Medical audit in clinical pathology

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Introduction

There are now many definitions of medical audit, varying from that of Working Paper 6, through those of various authors on the topic, to that of a lay member of our health authority who commented that "medical audit is asking the questions the patient would ask if they knew what questions to ask". From these definitions certain key attributes of medical audit may be gleaned.

First, medical audit is aimed at improving quality both of the service provided and the quality of life for the patient.¹ It is centred on the patient rather than dealing with professional standards.

Secondly, it involves peer review of practice which is an essential element of professional behaviour and is the basis of professional development.²

Thirdly, medical audit is educational both in the sense that it is an activity which of itself promotes learning but also by its links with more formal educational processes.³

Fourthly, it is based on the setting of standards of clinical activity and monitoring actual practice against these standards. Standards are explicit statements of some aspects of practice which are capable of being measured in an agreed fashion.⁴

Fifthly, that where standards are not met there is an effective process to remedy the situation. This involves change whether of organisation and systems or within individuals in terms of knowledge, skills, or attitudes.

Clinical pathology: previous activity in quality improvement

In many respects the National Quality Assurance Schemes (NEQAS) have been some of the most effective nationwide medical audit schemes devised. Their success has run in parallel with improved standard setting of analytical performance within departments and the monitoring of these standards, not only by review of daily quality control samples but by elucidating trends by Levey Jennings plots. The national schemes have been able to show improvement in performance of laboratories which failed to meet the criteria of schemes, and although analytical performance overall has improved, it is difficult to disaggregate the effects of technological advance from that of NEQAS.

NEQAS has inevitably concentrated its efforts on laboratory procedures that yield numerical data and has only more recently reviewed performance in blood transfusion, coagulation, detection and identification of

micro-organisms and opinion on cytological preparations. Local, regional, and national groups have been formed to review opinions on histological slides. The value of such approaches will increase with time as the clinical outcomes of the patients whose samples are studied become known—this is particularly relevant for groups such as the Melanoma Club in the United Kingdom.

Accreditation and medical audit

Accreditation schemes in North America and Australasia have set standards of performance in laboratories well beyond simply analytical activity by extending standards and review to systems as well as processes of laboratory work. Participating laboratories have found that the effort required in preparation for accreditation has been considerable but has given confidence to laboratory staff and users in the quality and effectiveness of the laboratory.

The recent pilot scheme in England has had a similar effect in quality improvement,⁵ although the effort required by many laboratories in documentation before the accrediting visit has been unexpectedly great.

Currently the Clinical Pathology Accreditation scheme lists 44 standards grouped under six headings: organisation and administration; personnel; facilities and equipment; policies and procedures; education; and quality assessment. Rather than stating standards which are to be met, the current approach gives a framework within which individual laboratories and departments may set their own standards, and is therefore much less prescriptive than some other national schemes. Such an approach promotes audit of performance within the laboratory, the setting of standards which are "owned" locally and meet local needs, and takes the review of laboratory performance into a much wider range of functions than merely analytical ability. Accreditation in this style may be seen as promoting medical audit within clinical pathology as it inevitably involves laboratories in the key features of medical audit listed above.

In the United States of America in particular, medical audit of the use of laboratory services has become more important since the introduction by insurance companies of payments related to the patient's clinical condition rather than hospital costs—the system of diagnostic related grouping. But this type of medical audit, it seems, has more in common with United Kingdom hospital resource management than with medical audit as a way of enhancing clinical service and the professional development of doctors.

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Educational aspects of medical audit in pathology

Medical audit will undoubtedly reveal shortcomings in individual clinical performance, which lead to development of specific educational programmes, but the process may be considered an essential part of the continuing professional development of the individual and the team. As audit is based on the experience of clinical activity it is a rich source for learning ways of enhancing both the quality and quantity of the service provided.

As pathology services concentrate more on pre and post-analytical aspects of laboratory work, medical audit will need to review the effectiveness with which users of the service avail themselves of analytical work and interpret the results within the clinical context. Such areas may include:

- appropriate use of tests
 - time of samples
 - choice of analyses
 - intended use of information gained
- appropriate interpretation of results in the context
 - concept of test specificity, sensitivity, and predictive value
- appropriate action on the basis of results

Laboratories should consider ways of assessing their effectiveness in educating users in the appropriate use of their services, thus enhancing the clinical value of laboratory effort and leading to demand control.

An agenda for medical audit in clinical pathology

For laboratory doctors who have been much involved in analytical audit schemes there may be a temptation to consider that nothing more is required of them. In most of the quality assurance schemes, however, there is very little emphasis on pre- or post-analytical activity and, although accreditation is much more wide ranging in its approach, it will only review performance at five yearly intervals.

Laboratory disciplines will inevitably become involved in the medical audit of other disciplines when bed holding specialists wish to assess their use of analytical services, review histology, or have test results as a marker of appropriate disease control. Such activity, while of interest and value to the laboratory disciplines, does not always view matters from the laboratory position, nor does it necessarily cover the range of audit activities appropriate for laboratory doctors. For instance, medical staff with an interest in diabetes may wish to review whether all insulin dependent diabetic patients have their glycated haemoglobin assayed annually and to assess their diabetic control in terms of the mean glycated haemoglobin of this group of patients. Following this they may decide to review all patients with a value greater than, say, 10%. The laboratory computer may be able to help them assess their criterion of uptake of the test and the number of values above the threshold set. From the laboratory stance it may be more interesting to find which patients had more than one assay of glycated haemoglobin when

the first value was acceptable or to assess the clinician's response to a report of a high value. There are obviously opportunities to combine these approaches in a single audit process.

To help doctors consider approaches to medical audit the range of audit activities may be conveniently grouped into the following:

- Access
- Process
- Outputs
- Outcomes
- Use of resources

(1) Access may include the availability of a test or opinion to meet clinical need, information on the test, together with sample required and volume, transport and storage needs, suitability of request forms. (2) Process includes not only analytical aspects but also sample preparation, patient identification, and reporting systems. (3) Outputs are usually measures of throughput such as requests for certain tests by consultant or practice and perhaps the rate of detection of disease associated findings. (4) Outcomes deal with how laboratory data enhance the care of the patient perhaps in terms of diagnosis made, treatment initiated or monitored, or early detection of complications. (5) Use of resources covers the use of staff, equipment, and other facilities needed for achieving the work of the laboratory. This agenda for medical audit has been found to be useful and certainly seems appropriate to pathology disciplines. It should be remembered, however, that the topics chosen for audit must be considered important to the function of the laboratory.

Examples of approaches to medical audit in pathology

The following examples of medical audits, which may be undertaken by the major pathology disciplines, are laid out according to the agenda given above.

A chemical pathology topic—general practitioner use of thyroid function tests

Access

- range of assays available
- request card design
- information on sample volume, tube, and storage

Process

- accuracy of results
- sensitivity of tests for users needs
- turnround time
- information on referent data
- value of comments made on results
- security of result for patient

Outputs

- requests per unit time
- requests per 1000 patients by practice
- reasons for request by practice

Outcomes

- rate of positive results
- rate by reason for request
- rate by practitioner
- frequency of treatment initiated on results
- frequency of patient improvement

Use of resources

- consideration of testing strategies

staff, equipment and reagent costs of these value of treatment initiated or changed value of patient improvement

When undertaking parts of an audit of this style we were interested to find that 52% of requests for thyroid function tests from general practitioners were to detect myxoedema, 18% thyrotoxicosis, and 20% monitoring thyroxine replacement therapy, and that, overall, 75% of requesting reasons would normally be answered by a TSH assay alone. This led us to consider our thyroid testing strategy with possible improvements in service and use of resources. The range of requests for thyroid function tests varied from 18 per 1000 patients in one practice to 87 per 1000 patients in another.⁶ The possibility of further audit work on this is being discussed with the local Medical Audit Advisory Group as a combined audit between the laboratory and local general practitioners.

B Haematology—anticoagulant treatment control

Access

agreed role for the laboratory in hospital anticoagulant policy
effectiveness of referring to service
information on target International Normalised Ratio (INR) for patient groups

Process

quality control
quality assurance
prescribing advice

Outputs

use of service by specialty
achievement of INR targets
time course to achieve target values

Outcomes

frequency of complications of therapy
frequency of DVT/PE
response to unexpected INR values
duration of treatment against agreed targets
user satisfaction with service

Use of resources

cost per test/patient
cost of complications of treatment
benefit per PE “prevented”

C Histopathology—frozen section service

Access

availability of frozen sections
booking system
emergency within/without hours

Process

appropriateness of requests
adequacy of sample
quality of section/staining
adequacy of communication of findings

Outputs

reporting systems
use of service by consultant/procedure
differences between frozen/fixed opinion
user satisfaction with service

Outcomes

surgeon’s response to information given—for example, wider excision, further dissection, etc

Use of resources

cost per procedure

opportunity costs of waiting for sample
opportunity costs of waiting for opinion

D Microbiology—midstream urine specimens

Access

availability of sample containers
suitability of containers for overnight storage
request forms and information requested
out of hours service

Process

turnround time
sensitivity reporting and its accuracy
detection of more unusual pathogens—for example, in renal transplant recipients

Outputs

reporting systems
communication of unexpected findings
cross-infection source detection
requesting frequency and positive yield rate

Outcomes

requestor’s response to positive findings
choice of antimicrobial treatment
follow up cultures after treatment

Use of resources

cost per specimen
cost per positive result by user

Getting going in medical audit in pathology

Having some ideas for medical audit is obviously an essential starting point, but translating ideas into measurable standards often proves difficult. Two approaches may help.—First, the use of standards published by others, or secondly a normative approach of comparison of current performance with neighbouring laboratories, followed by discussion to determine appropriate standards. Such an approach is currently being undertaken by chemical pathology laboratories in Wessex. Topics chosen for medical audit must be important to laboratory function if the effort of audit is to be justified. User views of the service may give a good starting point in finding areas for review and standard setting.

Sentinel events

An alternative approach to medical audit based on criteria of performance is to use sentinel events. These may be defined as untoward, unusual, or adverse events in laboratory practice in terms of their effect on patient care. They may be actual events or occasions of “near miss”. Examples of such sentinel events are failure to report to a suitably senior clinician the unexpected finding of a very high serum calcium in a recently admitted patient, reporting of cervical cytology as acceptable in a woman who presents with cervical carcinoma a year later, or discovery of a blood transfusion miss match. More general points with potential for litigation include other phenomena which may be linked with “patient damage” such as lost samples, lost results, and wrong tests performed. Intensive investigation and critical thought of such occasions are important in highlighting key elements of laboratory practice and standards required to maintain a high level of quality and competency.

Audit by cross-correlation

As clinical investigative techniques involve an increasing variety of approaches, including diagnostic imaging and endoscopy, the opportunity arises to compare the results of pathology with those of other techniques to assess their effectiveness in determining accurate diagnosis. This may be simply comparing liver function test profiles indicating obstructive jaundice with diagnostic imaging and histology findings. Many breast screening programmes have as part of their process a system of review of mamography, fine needle aspiration cytology, and histopathology results.

Clinical opinion

Much of the purpose of consultant clinical practice is related to opinions given on clinical problems both in terms of investigative pathways and interpretation of results. In histopathology schemes of slide exchange for opinion inevitably involve the consultant's personal views being compared with those of his/her peers. Attempts to introduce clinical opinion into chemical pathology have remained at the level of simple diagnostic categorisation.

Two approaches to medical audit of clinical advice are user satisfaction and modification of the "hot review" approach. The first may be undertaken by a survey of the perceived value by users of comments made on report forms, at ward rounds, or on telephone enquiry. Distribution of questionnaires and collation of data need to be anonymous and perhaps better undertaken by a trusted third party.

"Hot review" is a scheme introduced into general practice training in South Wales⁷ but which may be modified as an audit tool to review a clinical opinion given on a specific case. The process requires a colleague to choose a comment made on a form, a telephone enquiry, a letter or an investigation plan and then to determine the area for review. Four review areas are described in a clinical consultation—namely, presenting complaint, patient behaviour, chronic care and risk factors. In the

context of pathology the author has attempted to use this system but taking current data, meeting needs expressed on the request form, previous data on the patient including that from other pathology disciplines and suggested further action—appropriate response such as telephoning the referring doctor. The system gives a formality to the review process especially if a scoring system is used and enhances the learning of both reviewer and reviewee.

Confidentiality

The characteristics of medical audit with its open discussion of individual and group performance using peer review demands an effective system of confidentiality to avoid abuse of information gained. Many hospitals and organisations have spent considerable efforts in preparing codes of practice for confidentiality, although, unfortunately, this does not appear to be universal.

Conclusions

Although quality assurance schemes and accreditation are important in maintaining and enhancing the quality of clinical pathology services, medical audit has much to offer to complement these activities. Three different approaches have been described—criterion referenced medical audit, sentinel event and "hot review". All have advantages in terms of reviewing key factors in laboratory performance and may be undertaken in parallel.

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