



The Royal College of Pathologists  
*Pathology: the science behind the cure*

**Code of practice for clinical biochemists (chemical pathologists) and clinical biochemistry services**

**May 2005**

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**Prof John A Lee**  
**Director of Publications**  
**The Royal College of Pathologists**

# **Code of practice for clinical biochemists (chemical pathologists) and clinical biochemistry services**

## **Preface**

The Codes of Practice for pathology services draw together, for each specialty, all relevant guidelines and standards issued by The Royal College of Pathologists.

Each Code of Practice comprises a coherent description of what is required for the provision of an effective, reliable and safe pathology service in that specialty. Thus, the codes and the documents cited within them can be used to assist in the appropriate delivery of pathology services and to help assess whether relevant standards for laboratory accreditation are being met.

**Professor Sir James Underwood**  
**President**

**May 2005**

This code of practice is intended as a supplement to the required standards of practice for Clinical Pathology Accreditation (UK) Ltd (CPA), which is now compulsory, and NHS clinical governance through the Commission for Health, Audit and Inspection (CHAI).

Throughout the code of practice, reference is made to existing guidance documents that give more detailed information, published either by The Royal College of Pathologists and other organisations. These are shown in the bulleted lists. All College documents can be downloaded from the website ([www.rcpath.org](http://www.rcpath.org)).

- *Standards for the Medical Laboratory*. Clinical Pathology Accreditation (UK) Ltd, 2003.

## 1 Introduction

Clinical biochemistry (also called chemical pathology) is the branch of pathology and laboratory medicine in which the chemical and biochemical investigation of body fluids and tissues provides data on the physiology and pathology of individuals and so contributes to the diagnosis and management of patients. Clinical biochemists, who may be either medical doctors (also known as chemical pathologists) or clinical scientists, provide diagnostic expertise and clinical advice and work in clinical teams that care for patients. Clinical biochemists work in partnership with biomedical scientists (BMS) and laboratory managers to provide the best possible clinical biochemistry standards and service.

- *Pathology: The Hidden Science That Saves Lives*. The Royal College of Pathologists, 2000.
- Pathology Alliance. *Careers in Pathology*. London: The Royal College of Pathologists, 2002.

## 2 Management of services

A consultant clinical biochemist should be prepared and able to take on the role of head of department and budget holder, as recommended in the *Strategic Review of Pathology Services*.

- *Strategic Review of Pathology Services* (NHS Executive, 1995).

In addition to his/her role in departmental administration, he/she should contribute to planning decisions at the relevant hospital, district or regional level. The impact of any potential service reconfigurations or changes in commissioning on clinical biochemistry services must be recognised and allowed for.

Clinical biochemistry services play a key role in all hospital and community health settings, through the provision of biochemical data and clinical interpretation that contribute to individual patient diagnoses and the decision-making process in patient therapy and management. Clinical audit depends heavily on clinical biochemistry data and the clinical biochemist has a key role in participating in multidisciplinary and case review meetings. The clinical biochemist must ensure that this role is recognised, and that adequate facilities are made available to meet these requirements and their job plan reflects these activities.

Increasingly, medical consultant clinical biochemists are involved in direct patient care and the sub-specialty of metabolic medicine has received joint recognition from The Royal College of Physicians and The Royal College of Pathologists. The clinical workload of medical consultants should be determined at local level and incorporated into the job plan of the consultant. Employers should recognise that increasing clinical duties will reduce the time available for laboratory-based duties and that there may be a requirement for additional clinical biochemist sessions within the laboratory.

Clinical biochemists are often called upon to be involved in managed networks and in regional and national managerial roles, including work for medical royal colleges and other professional bodies or specialist societies. This is necessary to ensure adequate representation on these bodies and global maintenance of standards and improvement of services. This should be recognised as a legitimate part of a clinical biochemist's work and practised to the same high professional standards as clinical work and more local managerial roles. This should be recognised and allowed for in the clinical biochemist's job plan.

### **3 Staffing and workload**

Clinical biochemistry workload originates from a variety of sources including hospital inpatients and outpatients, primary care, the independent sector, pharmaceutical companies and other external agents. Some departments act as secondary and tertiary referral centres for more complex analytical and/or diagnostic services. Clinical biochemistry departments have seen workload rise at approximately 10% per annum for many years, without the corresponding investment into staff. This has been compounded by the increased demand for an extended repertoire of services on a 24/7 basis and almost all departments are working under considerable pressure. In response to this pressure, different working practices are evolving that include pathology networks and this development has been accelerated by the Department of Health publication on pathology modernisation and the formation of its 'Diagnostics' branch. The skill mix of staff within a department and a network should be adequate and appropriate for the workload and repertoire and agreed with local clinicians and managers. Guidelines for consultant staffing in clinical biochemistry are outlined in *NHS Clinical Biochemistry: A Profession under Siege*.

Job descriptions for new and replacement clinical biochemist posts should conform to College recommendations. Clinical biochemists should have job plans that are workable and practical and allow protected time for clinical audit, appraisal, administration, teaching and other duties. Consultants should try to actively manage their workload by adjusting skill mix, employing automation, educating users and employing demand management techniques. Out-of-hours on-call rotas should be adequately funded; single-handed consultant rotas should be avoided.

- *NHS Clinical Biochemistry: A Profession Under Siege*. The Royal College of Pathologists, 2002.
- *Modernising Pathology Services*. Department of Health (England), 2004.
- Guidelines for consultant job descriptions (general and specialty-specific). The Royal College of Pathologists, 2002.

### **4 Safety**

Safety in the clinical biochemistry laboratory is the joint responsibility of the consultant clinical biochemist, appropriate senior staff and a designated safety officer. They should make periodic inspections of the department to ensure relevant safety procedures are being observed. Each department should comply with regulations of the Health and Safety Executive, the Advisory Committee on Dangerous Pathogens and CPA standards. All procedures should be covered by written standard operating procedures that are reviewed regularly.

- *Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities*. Health and Safety Executive, 2003.

### **5 Relation to users of the service**

The needs and requirements of patients and users are central to determining the service repertoire and specifications of the clinical biochemistry department. Clinical biochemists should assess the needs of users by attending ward rounds, grand rounds and clinical meetings and by being available to listen to and give advice to general practitioners. Clinical audit is an essential element in ensuring that the service is fit for purpose and being used optimally.

## 6 Pre-analytical procedures

Clinical biochemistry departments should have written procedures to describe the correct specimen collection arrangements for each item of service in its repertoire. The procedures should include patient preparation, the timing of specimen collection, the specimen type and transport requirements.

Clinical biochemistry departments should have written procedures for the transport, receipt and recording of biological specimens, which include blood, urine, faeces, saliva, cerebrospinal fluid and other body tissues. Requesting may be either electronic or on a conventional request form. Transport to the laboratory may be by porter, pneumatic tube or a courier service, including the postal service.

Upon receipt, specimens must be matched with requests and a unique accession number attached to both specimen and request. Criteria for establishing adequate patient identification data should be clear to laboratory staff and users and be consistent across pathology departments in the hospital. Incorrectly labelled specimens should not be analysed. Staff should be trained in the safety aspects of handling biological specimens and the use of equipment, including centrifuges. All specimen aliquots should contain the same unique specimen identifier. Specimens should be stored in appropriate conditions for the investigations requested

Patient and specimen details are entered into the laboratory computer by trained staff. Written procedures should be available for the use of the laboratory computer and its interface with the hospital information service, including patient confidentiality and data security.

## 7 Analytical procedures

Clinical biochemists are responsible for determining the repertoire of analyses provided by the department and any network to which the department belongs. The repertoire should have regard to the needs of users of the service, the equipment available, the competence of staff to undertake the analyses and external regulations, including the European Union In-Vitro Diagnostic Devices Directive.

- *The European Union Diagnostic Devices Directive*. European Commission, 1998.  
[http://europa.eu.int/comm/enterprise/medical\\_devices/index.htm](http://europa.eu.int/comm/enterprise/medical_devices/index.htm)

Specimen analysis must only be performed by suitably qualified and trained staff. All staff members working unsupervised must be registered professionals with either the Health Professions Council (HPC) or the General Medical Council (GMC).

All laboratory analytical methods must be supported by detailed written procedures, which are verified and updated at planned intervals. Written procedures should include instructions for performing the analysis, the source of the method, details of reference intervals, criteria for assessing the quality of results, guidance on troubleshooting, and instructions for the maintenance of any equipment used. A designated member of staff should check quality criteria and ensure technical validation before results are submitted to the laboratory computer.

## 8 Post-analytical procedures

Clinical biochemists are responsible for ensuring the results are reported in a timely manner with the inclusion of relevant interpretative comments and clinical liaison as

appropriate. Only appropriately qualified and trained clinical biochemists may perform interpretation and clinical authorisation unsupervised.

Written procedures should be available to describe the criteria used in selecting results for computer-generated reports. Detailed written guidelines should be produced to assist with manual reporting. Reports, both electronic and in hard copy, must indicate how they were scrutinised and/or authorised. Interpretative comments should be clear and concise and take into account the likely recipient of the report. Urgent or abnormal results that may affect patient management should be telephoned to the requesting clinician, as appropriate. Clinical biochemists should contact requesting physicians to discuss interesting or unusual sets of results or cases. Such discussions could include advice on the meaning of results, follow-up investigations or therapy where appropriate. Reporting procedures should comply with CPA standards.

## **9 Out-of-hours service provision**

Most clinical biochemistry departments are required to offer a 24/7 analytical and interpretative service. The consultant clinical biochemist, in consultation with users, has responsibility for determining the range of services provided on a 24/7 basis. A written description of the 24/7 service should be available and documents should be available to describe the pre-analytical, analytical and post-analytical procedures undertaken by the department. Only staff registered with the HPC or GMC may undertake analytical work out of normal working hours

Clinical biochemists provide a 24/7 clinical advisory service, usually by telephone or pager link. A written rota for the clinical biochemistry advisory service should be available and users should know how to contact the clinical biochemist on call. Whilst only one clinical biochemist will be on call at any time, the College recommends that at least two clinical biochemists should be available to participate in each out-of-hours advisory service rota.

## **10 Disposal of specimens and records**

Protocols and policies for consent and the retention and disposal of specimens and records should be available and should conform to latest national guidelines from the College, the Department of Health and the Human Tissue Bill.

- *The Retention and Storage of Pathological Records and Archives (2nd edition)*. The Royal College of Pathologists, 1999 – corrected August 2003.
- *Transitional Guidelines to Facilitate Changes in Procedures for Handling ‘Surplus’ and Archival Material from Human Biological Samples*. The Royal College of Pathologists, 2001.

## **11 Point of care testing**

Clinical biochemists have a responsibility for the range and quality of biochemical point of care testing (POCT) that is performed in local hospitals, and with appropriate agreement and resources in primary care centres and pharmacies. All POCT should comply with the guidelines of the Medicines and Healthcare products Regulatory Agency (MHRA).

- *DB2002(03) Management and Use of IVD Point of Care Test Devices*. Medicines and Healthcare Products Regulatory Agency, 2003.
- *Point of Care Testing: Top Ten Tips*. Medicines and Healthcare Products regulatory Agency, 2004.

## **12 Quality assurance**

The head of each clinical biochemistry department is responsible for the establishment and maintenance of quality standards in all aspects of work in the department. In line with CPA standards, he/she should appoint a quality manager to monitor quality standards on a day-to-day basis. The quality manager may function in more than one department or discipline. Each department should have up-to-date documentation detailing all laboratory procedures and a well-defined mechanism for document control.

Clinical biochemistry departments should undertake both internal quality control (IQC) and external quality assessment (EQA) for all tests that are within the service provision. Results of IQC and EQA should be made available to all members of the department and on request from users of the service. Clinical biochemistry laboratories should appoint a quality control officer.

## **13 Risk management and critical incident reporting**

Clinical biochemists and their departments should participate in appropriate critical incident reporting schemes as required by clinical governance.

## **14 Information technology (IT)**

Laboratory IT systems should be adequate for the needs of the service in terms of routine patient and specimen recording, results access for users, and the provision of data for audit and benchmarking purposes.

Consultant clinical biochemists should each have an individual computer with access to departmental and other appropriate PAS files, email, intranet and internet.

## **15 Clinical audit**

Clinical biochemists and their departments should participate in clinical audit to assess the quality and appropriateness of the services provided. Audit activity should include some multi-professional and multidisciplinary elements and departmental audit should include both horizontal and vertical elements as required by CPA.

Individual clinical biochemists are encouraged to participate in relevant interpretative EQA schemes. They should also:

- a) assure, through appraisal, the quality of their clinical skills and/or clinical advice
- b) ensure the quality and timeliness of reports and clinical advice
- c) be available and willing to discuss clinical and professional issues
- d) know their diagnostic limitations and scope of practice
- e) participate in multidisciplinary team meetings
- f) be willing to undertake a peer questionnaire of 360° review of practice.

## **16 Relationship to clinical colleagues/good medical practice**

Clinical biochemists should endeavour to work effectively and cooperatively with their clinical and laboratory colleagues. The clinical biochemist should seek to become a member of relevant multidisciplinary teams in order to ensure that the department provides optimal clinical biochemistry services.

Clinical biochemists should not work outside their area of expertise; this guidance applies to any non-NHS work and on-call rotas as well as to their daily practice within the NHS.

- *Good Medical Practice in Pathology*. The Royal College of Pathologists, 2002.
- *Substandard Professional Performance. Guidance for Trusts and Pathologists*. The Royal College of Pathologists, 2002.
- *Standards of Performance, Conduct and Ethics*. Health Professions Council, 2003.

## **17 Continuing professional development, appraisal and clinical governance**

Clinical biochemists should ensure that they are up to date and participating in continuing professional development and annual appraisal to ensure GMC revalidation or re-registration with HPC. All clinical biochemists must take adequate steps to maintain their own professional standards and be aware of developments in their discipline. They must also ensure that trainee clinical biochemists working with them develop and maintain high standards. Clinical biochemists should also be aware of the clinical governance requirements in their place of work and play a part in their implementation. The same standards of professional behaviour and practice should be applied to any non-NHS work and should not impinge on contracted hours/duties with the employer or on employer facilities/equipment.

## **18 Research**

Where appropriate, clinical biochemists should actively encourage and participate in research. Departments with trainee clinical biochemists must ensure that the trainees have time, the opportunity and the encouragement to be involved in research during their training. Clinical biochemists must adhere to both national and local ethics and research procedures/policies and ensure appropriate approval and consent is obtained for all research undertaken.

- *Central Office for Research Ethics Committees*. [www.corec.org.uk](http://www.corec.org.uk)

## **19 Teaching and training**

All clinical biochemists should be willing and able to teach as required. The head of department is responsible for ensuring that all grades of staff receive appropriate in-service and professional training. Consultants should have time recognised in their job plans for their own CPD as well as for training junior medical staff, other healthcare professionals and undergraduate medical students. Access to journals and books, particularly frequently used reference sources, should be easily available. Ongoing departmental educational activity including tutorials, seminars, case discussions and participation in EQA reviews is recommended.

- Joint Committee on Higher Pathology Training. *Handbook for Postgraduate Medical Education and Training in Pathology*. The Royal College of Pathologists, 2002.

**Specialty Advisory Committee on Clinical Biochemistry**

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