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# **A National Blood Conservation Strategy for NBTC and NBS**

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**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**

*(Sub-Group of the Blood and Tissue Safety Assurance Group)*

**Compiled  
by  
Virge James**

*Available to the NBTC Executive Group on 15<sup>th</sup> January 2004  
and  
Presented to the Appropriate Use of Blood Sub-Group on 27<sup>th</sup> January 2004*

# Contents

<b>Terminology Used</b>	..	..	..	..	..	..	..	..	..	2
<b>Executive Summary</b>	..	..	..	..	..	..	..	..	..	3
<b>Introduction</b>	..	..	..	..	..	..	..	..	..	4
<b>Chapter 1:</b>	Important considerations for ensuring appropriate transfusion in all patients									6
<b>Chapter 2:</b>	Alternatives to blood transfusion									8
<b>Chapter 3:</b>	Oxygen therapeutics									12
<b>Chapter 4:</b>	Blood use in surgical patients									15
	<ul style="list-style-type: none"> <li>• Preparing patients for surgery</li> <li>• Anaesthetic techniques to reduce blood use</li> <li>• Surgical techniques to reduce blood loss</li> <li>• Transfusion targets</li> <li>• Near patient testing</li> </ul>									
<b>Chapter 5:</b>	Autologous transfusion									28
	<ul style="list-style-type: none"> <li>• Pre-deposit Autologous Donation (PAD)</li> <li>• Intraoperative Cell Salvage (ICS)</li> <li>• Acute Normovolaemic Haemodilution (ANH)</li> <li>• Post-operative Cell Salvage (PoCS)</li> </ul>									
<b>Chapter 6:</b>	Recommendations for implementation and monitoring interventions									32
<b>Chapter 7:</b>	The emergency situation									41
<b>Chapter 8:</b>	Further research..									43
<b>Conclusion to Strategy Proposal</b>	..	..	..	..	..	..	..	..	..	47
<b>Background to Strategy Proposal</b>	..	..	..	..	..	..	..	..	..	48
<b>Appendix 1:</b>	Executive Summary of the Trent Peri-Operative Cell Salvage Pilot Study									56
<b>Appendix 2:</b>	Trent Intra-Operative Cell Salvage Data Collection Form									57
<b>Appendix 3:</b>	Executive Summary of the SchARR Report (Economic Analysis for Chapters 4 & 5)									58
<b>Acknowledgements</b>	..	..	..	..	..	..	..	..	..	59

# Terminology Used

Acute Normovolaemic Haemodilution:	ANH
Alternatives to Transfusion:	ALT
Autologous Transfusion:	AT
Autologous Transfusion Special Interest Group:	ATSig
Blood and Tissue Safety Assurance Group (NBS):	BTSAG
British Blood Transfusion Society:	BBTS
British Committee for Standards in Haematology:	BCSH
Economic Operational Research:	EOR
Health Technology Assessment:	HTA
Intraoperative Cell Salvage:	ICS
Joint UKBTS/NIBSC Professional Advisory Committee:	JPAC
Multi Disciplinary Team:	MDT
National Blood Transfusion Committee:	NBTC
Operating Department Practitioners:	ODP
NHS Purchasing and Supply Agency:	PaSA
Post-operative Cell Salvage:	PoCS
Preparing Patients for Surgery:	PPS
Pre-deposit Autologous Donation:	PAD
Regional Transfusion Committee:	RTC
School of Health and Related Research (Sheffield)	ScHARR
Thromboelastography:	TEG
Working Parties:	WP
Working Party on Autologous Transfusion:	WPAT
Working Party on Alternatives to Transfusion:	WPALT

# Executive Summary

This strategy proposing actions for the NBTC supported by the NBS has been prepared by Working Parties of the Sub-Group on Appropriate Use of Blood (Sub-Group of BTSAG). The recommendations are consistent with HSC 2002/009 Better Blood Transfusion: Appropriate Use of Blood and the NBS Business Plan for 2003/2004, which aims to “develop and maintain sound links with the wider health care community, so that we (the NBS) can actively encourage the implementation of BBT2”.

The Working Parties considered the following interventions to be most important to success and therefore the emphasis should be directed at these initiatives.

1. Education of all who prescribe and administer blood transfusions. Multidisciplinary cohesive approach.
2. Audit of all relevant practice with identified lines of implementation of audit findings and recommendations.
3. Preparing Patients for Surgery Clinics for all blood using elective surgery (estimated donor blood saving 246,000 units per annum - SchARR). Fit in with the NHS Plan 2000 – EOR to reassess impact and risk reduction.
4. Introduction of ICS as routine for all surgery where blood loss is expected to exceed 1 litre (estimated blood saving 160,000 units per annum - SchARR). EOR to assess cost benefit.
5. Facilitate research in relevant areas.

The Working Parties also considered the detailed implementation of these 4 key interventions and made recommendations. (The recommendations for implementation are detailed in Chapter 6 and the recommendations for further research are detailed in Chapter 8).

A short summary of this report has been distributed to the National Blood Transfusion Committee Executive Group for discussion on 15<sup>th</sup> January 2004.

# Introduction

When the Working Parties started their discussions it became apparent that the simple remits of analysing the roles of autologous transfusion and alternatives to transfusion, and the contribution these techniques could make in a blood shortage situation, inevitably led to suggestions which would result in better blood transfusion practice. The whole emphasis of the work of the Working Parties therefore changed, from considering a strategy in response to a possible donor blood shortage, to assessing blood conservation techniques as part of better transfusion practice regardless of possible pending blood shortages.

It is the view of the Working Parties, substantiated by the analysis by SchARR, that should all the initiatives outlined in the recommendations come to fruition then the overall need for donor blood would fall substantially. Such falls in demand are already evident and the 2003/2004 Business Plan for the NBS forecasts a drop of 2.5% in blood issues. The reasons are multifactorial ranging from educational efforts, to newer surgical techniques, with increasing general acceptance of lower transfusion trigger and economic factors. It will prove impossible to disentangle the influence of any particular aspect.

The cost implications of the recommended interventions have been touched on briefly, but much greater and more in depth analyses are required. This was not considered part of the remit of the Working Parties; nevertheless the analysis by SchARR provides a framework which can be further elaborated by EOR.

The literature on relevant subjects such as transfusion triggers, available drugs and available technologies has moved rapidly during the duration of the Working Parties and the report does not aim to contain a comprehensive list of references. Every section is limited to key references only which are presented at the end of the report.

## Current (2003) relevant systematic reviews in progress which will further inform the debate are:

- **Cochrane Collaboration**

A meta-analysis of effectiveness of cell salvage to minimise perioperative allogeneic blood transfusion in cardiac and orthopaedic surgery.

Systematic reviews of progress in 2002

- ☐ Cell salvage for minimising perioperative allogeneic blood transfusion.
- ☐ Erythropoietins for minimising perioperative allogeneic blood transfusion.
- ☐ Acute normovolaemic haemodilution for minimising perioperative allogeneic blood transfusion.

- **ISPOT: International Study of Perioperative Transfusions**

- ☐ Involves 10 countries and co-ordination through Ottawa.  
[www.lri.ca/programs/ceu/ispot/default.htm](http://www.lri.ca/programs/ceu/ispot/default.htm)

- **NICE**
    - ICS in malignancy under review 2003
    - Anaemia (chemotherapy-induced): erythropoetin (alpha and beta) and darbepoetin 2004
  - **Canadian Co-ordinating Office for Health Technology Assessment** <sup>(Ref. 1)</sup>
  - **Health Technology Assessment (UK)**
    - Proposal 2003: Cell Salvage – state of the art and cost effectiveness <sup>(Ref. 2)</sup>
1. Graham, I.D., Fergusson, D., McAuley, L. & Laupacis, A. (2000) The use of technologies to minimize exposure to perioperative allogeneic blood transfusion in elective surgery. A survey of Canadian hospitals. *Int J Technol Assess Health Care*, 16(1), 228-241.
  2. Cost effectiveness of cell salvage and alternative methods of minimising perioperative allogeneic blood transfusion. Contact: Ms Linda M Davies, Health Economics Research at Manchester (HERaM), School of Psychiatry & Behavioural Sciences, University of Manchester, Oxford Road, Manchester, M13 9WL.

# Chapter 1: Important considerations for ensuring appropriate transfusion in all patients

Good transfusion management should be viewed as good management of the patient who is at risk of transfusion <sup>(Ref. 1)</sup>. Success is to transfuse only when the benefits outweigh the risks. Good practice implies that measures to prevent or pre-empt the need to transfuse should be fully utilised. This statement embraces many aspects of routine clinical management as well as the use of specific blood conservation measures.

The prescribing clinician should:

**1. Anticipate and plan ahead for the situation that may necessitate transfusion and aim to reduce the chance that the patient will actually need to be given blood**

Correct any anaemia: where possible stop medications that may impair haemostasis: make sure there is no clinical history suggestive of a bleeding disorder, and if there is, investigate it in time.

**2. If transfusion has to be given.** The following should be available :

A simple protocol that everyone uses that ensures that blood is available promptly and safely when needed

Systems that ensure that the reason for giving a transfusion is always written in the patient's case record

A simple protocol that everyone uses for keeping the patient under observation during the transfusion

Systems for independent audits of practice

Safe and efficient and non wasteful supply of blood to the patient depends on excellent co-operation between the blood bank, the clinical users and the hospitals transport, portering, and communications systems.

## Improved Prescribing of Blood

Guidelines recommend that clinicians prescribing red cell transfusions <sup>(Ref. 2 & 3)</sup> should be aware of the appropriate indications, and the risks and benefits of transfusion together with possible alternatives including autologous transfusion. However, the evidence of very significant variation in the use of blood, for example as provided by the Sanguis study <sup>(Ref. 4)</sup> and recent audits of the use of blood in the UK suggest that currently available guidelines have little impact on clinical practice.

The prescription of blood is the responsibility of medical staff. The task of providing education and training in the appropriate use of blood for the multitude of senior and junior medical staff is considerable. Transfusion is practiced throughout all disciplines and seldom features on medical education courses. This has been recognised and a Health Service Circular HSC 2002/009 Better Blood Transfusion <sup>(Ref. 5)</sup> appropriate use of blood sets out specific actions for Chief Executive of NHS Health Authorities, NHS Trusts PCTs and Directors of Public Health.

This HSC also sets deadlines for action on a number of key initiatives, mostly for April 2002 and April 2003. A previous HSC 1998/224 had made similar recommendations but not outlined actions nor set deadlines. When the implementation of this was surveyed <sup>(Ref. 6)</sup>. It was found that by 2001

most hospitals had established HTC's and developed protocols for the process of transfusion and were participating in SHOT, but there was limited compliance with all other recommendations including training of relevant staff.

A similar survey of the effect of HSC 2002/009 is in progress.

A number of the initiatives outlined have been used in different parts of the world, for example restricting the prescription of blood for non-urgent transfusion to a limited number of clinicians (Marconi et al, 1996) <sup>(Ref. 7)</sup>.

Reductions in the use of blood have been shown by the use of computer requesting of transfusions using agreed algorithms and referral of unapproved requests to a haematologist (Lapierre et al, 2000) <sup>(Ref. 8)</sup>.

**Recommendation:** Continue to support and monitor the implementation of all initiatives outlined in HSC 2002/009.

**Appropriate Organisation:** NBTC

1. Hill, S.R., Carless, P.A., Henry, D.A., Carson, J.L., Hebert, P.C., McClelland D.B.L. & Henderson, K.M. (2002) Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. *Cochrane Database Syst Review*, **2**, CD002042.
2. The Handbook of Transfusion Medicine. ISBN 0-11-322427-3 and [www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk)
3. British Committee for Standards in Haematology (BCSH). Guidelines on the clinical use of red cell transfusions. *British Journal of Haematology*, 2001, **113**, 24-31.
4. The Sanguis Study Group (1994). Use of blood products for elective surgery in 43 European hospitals. *Transfusion Medicine*, **4**, 251-268.
5. HSC 2002/009 Better Blood Transfusion Appropriate use of blood [www.doh.gov.uk/publications/coinh.html](http://www.doh.gov.uk/publications/coinh.html)
6. Murphy, M.F., Edbury, C., & Wickenden, C. (2003) Survey of the implementation of the recommendations in the Health Services Circular 1998/224 'Better Blood Transfusion'. *Transfusion Medicine*, **13**, 121-125.
7. Marconi, M. et al. Quality assurance of clinical transfusion practice by implementation of the privilege of blood prescription and computerized prospective audit of blood requests. *Transfusion Medicine*, 1996, **6**, 11-19.
8. Lapierre, V. et al. Implementation of a specific approval process for blood components prescription. *Lancet*, 2000, **355**, 465.



## Chapter 2: Alternatives to blood transfusion

### 2.1. Iron Supplementation

The Health Survey for England conducted in 2000 shows a very high prevalence of iron deficiency. Using a lower cut-off of 13g/dl in men and 12g/dl in women the prevalence of anaemia was 4.1% in men and 10.8% in women. In those older than 75 years of age 25% of men were anaemic compared with 14% of women. In people with a normal haemoglobin 19.9% of men and 16.5% of women had low ferritin levels. Overall 1.6% of men and 6% of women had low haemoglobin together with low ferritin. In men the highest prevalence of low haemoglobin and low ferritin were seen in the over 65s (4.5%). In women the highest prevalence of low haemoglobin with low ferritin was in the age range 16-44 years (7.2%). Samples taken from children between the ages of 11-15 showed prevalence of anaemia of around 1% (haemoglobin less than 11g/dl for both sexes). The elderly in care homes were found to be 2.5 times more likely to be anaemic than those in private households. The prevalence of anaemia increased from the age of 65 to 80.

These data showed that iron deficiency anaemia and iron depletion are a major public health issue even in a Western industrialised country such as England. People suffering from iron deficiency who then undergo further physiological stresses are much more likely to require blood transfusions. Women who are pregnant or breast feeding, anyone undergoing surgical procedures or anyone suffering from other illnesses, such as malignancy or heart disease or renal failure, will be more likely to become symptomatically anaemic. Blood transfusion corrects the anaemia temporarily but does not treat the iron deficiency.

In the surgical setting that the 'risk of transfusion' is magnified several fold in the presence of sub-normal pre-operative haemoglobin. Conversely those going for elective surgery (e.g. hip replacement) with a mid-normal haemoglobin are unlikely to require blood.

The assessment of iron status in both medical and surgical patients and the appropriate management of iron deficiency would reduce the need for blood transfusion in all the groups of patients mentioned above. Both oral iron tablets and intravenous iron sucrose are inexpensive products compared with the transfusion of red cells or the use of erythropoietin.

### 2.2. Recombinant Human Erythropoietin

Erythropoietin (EPO) is a haemopoietic growth factor normally produced by the kidney in response to anaemia and low oxygen tension. It stimulates the production of red cells in the bone marrow. The use of recombinant human erythropoietin (rHuEPO) has become standard treatment of the anaemia of chronic renal failure in which endogenous EPO production is reduced by failure of kidney function.

Erythropoietin levels can be demonstrably low in patients with malignancy. For example those with chronic lymphocytic leukaemia, myeloma, non Hodgkin's lymphoma and many solid tumours. Anaemia in malignancy may also be due to marrow infiltration by disease, the direct effect of cancer chemotherapy, or non-specific inhibition of marrow red cell production ('anaemia of chronic disease') as well as iron deficiency.

There is now a wealth of literature <sup>(Ref. 3, 5, 6 & 7)</sup> in the scientific press supporting the use of erythropoietin in some groups of patients with malignancy to alleviate the symptoms and

signs of anaemia. In many cases a reduction in the need for blood transfusion has been demonstrated.

ASCO/ASH have produced guidelines for the use of erythropoietin in patients with cancer with emphasis on its use in those with haemoglobin less than 10g/dl.

Randomised studies between EPO and IV iron sucrose are very few and more data should be gathered in this area to delineate which patient groups may benefit from iron therapy alone and which require iron and EPO or EPO alone.

The efficacy of EPO in alleviating anaemia in non-malignant conditions has been less investigated<sup>(Ref. 8 & 9)</sup>. Initial studies in anaemia of chronic heart failure, connective tissue and inflammatory conditions such as rheumatoid arthritis, critically ill patients and premature infants look exciting but again more data is required. In all these patients lack of bio-available iron may be a significant contributing factor to anaemia and studies are required to try and assess which patients would benefit most from EPO therapy.

## 2.3. Summary

There is no doubt that iron deficiency is more prevalent than realised and that this in turn results in an excessive and unnecessary need for blood transfusion. The timely identification and correction of iron depletion in patients would mean that less blood transfusion therapy was required. There is a role for erythropoietin in malignancy and in other medical conditions, as well as in the pre-operative surgical setting. However this is a costly product and its use should be confined to those areas where simple measures such as treatment of iron deficiency are ineffective or inappropriate.

1. Rizzo, J.D. *et al* (2002) Use of Epoetin in patients with cancer: Evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Haematology. *Blood*, **100** (7), 2303-2320
2. WHO/Health Survey for England 2000
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4. Millman, N. *et al* (1999) Iron status and iron balance during pregnancy. A critical reappraisal of iron supplementation. *Acta Obstet. Gynecol. Scand*, **78**, 749-757
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6. Corwin, H.L. *et al* (2002) Efficacy of recombinant human erythropoietin in critically ill patients. A randomised controlled trial. *JAMA*, **288**(22), 2827-2835.
7. Vamvakas, E.C. *et al* (2001) Meta-analysis of controlled clinical trials studying the efficacy of rHuEPO in reducing blood transfusion in the anaemia of prematurity. *Transfusion*, **41**, 406-415

8. Murphy, E.A. *et al* (1994) Study of erythropoietin in treatment of anaemia in patients with rheumatoid arthritis. *BMJ*, **309** (6965), 1337-1338
9. Earnshaw, P. (2001) Blood conservation in orthopaedic surgery: the role of epoetin alpha. *International Orthopaedics (SICOT)*, **25**, 273-278

## 2.4. Platelet Substitutes – State of the Art 2003

None are clinically available. The three ongoing projects are:

1. **Synthocytes** (fibrinogen coated albumin microspheres). There is ongoing theoretical interest. Data shows reasonable shortening of bleeding time in thrombocytopenic rabbits<sup>(Ref. 1)</sup>.
  1. Levi, M., et al (1999) Fibrinogen-coated albumin microcapsules reduce bleeding in severely thrombocytopenic rabbits. *Nature Medicine*, **5**(1), 107-111.
2. **Infusible platelet microvesicles** (made from outdated platelets - the Dutch central laboratories). This is the only "substitute" product that has been infused to patients and showed some correction of bleeding time in a few thrombocytopenic patients (as it does in the rabbit model).
3. **Freeze dried platelets**. Work progressing.

Other approaches are:

- Growth factors – (see table) - TpO and PEG-MGDF - only IL-11 and TpO continue and latter not yet licensed. IL-11 is in specific indications.
- Recombinant factor VIIa - the manufacturer is gathering data on use in platelet deficiency.

Prowse, C. (1999) Alternatives to standard blood transfusion: availability and promise. *Transfus Med.* **9**(4), 287-99. Review.

**Table 1. Platelet Substitutes**

Product	Type	Developer	Status	Ref
Frozen platelets	in DMSO	Wayne State US Army & Navy	Phase I	Lee & Blajchman, 1998 Reid et al 1999
Thrombosol	frozen in DMSO	Lifecell Corporation	Limited experience	Currie et al, 1999
NeoRx	?frozen in anti-freeze glycoprotein	A/F Protein	Pre-clinical	Lee & Blajchman, 1998
Quadrocytes	trehalose air dried	Quadrant (Pall)	Phase I	Menys et al, 1998
	dried in amphipathic polymers	(Cryopharm) Cobe	Pre-clinical	Lee & Blajchman, 1998
	aldehyde fixed + freeze-dried	Bode (Centeon)	Pre-clinical	Bode et al, 1999
Cyplex	IPM (infusable platelet membranes)	Cypress	Phase II (on hold)	Chao et al, 1996
Thrombospheres	fibrinogen + albumin microspheres	Hemosphere	Pre-clinical	Yen & Yorba, 1996
Synthocyte	fibrinogen + albumin microsphere	Andaris/Quadrant	Phase I/II	Levi et al, 1999
Thromboerythrocytes	RGDS peptide on red cells	Coller/SUNY	Pre-clinical	Lee & Blajchman, 1998
-	Liposome + inserted glycoprotein GPIb/IX	Green Cross	Pre-clinical	World patent WO 97/29128
-	Lipid mixtures	Alving/Galan	Pre-clinical	Alving, 1998

**Table 2. Endogenous Modulators**

Cell type	Modulator	Status	Reference
Red cell	epO (erythropoietin)	licensed	Spivak, 1994
	NESP	Phase III (Amgen)	Amgen, 1999
	mimetic	Pre-clinical	Wrighton et al, 1997
Platelet	TpO (thrombopoietin)	Phase II/III	Kaushansky, 1995; Kuter et al, 1999 SCRIP, 1998 Hamblin 1997
	PEG-hMGDF	Abandoned	
	IL-3	Phase II	
	IL-6	Phase II	
	IL-11 (Neumega)	Niche licence	
	scf (stem cell factor)	Phase III	
	Promegapoietin (TpO/IL-3)	pre-clinical	
	Progenipoietin (flt3.GCSF)	pre-clinical	
	Mimetic	pre-clinical	Cwirla et al, 1997

# Chapter 3: Oxygen therapeutics

## Background

Research and development with so-called ‘blood substitutes’ has been on going for over 20 years. Available formulations should be more accurately described as ‘red cell substitutes’ or ‘oxygen therapeutics’<sup>(Ref. 1)</sup>. Although there is much talk about these none are currently available in the United Kingdom, even on a “named patient” basis. Nevertheless it is important to be aware of current developments.

### 3.1. Chemically-Modified Haemoglobin <sup>(Ref. 2 & 3)</sup>

- Animal (bovine) haemoglobin (*Hemopure*<sup>TM</sup>, *Haemospan*<sup>TM</sup>, *Haemospan PS*<sup>TM</sup>).
- Human haemoglobin (e.g. *HemoLink*<sup>TM</sup>).
- Bioengineered (recombinant) haemoglobin.(e.g. *Optro*<sup>TM</sup>)
- Liposome-encapsulated haemoglobin.

#### *Hemopure*<sup>TM</sup>

*Hemopure*<sup>TM</sup> (Biopure Corporation, Cambridge, MA, USA), based on pyridoxylated, glutaraldehyde-polymerised, bovine haemoglobin, received regulatory approval in South Africa in 2001 for clinical use in the treatment of acute anaemia and avoidance of allogeneic blood during surgery in adults. *Hemopure*<sup>TM</sup> is licensed to Tshepo Pharmaceuticals Ltd (SA) and the product will be launched commercially in early 2003. There are concerns over the acceptability to the UK public of a bovine haemoglobin-based product because of concerns about the transmission of BSE. There is also a risk that such animal haemoglobin may adversely affect the human immune system, especially on repeat infusion.

#### *Haemospan*<sup>TM</sup>, *Haemospan PS*<sup>TM</sup> (Sangart)

Polyethylene glycol codified human Hb<sup>(Ref.4)</sup>.

#### *HemoLink*<sup>TM</sup> (Hemosol Inc.)

*HemoLink*<sup>TM</sup> is based on O-raffinose intra- and inter-molecular cross-linked human haemoglobin and manufactured. However it was just announced in March 2003 that Hemosol has suspended clinical trials.

#### Bioengineered (recombinant) haemoglobin

Human haemoglobin has been produced from both genetically modified micro-organisms and plants. This avoids using human or animal blood as starting material, thereby overcoming cultural and ethical objections to animal or human donor blood-derived haemoglobin and the theoretical problem of transmitting infections. Such recombinant molecules are, in principle, virus free and contain no residual red cell membrane contaminants. The most advanced material in this category is *Optro*<sup>TM</sup> (Baxter, Deerfield, IL, USA) that contains cross-linked haemoglobin (rHb1.1) and is produced in *Escherichia coli* through the expression of a modified human haemoglobin gene. Clinical efficacy (Phase II) trials with *Optro*<sup>TM</sup> in surgical patients were completed in 1999. Recombinant haemoglobins are a logical way forward for oxygen therapeutics since ‘tailor-made’ molecules can, in principle, be produced.

Recombinant technology has been used to produce haemoglobin mutants having altered affinity for nitric oxide, thereby overcoming the transient, but unwanted, hypertensive side-effects that have been considered as a major flaw in the ultimate usefulness of haemoglobin-based blood substitutes. It is expected that such technology will come to the forefront in coming years.

### **Liposome-encapsulated haemoglobin**

One fairly recent development has been the encapsulation of haemoglobin within biodegradable polymer membranes as the first step to producing so-called 'synthetic red cells'. Other refinements have been to entrap anti-oxidant enzymes, especially superoxide dismutase and catalase, with haemoglobin to create a microenvironment that much more closely resembles that of the natural red blood cell. This is ambitious, basic research that is soon expected to yield a range of 'third-generation' haemoglobin-based blood substitutes for clinical testing.

## **3.2. Synthetic, Inert, Perfluorinated Compounds**

- Droplets (< 0.2  $\mu\text{m}$  diameter) of perfluorochemical (PFCs) in emulsion with aqueous disperse phase.

The second broad approach to the development of blood substitutes involves the use of PFC liquids that dissolve large volumes of respiratory gases. For use in the blood circulation, PFCs must be prepared as emulsions. This is because PFC liquids are immiscible in aqueous systems, including blood plasma.

### ***Oxygent*<sup>TM</sup>** (Ref. 5 & 6)

The current front runner amongst 'second-generation' commercial PFC emulsions is *Oxygent*<sup>TM</sup> (Alliance Pharmaceutical Corporation, San Diego, CA, USA) containing 58% (w/v) perflubron and 2% (w/v) perfluoro-decyl bromide, stabilised with 3.6% (w/v) egg yolk phospholipids. *Oxygent*<sup>TM</sup> is sterile, non-pyrogenic and stable for > 1 year when stored refrigerated. *Oxygent*<sup>TM</sup> has been evaluated in Phase III clinical trials as a temporary intravascular oxygenation fluid for use in patients undergoing potentially high blood loss (typically 3 units or more) surgery, including cardiopulmonary bypass (CPB) procedures.

Reports on clinical safety (Phase I) studies using *Oxygent*<sup>TM</sup> infused intravascularly into healthy volunteers (1.2-1.8 g PFC kg<sup>-1</sup> body weight) indicated that there were no marked adverse effects on blood coagulation parameters, excepting a 17% reduction in the platelet count after 3 days with the higher dose. Some subjects also exhibited minor flu-like symptoms, coupled with an increased serum interleukin-6 concentration, at 24 h after receiving the emulsion. Multiple-site Phase II trials with *Oxygent*<sup>TM</sup> in surgical patients began in the USA and Europe during 1995-96. In one study, patients were initially subjected to acute normovolaemic blood dilution (ANH) with a colloidal plasma expander to collect *ca.* 2 units of fresh autologous blood from each individual immediately before surgery. A single bolus dose of a 90% (w/v) perflubron emulsion (0.9 g PFC kg<sup>-1</sup> body weight) was infused into 100% oxygen-breathing patients as an alternative to blood. Infusion of the emulsion was followed by a 17% increase in mixed venous oxygen tension, an index of tissue oxygenation. In a larger clinical study, infusion of Perflubron emulsion (1.8 g of kg<sup>-1</sup> body weight) combined with 100% oxygen breathing was more effective than autologous blood or colloid solution in reversing physiologic transfusion triggers. Such use of relatively low doses of PFC emulsion to maintain tissue oxygenation means that autologous blood can be conserved

and re-infused into the patient towards the end of surgery, or in the post-operative period, as needed. Thus, the use of PFC emulsion in conjunction with ANH not only minimises the need to infuse allogeneic blood, but also allows surgery to be initiated at a lowered packed cell volume, thereby reducing red cell loss during subsequent bleeding.

By November 2000, over 1300 surgical patients had received *Oxygent*<sup>TM</sup> during the Phase II clinical trials. Multi-centre Phase III clinical studies with *Oxygent*<sup>TM</sup> in surgical patients were initiated in 1998. An Alliance press release on 19 October 2001 reported that intravenous *Oxygent*<sup>TM</sup> during CPB surgery significantly improved post-operative gastrointestinal tract function. The same statement also indicated that, in a separate study involving 492 general surgery patients, treatment with *Oxygent*<sup>TM</sup> reduced both the frequency and volume of intra-operative blood use

In 2001, Alliance voluntarily suspended enrolment in a Phase III cardiac surgery study with *Oxygent*<sup>TM</sup> to evaluate what appears to be an increased incidence of stroke in patients in the treatment arm relative to those in the control group. In March 2002, an Alliance Press release announced a re-structuring of European Phase III studies with *Oxygent*<sup>TM</sup> to focus, in future, on its use in surgical patients (with no ANH) as an alternative to donor blood.

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# Chapter 4: Blood use in surgical patients

## General Principles

Major surgery is associated with transfusion in the minds of most patients and clinicians, but large numbers of major procedures are done without recourse to the blood bank. The most striking examples are those units that specialise in “bloodless surgery” for those whose beliefs preclude transfusion. The patterns of blood use among many different units performing the same procedures on very similar patients vary. This is acknowledged world-wide.

There is no clear evidence at the moment linking patient outcome to blood use, although some published work seems to suggest that a restricted transfusion policy is linked to better outcomes <sup>(Ref.1)</sup>.

It is interesting to note that much detailed work is currently being undertaken by the DoH (e.g. NHS Modernisation Board, NICE, HTA) and surgical societies (e.g. Association of Anaesthetists, Vascular Surgeons, Gastrointestinal Surgeons) but they seldom include blood transfusion. This situation should be rectified by the work of the NBTC.

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## 4.1. Preparing Patients for Surgery

All patients should be properly prepared for the surgery they require. This approach is consistent with the NHS Plan 2000 “putting patients and people at the heart of the health service”.

The NHS Modernisation Agency [www.modern.nhs.uk](http://www.modern.nhs.uk) has launched good practice guidelines to assist NHS Trusts to improve patient’s experience.

**The strategy proposal is that the “preparing patients for surgery” clinics should also explore the aspects of patient health relevant to their requirements for blood transfusion both autologous and allogeneic. Although the proposals from the NHS Modernisation Board outlined in National Good Practice Guidance on Pre-Operative Assessment for Inpatients/Day Surgery are detailed proposals they do not take account of transfusion requirements. This needs to be added in the plans.** (See Pre-operative Assessment for Inpatient Surgery Contents list on page 17)

The development of Multi Disciplinary Teams, the NHS National Booked Admission Project (launched in 1998, and compulsory by 2005 for all Trusts, every test, appointment and procedure) all indicate the need for thorough assessment of surgical patients.

NICE has recently published guidance on preoperative tests [www.nice.nhs.uk](http://www.nice.nhs.uk). (See NICE Contents lists on page 18 and 19)



#### 4.1.1. Assessment of patients specific to blood conservation

- Diagnosis of any anaemia: Iron deficiency is very common in the UK (see Chapter 2). Iron deficiency can be corrected over a reasonably short period (8-12 weeks) either by oral iron or more speedily by intravenous iron (estimate 1-2 weeks).
- Diagnosis of any bleeding disorder: Previously undiagnosed bleeding disorders are common and can lead to greater use of donor blood if not known about prior to surgery. Consider specific questions about bleeding history in standard pre-surgical assessment.
- Assessment of patient's current medication, its potential for increasing bleeding tendency and impact on recovery: Commonly used drugs increase bleeding time - aspirin, NSAIDs, coumarins. Some of these drugs can be stopped prior to surgery, others may need to be continued but the surgical team need to be aware.
- Identification of problems which may require specialist intervention (sickle cell disease, ITP, PTP, presence of red cell antibodies).
- Patient beliefs (e.g. Jehovah's Witnesses <sup>(Ref.1)</sup>).

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#### 4.1.2. Organisation of clinics/Staffing/Timing

The suggestion in the NHS modernisation guidance [www.modern.nhs.uk/theatreprogramme/preop](http://www.modern.nhs.uk/theatreprogramme/preop) should be followed. They include primary care as well as secondary care.

#### 4.1.3. Protocols

Clinics should prepare protocols to be followed and documented. Protocols should include the blood tests to be carried out depending on the medical history of the patient and initial FBC.

NICE has produced in June 2003: Pre-operative Tests. The use of routine pre-operative tests for elective surgery (National Collaboration Centre for Acute Care). These include consideration of when a full blood count is necessary. Local haematologists should be involved in deciding local protocols.

#### 4.1.4. Examples of effective practice in preparing patients for surgery

(Also see [www.modern.nhs.uk](http://www.modern.nhs.uk))

- The Royal Brompton and Harefield Trust, pilot hospital for the NHS National Booked Admission Project <sup>(Ref. 1)</sup>.
- Sheffield United Teaching Hospitals Trust: Patients for bowel surgery (JAR Smith)
- Good Hope Hospital NHS Trust

- North Middlesex University Hospital NHS Trust
  - Doncaster and Bassetlaw Hospitals NHS Trust
  - South Derbyshire Acute Hospitals NHS Trust
  - Princess Alexandra Hospital NHS Trust
1. National benchmarking audit of blood and component use in primary myocardial revascularisation. NBS & Royal Brompton and Harefield Trust.

#### 4.1.5. Contents page of the Pre-operative Assessment for Inpatient Surgery

### National Good Practice Guidance on Pre-operative Assessment for Inpatient Surgery

Contents	Page
1. Introduction	2
2. The objectives of pre-operative assessment	5
3. The pre-operative assessment process for inpatient surgery	6
3.1 Who should undergo pre-operative assessment	6
3.2 When should pre-operative assessment take place?	11
3.3 Where should pre-operative assessment take place?	11
3.4 Who should perform pre-operative assessment?	12
3.5 Risks, benefits and informed consent	15
3.6 What should happen after pre-operative assessment?	15
3.7 What information should be given to patients?	17
3.8 How should records be kept?	18
3.9 How should the pre-operative assessment service be audited?	19
3.10 Is the pre-operative service suitable for training?	20
3.11 Examples of effective practice	21
Appendices	
A 12 key points on consent	23
B Fasting guidelines	25
C References & links	26
D Acknowledgements	28
E Pre-operative assessment pilot sites	29

Electronic copies of this guidance and examples of good practice documents  
are available from  
[www.modern.nhs.uk/theatreprogramme/preop](http://www.modern.nhs.uk/theatreprogramme/preop)

#### 4.1.6. Contents pages from NICE

## Contents

	Abbreviations and Glossary of Terms	3.5	Preoperative haemostasis tests	33
	Guideline Development Group Membership and Acknowledgements	3.6	Preoperative biochemistry tests	34
		3.7	Preoperative urine tests	35
		3.8	Preoperative pregnancy tests	36
		3.9	Preoperative sickle cell disease/trait tests	37
		3.10	Preoperative lung function tests	37
		3.11	Preoperative blood gas tests	38
<b>1</b>	<b>Introduction</b>	<b>4</b>	<b>Interview Results:</b>	
1.1	Background		<b>Testing the Assumptions</b>	40
1.2	Objectives of the guideline	4.1	Interview part 1: reasons for testing	40
1.3	The purpose of the guideline	4.2	Interview part 2: physiological models	43
1.4	Who developed the guideline?	4.3	Interview part 3: sickle cell testing	45
1.5	Scope of the guideline	4.4	Interview part 4: pregnancy testing	46
<b>2</b>	<b>Methods</b>	<b>5</b>	<b>Consensus Results</b>	47
2.1	Outline of methods used	5.1	Membership of consensus panels	47
2.2	Assembly of an advisory group	5.2	Development of the consensus questionnaire	47
2.3	Aims and scope of the guideline	5.3	First round of consensus	47
2.4	Systematic review methods	5.4	Second round: consensus meetings	47
2.5	Economic review of the cost of tests included in the guideline	5.5	Presentation of results	48
2.6	Choice of development method by formal consensus	5.6	General comments and assumptions made by the panellists	48
2.7	Testing the assumptions: informal consensus interviews with surgical trainees and consultant anaesthetists	5.7	Definitions of consensus and key to the results tables	49
2.8	Consensus: selection of consensus panel	5.8	Chest x-ray	49
2.9	Development of the consensus questionnaire	5.9	Resting electrocardiogram (ECG)	52
2.10	Consensus: round 1 – initial rating	5.10	Full blood counts	54
2.11	Consensus: round 2 – meeting	5.11	Haemostasis tests	57
2.12	Drafting the guideline	5.12	Renal function tests	59
2.13	Adjustments made in light of comments from stakeholders	5.13	Random blood glucose tests	61
<b>3</b>	<b>Findings from the Systematic Review of the Literature</b>	5.14	Urine analysis	64
3.1	Papers identified for the review	5.15	Testing of blood gases (ASA grades 2 and 3 only)	67
3.2	Preoperative chest x-rays	5.16	Lung function tests	68
3.3	Preoperative electrocardiograms	5.17	Tests for sickle cell disease/trait	70
3.4	Preoperative haemoglobin, haematocrit and full blood count tests	5.18	Pregnancy testing	71

<b>6</b>	<b>Guideline for Preoperative Investigations in Patients Undergoing Elective Surgery</b>	<b>72</b>	<b>Appendices</b>
			(Please see attached CD ROM)
6.1	Types of recommendation	72	Appendix 1 Results of a Systematic Review of the Literature for Routine Preoperative Testing
6.2	Level of evidence and grading for recommendations	72	Appendix 2 Examples of Surgical Procedures by Severity of Grading
6.3	How to use this guideline	73	Appendix 3 Phase A consensus questionnaire (results)
6.4	ASA grade 1 Adults (age ≥ 16 years)	77	Appendix 4 Phase B consensus questionnaire (results)
6.5	ASA grade 1 Children (age < 16 years)	78	Appendix 5 Economics of routine preoperative testing
6.6	ASA grade 2 with cardiovascular disease comorbidity	79	<b>Contents of CD ROM</b>
6.7	ASA grade 3 Adults with cardiovascular disease comorbidity	80	Full guideline
6.8	ASA grade 2 Adults with comorbidity from respiratory disease	81	NICE guideline (short guideline)
6.9	ASA grade 3 Adults with comorbidity from respiratory disease	82	Information for the Public
6.10	ASA grade 2 Adults with comorbidity from renal disease	83	Appendices
6.11	ASA grade 3 Adults with comorbidity from renal disease	84	
6.12	Grade 1 surgery	88	
6.13	Grade 2 surgery	90	
6.14	Grade 3 surgery	92	
6.15	Grade 4 surgery	94	
6.16	Neurosurgery	96	
6.17	Cardiovascular surgery	96	
6.18	Tests for sickle cell gene adults and children	97	
6.19	Pregnancy testing	97	
6.20	Good practice recommendations	98	
6.21	Implementation in the NHS	99	
6.22	Audit criteria	100	
6.23	Costs and cost-effectiveness	100	→
<b>7</b>	<b>Discussion and Research Recommendations</b>	<b>102</b>	
7.1	Limitations of the guideline	102	
7.2	Factors not considered in the development of the guideline	104	
7.3	Research recommendations	106	

## 4.2. Anaesthetic Techniques to Reduce Blood Use

### 4.2.1. General

There are some basic things that the anaesthetist and surgeon can do to reduce blood loss during surgery:

- positioning of the anaesthetized patient so as to minimize any venous congestion in the operating field
- the use of local vasoconstrictors
- the sequencing of a multi stage procedure. (ex: a coronary artery bypass procedure where the saphenous vein is harvested by one member of the team as another is opening and preparing the chest. The vein harvester needs to close his operation site fully before ascending to assist with the chest)

### 4.2.2. Specific

There are also some specific procedures that may help in reducing transfusion and these are discussed below.

- Preventing Hypertension

Good anaesthetic management should involve preventing the patient becoming hypertensive (and provoking excessive bleeding), and in major surgery this needs to be supported by good post operative analgesia (lest the patient bleed excessively post-operatively). This is especially important in cases where there are suture lines in major vessels e.g. cardiac or vascular cases.

- Preventing Hypothermia

Unintentional hypothermia is to be avoided as this will contribute to post operative shivering, acidosis and possibly even coagulopathy. Pannen <sup>(Ref. 6)</sup> found a drop in core temperature of over 2 degrees C had been recorded in more than 50% of all patients undergoing an operation. While this may not be applicable in the UK it emphasizes the importance of monitoring the temperature during anaesthesia and taking all necessary steps to prevent hypothermia.

- Controlled hypotension

This has been defined as a reduction of systolic blood pressure to 80 to 90 mm Hg, a reduction of mean arterial pressure (MAP) to 50 to 65 mm Hg or a 30 point reduction of baseline MAP <sup>(Ref. 1)</sup>. This reduction can be obtained using a variety of agents in conjunction with the anaesthesia and has been shown to reduce blood loss in certain surgical procedures <sup>(Ref. 2)</sup>. The reduction in bleeding may make the operative field easier for surgery as in the previous reference, or the technique may be employed as a blood sparing measure. For a procedure to be used to reduce exposure to allogeneic blood, the procedure should itself have a safety level that is comparable with allogeneic blood. In the case of controlled hypotension, this is arguable. The technique has been associated with adverse events such as unexplained visual loss following spinal surgery <sup>(Ref. 3)</sup>; it appears to be contra-indicated in surgery for sub-arachnoid haemorrhage <sup>(Ref. 4)</sup> and has been described by Jones as “a controversial technique and it may be argued that it is inappropriate in modern anaesthetic practice” <sup>(Ref. 5)</sup>. The technique cannot be advocated for widespread use until it is supported by better safety data than the above.

- Aprotinin, DDAVP and Tranexamic acid

The subject of drugs to reduce blood loss in cardiac surgery has been reviewed by Laupacis and Fergusson <sup>(Ref. 9)</sup>, Aprotinin and Tranexamic acid were both proven to be effective, whereas routine use of DDAVP was not.

Aprotinin is a non-specific protease inhibitor that has been shown to be effective in reducing blood loss in cardiac surgery. The initial studies were in repeat coronary artery surgery (CABG) however Rich <sup>(Ref. 7)</sup> reviewed 21 studies in first time CABG demonstrating anywhere from 33% to 66% reduction in blood loss. Only fifteen of the studies showed a reduction in blood use, probably because factors other than just blood loss govern transfusion requirements. The real issue is whether Aprotinin predisposes CABG patients to early graft failure. Many trials have shown a higher incidence of graft failure in the aprotinin group, but it has never reached statistical significance (even in the meta-analyses) as the studies were powered to look at blood usage and not graft failure rate. The IMAGE study was a very large multi center study designed to answer this sort of question, but the conclusions were not totally clear. Alderman <sup>(Ref. 8)</sup> using data from the IMAGE study concluded that in a subgroup of patients with more adverse characteristics predisposing to early graft failure, aprotinin did significantly increase the occlusion rate (23% versus 12.4%).

More widespread use of aprotinin would certainly reduce blood loss and to some extent reduce transfusion in CABG patients, but would it actually increase the risks to these patients?

Tranexamic acid is cheaper than aprotinin and has not been “tainted” by the debate regarding early graft failure. This however only reflects the fact that to date it has not been as extensively researched as aprotinin. Both drugs work in similar ways and if one of them has a potential to cause early graft failure, it would be wrong to assume in the absence of data that the other did not. The routine use of these drugs in cardiac surgery will continue to be controversial. Their use in specific situations like redo valve surgery, and in patients with active endocarditis who require urgent surgery is proven and uncontroversial.

- Fibrin Sealant

Fibrin sealants have been used in surgery for over 20 years. They generally contain fibrinogen (with or without factor XIII) and thrombin (plus calcium with or without antifibrinolytic drugs) which can be applied to a wound surface sequentially or simultaneously.

Systematic review<sup>(Ref. 10)</sup> of the use of fibrin sealant to minimize perioperative allogeneic blood transfusion concluded that the overall results suggest that fibrin sealants are efficacious. It suggests that large methodologically rigorous trials of fibrin sealants with clinical outcomes are needed.

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### 4.3. Surgical techniques to reduce blood loss

#### Mechanical methods to reduce surgical bleeding

These can be categorized in two broad groups: Dissecting instruments and Topical haemostatic agents.

##### 4.3.1. Dissecting instruments

The ideal haemostatic instrument should allow the surgeon to dissect tissues while simultaneously applying an energy source to reliably and rapidly achieve haemostasis, with little injury to surrounding tissues. No such tool currently exists but some instruments are able to provide a degree of haemostasis or spare significant blood vessels during tissue cutting; these include:

- monopolar diathermy knife
- bipolar scissors
- lasers
- ultrasonic dissector/coagulator (harmonic scalpel)

These instruments ensure a variable degree of haemostasis at the expense of some surrounding tissue damage and they have been successfully used to achieve a relatively bloodless field in various types of surgery.

#### 4.3.2. Topical haemostatic agents

These are substances which, applied locally, expedite haemostasis by activating coagulation. Several compounds have been used and are commercially available, including oxidised cellulose, calcium alginate, fibrin-based, gelatin-based and thrombin-based sealants. Topical haemostatic agents come either as a sheet containing the active compound, or as a fluid, which is mixed and activated 'in situ', and have been shown to achieve haemostasis more rapidly than simple pressure in a variety of settings, mainly in cardiovascular surgery. Their influence on transfusion requirements however is more difficult to ascertain. Although these compounds are supposed to be absorbable, serious complications have been reported, particularly with oxidised cellulose (probably the most widely used) forming persistent masses requiring secondary surgery, or even leading to paraplegia, when used near the spine. Sealants prepared from human sources may, theoretically, transmit infectious agents, including vCJD.

The relevance of haemostatic dissecting instruments and topical haemostatic agents versus individual surgical technique is questionable. However, while further evidence is still needed, every surgeon should be aware of the possible benefits of such tools in relation to type of surgery performed and personal technique, and, if necessary, implement one or more of them to achieve minimal blood loss.

#### 4.4. Transfusion Targets

There is considerable variation in view about what a suitable level of haemoglobin is for a patient recovering from major surgery. Transfusion rates have been shown to be dependent on a number of factors, but one of the most important of these is the surgical and anaesthetic team<sup>(Ref. 1)</sup>. Speiss<sup>(Ref. 2)</sup> and colleagues found that a high initial haematocrit on arrival in ITU after cardiac surgery was an independent predictor of q wave myocardial infarction. In the management of critically ill patients in intensive care, the TRICC study<sup>(Ref. 3)</sup> found that the group managed with a conservative transfusion strategy (Hb 7-9 g/dl) did significantly better than a group given a liberal transfusion management (Hb 10-12 g/dl) in terms of in-hospital mortality, adverse cardiac events, rate of organ dysfunction and overall transfusion rates. The transfusion rates were 54% lower. The beneficial effects of the restrictive transfusion strategy were more evident for patients with APACHE scores below twenty or those below 55 years of age.

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#### 4.4.1. Specific Recommendations - An example of indication codes for transfusion – Dr Mike Murphy

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### INDICATION CODES FOR TRANSFUSION – AN AUDIT TOOL

The indications for transfusion provided below are taken from UK national guidelines for the use of blood components (see references). Although it is accepted that clinical judgement plays an essential part in the decision to transfuse or not, the purpose of drawing available transfusion guidelines together into one short document is to help clinicians decide when blood transfusion is appropriate, and to minimise unnecessary exposure to transfusion.

Each indication has been assigned a number, which may be used by clinicians when requesting blood or for purposes of audit. Specific details regarding the patient's diagnosis and any relevant procedures to be undertaken should also be provided.

These are current guidelines and may change depending on new evidence.

#### Red cell concentrates

##### **R1. Acute blood loss (*British Committee for Standards in Haematology, 2001*):-**

Objective: to maintain circulating blood volume and haemoglobin (Hb) concentration > 7 g/dl in otherwise fit patients, and > 9g/dl in older patients and those with known cardiovascular disease.

*15-30% loss of blood volume (800-1500ml in an adult):* transfuse crystalloids or synthetic colloids. Red cell transfusion is unlikely to be necessary.

*30-40% loss of blood volume (1500-2000ml in an adult):* rapid volume replacement is required with crystalloids or synthetic colloids. Red cell transfusion will probably be required to maintain recommended Hb levels.

*>40% loss of blood volume (>2000ml in an adult):* rapid volume replacement including red cell transfusion is required.

##### **Peri-operative transfusion (*Association of Anaesthetists, 2001; British Committee for Standards in Haematology, 2001; Scottish Intercollegiate Guidelines Network, 2001*):-**

Many patients undergoing elective surgical operations should not require transfusion support if their Hb concentration is normal before surgery. Assuming normovolaemia has been maintained, the Hb can be used to guide the use of red cell transfusion.

R2. Hb concentration below 7g/dl.

R3. Hb concentration below 9 g/dl in a patient with known cardiovascular disease, or those with significant risk factors for cardiovascular disease (e.g. elderly patients, and those with hypertension, diabetes mellitus, peripheral vascular disease).

##### **Critical Care (*British Committee for Standards in Haematology, 2001*):**

R4. Transfuse to maintain the Hb >7g/dl.

#### Post-chemotherapy

R5. There is no evidence-base to guide practice. Most hospitals use a transfusion threshold of a Hb of 8 or 9g/dl.

#### Radiotherapy

R6. Transfuse to maintain Hb above 10g/dl.

##### **Chronic anaemia (*British Committee for Standards in Haematology, 2001*):-**

R7. Transfuse to maintain the haemoglobin just above the lowest concentration which is not associated with symptoms of anaemia. Many patients with chronic anaemia may be asymptomatic with a haemoglobin concentration >8g/dl.

**Fresh frozen plasma** (British Committee for Standards in Haematology, 1992)

(Dose - 12-15 ml/kg body weight equivalent to 4 units for an adult)

- F1. Replacement of single coagulation factor deficiencies, where a specific or combined factor concentrate is unavailable e.g. factors V.
- F2. Immediate reversal of warfarin effect, in the presence of life-threatening bleeding.
- F3. Acute disseminated intravascular coagulation (DIC) in the presence of bleeding and abnormal coagulation results.
- F4. Thrombotic thrombocytopenic purpura (TTP), usually in conjunction with plasma exchange.
- F5. Massive transfusion, coagulation factor deficiency can be expected after blood loss of 1.5 x blood volume, aim for PT & APTT < 1.5 of the control value.
- F6. Liver disease, to correct bleeding or as prophylaxis before surgery when the prothrombin time is >1.5 the control value.

**Cryoprecipitate**

(Dose - 1 unit/5kg body weight equivalent to 10 units for an adult)

- C1. Acute disseminated intravascular coagulation (DIC), where there is bleeding and a fibrinogen level < 1g/l.
- C2. Advanced liver disease, to correct bleeding or as prophylaxis before surgery, when the fibrinogen level < 1g/l.
- C3. Bleeding associated with thrombolytic therapy causing hypofibrinogenaemia.
- C4. Hypofibrinogenaemia (fibrinogen level < 1g/l) secondary to massive transfusion
- C5. Renal failure or liver failure associated with abnormal bleeding where DDAVP is contraindicated or ineffective

**Platelet concentrates** (British Committee for Standards in Haematology, 1992; Consensus Conference on Platelet Transfusion, 1998; Schiffer et al for the American Society of Clinical Oncology, 2001)

(Dose - 15 ml/kg body weight equivalent to 1 adult therapeutic dose for an adult)

Bone marrow failure

- P1. To prevent spontaneous bleeding when the platelet count <  $10 \times 10^9/l$ .
- P2. To prevent spontaneous bleeding when the platelet count <  $20 \times 10^9/l$  in the presence of additional risk factors for bleeding such as sepsis or haemostatic abnormalities.
- P3. To prevent bleeding associated with invasive procedures. The platelet count should be raised to >  $50 \times 10^9/l$  before lumbar puncture, epidural anaesthesia, insertion of intravascular lines, transbronchial and liver biopsy, and laparotomy, and to >  $100 \times 10^9/L$  before surgery in critical sites such as the brain or the eyes.

**Critical care/surgery**

- P4. Massive blood transfusion. The platelet count can be anticipated to be <  $50 \times 10^9/l$  after 1.5-2 x blood volume replacement. Aim to maintain platelet count >  $50 \times 10^9/l$ .
- P5. Bleeding, not surgically correctable and associated acquired platelet dysfunction e.g. post-cardiopulmonary bypass, possibly combined with the use of potent anti-platelet agents such as clopidogrel.
- P6. Acute disseminated intravascular coagulation (DIC) in the presence of bleeding and severe thrombocytopenia.
- P7. Inherited platelet dysfunction e.g. Glanzmanns thrombasthenia with bleeding or as prophylaxis before surgery.

Immune thrombocytopenia

- P8. Autoimmune thrombocytopenia, in the presence of major haemorrhage.
- P9. Post-transfusion purpura, in the presence of major haemorrhage.
- P10. Neonatal alloimmune thrombocytopenia, to treat bleeding or as prophylaxis to maintain the platelet count >  $50 \times 10^9/l$ .

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## 4.5. Near Patient Testing

Near patient testing, in this context, means using simple laboratory equipment in operating theatres. Two in particular are relevant:

- Measuring Haemoglobin
- Assessing coagulation status

### 4.5.1. Haemoglobin

Simple to use and reliable apparatus is available, which requires minimal training. For successful use laboratories and theatre staff should work together in introducing these to theatres so as to ensure clear responsibility for Quality Control of the equipment<sup>(Ref. 1)</sup>.

### 4.5.2. Assessing coagulation status: Thromboelastography

The TEG is a near patient monitor which analyses the visco-elastic properties of whole blood and produces graphic displays, easily interpreted in operating theatres. These results can demonstrate primary fibrinolysis, secondary fibrinolysis, the effects of excessive heparinisation, or excess protamins.

Easy to follow protocols can be used correlating TEG values and traces, with clinical causes and suggesting appropriate corrective actions (such as volumes of FFP to be infused). The patient's progress can be monitored with successive tests.

Further research into the benefits of using TEG is needed (see Chapter 8).

The TEG is in use in numerous cardiac operating theatres. One of its main advantages is the speed of results obtained by operating staff<sup>(Ref. 2)</sup>.

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2. Shore-Lesserson, L., Manspeizer, H.E., DePerio, M., Francis, S., Vela-Cantos, F. & Ergin, M.A. (1999) Thromboelastography-guided transfusion algorithm reduces transfusions in complex cardiac surgery. *Anesth Analg.*, **88**(2), 312-319

## 4.6. Audit

The decision making process behind why patients are transfused is not well documented in many Trusts, and even when it is there is often inadequate resource available to audit the process. A number of Trusts have developed audit systems for transfusion that provide feedback to clinicians on how much blood they are using in particular surgical procedures and have found the process beneficial in reducing transfusion rates. Since audit should be non confrontational and seen as a tool to improve practice and used in all Trusts.

NBS/RCP national comparative audit programme will begin carrying out national audits of appropriate use in surgery (and medicine) in late 2003/early 2004.

## Chapter 5: Autologous Transfusion

Autologous transfusion occurs when the donor and the recipient are the same person. However, this type of transfusion is not suitable for all patients. There are different forms of autologous transfusion and all require careful selection of suitable patients.

### 5.1. Pre-deposit Autologous Donation (PAD)

#### Recommendations for Preoperative Autologous Blood Donation

The use of PAD has been extensively reviewed <sup>(Ref. 1)</sup>.

Limited use of PAD:

1. For patients who have extremely rare blood types or combinations of red cell antibodies, where suitable donor blood is not available. If such patients require planned surgery, then autologous blood should be collected well in advance of the planned procedure and the red cells frozen. As an alternative, erythropoietin may be used for patients with rare blood in order to maintain haemoglobin levels during PAD. (Pregnant patients with rare blood types or combinations of red cell antibodies and for whom allogeneic blood is not available, should donate their blood during the first trimester of pregnancy for freezing and storage).
2. PAD is currently recommended for patients donating bone marrow (BM). This includes children, although PAD for paediatric BM donors will be organised within a hospital setting. This use of PAD with iron supplementation for BM donors is under review, since PAD tends to lower the haemoglobin level at which the patient undergoes bone marrow harvest in the same way as it does for patients undergoing other planned procedures.
3. For patients who are fit enough to donate preoperative autologous blood and are so fearful of receiving allogeneic blood, that they are reluctant to undergo planned surgery unless they can donate their own blood preoperatively. Patient demand has increased due to heightened awareness of this procedure, but inappropriate requests should be resisted.

The WPs do not recommend that PAD (with iron supplementation) should be undertaken in any situations other than those listed above. There is evidence that if erythropoietin is used, then haemoglobin levels can be maintained whilst the patient is donating several units of autologous blood. But the use of erythropoietin in conjunction with PAD is not recommended at present except in a very limited number of circumstances.

1. Cochrane Systematic Review 2002 (2) CD 003602.

### 5.2. Intraoperative Cell Salvage (ICS)

The WPs considered ICS as an important development and regretted that the UK generally lagged behind Europe and the US in using these techniques.

Intraoperative cell salvage (ICS) is a method of scavenging blood from the operative field and re-infusing it back into the patient. The most widely used method for performing ICS is by

centrifugal cell separation. Published guidelines are available for the practice of ICS <sup>(Ref. 1)</sup>, and a Cochrane review is in progress <sup>(ref. 2)</sup>.

### 5.2.1. Advantages of ICS

- Fresh red cells that would otherwise be lost are reinfused.
- Provides a ready supply of blood that is available in proportion to the losses that are occurring.
- Reduces allogeneic blood usage in surgical procedures associated with significant blood loss (>1000ml in adults).
- Is at least cost neutral when used appropriately <sup>(Ref. 2)</sup>.
- By minimising exposure to allogeneic blood, reduces the risk of immunomodulation and post-operative infection
- Should be associated with no risk of clerical error.
- Acceptable to the majority of Jehovah's Witnesses

### 5.2.2. Disadvantages of ICS

- Use restricted: currently contraindicated in malignancy, contaminated fields and sickle cell anaemia. The aspiration of procoagulants (e.g. amniotic or ascitic fluid, haemostatic agents) also presents theoretical risks and should be avoided.

### 5.2.3. Suitable procedures

ICS should be considered for patients undergoing surgery where the anticipated surgical blood loss exceeds 1000ml. Within surgical procedures blood losses might vary. Where blood losses are highly variable for a given operation, it would be advisable to collect the blood in cell salvage reservoirs, reserving the decision to process as appropriate. Individual surgeons would be advised to audit their practice to optimise the use of ICS.

The following are examples of suitable procedures:

Orthopaedics:	Major spinal reconstructions Revision joint replacement (non-infected)
Cardiac:	All major procedures
General:	Major hepatectomies Pelvic clearances Major abdominal/thoracic trauma Accident & Emergency
Urology/Gynaecology:	Radical cystectomy Radical prostatectomy Radical hysterectomy
Transplant:	Liver/heart/lung
Vascular:	Elective or emergency aortic reconstructions
Jehovah's Witnesses:	All surgical procedures where blood loss is expected to have an impact (in contraindicated procedures the relative risks should be taken into account).

### 5.2.4. Considerations

- Who operates the machine?

- How should they be trained?
- Competency testing and accreditation
- Liability/responsibility
- Availability in emergency situations

The experience of the Trent Pilot has resulted in the following recommendations:

- Hospitals should identify the staff they wish to use the ICS equipment
- These staff should be trained by key trainers or trained by the company
- Certificates of competence should be issued by the hospital
- A record of training and assessment of on-going competency should be documented
- With the development of the ULH electronic training package this should be made available throughout the NHS and private hospitals in England.
- The training package could be funded by the companies and thus be constantly updated (currently being negotiated).
- An assessment tool could be attached to the training package which will issue certificates and also serve as a management tool for monitoring staff competencies.
- This could become a module in the NVQ for ODPs, although other staff could also undertake the training (currently being investigated).

Solutions to training issues are outlined in the Trent Pilot Report.

1. Napier, J.A., Bruce, M., Chapman, J., Duguid, J.K., Kelsey, P.R., Knowles, S.M., Murphy, M.F., Williamson, L.M., Wood, J.K., Lee, D., Contreras, M., Cross, N., Desmond, M.J., Gillon, J., Lardy, A. & Williams, F.G. (1997) Guidelines for autologous transfusion. II. Perioperative haemodilution and cell salvage. British Committee for Standards in Haematology Blood Transfusion Task Force. Autologous Transfusion Working Party. *Br J Anaesth*, **78**(6), 768-771.
2. Laupacis, A., Fergusson, D., Henry, D.A., Moxey, A.J., Carless, P.A., Salmi, R., Rubins, F., Koopman van Gemert, A., Huet, C. (2003) Cell salvage for minimising perioperative allogeneic blood transfusion (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 3, 2003. Oxford: Update Software
3. Haynes, S.L., Torella, F., Wong, J.C., Dalrymple, K., James, M., McCollum, C.N. (2002). Economic evaluation of a randomized clinical trial of haemodilution with cell salvage in aortic surgery. *Br J Surg*; **89**(6):731-736.

### **5.3. Acute Normovolaemic Haemodilution (ANH)**

The WPs considered the evidence on ANH was inconclusive and further work is needed to establish its efficacy (see Chapter 8: Further Research).

## **5.4. Post-Operative Cell Salvage (PoCS)**

Use of Post-operative Cell Salvage is increasing. Nevertheless the WPs considered the evidence for PoCS is inconclusive and further work is needed (see Chapter 8: Further Research).



## Chapter 6: Recommendations for Implementation and Monitoring Interventions

The recommendations of the WPs fall into 3 separate categories:

- interventions
- effective implementation of interventions
- effective monitoring of implementation

The key interventions are:

- a) education
- b) widespread introduction of PPS
- c) introduction of ICS and near patient testing where appropriate
- d) audit of implementation

Suggestions for further relevant research are made in Chapter 8.

The previous chapters have detailed the recommended interventions. We feel confident that these will prove to be substantiated by work in progress by other bodies; Cochrane, HTA and varying audits in progress in the hospitals and NBS.

This chapter makes recommendations for the effective introduction of the interventions and monitoring of the implementation.

If all professional “learned societies” nominated one of their members to undertake liaison with transfusion specialists much duplication of work could be saved.

### 6.1. Education

All staff involved in transfusing patients whether prescribing blood or administering blood and components need to be fully aware of the appropriate guidelines. Blood Transfusion is an integral part of most modern medicine but often ignored by specialists other than haematologists.

**Recommendation:** *Identify one key web-site for such guidelines which will need to link to other relevant sites. The prime candidate for this function is [www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk).*

**Appropriate Organisation(s):** JPAC, BCSH, NBTC

#### 6.1.1. Further guidelines are needed

In the UK the current guidelines for the use of autologous transfusion are lacking. The BCSH is in the process of reviewing the guidelines for PAD, but we also need such guidelines for ICS, PoCS and possibly ANH. The Scottish Intercollegiate Guidelines Network produced

guidance in 2001, but these will be updated in 2003 [www.sign.ac.uk/guidelines/fulltext/index](http://www.sign.ac.uk/guidelines/fulltext/index) (Ref. 1).

Guidelines are available from other countries; the AABB has produced its first edition of Standards for perioperative autologous blood collection (Ref. 2). However such guidance needs to be adapted to the prevailing circumstances in the UK.

1. The Scottish Intercollegiate Guidelines Network: Perioperative blood transfusion for elective surgery SIGN Publication No. 54, ISBN 1899893 77 6, Published October 2001.
2. AABB: Standards for perioperative autologous blood collection and administration. AABB 2001, ISBN 156395 143 6 and Guidelines to these standards ISBN 156395 164 9.

One hindrance to the further introduction to ICS is the standing recommendation that it should not be used for malignant surgery. Available evidence shows that this recommendation needs to be reviewed to facilitate such use, at least in carefully defined conditions. More hospitals with large malignant surgery units, but lacking cardiac or vascular surgery, could then participate in ICS. The misunderstandings surrounding clinical governance have made surgeons reluctant to use this technique without the full backing of their Trust, and they require accepted peer approved guidelines.

**Recommendation:** Multidisciplinary task forces develop guidelines for ICS & PoCS soon so the best practice is introduced in this area. Although the WPs do not recommend widespread use of PoCS the practice is creeping in without any guidelines.

**Appropriate Organisation(s):** Involved Professional Societies

### 6.1.2. Changing clinical practice

Putting guidelines and new learning into practice is proving a challenge for all organisations.

Much research work has been published in this field (Ref. 1). The Health Development Agency (HAD) took over from the Health Education Authority in April 2000. Its core purpose is to “build and disseminate the evidence base for public health, focusing on reducing inequalities”. Although the main targets are the general public, the HDA is actively researching which interventions yield the best results. The main interventions which have been used to change transfusion practice among clinicians are prospective audits and education.

One particular intervention “academic detailing” or “educational outreach”, introduced in the 1980s, is currently receiving attention world-wide (Ref. 2).

This intervention involves individual face to face educational exchange between specialists with expert knowledge of a practice, and the physician whose practice needs to be changed. It has been shown to be one of the more successful interventions but further data needs to be collected on the economics of such time and specialist intensive interventions.

**Recommendation:** Encourage appointment of lead committed clinicians with the recognised responsibility of promoting these interventions locally. This can be achieved through Hospital Transfusion Committees but needs to be resourced

**Appropriate Organisation(s):** NBTC and Hospital Trusts

1. Wilson, K., MacDougall, L., Fergusson, D., Graham, I., Tinmouth, A. & Hebert, P.C. (2002) The effectiveness of interventions to reduce physician's levels of inappropriate transfusion: what can be learned from a systematic review of the literature. *Transfusion*, **42**(9),1224-1229.
2. Soumerai, S.B., Salem-Schatz, S., Avorn, J., Casteris, C.S., Ross-Degnan, D. & Popovsky, M.A. (1993) A controlled trial of educational outreach to improve blood transfusion practice. *JAMA*, **270**(8), 961-966.

### 6.1.3. Continuing Professional Development: life long learning

An acknowledged effective means of changing clinical practice is peer pressure. This requires multidisciplinary communication of better clinical practice.

Every medical and surgical specialty has a learned professional society. Blood transfusion is a medical intervention which suffuses most such practice and therefore introducing sessions on blood transfusion to such society meetings is an excellent way of increasing awareness and sharing better practice in transfusion. This is beginning to happen but should be encouraged further.

**Recommendation:** The momentum is maintained by ensuring that the relevant societies and professional bodies have blood transfusion/conservation on their agendas.

**Appropriate Organisation(s):** Involved Professional Societies – nominate “leads” for transfusion, NBTC to suggest.

Consensus statements from the professional bodies also have a role to play in changing clinical practice. However, to develop such consensus statements data is required on which to base the decisions. Such data is available but it is not easily accessible.

**Recommendation:** Develop links between all data collection in the areas of ICS, PoCS and PAD, uniform questionnaires and comparable results.

**Appropriate Organisation(s):** Professional bodies, database organisations and DoH, NBTC.

#### 6.1.4. Making information and experience easily available

Published work does not reflect the experience and information available. There are many databases, either speciality specific or within hospital departments which are a rich resource of information. Sadly most do not collect data on blood usage. The information in the local hospital databases is often not analysed and generally not available.

#### 6.1.5. Known existing national databases

The main problem with current databases is that participation is voluntary and therefore data is incomplete. Blood transfusion data has mostly been ignored or not collected.

- National vascular database (Vascular and Surgical Society of Great Britain) Dendrite clinical systems. Publishing@e-dendrite.com
- National audit cardiac surgical database (Society of cardiothoracic Surgeons of Great Britain and Ireland) Dendrite clinical systems.
- AUGIS database (Association of Uppergastrointestinal Surgeons of Great Britain and Ireland) Dendrite clinical systems.
- ACPGBI colorectal cancer study (Association of Coloproctology of Great Britain and Ireland) Dendrite clinical systems.
- Hip and knee register
- National joint registry (launched April 2003)

***Recommendation:***

Obtain lists of available databases and ensure that all surgical units collect data on ICS and blood usage during and following operation, and outcomes such as length of hospitalisation and infection rates and make the non confidential data widely available.

Reports from the databases could be accessed via one Internet site, either a new site or use the DoH BBT2 site. A multidisciplinary approach is needed and the NBTC should take the lead in appointing one responsible person to co-ordinate this effort. (Suggested audit form for ICS & PoCS appears in Appendix 2).

***Appropriate Organisation(s):*** NBTC and Professional Societies

## 6.2. Widespread Introduction of PPS

The NHS Plan 2000 envisages “putting patients and people” at the heart of the NHS.

The Modernisation Board is leading such changes. The DoH has put in place 10 taskforces to drive forward the ideas and improvements outlined in the NHS Plan. 6 focus on “what services” to improve and 4 focus on “how” the improvements will be made.

The Modernisation Agency plays a crucial role in ensuring commitments are translated into reality. The Theatre programme details excellent arrangements for Preparing Patients for

Surgery. Blood transfusion and blood conservation are not mentioned in the programme, no haematologist was on the Steering Board for the guidance. Nevertheless the NBTC could influence the DoH to add blood use/conservation to the programme.

Discussions are currently ongoing with Johanna Reilly, National Programme Manager and Pre-Op Assessment Manager at the Modernisation Agency.

**Recommendation:** The NBTC nominate a lead to liaise with the Modernisation Agency theatre programme.

### 6.3. Introduction of ICS and Near Patient Testing Where Appropriate

The introduction of ICS in the UK has been slow, nevertheless, its potential in meeting patient expectation and reducing allogeneic blood loss should not be underestimated.

**Introducing change in a changing NHS environment:** Shifting the Balance of Power: Securing Delivery

[www.doh.gov.uk/shiftingthebalance/index.htm](http://www.doh.gov.uk/shiftingthebalance/index.htm)

*“The NHS plan is about delivering improvements for patients and the public”.*

The key elements are:

- empowering front line staff to use their skills and knowledge to develop innovative services with more say on how services are delivered and resources allocated
- empowering patients to become informed and active partners in their care
- changing the NHS culture and structure, and by building clinical networks across organisations.

The recommendations of the WPs all fit neatly into this very environment. Currently there are numerous NHS targets for Trust Chief Executives to achieve: bed targets, patient throughput, patient admission policy etc. There are also other NHS initiatives: Clinical Negligence Scheme for Trusts, CHAI, National Patient Safety Agency, hospital league tables NHS Modernisation Board. Patient's demand for alternative solutions to allogeneic transfusion is an increasing demand.

**Recommendation:** Appropriate use of ICS and blood conservation should be added as achievable targets for Trusts.

**Appropriate Organisation(s):** DoH

#### 6.3.1. Overcoming identified hindrances to the introduction to ICS

3 key hindrances have been identified in the autologous survey <sup>(Ref. 1)</sup> and in the Trent Pilot Study:

- logistics – not knowing how to go about it
- finance
- training

#### Logistics

Once a clinical team became aware of the benefits of ICS in their department and wish to introduce the technique they need a “tool kit” of how to proceed.

### **6.3.2. Negotiations with suppliers and contracting**

One very positive result of the Trent Pilot has been co-operation with the NHS Procurement and Supplies Agency (PaSA) which undertook to procure and supply such equipment and disposables. As of April 2003 information on several manufacturer's of equipment and disposables will be available from PaSA, thus reducing the time and effort at local level. This information is currently being distributed to hospitals by numerous routes.

1. Hill, J. & James, V. (2003) Survey of autologous blood transfusion activity in England (2001). *Transfusion Medicine*, **13**, 9-15.

**Recommendation:** The DoH web-site to carry such a “tool kit”. How to identify suppliers, select the most suitable equipment, arrange finance and arrange training.

**Appropriate Organisation(s):** DoH

**Recommendation:** The NBTC support the PaSA initiative and encourage all manufacturers to take part. The DoH to advertise the Service.

#### Finance

Finding the resources necessary to introduce ICS is a major hurdle for most hospitals, even if it is accepted that the end result is cost-neutral.

**Recommendation:** DoH with the NBS and NBTC, to consider all aspects of budget allocation either nationally or locally which would encourage blood conservation.

**Appropriate Organisation(s):** DoH, NBTC and NBS

#### Training

For effective use of ICS sufficient operatives should be trained to provide a 24 hour ICS service in hospitals with the appropriate portfolios of suitable surgical procedures. The training should result in Accreditation.

**Recommendation:** The NBTC work closely with the Trent Cell Salvage Group (a sub-group of the Trent RTC) to further develop the training initiatives. Involve Specialist Practitioners of Transfusion and Perioperative Specialist Practitioners.

### 6.3.3. Time management

Any introduction of change requires time. A great deal of time is spent developing protocols and there is much duplication. The NHS Modernisation Board, NICE and HTA have all developed hospital programmes, but have generally paid scant attention to blood transfusion.

**Recommendation:** The NBTC be responsible for holding template protocols relevant to PPS and autologous transfusion and these could be accessed and developed for individual Trust use.

## 6.4. Audit of Implementation

Change and development are a constant feature of medical practice and the NHS however much of such change and development is not monitored and the effects of the changes remain unknown.

Clinical audit is proving a most useful tool in assessing changes in practice. As long as systems are in place to implement the findings of the audit, and re-audit once changes have occurred, becomes an automatic part of the process.

**Recommendation:** The NBTC encourages use of clinical audit and initiatives to make sure the results are accessible.

The RCPATH holds a database of audits, but all submissions are voluntary and a comprehensive picture of audits for interventions is currently unavailable.

Every audit should identify systems that will lead to implementation of the audit findings and such implementation should be monitored.

#### 6.4.1. Communicating the information to the general public and patients

Increasing public demand for alternatives to allogeneic donor blood is a further driver to action in this regard. A patient information leaflet for PoCS is available endorsed by the Patient's Association. However, this has been produced by a commercial company.

***Recommendation:***

The NBTC produce a patient leaflet explaining the use and availability of the various forms of autologous transfusion.

The NBTC work with the Patient's Association to ensure reliable information about transfusion and alternatives is available.



## 6.5. Summary of Intervention, Implementation and Monitoring

**General key intervention:** The NBTC to promote awareness of blood transfusion throughout the NHS so all relevant developing programmes take it into account.

Intervention	Implementation	Monitoring
<b>EDUCATION</b> <pre> graph TD     Guidelines --&gt; Existing     Guidelines --&gt; New     Existing --&gt; Review[Review &amp; update (autologous)]     New --&gt; Perioperative     Review --&gt; Improve[Improve availability internet access]     Perioperative --&gt; Improve           </pre>	<ul style="list-style-type: none"> <li>BCSH and multidisciplinary task forces.</li> <li>Changing clinical practice*               <ul style="list-style-type: none"> <li>NBTC and Trusts</li> <li>Involve specialist practitioners of transfusion</li> <li>Nominated local lead clinicians</li> </ul> </li> <li>1 site to access all “approved” guidelines <a href="http://www.transfusionguidelines.org.uk">www.transfusionguidelines.org.uk</a></li> </ul>	<b>Clinical Audit</b> <ul style="list-style-type: none"> <li>Local hospitals</li> <li>National (NBTC, NBS and Royal Colleges)</li> <li>Site owners</li> </ul>
<b>Continuing Professional Development</b>	<ul style="list-style-type: none"> <li>All blood using specialties to remember importance of blood</li> <li>Professional societies asked to nominate a transfusion lead</li> <li>Multidisciplinary joint meetings – NBTC to promote.</li> </ul>	Audit effect*.
<b>Making data and expertise more available</b>	NBTC to: <ul style="list-style-type: none"> <li>list all current available databases</li> <li>help develop new society for CS sharing expertise and data and making analysed data available*.</li> </ul>	Audit effect*.
<b>Patient Information Leaflet</b>	NBTC and NBS	Feedback from the Patient’s Association.
<b>PPS</b>	<ul style="list-style-type: none"> <li>NHS Modernisation Board:               <ul style="list-style-type: none"> <li>Follow NHS modernisation theatre programme with addition of consideration of autologous/allogeneic blood use</li> </ul> </li> <li>Protocols from NICE and professional bodies</li> </ul>	As planned by NHS Modernisation Board.
<b>ICS</b>	<ul style="list-style-type: none"> <li>Address hindrances:               <ul style="list-style-type: none"> <li>finance</li> <li>training*</li> </ul> </li> <li>Develop tool kit on DoH site</li> <li>Encourage use of PaSA</li> </ul>	DoH, CHAI, CNST
<b>AUDIT</b>	<ul style="list-style-type: none"> <li>NBTC to promote a National Audit database*</li> <li>NBS to repeat survey of autologous transfusion in 2006</li> </ul>	CHAI, CNST, Royal Colleges  NBS Audit Department

\* Resources required

## Chapter 7: The Emergency Situation

Although the driving force for setting up the Working Parties was the shadow cast by vCJD, and its effect on the numbers of donors and donations, it soon became clear that the proposed interventions would all lead to better transfusion practice and save donor blood, although exact estimates of such savings are impossible to calculate. ScHARR estimates a saving of over 650,000 units per annum.

The WPs, nevertheless had a remit to consider a drop in supplies of 10% and 50%. We feel that the 10% drop could easily be accommodated with the introduction of even a few of the interventions; the 50% drop would therefore be considered as the “Real Emergency” situation.

### 7.1. Non-Surgical Patients

The role of agents to stimulate blood cell growth and development:

For red cell production: Haematinics: iron, folic acid, vitamin B12 % nutritional advice

Erythropoietin

Increased use of EPO and all available alternatives....

For white cell production: r-Hu-G-CFS:  
r- Hu- GM- CSF

For platelets: r-Hu-IL-11  
r-Hu-TPO

Stem cell transplantation and gene therapy may have an increased role in congenital conditions requiring lifelong transfusion support.

These agents all have particular problems and more extended use will need to be investigated, funded and promoted.

### 7.2. Surgical Patients

Should blood supplies be limited then it is the non-surgical patients for whom alternative approaches will be more difficult to apply and therefore the limited blood supply will be directed to these patients and accidental injuries. Alternative approaches will have to be found for surgical patients.

All the discussed interventions can be expanded.

The role of PAD can be extended (in combination with erythropoietin).

In this scenario the WPs recommend the setting up of a parallel Transfusion Service to the NBS specifically to provide PAD. The donations could be collected by small mobile units at appropriate hospital or PCT sites.

- The guidelines for PAD will need to be extended to allow case by case assessment by clinicians
- Crossover for donations from appropriate patients not needed by the donor into the allogeneic pool could be allowed
- Directed donations could be allowed
- Freezing and storage of pre-donated blood on a large scale could, with the latest technology, be developed.

Importation of blood:

- Importation from EU Countries with a surplus (countries who used to send RBC to the US) could be negotiated and contracted.

<b>Recommendation:</b>	Planning these services will take a long time and this planning process could be initiated through the NBS Contingency Planning Group.
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### 7.3. Surgical and Anaesthetic Techniques

Assessment of individual surgical and anaesthetic skills and blood loss would become necessary and Hospital Trusts may then need to take appropriate action to limit the surgical portfolio of the surgeons and anaesthetists with the most significant blood loss.

### 7.4. Rationing

Should the blood supply situation continue to deteriorate then hospitals will be tasked with rationing the distribution of available donor blood (see NBS Contingency Planning Report).

# Chapter 8: Further Research

## Many areas need further research

Some of this is currently being carried out but needs collating:

- Where does donor blood go?
- Effect of falling transfusion triggers and undertransfusion
- Electronic patient records and accessibility
- Acute normovolaemic haemodilution (ANH)
- Fibrin sealants – multidisciplinary
- Cost effectiveness of TEG equipment
- Post-Operative Cell Salvage (PoCS)
- Database use

### 8.1. Current Status of ANH

ANH involves the removal of blood at the induction of anaesthesia immediately prior to surgery with the simultaneous replacement with crystalloid or colloid fluid to maintain normovolaemia <sup>(Ref. 1)</sup>. The volume of fresh autologous blood usually removed is approximately 450-1350mls, thereby reducing the preoperative haemoglobin to somewhere in the region of 10.5-11g/dl. Blood units are stored at room temperature to maintain platelet function and reinfused at the end of the procedure once haemostasis is secured.

#### 8.1.1. Advantages of ANH

Surgical blood loss is reduced as the blood that is lost is more dilute. Each unit of haemodiluted blood is equivalent to one unit of RBC and FFP and 1.5-2 units of platelets. By storing the blood at room temperature platelet function and coagulation factors are preserved. The patient receives their own blood hence it will be free of transmitted diseases and the immunomodulatory effects of allogeneic blood. The incidence of haemolytic and allergic reactions should be significantly reduced.

ANH blood is stored in the operating theatre and re-infused back to the patient when major blood loss has ceased or before if deemed necessary by the anaesthetist, consequently the theoretical possibility of making a clerical error should be significantly reduced. Reduced blood viscosity during the operation has benefits in terms of increasing oxygen extraction from the remaining haemoglobin and a shift in the oxygen dissociation curve to the right, which favours the release of oxygen to the periphery.

#### 8.1.2. Disadvantages of ANH

Risk of myocardial ischaemia. Close monitoring required to prevent hypovolaemia. Not advisable in conjunction with some anaesthetic agents in particular the use of ANH and

PGE1-induced controlled hypotension has been shown to cause changes in the renin-angiotension response under isoflurane anaesthesia.

The use of large volumes of crystalloid to maintain normovolaemia may lead to peripheral oedema requiring diuretic therapy or an increase in lung water. It is possible that these effects may have implications for wound healing and post-operative lung function. potentially time consuming

### 8.1.3. Efficacy of ANH

There have been two systematic reviews published on ANH as a means of reducing allogeneic blood requirement in surgery<sup>(Ref. 1 & 2)</sup>. In 1996, Bryson et al<sup>(Ref. 2)</sup> reported a meta-analysis on 24 randomised clinical trials involving 1218 patients:

Most trials were underpowered, recruiting a median of 30 patients only.  
Trial design was generally poor, with a Jadad score of 1/5 for 19 trials and 2/5 for six trials.  
The majority of trials failed to specify transfusion protocols.

As a result, there can be little confidence in the reduction in allogeneic blood requirements reported in many of these small studies. A review carried out for the Royal College of Physicians of Edinburgh Consensus Conference on Autologous Transfusion<sup>(Ref. 3)</sup> identified 75 papers on ANH published between 1993 and 1998. Only two were randomised controlled trials and none were of sufficient quality to influence transfusion strategy.

In summary although the ability of ANH to reduce allogeneic blood transfusion requirements in a variety of different types of surgery has been documented in several studies, most of these studies either lack a proper control group or use historical controls. Other problems include inadequate numbers and no record of post-operative haemoglobin levels. More reliable and comprehensive evidence, in the form of well designed prospective randomised clinical trials, is needed before ANH can be endorsed.

1. Napier, J.A., Bruce, M., Chapman, J., Duguid, J.K., Kelsey, P.R., Knowles, S.M., Murphy, M.F., Williamson, L.M., Wood, J.K., Lee, D., Contreras, M., Cross, N., Desmond, M.J., Gillon, J., Lardy, A. & Williams, F.G. (1997) Guidelines for autologous transfusion. II. Perioperative haemodilution and cell salvage. British Committee for Standards in Haematology Blood Transfusion Task Force. Autologous Transfusion Working Party. *Br J Anaesth*, **78**(6), 768-771.
2. Bryson, G.L., Laupacis, A. & Wells, G.A. (1998) International Study of Perioperative Transfusion. Does acute normovolemic hemodilution reduce perioperative allogeneic transfusion? A meta-analysis. *Anesth Analg*, **86**, 9-15
3. Gillon, J., Desmond, M., Thomas, M.J. (1999) Acute normovolaemic haemodilution. *Transfusion Medicine*, **9**(3), 259-64

## 8.2. Current Status of PoCS

Post-operative cell salvage is the technique whereby blood drained from an operative site is filtered, and then returned to the patient direct. There are several commercially available devices suitable for this purpose, all depending upon a negative pressure in the collection vessel, and a filter to remove any debris from the salvaged blood. It should be noted that the blood thus salvaged is not washed, unlike blood salvaged intra-operatively.

There are several centres around the UK who currently use post-operative cell salvage, notably in orthopaedic surgery. This type of surgery is suitable for such a technique, as often the blood lost post-operatively is relatively clean, much of the loss being in the early post-operative period.

The use of such techniques, for example in total knee replacement, has been routine in certain centres around the country, but many other centres are now adopting such techniques.

#### **8.2.1. Advantages of Post-operative Cell Salvage**

Applicable to well defined patient groups (example total knee replacement).  
Available drains are relatively easy to use and probably economical.  
If used in appropriate patient groups blood is usually clean.  
Can often re-transfuse 1-2 units of blood, which would otherwise be lost.  
Acceptable to certain religious groups.

#### **8.2.2. Disadvantages of Post-operative Cell Salvage**

Not suitable for use in infected orthopaedic cases.  
Blood can only be re-transfused for up to 8 hours from wound closure.  
Systems may be unfamiliar to untrained staff.

#### **8.2.3. Current Indications**

Total knee replacement has been suggested as the ideal indication, as much of the blood loss occurs in the early post-operative period and the blood is relatively clean. Nevertheless other orthopaedic operations, such as spinal surgery, clean revision arthroplasty surgery, and pelvic fracture surgery might lend itself to such techniques.

Its use in infected cases, or cases where a malignancy is present is probably contra-indicated.

#### **8.2.4. Evidence for Reduction in Banked Blood Use**

There is much evidence in the literature to support post-operative cell salvage, particularly in knee replacement surgery. In a well performed randomised trial, 7% of patients in an auto-transfusion group required allogeneic transfusion compared to 28% in the controlled population ( $P < 0.001$ )<sup>(Ref. 1)</sup>. Some concern has been raised about the increased cytokine concentration in salvaged blood in comparison to washed red cells, but no adverse affect on post-operative haemoglobin recovery was noted<sup>(Ref. 2)</sup>. There is little published evidence concerning the use of post-operative cell salvage in other branches of orthopaedic surgery.

1. Thomas, D., Wareham, K., Cohen, D and Hutchings, H. (2001) Autologous blood transfusion in total knee replacement surgery. *British Journal of Anaesthesia*, **86**, 669-673. (washed)
2. Avall, A., Hyllner, M., Bengtson, J.P., Carlsson, L and Bengtsson, A. (1999) Greater increase in cytokine concentration after salvage with filtered whole blood than with washed red cells, but no difference in postoperative hemoglobin recovery. *Transfusion*.

1999, **39**(3), 271-276.

Local experience with post-operative cell salvage at the Northern General Hospital, Sheffield, in a group of 56 patients was associated with no need for allogeneic blood transfusion in 44 of the patients. The mean volume of blood re-transfused in this group was 493mls per patient, equating to approximately 1.5 units of banked blood.

#### **8.2.5. The main issues to be explored**

Comparisons of using PoCS v. no transfusion at all.

Comparison between using PoCS systems delivering washed v. unwashed blood.

UK guidelines are required before widespread introduction.

Economic Analysis EOR:

- ☐ Assessment of reduction of risk to patients from reduced 1<sup>st</sup> time donor requirement.
- ☐ Liaise with HTA

# Conclusion to Strategy Proposal

The consideration of alternative solutions to the use of allogeneic blood has led the Working Parties down numerous interesting routes. Many initiatives are already undertaking in different areas of the Country and part of the NHS. The main task was to pull these together, evaluate their significance and reach clear recommendations to disseminate best practice.

We hope this Strategy Proposal achieves this and that the recommendations are taken forward through the appropriate routes.



# Background to the Strategy Proposal

In December 2000, the NBS held a workshop to consider their approach to concerns raised about the impact of vCJD on the blood supply in England. As a result a vCJD Steering Group was set up with the following Terms of Reference:

“The main purpose of the vCJD Steering Group is to ensure that the NBS, in partnership with the wider blood community, is aware and contributes to the identification of further strategies to mitigate the unknown risk of transmission of vCJD to recipients through transfusion/transplantation of blood and tissues, and that the NBS prepares for, and subsequently effectively implements any such strategies. In addition to overseeing internal activities, the vCJD group will review links with various external bodies and organisations as well as advising on arrangements for decision making”.

The first meeting of this group was held on 12<sup>th</sup> February 2001 under the chairmanship of Martin Gorham. Several sub-groups were set up. The Donor Sub-group (which had already met on February 5<sup>th</sup>), Testing Sub-group, Processing Sub-group, Tissues Sub-group, Appropriate Use Sub-group and Intelligence in R&D Sub-group.

The vCJD Steering Group changed its name to the Blood and Tissue Safety Assurance Group (BTSAG) to emphasise that all aspects of blood and tissue safety, not just vCJD, should be considered.

The NBS Sub-Group on Appropriate Use of Blood, under the chairmanship of Dr Angela Robinson, held its first meeting on 3<sup>rd</sup> April 2001, with the key Terms of Reference: to promote the appropriate use of blood and alternatives.

Again several working parties were set up, including the Working Party on Autologous Transfusion (Chair Dr Virge James) and the Working Party on Alternatives to Transfusion (Chair Dr Clare Taylor).

## 1. Working Party on Autologous Transfusion

### Terms of Reference

- Compile from completed and planned surveys, data on the present use of various forms of autologous transfusion in the UK, including any recent trends towards increase or decrease in usage.
- Provide a brief summary of the evidence base for the use of autologous transfusion, including a consideration of current obstacles, to a greater use of autologous transfusion and potential for increase in use in the UK.
- Make recommendations on how to increase the usage of AT and mechanisms by which an increase can be achieved, including consideration of the role of the NBS in facilitating the various forms of AT.
- Consider and make recommendations on the practical aspects of AT including patient selection, clinical information, collection of blood, documentation and testing.

To these formal Terms of Reference was added a request to hold a national meeting at the conclusion of the work and promulgate the message.

The strategy was also asked specifically to include data on what contribution AT and ALT could make to a scenario with a loss of 10% of donations and another with a loss of 50% of donations.

### **Membership of the Group**

- Dr John Burman, Consultant Haematologist, Royal Brompton Hospital
- Dr Mike Desmond, Consultant Anaesthetist, The Cardiothoracic Centre
- Mr Steve Elcoate, Blood Bank Manager, Royal Devon & Exeter Hospital (Wonford)
- Dr Moji Gesinde, Lead Consultant Apheresis, National Blood Service, Leeds Centre
- Mr Andy Hamer, Consultant Orthopaedic Surgeon, Northern General Hospital, Sheffield
- Dr Jean Harrison, Consultant Haematologist, National Blood Service, North London
- Dr Sarah Haynes, Autologous Transfusion Co-ordinator, Dept. of Surgery, South Manchester University Hospital
- Mr Francesco Torella, Department of Surgery, South Manchester University Hospital
- Mrs Catherine Howell, Lead Nurse, Clinical Developments, National Blood Service, Oxford Centre
- Dr Virge James (Chair), Consultant Haematologist, National Blood Service, Sheffield Centre
- Dr Chris Kenny, Consultant in Public Health Medicine, NHS Executive, Trent
- Mr Chris Sims, Planning & Management Accountant PCS & Support Services, National Blood Service, Leeds Centre
- Dr Dafydd Thomas, Consultant in Anaesthesia & Intensive Therapy, Morriston Hospital
- Dr Gill Turner, Consultant Haematologist, Norfolk and Norwich Hospital

Colonel Michael Thomas was invited to comment on the proposals and share expertise.

The agreed method of working was that there would be few meetings of the group; these would be used mainly to discuss issues and obtain consensus, but much of the work would be done by participants outside the meetings.

Short, referenced position papers were provided on the 3 main forms of autologous transfusion: Pre-deposit (PAD), Intraoperative Cell Salvage (ICS; including acute normovolaemic haemodilution ANH), and Post-operative Cell Salvage (PoCS).

### **Meetings Held**

First meeting held: 28<sup>th</sup> September 2001

- This was used to prepare for the UK CMOs Seminar on Better Blood Transfusion for September 29<sup>th</sup> 2001 and plan the work.

Second meeting held: 30<sup>th</sup> November 2001

- This meeting considered the outcome of the UK CMOs Seminar on Better Blood Transfusion, and discussed key relevant issues arising.

## **2. Working Party on Alternatives to Transfusion**

### **Objectives**

To explore and evaluate the breadth of new and established methods available to reduce the need for allogeneic blood transfusion, and to facilitate their early implementation by blood users. (This excludes autologous blood transfusion which is to be addressed by a separate working group)

### **Terms of Reference**

- To gather data on methods of reducing allogeneic blood exposure already in use, and canvas current opinion about efficacy, feasibility and acceptability.
- To compile and classify an evidence base for the following areas:
  - pre operative normalisation of Hb with haematinics
  - pre operative erythropoietin
  - re-evaluation of transfusion triggers
  - algorithms for estimation of acceptable blood loss
  - alternative fluid replacement
  - oxygen carrying Hb substitutes
  - platelet substitutes
  - role of recombinant coagulation factors
  - pharmacological methods to reduce blood loss
  - anaesthetic methods to reduce blood loss
  - enhancement of surgical haemostasis
  - post operative haematinics and erythropoietin
  - use of erythropoietin in medical, haematology and oncology patients
- to identify reasons why such methods are not in use
- to evaluate potential costs of these methods
- to educate blood users and disseminate information to all personnel involved in transfusion decision making
- to encourage prospective studies of methods of reducing allogeneic blood exposure

### **Output**

- Contingency plan which can rapidly effected in the event of a 15% reduction in the quantity of red cells available for transfusion. This is the predicted impact of a decision to exclude donors who have received blood products.
- Contingency plan in the event of a 50% reduction in the blood supply. This is a possible scenario if a prion test is applied to donor blood, due to the predicted fall off in willing donors.
- The development of a 'bloodless surgery' unit in a small number of hospitals.

- The establishment of a ‘bloodless surgery’ educational team who can then offer their services in setting up similar units at other hospitals.

## **Membership**

To be multidisciplinary, including Regional Lead Consultant for Hospital Liaison, perfusionists, anaesthetists and intensivists, surgical specialists, pharmacy managers, general physicians (e.g. gastroenterologists), coagulation and transfusion haematologists, BPL representatives and auditors.

- Clare Taylor (Chair), Consultant in Transfusion Medicine, National Blood Service
- Chris Prowse, Research Director, SNBTS National Science Laboratory
- Hari Boralessa, Consultant Haematologist, National Blood Service, Brentwood Centre
- Monty Mythen, CD, Critical Care, UCLH
- Cliff Morgan, Consultant Anaesthetist, Brompton and Harefield Hospital
- Neil Watson, Pharmacy Manager, Brompton and Harefield Hospital
- John Thompson, Consultant Vascular Surgeon, Royal Devon & Exeter Hospital
- Ken Lowe, Reader in Biotechnology, Nottingham University
- Mike Murphy, Lead Consultant for Hospital Liaison, National Blood Service
- Geoff Hazlehurst, Blood Bank Manager, Royal Free Hospital
- Derek Norfolk, Department of Haematology, The General Infirmary at Leeds
- Brian McClelland, National Strategy Director, Scottish National Blood Transfusion Service
- Charles McCollum, Research & Teaching Building, University Hospital of South Manchester

## **Meetings Held**

First meeting held: 26<sup>th</sup> July 2001

Second meeting held: 2<sup>nd</sup> October 2001

### **3. Fusion of the WPAT & WPALT**

It was soon realised that there was considerable overlap of interests in WPAT and WPALT and a joint meeting was held on 11<sup>th</sup> January 2002, followed by a further joint meeting on 22<sup>nd</sup> April 2002. During these meetings the main thrust of the proposed strategy was clarified.

#### **Final Joint Meeting 22<sup>nd</sup> April 2002**

At this meeting the outline of the report was constructed. Following all the discussions held it was decided that the realistic strategy to be proposed should concentrate on 4 key initiatives:

- Nation-wide preparing patients for surgery clinics
- Promoting intraoperative cell salvage
- Promoting continuous audit and improvement
- Promoting early education of surgeons & anaesthetists in blood conservation techniques

It was agreed that Virge James would prepare the outline of the report and all participants would contribute short sections with 2-3 key references. At the time the final report was requested by Dr Angela Robinson by the end of 2002. The report would go to the parent Appropriate Use of Blood group, then to the BTSAG and finally the National Blood Transfusion Committee (NBTC).

The NBS and National Blood Transfusion Committee would consider the recommendations and implement those which receive support.

#### **Commissioned Work**

To assist the working group two pieces of work were commissioned (both previously circulated to the Sub-Group on the Appropriate Use of Blood and copies are available on request):

##### **1. A National Autologous Survey**

From the NBS Audit Department: A survey of current practice of autologous transfusion in hospitals in England.

Hill, J. & James, V. (2003) Survey of autologous blood transfusion activity in England (2001). *Transfusion Medicine*, **13**, 9-15.

##### **2. A Health Economic Analysis**

From ScHARR, by the NBS: A health economic evaluation of 4 interventions: Preparing patients for surgery clinics (PPS), Pre-deposit Autologous Donation (PAD), Intraoperative cell Salvage (ICS), Post operative cell salvage (PoCS).

Dixon, S., Hind, D. (April 2003) An economic analysis of the implementation of autologous transfusion technologies throughout England. The University of Sheffield, Schoole of Health & Related Research, 30 Regent Court, Sheffield, S1 4DA.

#### **Trent Pilot – to be published in 2003**

It was also recognised that a pilot study between the NBS and 5 hospitals in Trent (The Trent Pilot) was in progress aimed at introducing ICS more widely in these hospitals. The pilot would have finished in the autumn of 2002 and would inform the proposed strategy.

#### **4. Developments since the Working Party draft report was submitted**

**29<sup>th</sup> May 2003:** The draft report was discussed at the Appropriate Use of Blood Sub-Group. It was well received, but the following changes were requested.

1. Change of emphasis for recommended actions. Rather than directed as actions to the NBS these should be directed to the NBTC. The proposals should be endorsed by BTSAG. They could form the basis for Better Blood Transfusion 3.
2. The report needs condensing. Dr C Taylor to rewrite chapters 1, 2 and 3 and Dr V James to rewrite the other chapters. The minutes of the Appropriate Use of Blood Sub-Group meeting on 29<sup>th</sup> May detail the key changes.
3. The report to be re-submitted by the end of August 2003 for the meeting of the NBTC on 29<sup>th</sup> September 2003.
4. It is hoped that the NBTC will nominate people to take the initiative forward according to the outline action plan in Chapter 6.
5. It is hoped the NBTC, NBS and other appropriate bodies will encourage the outlined research.

**This strategy does not aim to set guidelines, merely to draw attention to what already exists and suggest means of implementing the most effective guidance.**

## 5. The National Autologous Survey

As a basis of background information a survey of the current (2001) extent of AT in England was undertaken by Joanne Hill (NBS Audit Department). Information was gathered on the extent of use of autologous transfusions (categorised into 4 groups for avoidance of confusion: PAD, ICS, ANH, POS). Views on the main hindrances to increased use were also gathered and opinions about how any increase could be facilitated. This information was subsequently used in the ScHARR Health Economic Evaluation.

### Summary Findings of the Survey

Questionnaires were returned from 265 of the 310 (85.4%) hospitals served by the National Blood Service.

60% of respondents performed at least one autologous technique, although practice was limited to a few clinicians within each hospital. Pre-deposit donation was the most widespread technique, but involved very few patients. Intra and post-operative cell salvage techniques were practised in fewer hospitals, but on many more patients. The main constraints to increasing use of autologous techniques were perceived to be logistical, but removal of constraints may only result in small increases in individual practice. More clinicians need to be encouraged to utilise appropriate, evidence based autologous techniques.

A similar survey had been commissioned by Ms Kath Firth of PaSA in view of the increasing use of disposables used in post-operative autologous transfusion. The information was obtained by a different route via operating theatre managers as opposed to the consultants in charge of blood banks. The response rate was only 32% but nevertheless indicated that of the responding hospitals 50% were practising some form of autologous transfusion (personal communication).

Subsequently further data has become available from the questionnaire survey of BBT1.

Murphy, M.F., Edbury, C., & Wickenden, C. (2003) Survey of the implementation of the recommendations in the Health Services Circular 1998/224 'Better Blood Transfusion'. *Transfusion Medicine*, **13**, 121-125.

<b>Recommendation:</b>	The NBS Audit Department survey to be repeated in 5 years (2006) and the repeat study should also attempt to establish the key factors that led to any change in practice.
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## 6. Current (2001/2002) use of allogeneic blood in the United Kingdom

Since the aim of the Working Parties is to produce a strategy aimed at reducing the use of donor blood it is important to have data on which specialities currently use donor blood and to what extent.

Good and reliable baseline information on current blood use by speciality is lacking. Accumulated data from 3 UK studies is available and a prospective study by the NBS clinical trials unit is in progress.

1. **August 1999:** Single Centre pilot study Oxford Radcliffe Hospitals (Mike Murphy): All blood components transfused in a single institution during a single month (106 red cells). Result: Surgical 52%, Medical 48%.
2. **April 1997 to March 1998:** 62 hospitals in London and South East England (Hari Boralessa). A total of 594,810 units were successfully traced to their respective clinical specialities: 51.2% were used in surgical specialities and 36.6% in medical specialities (including haematology).
3. **North of England population based October 1999 and July 2000:** (9774 RBC) (A Wells and D Stainsby). Result: Surgical 40.7%. Medical 51.6% (including haematology) (Ref. 1)

Further data is expected from a national study (Lorna Williamson and Mike Murphy) and results from a pilot study are already available. In the meantime it seemed reasonable to base any proposed strategy on the assumption that 50% of allogeneic blood is used in association with surgery.

The proposed strategy considers the use of red cells only. The other components, FFP and cryoprecipitate, are to a large extent bi-products of red cell production. The indications for platelet transfusions, and hence any consideration of strategies for alternatives to platelets, are outwith the remit of the Working Party.

Paediatric patients: Special considerations apply and will be highlighted when relevant under special headings.

1. Wells, A.W., Mounter, P.J., Chapman, C.E., Stainsby, D. & Wallis, J.P. (2002) Where does blood go? Prospective observational study of red cell transfusion in north England. *British Medical Journal*, **325**, 803-807.



# Appendix 1

## Executive Summary of Trent Pilot

(From the Report of the NHS Executive (Trent) / National Blood Service Intraoperative Cell Salvage Pilot Scheme (December 2001 to September 2002))

The HSC 1998/224 “Better Blood Transfusion” required NHS Trusts to explore the feasibility of autologous transfusion.

The National Blood Service, Sheffield Centre, and NHS Executive Trent set up a Working Group, supported by Trust Chief Executives known as the Trent Perioperative Cell Salvage Working Group.

The Group designed a pilot scheme aimed at increasing, or introducing, the use of intraoperative cell salvage to run in 5 major hospitals in Trent: Leicester Royal Infirmary, Northern General Hospital (Sheffield), Nottingham City Hospital, Queen’s Medical Centre, (Nottingham) and Derbyshire Royal Infirmary.

The scheme was supported by Martin Gorham, Chief Executive of the National Blood Service (NBS), and involved the NBS reimbursing the 5 Trusts for defined numbers of Intraoperative Cell Salvage equipment and disposables to be used during a period of 6 months.

The use of the technique and disposables was monitored by an audit form analysed by the NBS Audit Department.

The Cost Minimisation Analysis used the assumption that:-

- ◆ *Cost of ICS = cost of disposable (range £125 to £176) + operator time (£4.09)*
- ◆ *Cost of BB RBC = cost of RBC unit (£99.96) + crossmatch costs (range £3.74 to £11)*

Analysis of 353 audit forms has shown that, on average, RBC obtained via ICS are 24% cheaper than using allogeneic RBC for surgical patients. The table below details results from all hospitals taking part in the pilot. However, due to operational differences, affecting the amount of whole blood processed, the 726 cardiac forms were analysed separately.

Hospital	Equivalent no of ICS Units Tx	Total Cost for same vol of BB RBC (£)	Total Cost of RBC via ICS (£)	Diff (£)	Cost per BB unit (£)	Cost per ICS unit (£)	Diff (£)
NGH	262.23	27304.66	15014.07	12290.59	103.82	57.26	46.56
QMC	177.24	18536.92	15462.02	3074.905	104.14	87.24	16.90
NCH	76.164	8543.92	5941.78	2602.145	110.96	78.01	32.95
DER	53.489	5599.8	4572.49	1027.315	103.7	85.48	18.22
LEIC	73.211	7989.04	10706.77	-2717.73	107.96	146.25	-38.29
<b>TOTAL</b>	<b>642.33</b>	<b>67974.34</b>	<b>51697.11</b>	<b>16277.23</b>	<b>106.12</b>	<b>80.48</b>	<b>25.63</b>
Cardiac	1826.8	189,658.38	114,047.34	75606.04	103.82	62.43	41.39

At the conclusion of the Pilot 4 of the 5 hospitals are retaining and using the extra ICS equipment provided for the pilot. The fifth (NCH) will use the equipment it already owns, and will negotiate with the suppliers if its needs increase.

The pilot scheme provides evidence of the cost effectiveness of using ICS and savings in donor blood.

## Appendix 2

<b>Trent Intra-Operative Cell Salvage Data Collection Form</b>			
This form should be completed for every surgical case where blood has been collected with the intention of intra-operative cell salvage EVEN if the blood collected is not processed.			
<b>1. Hospital</b> <input type="checkbox"/> NGH <input type="checkbox"/> QMC <input type="checkbox"/> DRI <input type="checkbox"/> DCH <input type="checkbox"/> LRI <input type="checkbox"/> LGH <input type="checkbox"/> Glenfield			
<b>2. Patient Details</b> (stickers on all copies please)		<b>3. Procedure details</b>	
Surname:		Name of Procedure :	
Forename:		Date of Operation:	
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female		<input type="checkbox"/> In Hours <input type="checkbox"/> Emergency <input type="checkbox"/> Out of Hours <input type="checkbox"/> Elective	
Address:		Name of Surgeon :	
Hospital Number:		Name of Anaesthetist :	
D.O.B:		Name of Cell Saver Operator:	
Height (m):	Weight (kg):		
<b>4. Cell Saver Equipment Used</b>			
<input type="checkbox"/> CATS <input type="checkbox"/> Haemonetics <input type="checkbox"/> Dideco <input type="checkbox"/> Other _____			
Anti-coag used:	<input type="checkbox"/> Heparin <input type="checkbox"/> Citrate <input type="checkbox"/> Other _____		
Blood Filter Used:	<input type="checkbox"/> 40u Blood Filter <input type="checkbox"/> No Filter <input type="checkbox"/> Other _____		
<b>5. Reason Why Collection Set Was Used But The Blood Was Not Processed</b>			
<input type="checkbox"/> Inadequate Volume Collection <input type="checkbox"/> Training Purposes <input type="checkbox"/> Technical Problem			
<b>Equipment Used (Unprocessed cases only)</b>			
<input type="checkbox"/> Collection Reservoir Only <input type="checkbox"/> Collection Reservoir and Bowl <input type="checkbox"/> Collection Reservoir, Bowl and waste bag <input type="checkbox"/> Whole set			
<b>Comments / Technical Problems</b>			
<b>6. Blood Volume Details</b>			
Total Volume Processed (ml)		Time when Collection Started	
Volume packed RBC produced (ml)		Time when Processing Started	
Volume packed RBC transfused (ml)		Time when Transfusion Started	
Volume of Anti-coagulant Used (ml)		Number of Bank RBC units given	
Estimated Unsalvaged Blood Loss (ml)		Number of Bank FFP units given	
Estimated Total Blood Loss (ml)		Number of Bank Platelet units given	
Why were additional blood components given?			
<b>7. Comments / Problems / Critical Incidents</b> (please use another form if required)			
<b>WhiteTop Copy</b> - Keep with Machine <b>Copy 1</b> - Keep in patients Notes <b>Copy 2</b> - Audit Form			

jh/cellsalvform2/March2003

## Appendix 3

### Executive Summary of the ScHARR Report (April 2003)

- Very little is known about the potential costs and effects of implementing blood sparing technologies in the UK. This study provides the first estimates of the costs and effects of the large scale introduction of these technologies into the NHS.
- A model was constructed to allow disparate data sources to be combined to produce estimates of the scale, costs and effects of introducing four interventions. The interventions considered were; preparing patients for surgery (PPS) clinics, pre-operative autologous donation (PAD), intra-operative cell salvage (ICS) and post-operative cell salvage (PoCS).
- Data sources were as follows:
  - Eligible operations were based on those included in the Maximum Blood Ordering Schedule of a large university hospital.
  - Blood use was based on blood bank and inpatient data from a (different) large university hospital.
  - National activity data were taken from Hospital Episodes Statistics.
  - Reductions in blood use were based on professional opinion.
  - Reductions in length of stay were based on previous research findings.
- The key determinants of cost per operation are the anticipated level of reductions in blood use, the mean level of blood use, mean length of stay and the cost of the technology.
- The results show the potential for considerable reductions in blood use. The greatest reductions are anticipated to be through the use of PPS (246,000 units per annum) and ICS (160,000 units per annum).
- Applying ICS to non-G&S procedures appears to be the best value for money, followed by PoCS, PPS, ICS for all operations and lastly, PAD.
- Vascular surgery, transplant surgery and cardiothoracic surgery appear to be the specialties that will benefit most from the technologies.
- Several simplifications were used in the production of these estimates and consequently caution should be used in their interpretation and use.
- The interpretation of the 'cost savings' need to be undertaken carefully as many of them will not be realised. Some consideration also needs to be given to the implementation of the interventions.
- Some will have consequences for training and the organisation of the health service more generally. The most important issue, however, is considered to be the capacity of hospitals to provide the additional PPS clinics and PAD sessions.
- The figures produced in this report should be considered as preliminary estimates. Improvements to the estimates can be made incrementally, as more reliable figures are produced. Despite the drawbacks in the methods used in the study, the model forms a basis for amalgamating the data necessary to make informed decisions.

# Acknowledgements

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