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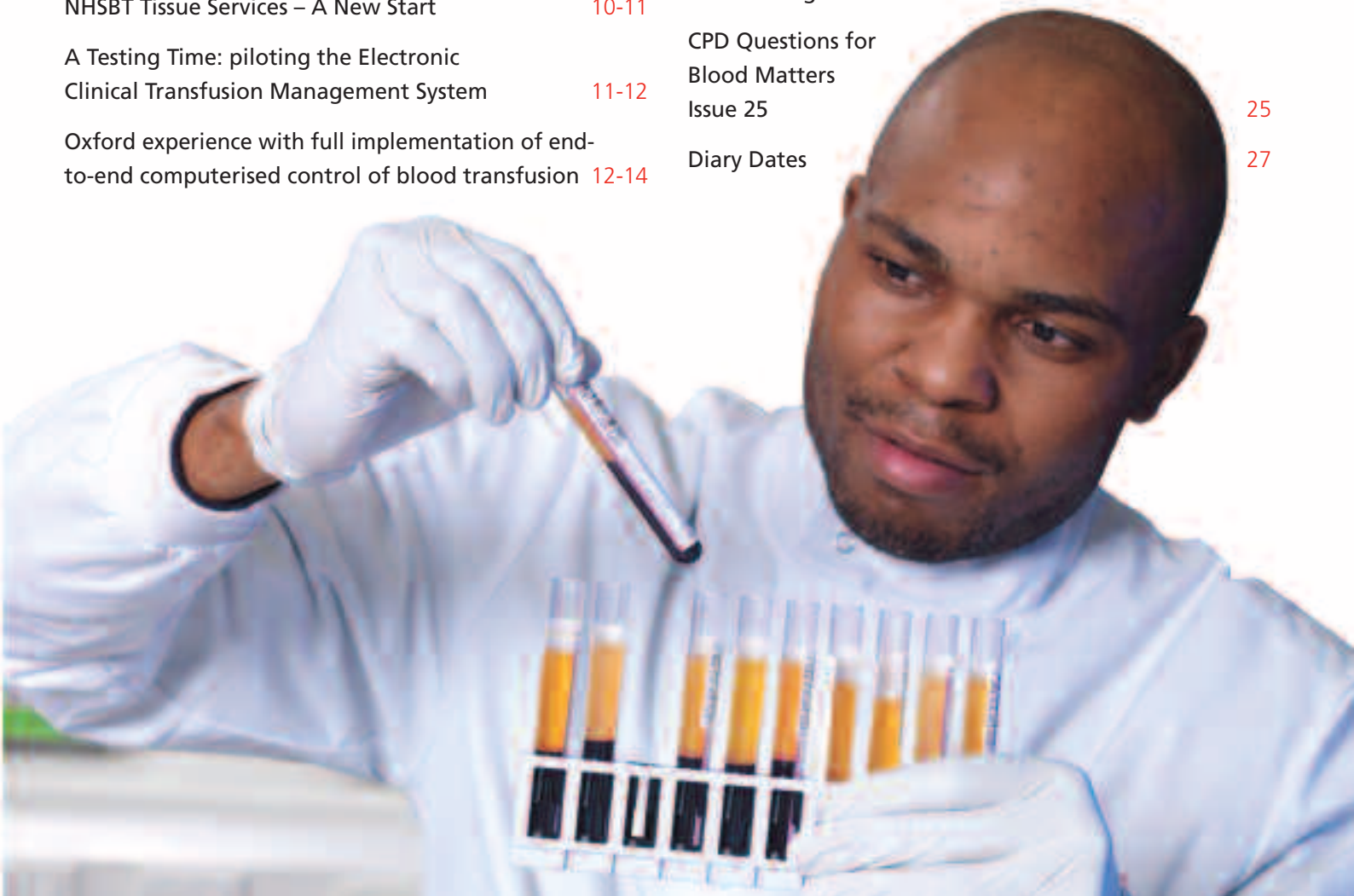
NHS Blood and Transplant

Blood Matters

Information for hospitals served by NHS Blood and Transplant

Inside



Editorial

In this edition of ***Blood Matters*** you will find six articles that explain the outcome of NHSBT's Strategic Review and how it aims to provide consolidated facilities that deliver improved products and services. Sue Carrington describes the challenges that Donor Services face and points out that if NHSBT was to take no action whatsoever there might be a shortfall of 50,000 units of donated blood each year. A number of important changes are projected and it is clear that the service will be judged on its ability to maintain good blood stocks in times where the general public seems to be less altruistic than hitherto. Teresa Allen explains to us the changes that are being made to the supply chain to create up-to-date processing space which conforms to the current regulatory requirements. Accordingly there will be consolidation with only six processing centres in the future but the supply chain will still require a network of 15 issue sites to supply both routine and specialist products more efficiently to NHSBT's customer hospitals.

The specifications for the products that the UK blood services provide are set out in the Guidelines for the Blood Transfusion Services in the United Kingdom – affectionately known as the Red Book. The latest NBS blood components portfolio was published in 2006 and has introduced some major changes with safety, as always, at the forefront. In her article Sheila MacLennan tells us how work has now started on the next logical development which is a move towards a harmonised UK BTS components portfolio. In his article on Diagnostic Services Tim Wallington explains how a comprehensive review of Specialist Services was undertaken in 2007. NHSBT is, of course, the main provider of red cell immunohaematology and platelet and granulocyte immunology services and provides a significant proportion of histocompatibility and immunogenetics services which are essential to the supply of blood components, haemopoietic stem cells and so on. Some consolidation of service sites in accredited laboratories together with a service expansion is being implemented. Tim draws to our attention the importance that NHSBT attaches to its partnerships with hospitals.

The concept of a single, flexible, customer-focused workforce for Specialist Diagnostic Services is discussed by Andrew Hadley. Such services are being reconfigured around staff competencies and crucial core technologies such as molecular diagnostics and flow cytometry. This will facilitate access in the future to a single diagnostics service. Consolidation has also been the theme of the Tissue Services reorganisation and John Kearney describes the new centre in Liverpool and its purpose-built facilities which include operating rooms for tissue retrieval. Other developments include an enhanced Customer Service Department, a comprehensive new website and a number of surgical user groups.

The remainder of this issue contains articles on a range of different subjects. Chris Ranger describes the electronic clinical transfusion management scheme; the pilot for this will be run at the Mayday Healthcare NHS Trust commencing in July 2008. This IT tracking project is a partnership between the National Patient Safety Agency, the National Blood Transfusion Committee and the SHOT scheme. Another article in a similar vein from Mike Murphy reviews the Oxford experience of computerised control of blood transfusion. Audits were carried out before and after the introduction of a barcoded patient identification system involving hand-held computers for blood sample collection and the administration of blood. This system is preferred by staff but has involved significant challenges, for example the installation of a whole trust wireless data network.

Most of our readers will be familiar with the ISBT 128 barcode labelling system which is used by NHSBT for blood components. The 2004 European Union Directive on Tissues and Cells (2004/23/EC) requires product traceability to be ensured at the European Community level assisted by the collaborative design of a single European coding system for tissues and cells. Since dozens of donated tissues and organs from a single donor can be sent to recipients in different centres and since over 40% of haemopoietic stem cell donations now cross international boundaries it is essential that internationally accepted systems are in place to allow coding and traceability of donations. Ruth Warwick explains to us how a European Committee for Standardisation (CEN) open workshop considered all the issues involved and finally agreed to recommend a system based on ISBT 128 for labelling both tissues and haemopoietic stem cell donations. Deirdre Fehily describes the aims of the European Union Standards and Training for the Inspection of Tissue Establishments (EUSTITE) Project. These are to "promote standardisation to best practice in inspection of tissue establishments and to develop common optimal systems for the notification and management of adverse events and reactions related to the quality and safety of tissues and cells applied to patients in the EU". Deirdre explains how this EU funded project is developing with specific reference to inspection guidelines, inspector training and tools for vigilance and surveillance.

Assessment of the haemoglobin level and iron stores in individual donors has always been problematic and, of course, many donor sessions still rely on the copper sulphate test first developed more than half-a-century ago. Frank Boulton reviews this issue for us and explains how a healthy male donor donating three times a year may develop iron deficiency after two years if not given iron supplements. Khaled El-Ghariani summarises the clinical usage of intravenous immunoglobulin in 2008 and beyond. Demand for this product has increased as a result of its use in the treatment of autoimmune and inflammatory disease processes by 30% over the last three years against a background of a world shortage which has prompted the Department of Health to implement a demand management programme in the UK. This consists of guidelines, local assessment panels and the establishment of colour coded categories indicating whether the use is firmly indicated or at the other extreme likely to be of little or no benefit.

Marion Scott in her update on scientific and technical training picks up the theme of the need to modernise the scientific workforce introduced by Andrew Hadley. She explains that work done by Sue Hill, the Chief Scientific Officer, has looked at the contribution of healthcare scientists to the eight care pathways planned by Lord Darzi; there is a clear need to modernise scientific careers so that teams will work across current professional barriers in a flexible way thus ensuring the best use of their skills and knowledge. This will lead to more flexible career structures and transferable competencies – current systems are rigid and inappropriate. Finally, we have included an update on e-learning where Andy Miller discusses whether or not we are making the most of this new tool in the 21st century. Andy reminds us that whereas in the past we often acquired knowledge simply for the sake of having it this is now being replaced by the acquisition and application of knowledge in the workplace. His article contains some very useful hints on the production of e-learning material.

At the time of writing this we are beginning to analyse the feedback received on the survey contained in the last issue. In general the feedback that we have had has been very positive and we have received many useful suggestions that will help in the planning of future editions of ***Blood Matters***.

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'Blood Donation: more challenging times ahead'

A review of the NBS blood collection strategy identified a clear challenge of ensuring a sustainable supply of blood. Over the past six years the donor pool has shrunk by 25%, leaving the organisation increasingly reliant on a decreasing number of regular donors. To estimate the size of the challenge and understand the profile and cause of the decline in the donor base the NBS undertook market research and analysis. This informed a comprehensive programme of change which is currently being rolled out across Donor Services.

Our plan is to focus on improving people's donation experience and remove the barriers to donation, thereby increasing retention of existing blood donors and encouraging donors to give blood two or three times a year.

We have instigated an initial change programme within Donor Services.

Firstly, we've made some immediate changes to improve sessions and the experience of our donors, known as 'quick wins'.

Secondly, we've started work on several marketing initiatives designed to deliver results in 2008/09.

Finally, we've launched an operational transformation programme to identify new ways of working and best practice.

This will be underpinned by a substantial change programme over the next three years.

Sharing best practice

Small changes can make a big difference. Research within our blood collection teams and other staff members identified the potential for 30 small 'quick wins' to improve the service for donors and start to address the challenge of losing donors.

We have focused on the following key areas:

1. Matching capacity and demand, particularly in managing appointments and walk-in donors.
2. Minor clinical and administrative changes to improve and standardise session procedures.
3. Improvements to session management, specifically focusing on key roles on the frontline including managers and nurses.
4. Improvements to performance management, establishing clear accountability for performance to meet specific targets.

The strong focus on performance management is designed to create a supportive learning environment, resulting in best practice being shared.

Strengthening relationships

Several new marketing initiatives aim to address the projected shortfall in blood. If the NBS did nothing over and above existing practices we would be short of 50,000 units by the year end – these new initiatives will avert that projected shortfall.

The focus is on strengthening the relationship with donors and to increase the number of people coming back to donate a second time by focusing on improving interactions with first time donors;

- Encourage donors to make three donations every year;
- Improve the use of mobile technology to communicate with regular donors;
- Encourage donors to become advocates for blood donation and actively encourage others to donate;
- Improve systems to ensure donor contact details are maintained accurately and used effectively.

Operational transformation

Launched at the beginning of March, the Operational Transformation Programme looks at several crucial issues. The programme is specifically looking at appointments, complications in the screening process, session flow, donor requirements and the back-up services needed to help the collection teams function effectively.

It consists of a six month programme to transform operations, including piloting the solutions, then an eighteen month programme to transfer and consolidate across Donor Services.

Our frontline staff are working with us to design the solutions and make the changes. Recognising that our people on the frontline know best represents a different approach to the norm.

Changing the hours we are open

The research identified a number of factors which we will address as part of the programme:

1. 69% of those who donated in the past six months would like to donate after 6pm on week-days.
2. Opening times are an important factor both for donors who chose to no longer donate and less frequent donors in making their next appointment.
3. About 50% of non-donors would like to give blood at weekends.

We will address these by:

- Piloting changed opening times in a new site located within Boots the chemist in Poole.
- Next year starting to extend opening times to meet donors' expectation of evenings and weekends.

Safety and reduction of Risk to Patients

Platelet donation by apheresis is part of the on-going patient safety, risk reduction measure, within which we are planning to move from collecting 60% of our platelets through component donation to 80% in 2008/09.

Component donation is where a donor gives blood using component machine technology rather than the usual 'gravity' donation. This technology allows us to extract what products are needed (platelets, red cells or plasma) and return fluids to the donor. The advantage of this is a single donor source of platelets rather than a pooled source of platelets. It also provides dedicated platelet donors who can give more often.

Further changes

We will also be undertaking more in-depth analysis and planning for other potential improvements to Donor Services. These include Double Red Cell collection – really understanding the possibilities and implications of expanding double red cell collections.

We need to understand defined sections of the donor population and areas where collection rates are currently poor (London and the North West) and see how we can improve our service.

Overall aims of the programme

We expect to see a significant improvement in the level of donor satisfaction, productivity, waiting times and donation lead time.

Specific targets include:

- all these changes is the need to maintain robust blood stocks.
- More donors giving two or three times in a year.
- A donor base we can call on to give more often at times of shortage.
- Donors who experience and learn to expect excellent customer service and recognition for what they do.
- A more customer-focused workforce.
- Collection teams achieving their targets daily.
- Significant improvements in productivity.

In conclusion

Continuing to maintain our values and guiding principles

To meet demand we have to change and adapt to deliver a service geared towards our donors, and the trends in our society.

This will affect the way in which we operate, but at the heart of all these changes are the need to increase blood donation and meet external stakeholder expectations; hospitals need to have the right product when they need it, at the right cost, and produced safely.

Patients have the right to a safe, sustainable service.

Last but not least, our relationship with donors at all stages in the donation process is critical and will be a key focus for all in the NBS.

Our change programme is designed to achieve all this.

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Impact of the Supply Chain Changes on Hospitals

Last year, as part of the strategic review, the National Blood Service (NBS) held a number of meetings across the country with hospital representatives from both the transfusion and the transplantation communities. The purpose of these meetings was to listen directly to concerns about our strategic plans and to get a greater understanding of customer priorities for improvements to services in the future.

Most of the issues raised related to our specialist services but our supply chain modernisation plans such as consolidation of testing and processing activities were also considered and much of the discussion was related to stock holding, phenotyping, wastage and logistics.

The primary objectives of the supply chain arm of the review were as follows *"to provide a sustainable supply of blood and blood components for patients that meet clinical, safety and accreditation standards as efficiently as possible, now and in the future"*. This high level aspiration does not specifically mention logistics but not unsurprisingly, two of the concerns raised consistently with respect to the supply chain were our logistics infrastructure and our stockholding levels of specialised components at local issue departments. We were also asked to ensure that we could still process and test some of the more specialised short dated components and deliver them to our hospitals within an acceptable timeframe. The supply chain arm of the review work recognised all of these issues as real risks and included a piece of work directly related to logistics and also new models for "replenishing" hospital stocks of blood. Hospitals also identified the potential for Information Technology solutions to modernise specific aspects of the supply chain and we are currently looking at the best way to implement some of these initiatives.

The supply chain arm of the recent NBS review evaluated key logistical stages, and each of the processing, testing and storage steps that donated blood passes through on its journey from our donor collection sites right through to hospitals. Performance benchmarking was a key element of this work and the review group compared the performance of each of our processing and testing sites both against each other, and other blood services where information was available.

Planned changes will:

- Ensure the collection of sufficient red cells and platelets to meet current and future demand.
- Avoid further significant increases in red cell prices by reducing costs and improving efficiency in-line with the anticipated on-going fall in demand.
- Ensure that the organisation has the appropriate level of capacity and capability to process blood to the standards required by modernising its production and testing infrastructure.
- Reduce the residual risk of transfusion through continued implementation of agreed blood safety initiatives.

Addressing the issue of the declining numbers of blood donors is discussed in the article by Sue Carrington (page 3).

Blood Processing, Testing and Issue

Due to the fall in red cell demand since 2001 we are currently collectively operating at 40% excess capacity in our processing departments and 35% in our testing laboratories.

Some of our buildings were designed long before the introduction of leucodepletion and automated molecular and serological testing. This means that some of them lack the congruent space and flexibility to cope with the introduction of further blood safety measures and new processing models.

The review established that the optimal configuration is to consolidate our blood production to six processing and five testing centres; to consolidate to fewer would require significant investment in terms of expansion of some sites. Data suggests that a reduction to fewer processing and testing sites would not generate significantly more benefits and would increase logistical challenges. Opportunities exist to improve performance in the least productive sites by implementing best practice across all sites. Processing will remain at Brentwood, Colindale, Manchester, Newcastle and Sheffield and be introduced at Filton (near Bristol). Colindale, Filton, Manchester, Newcastle and Sheffield will have Testing departments. The impact of this consolidation on hospitals will be minimal. We currently have a supply chain group mapping hospital requests for specialist components to ensure that each issue site holds adequate stocks as close to patients as possible.

We will keep the current network of 15 issue sites open. These sites will continue to supply hospitals with blood and blood components, including specialist products, as and when they need them.

These changes will:

- Remove appropriate excess capacity.
- Maintain the most flexible estate.
- Provide sufficient potential space of good quality.
- Maximise cost savings and help prevent price increases to hospitals.
- Not impact on transport costs nor create additional environmental problems.
- Provide good geographical coverage in both the North and South.

Our programme of consolidation into the new centre at Filton is progressing well. The new processing unit at Filton will be a modern facility manufacturing 600,000 donations annually. The facility has been designed to be efficient and resilient with a "state of the art" production system, which is flexible and future proofed. Emphasis at the new facility has been placed on GMP and compliance with regulations. It has been designed with "Lean" principles in mind giving a systematic approach to identifying and eliminating waste through continuous improvement. The peaks and troughs of activity will be smoothed by the use of overnight hold of donations.

New manufacturing cells will be used with improved layouts, unidirectional flow and balanced throughput thus making the process from donation to validation for issue much more efficient. There will be 24 hour senior staff presence on site and the ability to manufacture most specialist components within 24 hours.

Impact on Hospitals

Consolidation of our testing infrastructure should have minimal impact on hospitals, however overnight hold of blood components returning from blood collection teams will result in the bulk of our testing being done on day one (where day 0 is the day of collection). The age of blood across a geographical region will be more evenly distributed than currently.

Our vision for the future involves a much stronger focus on Customer Service and to achieve this we need to achieve a cultural change in behaviour. In the South West, we are renaming our issue departments Hospital Services and the new job descriptions for postholders in these departments have a much greater focus on customer service and getting the correct blood orders out to every hospital.

The review has highlighted a number of other areas where hospitals would like to see improvements. To support delivery of some of these changes, we are currently mapping out all of our customer interactions from blood ordering through to invoicing. We are also mapping out different future service delivery models which could deliver tangible benefits to hospitals and we look forward to sharing this work with hospitals when it is complete. Hospital Services (formally Issue) will be a front facing customer service department. Staff will be flexible and dedicated enabling best use of resources. There will be a focus on ongoing improvement in service and efficiency. We will develop people, technology and processes to improve customer service. We will aim to instil a "right first time culture".

Summary

Processing and testing sites are being configured to ensure that we have the necessary capability, flexibility and geographical spread, while delivering cost savings. We will ensure that we are rigorous in meeting efficiency and regulatory standards consistently across the country, with sufficient flexibility to meet clinical, safety and regulatory requirements now and in the future, providing the best possible service.

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The NHSBT Blood Components Portfolio

The specification, manufacturing process and content of blood components manufactured by NHSBT for clinical transfusion has evolved over the years, with changes being dictated by, for example, safety initiatives (such as the introduction of leucodepletion) or technological advances (for instance collection of hyperconcentrated platelets for intrauterine transfusion). Specifications are set out in guidelines, the main one in the UK being the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book), (UKBTS/NIBSC Joint Professional Advisory Committee, 2005). The UK Blood Services, however, through the Joint Professional Advisory Committee (JPAC) also contribute to revisions of the Council of Europe 'Guide to the Preparation, Use and Quality Assurance of Blood Components' (Council of Europe, 2007) and the Blood Safety and Quality Regulations (2005) are now enshrined in law.

It is the remit of the JPAC Standing Advisory Committee on Blood Components (SACBC) to revise at intervals specifications for blood components in the Red Book and also review data on and approve potential new blood components for use in the UK. Each Blood Service, however, is able to decide operationally which components they produce in conjunction with users (while meeting relevant specifications); the main forum for this as far as NHSBT is concerned being the National Blood Transfusion Committee.

In 2006 the NBS issued its first Components Portfolio. The purpose of this document was to list all blood components available from NHSBT for the information of hospitals. The Portfolio gives specifications and mean active ingredient content for individual components, and in addition contains some information on component use and component bar codes for use in hospitals. The latest version is available on http://hospital.blood.co.uk/library/pdf/components/SPN_PTI_PR_030_03_Component_Portfolio.pdf

Any major changes in blood component inventory, particularly those which involve significant expense (and which are usually blood safety initiatives), require approval by the Department of Health. An example of this was the importation of plasma for manufacture of fresh frozen plasma for children as a vCJD safety measure. A further example that is under consideration is the use of Pathogen Inactivation techniques as an alternative to bacterial screening for reduction in the risk of bacterially contaminated platelets. For less significant changes, the Components Strategy Group within NHSBT leads on decision-making with regard to blood components. Personnel from the Components Development Laboratory (CDL) are an integral part of this group as they perform much of the investigative work on which decision for change is based. A recent example is that of the pooled buffy coat component developed by CDL for granulocyte transfusion as reported in the last edition of ***Blood Matters*** (Spring 2008 – Issue 24). This component is currently undergoing clinical trial but again once approved, could replace single buffy coats when granulocytes are requested for neutropenic patients with severe infection.

Methylene blue treated cryoprecipitate is shortly to be introduced to the NHSBT Components Portfolio for transfusion to neonates and children under the age of sixteen. One area where the Red Book specifications have not been very clear is neonatal transfusion, for which various different red cell components have been described. Dr Helen New, Paediatric Haematologist at NHSBT and Imperial College Healthcare NHS Trust, recently reviewed the requirements for this age group (***Blood Matters***, Autumn 2006, Issue 20) and the most recent version of the Portfolio includes the revised haematocrit specifications for red cells for neonatal exchange transfusion (0.5 to 0.55), and new specifications for blood components for large volume transfusion in neonates and infants under one year of age.

Other evaluations currently in progress include automated washing of red cells with resuspension into SAG-M, so that washed red cells can have a longer shelf life as opposed to the current 24 hours, and validation of an x-ray (as opposed to a gamma-irradiator) for prevention of transfusion-associated Graft Versus-Host Disease. The latter has considerable benefits from a security and cost point of view. A considerable amount of work is currently being done on the evaluation of prion filtered red cells, not only to assure their safety and function, but also to assess what other processes may need to change were we to implement them. For example, we know that levels of at least one coagulation factor are decreased by the filter and therefore processing methods for neonatal exchange units, which require plasma as well as red cells, would have to be revised.

Over the last year, a project has been underway to develop a common Blood Component Portfolio for the whole of the UK (including NHSBT, the Scottish National Blood Transfusion Service, and the Welsh and Northern Irish Blood Services). SACBC and the SAC on IT for JPAC have been working jointly on this and we hope that it will be implemented by April 2009. The advantages of having a common Portfolio are that codes and labelling will be common to all four UK Blood Services, in addition to component specifications, which will greatly facilitate movement of supplies across borders. The development of the Portfolio has also given us an opportunity to review our current inventories and ensure that we are manufacturing the most appropriate components, an exercise that has already been done and in which good consensus was achieved. When the UK Portfolio is published, it is envisaged that each Service will be able to select its own inventory from the common list, following which a Users Portfolio can be developed for each Blood Service.

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References

The Blood Safety and Quality Regulations. 2005 No. 50. 2005.

Council of Europe (2007) *Guide to the preparation, use and quality assurance of blood components*, 13th edn, Council of Europe Publishing, Strasbourg.

UKBTS/NIBSC Joint Professional Advisory Committee (2005) *Guidelines for the Blood Transfusion Services in the United Kingdom*, 7th edn, TSO, Norwich.

Future Plans for Diagnostic Services provided by NHSBT

A comprehensive review of Specialist Services provided by NHSBT was undertaken in October and November 2007. This included a major effort to listen to the views of customers in local and regional meetings, as well as the consideration of advice from an expert group of senior stakeholders. It affirmed the importance of NHSBT as the main provider of reference diagnostic services in Red Cell Immunology (RCI), Platelet and Granulocyte Immunology (PGI) and of comprehensive Histocompatibility and Immunogenetics (H&I) services to a significant proportion of England. These services are both essential to the testing and supply of blood components and haemopoetic stem cells and to support the diagnosis, transfusion and transplantation of individual patients. NHSBT is committed to ensuring that these services are cost efficient and sensitive to customers' needs, and are of high quality with the flexibility to keep pace with future needs and developments. To that end a strategy of consolidation of laboratory sites and service expansion is being progressively implemented. The recent review re-examined the assumptions behind that strategy and has adjusted it. The information gathered during the meetings with users of these services played an important part in the review process.

Timely and effective provision of RCI services to patients depends on partnership between hospital blood transfusion laboratories and the reference services provided by NHSBT. The reference service brings special expertise, the availability of rare reagents and close access to large blood stocks to the partnership. It must be able to respond promptly to clinical emergencies and be available twenty four hours a day. Each reference laboratory has to have a minimum throughput of samples to achieve this. NHSBT RCI will concentrate on its reference role providing services from Newcastle, Leeds, Sheffield, Liverpool, Birmingham, Bristol, Colindale and Tooting. The reprovision of the Cambridge service at a site in East Anglia is being explored so as to keep it as close as possible to the hospitals that use it. The intention is for the service to be Trust laboratory based and directly supported by NHSBT. The effectiveness of services is closely monitored and will be as further changes are made. By contrast, in many parts of the country antenatal screening is provided by the hospital laboratory using equipment required for the routine repertoire. Analysis shows this to be a cost effective approach that retains the quality of service. Rather than consolidating as was planned, NHSBT will withdraw from antenatal screening but continue to provide reference testing to support alloimmunised pregnant women.

Where NHSBT provides services in H&I to hospitals it is effectively the sole provider. NHSBT H&I laboratories also support the supply of blood components, particularly platelets to refractory patients, the British Bone Marrow Registry, the Cord Blood Bank and Stem Cell Immunotherapy services, all of which will remain in the NHSBT portfolio. H&I services to hospitals will continue to be provided from all of the current sites but there will be some internal adjustments to provide space for other services at Colindale. These adjustments will not affect the service received by hospitals that use the Colindale laboratory. H&I activity particularly in support of organ transplants is set to grow significantly and NHSBT is planning to cope with that growth. NHSBT H&I laboratories are all accredited by both CPA and the European Federation for Immunogenetics (EFI) and are able to support clinical units requiring this for their own accreditation.

All NHSBT diagnostic services will continue to be consultant led with expert clinical and scientific advice available at all times. They will be customer driven and their performance carefully monitored to make sure it meets expectation. The withdrawal from antenatal screening will be managed with the new providers. Adequate time will be allowed for the completion of withdrawal; the safe and effective transfer of services is a priority. Currently these services are partly funded from the price paid by hospitals for blood components. This "cross-subsidy" will progressively be removed by more efficient working and a rise in the cost of the services themselves, as well as the increasing volumes, inherent particularly in increased transplantation activity. These services are set a big challenge if all of these objectives are to be met. We believe the answer lies in exploiting research and new technologies and moving to manage our diagnostic services as an entity. We have a head start given the quality of much relevant research we perform and the expertise and dedication of our staff providing diagnostic services. In the next article Andrew Hadley discusses the changes of approach that we are planning.

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Modernising Diagnostic Services for Transfusion and Transplantation

Introduction

The strategic review of the National Blood Service during 2007 considered the future of NBS specialist services. The review was guided by a vision of NBS specialist services 'saving and improving patients' lives by providing a portfolio of clinical services achieving best quality, safety and value for money for the NHS'. As part of a challenging set of recommendations for improving service quality and financial sustainability, the review advocated a re-alignment of Red Cell Immunohaematology (RCI) and Histocompatibility and Immunogenetics (H&I) activities in order to derive operational, workforce and financial benefits. An NBS working group is looking at the feasibility of deriving these benefits in more detail. This report reviews the rationale behind the concept of a single, flexible, customer-focused workforce providing specialist diagnostic services.

Workforce and Technology

In the wider NHS, pathology services are starting to derive increased flexibility and cost efficiencies by configuring service provision around core technologies and staff competencies. Recent and proposed changes to career pathways for healthcare scientists may be an important enabler for a similar re-alignment of RCI and H&I services. For example, it seems likely that biomedical scientist and clinical scientist roles will converge to a single pathway for state registered healthcare scientists. Importantly, graduates entering this pathway will likely require some years of training in both transfusion and transplantation before specialising in one modality. The NBS may be best able to deliver training and development for these staff from laboratories supporting both transfusion and transplantation.

Any realignment of RCI and H&I will require the functions to use similar technologies. In the recent past, the absence of automation and the use of relatively difficult cell-based assays (in H&I in particular) would have made any re-alignment particularly challenging. However, the recent introduction of laboratory automation in H&I (e.g. Luminex[1]) and RCI (e.g. Diamed[2]) means that the scientific and technical skills required for many H&I investigations are the same as those required in RCI. Moreover, within several years, it seems possible that transfusion and transplantation laboratories may be using identical technologies exploiting arrays of DNA-based and/or recombinant antigen-based probes. This convergence of technology is already happening for molecular (DNA-based) diagnostics and flow cytometry. The management of laboratory information in a co-ordinated manner would also be key for any re-alignment of activities. To that end, the recent introduction of Hematos[3] will be important.

The Merits of Workforce Modernisation

Early work suggests that it should be feasible to re-align much of the scientific workforce engaged in SOP-based laboratory activities supporting transfusion and transplantation. This would facilitate the consolidation of various support activities such as storage, quality assurance and compliance, health and safety, sample reception and registration, procurement, equipment maintenance and so on. Savings on accommodation costs should accrue as activities take up less space. However, the biggest benefits may be in relation to the scope and quality of NBS clinical services as a more flexible and dynamic workforce is able to offer new services. One example would be the ready availability of H&I equipment and expertise for rapid genotyping allowing the introduction, at marginal cost, of new services (better typed components) for patients with red cell autoantibodies or who are multi-transfused. Looking further ahead, a similar approach combined with microarray technology may allow for full genotyping (red cell and HLA antigens) of patients and donors leading to reduced incidences of alloimmunisation and associated transfusion reactions.

From a customer perspective an additional advantage would be access to a single service for all specialist diagnostics. Indeed, RCI and H&I laboratories jointly contribute to the management of several patient groups. These include, for example, patients with haematological malignancies (provision of red cells and platelets), solid organ transplantation (ABO and HLA typing) and renal transplantation (ABO and HLA antibody titration and detection). Importantly, by increasing the critical mass of staff at individual centres, it should be possible to respond more cost-effectively to an increasing requirement to provide red cell reference services on a 24/7 basis.

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Footnotes

1. Luminex xMAP technology uses mixtures of up to 100 different colour-coded microspheres. Each bead set can be coated with a reagent specific to a particular bioassay, allowing the capture and detection of specific analytes from a sample. Within the Luminex analyzer, lasers excite the internal dyes that identify each microsphere particle, and also any reporter dye captured during the assay. Many readings are made on each bead set, further validating the results. In this way, xMAP technology allows multiplexing of up to 100 unique assays within a single sample, both rapidly and precisely.
2. Diamed, in common with other reagents suppliers, now produce fully automated analysers allowing relatively high throughput workloads for standard immunohaematology investigations. User interface is via computer touch screen.
3. Hematos is a 'core' IT system used by the NBS to manage all patient-related workload. Importantly, the system supports access to a single database of patient information.

NHSBT Tissue Services: – A New Start

In July 2005, Tissue Services moved into a "state of the art" world class tissue facility at the newly built Liverpool Blood Centre in Speke. By 1st April 2008 consolidation of all other NHSBT tissue banks (Wakefield, Wrexham, Oxford, Cambridge and Edgware) into the new tissue bank was finally completed. The new facility includes a clean room suite (12 Class B and 2 Class C clean rooms) which all have continuous particle monitoring to each clean room and to each safety cabinet within the clean rooms. Part of the suite is dedicated to routine tissue processing and the other part is a Technology Centre where more complex tissue grafts and tissue engineered products are prepared. This is further supported by a Tissue Development Laboratory where new product development is the major focus.

In addition, for the first time, Tissue Services now has a purpose built operating theatre where tissue retrieval can take place under controlled conditions. There is also a National Referral Centre, where all of our tissue donor co-ordinator nurses work. A change in shift patterns has facilitated 24/7 working which means that colleagues in hospitals should now be able to contact the referral centre whenever needed. Bringing the co-ordinator nurses to a single site has facilitated team working and mutual support. In fact, throughout the staffing structure all groups are now well above critical mass, providing contingency for unexpected situations.

Having all tissue processing activity taking place in a single facility has numerous advantages. Firstly there are economies of scale. A lean review was undertaken to determine how the processing of tissues in high volume and high throughput could improve efficiency. In addition, shift patterns were changed to facilitate 7-day working. Together these initiatives have generated an enormous efficiency improvement. This has not in any way adversely impacted on quality. In fact, operating at a single site has resulted in consistently high quality and standardisation. There have also been changes to the activities carried out by the different staff groups. Previously, the production staff at each of the tissue banks carried out tissue retrieval, having first travelled to the donor hospital, as well as tissue processing. This led to conflicting priorities. As of 1st April 2008, the production staff, now all based at Liverpool, exclusively carry out processing of tissues including bone, skin, heart valves, blood vessels and tendons. For the retrieval of tissues from donors we now have three area teams based at Liverpool, Leeds and North London. These teams include both nurses and scientific/technical staff. They collect tissues from both the deceased donors and from the living donor programmes (eg femoral heads from hip replacement patients).

There have also been significant improvements to the interface with the surgeons who use our tissue grafts. We have introduced a dedicated Customer Service Department to deal with all orders nationally and also any complaints or queries that are raised by hospitals. Approximately 350 hospitals in the UK have signed Service Level Agreements with Tissue Services.

The Customer Service Department has also begun an e-mailing service to let surgeons know about issue stock levels for each of our tissue grafts, at a prescribed frequency. In the past, stock levels fluctuated and therefore sometimes the order could not be filled immediately. Because of the recent improvements in processing efficiency we now plan to maintain higher issue stock levels of each graft and to iron out fluctuations. Although only a snapshot in time, the regular issue stock e-mail service will give confidence to surgeons that stocks are currently healthy and availability can be anticipated for forthcoming surgery. If you wish to be e-mailed about any of the major groupings of tissue grafts, just contact Customer Services.

A comprehensive new website has also been developed which can be found at **www.nhsbttissueservices.co.uk**. This has a detailed review of all tissue grafts, their specifications and information leaflets on the use of the tissue. There is also a facility for ordering tissue grafts on-line. We now store issue stock at two blood issue departments, one in the North at the Liverpool Blood Centre, and one in the South at the Colindale Blood Centre. As well as providing contingency, this helps to ensure that logistics are simplified, and transport time minimised.

We have established a number of surgical user groups. This includes a longstanding relationship with the British Association for Surgery of the Knee (BASK). A BASK subgroup has helped us enormously in providing advice for rationalising our graft range, in setting exclusion/inclusion criteria for donated tissue, in advising about potential new grafts, and more recently helping to establish a system to follow up post-grafting clinical performance. A similar user group of burns surgeons has been established to advise on skin grafts. In addition we have begun to establish expert groups including surgeons when developing and validating new products. The Vascular Society of Great Britain and Ireland has helped enormously with our project to set up a blood vessel bank and local expert orthopods in the NW are participating in our development of bone grafts. Finally, in the field of Tissue Engineering, our longstanding collaboration with scientists and surgeons at the Universities of Leeds and York has resulted in a substantial pipeline of grafts utilising tissue engineering principles which should be available clinically in the near future.

Summary

All of the changes detailed above have been carried out as seamlessly as possible, avoiding any disruption to the supply chain. We are now confident that our new facility will meet all current and all anticipated future regulatory requirements, and will continue to comply with GMP (Good Manufacturing Practice) guidelines, ensuring that only tissue grafts of the highest standards of quality and safety are supplied by us to the NHS. We remain grateful to all colleagues in the NHS for their support.

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A Testing Time: piloting the Electronic Clinical Transfusion Management System

This article explores the pilot of the Electronic Clinical Transfusion Management System (ECTMS) for blood transfusion which is being undertaken at Mayday Healthcare NHS Trust. It explains the background to it, why and how it is being carried out and what outputs and learning there will be for the NHS.

Where did the ECTMS originate?

The ECTMS was one of the outputs of a joint initiative between the National Patient Safety Agency (NPSA), the National Blood Transfusion Committee (NBTC) and the Serious Hazards of Transfusion (SHOT). In November 2006 the three organisations jointly issued a Safer Practice Notice, *Right patient, right blood* that made a number of recommendations to the NHS about measures for greater blood safety. The ECTMS was the recommended high tech solution, based on work carried out by the Do Once and Share blood transfusion project at the Oxford John Radcliffe for NHS Connecting for Health (NHS CFH) and the NBTC.

What is new about the ECTMS?

The ECTMS is a standard specification for IT tracking systems, which is compliant with the traceability requirements of the 2005 Blood Safety and Quality Regulations. It complies with all the safety and functionality issues that the NPSA, SHOT and the NBTC were aware of when it was developed, and that future systems will need to address. It focuses on the steps in the transfusion pathway and can be used with technologies such as barcoding and radio frequency identification (RFID). The implementation of the ECTMS requires more than the development of software as it needs to be integrated with, for example, server hardware, client devices and remote terminals.

Why is the ECTMS being piloted?

NHS CFH wants to gain maximum learning for the NHS from the development of the ECTMS by testing how it could be implemented in a small, non-teaching hospital. The aims of the pilot are:

- to determine whether the ECTMS can be readily adopted by such hospitals;
- to feed back learning to the NHS;
- to look at the prospects for using the same technology in other areas such as medication and radiology (i.e. for multiple applications).

After a rigorous selection process, the pilot was placed with Mayday Healthcare NHS Trust as they met all the criteria and had the best plan for piloting it. The pilot will take place in part of the London wing, and this will permit comparison of implementation with other parts of the Trust which are not participating in the pilot.

How will the pilot work?

The Mayday Trust is currently setting up the pilot and aims to have systems in place by July 2008, after which it will run for a year to test its effectiveness and identify any problems and potential changes. Setting up the pilot has involved three tenders – for the electronic blood tracking system; the wi-fi based asset tracking system; and for various hardware, software and consumables, including wristbands and associated printers and scanners. The Trust has also gathered baseline data on the current system for comparison with data gathered after the new system is in place and working effectively.

What technologies are to be used?

The pilot is using both barcoding and RFID technology. Barcoding is being used for staff ID badges, which will be scanned to identify staff using the blood tracking system. Sample tube labels will have a barcode linking the sample to the order for bloods and to patient details on the Pathology Laboratory Information System. The compatibility label on the blood bag will have a 2D barcode containing the patient demographic details. Active RFID tags will be used on all blood bags to track their journey once they leave the issue fridge. Passive

RFID tags will be used in patient wristbands and will be read electronically by staff using hand-held readers, to check each patient's identity and to ensure that patients get the right blood. The Trust is exploring currently available mobile technology to enable treatment of patients at the bedside.

What systems are being used?

Following tendering processes, the electronic blood tracking system is being put in by NeotericTechnology Ltd; the system being installed is BloodTrack and utilises their modules BloodTrack Courier and BloodTrack Tx. As the Trust will be using its existing Order Communications system, development is required to ensure a full phlebotomy interface. Programming is required to achieve the layout/format of data on wristbands so they comply with the recommendations of the NPSA Safer Practice Notice *Standardising wristbands improves patient safety*. Passive RFID wristbands are being provided by SATO UK Ltd and RFID scanners by Codegate Ltd. Barcode Warehouse are providing Zebra Printer hardware and ZBI programming application is being utilised to manipulate data in the RFID chip and barcodes. Bluestar Systems Ltd are providing the Wi-Fi based Asset Tracking system.

How will the GS1 coding standard be used?

NHS CFH is working on auto-ID and data capture technologies and the related purchase of GS1 identifiers for the NHS in accordance with guidance in the DH publication *Coding for Success*, issued in February 2007. GS1 are currently developing a High Frequency standard, but as that is not yet ratified, the Trust will use the GS1 recommended GDTI-113 specification as an interim measure.

How will the pilot be evaluated?

The Trust will evaluate the system to assess its effectiveness for managing blood and reducing the likelihood of errors in blood transfusions, and its potential applicability to other areas of healthcare delivery. The Trust will also facilitate a full independent evaluation of the pilot which is being undertaken by and funded through, the NHS CFH Evaluation Programme (NHS CFHEP) and carried out by a City University Team.

How will NHS CFH feed back learning to the NHS?

In December 2007, NHS CFH put the first instalment of regular feedback to the NHS on their website at **http://www.connectingforhealth.nhs.uk/systemsandservices/bloodpilot**. This is being updated regularly and supplemented with Frequently Asked Questions, which will be added to as the project progresses. Subject to any slippage, the final report will be shared with the NHS in autumn 2009.

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Oxford experience with full implementation of end-to-end computerised control of blood transfusion

For seven years, we have been developing and evaluating a barcode patient identification system involving handheld computers for blood sample collection and the administration of blood. Audits of practice were carried out before and after its introduction in different clinical settings. The first baseline audit in day-case haematology revealed poor practice, particularly in patient identification. Significant improvements were found in the procedure for the administration of blood following the introduction of the new process involving barcode patient identification, including an improvement from 11.8% to 100% in the correct verbal identification of patients (Turner *et al*, 2003). Staff found the barcode identification system easy to operate, and preferred it to standard procedures.

The process involving barcode patient identification compelled staff to adhere to certain actions, for example the checking of patient identification wristbands. During the baseline audit, it was observed that individuals were frequently distracted and interrupted whilst checking blood, for example interrupting a procedure to answer the telephone or to respond to questions from patients and colleagues.

Was the positive impact on compliance with policy as a direct result of the technology or the allied education and training? Could a comparable result be achieved with training alone, which is possibly a cheaper option? An additional audit was conducted to compare compliance with policy before the provision of training, after training and then again after the barcode patient identification system was implemented. It was found that education and training had a positive impact on compliance with policy, but only from 5% to 40%. However, there was 100% compliance following the introduction of the barcode identification process (Turner *et al*, 2003).

The same system was introduced into cardiac surgery. Revisions were made to the software to allow rapid

checking of units for urgent transfusions. Control of blood collection from blood refrigerators was added, providing full electronic control of the hospital transfusion process from sample collection through the laboratory, blood collection and the administration of blood (Davies *et al*, 2006). In addition, a novel automated system for *remote issue of blood* was developed using the rules for electronic issue and an electronic link between the blood bank computer and distant blood fridges to allow printing of compatibility labels at blood fridges rather than only in the blood transfusion laboratory (Staves *et al*, 2008). This provides rapid access to blood for patients requiring it urgently, and has the potential to reduce blood wastage because units of blood in blood fridges are available for any patient with the same ABO and RhD group rather than only the single patient for whom the blood has been labelled in the blood transfusion laboratory.

Traceability of each transfusion is a regulatory requirement. Robust documentation is very difficult with manual systems. In the system we have developed, information held on the handhelds can be downloaded into the blood transfusion laboratory IT system so that a complete record of the transfusion episode is documented, including that the right patient received the transfusion, when it was transfused, the bedside checks, observations, and the identification of the staff carrying out each step. In addition, we are developing links from the haematology IT system to the handhelds to provide recent blood count data to facilitate electronic ordering of blood and better compliance with local and national guidelines for its usage.

We worked with hospital senior management to obtain approval and funding to move from an extended pilot in haematology, cardiac surgery and critical care to full implementation across all the clinical services transfusing blood in the three acute hospitals in Oxford and Banbury. Approval for a managed service contract with Olympus worth £1.5 million over five years was given on the basis that the development of the additional module for bedside decision support for blood ordering would significantly accelerate reduction in blood usage.

The major challenges in moving from pilot to implementation were:-

a) achieving barcoded wristbands on all patients, which required providing access to the patient administration system in clinical areas for nursing staff,

b) avoiding institutional barriers to accurate patient identification including duplicate patient registration (often with minor differences in forenames), and varied formats of hospital numbers by different hospital IT systems which caused erroneous mismatches,

c) achieving barcode identification of all staff involved in blood transfusion so that each stage of the process can be tracked to an individual,

d) the provision of appropriate project management arrangements, given the size of the project involving 82 clinical areas over three acute hospital sites,

e) staff training for 3,200 nurses and 1,300 doctors, and the documentation of training,

f) the installation of a whole Trust wireless data network to simplify the downloading of data from the bedside handhelds to the laboratory management system to complete the audit trail for blood, and to enable haematology results to be accessed at the bedside using handheld computers,

g) developing mechanisms for monitoring progress.

Implementation began in July 2006. Staff were trained in 82 clinical areas using 110 handheld devices. The project was divided into several phases, each involving similar clinical areas on single sites. Simple written training materials were developed and training delivered in groups of staff and individually. In addition, a training module was developed on the handhelds for use with dummy blood bags to allow staff to practice the procedure in a 'non-live' setting.

The downloading of data on each stage of the bedside transfusion process makes it simple to monitor the number of transfusions carried out using the electronic system and whether it was performed correctly. Currently, 93% of transfusion samples are taken and 94% of transfusions administered using the electronic system. The reasons for the less than 100% compliance include the difficulty in training all junior doctors in sample collection, and the lack of a handheld in clinical areas rarely transfusing blood. We are making increased efforts to train medical students and junior doctors, and purchasing more handhelds to ensure that all clinical areas have at least one. Although the decision support module remains in development, usage of red cells reduced by 11.5% in the last year (a cost saving of over £400,000), possibly due to the high profile of transfusion within the Trust during the implementation of the electronic system. An additional benefit has been a reduction in the rate of sample rejection by the laboratory due to poor labelling. The rejection rate has reduced from 4.8% to 2.5%; the rejected samples are predominantly amongst those not taken using the electronic process.

Computerised transfusion aids cannot eliminate human error, but the less complicated and more 'user friendly' the procedure is, the less scope there is for error (Murphy & Kay, 2004). Their introduction should be accompanied by comprehensive education, training and continued support. There is the potential to facilitate audit of and compliance with standards for transfusion, and drive necessary improvements in practice. In this respect, there is the potential for the further development of electronic linkage between hospital transfusion laboratories and:

a) the National Blood Service: for ordering of blood, the results of investigations, and to provide information about the types of patients being transfused (age, gender, diagnosis and procedure) to monitor patterns of blood use and to inform planning to meet future demands,

b) the Blood Stocks Management Scheme and the national comparative audit of blood transfusion programme: to facilitate initiatives for blood stock management and blood usage,

c) the Serious Hazards of Transfusion scheme: for incident reporting.

The implementation costs for a hospital mean that to become accepted, the technology, including patient wristbands, staff badges and wireless networks, will have to be multi-functional for other procedures requiring patient identification and known to be prone to error, such as drug administration. A planned national approach is needed for the further development and evaluation of these systems, and for their implementation.

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References

Davies, A., Staves, J., Kay, J., Casbard, A. & Murphy, M.F. (2006) End-to-end electronic control of the hospital transfusion process to increase the safety of blood transfusion: strengths and weaknesses. *Transfusion*, **46**, 352-364.

Murphy, M.F. & Kay, J.D.S. (2004) Patient identification: problems and potential solutions. *Vox Sanguinis*, **87** (**suppl.2**), 197-202.

Staves, J., Davies, A., Kay, J., Pearson, O., Johnson, T. & Murphy, M.F. (2008) Electronic remote blood issue: a combination of remote blood issue with a system for end-to-end electronic control of transfusion to provide a "total solution" for a safe and timely hospital blood transfusion service. *Transfusion*, **48**, 415-424.

Turner, C.L., Casbard, A. & Murphy, M.F. (2003) Barcode technology: its role in increasing the safety of transfusion. *Transfusion*, **43**, 1200-9.

European Coding System for Tissues and Cells: A Challenge for 2008

The current situation relating to movement of tissues and cells:

- a single deceased donor may result in dozens of donated tissues and organs for recipients,
- tissue engineering and the development of future stem cell lines open the possibility of therapeutic materials for thousands of recipients from a single donor,
- tissue can be recovered, processed and implanted in different continents,
- the risk of disease transmission by tissue and cells is not zero and adverse event and reaction reporting, with active surveillance and learning from collated results is crucial,
- there are many national biovigilance models, but because human materials cross borders, national programmes need to be able to communicate with each other.

Not only may a single deceased donor donate organs through one establishment with subsequent tissue donation through numerous other establishments but some patients receive multiple donations of e.g. cord blood or pancreatic islet cells as a single therapeutic dose. To complicate matters further, pooled donations, batches and multiple tissue establishments may all need to be traced, as must autologous cells seeded onto a donor matrix, repeat donations for a

single or multiple recipients, and secondary processing events. The World Marrow Donor Association has shown that from 1997 to 2006, 40% of haemopoietic stem cells donations were distributed internationally.

Cross-border issues were further exemplified in 2006 when the US Food and Drugs Administration (FDA) undertook a tissue recall when Biomedical Tissue Services was found to have fraudulently obtained tissue from deceased individuals around New York without family consent. Nearly 1,000 bodies were 'stolen' affecting thousands of recipients world-wide. The tissue graft recall included Europe, Japan and Canada, and several dozen hospitals in the UK. Clearly traceability of tissues and cells is essential.

This complex environment led the writers of the European Directive 2004/23/EC to require procedures for ensuring traceability at European Community (EC) level assisted by the collaborative design of a single European Coding System for Tissues and Cells.

CEN Workshop

A European Committee for Standardisation (CEN) open Workshop for the Coding of Information and Traceability of Human Tissues and Cells was set up in April 2007 to identify how standardisation could play a role in fostering the effective implementation of the Directive requirement for coding and traceability. The Workshop was asked to propose guidelines and recommendations with a view to possible progression towards a European or International Standard. Explanations of coding terminology, and understanding that traceability is enabled by the combination of robust coding with robust records, were established.

Coding systems

These are a short means of representing textual information, e.g. a product description, and can stop meaning shift between languages. Human interpretability may also be desirable, as in labelling, whereas the use of symbols permits computer processing. A coding management system manages the relationship between coded and textual representations and is typically the responsibility of an independent organisation, commonly operated on a not for profit basis on behalf of stakeholders – usually with a committee of representatives to oversee governance.

A tissue or cell coding system underpins traceability by having:

- unique identification of the material,
- a combination of product description and the tissue or cell establishment, plus processing information.

This facilitates product exchange, stock control, integration of information in hospitals, and analysis of tissue graft or cell transplant outcome data. It can overcome language barriers, support regulatory and ethical control, communication between software systems (including that embedded in testing equipment) and support reporting requirements of tissue establishments (TE), competent authorities (CA) and the EC. Traceability can link all the products relating to a donation, tracking donations from donors. Various code symbologies include the well known 'barcode' (linear or two dimensional), and radio frequency tags (RFID).

Application of codes from donation through to a product and the association of the product code to a receiving patient's record therefore enables traceability in the opposite direction. In some countries in Europe, it is an absolute requirement for traceability code allocation to be via recognised authorities (often a CA).

Assessment of coding systems

Candidate coding systems were submitted for assessment by an expert panel. The ISBT128 coding system, incorporating definitions, reference tables, data structures, delivery mechanisms, as well as various aspects of labelling, was considered to be the only purely coding approach submitted. However, this coding system is associated with a single TE code, either at national or local level, whereas in some countries both the origin (donation unit) and TEs (there may be more than one) may need to be identified. This cannot be encoded in existing ISBT128 structures. The ISBT128 governing body, ICCBBA, has offered a new component, the Key Code, to meet international tissue banking requirements. This would augment existing coding systems and ISBT 128 code structures. With the problem of space in the ISBT 128 code solved, the Key Code was used to build an open solution with three variations, all preceded by the Key Code, and all in compliance with the EU DG SANCO (Director General for Heath and Consumers) working group's original specification for a European coding system. The variations are shown in the diagram at top of next page.

In the first variation, the globally unique donation code would be the ISBT128 unique donation number and the product code would be the ISBT128 product code. In the second variation, the unique donation number would comprise a national, regional or local donation code and in the third variation the product code would also be a national, regional or local code. There would be the opportunity to progress between variations and for different sectors to utilise different

EU DG SANCO WG	Country ID & TE	Unique Donation number	Product Code
Variation 1: Globally unique donation, product & 'key' codes	Country ID & CA + TE 'key code'	Globally unique Donation Code	Globally unique Product Code
Variation 2: National, regional or local donation code & globally unique product + 'key' codes	Country ID & CA + TE 'key code'	National, Regional, or Local Donation Code	Globally unique Product Code
Variation 3: National, regional or local donation & product codes + 'key' codes	Country ID & CA + TE 'key code'	National, Regional, or Local Donation Code	National, Regional, or Local Product Code

variations, all of them compatible with each other by virtue of the use of the Key Code.

There are advantages and disadvantages of each variation but all are compliant with the DG SANCO Working Group specification, are compatible with each other with regard to the Key Code, and do not impose any replacement code elements on Member States.

Looking forward

The European Coding System will inevitably result in operational changes and it is likely that implementation plans should incorporate transition phases. It has been recommended that DG SANCO establish a committee to ensure the minimum agreed specifications are met and to support implementation, as well as a forum to oversee EU definition of the Key Code with ICCBBA, and be a point of reference and advice to MS and TEs. ICCBBA has, at the point of writing, suggested that there could be a liaison member within their Board, who might be an EU nominee, and that there is need for an arrangement to deposit all ICCBBA information to a third party in the event that ICCBBA were no longer to continue its activities.

Member States will need to consider hardware, software and training within their jurisdiction, how TE's codes and donation numbers are allocated, controlled and issued, and translation tables for any transition period. They need to develop policies for a possible period of dual labelling, labelling of imported and exported materials and possible retrospective labelling of inventory.

Traceability is an essential safety tool, and can be facilitated using the code and the information it represents. The Spanish and Italian traceability systems have been offered as templates for use by other member states, and there are other national systems and commercial suppliers of software traceability systems available. A Workshop document has been circulated for approval to publish in April and, if approved, may be published later in 2008. This exciting innovation will improve the safety of materials of human origin in Europe and possibly beyond.

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Collaboration on Inspection of Cell Therapy and Tissue Facilities in Europe: the EUSTITE Project

Introduction and Background

Most European Union (EU) Member States have recently implemented, or are currently implementing, systems for the inspection and authorisation of tissue establishments and for surveillance of adverse events and reactions related to the quality or safety of the tissues and cells provided by these establishments. These are requirements of Directive 2004/23/EC and its associated technical implementing directives (2006/17/EC and 2006/86/EC). The EUSTITE project (European Union Standards and Training for the Inspection of Tissue Establishments) aims to promote standardisation to best practice in the inspection of tissue establishments and to develop common, optimal systems for the notification and management of adverse events and reactions related to the quality and safety of tissues and cells applied to patients in the EU. The project was proposed by the Italian National Transplant Centre (CNT) in response to the European Commission Public Health Call for Proposals in 2005. The proposal was approved for co-funding of 2.5 million Euros. It began on December 1st 2006 and will run for three years. The project consortium includes 11 organisations from 10 Member States and the World Health Organisation (WHO). Most of the partners are the nominated competent Authorities. The organisations are mostly Competent Authorities for tissues and cells, and the WHO provides an essential link to global regulatory and surveillance activities.

Project Objective

The primary objective of the EUSTITE project is to optimise and harmonise the standards and methods applied by Competent Authorities in the inspection and authorisation of tissue and cell procurement and tissue establishments within the EU, through the development of common guidelines and training. A secondary objective is to propose common systems for definition, classification and reporting of adverse events and reactions related to the safety and quality of tissues and cells used for transplantation, that could serve as a European or a global model for the future.

The State of the Art

The project began with an exploration of the current state of the art. A written survey of inspection methods and experience was conducted by the Spanish partner and is available on the project website (www.eustite.org). An exploratory workshop was hosted by the Irish Medicines Board in 2007 where project partners, together with other EU Competent Authority representatives and invited experts, explored the strengths and weaknesses of inspections systems already in place and agreed general principles of good practice for effective regulation in this field. A series of exchange visits were conducted whereby inspectors from one Member State had the opportunity to observe and evaluate the system in place in another Member State. A second workshop will be held in Poland, late in the project, to revisit the conclusions of the early workshop in the light of the work completed in the intervening period and to assess the impact of the project's outputs up to that point.

Inspection Guidelines

The Project has developed guidelines for the inspection of tissue and cell procurement and tissue establishments within the EU. The first edition was completed in September 2007 and was provided to all EU Competent Authorities for tissues and cells. That version was based on a review of existing related guidance documents including blood inspection guidance, GMP inspection guidance and tissue and cell inspection guidance that was in place in individual Member States. The drafting group has now used the outputs of a number of project activities to develop the second edition of the inspection guidelines. This edition was open for public consultation during April 2008 and the final version can be downloaded from the project website. It includes proposed standard formats for the documentation to be provided before a tissue establishment inspection (Tissue Establishment Dossier), for an inspection report and for an application for authorisation of a new preparation process (Preparation Process Document). The final version will be submitted to the European Commission which will present it to the Regulatory Committee for Directive 2004/23/EC for possible adoption as official non-binding EU guidelines.

Inspector Training

In the final year of the project a series of four inspector training courses will be held in different European locations. This aspect of the project is led by the Austrian partner, the Federal Ministry of Health and Women. The initial course is being designed, and course material produced, based on the proposed inspection guidelines and the findings of the workshop, survey and exchange visits. Courses will include a seven week e-learning module followed by a three day interactive and

practical residential module. This training programme will help to ensure that the agreed guidelines are applied consistently as inspection systems are implemented and improved. After the final course, a package including a course programme, a training specification and model training material for tissue establishment inspectors will be provided to the European Commission.

Vigilance and Surveillance

Existing vigilance tools and systems in the EU and beyond were examined in detail and two meetings of the project's Vigilance and Surveillance Medical Advisory Committee explored the principles that should be applied in an ideal system. One of these meetings was expanded to a global audience so that experience from the USA, Canada, South America and Asia could be explored. Using this work as a platform, the project has developed a series of 'tools' for the definition, classification, evaluation and management of adverse reactions and events associated with the quality or safety of tissues and cells used in clinical application. These include tools for the classification of severity, the assessment of imputability and the evaluation of the wider systems impact of an event or reaction. The tools have drawn significantly on experience in haemovigilance. The proposed model will be validated in a pilot programme from July 2008 to June 2009.

Discussion

Although Directive 2004/23/EC, together with its associated Commission directives, provides an essential common platform for the regulation of tissues and cells used therapeutically and in clinical trials, there remains the risk that Member States will apply the requirements in different ways, reducing the degree to which the Directives bring about a common EU approach. Supervision, inspection and accreditation/authorisation of donation, procurement, testing, processing, storage and distribution are fundamental aspects of the directives and will provide the confidence that tissues and cells applied to patients in one Member State are indeed equivalent in terms of safety and quality as those applied in another Member States.

If successful, the EUSTITE project will bring about greater understanding between inspectorates in EU Member States and will ensure that authorisation in one country can be considered equivalent to that in another. If the Regulatory Committee adopts the inspection guidelines for amendment and eventual adoption, the EU will have a common agreed basis for the conduct of inspections in this field. A tried and tested inspector training course will be available to all Member States to adapt and apply for the training of future inspectors. Communication between Member States and the European Commission will be greatly facilitated by the use of a common glossary and classification system for adverse events and reactions associated with safety or quality of tissues and cells.

Further information and updates on the project can be found at **www.eustite.org**

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Human Fertilisation and Embryology Authority, UK

Blood donation and iron status

Two effects of blood donation dominate donor management:

- post-donation fainting (syncope),
- donation-induced iron depletion.

Both relate directly to blood loss. Selection policies such as age and haemoglobin (Hb) thresholds, as well as collection volumes, vary internationally and often are poorly justified and sometimes anachronistic.

Current European rules require that no more than 13% of the donor's estimated blood volume (455ml in a donor who weighs 50kg) is collected at each standard donation, whereas the USA allows 15% (525ml). These rules are entirely pragmatic – and questionable. Even though body fat and Body Mass Index (BMI) have risen in Western peoples in recent decades, it would be ethically challenging to re-determine experimentally the relationship in donors between blood loss and syncope, although one in 198,000 American donors were hospitalized through severe post-donation syncope. The cardiovascular responses which include baroceptors and pathways in the autonomic nervous system, vary with age, weight and gender, and are enhanced by emotion and other factors. Good psychological preparation, audio-visual distraction of donors and even drinking water just before donation, are of proven benefit. Collection volumes have increased from around 450ml 12 years ago to around 500ml now, and this may be causing more faints. An important drive to collecting larger volumes is the bigger 'dead space 'i.e. the amount of blood that is lost in leucodepletion filters which will be exacerbated when prion filters are introduced. The risks of post-donation iron deficiency and of fainting require that urgent attention be given to minimize this waste by better filter system design.

Donation-induced iron depletion and deficiency

Before their first blood donation, pre-menopausal women may be functionally replete in iron but have minimal stores. The normal Hb range in non-pregnant younger British women is 130±9 g/l (mean and SD). An iron-replete 50Kg woman has about 3g total body iron. As 1ml red cells contains 1.1mg iron, 500ml of her blood contains almost 215mg of iron – 15% of total haemoglobin iron and 7% of body iron. After a first-time bleed of 190ml red cells, 50ml of red cells is 'regenerated' in one week and Hb is restored in six weeks.

Regular blood donation is accompanied by progressive decline of serum ferritin (an indicator of body iron stores) and rise in serum soluble transferrin receptor (STR). Iron deficiency is also indicated by the full cell count of fresh blood: the combination of cell indices ('CCI' – derived from [RDWx10^4xMCV^{-1}xMCH^{-1}] and normally 45±5, mean and SD) shows that the iron status of men giving three donations in two years resembles that of menstruating women. Men not taking iron supplements can become markedly deficient if donating six times in two years. Higher body weight (and eating meat) can protect against iron deficiency; but carrier status for genetic haemochromatosis does not.

Haemoglobin (Hb) concentration thresholds

Not only is the technical challenge of producing an immediate, reliable and meaningful estimate of pre-donation Hb very considerable, there are conceptual flaws in relying on a 'threshold' which demand a complete re-think of how to manage this fundamental aspect of donor selection.

Virge James, recently retired from the Sheffield Blood centre, reported that the HaemoCue machine performs better than the undoubtedly primitive copper sulphate gravimetry – 'the copper sulphate test'. This was developed over 50 years ago and can sometimes pass severely anaemic donors. But gravimetry is robust, cheap and simple to validate by comparing its performance with highly accurate hamoglobinometry performed on venous blood collected in the diversion pouch of current collection packs (these pouches were not available to Dr James).

Problems with the 'threshold Hb' approach (apart from methods and costs of determining Hb) include selecting and justifying the threshold(s), and the physiological variables, as described below:

- Sample site; blood from finger-sticks is generally closer to venous blood Hb than earlobe-sticks (which have higher Hb).
- Hb from different fingers can vary by over 10%.
- Methodology and performance variables: reported differences may be unreliable if each sample-type is analysed on different apparatus calibrated separately.
- Environmental conditions at donation sessions may affect Hb determination.
- Seasonal variation – Hb can decrease by 2g/l in summer as compared to winter.
- Ethnicity – normal Hb values are lower in Afro-American and SE Asian peoples.
- Age – Hb declines in men over 70; in women it rises following the menopause but declines after 70.
- Increased BMI is associated with higher Hb – this seems not to be an artifact through sampling from obese arms.
- Other physiological factors include posture, diurnal rhythms, prandial, altitude (or smoking) and menstrual cycle stage.

Hence, any single Hb value is a 'snapshot'. A venous sample at or after donation may better indicate Hb at the next attendance, and avoid the finger-stick. Given donor weight, gender and other factors the minimum time before the next blood donation appointment could be determined from the Hb and/or FBC (or CCI), although such ideas need validation.

Frequency of donation; iron supplementation and dietary advice

Four donations a year – or two 'double-dose red cell' collections by apheresis – remove about 1g of iron, or 3mg a day. Together with the physiological requirements this comes close to the maximum daily absorptive capacity of iron from the diet, and it may be reasonable to modify donation frequency, minimum body weight and even Hb threshold criteria, and supply iron supplements. There is evidence that the UK thresholds before 2005 (*venous* blood Hb120g/l for women and 130g/l for men) were safe; but current regulations require that these be 125 and 135 respectively.

Between two and five grammes of iron need to be taken orally to compensate for one donation. Opinions differ as to whether this should be by low doses over a long period or shorter courses of high doses – the latter risk gastro-intestinal (GI) intolerance. However supplementation can disguise signs in the stool of GI bleeding, and infants are still poisoned from iron prescribed for the mother. About 1% of UK residents are homozygous for *HFE* C282Y – the main gene for haemochromatosis – and should not receive supplements unless iron deficiency is proven.

Prevention and management of donation-induced iron deficiency – including apheresis component collection – needs constant appraisal.

References

Boulton, F. (2008). Evidence-based criteria for the care and selection of blood donors, with some comments on the relationship to blood supply, and emphasis on the management of donation-induced iron deficiency. *Transfusion Medicine;* **18**: 13-27.

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Clinical usage of IVIG in 2008 and beyond

Immunoglobulin preparations were first used in the 1950s as a replacement therapy for immunodeficiency. Currently, pooled normal human immunoglobulin (IVIG) is also administered in relatively larger quantities to treat conditions other than immunodeficiency, such as autoimmune and inflammatory processes, across most medical specialities, in particular immunology, haematology and neurology. Demand has increased by 30% in the last three years and it is predicted to increase by 10-15% annually for the next three years. IVIG is now the most widely used product of plasma fractionation in developed countries. The emergence of new therapeutic indications, widespread off-label use and an indefinite duration of use in some indications, have contributed to increased demand.

For some time, there have been concerns over the availability and usage of IVIG in the NHS. This is because of several factors, including the current worldwide shortage and the increasing cost of this product, which have risen by 30% since 2005. The total annual cost of immunoglobulin in England alone is currently £75 million. Another cause for concern is the limited evidence of benefit of the use of IVIG in certain conditions and the risk that usage for such indications may unfairly compete with usage in life saving indications, such as primary immunodeficiency, in times of severe shortage. In the context of a worldwide shortage and escalating demand and costs, the Department of Health (DH) Commercial Directorate and NHS Purchasing and Supply Agency are negotiating with suppliers of IVIG to ensure that adequate supplies, at an affordable price, are available to the NHS. The DH has also implemented a demand management programme in the UK to ensure that the limited supply of immunoglobulin is used appropriately, both to secure supplies for critical patients who rely on immunoglobulin for survival and to help to control use of an expensive drug.

In November 2007 the DH communicated the Demand Management Programme to the wider NHS.

The Demand Management Programme consists of three strands:

1. Establishment of National Clinical Guidelines for the appropriate use of IVIG: These guidelines are supported by grade of evidence and, when available, any alternative therapies other than IVIG that can be used to treat a particular condition. Some relevant conditions where IVIG is not recommended are also listed. A regular revision of these guidelines is planned and a new version will be published on 30th May 2008, following a consultation with over 20 Royal Colleges and Professional Societies.

2. The Demand Management Plan: This initiative provides guidance on the implementation of appropriate use of IVIG. Recommendations include the establishment of a local Immunoglobulin Assessment Panel in every Trust/SHA, in conjunction with local commissioners and pharmaceutical advisors. This panel will be expected to establish local policies based on DH recommendations, approve applications for use, respond to shortage situations and also monitor and review local usage.

   The Demand Management Plan divides indications for usage of IVIG into three colour-coded categories, based on patient clinical needs and level of evidence. The red list includes situations where treatment is essential, such as ongoing maintenance therapy for primary immune deficiency. The blue list includes indications where

alternative therapies should be pursued in times of shortages. The white list includes indications where there is little or no evidence of benefits. This includes rare disorders for which it has been difficult to gather any systemic evidence and other disorders for which there is no evidence of effect, or no positive evidence to show effect. Except for acute situations where an initial dose of IVIG needs to be given to treat a condition within the red list, all other applications for use of IVIG are required to be approved by the Panel. Table 1 shows recommendations for the use of immunoglobulin in some haematological conditions.

3. Establishment of a National Clinical Database on use of IVIG for long-term planning: This database gives information on the amount used and clinical indications of IVIG in each Trust. The clinical database is currently being piloted and it will be rolled out nationally in May 2008.

IVIG, as a high cost drug, is currently excluded from the payment by results tariff. It is often unclear how Trusts recoup the cost of administering immunoglobulin. When the above guidelines were drawn up, there was no commissioner input into the process. Consequently, it was agreed that there was still a need for commissioners to consider, as a separate exercise, what indications they would actually agree to fund. A Task and Finish Group with Standards Consulting Group, public health and commissioner representatives, was set up in autumn 2007 to draft the Model Commissioning Policy. The planned publication date for this policy is July 2008.

Despite recent DH communication, it is of concern that key personnel, such as the Medical Director, Chief Pharmacist, relevant clinicians and contracting managers, in some Trusts are not aware of, or not involved enough with, the DH Demand Management Plan. The implications of such a programme on the management of increasing demands for IVIG and potential acute shortages are obvious and Commissioners have been encouraged to draw the attention of Trusts to the DH Demand Management programme.

Reference

The DH letter, the Clinical Guidelines and Demand Management Plan for the appropriate use of IVIG are available on the DH website: **www.dh.gov.uk** and on the IVIG website: **www.intravenousimmunoglobulin.org**.

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Table 1 – Recommendations for the use of Immunoglobulin for some Haematological Disorders

Condition	Recommend?		Grade of Evidence
	Acute	Maintenance	
Adult HIV-associated thrombocytopenia	AS LAST RESORT	NO	A, Ib
Autoimmune haemolytic anaemia	SELECTED	NO	C, III
Autoimmune thrombocytopenia	SELECTED	NO	A,1a
Evan's Syndrome	SELECTED	NO	C, III
Idiopathic thrombocytopenic purpura (adults)	SELECTED	NO	A, 1a
Post transfusion purpura	SELECTED	NO	C, III
Bone marrow transplant: Graft versus host disease following allogeneic bone marrow or HSCT	NO	NO	A, Ib
Bone marrow transplant: Low serum Ig levels (<4.0 g/L) following stem cell transplantation	YES	SELECTED	B, IIb
Bone marrow transplant: Infection following allogeneic bone marrow or HSCT	NO	NO	A, Ia
Chronic Lymphocytic Leukaemia with recurrent infections associated with low serum Ig levels	NO	SELECTED	A, Ib
Multiple Myeloma (plateau phase only + recurrent infections)	NO	SELECTED	A, Ib

A full list of recommendations is available from the IVIG website

Scientific & Technical Training Update

Introduction to Modernising Scientific Careers

The UK health departments are currently developing important proposals concerning the redesign and definition of healthcare scientists' (HCS) careers in the NHS. The programme of work is called the "Modernising Scientific Careers Programme".

The Chief Scientific Officer for England, Professor Sue Hill, has appointed Professor Shelley Heard as Programme Director for the project. Professor Heard leads a small team that is developing coherent plans for training and implementing the career framework, based on discussion and consultation with the UK health departments, the professional bodies and the service. The work is based on work previously undertaken on National Occupational Standards and the HCS Career Framework.

The need for change

Work through the CSO's office has looked at the contribution of HCS to the eight planned Darzi care pathways. It is apparent that we need teams working across current professional barriers, working in a flexible way to ensure best use of skills and knowledge. We need to be streamlined to harness and enable the introduction of new technologies. To achieve this we need to modernise education and training for HCS to produce new and more flexible career structures, with demonstrable transferable competences. We currently have complex training systems and inflexible career structures which do not promote research and innovation.

Within HCS, 45 different career routes have been identified, in 26 disciplines. Within Transfusion and Transplantation we have two types of state registration (Clinical Scientist (CS) and Biomedical Scientist (BMS)) and many unregistered practitioners in the newer disciplines such as stem cells and tissue banking. The use of these different types of staff varies across our laboratories, with red cell immunohaematology and blood bank labs being traditionally staffed with BMS staff, whilst Histocompatibility and Immunogenetics labs employ many more CS staff. The reasons for these discrepancies are often unclear. There is currently a disconnect between preregistration and postregistration training, and academic careers are not well supported. Generally throughout HCS there are a confusing number of professions and grades, careers are not flexible enough and training programmes aren't independently assessed.

Agenda for Change has revealed an unaffordable, inappropriate HCS workforce, that is in urgent need of review. Technologies in our laboratories have changed, and tended towards more automation. We don't need graduate HCS's to run machines, but we do need good, well-trained scientists to design processes, innovate, interpret results and provide clinical advice.

The Way Forward

The Modernising Scientific Careers Programme aims to introduce a common framework across all disciplines, to encourage research and innovation and to promote leadership and allow effective future workforce planning. Proposals are still being developed, and a formal discussion document is expected to be released towards the end of May 2008.

At present it is envisaged that there will be one training scheme for GCSE level staff entering at career stages 1-2, which will enable them to progress through to stages 4 and 5 as technical support staff. This will involve in service NVQs, leading to proposed registration as an Assistant Practitioner at the top of stage 3. Associate Practitioners could then undertake modules of a foundation degree at stage 4, with options to convert this to an Honours degree to gain entry to the scientist training programme.

Entry to the scientific training programme at stage 5 will be for honours graduates with any relevant degree. It is currently envisaged that this programme will start with a two-three year training scheme to achieve registration as an HCS – the green boxes in figure 1. Current discussions are based around how much of this training can be generic across many disciplines, and how much needs to be discipline specific. There is also discussion as to whether these trainees will be supernumerary, or employed by the Trusts. There will be a core learning higher education programme supporting this, but it is under debate at the moment as to whether this will be to post-graduate diploma or master's level.

Having achieved Registration as a HCS, staff will have two options. They can then apply for stage 6 posts in the normal way, or apply to join a competitive entry fast-track training scheme designed to prepare them for Registration as a Higher Specialist HCS. The fast track scheme (shown in purple in figure 1) is intended to be supernumerary, and guarantee progression through stages 6 and 7 in a speciality. It is envisaged that this will be a five year programme, aimed in the Life Sciences towards MRCPath. It will involve academic and clinical training, probably including a Ph.D. Once staff have gained Registration as a Higher Specialist HCS, it is envisaged that they would be eligible to apply for Consultant HCS posts.

Staff who are not in the fast-track scheme (shown in turquoise in figure 1) can progress through employment in the normal way to stage 7, as and when such more senior posts are available, and could also apply to join the programme for Specialist State Registration at any stage, but their entry would not be guaranteed.

What Happens Next?

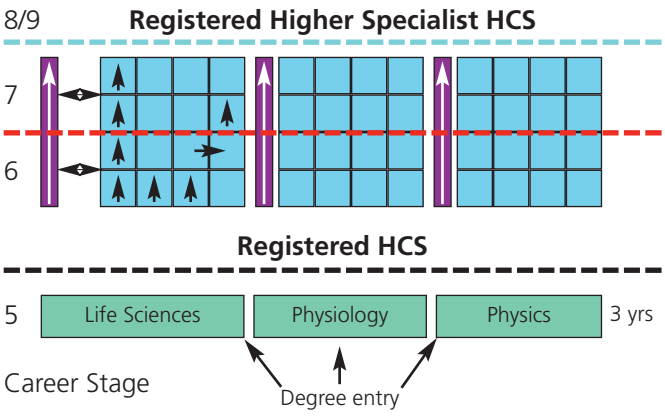
There is much work to be done on filling in the detail to this framework, and also working out transition arrangements for staff who are already in post. There is a clear requirement for the formation of an over-arching body to be responsible for assessment, validation and accreditation of the education and training programmes for all HCS and support staff. Good interfaces will need to be established with Higher Education Institutes to ensure provision of the right courses and awards.

We are considering how much training at each level can be broad, and how much has to be specialised, to obtain maximum flexibility for the workforce, whilst ensuring retention of specialist knowledge. Transfusion and Transplantation Sciences has been proposed as one general modality, with the possibility of crossing over with haematology, immunology and biochemistry as required. At present we are working with a very broad framework of "Blood Sciences", "Infection Sciences" and "Cellular Sciences" within Life Sciences.

How can you have an input?

Much of the work on the programme is being undertaken through professional body representation – e.g. the British Blood Transfusion Society, British Society for Histocompatibility and Immunogenetics, Institute of Biomedical Science, and the overarching Federation of Healthcare Scientists, and you can obtain information and route your comments and input through these organisations. You can also e-mail any comments directly to the programme at **msc.office@dh.gsi.gov.uk**, and register to receive newsletters from them.

Figure 1 – The proposed career framework for scientific staff



The two-three year training program is shown in green. The fast-track higher specialist training programme is shown in purple. Progression through employment is shown in turquoise.

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New Directions in Training and Education – E-Learning

If there was a buzz-word in training and education in the NHS recently it would be "e-learning" but are we making the most of this fantastic new tool of the 21st century?

Firstly, it is not a new concept – anybody who has done one of the old-fashioned correspondence courses will have undertaken that course under the same thinking as there is behind the e-learning concept. The thing which has changed is how these "distance-learning" courses are delivered – using electronic methods instead of paper and ink.

In our education roles, many of us have not fully considered the impact of changing from ink-based to electronic forms of education. Before, we would consider how material would be received by the learner, ensure its appropriateness and consider difficulties they may have with it. Now, for the most part, we make a PowerPoint file on a shared computer drive or the Internet, and call it e-learning often with little regard as to what the learner should get out of the process, how they are going to actually learn from it and regard for the issues of copyright and intellectual property rights. This approach is not considered e-learning.

The current trend within the NHS is to move away from education as a thing which is done *to* employees and more towards good practice which professionals undertake *themselves* as part of their continuing professional development. The introduction of the Knowledge and Skills Framework and its Personal Development Reviews is part of this process – "knowledge for the sake of knowing" is giving way to the "gathering and application of knowledge" in the workplace. Thus, education (including e-learning) is becoming more of a commodity rather than an undertaking. As a commodity, learning material must deliver, and be seen to deliver what it is designed to do.

As employees take more and more ownership and interest in their own development, the amount and range of learning which needs to be provided increases seemingly exponentially. In many organisations there are

simply not enough trainers developing the training material required to meet the needs of the learners if only traditional face-to-face training is undertaken. E-learning, when done properly, allows the learner the flexibility in time and topic to ensure they receive the knowledge and skills appropriate for them.

With the development of much more interactive aspects of the Internet, the opportunities to make e-learning more dynamic are increasing vastly. Social networking sites, wikis (websites which users can alter themselves), virtual reality worlds like Second Life and many more "applications" are collectively known as "Web 2.0 technologies" and can reduce the loneliness and alienation many e-learners experience.

So, rather than thinking of e-learning as an afterthought to "proper", traditional face-to-face teaching, it should be thought of as a new method of teaching. Many skills acquired from face-to-face teaching can be applied to e-learning but it is important to remember that many cannot. Provision of e-learning can take up more time than face-to-face teaching but reach a much larger audience. Developing e-learning material, publishing it and then forgetting about it is not an option as it will quickly become out-of-date.

In conclusion, the role of e-learning within the NHS can only expand as time goes on. As educators, we must ensure that the materials provided for distance learning are appropriate, high-quality, up-to-date and stimulating for the distance-learner.

Some tips when writing e-learning material:

- The most important thing is to remember that you will not be there – everything you do must be able to stand on its own.
- Think about what the learner will have to actually *do*. We learn little from just reading material be it an article or a presentation. We learn far better when we do things – the application of the knowledge we have just learned by reading. In face-to-face classes this is done by discussion. When considering e-learning that option is seldom available to the learner so include *lots* of tasks and problem-solving to apply or use the knowledge attained (or give people the opportunity to discuss results and ideas with their peers).
- Ensure that material contains lots of opportunities for the learners to assess their progress and apply their newly-gained knowledge.
- E-learning, by its very nature is "published" onto a computer drive, intranet, internet or CD – copyright laws and intellectual property rights must be observed and satisfied.
- Vary the delivery of the material – lots of PowerPoint lectures put together is hardly stimulating without the lecturer there to deliver them.
- Ensure that the intended target audience for material can actually access it – there are many restrictions on software and applications within the NHS because of electronic security. There is no point producing all-singing-all-dancing e-learning material if the target audience cannot open the files.
- Plan your e-learning material production – don't let it be a second-best application or afterthought.
- Learning outcomes must be written – the reason the e-learning material is being developed in the first place and what it is expected to do.
- If the learning outcome written includes phrases like, "understand…", "know how to…", "be able to…", then there must be some mechanism of assessing that, both for the material designers and the learners.
- There must be a method of knowing who has done what and how they have performed. The best method of doing this is to use a virtual learning environment (VLE) which is a software package designed to organise and organise material and learners. Many excellent VLEs are available on the internet for free or at very small cost – examples include Moodle™ and Training Tracker™.
- To make e-learning appropriate and to indicate its use map any e-learning material to current standards or guidelines such as the KSF dimensions, National Occupational Standards, BCSH Guidelines, BBT3 etc. so that learners can understand why the material has been produced and auditors, such as CPA, MHRA and the HPC can ascertain its usefulness.
- Review your e-learning material regularly and encourage honest feedback. Act upon their suggestions and comments.

If you would like to experience e-learning using a wiki (and "editable website") then please contact Andy Miller on **andy.miller@nbs.nhs.uk**

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CPD Questions for Blood Matters Issue 25

1. Blood Donation: more challenging times ahead.

   Over the past six years the donor pool has:

   a) grown by 25%
   b) grown by 15%
   c) remained static
   d) shrunk by 15%
   e) shrunk by 25%

2. If the NBS did nothing over and above existing practices

   a) we would be in excess of 50,000 units by the year end
   b) we would be in excess of 80,000 units by the year end
   c) we would be short of 50,000 units by the year end
   d) we would be short of 80,000 units by the year end

3. Impact of the supply chain changes on hospitals

   At present the NBS is operating at:

   a) 40% excess capacity in our Processing Departments
   b) 25% excess capacity in our Testing Laboratories
   c) 35% excess capacity in our Processing Departments
   d) 40% excess capacity in our Testing Laboratories

4. Impact of the supply chain changes on hospitals

   a) The age of blood across a geographical region will be less evenly distributed than currently
   b) Consolidation of our testing infrastructure should have a minimal impact on hospitals
   c) The peaks and troughs of activity will remain a problem, despite the use of overnight hold of donations
   d) Senior staff presence will be restricted to normal 'office' hours

5. The Components Portfolio

   a) The 'Red Book' has clear specifications on neonatal transfusion
   b) The NBS has always had a Components Portfolio
   c) Methylene blue treated cryoprecipitate cannot be introduced
   d) Validation of x-irradiation for cellular products for the prevention of graft-versus-host disease is being undertaken

6. Future plans for Diagnostic Services provided by NHSBT

   In the future:

   a) reference testing to support alloimmunised pregnant women will not be provided by NHSBT
   b) antenatal screening will not be provided by NHSBT
   c) H&I laboratory support of the supply of platelets to refractory patients will cease
   d) the British Bone Marrow Registry will no longer be supported by NHSBT

7. NHSBT Tissue Services: a new start

   NHSBT Tissue Services:

   a) are still operating from multiple, old sites
   b) possess a new product development laboratory
   c) are restricted to 'office' hours referral contacts
   d) can only retrieve tissue from the Speke area of Liverpool

8. NHSBT Tissue Services: a new start

   a) The production staff are also responsible for tissue retrieval
   b) Only a few hospitals in the United Kingdom have signed the service level agreement with Tissue Services
   c) Tissue Engineering is not part of the Tissue Service portfolio
   d) Operating at a single site has resulted in consistently high quality of standardisation

9. Electronic Clinical Transfusion Management Systems (ECTMS)

   a) A pilot is required to see whether ECTMS can be readily adopted by small non-teaching hospitals
   b) RFID has a standard available
   c) Does not require barcoded or RFID wristbands for patients
   d) Can result in an increase in rejected samples

10. European Coding System for Tissues and Cells

    a) The European Coding System will not result in operational changes
    b) It is not based upon ISBT 128
    c) The information represented by the code can facilitate traceability
    d) Number status will not need to consider how donation numbers are allocated

11. Blood donation of iron status

    a) Current European rules require that no more than 15% of the donor's estimated blood volume is collected
    b) Collection volumes have increased from around 450mls 12 years ago to around 520mls now
    c) After a first-time bleed of 190ml red cells, 50ml of red cells are 'regenerated' in one week and Hb is restored in six weeks
    d) Four donations a year remove about 0.5g of iron

12. Clinical usage of IVIG in 2008

    a) There are no guidelines for the appropriate use of IVIG
    b) A national clinical database on the use of IVIG is available
    c) The total cost of immunoglobulin in England is currently less than £50 million each year
    d) Demand for IVIG has increased by 30% in the last three years

CPD

Objective

After evaluation of specific articles published in '***Blood Matters***', participants in the CPD Questionnaire should be able to demonstrate an increase in, or affirmation of, their knowledge of Transfusion Medicine.

Credits

Each participant can earn CPD credits, as reflective learning – as designated by the participant's scheme (for example one credit per hour of reflective study in the RCPath scheme). Each participant should claim only those credits that he or she actually spent in the activity and should write reflective notes in the relevant section of his/her portfolio.

Answers

Blood Matters does not publish the answers to the CPD questions. They are to be found in the text of the articles from which they are derived.

Next Edition

The next edition of ***Blood Matters*** will feature the following articles:

- New Government Advisory Committee for the Safety of Blood Tissues and Organs
- Summary of SHOT data
- What it means to implement the EU Blood Directive and the BSQR's
- Battlefield blood transfusion – is whole blood making a comeback?
- How should transfusion reactions be investigated and managed?
- Blood substitutes – the current position
- How to influence the way clinicians use blood
- Informing Healthcare Wales
- Clinical trials in haemopoietic stem cell transplantation
- Research and Clinical Audit

Diary Dates

Summer 2008

11-13 September

BBTS Annual Scientific Meeting. Llandudno, North Wales. Further information: www.bbts.org.uk

22-26 September

40th Annual Course – Advances in Haematology. Hammersmith Conference Centre. Further information from Imperial on: hcc@imperial.nhs.uk Register online: www.hhnt.org/hcc/conferences/advancesinhaematology2008/index.htm

15-18 October

Platelets 2008 International Symposium. Woods Hole, Massachusetts, USA. Further information: rsimak@platelets2008.org View programme and register online: www.platelets2008.org

16 October

British Society of Blood and Marrow Transplantation Education Day (including **Autumn Open Meeting**), RIBA, London. Further information: www.bsbmt.org

14 November

Recent Advances in Flow Cytometric Techniques and Instrumentation. London. Further information: enquiries@euroscicon.com View programme and register online: www.euroscicon.com

17 November

13th Meeting of the BSH Obstetric Haematology Group. St. Thomas' Hospital, London. Further information: julie.d.woolley@uhl-tr.nhs.uk

26-27 November

Transfusion Medicine Today. Royal College of Pathologists, London. Further information: michelle.merrett@rcpath.org View programme and register online: http://www.rcpath.org/conferences

6-9 December

American Society of Hematology. San Francisco, USA. View programme and register online: www.hematology.org/meetings/2008/index.cfm

11 December

AAGBI: Bleeding, Clotting & Haemorrhage – an update. 76 Portland Place, London. Further information: gemmawilliams@aagbi.org

2009

27-29 April 2009

BSH 49th Annual Scientific Meeting. The Brighton Centre, Brighton. Further information from Sarah Lapsley: sarah@b-s-h.org.uk View programme and register online: http://www.b-s-h.org

A full diary of events and training courses can be viewed on the following websites:

www.transfusionguidelines.org.uk
www.blood.co.uk/hospitals

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