetings	19
	Who should organise them?	19
	Choosing a method of audit	20
	Choosing a subject	25

		page
4	Administrative issues	34
	Support and resources	34
	Data	36
	Clinical databases	38
	Computers and audit	39
	Classification and coding	46
	Medical records	46
	Extending the scope of audit	47
	Medical staff organisation	48
	Confidentiality and legal issues	50
5	Reflections on audit	52
	General reactions	52
	Future prospects	53

Appendix: Recommendations from the Netherlands

INTRODUCTION

Medical audit is not new. One of the functions of the Royal College of Physicians of London, incorporated in the original charter of 1518, is to uphold the standards of medicine 'both for their own honour and public benefit'. It is precisely in the pursuit of these standards that individual clinicians or groups of clinicians have organised a systematic analysis of their own work with a view to improving the quality of practice. Often this is being done by enthusiasts with limited resources, but with a commitment to provide a service of the highest quality. They have undertaken medical audit not because of any pressure on them to do so but because they believe it will be useful and will enable them to practise the sort of medicine to which they aspire. In spite of these successes medical audit has not become widespread.

One reason is that the medical profession already believes itself to be looking critically at its work through, for example, post graduate meetings and case conferences. Yet it has been shown many times that where clinical practice has been reviewed in a more systematic and organised way unexpected findings are common and improvements often possible: 'no one knows what they do until they start looking'. In the present debate on health services — in Britain and overseas — demands for medical effectiveness are increasingly being heard and doctors as well as hospitals are being pressed to justify their performance. Medical audit is one component of quality assurance, and quality assurance is an essential part of any management process. It follows that audit should be an essential part of clinical practice, to be undertaken alongside running a service, looking after patients, and keeping up to date through continuing education and research.

It is only a matter of time before medical audit becomes an established part of all medical practice. The objective of this booklet is to provide an explanation of audit and examples of work currently being undertaken and to provide a guide as to how interested clinicians could go about initiating audit in their district. It also aims to illustrate to doctors the intellectual stimulation of asking questions about entrenched practices and to show that audit, like other forms of research, is the pursuit of knowledge which may throw new light on medical practice. Although many of the principles are also applicable to general practice, this volume is aimed primarily at hospital audit.

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1THE CONTEXT OF MEDICAL AUDIT

1.1 QUALITY ASSURANCE AND MEDICAL AUDIT

Quality assurance implies the definition of standards, the measurement of their achievement and the mechanisms to improve performance. Quality in health care may be seen from various angles: equity and accessibility (the provision and availability of service to everyone), effectiveness (technical accuracy in achieving the intended benefits), acceptability (to the consumer and the provider) and efficiency (the avoidance of waste).

A variety of mechanisms exist to assess and improve these elements in health services in Britain. But there are problems in the measurement of effectiveness; with few exceptions we know little about everyday patterns of clinical practice and even less about the cumulative results achieved locally.

Neither national experts nor local managers are in a position to assess and control the quality of local clinical practice on a regular basis. But internal 'peer review' by practising local clinicians can help to assure quality if it is regular, objective, explicit and effective. That is medical audit.

1.2 CHANGING TRADITIONS

Questions about quality are neither new, nor limited to health care; increasingly people question traditional assumptions. The public is generally better informed, by virtue of communications technology as well as consumer organisations and formal education; employees have negotiated for, and expect, more information about and involvement in their work; and managers are shifting emphasis away from the product towards the customer as final arbiter of quality.

In health care, a growing interest in quality is common to most developed countries; what differs is the means by which this interest is expressed and the mechanisms by which quality is monitored. Some countries, such as Australia, Canada and the USA have formal organisations which act as national champions of quality, independent of the government or paying agencies; others, such as Spain, are developing similar systems but which are clearly directed by government. The British National Health Service (NHS) has always been constrained by central budget allocation, but has been relatively unregulated either voluntarily or by statute as to how it should perform its task.

Attitudes are now changing. The question is no longer whether we should make an issue of the quality and effectiveness of the service, but who will take the lead in assuring quality — government, managers, the public or the professions. This booklet assumes that the medical profession can and should make a significant contribution through formal peer review of medical practice — 'medical audit'.

1.3 GROUNDS FOR CONCERN

Variations in clinical practice

Antipathy to medical audit is based on a variety of arguments, such as:

- there is no problem since medical practice is self-auditing
- problems cannot be solved by audit
- medical practice cannot be measured
- resources, information and time are not available.

The three last issues will be dealt with in chapters 2, 3 and 4 respectively: let us examine the first point.

Those who argue that there is no problem assume that clinical practice is always technically, socially and professionally acceptable. Objective studies of normal working practice rarely — if ever — show this to be true, either at local or national level; on the contrary, audit often demonstrates wider and more unacceptable variations in practice and in outcome than were expected. Relatively poor performance, which may not be discernible by anecdotal review, often becomes evident only by measurement and by comparison of quantified patterns of care.

Examples from clinical practice

Communication: a quarter of all cases of 'malpractice' handled by medical defence organisations involved failure of communication between professionals, or between them and their patients.

Drug interactions: 24% of elderly people admitted to a teaching hospital were on drugs which were contraindicated or interacting ¹.

Surgical audit: 54% of surgeons and 40% of anaesthetists did not hold regular reviews of their operation results².

Consultant supervision: in 42% of perioperative deaths, junior surgeons had not sought consultant advice ².

Examples from clinical outcome

Mortality: the chances that conditions which are generally considered to be amenable to treatment will prove fatal were three times higher in some areas of England and Wales than in others³.

In the age range 5-64 the risks of dying from hernia, gallstones or appendicitis varied tenfold among districts in England and Wales (figure 1) ⁴. Deaths among people aged 5-44 from asthma also show wide variation (figure 2) ⁴ Although population risk is related to the incidence of these conditions, the

variations in outcome imply differences in the technical effectiveness of medical care.

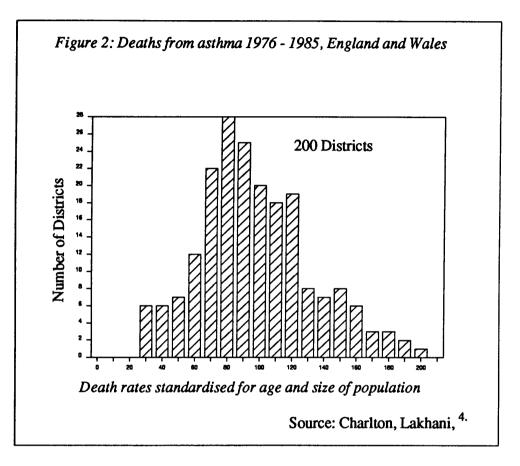
Figure 1: Deaths from Appendicitis, Hernia and Gallstones
1976 - 1985, England and Wales

200 Districts

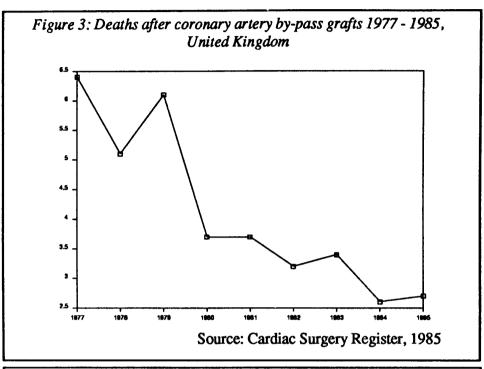
Death Rates Standardised for Age and Size of Population

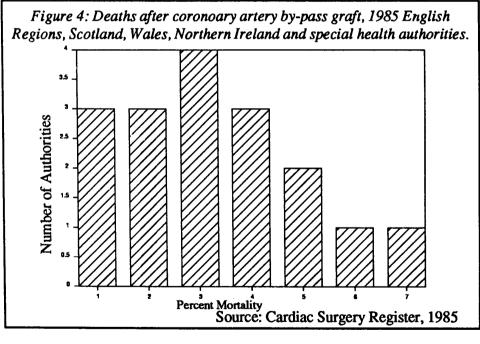
Source: Charlton, Lakhani

4



Surgical outcome: comparison between units showed better results, especially in bowel, vascular and urological surgery, in departments with primary expertise or higher workloads. This was demonstrated by the Lothian audit⁵, the Confidential Enquiry into Perioperative Deaths (CEPOD)² and the UK Cardiac Surgical Register⁶. The association of advancing techniques and the sharing of accurate data on results over time is shown for coronary artery by-pass grafts in figure 3. The range of post-operative mortality between regions is shown in figure 4.





Quality-related costs

Apart from clinical reasons for analysing medical practice, there are also reasons of efficiency and good management.

A valuable concept in industry is the cost of over-using resources or simply not getting it right first time. In health care, elements of this can be identified in terms of resource costs to the health system, which are quite separate from the human cost and inconvenience to the patient.

Examples of resource costs

Detectable conditions: the costs of managing congenital dislocation of the hip, neural tube defects or Down's Syndrome which could have been avoided or treated early.

Extra materials: unnecessary or excessive use of drugs, intravenous fluids, investigations, or sterile supplies.

Extra morbidity: illness, delaying discharge caused or exacerbated by treatment (such as drug interactions, post-operative infection or wound breakdown).

Extra services: unnecessary outpatient reattendances.

Extra inpatient days: waiting for treatment or for investigations to be done (or reported); waiting for authority to discharge.

Inappropriate admission: admission when it is not clinically required or to inappropriate beds (eg general medical rather than geriatric) causing longer eventual stay.

Opportunity costs: theatre lists, outpatient clinics or X-ray screening sessions cancelled at short notice.

1.4 INDICATIONS FOR MEDICAL AUDIT

General motivation

Professional reasons for embarking on audit include:⁷

Hippocratic: striving for continued improvement of performance and the highest standards of excellence.

Societal: accountability to the society from which the profession obtains authorisation and economic support to practise.

Educational: accommodation to the growing technical and administrative complexity of medical practice, where errors can prove costly in human disability and economic loss.

Survival: maintenance of professional independence and status. Litigation, private sector competition, and suggestions of short-term contracts, re-licencing and internal marketing in the NHS all make it necessary for doctors to be able to demonstrate proficiency.

Local incentives

Doctors are already busy with clinical, teaching, research and administrative commitments; a formal approach to audit is yet another demand on their time. What benefits can it offer to patients, staff and doctors themselves?

Examples of benefits from audit

Improvement of clinical care: audit should demonstrate objectively what is happening. Quite apart from mistakes, suboptimal care may be due to a variety of professional and administrative problems which tend to escape anecdotal case reviews⁸.

Enhancement of education and training: structured review allows analysis, comparison and evaluation of individual performance; it promotes adherence to local clinical policies and offers opportunity for publication of results.

Educational programmes can be constructed to meet demonstrated needs of individuals and groups.

Recognition of training posts: Royal Colleges and faculties increasingly seek evidence of formally organised review and could withdraw recognition from departments which do not provide this.

Demonstration of effectiveness and efficiency: tangible evidence of effective use of existing clinical resources is increasingly important in bargaining for more — or even in resisting cuts.

1.5 ATTITUDES OF NATIONAL BODIES

The use of medical audit has been increasingly reinforced by the requirement for some form of internal clinical review as a condition of accreditation of training posts in individual hospitals. Several colleges have established committees or working parties to catalogue and promote quality assurance⁹.

Recent reports, such as *The composition of the surgical team* (Royal College of Surgeons of England)¹⁰ and CEPOD (Association of Anaesthetists and Association of Surgeons)² explicitly promote audit as an essential and legitimate element of clinical practice.

Although the DHSS White Paper on primary care, *Promoting Better Health* explicitly supported the monitoring of GP performance¹¹, no similar statements had been made about hospital doctors prior to the review published in 1989.

As demands increase for the NHS to be 'managed', the medical profession must be seen to be able and willing to regulate itself. At an individual level, this means formal analysis of clinical work — medical audit by peer review.

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2 EFFECTIVE MEDICAL AUDIT

2.1 DOES AUDIT CHANGE ANYTHING?

Medical audit, like quality assurance, is a three-part cycle. The first stage is to define expectations, the second to compare these with observed reality, and the third to bring about appropriate change in clinical practice. Inability to succeed in the third phase is probably the most realistic argument against embarking on the previous two.

Changes may not be immediately obvious; the agreement of explicit clinical guidelines among a group of doctors may be a significant step forward. A demonstrable change in the process of clinical practice towards an approved outcome may be an approximate measure of success. The ultimate measure is an improved outcome for the individual patient or group of patients — but, even when audit brings this about, a causal link may be hard to prove.

Change in clinical practice

Reports of significant and sustained changes in clinical practice associated with the introduction of peer review have appeared in many countries, including the United States. For example, regular scrutiny and feedback led to a reduction in admission rates and length of stay in Ohio¹ and in a halving of diagnostic tests — notably when audit was used in conjunction with explicit guidelines.² Similarly, in Britain, Young³ and Fowkes⁴ reported sustained reductions in these tests where active review was undertaken. This contrasts with the demonstration by Fowkes elsewhere⁵, Heasman⁶ and Heath¹ that passive feedback of data without active participation and explicit guidelines was not accompanied by demonstrable change in clinical practice. A steady rise in the caesarean section rate over ten years in a large Scottish maternity hospital stopped and reversed when preliminary discussions began on a prospective audit.8

The first five years of formal surgical audit in Lothian were associated with less radical surgery and an increase in cross-referrals to specialist surgeons, particularly for prostatectomy, vascular and breast surgery, where results had been shown to be better in specialist units⁹.

Change in clinical outcome

The Lothian audit, which involved over 30 consultants in regular meetings, also demonstrated a statistically significant reduction in re-operation rates for intra-abdominal surgery (particularly for subphrenic abscess), gallstones, arterial grafts and primary amputations. Operative mortality also fell significantly for aortic aneurysms, other arterial grafts, biliary and pancreatic surgery and large bowel resection for benign disease. Reductions in wound infection rates have been linked to peer review by various writers, including Sellu¹⁰ in Ealing. Sellu demonstrated a 50% fall in infection rates over a three year period which was confined to the participating surgical firms with an estimated saving of £40.00 per patient — or £23,000 per year. Similar improvements in infection rates were shown by Collopy in Melbourne¹¹

2.2 MECHANISMS FOR CHANGE

General strategies

Doctors in Britain have a high degree of clinical autonomy compared with those in North America; there are no general mechanisms for regular formal review by peer groups, by licensing bodies, by Royal Colleges or by employers. In the absence of such central control, medical audit in this country relies heavily on peer group pressure for continuing education.

Education and clinical guidelines

Many postgraduate programmes are planned with little or no reference to deficits in performance or knowledge demonstrated by review of clinical practice. Audit offers a chance to link the design of programmes to evidence of educational needs.

Education is not a universal cure for poor performance, unless the underlying problem is lack of knowledge ¹². In reality it is frequently not lack of knowledge but failure to apply it — for a variety of behavioural, organisational and environmental reasons — that produces poor performance ¹³. A study by Ashbaugh and McKean in the US of the records of 4,500 patients showed that 94% of poor outcomes were failures of performance rather than of knowledge ¹⁴. It is therefore important to consider other approaches to change ¹⁵.

The availability and application of explicit guidelines can alter clinical practice if there is regular feedback on adherence to these guidelines, and if there is overt support from influential colleagues ¹⁶. Such guidelines must reflect appropriate, research-based evidence linking patterns of practice to desired outcomes and be agreed and accepted locally, rather than imposed. The active ingredient may not be compliance with the guidelines so much as the greater clinical discrimination fostered by attention to the issue.

Prior control (by explicit clinical guidelines) or feedback control (by regular peer review of performance) can effect greater changes in clinical practice than can educational programmes alone.

2.3 CHARACTERISTICS OF EFFECTIVE MEDICAL AUDIT

Several general requirements for the conduct of successful audit can be identified:

Intention: the purpose of review must be — and be seen to be — educational and relevant to patient care.

Leadership: the support and overt enthusiasm of senior and influential colleagues is essential.

Participation: involvement of clinicians with their peer group must be as active and direct as possible — not through intermediaries or impersonal statistics.

Control: should be by clinical peers and participation should be voluntary.

Method: should be non-threatening, interesting, objective and systematic enough to provide reliable comparisons over time.

Resources: audit should be cheap and simple and cause minimal disruption to clinical work.

Guidelines: expectations of agreed good practice or decisions about desired policy changes must be made explicit.

Comparison: performance should be measured as objectively and consistently as possible for comparison over time and with others.

Conclusions: agreed changes in policy or future action must be spelled out.

Feedback: individuals must be made aware of their performance according to the above criteria.

2.4 EXISTING REVIEW MECHANISMS

Many formal and informal activities which fulfil some of these criteria are common practice: ward rounds, postgraduate lectures, clinical presentations and morbidity and mortality meetings contribute to review of performance which is mostly related to individual cases. Surgical morbidity and mortality meetings have been described by Campbell ¹⁷.

The essential difference of formal medical audit is to generalise conclusions which can be effectively implemented in the future. This requires review which provides:

- explicit criteria for good practice
- objective measurement of performance
- random case selection
- comparison of results among peers
- identification of corrective action
- documentation of review procedure and results

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3 GETTING STARTED

3.1 WHO SHOULD BEGIN?

Regular, formal medical audit requires organisation and leadership. This may be from the clinical tutor, a chairman of a specialty, or a self-appointed, enthusiastic consultant. Without active consultant support, junior staff have little chance of setting up effective review. Some leaders seek out like-minded colleagues to make informal local audit groups; others use the established professional specialty structure. It is useful to invite a senior colleague with experience of audit to visit at the start.

3.2 WHO SHOULD BE INCLUDED?

The largest meetings involve up to 30 consultant firms with a common clinical interest. Occasional topics may merit an ad hoc joint meeting of, for example, gynaecologists, radiotherapists and anaesthetists, but beginners would be wise to keep it simple. Self-review by one firm has minimal educational value; but the involvement of other clinically coherent firms provides valuable comparisons.

If a specialty has fewer than three senior medical staff, or if there are close working links with an adjacent district or health board, joint meetings with neighbours are useful. Once confidence has been established, reviews with outsiders are valuable.

All junior medical staff should be required to attend for discussion of the work of their department. If consultants decline to participate, tact and local knowledge should be used to encourage their juniors to do so. Most find the time well spent, and many have published papers on the results of local audit studies.

Most groups sooner or later discover that review of their own work needs the help of other clinical professionals such as the ward sister or physiotherapist.

3.3 WHEN TO ARRANGE MEETINGS?

Most groups meet from once to four times a month on weekdays, for about an hour. While this can legitimately be claimed to be an integral part of clinical practice, meetings tend to be held at 8.00 a.m., lunchtime or 5.00 p.m; they may be alternative to more traditional clinical meetings and share their allocation in postgraduate educational programmes.

3.4 WHO SHOULD ORGANISE THEM?

Once a regular schedule has been agreed, administrative arrangements become routine. No agenda or minutes apart from policy conclusions need circulating as long as the relevant people know who is responsible for the meeting itself.

Direction of the meetings depends on the subject and on the method of review adopted. For example, the consultant clinicians could take the chair in rotation; this allows a variety of approaches and reduces anxieties about undue control. Alternatively, just one person, such as a histopathologist, might be more appropriate. Once the subject and the approach are agreed, the principal task of the person chairing the meeting is to select material for the presentation and to see that appropriate conclusions are reached and followed through. Sharing the commitment reduces the time spent on audit - for example, in a group of six which meets monthly, each consultant (or his junior) would need less than an hour twice a year to select four cases for mortality review from a shortlist of all deaths in the previous month.

Whether selected cases are presented by the chairman's firm or the firm originally involved is a matter for local discussion. Presentation by different staff results in a fresh approach and is a more realistic test of the ability of the medical record to convey what happened and why.

3.5 CHOOSING A METHOD OF AUDIT

For most hospital doctors, the most practical method of audit is internal (within a specialty or hospital) and retrospective (using records to review events in the past). However, in smaller district specialties such as rheumatology, haematology or neurology, it may be helpful to collaborate with colleagues in other districts, a whole region - or even regions. In "external audit" assessment is by an outside group - such as in the Confidential Enquiry into Perioperative Deaths (CEPOD).

"Concurrent" audit of the day-to-day management of patients still under care needs pre-defined protocols or patient care plans - and information systems more timely and sensitive than those found in most British hospitals. It is widely used in North America, particularly in "utilisation review" such as in monitoring long-stay patients or expensive interventions. However, it can also be used to monitor adherence to clinical plans - including in Britain. 1

The aim of audit is to improve clinical care by comparing actual practice with the general body of scientific knowledge and, if necessary, by reducing any discrepancy between the two. This requires a more structured approach than the anecdotal presentation of individual clinical cases; it requires the regular definition and review of common practice, and the search for possible improvements.

The idea of objective selection and presentation of case material or clinical practice to a peer group, perhaps using statistical analysis, is foreign to many doctors. In some hospitals, death and complications meetings have been routine practice for years but this is far from universal. Case selection (by virtue of death, which is usually recorded, or of complications, which are often not) is fairly systematic, but subsequent discussion tends to be specific, general conclusions are lost, and no effective action is taken to follow up or to alter clinical practice.

These problems can be reduced by criterion-based audit which is widely used in Australia, the Netherlands and North America. Explicit, measurable criteria for good practice are agreed against which local practice can be compared. Records which do not appear to comply can be identified by

non-clinicans so that discrepancies can be analysed in detail by clinicians.

The advantages are that:

- variations from the expected can be quantified
- comparable criteria can be obtained from other hospitals
- improvements can be measured over time
- much of the initial screening can be done by non-medical staff

For example, criteria for the management of psoriasis may resemble those laid out in figure 5. It should be emphasised that the criteria are not intended to be clinically complete, but merely provide a basis for selecting records for more detailed clinical scrutiny, when other criteria will often become apparent. One sheet is completed for each record and the aggregated results of 20 or 30 cases tabulated by records staff.

Figure 5: Criterion-Based Audit — Psoriasis

Consultant Date first seenNumber				
Ana	lysis of the hospital record identifies:	YES	NO	
Patio	ents record			
1. 2. 3.	Clinic visit date Entry signed by doctor Consultant identified	••••	••••	
Hist	ory			
4. 5.	Patient's symptoms or psoriasis disability Reference to current and/or previous drug therapy	• • • •	• • • •	
Exa	mination			
6. 7.	Distribution of rash described Extent of disease ♦	• • • •	• • • •	
Diag	gnosis			
8.	Particular type of psoriasis specified *		• • • •	
Trea	atment			
9. 10.	Drug or physical treatment specified Written information given to patient	••••	••••	

Response and follow-up

11.	Letter to referring physician dated within 7 days of clinic	••••	
122	Patient's assessment of progress noted *	••••	•••
	Doctor's assessment of progress noted •	• • • •	• • •
120.	Doctor's assessment of progress noted •	• • • •	• • •
13.	If on second—line therapy*, haematology and biochemistry results correctly filed in case record		
14.	If patient did not attend, GP informed	• • • •	• • •
- ••	pulsan u.e not unitario, e.e = 10-1100	••••	•••
Outo	come		
15.			
	or symptoms (item 4)	• • • •	• • •
16.	Any record of consultant assessment within		
	first 3 visits	• • • •	
17.	Patient discharged to GP within 5 clinic visits	• • • •	• • •
Abst	racted by Date	• • • • • • •	• • • • •
* No	tes for analysis of records		
1.	"Type of psoriasis" should specify one of: Plaque (small or large); guttate; erythrodermic; pustular; nail; joint; scalp		
2.	"Second line therapy" for this purpose includes: Meretretinate; cyclosporine; azothiaprine; hydroxyurea	thotrexate	;
♣ If	not evident whether doctor's or patient's assessment "not evident"	. record	
♦ Ei	ther graphically or by percentage involvement		

Example:

Medical Division, St. Chad's Hospital, Birmingham (Dr D W Young)

Method:

monthly mortality conferences with rotating chairman drawn from among five consultants, who select 2 or 3 cases for discussion. Meetings were voluntary, juniors were invited to join in.

Results:

the method was agreed to be valuable and interesting, but most cases reviewed were of elderly patients, many not amenable to treatment. The same conditions kept cropping up, but non-fatal conditions, readmissions and complications were never discussed. Time required was less than for formal case presentations.

The criterion-based approach requires not only enthusiasm for audit among doctors but also special training of records staff and accuracy in the medical record itself. The challenge of this method to medical staff is in agreeing even very basic criteria for good clinical management. A further philosophical difficulty is the argument that explicit criteria are impossible to define, inimical to clinical versatility, or unintelligible to non-medical people. None of these has proved to be a real problem in practice — as long as there is room to provide clinical explanations for cases which fall outside the agreed criteria.

A further advantage of criterion-based audit is that it does not require a manual or computer database (other than a diagnostic index). Also, it is applicable to any specialty.

3.6 CHOOSING A SUBJECT

Financial audit focuses on the structure and resources of healthcare; medical audit, ideally, would focus on clinical outcome. In reality, the relatively small numbers of clinically comparable cases seen by individual doctors, combined with the difficulty of long-term follow-up after discharge from hospital, make audit of "process" a more practical alternative. This process audit is a legitimate proxy for outcome audit if there is good evidence (such as from controlled trials) that a given procedure or regimen is appropriate to a given condition.

Looked at in this way, an individual audit study may be specific to:

- . administrative process (such as medical records, referral letters or discharge letters)
- clinical process (such as use of selected operations, drugs, investigations, intravenous fluids or pre-operative shaving)
- clinical condition (such as acute myocardial infarction, inguinal hernia repair, cardiac arrest or fractured femur)
- positive outcome (such as relief of pain, return to work or ambulation)
- negative outcome (such as in-hospital infection, pressure sores or unexpected death).

Any clinical diagnosis, procedure or situation may be appropriate and amenable to review, but priorities may be suggested among subjects which involve:

- high risk
- high volume
- high cost
- wide variation in clinical practice
- local clinical anxiety

Published audits range from the general to the specific. The following examples illustrate a variety of approaches and subjects:

Use of hospital services

Duration of clinic follow-up²

the perceived value of clinic visits by 139 consecutive patients was assessed by both patients and doctors. There was general agreement from both that about a quarter of visits were too frequent.

Discharge of elderly patients³

home visits to 100 elderly patients discharged from an accident unit showed scant attention to home conditions and underusage of available community services.

Use of diagnostic procedures

Barium enema⁴

a retrospective study showed that 97% of carcinomas of the colon were disclosed, but only 77% were identified on X-ray at the time.

Abnormal cervical smears⁵

a review of 1,062 women after abnormal smear report showed that 50 had not been followed up.

Management of selected conditions

Extradural haematoma⁶

a retrospective study of 100 patients admitted to a neurosurgical unit indicated that 96% of cases could be identified by junior staff if proposed guidelines were used.

Acute myocardial infarction⁷

a review of 100 consecutive patients identified the need for improved stress testing, doctor-patient communication and discharge coordination.

Example:

Orthopaedic Department, Brighton

Method:

fortnightly formal quality assurance meetings held since January 1984 with no published agenda but chaired by consultant who decides the subject for review. All medical staff attend, plus other disciplines when relevant. Subjects have included clinical conditions, teaching, communication between doctors, other staff and patients. Notes are kept by Department of Community Medicine.

Results:

over three years, a number of clinical and organisational benefits emerged, including:

- Clinical practice: agreement on policy for the prophylactic use of some antibiotics
- Organisational change: definition of minimum requirements for pre-operative availability of laboratory and X-ray reports
- Equipment review: demonstration of priority for replacement of image intensifier subsequently obtained
- Data collection: establishment of a prospective study of surgical results
- General practitioner survey: collection of information on, and discussion of referral patterns and GP/orthopaedic workload, leading to resolution of several long-standing issues.

Results of surgical procedures

Total hip replacement⁸

100 cases from each of four hospitals were screened by a records officer using pre-agreed criteria. Subsequent review by orthopaedic surgeons showed there was some variation in incidence of infection, but overall rates were low.

Carotid artery surgery9

Criterion audit of 100 cases from each of seven teaching hospitals showed considerable variation between hospitals with regard to indications for surgery, but the outcome was not significantly different.

Example:

General Surgical Unit, Ealing (Mr D Sellu)

Method:

the weekly surgical meeting was enlivened by numerical

presentation of comparative morbidity and mortality from

the microcomputer database.

Results:

discovered unrewarding urge to include excessive data on file, but resulting information was more complete and accurate than hospital Patient Administration System. Demonstration of variations in wound infection, pressure sores and long-stay rates generated real interest and led to

measurable improvements.

General therapeutics

Prescribing of anti-microbials 10

prescribing antimicrobials to 50 maternity patients was considered to be appropriate in only 26% of the cases examined.

Use of blood fractions 11

review of orders of blood for patients undergoing laminectomy showed that only 0.7% was used. It was concluded that the cross-match to transfusion ratio could be reduced from 135:1 to 4:1 without compromising patient care.

Example:

Medical Department, Queen Elizabeth Hospital, Birmingham (Dr D A Heath)

Method: weekly lunchtime meetings. In advance, one person picked

20 percent of notes entirely at random (after the discharge summary was completed) and distributed them to the other three academic firms for comment on treatment, diagnosis,

recording and overall management.

Results: raised useful discussion even if nothing found 'wrong' (eg

value of barium enema in the elderly) but randomness allowed problems to be missed and no out-patients were included. No statistics involved. Led to better clinical

records.

Communication

Medical records¹²

following retrospective analysis according to 18 agreed criteria, feedback to individual doctors improved clinical behaviour in a general medical unit.

Deaths in hospital¹³

the notifications to GPs of 193 consecutive in-hospital deaths over 14 months were analysed. 42% of cases were not notified by immediate telephone call and 51% were not reported by letter within a week. A subsequent medical circular failed to improve this.

Adverse outcomes

Missed fractures¹⁴

490 radiological abnormalities were missed in 10,111 patients examined in a casualty department; in at least 135 cases this error was due to insufficient care in examining the film. The conclusion reached was that casualty officers should re-examine patients when taking over from colleagues, should insist on adequate X-rays and should beware of overconfidence during their last month in post.

Example:

Medical Department, North Staffordshire Hospital Centre (Dr W van't Hoff)

Method:

monthly audit meetings have been held since 1979, involving 32 physicians of whom 13 participated in general acute admissions rota. Chairmanship taken up in rotation once every two years by each consultant. He reviewed 12—15 records from among about 60 deaths and selected 3 or 4 for presentation by the firm concerned. No discussion or conclusions were recorded.

Results:

apart from being enjoyable and instructive, the audit meetings resulted in organisational improvements, such as increased nurse staffing and amalgamation of notes of all departments into the main hospital record.

Deaths from asthma¹⁵

of 35 deaths from asthma in one region, independent assessors found important defects in management in 83%, as compared with 40% in controls. It was concluded that hospital care of asthma patients could generally be improved.

3.7 RECOMMENDATIONS FROM THE NETHERLANDS

One country which has developed national medical audit in the past ten years is the Netherlands. The National Organisation for Quality Assurance in Hospitals was set up by the Dutch Medical Association in 1976 and voluntary, structured audit has since been introduced to most of the country's 200 acute general hospitals. General recommendations, based on Dutch experience, offered for consideration in other countries facing the same challenge are reproduced in the appendix.

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4 ADMINISTRATIVE ISSUES

4.1 SUPPORT AND RESOURCES

Medical audit can be started on a shoestring; many enthusiasts have demonstrated this. However it does merit the recognition from management that some help is required if medical time is to be well spent. This involves three main areas:

Clinical time

If audit is to be an integral part of clinical practice, if medical staff's time is already occupied, and if employing authorities agree that more time should be spent, then audit must be acknowledged in individual consultant programmes. It may be necessary to designate a regular schedule, perhaps during time devoted to post-graduate education. The health authority must then accept that clinical work will be proportionately reduced and consultants must accept that audit becomes an obligation of employment.

Selection and preparation of subjects for discussion requires time and has to be organised well in advance of the meeting. Gathering information is time-consuming, tedious and frustrating — and is itself a part of audit.

Of the various commitments (such as planning, budgetting and management) which compete for consultants' time, medical audit must deserve some clinical priority as a mechanism for education and for improving medical practice.

Clerical time

The identification and retrieval of 15 or 20 cases selected from a recent listing of, say, 50 operations or diagnoses, takes time. The ability of a department to absorb this depends on enthusiasm, existing staff, and the method used to retrieve data and records. Additional secretarial or records clerk assistance, perhaps part-time, may be needed. Some health authorities are willing to fund two or more sessions for consultants coordination of medical audit within a district or a large hospital.

Information specialists

Accurate, timely, well-presented data are needed. The medical librarian, records officer and the information officer may all be involved. A specialist in community medicine should be able to advise on the availability, collection, analysis, presentation and interpretation of data. Active support from the district medical officer and general manager is crucial.

4.2 DATA

Statistics are not necessary to start audit; discharge summaries, referral letters and theatre registers can provide the necessary information. However, hospital computer systems may be able to provide data for clinical analysis.

The extent and capacity of the patient administration system (PAS) varies among hospitals. It includes identification and administrative details of each patient episode, is concurrent and generally accurate. But, for reviewing individual patients, rather than comparing workload, its main contribution is in generating lists of patients who have been treated by a firm, ward or specialty, or lists of deaths.

Clinical Data Capture (CDC), born of Hospital Activity Analysis (HAA), is a clinical extension of PAS which includes diagnosis, operations and complications. It should be capable of providing, for example, rates for age-specific, in-hospital mortality from acute myocardial infarction for each consultant firm. Since CDC data are collected nationally in the Hospital Episode System (HES — the successor of the Hospital In-Patient Enquiry) it is possible to compare, for example, admission rates for a given operation or diagnosis with other parts of the country.

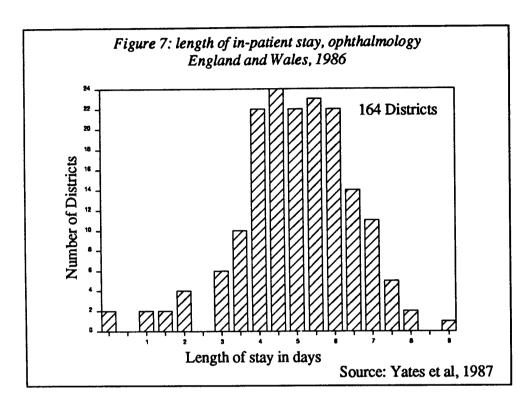
CDC data are often delayed, incomplete and clinically inaccurate, because hospitals do not have adequate systems for transferring and coding clinical details, or (more often) because medical staff leave coding to clerical staff rather than supplying the information themselves. Before rejecting CDC, doctors would be wise to try it out because nothing improves data faster than to be regularly used, challenged and corrected.

Performance indicators (PIs) are now widely available on microcomputer, providing comparisons between clinical specialties in different hospitals, districts and regions. Their particular interest may be in comparing resources and activity; for example, wide local variations in out-patient reattendance rates are easily identified and offer a practical starting point for discussion of clinical management. There is currently little information on clinical outcome. However, PIs are worth investigating locally with the help of someone who can find their way around the (relatively simple) computer system. Two samples are shown below:

Figure 6: Clinic reattendance, general surgery/urology
England and Wales, 1986

209 Districts

Out-patient attendance rate
(average number of times an out-patient attends OP clinics)
Source: Yates et al, 1987



4.3 CLINICAL DATABASES

Many doctors have set up their own manual or computer data files for research and review. These have several advantages over the standard hospital systems:

- personal 'ownership' produces better data
- they can select their own parameters for recording information (limited facilities for this are available on CDC)
- data are readily accessible at all times
- they can be used, for example, to generate discharge summaries, reminders of patients due for review, and listings of procedures done by an individual doctor

 computers for clinical research (which may be used for word-processing) may be bought from trust funds and be exempt from VAT

There are some disadvantages and potential pitfalls in setting up independent systems:

- someone (probably a doctor or secretary) has to enter the data (much of which duplicates that held on PAS)
- the scope and coding of data may be incompatible with other systems, preventing direct comparisons
- there is a temptation to collect too much data
- maintenance of the system after its originator has left is a problem

4.4 COMPUTERS AND AUDIT

Software

Several commercial systems suitable for clinical audit are now marketed. Some of these have been adapted from existing commercial software for clinical use; others have been developed by clinicians for their own purpose. Several enthusiastic pioneers have eventually returned to professional software houses to develop and market their systems. So far, most of these have been developed for surgical specialties, but several are now expanding into medical and other specialties.

Reference to published reports may be found in Quality Assurance Abstracts. ²

What they offer

Common to all systems is the facility to provide:

- statistics on workload and clinical results
- selected listings of, for example, procedures, deaths, complications, or patients with the same diagnosis
- discharge summaries, with the capacity to add further clinical details to a basic matrix
- automatic ICD and OPCS coding
- word processing

All systems have some capacity to be adapted for local use. The amount of data produced depends largely on what is put in.

Some systems provide further facilities:

- inpatient and outpatient waiting list management
- admission letters
- operating lists
- theatre utilisation
- lists of operations done by individual staff
- graphic presentations
- surgical costings (using health authority cost data)
- 'overdue prompts' for example, for long stay inpatients, overdue follow ups, or outstanding pathology reports
- fax facility for transmission to general practitioners

What they do for staff

Medical staff

Some advantages, not exclusive to medical staff, include:

- data and summaries for clinical audit (and arguing with management!)
- automatic and immediate discharge summaries the average time is approximately halved to eight minutes for the process of dictation and transcribing a summary.
- GPs receive summaries more quickly
- summaries are available at the next clinic attendance
- improvement of clinical policy decisions
- improvement in management of the service

Secretaries

- reduction in repetitive work
- work is more interesting and preferable to traditional systems
- status is enhanced

Managers

• accurate data capture; doctors 'own' their information

- coded input is available for hospital CDC
- increased clinical and managerial efficiency and productivity
- earlier return of notes to records department
- possible reduction in secretarial time
- generation of Körner statistics

Comparing products

Choosing a computer system is not easy for the occasional user. Some criteria are suggested below and in other published sources ^{3 4}.

'Friendliness'

- Ease of learning: new staff should be able to master the system within one to two days
- Ease of input: any proforma should be easily read and completed; keyboard entry should be simple and quick

Capabilities

- Capacity: choose a system to allow for growth in your own workload and the inclusion of other firms
- Flexibility: in general, the more flexible the system, the more slowly it will run. Look for capability to modify input and output formats, expansion of the discharge summary by the addition of free-hand entries, and capability to split (e.g. into years) and to merge files (e.g. between firms)
- Compatibility: the more compatible the system is with those already in use within the hospital or region, the more chance there is to exchange data, and the cheaper it is to maintain the system. Check

that the system is compatible with local policy, but do not expect total linkage with the hospital PAS system or other networks

- Multi-user capability: multi-user systems are more expensive but allow for easy transfer and sharing of data between firms or between hospitals. Audit of one firm without external comparisons is of limited interest and educational value
- Reliability: a system which has been proven in practice over a period
 of, for example, three years in several sites is more likely to be
 reliable. Ask other users and the manufacturers about safeguards, such
 as against power failure
- Word processing: what software is used? Is the keyboard easy for word processing use? Does your secretary agree?

Output

• Graphics and tables may be valuable in presentation of data; data should be easily modifiable by the user

Support

• Ensure that the company will provide initial training and system support in the long term. Are other users happy with the company's record?

Costs

 Costs of equipment and software vary according to the choice of system and hardware, and according to the amount of support which will be provided by the company. Revenue costs include consumables such as discs and paper as well as support and maintenance of hardware and software. Many hospitals provide in-house hardware support, but software support may cost 5% per annum of the initial software cost

Some practical tips

- First discover whether your hospital PAS system could fulfil these requirements now or in the near future. Advantages of direct linkage to the main hospital system include:
 - demographic data transferred automatically, avoiding duplication of entry
 - same terminal serving both functions (of hospital and department)
 - access to personal data base from any terminal in hospital (or even in peripheral hospitals)
 - no limit to number of linked terminals
 - capacity for region-wide collaboration in data collection
 - lower unit costs to hospital.

Disadvantages include:

- inaccessible during daily back-up time (or if hospital system is otherwise down)
- less easy to limit physical access.
- Don't worry about security. The system should have a password for entry and daily backup onto discs to provide duplicate files. (This requires about 20 minutes per day for an average surgical firm).
- Keep data minimal. Resist the temptation to include items which you will not use. Excessive data causes confusion and increases the time required for input. For example, data for discharge summaries should take not more than five minutes to enter and the whole process should be no longer than traditional systems. An agreed local or regional data set for general surgery may include the information set out in Table 1.

- Choose whether secretaries or medical staff will do the keyboard entry. Proponents claim benefits either way in terms of continuity, consistency of coding and avoidance of computer phobia, especially in high turnover junior medical staff. What is essential is that the recording of clinical data is an integral part of the medical responsibility for the patient's management. Data collection by medical staff may be facilitated by a proforma from which a secretary enters onto the computer; the design of this requires many revisions to ensure compatibility with the systems and the required output.
- Go for multi-user systems. Even if you are the first enthusiast in the department, allow for the inclusion of other consultant firms later on.

Table 1: Example of minimum data required, general surgery

Identification

Patient's name, number, date of birth, address

Admission

Date, ward, GP, consultant, source

Diagnostic procedures

Operative procedures

Date, surgeon, anaesthetist (junior and responsible consultant)

Diagnoses/complications

Discharge/transfer

Date, disposal, autopsy if died

Medications

Drug, dose, frequency, supply

Follow-up arranged

Information given (to relatives or patient)

Completion of data

Date, doctor's name

4.5 CLASSIFICATION AND CODING

Nomenclature, classification and coding must be internally consistent as well as externally compatible with other systems if valid comparisons are to be made. Even with a basic classification, it is safer to adapt a condensed version of a proven one than to take on the surprisingly difficult task of inventing a new one. Existing systems for coding include:

- Diagnosis: International Classification of Disease (ICD), a four-digit code for diseases, injuries and other conditions used in CDC and HES
- Pathology: Standard Nomenclature of Pathology (SNOP)
- Operation: the classification of the Office of Population Censuses and Surveys (OPCS) is used in CDC and HES and has recently been revised.

The surgical Audit Committee of the Edinburgh and Lothian Area has recently developed a coding system which combines simplicity of use with serious audit value and considerable clinical detail⁵.

Ideally, the identification, coding and data entry of clinical details should be done by one of the medical staff responsible for the case. Alternatively, it can be done by a skilled secretary or records officer, assuming all the required clinical details are recorded legibly, in the right place and in standard nomenclature by a doctor. Data required for a well designed but basic surgical audit takes only five or six minutes per patient to abstract from the clinical record and enter into a computer.

4.6 MEDICAL RECORDS

An early and predictable achievement of medical audit is to highlight the inadequacy of medical record systems. Problems are likely to appear in:

 Patient listings: some records departments have difficulty in generating from PAS timely and accurate lists of patients for review.
 Fulfilling such requests should be regarded as the department's contribution to quality assurance.

- File retrieval: even when cases are identified, records may not be traceable. If this is a large problem, it could itself be subjected to audit.
- Organisation of records: information may be hard to retrieve owing to absence of reports, misfiling, or an excess of irrelevant and untidy sheets.
- Content of records: there may be no record of key positive or negative findings and events in the appropriate place.

Many of these problems are the responsibility of hospital managers who should be willing to respond to demonstrated deficiencies; many of them are the responsibility of the medical staff who should be similarly willing to respond.

4.7 EXTENDING THE SCOPE OF AUDIT

Multihospital review

Although it may be simplest to start audit among immediate colleagues, there are advantages in extending outwards. By joining with similar specialties in neighbouring hospitals it is possible to tap a larger pool of experience. Successful collaborative surgical audit has long been established in Edinburgh and Lothian ⁶ and a similar system of data sharing is being set up in the North West Thames region. Regional specialties need a national network to provide valid comparisons: one example is the annual register of cardiothoracic surgery, co-ordinated by the Society of Cardiothoracic Surgeons of Great Britain and Ireland ⁷.

Multispecialty review

Many situations involve close co-operation between specialties both in clinical practice and in audit. A recent example is the enquiry by surgeons and anaesthetists into perioperative deaths ⁸. Joint general practice/hospital review of referral procedures or follow-up of chronic conditions is a further example.

Multidisciplinary review

Specialties such as psychiatry and geriatrics, which actively involve other disciplines in the clinical team, tend also to include them in audit. The inclusion of nursing and/or paramedical staff soon becomes a logical development in most specialties: the result is sometimes termed 'clinical audit', as opposed to medical, surgical or nursing audit.

4.8 FORMAL MEDICAL STAFF ORGANISATION

The purpose of audit is to improve patient care by improving clinical and administrative practice. Medical staff may accept certain corporate responsibilities:

- To monitor the quality and effectiveness of the delivery and use of clinical services
- To establish appropriate policies and procedures
- To advise the health authority on the provision of patient care
- To advise the health authority on the best use of resources

A variety of mechanisms exist for communicating advice and influencing change:

• Specialist divisions/departments: these provide the logical nidus for audit if numbers are large enough

- Advisory committees: groups such as pharmacy and therapeutics and infection control committees may contribute to particular aspects of audit
- Audit committee: some hospitals have set up steering committees, either to undertake audit itself or to co-ordinate the work. Some cover a whole district and some make up a multidisciplinary 'quality assurance committee', as in Brighton Health Authority (see table 2). In some large European hospitals a director of audit (usually medical) is supported by an audit committee.

Table 2:

Sample objectives of a district Quality Assurance Committee

OBJECTIVES

Obtain accurate information on each department's performance

Compare it with pre-defined standards

Abolish the unnecessary and extravagant

Encourage improvements in individual performance

Reward efficient departments with finance for development

Improve teaching

Improve quality of patient care (clinical departments)

IMPLICATIONS FOR INDIVIDUAL DEPARTMENTS

Set up (formalise) regular mortality and morbidity meetings

Introduce standard operational policies

Regularly review long stay patients in acute beds, ideal

length of stay for specific diseases, and diagnostic

categories of cases appropriate for day care

Improve the hospital notes

Improve communications

Formalise teaching programmes

Consider how better information might be obtained

Elect a member of the District Quality Assurance Committee

Derived from Brighton Health Authority Quality Assurance Committee by permission of the Chairman, Mr Bob Gumpert.

4.9 CONFIDENTIALITY AND LEGAL ISSUES

Access to Patient Records

Peer review requires doctors other than those directly involved in the care of an individual patient to have access to clinical records. As they are bound by the same ethical principles, doctors may legitimately share such information as in other forms of teaching and case presentation. If the review involves other disciplines, different principles may apply and disclosure of information may not be subject to the same controls.

Documentation

Concern has been expressed, mostly overseas, lest adverse judgments following medical audit should encourage or influence litigation against the staff or hospital concerned. In some states and provinces of North America, legislation has specifically acknowledged the protection of such judgments from legal discovery.

It should be recorded in the patient's notes that they were subjected to routine review; and the cases reviewed at a meeting should be listed and a summary made of general conclusions of the meeting and action to be taken. Without the latter, audit has little chance of influencing change or of being shown to have happened at all.

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5. REFLECTIONS ON AUDIT

5.1 GENERAL REACTIONS

Many doctors have already trodden the path of audit. Early frustration usually gives way to satisfaction, with various common experiences in between:

• Early tribulations:

"we couldn't get hold of up-to-date, accurate lists of patients",

"records seem to hide — especially following autopsy"

Early discoveries:

"the notes just don't explain what happened or why",

"no-one knows what they do until they start looking"

Early conclusions:

"good practice is nearly always financially rewarding",

"don't worry about incomplete or inaccurate data: they will be refined by feeding back information obtained",

"clinical and specialty tutors need to be involved as this is primarily an educational exercise",

"most improvements involve organisation rather than expense",

"there are always some non-participants".

One particular caution concerns diplomacy in presenting data, even privately, which imply that an individual has results much above or below the majority of his colleagues. Not surprisingly, the 'good' performer welcomes the figures with satisfaction and asks for more; but, no matter how robust the data, the 'poor' performer may respond with something similar to a grief reaction — denial, anger and argument before reconciliation. It is not human nature to accept readily that a long-standing pattern of personal practice may need reconsideration; it is wise to allow time for this and not to expect an immediate change.

5.2 FUTURE PROSPECTS

Although little is known about the prevalence of formal audit throughout Britain, it appears that at the moment only a minority of doctors are involved.

In common with the diffusion of innovation in any professional body, it is likely that a significant time will have elapsed before the concept of audit is more widely and rapidly adopted; and, even then, there will always remain a resistant minority.

But the political and public climate is now favourable towards medical audit as evidence of professional self-regulation — as well as a means of continuing education. Government, management and professional bodies now agree on this nationally; the challenge is to translate that message into voluntary local action.

APPENDIX

Recommendations for national quality assurance programmes

Organisations and individuals in other countries engaged in setting up quality assurance mechanisms in the health care sector may profit from the experiences of the Dutch national quality assurance programme. The following recommendations can be made. They are process-oriented and therefore can be applied in other health care systems. There is no set priority in this list: all points are equally important.

1 Take the initiative

It is the medical profession's duty to deliver care of high quality. It is also its responsibility periodically to evaluate the level of quality and improve services when and where necessary. The quality assurance mechanism must be firmly in the hands of the health professions. To have it set up and controlled according to the professional rules is infinitely better than to have it imposed by outside agencies or the government.

2 Know what you are doing

It is mandatory to have scientifically sound methods and a structured programme. Consider establishing a dedicated support organisation if these elements are insufficiently covered.

3 Establish early contacts with leading agencies and individuals

It is unnecessary to make enemies while implementing a national quality assurance programme. The responsibilities of agencies which participate in health care delivery must be recognized, preferably leading to participating in the programme. Shared work is always better than having to explain to your partner what you are doing.

4 While working keep your eyes open

Once a programme is set up, its manager must focus on the goals of the programme. Unfortunately, society changes at a rapid pace, and the goals may need to be changed. This may cause dilemmas especially in situations when loyalties go in different directions.

5 Recognize the need for assistance and guidance to professionals, and do not confuse the task at hand with scientific research

Quality assurance involves problem-solving — not unlike the physician's own work. Support of quality assurance consists of education and management. Research activities, however relevant and laudable, do not lead directly to changes in behaviour.

6 Act as a change agent while introducing quality assurance

Quality assurance in medical care can be considered a major innovation: as such it threatens the status quo. A support organisation should recognize the dangers inherent in this change-agent role. Quality assurance may be the threat: the support organisation can also be a menace. This calls for clear organisation, formal feedback channels and commitment to methods and procedures. Clinicians are responsible for the quality of care and the support organisation should recognize that fact.

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About the author

Charles Shaw graduated from The Middlesex Hospital, London, in 1969. After a pre-registration year in Cheltenham he held various posts at home and abroad and became medical director of the King Edward VII Memorial Hospital in Bermuda in 1972. Thence sprung an enthusiasm for medical management and, by virtue of secondment to the Canadian Council on Hospital Accreditation, for the defining and measurement of standards both of clinical practice and of hospital organisation.

Returning to community medicine in the British National Health Service in 1978, he found a relative absence of both — and set about filling the hiatus with papers and books on medical audit and standards in health care organisation. He founded the Quality Assurance Programme with the King's Fund in 1984, obtained a PhD from the University of Wales in 1987 (on standards in the NHS) and was unit general manager in Cheltenham from 1985 to 1988.

He is now employed by the King's Fund Centre to direct their medical audit programme, assisting individuals and groups of doctors to develop local peer review.

The King's Fund Centre for Health Services Development, which dates from 1963, is in purpose-built premises in Camden Town. Its aim is to support innovations in the NHS and related organisations, to learn from them, and to encourage the use of good new ideas and practices. The Centre also provides conference facilities and a library service for those interested in health care.



