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Blood Matters

Quarterly information for hospitals served by the National Blood Service

NATIONAL BLOOD SERVICE

Editorial

The Processing, Testing and Issue (PTI) Directorate is a large and complex Directorate at the very heart of the NBS. PTI is responsible for a range of activities covering:-

- The processing of blood donations from the point of receipt at the NBS Blood Centre
- The testing of blood donations from the point of receipt of samples to delivery of results including NAT
- The issuing of blood components and products from the point of receipt of the request from the hospital to the time of handover of the order for transportation to the hospital.
- Stock management of blood components.
- Tissue Services - covering the retrieval, processing, testing and supply of tissue donations.
- Quality Assurance directing all aspects of operational quality and GMP across the NBS.
- Internal and external emergency plans.

Over the last year we have been carrying out a strategic review of our activities so that we can put in place plans for the future and the direction we will need to move in to support ever more demanding blood safety standards. This long term planning process is still underway and we hope to have the results in the next few months.

The two key elements of the way PTI will be organised in the future will be tactical and strategic:

- Tactical - Local management has been strengthened by appointing PTI Managers to co-ordinate PTI activities which form the central part of the supply chain between the donor and patient across each locality.

  The PTI Manager will be one of the official names on our MCA licence and also will be a key player on the Local Services Group. To support this arrangement and to help deliver quality across the NBS, Quality Assurance Managers have also been appointed, matching the PTI Managers in number and locality. Working together and with others these key individuals will ensure the safe, effective and efficient delivery of NBS components and core services locally.

- Strategic - For a long time, strategic development has been far down the list of priorities of senior personnel due to the competing pressures on their time.

  This has sometimes created conflict between remaining focused on the day to day operational activities and the delivery of timely and quality national strategic processes and projects.

  Therefore, a number of strategic development posts are being put in place. Each will report to a Head of Function, who will be responsible for driving forward standardisation and major improvements within PTI in the medium to long term

The PTI Senior Management Team

The PTI Senior Management Team is responsible for the strategic development of the PTI functions, ensuring initiatives are in line with the Corporate Objectives and Business Plans and that operationally PTI provides an effective and efficient service to patient care.

PTI Senior Management Team members are as follows:-

PTI SENIOR MANAGEMENT TEAM	
Peter Garwood	Director, PTI
Richard Bedford	Assistant Director, PTI
Michelle Ashford	Head of Processing
Chris Hodson	Head of Testing
Catharine Harris	Head of Issue
Deirdre Fehily	Head of Tissue Services
Alan Slopecki	Head of Quality Assurance
Lorna Williamson	Lead Consultant – Components
Stephen Dean	Senior Human Resources Manager - PTI
Vaughan Sydenham	Planning/Management Accountant – PTI

Strategic Development

Over the next few months specialised strategic development posts will be appointed to support the Heads of Function to ensure relevant and sufficient time is given to planning and developing for the future and to support the Directorate in IT issues, projects, staff development and other matters.

Several other strategic posts are planned for the future e.g. a Risk Manager and Process Development specialist.

Local PTI Management

Ten PTI and QA Managers have been appointed to be responsible for the local implementation of national PTI strategies and the local delivery of components and core services to external and internal customers. Some PTI Managers have responsibility for PTI across a number of inter-related sites e.g. South West encompasses Bristol, Oxford and Plymouth. PTI Managers report to the Assistant Director of PTI and QA Managers to the Head of Quality Assurance.

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Tissue Services

Tissue banking has grown within the NBS since the early 1990s, making use of the donor selection, donation testing and quality expertise already in place for blood. A number of pre-existing tissue banks decided to join the NBS for the above reasons.

Tissue Services runs three separate donation programmes, surgical bone donation, Cadaveric tissue donation and unrelated cord blood donations. The number of all types of donations has dramatically risen in the last few years. For example with unrelated cord blood, the London and Newcastle Tissue banks now have 3,945 units available for searching on international registers.

Within Tissue Services, a small Research and Development team, develops new products and processes to increase efficiency of processes and the quality of patient care.

The year ahead for PTI

The PTI directorate has an interesting and challenging time ahead in 2001/02 to meet the key objectives in the NBS Business Plan. These challenges include amongst others: -

- The implementation of nucleic acid testing (NAT) for HCV as a release criteria for red cells and platelets
- Ensuring that the NBS is in a fit state to supply the NHS with regard to tissue products and to respond to potential demand increases
- The reduction of production loss through efficient practice and operational management
- Support completion of the strategic review of platelet provision
- The further development of integrated emergency planning arrangements
- The review of existing, and develop an improved, national quality framework within PTI
- Support and respond to ministerial guidance on the future of fresh frozen plasma

The PTI Directorate is entirely dependent on the co-operation of other functions within the NBS if it is to ensure that we continue to provide sufficient high quality blood components and related services to hospitals in a timely manner. We would therefore like to take this opportunity to thank hospitals and other Directorates within the NBS for their continued support.

Peter Garwood
Director of Processing, Testing and Issue

Tissue Matters

Tissue banking has grown within the NBS since the early 90s, utilising the donor selection, donation testing and quality system expertise already established for blood. The growth has resulted from both the development of tissue banking services by individual blood centres in response to local clinical demand and the decision by a number of well established banks (North Wales and Oswestry Tissue Bank in Wrexham, Yorkshire Regional Tissue Bank at Wakefield and the Sheffield Skin Bank) to become part of the NBS. The Yorkshire Regional Tissue Bank had a long and distinguished history as one of the first multi-tissue banks in the world. Many of the processing techniques developed there in the '60s are still used worldwide. The growth of NBS tissue banking has been quite rapid, as shown in Figure 1.

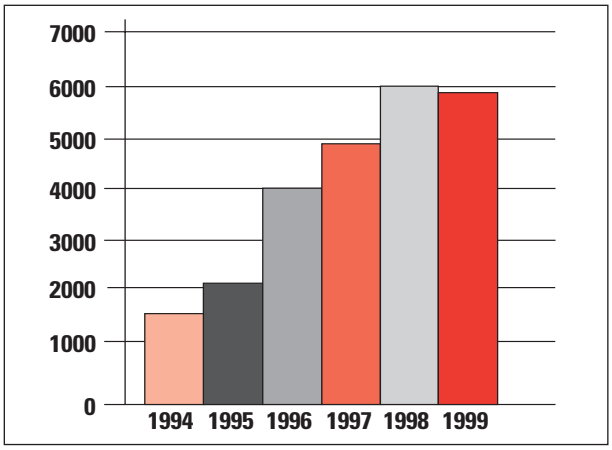

Figure 1: The annual growth of tissue donations to the NBS from April 1994 to March 2000

The importance of this new activity is reflected in the inclusion of tissues in the NBS Mission Statement:

"To save and improve lives by meeting patients' needs for blood, blood products, tissues and related services'.

Tissue Donation

Tissue Services runs two separate donation programmes:

- SURGICAL BONE DONATION

  Femoral heads are removed during primary hip replacement and banked for future use by other patients. This programme requires close co-operation with over 60 hospitals. Many hospital blood banks co-operate with this activity by storing bone and associated samples following donation for later collection by NBS drivers. Over 5,500 donations were collected in 1999/2000. Collection is organised from the following centres:

  Newcastle, Manchester, Liverpool, Wakefield, Birmingham, Bristol, Oxford, North London, South Thames, Brentwood and East Anglia.

  It is a requirement that these donors are tested for the mandatory markers on two occasions at least 6 months apart before the tissue can be released for issue.

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CADAVERIC TISSUE DONATION

Bone, tendons, skin and heart valves are retrieved from donors after death.

Approximately half of the donor family interviews are conducted by Organ Transplant Co-ordinators on behalf of Tissue Services. The remainder are conducted by Tissue Services Donor Co-ordinators who also manage a donor recruitment and education programme. Retrieval teams go to the mortuary to carry out the retrieval operation for all tissues except heart valves; pathologists are asked to remove hearts for valve dissection on behalf of Tissue Services. Cadaveric tissue retrieval teams are organised from 3 centres: Wakefield, North London and Wrexham.

Tissue Processing and Usage

A proportion of femoral heads are issued for use without processing, as long as the results of bacteriology testing are negative. The remaining surgical bone donations, and all cadaveric bone donations, are processed before issue. Bone processing is conducted at three centres: North London, Wrexham and Wakefield. Processing involves washing and shaping or grinding followed by either freeze-drying or deep freezing, with exposure in the final packaging to either ethylene oxide or gamma irradiation.

The great majority of bone is used during revision joint replacement surgery. The development of impaction grafting techniques has caused significant growth in the clinical demand for unprocessed femoral heads, which are morcellised by the surgical team in theatre, and for processed ground bone (Figure 2)

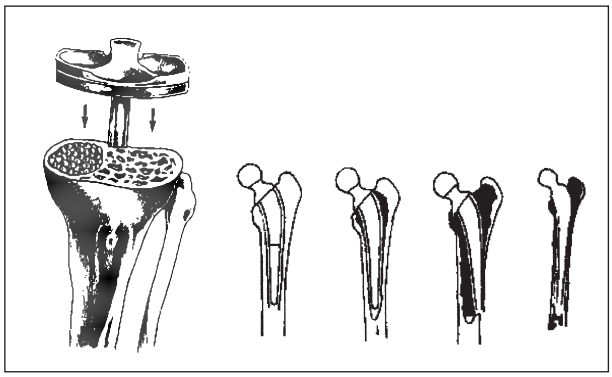

Figure 2: Bone impaction grafting in revision joint therapy

Skin and heart valves are processed at Tissue Services Wakefield and East Anglia. The process involves decontamination in an antibiotic cocktail and cryopreservation with storage in the vapour phase of nitrogen. Skin is supplied for the treatment of major burns surgery where it is usually meshed before application to increase the surface area covered.

Tendons are processed at Wakefield and East Anglia and are mostly used in knee recontructive surgery (Figure 3). A number of small volume specialist tissue products are also supplied, including frozen amniotic membrane for ophthalmic surgery and large sections of frozen long bones (massive allografts). Other tissue products are under development, e.g. meniscus.

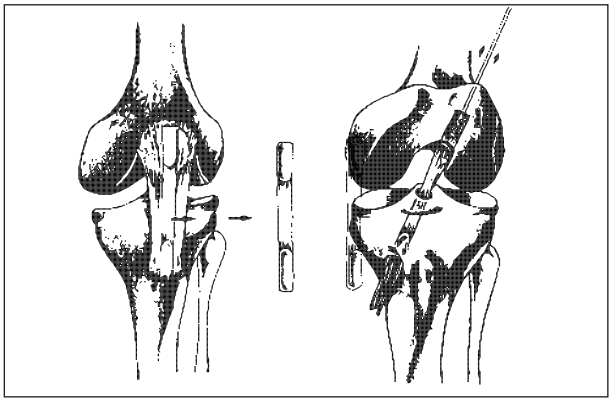

Figure 3: Retrieval of patella tendon and grafting into the anterior cruciate ligament position on the knee

Supply to Hospitals

Many processed tissue products are currently supplied without barcoded identification and are delivered direct to theatres. The NBS is advanced in a project which is incorporating tissue banking into the PULSE IT system. Donations and associated samples are now all identified and labelled with ISBT 128 barcoded numbers. A product description coding system, also based on ISBT 128, has been proposed by the the UK Blood Services and accepted internationally. This will allow tissue products to be supplied with barcoded identification and product description labels in the same way as blood products. It is considered that this enhancement will assist hospitals in maintaining a secure audit trail from receipt to implantation.

Tissue Services Research & Development

The demand for different tissue grafts, the way in which they are processed and presented, and the range of operations in which they can be used, changes through time, sometimes very rapidly. In order to respond to these changes, a continuous research and development programme is essential. The Tissue Services R&D department is responsible for the new product development cycle, i.e. development of new products or processes, their subsequent validation, clinical evaluation in collaboration with clinical colleagues, and finally scale up and implementation. Another important role is to effect continual improvements in the safety and efficacy of the current portfolio of tissue grafts. Horizon scanning is the third critical function of the R&D unit. Occasionally in science a subject area changes so fundamentally and so rapidly that a new paradigm or paradigm shift is said to occur. This appears to be happening in tissue banking.

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The science fiction idea of being able to grow new tissues or even organs is rapidly becoming a reality. Already, for example, it is possible to grow new cartilage, skin, bone and other tissues in bio-reactors, from tiny slivers of the patients tissue. In addition rapid advances in stem cell technology mean that even these tissue fragments might not be needed as sources of tissue cells in the future.

Tissue Services believes that the NBS will have a significant role to play in delivering this new technology to benefit patients in the NHS.

Management

Tissue Services is managed within the PTI Directorate, with senior staff on the PTI Senior Management Team. (See chart at foot of page).

There are over 60 people employed in NBS tissue banking. These include nurses, scientists, technical and clerical staff. The activity is clinically supported by a team of consultants.

Regulation

A new regulatory scheme for tissue banks was introduced in April 2001, with inspection by the MCA. Following a transitional 2 year period, NHS hospitals will be required to use human tissues from accredited banks only. Inspection is against a Code of Practice for tissue banks (Department of Health, February 2001). The Code requires a Quality System approach to tissue banking which is very similar to that followed in blood banking.

Deirdre Fehily
Head of Tissue Services

VARIANT CJD, AN UPDATE

Introduction:

It is just over 12 months since I reported on this topic for Blood Matters. As the number of cases of vCJD has steadily increased (currently 97- as of April 2001 in the UK) and further observations in experimental animals have been published, concern has grown of the risk that Variant CJD might transmit with blood components. This short article is intended as an update on research and the status of the precautionary approach UK Blood Services are taking to reducing the risk that Variant CJD might be transmitted.

Areas of Research:

1. PRION LOCALISATION

So far PrPsc, the abnormal prion, has been detected in vCJD patients in tissue from brain, tonsil and appendix. By contrast PrP^c , the normal prion, is ubiquitous; a cell membrane glycoprotein found on and in all cells studied. As regard blood cells it is confirmed that red cells carry some but very little PrP^c. Most in blood, around 65%, is found on platelets. On this basis it has been suggested that platelet transfusion might be particularly high risk. There is no good reason to think that the distribution of PrP^c will determine the distribution of $PrPs^c$ in people with vCJD. The observed association with lymphoid cells in tonsil and appendix is backed up by mouse transmission studies that suggest that much of any infection, if present, will be in buffy coat cells. Leucodepletion remains a sensible risk reduction measure.

2. EFFECTS OF LEUCODEPLETION ON PRESENCE OF MICROVESCICLE

If leucodepletion removes leucocytes but generates microvescicles (effectively cell debris surrounded by a cell membrane) potentially carrying or containing $PrPs^c$ then this might reduce its worth as a risk reduction measure. Studies are near to completion and preliminary results can be summarised. Filter performance is not uniform for whole blood, microvescicles are detected in post filtered whole

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TISSUE SERVICES MANAGEMENT

PTI Director
Peter Garwood

Head of Tissue Services
Deirdre Fehily PhD
020 8732 5423

Lead Consultant Tissues
Ruth Warwick FRCP FRCPath
020 8732 5466

Head of Tissue Services R&D
John Kearney PhD
01924 360 273

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blood from some but not all filters examined. However for filtered components, no microvescicles are found.

3. TEST DEVELOPMENT

Monoclonal antibodies are available that allow the detection of $PrPs^c$ in immunohistochemical studies, using Western blotting and in a number of immuno assays. None of these test systems has achieved a sensitivity that is likely to be able to detect $PrPs^c$ in blood specimens, that is at the levels that animal experiments suggest might be present. This, not surprisingly is an active area of research in commercial biodiagnostics and a number of different approaches are under investigation. The report that plasminogen has high affinity for $PrPs^c$ might be opening up a promising approach. Molecules with specific affinity for amyloid also have demonstrable affinity for $PrPs^c$. The recent report that erythroid differentiation related factor (EDRF) is down regulated in erythroid precursors of infected animals suggests another exciting approach to testing. A test is not presently available but may well be soon. There are major questions around how such a test might be evaluated and then eventually used. They are being addressed in anticipation that a test will become available.

4. BLOOD TRANSMISSION STUDIES IN ANIMALS.

Sheep infected with BSE by feeding with involved cow brain develop a TSE very like vCJD, much more so than BSE itself. Experiments are ongoing at the Institute of Animal Health to study transfusion in this animal model of vCJD. The development of clinical spongiform encephalopathy in one sheep who had received whole blood from an infected donor sheep was reported in the Lancet last Autumn. The significance of this finding really must wait the conclusion of the full programme of experiments involving many more test animals and controls. Full results will become available over the next 12 - 18 months. This is a research project that promises to provide information highly relevant to the human transmission issue.

Squirrel monkeys can also be infected with both BSE and vCJD. Detailed transfusion experiments using these animals are underway in the USA. Again they promise a much clearer understanding than we have now. Results should be reported this year.

5. OTHER ACTIVE AREAS OF RESEARCH.

There are no new findings to report from the epidemiological review but this is a long term project and it is important that surveillance is maintained.

There is increasing evidence that fractionating plasma will reduce the content of any PrPsc it might contain. Spiking experiments are in progress in which a known dose of $PrPs^c$ is added to plasma or at later stages in the process and then traced through using animal inoculation. These are complex and time consuming and yet to report in detail.

Precautionary Measures:

1. CURRENT MEASURES.

Leucodepletion continues to be refined. The effectiveness of processes and filters is kept under continuing review. The statistical approach to quality assurance that was adopted is proving to be robust and the long term satisfactory performance of processes can be demonstrated. UK plasma is not fractionated. It has been effectively replaced with plasma sourced from donors who have not been exposed to BSE.

Efforts to promote appropriate blood transfusion continue. There are many routes to good practice, particularly important is good clinical governance through effective Hospital Transfusion Committees. Part of the problem is knowing what is good. With the MRC the NBS has set up a clinical trials unit, is participating in a blood transfusion specific Cochrane Collaboration and has established nationally organised clinical audit, all as facilitators to answering this question.

2. Further Measures.

On a theoretical basis there are a number of other measures that might be taken. One is to defer donors who have been treated themselves with blood products, particularly those where the risk should be higher, blood components rather than plasma products. Such deferral will make the collection of sufficient blood more difficult and that has to be considered in any risk assessment. The NBS has undertaken a survey of donors so that this policy can be properly assessed. Another is to plasma-deplete as well as leucodeplete, that means not use single donor plasma products made from locally donated blood and store platelets like red cells in an additive solution rather than plasma. Risk assessment and feasibility studies of this option are in progress.

In closing, I hope that this short article shows that the NBS has its “eye on the ball” as regards vCJD. Guiding our efforts in clinical blood transfusion is the aim to have sufficient, safe and safely used blood. Tackling vCJD is clearly important to that.

Tim Wallington
Consultant Immunologist,
Head of CPD and Manpower Planning

NBS vCJD Steering Group (vCJDSG)

Introduction

The National Blood Service (NBS) has convened a Steering Group (SG) to manage the developing concerns of clinicians, donors, patients and the media around variant Creuzfeldt-Jakob Disease (vCJD) within the context of transfusion / transplantation of blood and tissues.

The purpose of the vCJDSG is to ensure that the NBS in partnership with the wider 'blood community' is aware of, and contributes to, the identification of further strategies that might mitigate the unknown risk of transmission of vCJD to recipients. The group will also ensure that the NBS prepares for, and subsequently effectively implements, any such strategies.

Background

There is an unknown risk associated with the transmission of vCJD through transfusion/transplantation of blood and tissues. There is no direct evidence that this has ever occurred, but relevant UK authorities have already taken a number of steps to mitigate this risk, e.g. in 1998 Bio Products Laboratory (BPL) was instructed to source plasma for fractionation from non-UK donors and in 1998 the NBS was instructed to implement universal leucodepletion.

There is ongoing consideration being given to:

- Donors who have received a blood transfusion being barred from donating blood.
- Testing donors for vCJD when such testing systems become available.
- Plasma used for direct transfusion (e.g. FFP) being sourced from non-UK donors.
- Identification of 'best practice' with regard to appropriate use of blood components.
- Changes in processing methodologies for certain tissue products.

Purpose

It is recognised that a number of initiatives are already under consideration, but it is necessary for the NBS to demonstrate that all reasonable steps are being taken to:

- Identify and to co-ordinate appropriate initiatives.
- Commission any further relevant pieces of work.
- Consider the implications of emerging strategies.
- Incorporate any additional activities into the NBS's work plans.
- Prioritise such work appropriately (which may necessitate de-prioritising existing work and/or allocating additional resource).
- Plan for their implementation.
- Subsequently implement agreed strategies in a timely and effective manner.

It is further recognised that some aspects of this work will be undertaken by existing advisory groups e.g. the 'Red Book'. The NBS will work in co-operation with other UK and, European blood services and the external bodies, e.g. MSBT, SEAC, wherever possible, but the accountability for action by the NBS is vested in the NBS Chief Executive.

There are six areas of sub group work that require attention, i.e. donors, testing, processing, tissues including cord and stem cells, appropriate use and intelligence in R & D.

After an initial workshop in December 2000 the Steering Group has met three times and all the sub-groups are now up and running. Consideration is now being given to how best expand the membership of some of these sub-groups to get wider contribution from outside the NBS.

Martin Gorham
Chief Executive

The Hepatitis C Litigation

Mr. Justice Burton delivered Judgement in case on 26th March 2001. The claimants were 114 people infected with Hepatitis C through blood transfusions between 1st March 1988 (the date on which the Consumer Protection Act came into force) and 1st September 1991 (when the NBA introduced screening for Hepatitis C).

The Consumer Protection Act (CPA), which implemented the European Product Liability Directive, imposes strict liability on producers of defective products that cause injury. It does not consider whether or not the producer was "negligent". From a legal point of view, this was the first significant case brought under the CPA and consequently tested the "strict liability" regime.

The outcome was that the Judge held the NBA liable to all of the claimants. Six lead cases were heard and damages awarded, setting benchmark guidelines for the remaining cases.

The Judgement is long (more than 170 pages) and complex. The purpose of this note is to set out the main findings in layman's terms, not to consider the legal aspects from a lawyer's standpoint. Anyone wishing to study the Judgement can find it at www.courtservice.gov.uk

The Judge considered the case in two broad aspects: the general application of the law to these cases; and then the specific facts of the individual cases. As mentioned above, the CPA enacts the European Product Liability Directive and the Judgement is based on the provision of the Directive.

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Article 6 of the Directive lays down that a product is defective if it does not provide the safety that people are entitled to expect. The NBA argued that the risk of Hepatitis C infection from blood transfusion was known, in particular to the medical profession and that the public could not have had a legitimate expectation that there was no risk of infection. The Judge rejected this argument, holding that the public had a legitimate expectation that they would not be infected with Hepatitis C through blood transfusion; and that the knowledge of the medical profession was irrelevant.

The NBA further argued that all blood at the time carried a small risk of transmitting Hepatitis C and this was "unavoidable" for at least part of the time in question. The Judge rejected these arguments, concluding that blood infected by Hepatitis C was a "non-standard product" that did not meet the public's expectations of receiving infection-free blood. He did not accept the NBA's argument that blood, as a "biological" product, was different from other standard manufactured products.

Article 7 (e) of the Directive provides a defence for the producer of a defective product, namely that the state of technical and scientific knowledge at the time did not allow the defect to be discovered. The Judge ruled that as soon as the risk of infection was known, the defence was unavailable, thus disallowing the NBA's arguments that it was unable to "discover" the defect until the screening test became available.

While the outcome of the case depended purely upon the legal interpretation of the Directive, the Judge did reach a number of conclusions in relation to the history of the introduction of anti-hepatitis C screening. During the trial, the Judge considered the possibility of introducing two "surrogate tests", ALT and anti-HBc. The NBA contended that there was no scientific consensus favouring the introduction of either of the tests which, together, as the Judge found, would identify only 40% of infected donations and give a significant number of "false positives". The Judge rejected this contention, ruling that there was a legitimate expectation that both tests should be introduced by 1st March 1988; accordingly, blood not screened by these tests was defective. He further concluded that there was a legitimate expectation for the introduction of the anti-hepatitis C screening test by 1st March 1990.

The DoH has decided that there should not be an appeal against any part of the judgement.

Although an appeal would have provided an opportunity to seek clarification on some aspects of the Judgement that may have a bearing on the future liability of NHS bodies, the Government did not wish to subject the claimants to a further period of uncertainty whilst an Appeal was underway.

The Department is now focussing on the implications of this Judgement for the NHS as a whole, which will take time to consider.

Martin Gorham
Chief Executive

The Fourth Annual SHOT Report 1999-2000

The Fourth Annual Report of SHOT was published on the 29th March, and publicised at a 'launch' at University College London addressed by members of the SHOT panel (chair Dr Hannah Cohen, speakers included Dr Liz Love, Dr Audrey Todd, Dr John Barbara, Dr Mike Murphy). The following are the key findings:-

Throughout the UK there are 426 hospitals eligible to participate but only 155 (36.4%) submitted initial reports. However, this is an increase of 5.8% over previous years. A further 150 hospitals sent "nil to report cards" making overall participation 72% compared with 77.8% last year.

The biggest category of reports was still in the "incorrect blood component transfused" - 201 or 69.1%. Acute transfusion reactions (34) accounted for 11.7%; delayed transfusion reactions (28) for 9.6% and TRALI (19) for 6.5%. Post transfusion purpura (5) accounted for 1.7% and 4 transfusion transmitted infections were reported.

The wrong blood incidents are, without exception, avoidable errors and the Report has concluded that it is essential that every hospital puts existing guidelines into practice. These were reproduced in last year's SHOT report. Hospitals must ensure that ALL staff handling blood and blood components receive correct training; existing procedures should be examined for flaws; and hospital transfusion committees should be managerially empowered to play a key role in ensuring safe transfusion.

The bedside check is THE final opportunity. Every hospital must have a formal policy for this and every patient should be uniquely identified by a wristband or 'its equivalent'. This should be pursued for ALL patients in theatre and A&E departments.

Among all these "wrong blood incidents", there were 39 cases of ABO incompatibility and 2 deaths - one definitely and one probably related to the transfusion. There were 8 more cases of major morbidity. These figures mask a larger number of ABO/RhD compatible and RhD incompatible transfusions given in error but fortunately without ill-effect. Multiple errors - 47% of cases - continue to contribute to the bedside errors. Phlebotomy errors are a small but important cause of ABO incompatibility; and laboratory errors comprised 26.8% of the total. Laboratory errors included technical, sample transposition and labelling mistakes. About half occurred out-of-hours, but this is difficult to put in a more precise setting. There were a wide variety of errors in requesting, selection, issue and the administration of components. These include failure to irradiate. Twelve patients received anti-D immunoglobulin unnecessarily - reasons were variable but included mis-prescribing, sampling error and laboratory mis-grouping of patient samples.

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Basic epidemiological research is needed into the timing and location of transfusions in a hospital setting. Hence although we know that last year 2,737,572 red cells, 249,622 platelets (adult doses), 365,547 FFP, and 94,114 cryoprecipitate were transfused, more information on the number of transfusion episodes - and indeed the numbers of people getting transfused - will help set these incidents in a fuller context.

Of the immune complications of transfusion, acute reactions remained at the same level as last year (34); delayed haemolytic transfusions were slightly down from 31 to 28.

TRALI incidents increased from 16 to 19; six patients received multiple components, but four received just platelets, three just FFP, and two just red cells (in which most of the plasma had been replaced by optimal additive). Six died; two were already very ill. TRALI is thus the second most common immunological cause of major morbidity/death after ABO incompatibility. Six of the patients were already in ICU; eight were transferred to treat the TRALI and four were managed on the ward. Donor investigations were often incomplete - and some uncertainty remains about the significance of antibodies in parous women. Dr Todd suggested that an expert review of all the cases of TRALI be conducted, possibly by anaesthetists.

There were fewer cases of post-transfusion purpura (5 versus 10 last year); all cases were parous women, the symptoms developing 5 to 15 days after transfusion. All received intravenous immunoglobulin, and four received platelet concentrate. There were no cases of transfusion associated graft-versus-host (TAGVHD). Not too much can be concluded from the TAGVHD figures but it is interesting that this is the first year in which universal leucodepletion has been applied.

FFP and platelets are both "over represented" in the acute reaction group compared with red cells. Some of these life-threatening reactions were from products which patients probably did not require clinically. As far as red cell antibodies are concerned laboratories still need to be vigilant concerning low-level Kidd antibodies. Patients at risk of TA-GVHD should still carry a card to indicate the need for irradiated components. HPA antibodies may be a cause of refractoriness to random donor platelet transfusion.

All of the transfusion transmitted infections this year were due to bacteria - one fatality with Enterobacter aerogenes. Dr Barbara put particular emphasis on the need to improve vigilance - including donor arm cleansing (for which much work by the NBA is continuing) and by diverting the first 10-20ml of blood (for which the provisional results of the NBS trial are not quite as good as experience elsewhere). In Scotland there was one case of HBV transmission from a donor in the early incubation period.

The "near miss" project was continued this year, although it is not an official part of the SHOT scheme. Of the 157 reports received from 27 hospitals, 78 were sample errors, 30 were laboratory component, selection, handling and storage errors. Laboratory sample handling/testing errors counted for 27, component issue, transportation and patient identification errors counted for 12 and 9 were request errors. A clerical error of a wrong ABO group was noted on one report from a blood centre. On three occasions samples were transposed on wrong barcode labels applied within the laboratory.

Overall results from the last four years of SHOT reporting show a total of 862 errors. 602 were accompanied by minor or no morbidity but 143 had major morbidity.

There were 32 deaths definitely attributed to the transfusion and 16 more where transfusion was a closely associated factor.

Overall mortality/morbidity figures by full analysed questionnaires 1996-2000

	Total	IBCT	ATR	DTR	PTP	TA-GvHD	TRALI	TTI	UC[1]
Minor/no morbidity	602	406	96	71	24	0	0	0	5
Major morb	143	54	3	18	8	0	43	17	0
Death definately attributed	32	5	1	4	1	12	4	5	0
Death prob attributed	1	1	0	0	0	0	0	0	0
Death poss attributed	15	2	2	0	1	0	10	0	0
Death unrelated	60	37	10	9	3	0	0	1	0
Outcome unknown	9	4	3	0	0	0	0	0	2
Totals	**862**	**509**	**115**	**102**	**37**	**12**	**57**	**23**	**7**

[1]*UC = unclassified*

Taken from The SHOT report 29th March 2001

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Of all the 509 incorrect blood transfusion transfused cases, 267 had one error, 169 had 2, 56 had 3, 10 had 4, 1 had 5, 4 had 6 and 2 had 7 errors altogether.

The SHOT group are still advocating an over arching body to enable a full enquiry into the nature of these errors and introduce accountability.

There was continuing debate as to whether the SHOT scheme should go compulsory or remain a voluntary system. The fundamental feature of SHOT is its confidentiality and anonymity which it is essential to preserve. Nevertheless it is also essential for clinical governance to proceed to the highest level within hospitals and Trusts, and for the top management in the hospitals to take seriously the implications of these continuing errors. The increase in the numbers of transfusion nurses in hospitals is welcome but much more needs to be done in order to reduce the dangers to any patient requiring transfusion of any blood component in hospital.

Finally, Karl Landsteiner discovered the ABO groups 100 years ago (people must be getting tired of this message). He and his successors would be utterly shocked that 100 years later fundamental errors through non-application of their findings were still so common.

Frank Boulton
NBS Southampton

The editor thanks the British Blood Transfusion Society for allowing publication of this article, much of which will appear in their Newsletter of May 2001.

ISBT 128

The implementation of ISBT 128 only labelled donations has now been completed with all components now carrying the new barcode label format. Prior to the final phasing of the implementation on 23 April all hospitals served by the NBS received at least two units of red cells labelled in the new format and returned a fax indicating that they were able to receive and process these units. This enabled the NBS to finally stop using the dual barcode format number labels, although these will continue to be present on frozen components produced prior to the change until stocks have been used up.

This implementation has taken well over two years to complete and has involved every hospital blood bank, all hospital pathology computer suppliers and numerous NBS staff.

I would like to take this opportunity to thank all our hospital colleagues who worked so hard to ensure this change was able to take place.

Richard Bedford
Project Director

Millennium Festival of Medicine and National Blood Service Seminar Transfusion 2020

Royal College of Physicians, London on 18th October 2000

This seminar was part of the prestigious Millennium Festival of Medicine running throughout 2000, co-ordinated by the British Medical Association, supported by the British Medical Journal and involving all the “great and the good" active in medicine in the United Kingdom.

The NBS contribution to the Millennium Festival was an open meeting that explored the influence of the media on public perception of the risk of blood transfusion. The title of the meeting aimed to convey that we were seeking a clearer vision of what blood transfusion would be like in the year 2020. We needed to start to explore the cultural movements that would influence the direction which transfusion, as an acceptable medical intervention, would take.

The current world-wide demand for zero risk transfusion, a demand seemingly generated by the public and therefore, of necessity supported by politicians is leading to ever increased costs which may become insurmountable and still not meet the requirement. We wished to explore the role and responsibility of the media in influencing the perception and demands of the public at large, bearing in mind that we are all also part of that public.

The day was divided into presentations from four invited speakers, followed by a discussion involving well-known members of the media in the UK and the audience. Douglas Starr, author of the best selling compulsive read: “Blood - an Epic History of Medicine and Commerce", and Associate Professor of Journalism at Boston University and also co-Director of the graduate programme in Science Journalism, was the first speaker. The history of blood transfusion through the ages and different world philosophies came alive with stories not heard before. This put the topic in its historical context. Harvey Klein, Chief of the Department of Transfusion Medicine at the National Institute of Health and now President of the AABB, gave a wonderful and clear view of the most important current debate in our field -“Will transfusion ever be safe enough?" Claudine Hossenlopp, Director of Communication with the National Institute of Blood Transfusion in Paris spoke about what is involved in real communication and made the audience realise how much we all have to learn. Eamon Ferguson, Senior Lecturer in Psychology at the University of Nottingham, presented the research work carried out jointly with the Department of Life and Environmental Sciences

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(University of Nottingham) and the NBS. This explored the perceptions of risk and choice behaviour associated with blood transfusion within four key societal groups: general practitioners, anaesthetists, health/lifestyle journalists and blood donors.

The panel discussion which was chaired by the NBS Chairman Mike Fogden, started with Liz Love explaining the latest data from SHOT and John Barbara summarising the essentials of the cost effectiveness of differing activities related to blood safety. Katharine Whitehorn, the doyenne of female journalists writing for the Observer in the past and currently agony aunt for SAGA then explained that the best way to influence the media would be to cultivate relationships with the features writers, and remember that "the trouble with the press is we deal in extremes". Richard Hannaford, Health correspondent for BBC radio explained that his business was stories. He also said that there was a tendency amongst journalists to regard anyone in authority as having something to hide and quoted Jeremy Paxman: " I always interview politicians with a thought in my mind. What have these bastards got to hide?" It was interesting that the SHOT pie chart, which he had reported on, frightened him. If however the chart was presented differently, showing all the uneventful transfusions with only a tiny slice of adverse events he would not report it. He understood our current insoluble dilemma. Raj Persaud, psychiatrist at the Maudsley Hospital and also a media personality explained that the more we emphasise that there are no risks, the more we reinforce the very concept of risk. "If I told you about 150 safety features I had built into my plant you would think ...Blimey if it needs that many safety features it must be a very dangerous plant indeed!"

Prolonged discussion involving the audience then followed and the serious message that the transfusion services do indeed have an almost insoluble problem - how to communicate the risks of blood transfusion without distortion - became clear. However solutions need to be sought.

At this meeting we were able to start discussing acceptable risk rather than zero risk. There were also many helpful messages, which the services will need to take on board. Mike Fogden concluded the day with the words: "We go away being a little better informed; whether this actually translated itself into anything tangible that can be perceived only time will tell."

The proceedings of this meeting are reported in Transfusion Medicine, Volume 11, April 2001, pages 119-145.

Dr Virge James

NEWS & SNIPPETS

NAT TESTING

The application of testing for HCV by NAT as a release criterion for red cells with a shelf life of greater than five days was successfully completed on 30 April. The next phase of the extension of this test is to apply it to all short shelf life components, including platelets. Because of the time it takes to undertake this test, it will be applied initially to those components which are currently available on the day after donation but not to those currently available within 24 hours of donation, mainly granulocytes (apheresis concentrates and buffy coats) and occasional urgent special components for named patients.

Once again, because we will be "rolling out" the test progressively across the country, we will not be advising hospitals of the exact date at which it will be applied in particular areas of the country. We will, however, inform you of a date from which the release criterion will have been applied nationally as soon as this has been implemented. We are planning for this to take place during the summer months. There will be no recall of components associated with the introduction of these changes.

'BETTER BLOOD TRANSFUSION'

The last edition of Blood Matters indicated that a number of initiatives are being planned to determine how well the recommendations of the Health Services Circular (HSC) 1998/224 have been implemented, and how to provide a continued momentum to the development of a first class blood transfusion service. Unfortunately, the issue by the Department of Health of a questionnaire to NHS Trusts about the implementation of the recommendations of HSC 1998/224 has been delayed. The results of the questionnaire will be used to inform a second UK Chief Medical Officers' symposium on blood transfusion, which will now probably be held in October 2001. This symposium will be focussing on the appropriateness of the usage of blood and blood components, and alternatives to the use of blood. Its recommendations will be published in a further HSC on blood transfusion practice.

BBTS HOSPITAL-BASED TRANSFUSION PRACTICE SIG MEETING

The SIG Officers are planning a detailed programme on Transfusion in Trauma on Monday 25th June 2001, St Bartholomew's Hospital London, 10.15am to 4.30pm, chaired by Dr Frank Boulton. The provisional Programme includes the following

- Problems in Accident and Emergency - patient identification
- Military and civil aspects of major accidents/incidents

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- Blood Bank organisation for major accidents
- Developing the themes from SHOT
- Experiences of the Scottish Trauma Audit Group
- National NBS Plan and proposals for the management of massive transfusion
- Hospital Major Accident planning – do they know they need blood?
- Clinical guidelines – Speaker; Dr Sheila McClelland
- Success/survival through team work – Speaker; Aiden Hallegan

There will be plenty of time for discussions, and for viewing posters. Contact Dr Frank Boulton (023 8029 6704) or Dr Eric Watts. Attendance fees will be £20 for BBTS members and £35 for non-members.

THERAPEUTIC APHERESIS – ADVANCE NOTICE

A one day meeting on Therapeutic Apheresis will be held on Wednesday 19th September 2001 in the Wilson Theatre, PHLS, Colindale, 11am – 4pm. Further details and an application form will be available in May 2001 (e-mail suzanne.gilardoni@nbs.nhs.uk)

BBTS

The main BBTS 'Annual Scientific Meeting' will be held at Leeds from Thursday 6th to Sunday 9th September; further details available from the BBTS Office (www.bbts.org.uk)

TRANSFUSION MEDICINE SYMPOSIUM

A 2-day Symposium on 'Recent Advances in Transfusion Medicine' will be held on Tuesday 20th and Wednesday 21st November 2001 at the Royal College of Pathologists, London. Please contact the Royal College of Pathologists on tel 020 7451 6740, fax 020 7451 6701, or e-mail michelle.casey@rcpath.org.

GIVE BEFORE YOU GO!

Summer traditionally sees blood collection levels drop across the country as people jet off for their summer holidays. Following the success of last summer's campaign, the National Blood Service is again teaming up with Thomas Cook to encourage people to give blood before they go on holiday. So please remember to "give before you go!"

For further information about giving blood or to find your nearest blood donor session either telephone our national helpline on 08457 711 711, visit our website at www.blood.co.uk or view donor session details on Ceefax BBC2 page 465.

5TH EDITION OF THE RED BOOK 2001

The 5th Edition of the Red Book should be available in August 2001. A thorough editorial review by The Stationery Office editors has resulted in numerous stylistic changes aimed at making the book more user friendly and less in SOP format.

The book is divided into Parts, not Sections, and the chapters will run consecutively to avoid current confusion with several chapters with the same numbers. The subchapter numbering will only run to the first decimal point, all other subnumbers will be replaced by bullet points and then small squares for further subdivisions where necessary. This change has received unanimous support from a wide selection of users who have seen a few preview pages. All appendices will be at the end of the book rather than dispersed throughout. There will also be a comprehensive index .

Since many of the chapters have once again had a thorough rewrite we will aim to include at the start of each chapter a summary of the CHANGES in CONTENT for ease of reference .

An extended web page for the Red Book to include the publications, i.e. the Book itself, the Handbook of Transfusion Medicine and hopefully MAD and MAD-T, is currently being negotiated.

THE STRONGEST LINK

The NBS launched a new TV advertising campaign on the 18th June aimed at recruiting and retaining blood donors. Research has shown that the general public are mostly unaware of the uses and importance of blood and in consequence they probably know of someone close to them who has benefited but are not aware.

The three 30-second advertisements feature well known personalities talking about the ways in which blood, and blood donors, have impacted on their lives and the lives of friends and family.

The personalities who feature in the advertisements are Richard Branson, Gary Lineker, William Roache, Linda Robson, Heather Mills, Denise Welsh, Robbie Earle and Mo Mowlem. Each thanks the blood donors who appear with them and in doing so highlights some of the range of conditions for which blood is needed.

It is anticipated that the campaign will have a significant impact on donor retention, whilst helping the NBS recruit the extra 400,000 new blood donors needed this year.

FEEDBACK

We are always interested in your comments and feedback on Blood Matters. We are constantly striving to improve Blood Matters and your suggestions help us in this task. If you have any comments please contact Dr Angela Robinson on angela.robinson@nbs.nhs.uk, or phone 01923 486800 or fax 01923 486801.

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Editorial Board: Dr A Robinson, Dr F Boulton, Dr R Webster, Dr J Harrison, C Hartley