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

Code of practice for clinical biochemists/chemical pathologists and clinical biochemistry services

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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.

This *Code of Practice for clinical biochemists/chemical pathologists and clinical biochemistry services* is a revised version of the document that was originally published in May 2005. The code supplements the required standards of practice for Clinical Pathology Accreditation (UK) Ltd (CPA) accreditation and NHS clinical governance through the Care Quality Commission. Throughout the document, reference is made to existing guidance documents that give more detailed information, published by The Royal College of Pathologists and other organisations. All College documents can be downloaded from the College website (www.rcpath.org/publications).

- *Standards for the Medical Laboratory.* Clinical Pathology Accreditation (UK) Ltd. Version 2.02 (November 2010). www.cpa-uk.co.uk

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 pathophysiology 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.

2 Management of services

A consultant clinical biochemist should be prepared and able to take on various management roles, such as Head of Department, Laboratory Director or Clinical Lead, with responsibility for the overall professional direction of the department and service, as recommended in the *Strategic Review of Pathology Services* (NHS Executive, 1995) and in line with ISO 15189 and CPA's *Standards for the Medical Laboratory*. In larger departments or laboratory networks, the clinical biochemist may not have a senior operational management role, but should retain responsibility for service quality and clinical outcomes.

S/he should also be active and competent in managerial duties as required by local Trust (Hospital or Health Board in Scotland) arrangements, and should contribute to planning decisions at hospital, network or regional level as relevant to ensure that the impact on clinical biochemistry service of any proposed service reconfigurations or changes in commissioning patterns are recognised and taken into account. The clinical biochemist should work as a member of the Trust, Hospital or Health Board management team to ensure the provision of a high-quality, patient-focused, consultative laboratory service.

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 therapy and management. Clinical audit depends heavily on clinical biochemistry data, and the clinical biochemist has a key role in multidisciplinary and case review meetings. The clinical biochemist must ensure that this role is recognised, that adequate facilities are available and that their job plan supports these activities with an appropriate balance of direct clinical care and supporting activities appropriate to the individual's practice.

Increasingly, medical consultant clinical biochemists are involved in direct patient care, and the sub-specialty of metabolic medicine is jointly recognised by The Royal College of Pathologists and The Royal College of Physicians. The clinical workload of medical consultants should be determined locally and incorporated into the individual's job plan. Employers must recognise that increasing clinical commitments will reduce the time available for laboratory duties and oversight, and that there may be a consequent requirement for additional clinical biochemist sessions within the laboratory.

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

- ISO 15189:2007. *Medical Laboratories – Particular Requirements for Quality and Competence*. www.iso.org

- *Standards for the Medical Laboratory.* Clinical Pathology Accreditation (UK) Ltd. Version 2.02 (November 2010). www.cpa-uk.co.uk

3 Staffing and workload

The workload of a clinical biochemistry laboratory originates from a variety of sources, including hospital inpatients and outpatients, primary care, the independent sector, pharmaceutical companies and other external agencies. Some departments act as secondary and tertiary referral centres, within and outside established networks, for more complex analytical and/or diagnostic services. Staffing in clinical biochemistry departments remained static between 2001 and 2007, despite a 50% increase in gross workload. This pressure 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 extreme pressure. In response to this, and to resource constraints, different working practices are evolving that include the formation of pathology networks and initiatives to streamline processes within the laboratory. Whatever service delivery models are adopted, the skill mix of staff within individual departments and across networks should be adequate and appropriate for workload, repertoire and turnaround time, and strategies should be put into place to manage or reduce workload where staffing levels are inadequate. This should be done in agreement with local clinicians and managers. Guidelines for determining adequate levels of consultant staffing in clinical biochemistry are contained in *Consultants in Clinical Biochemistry: The Future.*

Job descriptions for new and replacement clinical biochemists should conform to College recommendations. Clinical biochemists should have job plans that are workable and practical, and allow protected time for clinical audit, quality assurance, continuing professional development (CPD), appraisal, administration, teaching, research and development and other duties. Consultants should actively manage their workload by adjusting skill mix, employing automation and information technology, educating users and employing demand management techniques implemented with appropriate risk management. Out-of-hours on-call and extended-hours rotas should be adequately funded. Single-handed consultant on-call rotas should be avoided.

- *Consultants in Clinical Biochemistry: The Future*. The Royal College of Pathologists, 2009.
- *Workload Management in Laboratory Medicine: Patient Safety and Professional Practices.* The Royal College of Pathologists, 2006.
- *Guidance for the Appointment of Career Grade Locum Pathologists*. The Royal College of Pathologists, 2005.
- The Royal College of Pathologists' current guidelines for consultant job descriptions:

  Generic guidance:
  - *Guidelines for job planning*
  - *Head of department*
  - *Model person specification (generic)*
  - *Consultant clinical scientist (generic) job description*
  - *Guidance notes on either/or appointments of medical consultants or consultant clinical scientists*

  Specialty-specific guidance:
  - *Clinical biochemist/chemical pathologist*.

4 Safety

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

As healthcare professionals, clinical biochemists also have a responsibility to ensure patient safety in all areas of their work. Effective risk management and clinical incident reporting systems should be in place, and safe patient care should be of paramount concern in planning and delivering all aspects of clinical biochemistry services. Clinical biochemists should take every care to ensure the correct interpretation and effective use of results produced by their laboratory.

5 Relation to users of the service

The needs and requirements of patients and clinical users are central to determining the service repertoire, turnaround requirements and specifications of clinical biochemistry departments. Clinical biochemists should actively seek to address the needs of users by attending ward rounds, grand rounds and clinical meetings and by being available to listen to and advise general practitioners. Clinical audit and user surveys are essential elements in ensuring that the service provided is fit for purpose and being used optimally. Clinical investigation pathways and protocols involving laboratory testing should be regularly reviewed and evaluated. Users should receive feedback on the appropriateness of their use of laboratory services.

Clinical biochemists should also ensure that appropriate information for patients is provided for laboratory tests, especially dynamic tests or those requiring administration of a stimulus. Patient information leaflets and web-based information should be clear, easily accessible and regularly reviewed for accuracy.

Consent procedures for sampling and the subsequent use and disposal of clinical samples should be understood and consistently applied.

Patients should be treated appropriately when they attend the laboratory to give samples, with phlebotomy areas that ensure privacy, confidentiality and dignity.

- *A Brief Guide on Consent for Pathologists*. The Royal College of Pathologists, 2009.
- *Guidance on Consent for the Processing and Analysis of Clinical Samples Following an Initial Consultation.* The Royal College of Pathologists, 2009.
- *Code of Practice 1: Consent.* The Human Tissue Authority, 2009. www.hta.gov.uk/publications
- *Use of Specimens from Healthy Volunteers.* The Royal College of Pathologists, 2005.

6 Pre-analytical procedures

Clinical biochemistry departments should have written procedures to describe the correct specimen collection arrangements for each item of service in their repertoire. These procedures should include patient preparation, the timing of sample collection, the specimen type and transport requirements. Telephone advice should be available to doctors and other health professionals on how to access investigations, the appropriateness of particular investigations and specimen collection requirements.

Clinical biochemistry departments should have written procedures for the transport, receipt and recording of biological specimens, which may include blood, urine, faeces, saliva, cerebrospinal fluid and other body fluids or tissues. Requesting may be either electronic or on a conventional paper form, but all requests must include a minimum patient identification dataset, including the NHS number. Transport to the laboratory may be by porter, courier (including the postal service) or pneumatic tube, as appropriate for the location and the tests requested.

Upon receipt, specimens must be correctly matched with requests and a unique accession number attached to both specimen and request document. All specimen aliquots should contain the same unique specimen identifier. Criteria for ensuring correct patient identification should be clear to laboratory staff and users, and consistent across pathology departments in the hospital

or network. Incorrectly or inadequately 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. This may involve training staff outside the laboratory who are involved in transport of specimens or in centrifugation of specimens in GP practices. Specimens should be stored under appropriate conditions for the investigations requested.

Patient and specimen details are entered into the laboratory information management system (LIMS) by trained staff. Written procedures should be available for the use of the LIMS and its interface with the hospital information system, including unequivocal patient identification and absolute data security.

Specimens collected for medicolegal purposes require special precautions.

- *Guidelines for Handling Medicolegal Specimens and Preserving the Chain of Evidence.* The Royal College of Pathologists, 2008.

7 Analytical procedures

Clinical biochemists are responsible for determining the repertoire of analyses provided by the department/network as appropriate. The repertoire should have due regard to the needs of users of the service (including patients), the equipment available, the competence of staff to undertake and interpret the analyses and relevant external regulations including the European Union In Vitro Diagnostics Devices Directorate as applied to methods devised within the institution. The laboratory repertoire should be regularly reviewed with the introduction of new tests based on evidence of clinical utility and cost-effectiveness, and the withdrawal or restriction of tests that have been shown to be ineffective.

- *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices.* http://eur-lex.europa.eu

Clinical biochemists must ensure that the performance of all analytical methods has been validated and is adequate to meet clinical requirements, including turnaround time, proper standardisation of results, precision at clinical decision points, etc.

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 and their derivation, criteria for assessing the quality of results, guidance on troubleshooting and instructions for the maintenance and safe operation of any equipment used. A designated member of staff should check quality criteria and ensure technical validation before results are released to the LIMS.

8 Post-analytical procedures

Clinical biochemists are responsible for ensuring that the results of analytical procedures are reported in a timely manner, with the inclusion of relevant interpretative comments (including potential interferences and other confounding effects) and appropriate liaison with the requesting

clinician. Only appropriately trained and qualified clinical biochemists may perform clinical authorisation and interpretation unsupervised, or give clinical advice for the diagnosis and/or management of patients.

Written procedures should be available that describe the criteria used for autovalidation of results by electronic systems. These criteria should be devised by clinical biochemists and regularly reviewed to ensure efficacy. Detailed written guidelines should be produced to assist with manual reporting. Both electronic and hard copy reports must indicate how they were scrutinised and authorised. Interpretative comments should be clear and concise, and take into account the level of knowledge and understanding of the likely recipient of the report. There should be procedures for assessment of the quality and timeliness of interpretative comments (e.g. the NEQAS Scheme for Interpretative Comments in Clinical Chemistry).

Urgent or abnormal results that may affect immediate patient management should be telephoned to the requesting clinician as appropriate. There should be proper procedures for the investigation of discrepant results. Clinical biochemists should contact requesting clinicians to discuss interesting, unusual or anomalous sets of results or cases. Such discussions could include advice on the meaning of results, follow-up investigations or therapeutic approaches where appropriate and within the competence of the clinical biochemist.

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, consultative and interpretative service. The consultant clinical biochemist, in consultation with service users, has responsibility for determining the range of services provided on a 24/7 basis. A written description of the service provided outside core hours should be available. Only staff registered with the HPC or GMC may undertake analytical work unsupervised outside normal laboratory working hours.

As many laboratories now operate extended hours working or continuous processing patterns, specimens from primary care may be analysed in the late evening, at night or during the weekend, when general practices may be closed. Markedly abnormal results requiring urgent clinical action may be generated during these times, and the laboratory must have clear procedures for identifying those results which require urgent notification to the primary care out-of-hours provider, and for contacting the out-of-hours provider. Full guidance is contained in:

- *Out-of-hours Reporting of Laboratory Results Requiring Urgent Clinical Action to Primary Care: Advice to Pathologists and those that work in Laboratory Medicine.* The Royal College of Pathologists, 2010.

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

10 Disposal of specimens and records

Protocols and policies for the consent (see section 5) and the retention and disposal of specimens and records should be available, and should conform to national guidelines from the College and the Human Tissue Authority and comply with the Human Tissue Act (2004) or the Human Tissue (Scotland) Act 2006 as appropriate.

- *The Retention and Storage of Pathological Records and Specimens*. The Royal College of Pathologists, 2009.
- *Codes of Practice.* The Human Tissue Authority, 2009. www.hta.gov.uk/publications
- *Guidance on the Use of Clinical Samples Retained in the Pathology Laboratory.* The Royal College of Pathologists, 2007.
- *Questions and Answers: The Human Tissue Act, 2004.* The Royal College of Pathologists, 2006.
- *Guidelines on the Release of Specimens and Data to the Police and Other Law Enforcement Agencies.* The Royal College of Pathologists, 2006.
- *The Human Tissue Act (2004)* and *The Human Tissue (Scotland) Act 2006.* The Human Tissue Authority, www.hta.gov.uk
- *College Advice Relating to the Ownership, Storage and Release of Pathology Results.* The Royal College of Pathologists, 2000.

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 service-level agreements and resources) in primary care centres, pharmacies and other community locations. All POCT should comply with CPA standards and the guidelines of the Medicines and Healthcare products Regulatory Agency (MHRA).

- *Additional Standards for Point-of-Care Testing (POCT) Facilities.* Clinical Pathology Accreditation (UK) Ltd. Version 1.01 (November 2010). www.cpa-uk.co.uk
- *Management and Use of IVD Point Of Care Test Devices – DB2010(02).* Medicines and Healthcare products Regulatory Agency, 2010. www.mhra.gov.uk/publications/index.htm
- *Clinical Governance of NHS Staff in Single-Handed Practice with Particular Reference to Point-of-Care Testing.* The Royal College of Pathologists, 2007.
- *Point of Care Testing – Cholesterol Testing*. Medicines and Healthcare products Regulatory Agency, 2005. www.mhra.gov.uk/publications/index.htm
- *Point of Care Testing – Top 10 Tips.* Medicines and Healthcare products Regulatory Agency, 2004. www.mhra.gov.uk/publications/index.htm
- *Guidelines on Point-of-Care Testing*. The Royal College of Pathologists, 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, s/he 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 within the provision of service. Results of IQC and EQA should be made available to all members of the department and, on request, to 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. Records of complaints and adverse incidents should be maintained.

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.

Electronic reporting systems should ensure that results are available to all those involved in a patient's care (with appropriate security safeguards), clearly marked with who ordered them, who currently has responsibility for them, who has looked at them and who has signed them off.

- *Acting upon Test Results in an Electronic World.* British Medical Association, 2010. www.bma.org.uk/images/electronictestresults_tcm41-200743.pdf

Consultant clinical biochemists should each have an individual computer with access to departmental LIMS and appropriate hospital information system files, internet, intranet and email.

15 Clinical audit and effectiveness

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 multi-disciplinary 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 (e.g. the NEQAS Scheme for Interpretative Comments in Clinical Chemistry).

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 the scope and limitations of their practice

e) participate in multi-disciplinary team meetings

f) be willing to participate in multi-source feedback and 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 be 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.

Clinical biochemists must comply with the ethical codes of their professional regulatory body.

- *The European Register of Specialists in Clinical Chemistry and Laboratory Medicine: Code of Conduct, Version 2, 2008*. *Clin Chem Lab Med* 2009;47:372–375.

- *Standards of Conduct, Performance and Ethics*. Health Professions Council, 2008. www.hpc-uk.org/publications/standards

- *Good Medical Practice.* General Medical Council, 2006. www.gmc-uk.org/guidance

- *Concerns about Performance in Pathology: Guidance for Healthcare Organisations and Pathologists.* The Royal College of Pathologists, 2006 (under review, 2011).

17 Continuing professional development, appraisal and clinical governance

Clinical biochemists should ensure that they are participating in, and up to date with, continuing professional development and annual appraisal to ensure revalidation with the General Medical Council 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 or duties with the employer, or on the employer's facilities or equipment.

18 Research

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

- National Research Ethics Service, www.nres.npsa.nhs.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, books and internet resources, 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.