The Royal College of Pathologists

Pathology: the science behind the cure

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

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In accordance with the College pre-publications policy, this document was shown to Council in 2004 and put on the College website for consultation from 6 December 2004 to 10 January 2005. One piece of feedback was received, which the Histocompatibility and Immunogenetics Sub-committee has incorporated into this final version of the publication.

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

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 the detection of 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, cornea), stem-cell 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). In addition, analysis of immunogenetic polymorphisms to determine the immune status, and aid the diagnosis and treatment of immunodeficiency disorders, autoimmune disease, 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 health care workers be protected by establishing criteria by which H&I laboratories can achieve uniform standards of performance which assure accuracy, reliability and safety.

The standards to which H&I laboratories should conform are recorded in detail by the following professional bodies: Clinical Pathology Accreditation (UK) Ltd, European Federation for Immunogenetics and the American Society for Histocompatibility and

Immunogenetics. 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 a PhD together with the FRCPath or MRCPath 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. Samples for analysis are referred by medical practitioners to the head of department who is responsible for the provision of the most appropriate tests and discussion with the clinician concerned. The head of department is responsible for ensuring that referral for tests in fulfilment of the Human Organ Transplant (HOT) Act are carried out by an approved HOT Act Tester, in accordance with current legislation.

4 General procedures

The head of the H&I department must ensure that proper written procedures are established for the receipt and recording of specimens received. Specimens must be transported to the laboratory in separate plastic bags to minimise risks to non-qualified handlers. Forms should be placed in a separate pocket of the bag to avoid contamination. Specimens may be transported to the laboratory by specimen porters who are part of the laboratory staff or by mechanical means, which can include pneumatic tube systems or by other means. Specimens can also be transported to the laboratory by a courier service.

Specimens must be identified on receipt and matched with request forms. Unlabelled specimens should not be analysed. Patients' request forms must have adequate identification. Specimens should be given an accession number when received in the laboratory. Inconsistencies should be brought to the attention of a senior member of the department, as should any potentially hazardous samples. Such samples may need to be dealt with in a safety cabinet. Specimens must be analysed by suitably qualified staff. *All methods should have detailed written protocols or standard operating procedures, including the standard risk assessment of the technique.* The standard procedures detailed in the laboratory manuals may only be changed with the authority of the head of

department or by a person designated to authorise changes. (Such changes should be dated and initialled).

All report forms should be signed after checking by a consultant clinical scientist, or an individual to whom such authority has been delegated. 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 principles of the *Human Bodies, Human Choices* code of conduct and the Human Tissue Bill (2004 Update). Patient information and test data should be stored and used in compliance with the above legislation and the data protection act.

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 being available to give advice when requested.

6 Quality control

One person should be assigned responsibilities as 'quality control officer', 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 log book to record all maintenance, faults, etc. Electrical equipment should comply with the DHSS Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE). Other equipment should comply with a relevant British Standard or code of practice.

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 and be state

registered (Health Professions Council). Senior clinical scientists (CS-B point 19 and above) would normally possess Dip RCPath in H&I and a PhD. Qualified staff should be enrolled for CPD. 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 the access to library facilities containing journals and books. The department should have an adequate departmental library covering all aspects of the service.

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 (CS-C or high grade CS-B) for each laboratory section, to supervise up to five clinical and/or biomedical scientists and support staff (e.g. medical laboratory assistants, medical technical officers).

Staffing levels and grading must be consummate with laboratory workload, range of services and repertoire of techniques and, where these exist, should be informed by appropriate national manpower 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 support of a dedicated laboratory manager, clerical and secretarial staff.

Histocompatibility and Immunogenetics Sub-committee
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