J Clin Pathol 1991;44:798–802

Pathology department accreditation in the United Kingdom: a synopsis

Advisory Task Force on Standards to the Audit Steering Committee of the Royal College of Pathologists

Introduction

Within a few months of the appearance of this article, if all goes according to plan, a scheme for the accreditation of pathology departments of (initially) the four major disciplines will be set up in the United Kingdom. It will be run by an independent body called Clinical Pathology Accreditation (CPA) (a non-profit making company) owned jointly by the Royal College of Pathologists, the Association of Clinical Pathologists, the Association of Clinical Biochemists, the Institute of Medical Laboratory Sciences, the Independent Healthcare Association, the Institute of Health Service Managers and the Faculty of Community Medicine of the Royal College of Physicians.

The small but broadly constituted CPA board will be served by discipline specific advisory committees which will define and review accreditation standards and advise on appeals. These committees will rely on a major input from specialist societies by nominated representatives. They will be constituted in the same way as the National External Quality Assessment Scheme (NEQAS) advisory panels, and the Chairmen of the NEQAS panels will sit on the CPA advisory Committees ex officio.

The background and full details of the structure of the initiative are described in the CPA handbook which can be obtained from the CPA office. The purpose of this article is to outline briefly the standards applicant departments will be expected to achieve and the process to which they will be subjected.

The purpose of accreditation is simple. It is an external audit of an applicant department's organisation and quality assurance programme. By declaring a defined standard of practice and having this independently confirmed by peer review, approved departments are able to offer reassurance to users and provide a hallmark of performance that is lacking in non-accredited laboratories.

The process is equally straightforward. The accrediting body (CPA) defines standards for organisation and performance of clinical pathology. Applicant departments assess themselves against those standards and fill in a form to indicate compliance with or exemption from them, and send this, together with details of their facilities and repertoire, to CPA. At that stage provisional accreditation is awarded if all seems to be in order.

Some time later (a considerable time in some cases in the early days of the scheme) the department is subjected to an on-site inspection. If all is seen to be well full accreditation is granted at that stage. Should the inspectors identify problems, full accreditation is withheld until the problems have been solved to the satisfaction of CPA. If that is not achieved within a reasonable time provisional accreditation lapses.

Accreditation will never be finally refused on the basis of a single visit by one team of inspectors, and any applicant department will have the right to appeal against such refusal to the CPA board. The board's decision will be binding.

CPA inspectors will usually visit departments in pairs, each team consisting of a consultant or equivalent clinical scientist and a senior medical laboratory scientific officer (MLSO). Suitable inspectors will be recruited and trained by CPA through its advisory committees. Their numbers will increase only gradually from a small core during the first two or three years of the scheme. They will be unpaid, receiving only expenses associated with site visits.

Both provisionally and fully accredited departments will be put on the CPA register. Departments with full approval will be subject to periodic reinspection at intervals (probably every four years). For all departments there will be a requirement for annual reregistration where a short questionnaire detailing any changes in staff, facilities, or repertoire will be returned with a small annual subscription. Important changes in the administration or repertoire of a fully accredited department may require an interim inspection visit.

Standards

Listed below are the 44 current standards grouped under six headings. Most are applicable to all pathology departments. Each is offered as a positive statement–"there is. . . " which can be interpreted as "there must be". Where appropriate, brief notes on their interpretation are appended.

(A) Organisation and administration

Standard A1 There is a document to describe the organisation and appropriate overall scope of the laboratory services which should include any satellite services for which the head of department is responsible.

There should be a written statement describing

Correspondence to:
Dr J S Lilleyman, Clinical Pathology Accreditation, The Children's Hospital, Western Bank, Sheffield S10 2TH

Accepted for publication 9 July 1991

the objective of the service in terms of repertoire, what quality of service it aims to achieve (a quality assurance programme), and a strategic plan for the medium to long term future. In other words, a brief business plan.

Standard A2 There is a documented line of managerial accountability from the head of the department to senior management in the institution concerned.

Standard A3 There are formal arrangements for meetings between senior laboratory staff and appropriate management or controlling advisory groups to review the service, set objectives and make appropriate financial arrangements.

Minutes should be kept of such meetings, and they should be held at least once a year.

(B) Staffing and direction

Standard B1 Each discipline is professionally directed by a consultant pathologist or clinical scientist of equivalent status.

Standard B2 There are appropriate numbers of staff with the required training to ensure a satisfactory operation of service.

Standard B3 There is a documented line of accountability for all staff to the head of the department.

It is important that unqualified staff should be supervised by someone qualified, and that job descriptions make clear who is accountable to whom.

Standard B4 The duties and responsibilities of all staff are specified in job descriptions.

All staff should possess an up-to-date copy of their job description.

Standard B5 All staff have a contract of employment which clearly states terms and conditions of service.

Manuals should be available outlining terms and conditions of service for all staff. Leave/sickness records should be maintained on all current employees.

Standard B6 Regular staff meetings are held to review services.

Regular documented meetings for all grades of staff should be held.

Standard B7 All new staff are given a comprehensive orientation and induction programme, including health and safety (see also standard C11).

Appropriate in-house safety rules should be issued to all new members of staff. Staff should have access to relevant safety information, and be advised about appropriate immunisations.

(C) Facilities and equipment

Standard C1 There is appropriate office and laboratory space.

The space available should be consistent with safe working practices for the services offered. There must be adequate space for the safe use of equipment in accordance with manufacturer's recommendations.

Standard C2 Where appropriate, there are adequate mortuary and post-mortem facilities.

There should be staff shower and changing facilities. A logbook should be kept of all bodies and necropsies. Facilities should be provided for weighing, photography, and for dictating or recording findings. There should be separate facilities for high risk infectious cases.

Standard C3 There are suitably located staff facilities.

These should include a coffee lounge, changing accommodation, toilets, personal lockers, and, where appropriate, overnight accommodation for on-call staff.

Standard C4 Where appropriate there are sufficient facilities for patients.

These should include a waiting area, examination room, phlebotomy room and toilets for specimen collection.

Standard C5 There is appropriate space available for specimen reception, despatch and handling.

Shared facilities should be adequate for each discipline, bearing in mind that requirements may differ between disciplines.

Standard C6 There are appropriate data storage, retrieval and communication facilities.

Departments should comply with the Data Protection Act (1984), and the laboratory should follow current guidelines relating to record retention. Special regulations apply to blood banks (see standard C10).

Standard C7 There is appropriate properly maintained scientific equipment to meet the demands of the service.

Relevant staff should be adequately trained to use any specialised equipment. All equipment should be clean, well maintained, and conform to current health and safety regulations. Where appropriate, there should be a planned preventative maintenance and replacement programme.

Standard C8 Where appropriate, there is adequate and safe provision of lighting, heating, ventilation, power, gases, water and drainage.

Standard C9 There are adequate storage facilities for specimens, reagents and records.

All containers should be properly labelled and their toxic content highlighted—for example, acids, caustics, corrosives, inflammable or radioactive materials. Liquid nitrogen storage should be well ventilated. There should be separate facilities, including refrigerators, for dealing with category 3 specimens. Where appropriate, inflammables should be stored in spark-proof refrigerators.

Standard C10 Where appropriate, there are adequate storage facilities for blood and blood products using designated refrigerators and freezers with adequate temperature alarm and recording systems.

Attention will be paid to compliance with recent legislation concerning product liability, and the need, for example, to retain records for 11 years.

Blood banks should retain responsibility for satellite blood storage refrigerators—for example, in operating theatre suites, and these should comply with the same standards.

When blood is transferred between hospitals the receiving hospital should request written confirmation of satisfactory prior storage conditions.

There should be a dedicated telephone line for the hospital blood bank.

Standard C11 There are adequate facilities to ensure a safe and healthy working environment in accordance with current legislation.

Each department must have a designated safety officer with the task of ensuring that this standard is complied with.

The visiting inspector will be expected to talk to the safety officer. There must be a departmental safety manual with which staff should be familiar (see standard B7). Safety goggles, gloves, and other protective clothing should be readily available if appropriate.

(D) Policies and protocols

Standard D1 In collaboration with service users, departmental policies, protocols and repertoire are fully documented in a readable and manageable form and contain comprehensive information about the availability of clinical advice and the content and limitations of the service.

This standard refers to the need for a user manual which should help clinicians to provide the right sample in the right container for the right test at the right time, and advise them on how to use the service to best effect and what advice and help is available.

Standard D2 Requests for laboratory investigations should include unique patient identity and adequate supporting information.

This should include the name of the referring doctor, investigations requested, time and date of sampling, relevant clinical information, identification of nature of specimen, location for report, and any special information or precaution relevant to specimen collection or handling.

Standard D3 Reports of laboratory results include adequate patient identity, time, date of collection, testing, and reporting; location and name of requesting clinician and a record of validation prior to despatch.

Standard D4 Interpretive reports are accurate, comprehensive and clinically relevant.

This applies particularly to reports on surgical specimens, biopsies, cytology, bone marrows and necropsies.

Standard D5 There are written protocols relating to specimen collection, handling and disposal.

These should take into account the Health and Safety Executive guidelines in *Safety in Health Laboratories*. There should be a written policy concerning the rejection of specimens. All staff should be trained in the safe handling, storage and disposal of category 3 specimens, including staff handling such material who work elsewhere in the organisation.

For compatibility testing there must be a written procedure for each stage from collection of the patient blood sample through to connection of the blood unit for transfusion.

Standard D6 If the hospital where the department is sited is a potential receiving centre for a major accident, there is a readily accessible document within the department instructing staff on procedure.

Standard D7 There is a written record of all reagents, calibration and quality control material.

The record should include the source, batch numbers, storage requirements, preparation for use, date of use and subsequent safe disposal of the material concerned.

Standard D8 There is a written signed and dated protocol for the performance of each test including where appropriate preparation of equipment, sample and reagents, calculation of results and interpretation of internal quality control performance.

Where appropriate, all test procedures should be carried out according to the manufacturer's instructions. If alterations have been made, there should be records of validation available agreed by the manufacturer.

Standard D9 There is a written protocol for the reporting of results of each test.

This should include, where appropriate, validation procedures, origin of reference ranges, data on potential pitfalls/interferences, and the procedure for rapid reporting of any results which might require prompt clinical attention. For specialist tests more details on interpretation may be required.

Standard D10 There is a written protocol for verbal transmission of results.

Standard D11 There are written protocols for the regular maintenance of equipment.

Where possible there should be a written log of such maintenance.

Standard D12 There are written protocols for the decontamination of all items of equipment and working space.

Equipment should be decontaminated before being serviced either on or off site.

Standard D13 There is a policy describing any out of hours service.

This should also be described in the laboratory handbook (see standard D1) and should include details of those tests requiring authorisation by the head of department.

Standard D14 In hospitals, a nominated consultant in the microbiology department is responsible for institutional infection control.

There must be a written policy describing all aspects of infection control; and there should be an infection control committee of which the head of the microbiology department must be a prominent member.

(E) Staff development and education

Standard E1 There is a written programme of training for all members of staff.

This should include health and safety matters related to specimens, equipment and reagents, dealing with patients, confidentiality, use of individual pieces of equipment, performance of all analytical procedures, and relevance of results.

Standard E2 There are appropriately sited facilities available to support training and continuing education.

These should include a quiet room, reference books, and information systems. There should be adequate reading matter and teaching equipment in the department.

Standard E3 There are facilities (including resources) to enable staff to attend appropriate seminars, meetings and conferences, together with relevant examinations.

Standard E4 There is a continuing education programme for all staff.

There should be evidence of regular updates of procedures and reviews of current practice. Details of courses in other institutions should be available, as should relevant scientific journals.

Standard E5 There is an established staff appraisal scheme.

This should be by trained staff following reputable guidelines.

(F) Evaluation

Standard F1 The department must participate in all appropriate external quality assessment programmes.

Departments should participate in relevant EQA schemes recognised by the CPA advisory committees. A list of such schemes will be available from the CPA office. Participation in other schemes is not in any way discouraged, but should be additional to approved exercises.

Standard F2 Where appropriate quality assessment programmes are widely publicised in the department with regular formal review of performance.

There should be evidence of adequate use of the information from EQA and other appropriate internal control results with formal review of performance at regular intervals.

Standard F3 Quality assurance evaluation includes continuing clinical audit of the service provided.

Local clinical audit of pathology should examine parts of the service such as access, process, output, outcome and use of resources.

Standard F4 Senior pathology staff regularly participate in the audit activities of other clinical specialties.

This standard refers to pathology staff attending NHS medical audit meetings of other clinical services where this is appropriate or possible.

Protocol for on-site inspection

The precise protocol to be followed at any site visit will vary according to local circumstances–how many departments are to be inspected at any one time, what the geographical constraints are, and how many additional specialist inspectors are required. Another factor that will influence arrangements will be the nature of the institution concerned, as the scheme will eventually cater for such diverse organisations as small independent hospitals and the hospital reference work of regional blood transfusion centres. Broadly, though, the format will be for inspector pairs (a pathologist/clinical scientist and an MLSO) each to spend one day in one department, methodically checking compliance with the above standards and taking the opportunity to solicit the confidential views of

service users and, where appropriate, institutional managers some time during that day. Geographically scattered services may need more than one day to be inspected, and multidisciplinary departments will require an inspector pair for each discipline.

This means that for an "average" NHS district hospital with four main pathology departments which all apply as a group to be accredited, eight inspectors will visit for one full day, functioning as four teams for detailed departmental inspections, and as one for the purpose of interviewing service users and hospital managers. One of the eight will be designated as chairman of the inspection team and, through the CPA office, will make the arrangements for the visit with the head of pathology services in the hospital concerned.

Following the site visit, the inspectors will return the completed application forms (to which their comments have been appended) to the CPA office. Subsequently the head of each department concerned will be notified of the outcome of the inspection. Where problems have been identified, these will be listed, together with any detailed explanation required. Departments wishing to appeal against any adverse comment or result will be referred in the first instance to the appropriate advisory committee, and, if necessary, to the Board (see above).

It should be made clear that the scheme will be voluntary and that the costs of its administration will fall to applicant departments. It might be supposed, though, that as the NHS reforms settle down those paying for pathology services will look for some objective assurance of quality.

The task force is grateful to the following organisations for their help in formulating the standards outlined in this article:
The Royal College of Pathologists, The Association of Clinical Pathologists, the Association of Clinical Biochemists, the Institute of Medical Laboratory Sciences, the Advisory Committee for the Assessment of Laboratory Standards, the British Society for Haematology, the British Committee for Standards in Haematology (including the British Blood Transfusion Society and the British Society for Haemostasis and Thrombosis), the Public Health Laboratory Service, the Association of Medical Microbiologists, the Association of Clinical Microbiologists, the Pathological Society of Great Britain and Ireland, the British Neuropathological Society, the British Society for Clinical Cytology, the Society for Inborn Errors of Metabolism, the National Health Service Management Executive, the four United Kingdom Government health departments and the King's Fund.