

# Blood Matters

Quarterly information for hospitals served by the National Blood Service

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Part of this 16th edition of Blood Matters is devoted to the European Blood Safety Directives due to become part of UK law in February 2005. Tom Kelly's article describes the administrative and legal processes now in progress to set up the necessary legislative framework to incorporate these Directives into UK law. The article by Joan Jones describes the work her group is doing to assess the impact of these Directives on hospitals and to provide planning guidance and recommendations, both for hospitals and for the Department of Health. To provide some background for the uninitiated, I thought it might be helpful to summarise how these EU Blood Safety Directives came into being.

The legislative process within the European Community is quite complex and lengthy and is organised in the following way. The European Commission has the executive power, is the guardian of the Treaties and has the right of legislative initiative. The Council of the EU acts in a co-decision procedure, with the European Parliament, on advice from the Social and Economic Committee and the Committee of the Regions. Until the Treaty of Amsterdam (1999), the European Commission did not have the remit to initiate legislation on the quality and safety of organs, blood and tissues. Prior to this, the only Directive (law) impacting on blood transfusion was Directive 89/381/EEC *'relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma'*. It established legal provisions for plasma derivatives and ruled that plasma derivatives were to be considered as medicinal products, and, as such, came under community legislation on medicines. In 1995, the European Council invited the European Commission to submit appropriate proposals to develop a framework for a blood safety strategy. The result was Council Recommendation 98/463/EEC *'on the suitability of blood and plasma donors and the screening of donated blood in the European Community'*. This was an intermediate step towards developing a blood safety Directive, the power to do so being provided by Article 152, 4a of the Treaty of Amsterdam. This Article invites the European Parliament and the Council *'to adopt measures that set high standards of quality and safety of organs and substances of human origin, blood and blood derivatives'*. Based on this Article, a proposal for a European Directive was submitted by the European Commission in December 2000 which entered the legislative process of the European Communities. Finally, after more than two years of negotiating, lobbying, compromising, etc., Directive 2002/98/EC was adopted on 27<sup>th</sup> January 2003, published on 8<sup>th</sup> February 2003 and due to be implemented throughout the EC by 8<sup>th</sup> February 2005.

This Directive sets standards for quality and safety for collection, testing, processing, storage and distribution of human blood and blood components. Two 'daughter' Directives have followed: one already adopted (2004/23/EC) specifying certain technical requirements for blood and blood components; the second is yet to be agreed by the now 25 member states prior to adoption. This second 'daughter' Directive deals with the technical requirements for quality management systems, traceability requirements and notification of serious adverse reactions and events. The 'mother' Directive (2002/98/EC) covers all these issues but in less detail and the purpose of the 2 'daughter' Directives is to set out the specific technical requirements necessary for compliance. These Directives do have some limitations as 'subsidiarity' dictates that the exclusive responsibility for health issues lies with the member states. The Treaty of Amsterdam, in Article 152, 5, specifies that *'Community action in the field of public health shall respect the responsibilities of member states for the organisation and delivery of health services and medical care. In particular, measures referred to in Article 152, 4a shall not affect national provisions on donation or medical use of organs and blood.'*

Imposition of tighter regulations through European Community Law can engender a degree of frustration, however in this case, it is important to remember that the objective is to improve the level of quality and safety in blood transfusion across Europe and that should be welcomed.

The rest of this edition is devoted to more 'user friendly' topics themed around 'Better Blood Transfusion'. There is a report on the CMOs meeting, a 'Spotlight on SHOT' from a Transfusion Nurse's point of view, an update on the place for autologous transfusion and highlights of the changes made to the newly updated FFP guidelines. The next edition will focus on some relevant IT issues and, as always, the Editor would welcome any suggestions for other topics or themes, as well as the offer of any 'Handy Hints' to be included.

### **Dr Angela Robinson**

Editor & NBS Medical Director

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## **European Blood Directives**

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This article aims to provide an overview of the current and future activity around some of the legal and administrative issues raised by the directive. The Department of Health (DH) in England, and the Northern Ireland, Scotland and Wales Health Departments (the 'devolved administrations') are taking a pan-UK approach. The proposed administrative timetable is as follows:

18 <sup>th</sup> October 2004 - 8 <sup>th</sup> January 2005:	12-week public consultation period on draft regulations
15 <sup>th</sup> November 2004:	Implementation guidance issued by DH
15 <sup>th</sup> January 2005:	Regulations (transposing Directive into law) laid before Parliament
<b>8<sup>th</sup> February 2005:</b>	<b>Directive becomes law in UK</b>

The UK Blood Services are also doing a lot of work around the details of the directive's requirements for 'Blood Establishments' to ensure that these are met by the due dates.

### Main Legal/Administrative Issues

A summary of the current position on the main associated issues is as follows:

- Departmental lawyers are preparing draft regulations to transpose the directive into law. Following a public consultation exercise on these, final draft regulations will be laid before Parliament and become law when approved. Contravention of the regulations will be an offence potentially subject to criminal proceedings.
- Following the recent report of the DH Arms Length Bodies review, the competent authority for the blood directive will be the new Regulatory Authority for Fertility and Tissue (RAFT) when it is established. Because of the directive's February 2005 implementation date, interim arrangements will need to be put in place.
- Although the directive will become law in February 2005, member states may maintain existing arrangements for nine months after that date providing certain legal requirements are met. These are being explored in an effort to allow the UK to take advantage of this provision.

### Hospital blood banks

Although the directive does not require accreditation, licensing or inspection of hospital blood banks, the following articles impose requirements on them:

- 7 (Operative date)
- 10 (Personnel)
- 11(1) & 12(1) (Quality Management – Quality system & Documentation)
- 14 & 15 (Haemovigilance – Traceability & Notification of serious adverse events and reactions)
- 22 (Quality and Safety of Blood and Blood Components – Storage, transport and distribution conditions)

- 24 (Data protection and confidentiality)

The requirements of most of these articles mirror the current CPA standard. Since the publication of "Modernising Pathology Services" (DH - February 2004), laboratory accreditation is no longer voluntary (in England). An initial comparative analysis suggests that broadly, the current CPA standard incorporates all of the relevant requirements apart from those in Articles 14 and 15.

Apart from a requirement for the retention of data for thirty years, article 14 on 'traceability' does not impose any more on hospitals than is currently specified in, for example, circular HSC 2002/009 – 'Better Blood Transfusion' – '*...Trusts should ensure that there is routine data recording and collection to enable the traceability and monitoring of the safe, effective and appropriate use of blood...*'

Article 15 requires a system for reporting adverse incidents to the competent authority. Currently transfusion-related adverse events are reported via the 'Serious Hazards of Transfusion' (SHOT) system, participation is specified in circular HSC 2002/009. The range of events reportable to the 'competent authority' under the directive may not be as wide as for SHOT. DH is exploring the implications with SHOT and others to have the appropriate arrangements in place by the due date.

Despite this network of existing systems satisfying the requirements of the directive, and participation in them specified in extant guidance (we are establishing the extent to which this position applies in respect of the 'devolved administrations'), we know that for example:

- not all laboratories are yet accredited or have applied for accreditation,
- the arrangements to ensure traceability, particularly with regard to transfusion or disposal of individual units of blood, are not always robust or reliable,
- currently, not all transfusion-related adverse incidents are reported to SHOT
- the assurances provided by existing systems may not meet the needs of all stakeholders.

The transposition of the directive into law means that some of these shortcomings could potentially result in enforcement action in respect of breaches of the regulations with the ultimate sanction of criminal proceedings. It is therefore imperative to rectify the position. Systems need to be meaningful and effective not only to avoid the possibility of enforcement action but, equally importantly, to achieve the directive's aim of ensuring improvements in patient care.

An item is planned for a ‘Chief Executives Bulletin’ in the near future to reinforce this message. The NHS Operational Impact Group is looking at ways of helping hospitals address the impact of the directive. The group will work through and make recommendations on how this is best tackled, the extent to which existing structures and networks are appropriate and best utilised and, whether new systems are required.

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## **Role of the European Blood Directive NHS Operational Impact Working Group**

This group originated as a sub-group of the “Appropriate Use” group (where hospital representatives and the NBS come together to develop ways of improving the safe and effective use of blood) and their remit was to help hospitals assess and plan for the impact of the European Blood Safety Directive. This role has changed following the first meeting and this article will aim to clarify to the readers what is happening regarding the EU Directive, the role of the NHS Operational Impact Working Group (OIG) and the issues as they impact on hospital blood banks.

### **Configuration of the Group**

The OIG is made up of Blood Bank Managers, Transfusion Practitioners, Consultant Haematologists, representatives from the Blood Services and as this is a UK group representatives from each of the devolved countries of N. Ireland, Scotland and Wales. It was agreed at this first meeting that we should also invite the Chair of the IT Working Group, a representative from the competent authority and a trust Chief Executive. It was also agreed to co-opt additional skills and expertise as the need arises.

### **Terms of Reference**

The OIG will consider and make recommendations to the Department of Health (DH) as to the minimum requirements of the directive and any improvements which could be made to current arrangements with regard to systems of accreditation, “traceability” and “adverse incident reporting”. The scope of the work for this group is large when it comes to:-

- assessing the impact on hospital transfusion processes.
- assessing potential resource implications.
- communication with all relevant parties.
- delivery of recommendations.

## **Plan of Work**

As discussed above, the task is huge so it was decided the most effective use of time and resources would be to set up subgroups. These are laid out in the table below along with the convenor of each group. If anybody feels when reading this article that they have something they may wish to contribute to the working group please make contact with myself [joan.jones@wbs.wales.nhs.uk](mailto:joan.jones@wbs.wales.nhs.uk) or one of the convenors.

Group	Subject	Convenor
1	Electronic Tracking, IT, Traceability	John Barker <a href="mailto:john.barker@ghnt.nhs.uk">john.barker@ghnt.nhs.uk</a>
2	Adverse Events, Lines of Reporting, QMS	Martin Bruce <a href="mailto:martin.bruce@snbts.csa.scot.nhs.uk">martin.bruce@snbts.csa.scot.nhs.uk</a>
3	Training/Education, Communication	Teresa Turvey <a href="mailto:Teresa.turvey@nbs.nhs.uk">Teresa.turvey@nbs.nhs.uk</a>

There are other issues to be considered including autologous blood collection, irradiation, pooling of products in hospitals and transfusion other than within the hospital setting. Each group will consider the following aspects:

- Current status
- Issues
- Action plan
- Possible solutions
- Priority – short/long term
- Cost

It is hoped that just this area of work will be completed by October so that we can communicate this information to the DH. It is also hoped that any differences between the UK countries will be available for the representatives to discuss with Health Department colleagues.

### **Communication**

It is realised by the OIG that effective communication with hospitals is an “absolute must”. Whenever and whatever we have to report will be reported and the list is quite long, but if you can see from this list that we have left someone off - let me know.

● Transfusion Lab Managers	● Consultant Haematologists (responsible for transfusion)
● Transfusion Practitioners	● Chairs of Hospital Transfusion Committees (Chair CMO NTC)
● Regional Chairs Hospital Transfusion Committees	● SHOT
● Health Departments	● MHRA
● IT Group	● Risk Managers

It is also hoped that information, as it is available, and minutes of the meetings will be available on the JPAC website ([www.transfusionguidelines.org](http://www.transfusionguidelines.org)).

As I have said more than once if you have good ideas which you are willing to share – we want to hear from you.

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## **Better Blood Transfusion – How To Make It Happen**

In the Minister of Health's statement in December 2003 announcing the first possible case of transfusion transmission of vCJD, he referred to the fact that *"much more blood and blood products are used clinically than need to be used."* He commented that although *"past attempts had been made to reduce the use of blood to situations where it is absolutely needed medically, these had only been partially successful"* and he called for more effective action.

In response, on 7<sup>th</sup> June 2004, the Chief Medical Officer (CMO), Professor Sir Liam Donaldson, hosted a meeting at the Royal College of Pathologists, chaired by Professor Ted Gordon-Smith, Chair of the National Blood Transfusion Committee (NBTC), and sponsored by the National Blood Service (NBS). The objective was to promote the importance and the implementation of the CMO's Better Blood Transfusion 2 Initiative (HSC 2002/009) and to discuss what more could be done to make it happen, hence the title "Better Blood Transfusion – How To Make It Happen". This meeting was organised for a selected audience, with invitations sent to Presidents of the Royal Colleges, professional Societies and institutions, whose members were likely to be blood users. To facilitate discussions, all members of the NBTC and the NBS Appropriate Use of Blood Sub-Group were invited along with representatives from Serious Hazards of Transfusion (SHOT), Blood Stocks Management Scheme (BSMS) and the MRC National Comparative Audit.

Three short keynote presentations were given following introductory remarks from the CMO. Professor Ted Gordon-Smith described the origins of the CMO's NBTC, how its role has evolved and how it is now functioning to promote Better Blood Transfusion through a network of Regional Transfusion Committees, with the support of active working sub-groups. The NBS Medical Director, Dr Angela Robinson, described the role that the NBS has been and is playing in supporting Better Blood Transfusion initiatives such as:-

- a nationally-led network of regional hospital transfusion teams (consultant, nurse and manager);

- the Appropriate Use of Blood Sub-Group of the NBS Executive;
- the NBS Systematic Reviews initiative (Cochrane collaboration)
- Clinical Studies Unit (MRC collaboration);
- funding and administering the Blood Stocks Management Scheme;
- funding for SHOT and the Joint Professional Advisory Committee (JPAC) machinery, which produces guidelines for the UK Blood Transfusion and Tissue Transplantation Services.

However, the point was made that the NBS can only facilitate Better Blood Transfusion by providing guidance, training, education and audit assistance but it cannot implement – that is down to NHS Trusts and their Hospital Transfusion Teams.

The third presentation was given by Professor Lindsey Davies, Chair of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT). She described how this committee delivers its role of advising Health Departments of the UK on measures to ensure microbiological safety of blood and tissues, whilst also maintaining an adequate supply of appropriate quality. Two key messages were:-

1. the need for an integrated national contingency plan to cope with short or long-term periods of blood shortages;
2. that shortages can be avoided in most circumstances through appropriate use of blood (up to 17%?)

A lively discussion ensued, led by the CMO, which resulted in the following messages and actions:-

### **Training and Education**

Good practice in transfusion must be seen as core knowledge for training, initially of SHOs and then SpRs, in all of the blood using specialties.

### **OUTCOMES TO DATE**

- Letter from Professor Gordon-Smith to all NBTC representatives of Royal Colleges, Faculties and Specialist Societies highlighting the importance of Better Blood Transfusion and the need for its implementation, with a request that a report of this meeting (key points provided) be circulated in their respective Bulletins and Newsletters (July 2004).
- Letter from Professor Sir Liam Donaldson, CMO, to Professor Sir John Temple, Chair of the Specialist Training Authority of the Medical Royal Colleges, regarding *"Improving Postgraduate Training in Appropriate Use of Blood"* (July 2004).

## **The Importance of Achieving the IT Capability That Is Required**

It will be important to ensure that hospital blood banking IT systems not only cater for the laboratory aspects of blood banking but are also capable of linking into the clinical aspects. A rolling audit of blood use is becoming essential. Electronic cross-matching will not only make the transfusion process safer, but will also save blood and it has the potential to enable streamlining of hospital transfusion services in the context of pathology modernisation networks.

## **The Importance of Better Blood Transfusion 2 and Management**

Instituting Better Blood Transfusion can become a properly organised project where the opportunities for efficiencies, both clinical and financial, can be realised if properly managed. Practice has demonstrated that where a specific manager is made part of the hospital Blood Transfusion Team, both financial and blood saving benefits do accrue. Standards will need to be established against which hospital performance can be assessed and will be necessary once the integrated plan for the management of blood shortages is implemented.

### **OUTCOMES TO DATE**

- Chapter in the CMOs Annual Report devoted to Better Blood Transfusion. Whilst re-emphasising all the recommendations of BBT2, particular focus is given to the need for post-graduate education and training programmes, contingency planning and the need for improved hospital IT systems to facilitate better blood stock management, traceability from donor to recipient and the routine monitoring of blood usage by clinical specialty. Improved IT is critical for the collection of information on the diagnoses and long-term survival of transfusion recipients, for the accurate prediction of future demand and for prioritisation of blood safety initiatives.
- Emergency Planning – development of an integrated plan for the management of blood shortages (NHS DH Gateway Ref 3344). The objective of this plan is that once implemented, management arrangements will ensure that blood is available for all essential transfusions to patients equally across the country, and that overall usage is reduced to ensure the most urgent cases receive the supply that is available.

## **The Need For A 'Toolkit'**

The web-based toolkit needs to be further developed to assist hospitals with implementation of the initiatives. It needs to be easily accessible, containing national guidance, audit tools and examples of good practice, providing current and timely information.

### **OUTCOME TO DATE**

- A UK-wide group led by the Department of Health (DH), supported by the NBTC, plans to develop a

web-based toolkit by the end of this year to assist Trusts with implementation. A working group has been convened to plan the content and maintenance of this site. *Watch this space!*

This was a dynamic meeting which certainly motivated all those present to maintain the impetus and drive to make Better Blood Transfusion happen, and you can rely on *Blood Matters* to keep you updated on progress.

### **Dr Angela Robinson**

NBS Medical Director and Chair, NBS Appropriate Use of Blood Sub-Group

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SERIOUS HAZARDS OF TRANSFUSION

# SHOT

## **Spotlight On SHOT**

### **Serious Hazards of Transfusion (SHOT) Annual Report 2003**

The 7<sup>th</sup> SHOT Annual Report for 2003 was launched at the Annual Progress Meeting on the 6<sup>th</sup> July 2004 at the Royal College of Physicians in London. This year's figures show an overall increase in the number of incidents reported (480 initial reports were received this year), but it is likely that this is related to the establishment of hospital transfusion teams and the appointment of Transfusion Practitioners, who drive greater vigilance, and hence reporting of errors, which may previously have gone unrecognised. There is also an overall downward trend in the number of ABO incompatible transfusions. This suggests that we may be starting to see improvement in the proportion of 'serious' events compared to overall events, which categorises a developing safety culture. The full report and summary can be downloaded from the website [www.shot-uk.org](http://www.shot-uk.org) along with presentations from the July meeting.

### **IBCT (Incorrect Blood Component Transfused)**

- IBCT continues to be the largest category of reported incidents. 358 reports were received this year, a further increase of 25% over the previous 12 months
- IBCT makes up 75% of all reports received
- Errors occur at all stages of the transfusion process; misidentification of patients' blood samples and blood components being the main source of the errors
- The most common site of failure continues to be failure of the bedside check (156 incidents out of a total of 588)
- 70% of reported errors occurred in clinical areas

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Reporting to SHOT is still 'voluntary', but hospitals are strongly encouraged by the UK Chief Medical Officers to participate. Evidence of participation is also required for the Clinical Negligence Scheme for Trusts ([www.nhs.uk](http://www.nhs.uk)) and to comply with Health Service Circular (HSC 2002/009) Better Blood Transfusion – Appropriate Use of Blood document ([www.doh.gov.uk/blood/bbt.htm](http://www.doh.gov.uk/blood/bbt.htm)). Reporting of serious adverse reactions to blood transfusion will become mandatory with implementation of the EU Directive 2002/98/EC on February 8<sup>th</sup> 2005.

### **Supporting SHOT**

Rebecca Gerrard, is employed by the National Blood Service as the Transfusion Liaison Nurse in the Northwest. As part of her role in supporting clinical colleagues in England to implement the initiatives in the HSC 2002/009, she is working with SHOT to raise the awareness and importance of reporting transfusion incidents that occur in hospitals. Rebecca is an invited member of the Standing Working Group and listed here are some of the key areas she has worked on with SHOT over the last few months:

- Facilitated a SHOT Workshop for Transfusion Practitioners in Northwest
- Delivered presentations about SHOT to a wide variety of groups.
- Following a pilot study, the results of which were submitted to the Steering Group for comment, conducted a national survey of all Transfusion Practitioners to better understand their knowledge of SHOT and its reporting system. Results are now being collated and a report and action plan will be submitted to the Steering Group.
- Written and piloted an 'Introduction to SHOT' which is now available on the SHOT website and includes definitions of SHOT categories, handy tips for completing the forms, a tool to measure compliance with the main SHOT recommendations, flow charts to help identify SHOT incidents and future challenges and changes for SHOT.
- Designed posters/PowerPoint slides for hospitals on 'Explanation of a Blood Pack Label' and 'Check for signs of Deterioration in blood, platelets and FFP'. A CD-ROM disk or colour A4 laminates of these pictures are available for Transfusion Practitioners. Please contact your regional Transfusion Liaison Nurse for more information.

Plans are being developed to further raise the profile of SHOT in hospitals and strengthen the link between SHOT and hospital staff, particularly the Transfusion Practitioners. Rebecca plans to assist hospitals to investigate and report transfusion incidents by providing frequent, regular information on SHOT and the reporting process. Root cause analysis of some specific IBCT incidents is to be conducted and summary reports submitted to the Steering Group. Specific learning points will be extracted from these events and reports produced to help health care staff

learn from errors that occur in the transfusion process. There are also plans to run education days on SHOT specifically for Transfusion Practitioners, the first one being in Manchester on 17<sup>th</sup> September. Discussions are underway for more training days in the South.

If you would like more information on SHOT or have other ideas on how SHOT can assist hospital staff with the investigation and reporting of incidents then please contact the SHOT office or Rebecca Gerrard.

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## **Getting Your Own Back – An Update On Autologous Transfusion**

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In January 2004, a document entitled 'A National Blood Conservation Strategy for NBTC (National Blood Transfusion Committee) and NBS (National Blood Service)', was presented to these bodies and it's recommendations accepted for implementation. One section deals with autologous transfusion.

Pre-operative autologous donation (PAD) prior to planned surgery was used extensively in the USA and Continental Europe from the mid 80's when there was increasing concern about the safety of donated blood. A limited amount of PAD was also introduced in the UK. Patients donate up to 4 units of blood in the month prior to planned surgery, whilst taking iron supplementation. The idea is that the patient's haemoglobin will rise between blood donations and that he/she will undergo surgery with a low-normal haemoglobin and a supply of autologous blood if transfusion is needed.

In practice, the haemoglobin rises little, if at all, between weekly autologous blood donations and the patient who embarks on a PAD programme with a haemoglobin (Hb) of 13g/dl will end up undergoing surgery with an Hb of approximately 10g/dl and 3 units of autologous blood in the blood bank. So the use of PAD with iron supplementation has suffered a decline in the USA and elsewhere and is no longer recommended by the NBS unless there are exceptional circumstances, eg a patient has a rare blood type or combination of antibodies which would make provision of donor blood very difficult. In these cases, autologous blood may be frozen in preparation for planned surgery.

If erythropoietin (Epo) as well as iron is used between autologous donations, then the patient's haemoglobin

level can be maintained. However, apart from the high cost of Epo, adverse effects of its use have been reported including deep venous thrombosis in elderly patients awaiting hip surgery and suppression of endogenous Epo so that patients remain anaemic post operatively. The NBS does not currently recommend the routine use of Epo in conjunction with PAD.

Acute normovolaemic haemodilution (ANH) is a procedure whereby 2 or 3 units of blood are collected immediately prior to surgery and the patient 'diluted' with crystalloids. The number of red cells lost by surgical haemorrhage will be reduced and the patient's autologous blood, containing active clotting factors and platelets as well as red cells, can be returned at the end of the operation. ANH is only suitable for surgical procedures where considerable blood loss is expected. Possible adverse effects include myocardial ischaemia, hypovolaemia, fluid overload and mis-identification of blood. The NBS Working Party on Autologous Transfusion considered that evidence for the efficacy of ANH is inconclusive, but that it may be of value when used together with intraoperative cell salvage (ICS). A recent meta-analysis of pre-operative acute normovolaemic haemodilution reported in *Transfusion* confirms this view, commenting that the literature supports only modest benefits from pre-operative ANH. The safety of the procedure is unproven due to the scarcity of reporting of adverse events and that widespread adoption of ANH cannot be encouraged.

During ICS, blood lost during surgery is anticoagulated, grossly filtered and collected in a sterile reservoir. The blood is then processed by a cell salvage device which separates, concentrates and washes the red cells and they are suspended in saline. 50-70% of the red cells shed can be salvaged and provide a supply of fresh oxygenated blood. The use of ICS has been shown to reduce allogeneic blood use in procedures where more than a litre of blood is lost. The risk of clerical error is minimised as the salvaged blood is transfused to the patient very shortly after collection. ICS is acceptable to the majority of Jehovah's Witnesses. There is a potential risk of air or fat embolism (modern machine technology ensures that such risks are very small), bacterial contamination and an enhancement of the inflammatory response by reinfusion of cytokines or complement.

The procedure is not suitable for all types of surgery. It is most often used for cardiac or vascular surgery and for orthopaedic procedures such as revision joint replacement and spinal surgery. It can also be used in radical hysterectomy, prostatectomy & cystectomy, major abdominal/thoracic trauma and liver, heart & lung transplant. The use of ICS during surgery for malignant disease, for gastrointestinal surgery and for postpartum haemorrhage, is not currently recommended, but it has been used for such procedures with the incorporation of an additional filtration step.

ICS is becoming cheaper and easier. There are three major manufacturers and machines can be rented or purchased. One manufacturer markets a machine which costs less than £5000 so that hospitals do not have to make a capital bid. Jehovah's Witnesses groups will sometimes assist with the purchase of machines. Harnesses now cost less than £100 each, which compares well with the cost of a unit of red cells. One harness per operative procedure is all that is required, and all manufacturers supply the harnesses in two parts. The suction device and reservoir can be set up first and this will cost about £20-£25. If haemorrhage is slight and the blood collected is not thought to be sufficient to warrant washing and reinfusion, the second part of the harness does not have to be opened and costs are minimised. Machines are simple to load and use and manufacturers will provide training for machine operators. Many hospitals use Operating Department Practitioners or Theatre Nurses to perform this task. It is essential that such staff are able to maintain and regularly update their skills. When setting up an ICS service, it is important to have an enthusiastic medical Consultant (usually an Anaesthetist or Perfusionist) to lead the implementation team. Quality monitoring of the product collected should be performed regularly.

The use of post-operative cell salvage (PCS) following joint replacement surgery is increasing. Blood collected post operatively via a drainage tube is collected, filtered and reinfused to the patient. There are several commercially available devices suitable for this purpose, all depending on a negative pressure in the collection vessel and a filter to remove any debris from the salvaged blood. The cost per patient is approximately £40. The blood collected is defibrinated, so fibrin degradation products are not present, but there is concern that because the blood is not washed, other contaminants may cause coagulopathy and that the filtered blood may contain potentially harmful cytokines. Blood must be transfused within 8 hours of wound closure. In practice this type of PCS has been undertaken without adverse effects, but by this method only 1 or 2 units of blood can be salvaged. There is much evidence in the literature to support the use of PCS, particularly for knee replacement surgery, although many such procedures do not require transfusion at all. There is little published evidence for the value of PCS for other surgical procedures.

One company has developed a machine that can be used in orthopaedic procedures, both intraoperatively and post operatively. Collection and washing of blood starts intraoperatively and then both patient and machine are moved to the ward where collection of blood via wound drains continues. The blood collected post operatively is washed and resuspended in saline before reinfusion to the patient. The harness cost per procedure is approximately £120.

The NBS Working Party on Autologous Transfusion concluded, as part of the National Blood Conservation Strategy, that ICS is currently the most valuable form

of autologous transfusion and that Trusts should be encouraged to establish its use where appropriate. Further studies are needed to investigate the safety of ICS in surgery for malignant disease and to study the value of ANH and PCS.

It has been estimated that, if all hospitals in England established the use of ICS with the current indications, for all procedures where a blood loss of more than one litre was anticipated, then more than 160,000 units of red cells per annum would be saved. This would not only represent a significant improvement in patient safety, but would make an enormous contribution to the conservation of blood stocks at a time of potential decline in donor numbers because of more stringent selection criteria.

## References

1. A National Blood Conservation Strategy for NBTC and NBS. Report from the Working Party on Autologous Transfusion and the Working Party on Alternatives to Transfusion of the NBS Sub-Group on Appropriate Use of blood. Compiled by Dr Virge James/January 2004.
2. Segal J B, Blasco-Colmenares E, Norris E J, Guallar E. Preoperative acute normovolemic hemodilution: a meta-analysis. *Transfusion* 2004; 44: 632-644

### Dr Jean Harrison

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### Note

If you require copies of the document (ref 1) or you have any enquiries or require NBS support for your autologous programme, please contact your NBS Regional Transfusion Liaison Nurse.

## Changes to the FFP Guidelines From The BCSH Transfusion Task Force (1992 to 2004)

In 1992, the BCSH Transfusion Task Force published guidelines on the use of FFP. These recommended that FFP be restricted to the replacement of single coagulation factor deficiencies, immediate reversal of warfarin effect, acute DIC and TTP. Use was conditionally recommended for massive transfusion, liver disease, cardiopulmonary bypass surgery and special paediatric indications (such as severe sepsis). Use for hypovolaemia, routine plasma exchange, 'formula' replacement, nutritional support and treatment of immunodeficiency states was stated as not justified. The 2004 revised guidelines largely reinforce these recommendations.

Several audits since 1992 have indicated considerable inappropriate use of FFP. A systematic identification

and appraisal of all randomised trials involving fresh frozen plasma undertaken in parallel to the drafting of the updated guidelines found that many areas of clinical use of FFP, as currently recommended, are not supported by evidence from randomised trials (Stanworth et al. What is the evidence base for the clinical use of FFP: a systematic review of randomised controlled trials. *Br J Haematol.* 2004;126:139-152).

The re-issue of the guidelines was, therefore, as much to re-inforce the general message to consider the appropriate use of FFP as to provide an update, and is specifically targeted to all clinical staff involved in care of acutely ill patients, from surgeons to biomedical scientists. The content is specifically British, with a clear explanation of the impact of vCJD on blood supply. Although this should not impact on the actual clinical decisions to use blood, implications for clinicians complicit in inappropriate use are thereby emphasised, quite apart from unnecessary morbidity, cost and waste.

Two important detailed differences relate to the blood group of the selected FFP – especially its Rh status – and the interval between thawing and clinical administration.

As previous guidelines have stated – including the recently issued guidelines on the use of blood for neonates and older children – the 1992 guidelines recommended that in view of the small amount of red cell stroma remaining in FFP, females of childbearing potential who are RhD negative should receive only RhD negative FFP. The 2004 FFP guidelines re-examined the evidence for this advice and concluded – as have other national authorities – that it is unjustified. RhD positive FFP can therefore be administered to RhD negative girls and younger women without the need for post-transfusion 'prophylaxis' with anti-D immunoglobulin. This also applies to cryosupernatant and cryoprecipitate (though not specifically stated in the text).

The 1992 guidelines recommended that FFP be 'administered with minimum delay (i.e. not more than 2 hours)'. However, post-thaw storage is allowed for up to 72 hours in parts of the USA, and apart from the labile factors (V, VIII, and vWF) clotting factor concentrations are well maintained at 4°C for up to 7 days. The 2004 UK guidelines recommend that post-thaw FFP may be stored at 4°C for 24 hours, which may ease some aspects of inventory control and issue.

The 2004 guidelines also give advice on the use of cryosupernatant (principally as an exchange medium in TTP) and cryoprecipitate (principally for hypofibrinogenaemia). Pathogen-reduced plasma (PRP), including solvent-detergent treated plasma such as 'Octaplas' (SD FFP) and methylene-blue/light treated plasma (MB FFP) are described and the case given for importing plasma from non-vCJD endemic countries for MB/light treatment for transfusion to children born after 1995. There is a useful table

comparing the properties of FFP, SD FFP and MB FFP, which also quotes figures for the risk of HIV, HBV and HCV transmission from standard FFP (very low).

Another development since 1992 has been the wider availability and use of near-patient clot test devices such as the Thrombo-elastogram (TEG).

The advice for reversing warfarin has been co-ordinated with advice from the Haemostasis Task Force of the BCSH, which also emphasises that no amount of FFP can be expected to completely correct the clotting time in severe liver disease (for example, prior to liver biopsy).

Use of FFP in neonates was discussed in more detail than in the 1992 guidelines. Specifically it was not recommended as a prophylactic for peri-ventricular haemorrhage in pre-term neonates. Regarding the very rare (but worrying) cases of red-cell T-antigen activation, in the absence of definitive data it was recommended that each unit prepare its own policies and protocols. PRP was also recommended for sick neonates with hypotension, sepsis, liver disorders and at risk of bleeding from an invasive procedure.

It is hoped that these will re-inforce appropriate use of FFP.

## **The New BCSH Guidelines for Frozen Components**

### **THE NEW GUIDELINES AND THE RH GROUP**

The recommendation in section 4.2 of the guidelines regarding Rh blood group compatibility states:

*Fresh-frozen plasma, MBFFP and SDFFP of any Rh type may be given regardless of the Rh status of the recipient. No anti-D prophylaxis is required if Rh D-negative patients receive Rh D-positive FFP.*

As a result of this the NBS is now issuing MB neonatal and paediatric FFP by ABO group only and not taking the RhD group into account. This began on 7<sup>th</sup> May for neonatal FFP and on 28<sup>th</sup> June for the paediatric component. This change will help to ensure the availability of these components, particularly as demand for group AB Rh D-negative MB FFP has greatly exceeded the original projections.

At this point the NBS has no plans to remove the Rh group label from any frozen components.

### **THE NEW GUIDELINES AND SHELF LIFE**

The recommendation in section 6.2 of the guidelines states:

*After thawing, and when FVIII replacement is not required, FFP and cryosupernatant may be stored at 4°C in an approved blood storage refrigerator before administration to the patient so long as the infusion is completed within 24 hours of thawing.*

The Standing Advisory Committee on Blood and Components (SACBC) are considering currently a revised wording for a new product label to reflect this change. Once confirmation of this change has been received from SACBC, the NBS will begin to produce components with the revised labelling. The NBS will provide information to hospitals of this change as soon as this information is received.

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## **Handy Hint: Storage of Compatibility Samples**

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The question has been raised recently of how long samples should be stored after compatibility testing, particularly in the context of investigating delayed haemolytic transfusion reactions. The joint IBMS/RCPATH document\* 'The Retention and Storage of Pathological Records and Archives' gives the following guidance.

### **Clotted blood for grouping, antibody screening and saving and/or cross matching:**

One week at 4°C

### **Serum from requests for grouping, antibody screening and saving:**

One week, optimally at -30°C or colder

### **Serum for cross matching:**

No minimum time is recommended. Storage should optimally be at -30°C or colder. May be stored for up to one month, and occasionally longer, prior to a planned procedure, provided no blood components are given during this time and that the patient has not been transfused or pregnant in the preceding four months.

### **Serum following a cross match or transfusion:**

One week. Storage should optimally be at -30°C or colder. This serum may only be used for the investigation of transfusion reactions and not further cross matching.

\* The Retention and Storage of Pathological Records and Archives. Report of the working party of the Royal College of Pathologists and the Institute of Biomedical Science. Second edition, 1999. The Royal College of Pathologists.

## CPD

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### Objective

After evaluating 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 participants scheme (for example 1 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.

### Next Edition

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The next edition of Blood Matters focuses on two areas – transfusion and IT, and appropriate use of blood and the better blood transfusion initiative. The role of IT in transfusion will be explored with articles on bedside identification, the national programme for IT, an explanation of SNOMED CT, and how to use the APEX browser. The theme of appropriate use of blood will be kicked off with the results of an audit of Better Blood Transfusion 2, recommendations on how to use the patient information leaflet following an audit, and further information on the paediatric patient information leaflet.

Be sure to get the next issue of Blood Matters, which is due out early next year. If you would like to receive a copy but are not currently on the mailing list please contact Charlotte Edbury (by email to [charlotte.edbury@nbs.nhs.uk](mailto:charlotte.edbury@nbs.nhs.uk) or by phone on 01865 440042).

### Erratum

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In the Winter 2003/2004 edition of *Blood Matters* (issue 14), an error occurred in the article entitled 'Principles of Blood Donor Selection', page 10, paragraph 2. The second sentence should read: "All three strategies are now used in the UK – the most recent development is the treatment of plasma for babies and young children with methylene blue and **white light** while processing it into FFP". A similar error also occurred in the CPD questionnaire on page 16. Question 6 should read: "Pathogen inactivation of FFP by methylene blue and **white light**".

## Diary Dates 2004-2005

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- 17-18 November 2004, *Transfusion Medicine Today*, Royal College of Pathologists, London. Contact: [michelle.casey@rcpath.org](mailto:michelle.casey@rcpath.org). Website: [www.rcpath.org](http://www.rcpath.org)
- 18 November 2004, *Third Annual Alternatives to Transfusion Meeting*, Winchester Guildhall, Winchester. Contact: [pat.darty@suht.swest.nhs.uk](mailto:pat.darty@suht.swest.nhs.uk)
- 23 November 2004, *Joint BBTS SIG and NIBSC Stem Cell Forum*, Potters Bar. Contact: [val.parry@nbs.nhs.uk](mailto:val.parry@nbs.nhs.uk) or [gathro@nibsc.ac.uk](mailto:gathro@nibsc.ac.uk)
- 26-28 November 2004, *ESH-HLA Medicine: Transplantations and Cell Therapies*, Sesimbra, Portugal. Contact [ghyslaine@esh.org](mailto:ghyslaine@esh.org) or [msimon@chu-stlouis.fr](mailto:msimon@chu-stlouis.fr). Website: [www.esh.org](http://www.esh.org)
- 4 December 2004, NBS Transfusion Science/Medicine Update, *It's Happened – Now What Do We Do?* (Transfusion Reactions & Mishaps), Royal Society of Medicine, London. Contact: [alan.devenish@nbs.nhs.uk](mailto:alan.devenish@nbs.nhs.uk)
- 4-7 December 2004, *American Society of Hematology 46th Annual Conference*, San Diego, California. Contact: [ash@hematology.org](mailto:ash@hematology.org). Website: [www.hematology.org](http://www.hematology.org)
- 1 March 2005, Consensus Conference – *Effectiveness and Safety of Blood Transfusion: Have We Lost The Plot?*, Royal College of Physicians, Edinburgh. Contact: [m.farquhar@rcpe.ac.uk](mailto:m.farquhar@rcpe.ac.uk).
- 11-13 April 2005, *4th British Society of Haematology 45th Annual Scientific Meeting*, Manchester. Contact: [sarah.lapsley@b-s-h.org.uk](mailto:sarah.lapsley@b-s-h.org.uk). Website: [www.b-s-h.org](http://www.b-s-h.org)
- 2-6 July 2005, *XV ISBT Regional Congress*, Athens, Greece. Contact: Eurocongres Conference Management, tel: +31 20 6793411; fax: +31 20 6737306 or email [isbt.athens@eurocongres.com](mailto:isbt.athens@eurocongres.com). Website: [www.isbt-web.org](http://www.isbt-web.org)
- 12 - 15 November 2005, *XVI ISBT Regional Congress*, Bangkok, Thailand. Contact: Eurocongres Conference Management, tel: +31 20 6793411; fax: +31 20 6737306 or email: [isbt.bangkok@eurocongres.com](mailto:isbt.bangkok@eurocongres.com). Website: [www.isbt-web.org](http://www.isbt-web.org)
- 2-6 December 2005, *Annual Meeting of American Society of Haematology*, New Orleans. Contact: [ash@hematology.org](mailto:ash@hematology.org). Website: [www.hematology.org](http://www.hematology.org)

## CPD Questionnaire

### Q1 Participation in SHOT

- a) All hospitals participated in the SHOT scheme
- b) Over 80% of hospitals participated in the SHOT scheme
- c) 85% of hospitals participated in the SHOT scheme
- d) Less than 80% of hospitals participated in the SHOT scheme

### Q2 Participation in SHOT

- a) All hospitals reported incidents
- b) Over 90% of hospitals reported incidents
- c) 85% of hospitals reported incidents
- d) Less than 80% of hospitals reported incidents

### Q3 Participation in SHOT

- a) Level of active participation has increased
- b) Level of active participation has remained unchanged
- c) Level of active participation has decreased

### Q4 The largest category of reported incidents is

- a) Transfusion-transmitted infection
- b) Transfusion-related acute lung injury
- c) Delayed haemolytic transfusion reaction
- d) Incorrect blood component transfused

### Q5 Incorrect blood component transfused IBCT incidents

- a) Have decreased over the previous equivalent 12 months
- b) Commonest error was failure of the pre-transfusion bedside check
- c) Less than 10% of errors occurred in the laboratories
- d) A single error was the cause in over 60% of events

### Q6 Transfusion-related lung injury

- a) Plasma rich components were implicated in over 90% of cases in which there was a proven leucocyte incompatibility
- b) Can be avoided by using whole blood
- c) Does not occur with the use of fresh frozen plasma or platelets
- d) Does not need specialised laboratory investigation to diagnose

### Q7 Fresh Frozen Plasma – FFP

- a) Should be used for reversal of warfarin, even in the absence of severe bleeding
- b) Patients with liver disease and a prothrombin time more than 4 seconds longer than control are likely to benefit from FFP
- c) When haemorrhage due to haemorrhagic disease of the newborn occurs, FFP is indicated, as well as intravenous vitamin K
- d) Routine administration of FFP to prevent intraventricular haemorrhage in preterm infants is indicated

### Q8 Fresh Frozen Plasma – FFP

- a) Must be same Rh D type as recipient
- b) Anti-D prophylaxis may be required if Rh D negative patient receives Rh D positive FFP
- c) FFP of any Rh type may be given regardless of Rh status of recipient

### Q9 Intra-operative cell salvage has been shown to reduce allogeneic blood use in procedures where

- a) More than 450ml of blood is lost
- b) More than 500ml of blood is lost
- c) More than 750ml of blood is lost
- d) More than 1000ml of blood is lost

### Q10 Post-operative cell salvage

- a) Blood collected has fibrin degradation products present
- b) Blood must be transfused within 8 hours of wound closure
- c) Blood does not contain cytokines
- d) Has a paucity of evidence in the literature to support its use