# Oh, what a tangled web

The relationships between hospital blood transfusion departments, service users, other agencies, and covering legislation and guidelines are complex. Using experience gained in Leeds, Chris Elliott attempts to clarify what can be a confusing situation.

I was asked to prepare a paper describing the interactions between stakeholders and the Leeds Teaching Hospitals (LTH) blood transfusion department because I was due to leaving to take up a post in another hospital. While writing the paper, it became evident that the vast majority of the relationships are the same irrespective of whether the transfusion department is large or small. This article is based on my experiences at LTH and some aspects may not apply, or slightly different terms or organisational structures may be described.

Hospital blood transfusion departments usually consist of two interrelated units comprising the laboratory and the hospital transfusion team (HTT), which work together to provide the necessary support for the host trust. The laboratory provides testing services, appropriate blood components and blood products, clinical and scientific advice and other transfusion-related support to the clinical teams. The HTT acts as the departmental arm that stretches into clinical areas to communicate policy, help alter clinical practice, support training and help achieve regulatory requirements pertaining directly to clinical areas (particularly traceability, incident reporting and NPSA competencies). Its existence is also a requirement under the Better Blood Transfusion (BBT) guidance.

## HOSPITAL TRANSFUSION COMMITTEE

The department has formal links with the clinical teams through the hospital transfusion committee (HTC), which meets on a regular basis. This allows communication of policy, practice and regulatory changes/requirements. Performance, quality, incidents and audits are also raised here, as are queries from the clinical teams.

There is a link between the HTC and a trust's clinical governance framework, with a requirement for an annual report on transfusion to the trust board. The department also has links with other clinical user groups in the trust, especially those developing major incident teamwork experience (MAJAX) policies.

## PATHOLOGY OPERATIONAL MANAGEMENT GROUP

The transfusion department is part of the pathology service and takes its operational management through the pathology operational management group (POMG). It must implement all the requirements that pathology departments must follow (eg EWTD, H&S law, Human Tissue Act, finance, HR etc). Other agencies that have significant relationships with the department are listed below.

## NHS BLOOD AND TRANSPLANT

NHS Blood and Transplant (NHSBT) supplies blood components as required and in the event of certain bioterrorist events the NHSBT (which acts as a central repository) will supply antidote pods to hospitals through the hospital transfusion laboratory. It also offers specialist testing services (red cell reference, HLA and platelet reference) for complex cases requiring methods or reagents unavailable to us.

There are service level agreements (SLAs) between trusts and the NHSBT governing its interactions (including costs).

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These are national agreements, the details of which are decided by a national commissioning group. The NHSBT organises regional meetings, regional transfusion committees and blood bank managers' forums, all of which require input and attendance from the hospital transfusion department. These feed into the National Blood Transfusion Committee that reports directly to the Chief Medical Officer.

Other agencies that have an effect on NHSBT and its practices are not mentioned here.

## MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

The Blood Safety and Quality Regulations (BSQR) came into effect in November 2005. These enshrine mandatory requirements controlled by criminal law and are enforced by a competent authority, currently the Medicines and Healthcare products Regulatory Agency (MHRA). However, the soon to be formed Regulatory Authority for Tissues and Embryology (RATE) will take over as the competent authority, but it may decide to use the MHRA as its inspectorate agency. The law covers blood centres and hospitals, although the mechanism for attaining compliance for each is different.

Hospitals are required to submit an annual compliance report for each site on which there is a laboratory. Based on the information in the report, the MHRA will decide whether to declare the department compliant for that year or to inspect to check compliance. This compliance report must be signed by the blood bank manager and the chief executive of the relevant trust, and represents a legally binding document.

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take actions against an institution. These can include a 'cease and desist' order or the instigation of a prosecution against individuals. If proved, the latter can result in a custodial sentence.

While the MHRA does not publish formal standards for hospitals to meet, it expects us to be meeting the requirements laid out in BSQR and working to the standards laid out in the European Good Manufacturing Guidance (provided in the 'Orange Guide'). There is a Blood Consultative Committee that acts as a liaison between the MHRA and the blood community that provides clarifications on issues thrown up by inspections.

The BSQR requires transfusion incidents to be reported, and the MHRA has an online reporting system (SABRE) that must be used for all appropriate incidents. There is also an annual collection of baseline data from the MHRA that must be completed, which is associated with this system.

The MHRA is also responsible for enforcement of the Medicines Act, which has consequences for us because a number of the products that might be released by the blood transfusion department are governed by this Act. These include blood products (eg albumin, anti D, coagulation concentrates) and other prescription-only medicines (eg solvent detergent washed fresh frozen plasma [SD FFP; Octoplas]).

While the MHRA as yet has not involved itself significantly in the control of these products, it is clear that issuing practices may have to be changed to meet legislation, and advice about how best to do this should be sought from pharmacy.

## CLINICAL PATHOLOGY ACCREDITATION

As is the case with other pathology departments, blood transfusion submits itself to Clinical Pathology Accreditation (UK) Ltd (CPA) inspection and accreditation. While not legally mandated, it is strongly supported in national guidance and is usually a requirement in SLAs with external clinical users. The new CPA standards and inspection regime require a significant investment in time and expertise to achieve and maintain accreditation. Meeting the CPA standards goes a long way to satisfying the MHRA requirements.

The MHRA will take failure to achieve CPA accreditation as a trigger to inspect for potential non-compliance with the BSQR and there is a legal requirement for departments to inform the MHRA of any changes in CPA accreditation status.

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## EXTERNAL CLINICAL USERS

The department may service a number of other users outside the host trust. These can include other NHS hospitals, hospices, independent surgical units, private hospitals or other providers of care (eg Marie Stopes clinics).

Procedures, policies and SLAs controlling the relationships between transfusion departments and these agencies must be produced annually, and be monitored and maintained. This is required by the BSQR and checked by the MHRA.

## SERIOUS HAZARDS OF TRANSFUSION

The Serious Hazards of Transfusion (SHOT) scheme is a transfusion incident reporting system that has been in existence for a number of years. While reporting to SHOT is not legally mandated, it is strongly supported in national guidance. Submissions are now made through a direct link in the Serious Adverse Blood Reactions & Events (SABRE) system. The department audits its practice against the recommendations and incidents recorded in SHOT reports.

## NATIONAL PATIENT SAFETY AGENCY

The National Patient Safety Agency (NPSA) has made the reduction of ABO-incompatible transfusions a priority. This has led to a number of Safety Notices with effects on transfusion practice. All trusts are required to enact these safety notices as part of their requirements of the Healthcare Commission standards. Of particular importance is the recent requirement for competence assessment in clinical areas for those involved in the transfusion process.

## NHSLA CLINICAL NEGLIGENCE SCHEME FOR TRUSTS

The NHS Litigation Authority (NHSLA) Clinical Negligence Scheme for Trusts (CNST) has a set of standards relating to transfusion practice. Most cover clinical practice and compliance is supported mainly through the HTT. Failure to meet these standards would mean that the trust would not achieve Level One compliance, and thus lose the current discount on its policy (this can cost the trust many thousands of pounds).

## BLOOD STOCKS MANAGEMENT SCHEME

Tranfusion departments should participate in the national Blood Stocks Management Scheme, which, while not compulsory, is strongly supported in national guidance. Leeds submits the required data (daily stock levels for red cells and platelets), participates in surveys and audits its practice against the benchmarks that the BSMS produces.

## UK NATIONAL EXTERNAL QUALITY ASSURANCE SCHEME

Like many other pathology departments, transfusion participates in the UK National External Quality Assurance Scheme (UK NEQAS), including the relevant Blood Group Serology and Fetomaternal Haemorrhage schemes. Failure to participate would be a critical non-compliance for CPA and would not be looked on favourably by MHRA.

## HEALTH PROFESSIONS COUNCIL & NURSING AND MIDWIFERY COUNCIL

The Health Professions Council (HPC) and the Nursing and Midwifery Council are bodies that regulate healthcare scientists and nurses, and maintain a register of practitioners. Departments must ensure that all scientific and nursing staff are trained to the required standard and that they maintain their eligibility to practise. The recent requirement to demonstrate continuing professional development, which will be audited in 2009, is a new aspect that needs monitoring. Medical staff registration is usually controlled through central trust procedures.

## NATIONAL GUIDELINES AND OTHER REQUIREMENTS

Guidelines – primarily but not exclusively from the British Committee for Standards in Haematology (BCSH) – direct many areas of practice, from technical laboratory practice to administrative practice on the wards. There are various guidelines that relate to the issue of blood components and products to various patient groups. Failure to adhere to these would generate a report to SHOT and often to the MHRA.

Policies and procedures must be checked regularly against these standards, especially when practices change or when new guidance is issued. While guidelines are not mandatory practice, they are accepted as nationally agreed best practice and therefore local deviations must be supported (and documented) by evidence from risk assessments. Failure to provide such evidence on inspection by CPA or

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the MHRA would lead to non-compliances (the nature of which would depend on the individual deviation).

**Better Blood Transfusion circulars**
Since 1998 a series of workshops led by the UK chief medical officers have been held. These have resulted in the release of Health Service Circulars which give recommendations about transfusion that trusts are expected to implement. The latest release, BBT 3, is imminent. Failure to implement the recommendations would lead to negative impacts on CNST and Healthcare Commission assessments, and may also have an impact on the BSQR assessment.

**Emergency blood management arrangements**
The Department of Health now requires all trusts to maintain emergency blood management arrangements (EBMAs) for red cells and platelets. These cover actions to be taken by the organisation, especially when shortages of these products are announced. These plans must be kept current and should be tested on a regular basis (annually should be sufficient).

**National occupational standards**
National occupation standards (NOSs) are the training standards to which the department trains its staff to ensure competence in their practice. These standards are to be built into the knowledge and skills framework (KSF) and into training procedures and competence assessment procedures in the future.

There are quite a number of generic NOSs that are relevant to all biomedical science specialties, and there are 22 NOSs relating specifically to blood transfusion (there are 13 NOSs relating specifically to biochemistry).

## FUTURE BENEFITS

The complexities of the relationships in a modern hospital transfusion service have increased significantly over the past 20 years. Consequently, the way hospital transfusion services are managed, organised and supported now needs to be overhauled, as many blood bank managers and their departments are suffering because they find themselves with little support or training and no time to ensure that all the necessary requirements are fulfilled.

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This is a situation that would benefit from the development of consultant healthcare scientist posts in transfusion. Such posts may need to cover networks of trusts (in a manner similar to the way clinical immunology services are often provided), as smaller units individually could not justify them. These consultants would work with blood bank managers (who would retain day-to-day operational responsibility) and clinical haematology consultants (who would retain clinical leadership and clinical advisory responsibility) to ensure that an accredited service was maintained. ■

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