



Best practice recommendations

Histocompatibility and immunogenetics services

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Comments	<p>This document supersedes the 2016 document titled <i>Code of practice for histocompatibility and immunogenetics (H&I) services</i>.</p> <p>In accordance with the College's pre-publication policy, this document was on the Royal College of Pathologists' website for consultation from 15 July to 29 July 2024. Responses and authors' comments are available to review on final publication at: www.rcpath.org/profession/publications/documents-in-development.html</p> <p>The following change was made to this BPR.</p> <ul style="list-style-type: none">• The year of the ISO standard on page 5 has been updated. <p>Dr Michael Eden Clinical Director of Quality and Safety</p>



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Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approaches of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every 5 years. The College will ask the authors of the BPR to consider whether or not the recommendations need to be revised. A review may be required sooner if new developments arise or changes in practice necessitate an update. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for 2 weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR was reviewed by the Professional Guidelines team. It was placed on the College website for consultation with the membership from 15 July to 29 July 2024. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Director of Quality and Safety.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Professional Guidelines team and are available on request. The authors of this document have declared that there are no conflicts of interest.

1 Introduction

Specialist histocompatibility and immunogenetics (H&I) laboratories (historically referred to as 'tissue typing') offer a comprehensive range of cellular, molecular and serological techniques to predominantly identify human leukocyte antigens (HLA) and characterise immunological sensitisation to HLA. The work of H&I laboratories is 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
- 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
- analysis of immunogenetic polymorphisms to determine the immune status and aid the development of immuno-modulatory therapeutics
- immunological monitoring in transplantation.

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 Royal College of Pathologists and the British Society for Histocompatibility and Immunogenetics (BSHI).

This BPR is intended to provide guidance on 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 bodies: the United Kingdom Accreditation Service (UKAS [ISO 15189: 2022]) and the European Federation for Immunogenetics (EFI). H&I laboratories that support blood

transfusion services are also required to be compliant with the Medicines and Healthcare products Regulatory Agency (MHRA).

All standards are designed to assure consistent performance of accurate and relevant laboratory procedures and delivery of reliable services. Compliance with standards must ensure that:

- the qualifications of the laboratory head, supervisory scientists, technical and other staff are adequate for the effective operation of the laboratory
- the maintenance of equipment, facilities and records ensures proper and effective operation of the laboratory
- the internal quality assurance programme is adequate and appropriate for accuracy and precision of the laboratory procedures and services
- participation in external quality assessment schemes are appropriate for accuracy and precision of laboratory procedures and services.

2 Recommendations

2.1 Budget

The H&I service should have a separate and defined budget under the control of the head of the H&I laboratory/department (hereon described as 'head of department') as the designated budget holder.

2.2 Head of department

The head of department must be a fully trained and experienced consultant clinical scientist or medically qualified consultant and would normally possess FRCPATH by examination in H&I. The head of department is accountable to their employing authority for all aspects of the H&I service, including validity of tests performed, quality management, 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 sample handling and testing are carried out in accordance with the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 and any other relevant UK legislation.

2.3 General procedures

The head of department must ensure that a robust quality management system is established, within which control of documentation including standard operating procedures (SOPs) and risk assessments for all laboratory processes are established. The quality management system must also control the evaluation of equipment and testing systems to ensure they are fit for purpose and must also allow the recording of errors with documented corrective and preventive actions.

All reports of testing results must be issued only after verification by a consultant clinical scientist, or an individual to whom such authority has been appropriately delegated according to defined training and competence assessment. There must 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 must be collected, held, tested, otherwise used and waste tissue disposed of in accordance with current UK legislation and the clinical guidelines and BPRs of the Royal College of Pathologists and the Institute of Biomedical Science (IBMS).

Patient information and test data must be stored and used in compliance with current legislation, including the Data Protection Act (2018).

To comply with the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006, it is the responsibility of the requestor (not the laboratory) to ensure that any patient or donor has been informed of and has consented (authorised in Scotland) to the tests being requested. Patients and donors must 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.

2.4 Relationship with clinical users

The interpretive and advisory role of senior scientific staff is essential for the delivery of an effective H&I service. Every effort must be made to facilitate the relationship with clinicians by attending regular clinical meetings and by maintaining availability to give advice when requested.

2.5 Quality control

1 individual 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 must be subject to internal quality control procedures to ensure the accuracy and precision of results. All laboratories must participate in external proficiency assessment schemes for every investigation undertaken. External proficiency assessment schemes should be UKAS accredited and approved for H&I by the EFI. External assessment samples must be handled in an identical manner to patient samples. The results must be reviewed as soon as they are received and appropriate action taken to remedy deficiencies.

2.6 Role of the 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, clinical and nursing staff and other non-clinical health service staff. This may involve the provision of tutorials, lectures or seminars, or supervising laboratory-based work.

2.7 Staff training

1 individual should be assigned responsibilities as training manager, either for the whole laboratory or for a section. All staff must have adequate training to perform the tasks they undertake. Continuing competence in trained staff must 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. Senior clinical scientists would normally have passed the FRCPath Part 1 examination in H&I and may have passed, or be working towards, Part 2.

Qualified staff must fulfil the requirements of a recognised continuing professional development scheme, such as those administered by RCPATH, IBMS or BSHI.

The head of department is responsible for the maintenance of standards of all aspects of the work. They must take necessary steps to maintain their own standards and ensure that all members of staff have access to further education, including access to library facilities containing relevant journals and books.

Where local resources permit, heads of departments may actively encourage research and development by members of staff. Collaboration with clinicians is an essential part of research procedures.

2.8 Laboratory organisation

Separate facilities and appropriate numbers of qualified staff are required to support various laboratory sections including cellular, molecular diagnostics and serology. Much of the work within H&I laboratories involves complex and skilled manual processing of patient and donor samples.

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, responsibility for the reporting of all laboratory test results and interpretative advice ultimately lies with 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).

2.9 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 their absence. This includes the provision of an out-of-hours 'on call' service if required. The head of department must actively pursue the development of the service and try to ensure that adequate funds are available for changing demands on the service. They must 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 and clerical and secretarial staff.