



The Royal College of Pathologists

Pathology: the science behind the cure

Code of practice for haematology departments

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

Code of practice for haematology departments

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

This code of practice provides guidance for the establishment of standards of performance, which ensure a consistently high level of reliability and accuracy in haematology departments.

Haematology is an acute clinical specialty and the haematology laboratory an integral and essential part of the service provided by and for this specialty. As such, it undertakes a range of tests for the diagnosis and management of haematology disorders, in addition to those undertaken in support of other specialties. Its functions include the performance of routine haematological investigations, together with more specialised tests in connection with haemostasis and thrombosis, haematological malignant disease, enzymes and vitamin assays, haemoglobinopathies and those involving the use of radioactive isotopes. In addition, it includes facilities for the selection and matching of appropriate blood transfusion, the supply of blood products and for the diagnosis of immune haematological disorders.

2 Head of department

The staff of the laboratory will include medical graduates, science graduates, biomedical scientists (BMSs) and medical laboratory assistants (MLAs) together with such ancillary, administrative and clerical staff as may be necessary for the efficient running of the department. A fully trained, medically qualified consultant haematologist or non-medical scientist of equivalent grade, who will be the budget holder, will head it and be accountable to the appropriate institutional manager for the management of the service provided by the haematology laboratory. This will include validation of analyses, quality assurance, determination of the range of tests to be undertaken and the selection of methods employed, interpretation of results, research, training and the staff and safety aspects of the laboratory. In addition, medical haematologists have major clinical responsibilities, not in the scope of the present code, but which must be considered in respect of the time available for laboratory duties. These responsibilities include direct patient care, clinical administration and the clinical training of junior medical staff. The

head of the department will need to be supported by an appointed deputy who will also usually be medically qualified. The day-to-day management of the scientific aspects of the laboratory may be delegated to the most senior BMS in the department, though in some laboratories it may be more appropriate for this to be the role of a consultant or senior scientist. Routine tests procedures should be agreed by the head of department.

3 General procedures

Layout of laboratory

This will vary but adequate space must be provided for procedures to be performed accurately and with safety. The following requirements should be met.

There should be separate sections for:

- a) phlebotomy (unless provided elsewhere)
- b) receipt and sorting of specimens
- c) blood transfusion
- d) routine analytical procedures
- e) microscopy
- f) office's secretarial work, report distribution and clerical duties
- g) locker rooms
- h) special procedures including isotope work and, where appropriate, research.

Offices for consultation and minor procedures should be located in the outpatient suite or day ward and should no longer be located in the laboratory.

Further information on laboratory space can be obtained from DHSS Building Note 5.

Receipt of specimens and issue of reports

As a general rule, the haematologist is responsible for blood samples from the time of their receipt in the specimen reception area. If a phlebotomy service is available and run by the haematology department, the haematologist is responsible for the training of phlebotomists and must ensure that measures are taken to protect the safety for both phlebotomist and patients. Any specimen received by post should comply with regulations. Special precautions are necessary in the case of blood transfusion (see below).

Proper procedures must be established for receipt and recording of specimens in the laboratory. These must be transported in sealed plastic bags; request forms may be attached be placed in a separate pocket of the bag to avoid contamination but arranged so as not to be separated from the specimen until matched in the laboratory. On arrival in the laboratory, specimens must be checked for correct type of container and for the correct amount of blood in relation to anticoagulant. Leaking specimens should be treated as high risk. Unreasonable delays between collection of specimens and receipt in the laboratory must be investigated.

Request forms and specimen containers must have adequate identification. If any specimen is not adequately labelled to ensure correct identification, that specimen should be discarded but the doctor making the request should be immediately told of this decision. Specimens should be given a laboratory number, and details entered into a current paper file or computer by BMS, MLA or clerical staff. All samples should be treated as potentially hazardous but each laboratory should have a protocol for those samples that are identified as 'high risk' conditions by the presence of a warning label on

the specimen and/or request form. Such specimens, if not processed on a regular basis, will be brought to the attention of senior scientific or medical member of the laboratory staff before unpacking and designated for special handling. Similarly, urgent specimens should be identified and dealt with appropriately to ensure rapid analysis.

Tests may be initiated within the laboratory for further elucidation of the abnormalities that have been detected. The head of department is responsible for the formulation of policies to direct these investigations.

Detailed written instructions should be given for the correct transcription of results to report forms or to computer-generated result sheets. Staff performing the work should ensure that the results are technically valid and that an appropriate quality control procedure has been used. All reports should be scrutinised and validated by appropriately trained staff, in accordance with a protocol that has been laid down by the head. Within defined and agreed parameters, 'vetting' may be performed electronically. Urgent results should be scrutinised by a qualified BMS and reported as 'provisional'. An appropriately trained haematologist should sign diagnostic reports based on the microscopic examination of bone marrow sample. The haematologist is responsible for ensuring that validated results are issued from the laboratory in a timely manner.

Arrangements for emergency and urgent specimens

Adequate arrangements should be made for 24-hour cover of the laboratory and on-call staff responsible for blood transfusion should, whenever possible, be resident in the hospital whilst on duty or live within easy travelling distance. A fully trained haematologist should always be available by radio-pager or telephone. All staff operating the on-call service should be familiar with the whole on-call repertoire of tests. This may require periodic updating of the staff members that do not perform the whole range in their daily work.

Major incidents

It is essential that each department have a written manual stating the exact procedures to be followed in the event of a major accident, when large numbers of casualties may be expected. Appropriate members of the staff should receive a copy on appointment and the manual should be displayed prominently, preferably in the blood transfusion section.

4 Role of department in clinical care

As haematology is an acute clinical specialty, the haematologist will be responsible for the care of patients across the whole range of haematological disorders. In addition, it will also be necessary to provide advice on the diagnosis and management of haematological problems presenting to both their consultant colleagues in other specialties and to general practitioners. This will include assistance with haematological aspects of other systemic diseases and advice on replacement therapy with both blood and blood products.

5 Quality assurance

It is mandatory for good laboratory practice that procedures are implemented to ensure internal and external quality control. External quality control is best managed by entry into the National External Quality Assessment Scheme (NEQAS), in addition to any regional and other local quality assessment schemes. The head of the laboratory should nominate an individual who is responsible for quality control audit, though the head is

ultimately responsible for laboratory performance and should regularly review results with the named contact.

Internal quality control methods will vary in individual laboratories and the following guidelines should be implemented.

1. At frequent intervals, but not less than twice each day, control samples must be included in the analytical procedure for routine tests. Final results for patients' samples should not be issued until it is clear that no drift in expected results has occurred, although preliminary results will usually be available on a computer screen in those departments with a network link to the requesters. Once consistency has been demonstrated, results may be issued. Additional techniques may be used to confirm the consistency of results throughout the 24-hour day. Control materials may be prepared in the laboratory or obtained commercially. During their preparation, they must undergo testing in accordance with established health and safety practice. When human blood is used it should, as far as possible, be prepared from donations that have been tested individually for HIV antibody and for hepatitis B surface antigen and shown to be negative. When it is necessary to use untested blood, this fact should be indicated on the label and the sample should be regarded as potentially infectious and treated with the same safety precautions as patients' specimens.
2. The essential requirements for using control material are described in *Standard Haematology Practice* and relevant guidelines from The British Committee for Standards in Haematology (BCSH).

Further advice can be obtained from UK NEQAS.

6 Laboratory accreditation

Laboratory accreditation systems are the key to clinical governance and quality improvement and all pathology services must be accredited with Clinical Pathology Accreditation (UK) Ltd (CPA) or another body accrediting to equivalent standard.

7 Blood transfusion

The blood transfusion service should operate in accordance with the Health Service Circular HSC 2002/009 *Better Blood Transfusion*. This states that there should be a hospital transfusion committee to oversee all aspects of transfusion with a hospital transfusion team to implement the policies

In addition to participation in the National External Quality Assessment Scheme for blood group serology, there should be an internal quality assurance scheme based on regular assessment of reagents, equipment and individual worker performance.

Reagents must comply with national specifications, where these exist. The guidelines on hospital blood bank documentation and procedures as prepared by the BCSH Blood Group and Transfusion Task Force should be followed. These guidelines define minimum requirements for documentation in relation to blood transfusion.

The principles on which the Task Force based its recommendations are as follows.

- a) The patient identification must be unique.

- b) There must be a clear link between each stage in the procedure from the collection of the patient's blood sample to the administration of the unit for transfusion to the patient.
- c) It must be possible to trace, at every stage, the time an event occurred and the individuals who were involved.

Local policies on antibody screening and identification compatibility testing and blood issue should be based on the relevant BCSH documents.

8 The role of the department in teaching outside the department and for users of the service

The head of the department is responsible for ensuring that both medical and non-medical members of the department are involved in providing appropriate training, both in haematology and the use of the laboratory, to other health service staff both within and without the hospital. Where a hospital operates induction schemes, haematology input should be provided for all relevant staff. Such opportunities should be used to facilitate cooperation and relationships with users of the service. There should be haematology and blood transfusion sections within the handbook.

9 The role of the department in training staff

It is mandatory that adequate time should be allowed for further education of all grades of both medical and scientific staff, who should be encouraged to attend scientific meetings and should have access to good library facilities within easy reach of the laboratory. The head of the department, or designated deputy, is responsible for arranging slide seminars, journal clubs, case commentaries, etc. on a regular basis, which both medical and scientific staff should be encouraged to attend. When teaching staff are studying for a qualification, there should be a curriculum and a learning contract specifying the commitment of the learner and teacher. Trainees should be taught and assessed on the skills commonly required in haematological practice. The department should be committed to the development of all staff through CME, CPD schemes and appraisal. The department should follow best practice in terms of error management, as described in *An Organisation with a Memory*.

10 The role of the department in forward planning

It is essential that the head of the laboratory should be involved in the broader planning process, so that adequate provision may be made for the expansion of the laboratory services necessary to encompass any increased workload resulting from developments in other services. In addition, the head of the laboratory will consult with both medical and scientific staff to plan for the introduction of appropriate developments occurring within the specialty of haematology.

Specialty Advisory Committee on Haematology

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