Code of practice for histocompatibility and immunogenetics (H&I) services

November 2016

This guidance was originally prepared in 2005 as part of ‘Codes of practice for pathology services and departments’ series. This document replaces the earlier edition.

In accordance with the College’s pre-publications policy, this document was placed on The Royal College of Pathologists’ website for consultation from 28 September to 26 October 2016. One item of feedback was received and the document was amended as necessary. Please email publishing@rcpath.org if you wish to see the response.

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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.

1 Introduction

Regional specialist histocompatibility and immunogenetics (H&I) laboratories (historically referred to as ‘tissue typing’) throughout the UK offer a comprehensive range of serological, molecular and cellular techniques to identify human leukocyte antigens (HLA) and characterise immunological sensitisation to HLA. These tests are carried out in support of supra-regional solid organ transplantation programmes (kidney, pancreas, liver, heart, lung, small bowel, multivisceral, cornea), stem-cell, purified islet cell and composite tissue transplantation, investigation and management of blood transfusion related reactions, platelet transfusion and as an aid to disease diagnosis (e.g. narcolepsy, actinic prurigo, ankylosing spondylitis, Reiter’s disease, uveitis, rheumatoid arthritis, coeliac disease, insulin dependent diabetes, Graves’ disease, multiple sclerosis and Behçet’s disease) and mitigation of pharmacological hypersensitivity reactions. In addition, analysis of immunogenetic polymorphisms to determine the immune status, and aid the development of immuno-modulatory therapeutics, the diagnosis and treatment of immunodeficiency disorders and autoimmune and vascular disease and transplantation immunological monitoring form part of the remit of H&I. The majority of requests are received through secondary and tertiary referrals, although direct access from primary care groups also takes place.

H&I is a consultant-led specialist pathology discipline and is represented in the UK by the British Society for Histocompatibility and Immunogenetics (BSHI).

This code is intended to provide guidance in the application of good laboratory practice in H&I departments. It is essential that the health and welfare of patients and healthcare workers be protected by establishing criteria by which H&I laboratories can achieve uniform standards of performance that assure accuracy, reliability and safety.

The standards to which H&I laboratories should conform are recorded in detail by the following professional bodies: the United Kingdom Accreditation Service (ISO 15189: 2012), Clinical Pathology Accreditation (UK) Ltd, European Federation for Immunogenetics, the American Society for Histocompatibility and Immunogenetics and the Medicines and Healthcare products Regulatory Agency. All standards are designed to assure consistent performance by laboratories of accurate laboratory procedures and reliable services, and should include:

a) the qualifications of the director of the laboratory, and other supervisory and technical staff and any other staff necessary for the adequate and effective operation of the laboratory with respect to the accuracy and reliability of testing performance
b) the maintenance of records, equipment and facilities necessary for proper and effective operation of the laboratory
c) the maintenance of an internal quality assurance programme adequate and appropriate for accuracy and precision of the laboratory procedures and services
d) participation in external quality assessment schemes appropriate for accuracy and precision of laboratory procedures and services.
2 **Budget**

The H&I service should have a separate and defined budget under the control of the head of department as the designated budget holder.

3 **Head of department**

The head of laboratory and budget holder must be a fully trained and experienced consultant clinical scientist or medically qualified consultant and would normally possess FRCPath or equivalent qualification in H&I. The head of laboratory would be accountable to his or her employing authority for all aspects of the H&I service, including validity of tests performed, quality assurance, selection of appropriate techniques employed, interpretation of results, research, training, staffing and safety. The day-to-day running of the technical aspects of the laboratory would normally be the delegated responsibility of designated senior staff in the department. The head of department is responsible for ensuring that referral for tests in fulfilment of the Human Tissue Act (2004) are carried out in accordance with current legislation.

4 **General procedures**

The head of the H&I department must ensure that proper written standard operating procedures (SOP) are established for all methods including the standard risk assessment of the technique. The SOP may only be changed with the authority of the head of department or by a person designated to authorise changes. (Such changes should be documented according to correct quality management principles.)

All reports should be signed after checking by a consultant clinical scientist, or an individual to whom such authority has been appropriately delegated according to the relevant standards. There should be a full audit trail of reagents, equipment and personnel used in the processing of patient samples, reporting of test results and clinical advice given. All patient samples should be collected, held, tested, otherwise used and waste tissue disposed of in accordance with the codes of practice of the Human Tissue Authority and the Human Tissue Act (2004). Patient information and test data should be stored and used in compliance with the above legislation, the Caldicott principles and the Data Protection Act (1998). To comply with the Human Tissue Act (2004), it is the responsibility of the requestor to ensure that any patient or donor has been informed of, and has consented to, the tests being requested. Patients/donors should be informed that any residual material of a sample may be stored as part of required archiving protocols or to enable further investigation for the benefit of the individual. They also must be informed that excess surplus material may be used anonymously for quality control purposes, service development or education and/or ethics committee-approved research projects.

5 **Relationship with clinical users**

The interpretive and advisory role of senior scientific staff is essential. Every effort should be made to facilitate the relationship with clinicians by attending regular clinical meetings, and by maintaining availability to give advice when requested.

6 **Quality control**

One person should be assigned responsibilities as quality manager, either for the whole laboratory or for a section. The designated individual(s) must have the authority to prevent
the release of any results not meeting agreed quality control procedures. This authority may be delegated to senior staff in sections.

All investigations should be subject to internal quality control procedures to ensure the accuracy and precision of the results. All laboratories should participate in external quality assessment schemes for every investigation undertaken. External quality assessment schemes should be under the purview of the National External Quality Assessment Scheme, the European Federation for Immunogenetics or the American Society for Histocompatibility and Immunogenetics. The results from these schemes should be reviewed as soon as they are received and appropriate action taken to remedy deficiencies. These samples must be handled in an identical manner to patient samples.

Records should be kept of supplies delivered to the laboratory and expiry dates or reagents. All laboratory equipment should be part of a documented maintenance programme. This means that all equipment should have a logbook to record all maintenance, faults, etc. Electrical and other equipment should comply with all relevant current legislation.

7 Role of department in teaching outside the department

Staff of the H&I department should be actively involved in the teaching of undergraduates, trainee scientists in H&I, specialist registrars and other clinical or non-clinical health service staff. This may involve the provision of tutorials, lectures or seminars, or supervising laboratory based work.

8 Staff training

All staff should have adequate training to perform the tasks they undertake. Continuing competence in trained staff should be demonstrated via a scheduled assessment programme. Scientific staff (clinical scientists and senior biomedical scientists) would normally be expected to have successfully completed the BSHI Diploma, specialist IBMS portfolio or Scientist Training Programme and be registered with the Health and Care Professions Council (HCPC). Senior clinical scientists would normally have passed the FRCPath Part 1 examination in H&I and may have passed, or be working towards, the Part 2.

Qualified staff must fulfil the requirements of a recognised continuing professional development (CPD) scheme such as that administered by the RCPPath, IBMS or the BSHI. All laboratory protocols on safety, quality control, etc. should be issued to staff, who should sign an undertaking that they have read and understood the contents. Staff should be trained in the laboratory in handling equipment. The head of department is responsible for maintenance of standards of all aspects of the work. He/she must take such steps as are necessary to maintain his/her own standards and ensure that all members of staff have access to further education, including access to library facilities containing relevant journals and books. The department should have an adequate departmental library covering all aspects of the service.

Where local resources permit, heads of departments may actively encourage research and development by members of staff. Trainees should have the time and supervision for research projects. Collaboration with clinicians is an essential part of research procedures.

9 Laboratory organisation

Separate facilities and appropriate numbers of qualified staff are required to support different laboratory sections including molecular diagnostics, serology and cellular. Much of the work within H&I laboratories involves complex and skilled manual processing of patient samples. A suitable ratio of staff is one senior scientist for each laboratory section, to supervise up to five
healthcare scientists and support staff (e.g. medical laboratory assistants, medical technical officers).

Staffing levels and grading must be commensurate with laboratory workload, range of services and repertoire of techniques and, where these exist, should be informed by appropriate national staffing models. Workforce levels must be sufficient to support staff personal development, annual leave and unexpected absence in accordance with professional society recommendations.

Although authority may be delegated, the responsibility for reporting of all laboratory test results and interpretative advice ultimately lies with of the head of department. In laboratories that provide 24-hour cover for emergency and urgent samples, there must be adequate qualified staffing levels to ensure safe provision of the service in accordance with the European Working Time regulations (including annual leave, study leave and unexpected absence).

10 Administration and management

The head of department is accountable for all aspects of the service, and must ensure appropriate provision for cover during periods of his/her absence. This includes the provision of an out-of-hours ‘on call’ service if required. The head of department should actively pursue the development of the service and try to ensure that adequate funds are available for changing demands on the service. He/she should be actively engaged in all planning processes, which will affect the future of their laboratory. Efficient use of skilled scientific staff and provision of laboratory services also requires the support of a dedicated laboratory manager, clerical and secretarial staff.