MEMBERS OF THE NORTHERN IRELAND ADVISORY COMMITTEE ON BLOOD SAFETY

24TH September 2002

Dear Colleague

I have pleasure in enclosing the agenda and papers for the forthcoming meeting of the above group which will take place on:

Thursday 3rd October 2002 from 2.30 PM – 5.00 PM in Room C3.18, Castle Buildings

Please report to reception and a member of DHSSPS staff will escort you to the meeting.

Yours faithfully

GRO-C

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MEETING OF THE NORTHERN IRELAND ADVISORY COMMITTEE ON BLOOD SAFETY
WEDNESDAY 3RD OCTOBER 2002
2.30PM – 5.00PM
ROOM C3.18 CASTLE BUILDINGS, STORMONT, BELFAST.

AGENDA

1.	Welcome	
2.	Apologies	
3.	Minutes of the Meeting held 6th September 2001	ACBS1/02
4.	Autologous Blood Transfusion Report	ACBS2/02
5.	Better Blood Transfusion – HSC Circular 2002/009	ACBS3/02
6.	National Comparative Audit in Blood Transfusion ~~*(to be tabled)*~~ Now attached	ACBS4/02
7	Update Report from NIBTS	ACBS5/02
8	S I G N Guidelines on peri-operative blood transfusion for elective surgery	ACBS6/02

FOR INFORMATION

- NI Survey of Blood Transfusion Practice ACBS7/02
- Results of a Questionnaire Survey in relation to the implementation of the Health Services Circular – 1998/224 ACBS8/02
- Shot Annual Report 2000/2001 ACBS9/02

MINUTES OF THE ADVISORY COMMITTEE ON BLOOD SAFETY HELD THURSDAY 6TH SEPTEMBER 2001 AT 2.00PM, ROOM C3.18, CASTLE BUILDINGS, STORMONT

PRESENT:

Dr H Campbell (Chairperson)
Dr L Doherty
Dr M Mark
Mr P Blair
Dr C Morris
Dr T Wyatt
Dr M McClelland
Dr B McClelland
Mrs J Henry (Secretary)

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1. WELCOME

Dr Campbell welcomed all members to the meeting.

2. APOLOGIES

Apologies were received from Prof. J Watson, Dr D Corrigan and Dr E Mitchell.

3. MINUTES OF MEETING HELD 12TH OCTOBER 2000

Minutes agreed.

4. MATTERS ARISING

Transfusion Medicine - Guidelines on the Administration of blood and blood components and the management of transfused patients

- Dr C Morris informed members that a considerable amount of work has been done in the Belfast City Hospital by the Blood Transfusion

Committee. Audit standards and local Best Practice Guidelines have been developed for Belfast City Hospital. Dr Morris advised that Belfast City Hospital would be happy to share these with other Hospital Transfusion Committees.

ACTION POINT: **DR MARK TO WRITE TO MEDICAL DIRECTORS RE: BELFAST CITY HOSPITAL TRANSFUSION COMMITTEE GUIDELINES**

5. AUTOLOGOUS BLOOD TRANSFUSION WORKING GROUP UP-DATE

Mr Blair gave an update on the Autologous Blood Transfusion Working Group. The first meeting of this group was held in September 1999. He described the Groups experiences.

- **Acute Normovolaemic Haemodilution**

This study had experienced difficulty with ethical committee approval and only one patient had been recruited. It was considered that this was not a feasible option.

- **Autologous Pre operative Donation**

This study had taken place in Musgrave Park Hospital. It had required a dedicated nurse and had considerable resource implications. This was considered feasible in elective surgery

- **Intraoperative Cell Salvage**

This technique was useful in a small number of patients. It was safe with no major side effects. There would be resource implications.

CMO said that consideration should be given to autologous blood transfusion. Dr M McClelland observed that during predeposit autologous transfusion study in Musgrave Park Hospital, overall use of blood in the hospital had reduced.

Dr M McClelland informed members that requests for autologous blood were increasing though were still small and that current guidelines only permit autologous blood to be used for the donating patients. Dr B McClelland said that the way forward in Blood Transfusion was to reduce the threshold for patients receiving blood and increase the use of autologous blood.

ACTION POINT: **MR P BLAIR TO FORWARD REPORT ON THE WORK OF THE SUBGROUP**

6. UPDATE REPORT FROM MBST

7. vCJD UPDATE

Dr Wyatt updated members on the continuing review of safety of blood components. HTLV screening for HIV is now undertaken in all regions. Fresh frozen plasma is now imported. Screening of blood donors is continuing to be monitored. The vCJD panel is considering the action to take if a person receives a blood component from a donor who subsequently develops vCJD. A Framework Document for public consultation is to be issued soon. Dr B McClelland informed the meeting that while at present no cases of vCJD have been linked to blood transfusion, concern about the safety of blood from vCJD continues. There were also concerns that there may be supply problems with insufficient amounts of blood. Dr B McClelland stated that for all of these reasons there should be a target of 10% reduction in blood usage.

CMO enquired if information was available on blood usage by speciality and consultant. Dr M McClelland said that a considerable amount of information was held in the N.I.B.T.S. and that he would make this available.

8. REPORT FROM NIBTS

Dr M McClelland updated members on recent and planed developments within

NIBTS that have an impact on the microbiological safety of the blood supply. He referred to paper 3/2001 which provided a brief summary on options for further enhancement of blood safety and factors which determine policy decisions on blood safety by NIBTS. He informed the meeting that at present there were adequate stocks of blood being donated and that the demand for blood had decreased.

ACTION POINT: DR M. MCCLELLAND TO PROVIDE INFORMATION ON BLOOD DEMAND BY HOSPITAL.

9. EFFICIENT USE OF BLOOD AND BLOOD PRODUCTS

Dr Morris pointed out that there is little incentive to manage blood at Trust level. There is a case for Hospital Consultant Transfusionists at Hospital level to oversee blood bank programmes, procedures and education in the better use of blood. Nurses can also address these issues. There is a shortage of haematologists and at present the 3rd consultant post in NIBTS is unfilled. Haemovigilance (Transfusion) Nurses have been very effectively used in Scotland and Republic of Ireland. Dr B McClelland stated that a programme of practice improvement has been introduced in Scotland.

10. BETTER BLOOD TRANSFUSION SURVEY

A survey is being conducted to provide feedback on the Trusts' expenses on implementing the actions requested in the Circular HSS(MD)3/99 entitled "Better Blood Transfusion". A similar study is being undertaken in England. Analysis of the results will allow comparison between the two countries and will be used to inform the second UK CMO "Better Blood Transfusion" seminar which will be held in London on 29 October 2001. The main aim of this conference is to help set the priorities for blood transfusion in the NHS for the coming 3-5 years.

11. BETTER USE OF BLOOD - TRAINING FOR MEDICAL STUDENTS AND JUNIOR HOUSE OFFICERS

CMO asked about the present training for medical students and junior house doctors in procedures for blood transfusion. Dr B McClelland informed the meeting that in Scotland responsibility for taking blood samples is taken by the nursing staff and that teaching material has been developed. Discussion followed on the need for compulsory training for junior hospital doctors during their induction period. Clinical tutors have responsibility for training and could organise courses to facilitate this. Target specialities for training would be Obstetrics and Gynaecology Surgery and Accident and Emergency.

ACTION POINT: **CMO TO WRITE TO POST GRAD MEDICAL COUNCIL AND MEDICAL DEAN RE EDUCATION AND TRAINING IN BLOOD TRANSFUSION**

ACTION POINT: **DR WYATT AND DR DOHERTY TO CONSIDER JHO TRAINING IN BLOOD TRANSFUSION**

12. CMO'S BLOOD TRANSFUSION CONFERENCE ON 29TH OCTOBER 2001

CMO updated the meeting on this Conference.

There being no other business, CMO thanked members for their attendance and closed the meeting.

Report on Autologous Blood Transfusion Working Group

Introduction

The Autologous Blood Transfusion Sub-Committee was set up at the request of the Northern Ireland Advisory Committee on blood safety. The Group was asked to assess the feasibility of a variety of autologous blood transfusion techniques. Members of the Autologous Blood Transfusion Working Group are listed in Table 1 below. The Group met on 7 occasions between 28.9.99 and 3.4.01 and presented its preliminary findings at the CREST meeting in 2001.

Table 1

Mr P Blair
Mr D Beverland
Dr D Connolly
Dr P Kettle
Dr G Lavery
Dr A Mairs
Dr K Morris
Dr B Morrow
SN Shirley Murray
Dr G McCarthy
Dr M McClelland
Dr C Rafferty
Mr C Soong
Dr T Wyatt

In forming the Autologous Blood Transfusion Working Group an attempt was made to include representatives from surgery, anaesthesia, intensive care, haematology and also members of the nursing staff. Although the Committee was serviced by the Department of Health, no additional funding was made available to conduct any of the studies included below. We are indebted to the enthusiasm of members of the medical, nursing and laboratory staff in addition to significant support from a variety of pharmaceutical companies.

Aims and Objectives

The ABTG (Autologous Blood Transfusion Group) was asked to report on the feasibility of a variety of autologous blood transfusion techniques. It was apparent from the published literature and recent national guidelines that 3 techniques should be explored (1) autologous pre donation (2) acute normovolaemic haemodilution and (3) inter-operative cell salvage. Individuals and centres were selected based on previous experience with particular techniques and the appropriateness of their hospital population. An attempt was made to recruit centres from outside the greater Belfast area but this proved quite difficult for a variety of reasons.

This short report attempts to summarise the results of the three sub-groups. However, to be fair to the individual centres, their complete reports are included as appendixes A, B and C.

Autologous Pre Donation (see Appendix A)

This study took place between 19.6.00 and 10.11.00. Criteria for referral and acceptance of patients have been described in the NIBTS protocol for autologous pre donation. Important considerations were adequate venous access, adequate haemoglobin, reliable date for surgery and separate quarantine and storage facilities in Musgrave Park Hospital blood bank for the handling of autologous donations. A total of 22 patients were referred with 18 patients being accepted. Two patients did not complete the study as one failed to attend and the autologous programme was abandoned on the second patient because of positive serology result for syphilis antibodies. A total of 34 autologous units were collected with 18 units ultimately being transfused. The remaining 16 autologous units were set to discard as per BCSH guidelines since arrangements are not in place in the UK for cross-over of autologous units into the blood bank inventory.

Results

Of the 16 patients only 3 required exposure to donor blood. It should be noted that the transfusion protocol in use in Musgrave Park was changed for the patients in the study with the threshold for transfusion being reduced by 1g/dl for patients in the study. While there was no proper control group in the study it appeared that the higher threshold for the immediate post-operative period and the lower threshold for the first, second and third post-operative days could account for the relatively large number of single unit transfusions given in the study.

A significant fall in haemoglobin following autologous transfusion was noted in all but one patient. The drop in pre-operative haemoglobin ranged from 0.9-2.2 g/dl. Donors were scheduled not to be bled sooner than 14 days pre-operatively, suggesting problems with compliance and/or the effectiveness of iron supplementation.

The following conclusions can be made:

- Autologous pre donation was proven to be feasible in orthopaedic patients.
- A significant fall in pre-operative haemoglobin occurred which did not recover by the time of surgery.
- At least 50% of autologous units were noted used.
- The unintended lowering of transfusion thresholds raises interesting questions about the appropriateness of current haemoglobin transfusion thresholds.
- Pre autologous donation required additional resources and organisational skills and required the appointment of a haemovigilance nurse to get the project off the ground.
- Current limitations on the scheduling of elective surgery, in other hospitals in Northern Ireland, may render the technique difficult.

Inter-operative Cell Salvage (see Appendix B)

The aim of this feasibility study was to assess the use of inter-operative cell salvage as a method of reducing the demand for allogeneic blood in a variety of surgical operations. It is contra-indicated in the presence of bacterial contamination of the operative field. Apart

from a few specialised centres malignant disease is also considered a relative contra indication due to the possibility of haematogenous dissemination of malignant cells.

Staff Nurse Shirley Murray undertook the study in the Royal Victoria Hospital as this centre had previous experience using a device over a period of approximately 4 years. It was also anticipated that the patient mix of vascular and trauma patients would be an appropriate study population. A variety of cell salvage machines were made available by respective companies for a number of months. The companies also provided technical support and initial and follow-up training as required. Over a 6 month period, between August 2000 and January 2001, a device for inter-operative cell salvage was used during 5 elective abdominal aortic aneurysm repairs. Three of the 5 patients required no allogeneic blood, the 2 remaining patients required 4 and 2 units respectively.

Summary and Conclusion

It would appear that the success of inter-operative cell salvage depended on the commitment of surgeons, anaesthetists and nursing staff. Although the companies set up initial training days, no expert trainers were resident in Northern Ireland which caused initial problems during initial training and trouble shooting. Skilled maintenance did not appear to be a problem during normal working hours, however, significant problems were encountered when out of hours use occurred. It was felt, however, that these difficulties should be overcome by increased investment in adequate resources with regard to education, training and operational support.

- The feasibility study suggested that inter-operative cell salvage could significantly reduce the demand for allogeneic blood and with adequate training and resources, a 24 hour service.

- The study was confined to vascular patients and the use of cell salvage and the use of cell salvage in malignant disease requires further assessment.

- The cost of the machine and disposables is significant and a careful assessment of an individual unit's allogeneic blood use would be required.

- It was the consideration of the Working Party and inter-operative cell salvage was a useful technique and should be encouraged in a variety of clinical situations.

Acute Normovolaemic Haemodilution (see Appendix C)

This study proved to be the most difficult of the three undertaken. The technique consists of removal of blood in the immediate pre-operative period with circulating volume being maintained by colloids or crystalloids. The removed blood is then retransfused during an appropriate stage of the operation. A more detailed description of the technique with background information is included in Appendix C. The study was conducted by Mr Chee Soong in the Belfast City Hospital.

There was considerable delay in obtaining ethical approval for this study with several changes being required to the patient information sheet and consent form. It became obvious during the study that the population of vascular patients was perhaps not the most appropriate. Only one patient met the inclusion criteria and agreed to participate. Unfortunately his haematocrit fell from 43% to 30% following two units of crystalloid infusion during induction of anaesthesia and he was therefore excluded from the study.

It was impossible to reach any conclusions due to the difficulties experienced with this study. From the current literature it would appear that the technique is useful for certain clinical situations but probably does not have wide application in the general surgical population.

Overall Summary and Conclusions

Three autologous blood transfusion techniques were assessed with regard to feasibility.

Pre autologous donation appeared to be feasible in a controlled elective environment in Musgrave Park Hospital. The appointment of a haemovigilance nurse appeared to be critical for the implementation of the technique. It is likely that additional resources will be required if this technique was to be adopted on a larger scale.

Per -perative cell salvage. This appeared to be quite a feasible technique in vascular patients although it did require a significant period of training. The initial cost of the machinery, combined with the use of disposables, should be compared to the increasing costs of allogeneic blood in addition to other physiological considerations. larger hospitals Experience with this technique at the Royal and published reports from other centres would suggest that it is a useful technique. It appeared particularly useful in trauma and vascular patients.

Acute normovolaemic haemodilution. Although this technique is well described in the literature it proved extremely difficult to implement in the population of vascular patients studied. The majority of patients did not meet the inclusion criteria suggesting that a more appropriate population should have been studied. The technique is well described in the literature and is undoubtedly useful in certain clinical situations.

I am indebted to the secretarial support of Jacqui Henry, the scientific advice of Dr Tim Wyatt and to the hard work and enthusiasm of the scientists, doctors and nurses listed in Table 1.

Appendix A

Autologous Pre Donation Pilot Study
NIBTS/Musgrave Park Hospital

The CREST sub-group on Autologous Blood Transfusion asked NIBTS and Musgrave Park Hospital to perform a feasibility study on autologous pre donation in orthopaedic patients. This study took place over the summer of the year 2000 with the first patient bled 19.06.00 and the last patient bled 10.11.00. The criteria for referral and acceptance of patients are as laid down in the NIBTS Protocol for Autologous Pre Donation. The essential points are adequate venous access, adequate haemoglobin, reliable date for surgery and separate quarantine and storage arrangements in Musgrave Park Hospital Blood Bank for handling of autologous donations.

22 patients were referred in all. 4 patients were deferred – these comprise 1 paediatric case (250 ml paediatric blood packs not available), 1 rheumatoid arthritis case Hb < 10g/dl, 1 case of epilepsy on treatment who did not have a fit free interval of > 3 years and 1 case underweight 42 kg < lower limit acceptable for blood donations.

18 patients were accepted, 1 patient failed to attend and in a further 1 case the autologous programme was abandoned because of a positive serology result for syphilis antibodies. NIBTS control procedures do not permit release of a donation which is positive on mandatory microbiology testing. One donation was taken from this patient and set to discard at NIBTS. The donation in fact would not have been a risk to the recipient as it represents a case of past treated syphilis which is not transmissible. Of the remaining 16 patients, 1 patient was bled twice giving two autologous units on two occasions. Incidentally, he represents the first and last referral during the study period.

15 patients gave 2 autologous units comprising 30 units. 1 of the 15 patients gave on a second occasion providing a further 2 units. 2 patients gave 1 unit each, the aforementioned positive syphilis antibody donor and also a late referral who gave 1 autologous unit 9 days prior to surgery. The total number of autologous units collected = 34.

18 autologous units were in fact transfused – 5 patients received both autologous units back and 8 patients received a single autologous unit back.

16 autologous units were in fact set to discard as per BCSH guidelines. Arrangements are not in place in the UK for cross over of autologous units into the normal Blood Bank inventory. 9 patients had a single autologous unit wasted – this comprises the 8 patients who in fact received a single unit back only and the ninth patient who gave a single unit following a late referral. 2 patients had 2 autologous units wasted. 1 patient had his operation cancelled after 2 autologous units had been taken and the further attrition of autologous unit was due to the positive syphilis antibody serology. Total autologous units wasted = 16.

An additional 10 units of allogeneic blood were ordered for 4 patients. In one case 2 autologous units were transfused and 2 allogeneic units returned. In the second case 2 autologous units were transfused and 2 allogeneic units were also transfused. In the third case 2 autologous units were transfused, 2 allogeneic units were transfused and a further 2 allogeneic units were returned. In the fourth case 2 autologous units were transfused, a single allogeneic unit was transfused and a single allogeneic unit was returned.

It is important to state that one important objective of the study was realised in that in only 3 cases was there exposure to donor blood and in all other cases exposure to donor blood was successfully avoided.

A number of important additional points must be made however:

1. The transfusion protocol in use in Musgrave Park Hospital was changed for the patients in the study. There are two aspects to the transfusion protocol. The first aspect relates to the haemoglobin on day 1, day 2 and day 3 post operatively. This was reduced by 1g/dl for patients in the study. Where the haemoglobin is in excess of 14.5g/dl it is not permitted to drop below 10g/dl and transfusion should be given to maintain it above 10g/dl. Where the pre-operative haemoglobin is 13.5g/dl it is not permitted to drop below 9g/dl and transfusion should be given to maintain it above 9 g/dl on each post operative day. In all cases the transfusion protocol was followed. The effect of lowering the post operative haemoglobin by 1g/dl would be to reduce the number of blood transfusions.

   The second aspect relates to the PCV in the post operative period. This was not altered for purposes of autologous patients. Where 4 hours post operatively the PCV is 0.32 and 8 hours post operatively the PCV is 0.28 transfusions are to be administered.

   While there was no proper control group in this study it would appear the higher threshold for the immediate post operative period and the lower threshold for the first, second and third post operative days would account for the relatively large number of single unit transfusions given in the study.

2. There is significant fall in haemoglobin following autologous donations. In all but one patient there was a drop in haemoglobin from the haemoglobin pre autologous donation to the haemoglobin on admission to hospital pre-operatively. In 1 case the haemoglobin pre autologous donation was 13.5 and the haemoglobin on admission to hospital was 13.6. In every other case there was a drop and the range of decrease was 0.9 – 2.2 g/dl, giving an average drop in haemoglobin of 1.6g/dl across 15 patients. This approximates to the amount of blood taken and raises a question about compliance with or effectiveness of iron supplementation. Donors were carefully scheduled not to be bled sooner than 14 days pre-operatively and were given appointments at –21 days, -14 days to allow adequate time for recovery haemoglobin following donation. This was complied with in all but one case (-9 days). An important effect of this is that no patient had haemoglobin 14.5g/dl in the pre-operative period permitting a drop to the lower haemoglobin level 9g/dl as per modified protocol.

The following conclusions can be made:

1. Autologous pre donation programme is feasible in orthopaedic patients.

2. There is significant fall off in the haemoglobin following donation which does not recover by the time of surgery.

3. Attrition of autologous units is of the order of 50%.

4. The "unintended" lowering of thresholds for the purposes of the study raises interesting questions about the appropriateness of haemoglobin thresholds and triggers in general. None of this small group of patients appears to have had any adverse effects from reduction in the haemoglobin threshold.

5. It would be necessary to perform a much wider study to validate these conclusions and it would also be appropriate to conduct studies examining the appropriateness of thresholds in the majority of patients who will receive allogeneic blood in the post operative period.

INTER-OPERATIVE CELL SALVAGE FEASIBILITY STUDY.

AUTOLOGOUS BLOOD TRANSFUSION
WORKING GROUP.

CONTENTS

1. AIM OF STUDY.

The purpose of this feasibility study was;

- To assess the use of inter-operative cell salvage as a method of reducing the demand for allogeneic blood.
- To assess the demand for inter-operative cell salvage in identified centres.
- To assess the demands of individual centres maintaining a cell salvage service.
- To establish capital and running costs of an inter-operative cell salvage service.

2. BACKGROUND.

Previous centres have suggested that inter-operative cell salvage is appropriate where there is a clean wound and the surgery, either elective or emergency, has an expected blood loss > 20% of the total blood volume (1,2,3.). The technique is therefore applicable to open heart surgery, vascular surgery, total joint replacement, spinal surgery, liver transplantation, ruptured ectopic pregnancy and some neurosurgical procedures. The technique is contraindicated in the presence of bacterial contamination of the operative field. Malignant disease has in the past been considered a contraindication due to the possible haematogenous dissemination of malignant cells that may metastasise (4,5,6). Recent publications suggest that this risk may be eliminated by the use of either filters or the irradiation of the salvaged blood (7,8,9,10,11,12,13,14). The processing machinery used in this local study employs a centrifuge system that concentrates and washes the red blood cells. A double lumen tube delivers heparinised saline to the operative field. The saline and shed blood are then aspirated to a reservoir. During processing the salvaged blood is concentrated and washed with normal saline. Plasma, washing fluid, heparin and debris are discarded. The end product is the patient's own red cells suspended in saline.
Cell salvage processing machines offer defined pre-programmed washing procedures with various washing speeds. In addition to this, operator defined options are available which allow for the alteration of centrifuge speed and flow rates.
The direct costs of providing a unit of processed salvaged blood are usually projected to be greater than a unit of allogeneic blood (15.). A break-even point usually occurs when one to two units of salvaged blood have been transfused, however this does not take account of the indirect savings such as the avoidance of post transfusion sequelae of allogeneic blood or cross matching difficulties as a result of atypical

antibodies. Jehovah's Witnesses will accept cell salvage if there is a continuous circuit between the operative field and the retransfused blood; this technique is possible with some cell salvage equipment (1.).

The benefits of cell salvage include:

- Rapid availability of blood perfectly matched to the patient.
- The elimination of viral infection.
- Reduced risks of allergic or haemoltic reactions.
- Blood is processed and transfused at room temperature, an advantage in the hypothermic patient requiring multiple transfusions.
- The blood available is in proportion to the losses that are occurring.
- In the case of massive haemorrhage the rate of blood loss may outstrip the availability of allogeneic supply.

Previously in the Royal Victoria Hospital a cell salvage service was offered using the Haemacell 350. During a four-year period this machine was used during a number of trauma cases where 3 to 4 litres of blood were salvaged and re-infused. The machine was also used on a regular basis during ruptured abdominal aortic aneurysms when it was not uncommon to process 1 to 2 litres of blood.

3. METHOD.

For the purpose of the feasibility study three cell salvage machines were offered to a number of participating local hospitals;

1. The Cell Saver 5 from Haemonetics.
2. The Brat 2 from Cobe.
3. The CATS from Fresenius.

In addition to these machines a Compact-A from Dideco was on loan to Cardiac theatre in the Royal Victoria for research in cardiac surgery. The machines were to be based in Vascular Theatre in the Royal Victoria, Vascular Theatre in the Belfast City and Vascular and Orthopaedics in Altnagelvin Hospital. Altnagelvin Hospital was invited to take part in the study to give a perspective of cell salvage in a district general hospital. At the time of writing this preliminary report Altnagelvin have not recruited patients yet due to operational difficulties.

In the two Belfast hospitals the individual companies provided training in the use and best practice of the cell salvage equipment. During the study period the companies

provided all technical support and additional training as required. All blood salvage equipment was used in strict compliance with the manufacturer's instructions. The type of surgery, during which cell salvage was carried out, was at the discretion of the individual centres.

Specimens of the processed blood were collected for the assessment of free plasma potassium, full blood count and free plasma haemoglobin.

4. EVALUATION OF THE STUDY (ROYAL VICTORIA).

Comparison of Demand for Allogeneic Blood.

	Salvaged blood average per patient.	Total of allogeneic units used per group.	Total cost of allogeneic units used per group.
Group 1 N=5	312mls	6 units	£546.00
Group 2 N=5	Nil	23 units	£2,093.00
Group 3 N=5	Nil	48 units	4,368.00

Figure 1.
Group 1: Scheduled abdominal aortic aneurysm repair using cell salvage.
Group 2: Scheduled abdominal aortic aneurysm repair without cell salvage. (retrospective non-matched review).
Group 3: Emergency abdominal aortic aneurysm repair without cell salvage. (retrospective non-matched review).

Inter-operative cell salvage was used during 5 elective abdominal aortic aneurysm repairs between August 2000 and January 2001 (Group 1 fig.1). 4 of the 5 aneurysms involved infra-renal cross clamping while the 5th required supra-renal clamping. Amounts of blood salvaged ranged from 500mls to 1200mls, following processing these amounts yielded packed cells of 150mls to 450mls respectively. Three of these patients received no allogeneic blood, one patient required 4 units and one patient 2 units. The cost of allogeneic blood for this group of patients totalled £546.00, based on a unit cost of £91.00, with an average cost of £109.20 per patient. If we include the cell salvage equipment cost of £134.00 per patient, maintaining haemodynamics in this group averaged a cost of £233.00 per patient. This figure does not include the capital investment of purchasing cell salvage equipment. However if a capital

investment of £17,000 was incorporated into a 5 year plan based on 100 patients per annum this would equate to an additional £34 per patient.

A retrospective review of 5 elective abdominal aortic aneurysm repairs, in which cell salvage was not used, was carried out (Group 2 fig.1). The surgery of the five cases was carried out between May 2000 and January 2001. No attempt was made to match these 2 groups of patients in any way. All of these 5 patients required allogeneic blood inter-operatively ranging from 2 units to 9 units with a total of 23 units for the group. This amount equates to a total cost of £2,093 based on a unit cost of £91. The average cost per case of maintaining the haemodynamics of this group was therefore £418.60 per patient.

Finally a retrospective review of 5 emergency abdominal aortic aneurysm repairs was carried out (Group3 fig.1). Cell salvage was not performed during this surgery. Allogeneic blood requirements in theatre ranged from 4 units to 14 units of packed cells. A total of 48 units of packed cells were used at a total cost of £4,368.00. This equates to an average cost per patient of £873.60 and does not include the additional costs of fresh frozen plasma and platelets received by this group.

The average cost per case of cell salvage can be taken as £168.00 including an estimated capital cost of £34 per case. Therefore the financial break-even point when comparing cell salvage to allogeneic blood would be 1.8 units of processed salvaged blood.

This is not a validation study however the sampling results of the processed blood are as follows.

Sampling Results of Processed Blood.

	Average.	Range
Haemoglobin	2.55g/dl	20.8 – 22.9g/dl
Haematocrit	0.59l/l	0.52 – 0.67l/l
Potassium	4.42mmol/l	4.3 – 4.6mmol/l
Free plasma haemoglobin	115.8mg/dl	55 – 216mg/dl

Figure 2.

The raised free plasma haemoglobin was most likely a result of sampling not processing.

5. CONCLUSIONS.

Success of a cell salvage service is dependent on the commitment of surgeons, anaesthetists and nursing staff. Lack of commitment in any one of these groups will result in failure of the service.

The four companies were not able to provide expert trainers in Northern Ireland. As a result difficulties were encountered arranging training and troubleshooting. There did not appear to be any difficulties maintaining training and skills for elective surgery on the Royal site. Difficulties were encountered in training and maintaining skills to offer an out of hours service. These training difficulties had previously been encountered with the Haemacell 350 system. Reluctance to take the system on board may be encountered in all grades of staff. This reluctance may be caused by economic and staffing issues and familiarity with and confidence in conventional allogeneic blood techniques. Difficulties such as this could be overcome by investing sufficient resources in education, training and operational support.

This small feasibility study would suggest that a cell salvage service can significantly reduce demand for allogeneic blood. With sufficient training to support a 24 hour service, this technique could prove to be a cost effective alternative to allogeneic blood. Recent publications take this issue further by suggesting that immunomodulation resulting from allogeneic blood results in increased post-operative infections delaying hospital discharges and requiring increased use of antibiotics (16.)

This feasibility study did not investigate the use of cell salvage in surgery for malignant disease and this is an area that would require guidelines. If this technique could be used safely in this type of surgery it would greatly increase demand.

The Edinburgh Consensus Conference on Autologous Transfusion concluded (17.)

"Providing that a rigid Standard Operating Procedure is in place and the equipment is easily available with appropriate staff training, the side effects of intraoperative salvage are fewer than those associated with allogeneic transfusion. An increasing body of evidence indicates that this procedure can substantially reduce the need for allogeneic blood"

REFERENCES.

1. Lee, D., Contreras, M., Cross, N., Desmond, M., Gillon, J., Lardy, A., Williams, F., *Guidelines for autologous transfusion. Part 2-Periopeative haemodilution and cell salvage*
2. Ouriel, K., Shortell, C.K., Green, R.M., DeWeese, J.A., Intraoperative autotransfusion in aortic surgery. *J. Vasc. Surg.* 18: 16. 1993.
3. Hallett, J.W., Popovsky, M., Ilstrup, D., Minimizing blood transfusion during abdominal aortic surgery: Recent advances in rapid autotransfusion. *J. Vasc. Surg.* 5: 601. 1987.
4. Yaw, P.B., Sentany, M., Link, W.J., Wahle, W.M. Glover, J.L., Tumour cells carried through autotransfusion. Contraindications to intraoperative blood recovery. *JAMA* 1975: 231: 490-1.
5. Dale, R.F., Kipling, R.M., Smith, M.F., Collier, D., Smith, P.J. Separation of malignant cells during autotransfusion. *Br J Surg* 1988: 75:581.
6. Hansen, E., Wolff, N., Knuechel, R., Ruschoff, J. Hofstaedter ,F. Taeger, K., Tumour cells in blood shed from the surgical fields. *Arch Surg* 1995: 130: 387-93.
7. Klimberg, I., Sirois, R.Wajsman, Z., Baker, J., Interoperative autotransfusion in urologic oncology. *Arch Surg* 1986: 121: 1326-9.
8. Hart, O.J. Klimberg, I.W., Wajsman, Z., Baker, J., Interoperative autotransfusion in radical cystectomy for carcinoma of the bladder. *Surg Gynec Obstet* 1989: 168: 302-6.
9. Pisters, L.L., Wajsman, Z., Use of predeposit autologous blood and interoperative autotransfusion in urologic cancer surgery. *Urology* 1992: 40: 211-5.
10. Miller, G.V., Ramsden, C.W. Primrose, J.N., Autologous transfusion: an alternative to transfusion with banked blood during surgery for cancer. *Br. J. Surg.* 1991: 78(6): 713-5.
11. Edelman, M.J., Potter,p., Mahaffey, K.G. The potential for reintroduction of tumour cells during intraoperative blood salvage: reduction of risk with use of the RC-400 leukocyte depletion filter. *Urology.* 1996: 47(2):179-81.
12. Torre, G.C., Ferrari, M., Favre, A. A new technique for intraoperative blood recovery in the cancer patient. *Eur. J. Surg. Oncol.* 1994: 20(5): 565-70.
13. Hansen, E., Schlosser,S., Altmeppen, J., Irradiation of wound blood from tumour surgery for retransfusion. *Beitr. Infusionsther. Transfusionsmed.* 1994: 32: 502-4.
14. Hansen, E., Altmeppen, J., Kutz, N. Experimental principles and general practice of intraoperative autotransfusion with blood irradiated in tumour operation. *Beitr. Infusionsther. Transfusionsmed.* 1996: 33: 184-190.
15. Blais, R.E., Hahjipavlou, A.G., Shulman, G. Efficacy of autotransfusion in spine surgery: Comparison of autotransfusion alone and with hemodilution and aphersis. *Spine.* 1996: 21:23: 2795-2800.
16. Blumberg, N., Heal, J.M. Effects of transfusion on immune function. *Arch. Pathol. Lab. Med.* 1994: 118: 371-9.
17. Desmond, M., Gillon, J., Thomas, M.J.G., Perioperative red cell salvage: A case for implementing the 1995 consensus statement. *Royal College of Physicians of Edinburgh* 1998:

Appendix C

The feasibility of acute normovolaemic haemodilution in patients undergoing elective endovascular repair of abdominal aortic aneurysm.

Introduction

Patients undergoing elective endovascular abdominal aortic aneurysm repair may lose on average a litre of blood and require 2-3 units transfused.**(1)** The blood transfused is normally obtained from the blood bank. Unfortunately, despite improvements in the safety in blood transfusion the risk of transfusion-transmitted diseases cannot be reduced to zero.**(2)** There is now the added theoretical risk of new variant Creutzfeldt-Jakob Disease. The first Serious Hazards of Transfusion report published in 1998 indicated that there were 169 cases of serious hazards following homologous blood transfusion. 81 of these involved a mismatch of one form or another while 8 were infective complications.**(3)**

There are many various ways of minimising the need for homologous blood. One technique is acute, normovolaemic haemodilution where blood is removed immediately preoperatively and circulating volume maintained with colloids or crystalloids.**(2)** The removed blood is retransfused once major blood lost has stopped or sooner if necessary. The concept is that the blood which is removed preoperatively has a higher haemoglobin concentration while blood that is lost during surgery has a lower haemoglobin content. Unfortunately, acute normovolaemic haemodilution have possible adverse effects such the development of peripheral and pulmonary oedema. There is also a potential risk of inducing myocardial ischaemia and delay in myocardial metabolic recovery.**(4)** However, these concerns have never been substantiated in properly controlled randomised studies.

In fact, haemodilution has been shown to increase cardiac output and decrease peripheral resistance due to decrease in blood viscosity.**(5)** It is suggested that the relative decrease in oxygen-carrying capacity of blood in the coronary circulation is compensated by an increase in coronary blood flow. This in effect will lead to an improvement in coronary perfusion and oxygenation. This may be why isovolaemic haemodilution was found to be well tolerated even in high risk patients undergoing abdominal aortic aneurysm repair.**(6)** In addition, by lowering haematocrit from 43% to 30% workers are able to reduce the number of units of homologous blood transfused from 2.5 units per patient to 0.8 unit per patient. This may in turn minimise the risk of transfusion-transmitted diseases and transfusion related reaction. When the blood is collected in standard citrate blood bank bags the blood can be stored at room temperature for up to 8 hours.**(2)** In freshly collected

blood platelet function is preserved for up to 24 hours and labile coagulation factors only begin to degrade after this time. There is an advantage therefore in transfusing blood collected pre-operatively and a potential reduction in coagulopathy.

Aim

The aim of this study is to assess the feasibility of using acute normovolaemic haemodilution to reduce the requirement of homologous blood transfusion in patients undergoing endovascular AAA repair.

Methodology

Patients undergoing elective endovascular AAA repair will be recruited after informed written consent. Patients over 85yr old, those with a body mass index of greater than 20% of ideal, patients with pre-operative haematocrit less than 40% and left ventricular ejection fraction less than 35% will be excluded. Patients will be taken to the high dependency unit 2 hours prior to surgery where lines for monitoring purposes will be placed. This is normal practice in all patients undergoing abdominal aortic aneurysm surgery and include a radial arterial line for blood pressure measurement and a central venous cannula for measurement of central venous pressure. In addition, patients will be connected to a continuous 12 lead ECG system with automated ST segment analysis (Aries Cardiology Software Suite). Cerebral function will be monitored with Bispectral Index monitor for the duration of the anaesthesia. All the monitoring will be according to the Association of Anaesthetist monitoring guidelines. All patients will have a urinary catheter and half-hourly urine output readings.

The procedure for ANH will be as follows. A baseline haematocrit will be measured using the OMNI 8 system. The blood loss required to produce a haematocrit of 30% will then be calculated using the formula:-

Allowable blood loss = (Estimated blood volume)x $[\ln(HCT_{start}/HCT_{target})]$
(Estimated blood volume will be taken as 70mls/kg)

Blood will be removed at a rate of no more than 50mls per minute with simultaneous replacement with the same volume of hetastarch (Hesteril) until 50% of the target blood loss has been achieved. A 20 minute period of redistribution will then be allowed and the haematocrit rechecked. A fresh calculation will then be made and the process repeated. ANH will be terminated when 1.2L of blood is removed or the target haematocrit is achieved which ever occurs first. No additional hetastarch will be administered after this point.

All patients will receive standardised anaesthestic of etomidate, alfentanil, vancuronium, 50% nitrous oxide in oxygen and isoflurane. Intraoperative maintenance losses will be replaced with Ringers lactate at a rate of 3ml/kg per hour plus the previous hour urine output, with a bolus of 100 mls of gelatin solution (Gelofusine) every 30 minutes if the CVP falls more than 5 mmHg from the post ANH value. The haematocrit will be checked intraoperatively every 30 minutes or at the discretion of the anaesthetist. Autologous blood will be returned to the patient if the intraoperative haematocrit falls to 25% or if there are significant ST segment changes for more than 5 minutes intraoperatively. Banked blood will only be used if it proves impossible to maintain the patients haematocrit over 28% in the acute situation and study terminated. Blood pressure will be maintained within a mean of 25% of the patients baseline value, while ventilation will be to normocapnia. All autologous blood remaining will be returned to the patient in the postoperative period.

Rationale for study

This study has been designed in accordance with the directive from the Department of Health and Social Services to evaluate the feasibility of using autologous transfusion to reduce the need of homologous blood transfusion in surgical patients. If acute normovolaemic haemodilution is found to be an acceptable option of conserving blood in this group of patients then a larger randomised controlled study will be performed to

assess its possible benefits in terms of reducing the requirement for homologous blood transfusion and cost savings.

References

1) Elmarasy NM, Soong CV, Walker SR, Wenham PW, Hopkinson BR. Sigmoid ischaemia and the inflammatory response following endovascular abdominal aortic aneurysm repair. J Endovasc Surg (In press)
2) Goodnough LT, Monk TG, Brecher ME. Acute normovolaemic hemodilution should replace the preoerative donation of autologous blood as a method of autologous procurement. Transfusion 1998; 38: 473-76.
3) Department of Health and Social Services. Document on better blood transfusion. 1999.
4) Gillon J. Controversies in transfusion medicine - Con. Transfusion 1994; 34: 269-71.
5) Stehling L, Zauder HL. Controversies in transfusion medicine. Perioperative hemodilution - Pro. Transfusion 1994;34:265-68.

Shah DM, Corson JD, Karmody AM, Leather RP. Effects of isovolaemic hemodilution on abdominal aortic aneurysmectomy in high risk patients. Ann Vasc Surg 1986; 1: 50-54.

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sets out a specific action on the part of the recipient with a deadline where appropriate

Better Blood Transfusion

Appropriate Use of Blood

For action by:

Health Authorities (England) - Chief Executive

Health Authorities (England) - Directors of Public Health

NHS Trusts - Chief Executives

Primary Care Trusts - Chief Executives and Main Contacts

For information to:

Chief Medical Officers Wales/Scotland/Northern Ireland

Chief Executive: National Blood Authority

Medical Director: National Blood Authority

Nursing Statutory Bodies - Chief Executives

Professional Associations and Royal Colleges

Regional Directors of Public Health

Regional Directors of Performance Management

Regional Nurse Directors

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It is also available on the Department of Health web site at

http://www.doh.gov.uk/publications/coinh.html

Better Blood Transfusion

Appropriate Use of Blood

Summary

This Health Service Circular replaces HSC 1998/224 *Better Blood Transfusion* and sets out a new programme of action for the NHS to:

- Ensure that *Better Blood Transfusion* is an integral part of NHS care
- As part of clinical governance responsibilities, make blood transfusion safer
- Avoid unnecessary use of blood in clinical practice
- Provide better information to patients and the public about blood transfusion

The programme of action should be considered in conjunction with Annex A of this circular that provides further detail on implementation.

There is an expectation that implementation/compliance to this guidance will be subject to inspection by CHI or its successor organisation.

A toolkit to assist Trusts is being developed and will be placed on the *Better Blood Transfusion* website and will include access to national guidance, patient leaflets and examples of good practice.

Rationale

The appropriate use of donor blood and the use of effective alternatives to donor blood are becoming increasingly important public health and clinical governance issues.

- Appropriate blood transfusion is an essential support to many medical treatments and is life-saving.
- Donated blood is a limited resource. As a result of further measures that may have to be taken to reduce the unknown risk of transmission of vCJD by blood transfusion, such as the introduction of a future screening test and limitations on the number of donors, blood supplies may be reduced.
- The safety of blood transfusion is highlighted yearly through the Serious Hazards of Transfusion (SHOT) scheme (a confidential enquiry for the reporting of serious complications of blood transfusion and near miss events in the UK). This scheme has shown that avoidable, serious hazards of blood transfusion continue to occur in Trusts the most common being giving the wrong blood to patients.
- There is continued wide variation in the use of blood (particularly in surgery and surgical specialities) even with the existence of national and local clinical guidelines developed by clinical professionals on the appropriate use of donor blood.

ACTION

- This guidance is addressed to all Trusts providing blood transfusion
- Primary Care Trusts (PCTs) and NHS Trusts should work together to implement the attached action programme
- NHS Trust Boards should formally review arrangements for Better Blood Transfusion and the appropriate use of blood at least annually;
- Health Authorities should ensure that the NHS has robust Better Blood Transfusion arrangements (including the implementation of clinical governance arrangements) in accordance with the timetable set out in this Circular

Action

- **Ensure that *Better Blood Transfusion* is an integral part of NHS care**

Objective	Action	By whom and when
Secure appropriate arrangements for *Better Blood Transfusion* and the appropriate use of blood.	• Ensure senior management and Board level commitment	Chief Executives of NHS Trusts By December 2002
	• Secure appropriate membership and functioning of the Hospital Transfusion Committee	Chief Executives of NHS Trusts By December 2002
	• Secure appropriate composition and functioning of a Hospital Transfusion Team (Annex A) including support staffing and resourcing	Chief Executives of NHS Trusts By April 2003
	• Ensure that appropriate blood transfusion policies are in place, implemented and monitored	Chief Executives of NHS Trusts with Hospital Transfusion Committees and Teams By April 2003
	• Ensure that education and documented annual training on blood transfusion policies are administered to all health care staff involved in the process of blood transfusion and is included in the induction and orientation programmes for new staff	Chief Executives of NHS Trusts working with Hospital Transfusion Committees and Teams By April 2003
Improve the quality of service provision through clinical audit and continuing professional development	• Review the blood transfusion content of clinical multi-disciplinary audit and CPD programmes for NHS Trust staff, including the Hospital Transfusion Team	Chief Executives of NHS Trusts working with clinical governance leads and Hospital Transfusion Committee and Teams By April 2003
	• Ensure participation in the Blood Stocks Management Scheme	Chief Executives of NHS Trusts with Hospital Blood Banks and Hospital Transfusion Teams By April 2003

- **Make blood transfusion safer**

Objective	Action	By whom and when
Improve the safety of the blood transfusion process	• Ensure that policies on patient identification are in place, implemented and monitored throughout the blood transfusion process from prescription, sampling, laboratory testing and issue of blood to collection and administration of blood transfusion	Chief Executives of NHS Trusts working with clinical governance leads, clinicians, hospital staff, blood transfusion laboratories, Hospital Transfusion Committees and Teams By December 2002
	• Ensure good hospital transfusion laboratory practice and encourage participation in national laboratory accreditation schemes	Chief Executives of NHS Trusts working with blood transfusion laboratories and Hospital Transfusion Committee By April 2003
Ensure that information for the traceability of blood is recorded and retrievable	• Review the data recording and retrieval systems for blood transfusion	Chief Executives of NHS Trusts working with clinical governance leads, Hospital Transfusion Committees and Teams By April 2003
Ensure that information is available for monitoring the safety and appropriate use of blood	• Ensure appropriate staffing and IT support to undertake monitoring	Chief Executives of NHS Trusts working with clinical governance leads, Hospital Transfusion Committees By April 2003
	• Ensure that a minimum dataset (see Annex A) for each transfusion is documented	Hospital Transfusion Committee and Teams working with clinicians By April 2003
Ensure that reporting of serious adverse events related to blood transfusion and near misses is being undertaken	• Ensure that appropriate and timely information is provided to the Hospital Transfusion Team	Chief Executives of NHS Trusts working with clinicians, blood transfusion laboratories, Hospital Transfusion Teams By December 2002
	• Ensure timely feedback to blood users on subsequent lessons learnt	Hospital Transfusion Teams By December 2002
	• Ensure participation in the Serious Hazards of Transfusion (SHOT) scheme and that timely reporting is in place	Chief Executives of NHS Trusts By December 2002

- **Avoid unnecessary use of donor blood in clinical practice**

Objective	Action	By whom and when
Ensure the appropriate use of blood and use of effective alternatives in clinical practice	• Implement existing national guidance (see Annex A) on the appropriate use of blood and alternatives	Chief Executives of NHS Trusts working with clinicians and Hospital Transfusion Committee and Teams By December 2002
Secure appropriate and cost-effective provision of blood transfusion and alternatives in surgical care	• Ensure that mechanisms are in place for the pre-operative assessment of patients for planned surgical procedures	Chief Executives of NHS Trusts working with clinicians and Hospital Transfusion Teams By April 2003
	• Ensure that indications for transfusion are in place, implemented and monitored	Hospital Transfusion Committees and Teams By April 2003
	• Review and explore the use of effective alternatives to donor blood and the appropriate use of autologous blood transfusion; pre-donation, peri-operative and post-operative cell salvage	Chief Executives of NHS Trusts working with clinicians and Hospital Transfusion Committees and Teams By April 2003

- **Provide better information to patients and the public about blood transfusion**

Objective	Action	By whom and when
Ensure patients at risk of transfusion are informed of their choices	• Ensure that timely written information is made available to patients on blood transfusion and alternatives	Hospital Transfusion Committees working with clinicians, patient groups and Primary Care Trusts By April 2003

- **Monitoring of arrangements for Better Blood transfusion**

Objective	Action	By whom and when
Promote the safe and appropriate use of blood and cost-effective alternatives in Trusts	• Ensure that services commissioned are safe and value for money in relation to *Better Blood Transfusion*	Primary Care Trusts working with NHS Trusts By April 2003
	• Ensure that services for *Better Blood Transfusion* being provided are operating effectively and are part of local performance management arrangements	Health Authorities By April 2003

Background

The Chief Medical Officer's *Better Blood Transfusion* conference was held in October 2001 jointly organised by the National Audit Office, the National Blood Service and the Department of Health and chaired by the UK four Chief Medical Officers. The aim of this multidisciplinary conference was to share views on how clinical blood transfusion practice could be improved with the following aims:

- Ensure that *Better Blood Transfusion* is an integral part of NHS care
- Make blood transfusion safer
- Avoid unnecessary use of blood in clinical practice
- Provide better information to patients and the public about blood transfusion

A survey of NHS Trusts in England of progress that had been made in blood transfusion practice since the first Evidence-Based Blood Transfusion conference in 1998 was presented at the conference.

It highlighted that in some areas of blood transfusion practice, there was very good progress:

- The establishment of Hospital Transfusion Committees
- Participation in the Serious Hazards of Transfusion (SHOT) scheme

In other areas, more needed to be done:

- Multidisciplinary staff training in the process of blood transfusion
- The availability of Hospital Transfusion Practitioners
- Local approved protocols based on national guidelines for the appropriate use of blood
- Audit of blood transfusion practice
- The use of autologous blood transfusion
- The provision of written information to patients on blood transfusion.

The results of the survey, presentations and conclusions from the conference workshops can be found on the *Better Blood Transfusion* website www.doh.gov.uk/bbt2.

Associated Documentation

ANNEX 1 - Information for Implementation of Better Blood Transfusion:

This Circular has been issued by:

Sir Liam Donaldson
Chief Medical Officer

ANNEX A

Information for Implementation of Better Blood Transfusion Managing Better Blood Transfusion at Trust level

1. Trusts involved in blood transfusion should establish a **Hospital Transfusion Committee** (HTC) with the authority and resources to take the necessary actions to improve transfusion practice or share a committee between Trusts.

   An HTC should:

   - Promote best practice through local protocols based on national guidelines.
   - Lead multi-professional audit of the use of blood components within the NHS Trust, focusing on specialties where demand is high e.g. certain surgical specialties and haemato-oncology.
   - Audit the practice of blood transfusion against the hospital policy and national guidelines, focussing on critical points.
   - Provide feedback on audit of transfusion practice and the use of blood to all hospital staff involved in blood transfusion.
   - Promote the education and training of all clinical, laboratory and support staff involved in blood transfusion, including the collection of specimens.
   - Have the authority to modify and improve existing blood transfusion protocols and to introduce appropriate changes to practice.
   - Be a focus for local contingency planning for and management of blood shortages.
   - Report regularly to Regional Transfusion Committees, and through them, to the National Blood Transfusion Committee.
   - Participate in the activities of the Regional Transfusion Committee.
   - Consult with local patient representative groups where appropriate.
   - Contribute to the development of clinical governance.

2. Trusts involved in blood transfusion should implement arrangements for promoting good transfusion practice through the development of an effective clinical infrastructure. Trusts should establish a **Hospital Transfusion Team** (HTT). This should consist of the **lead consultant for transfusion** in the Trust (with sessions dedicated to blood transfusion), a **hospital transfusion practitioner** or equivalent (e.g. nurses, biomedical scientists, medical professionals), and the **blood bank manager** with or without other members of the HTC. There should be identified clerical, technical, managerial and IT support as required, and access to audit and training resources to promote and monitor safe and effective use of blood and alternatives.

   The role of the HTT is to:

   - Assist in the implementation of the HTCs objectives
   - Promote and provide advice and support to clinical teams on the appropriate and safe use of blood
   - Actively promote the implementation of good transfusion practice
   - Be a source for training all hospital staff involved in the process of blood transfusion

3. Large Trusts or Trusts with more than one site will need to ensure they have adequate coverage by the hospital transfusion team and the hospital transfusion practitioner to ensure that good transfusion practice is implemented in all clinical areas. Further information on the role of the hospital transfusion practitioner will be made available through the *Better Blood Transfusion* website.

4. If a HTC or HTT and its members cover more than one Trust, arrangements should be in place to ensure that there is sufficient cross-Trust representation. Trusts should also ensure that there are adequate resources and mechanisms for ensuring the safe, effective and appropriate use of blood at all the Trust sites involved in blood transfusion.

5. HTCs should implement good transfusion practice through Trusts' frameworks for clinical governance, and performance and risk management (Clinical Negligence Standards for Trusts (CNST) standards). Senior Trust management should be represented on the HTC. There should

be HTC representation on the Trust's clinical governance / risk management committee and the HTC representative invited to present an annual report on blood transfusion.

6. HTCs should work in a partnership with blood users, blood services and patients to improve the safety and effectiveness of blood transfusion.

7. HTCs should participate in the appropriate activities of the Regional and National Blood Transfusion Committees for implementing and monitoring good transfusion practice.

Training and Education

8. Trusts should provide regular (annual) documented training in safe and effective transfusion practice for all staff involved in the transfusion process from prescription to final administration and monitoring (including phlebotomists, laboratory staff, porters, nurses and medical staff) in line with national guidelines. Examples of training modules and how they may be accessed will be made available through the *Better Blood Transfusion* website.

9. Trusts should review the blood transfusion content of clinical multi-disciplinary audit and CPD programmes for NHS Trust staff, including the Hospital Transfusion Team.

10. Trusts should ensure that blood transfusion is included in the induction and orientation programmes for new staff.

Patient Information

11. Trusts should provide timely written information about blood transfusion and its alternatives, wherever possible, to patients at risk of a blood transfusion.

12. National leaflets can be used and adapted for local use. An example of these and contacts for examples of leaflets for specific patient groups will be made available through the *Better Blood Transfusion* website.

Guidelines for Good Practice and Standards

13. Trusts should have agreed and disseminated protocols for safe and effective transfusion practice, based on national guidelines and supported by in-house training. Guidelines should include indications for transfusion, the laboratory details to be checked and actioned before and after transfusion, the monitoring required during transfusion, and the documentation required in the clinical records.

14. Trusts should adopt national guidelines for the appropriate use of blood.

15. The following national guidelines and web sites for the safe, effective and appropriate use of blood are recommended to all Trusts. These and additional guidelines, where available electronically, will be linked through the *Better Blood Transfusion* website.

- Scottish Intercollegiate Guidelines Network. ***Perioperative Blood Transfusion for Elective Surgery – A national clinical guideline.*** Number 54. October 2001. http://www.sign.ac.uk/

- The Association of Anaesthetists of Great Britain and Ireland. ***Blood Transfusion and the Anaesthetist. Red Cell Transfusion.*** December 2001.

- British Committee for Standards in Haematology, Blood Transfusion Task Force. ***Guidelines for the administration of blood and blood components and the management of transfused patients.*** Transfusion Medicine 1999; 9 :227-238. http://www.bcshguidelines.com

- British Committee for Standards in Haematology, Blood Transfusion Task Force. ***Guidelines for the clinical use of red cell transfusion***. British Journal of Haematology 2001; 113:24-31. http://www.bcshguidelines.com/

- The Stationary Office. ***Handbook of Transfusion Medicine***. Third Edition, 2001. https://www.thestationeryoffice.co.uk/nbs/handbook2001/index.htm]

- Joint National Institute of Biological Standards and Control and United Kingdom Blood Transfusion Services guidelines www.transfusionguidelines.org.uk .

Safety

All Trusts that undertake blood transfusion:

16. Should participate in the Serious Hazards of Transfusion (SHOT) scheme on the reporting of serious and near miss events. http://www.shot.demon.co.uk/

17. Should ensure that all patients (including outpatients) receiving a blood transfusion have a patient identification wristband or equivalent, and are monitored during transfusion according to national guidelines.

18. Should ensure good hospital transfusion laboratory practice and encourage participation in national laboratory accreditation schemes

Audit

All Trusts undertaking blood transfusion should:

19. Carry out regular multidisciplinary audit of transfusion practice and regularly feed back the results of audits of transfusion practice and the use of blood to relevant staff and ensure that improvements suggested by audit are put in place.

20. Participate in the joint Royal College of Physicians and National Blood Service national comparative audit of the clinical transfusion process and the use of blood and other future national audits.

    Initial information is available at http://www.doh.gov.uk/bbt2/lettertoce.htm and further information will be made available through the *Better Blood Transfusion* website.

21. Participate in the Blood Stocks Management Scheme. http://www.blood.co.uk/bsms/body.asp

Monitoring and traceability

22. Trusts should ensure that there is routine data recording and collection to enable the traceability and monitoring of the safe, effective and appropriate use of blood. Trusts should review and explore the development of electronic systems for this purpose.

23. Trusts should ensure that a minimum dataset for each transfusion is documented in the clinical notes (indication for transfusion, amount of blood transfused, assessment of the effectiveness of the transfusion, and any adverse effects and their management).

24. Trusts should ensure that the clinical indication for transfusion is provided on the request form for blood transfusion.

Pre-operative assessments, use of patient's own blood and alternatives to blood transfusion

25. Trusts should ensure that that there are adequate arrangements for the pre-operative assessment of patients. For planned surgery, the arrangements for pre-operative assessment should permit the diagnosis and correction of anaemia in advance of surgery and optimisation of haemostatic function peri-operatively (including discontinuation of anti-platelet drugs and haematological advice for patients on oral anticoagulation). Most patients undergoing elective surgery should not require transfusion support if their pre-operative haemoglobin level is normal. Formulae are available to calculate individual patients' transfusion requirements depending on the predictable blood loss from the procedure, and patient characteristics. The use of such formulae should allow each surgical team to set its own parameters for transfusion, and allow their use of blood to be audited to these parameters. Further information will be available through the *Better Blood Transfusion* website.

26. Trusts should review and explore the use of effective alternatives to donor blood and the appropriate use of autologous blood transfusion. Further information will be made available through the *Better Blood Transfusion* website

National Initiatives
Better Blood Transfusion Conference and Website

27. The website for '*Better Blood Transfusion*' has been created to promote the initiative and to share examples of good practice and is in development. This will be further developed and contain tools to assist in implementing *Better Blood Transfusion* initiative. The current website from the conference can be found at www.doh.gov.uk/bbt2.

Regional and National Transfusion Committees

28. The overall objective of the newly established National Blood Transfusion Committee and the Regional Transfusion Committees is to promote safe and effective good transfusion practice in hospitals in accordance with the *Better Blood Transfusion* initiative and with this HSC. The committees provide a framework to channel information and advice to hospitals and their transfusion committees on best practice and performance monitoring. The Regional Transfusion Committees support the activities of Hospital Transfusion Committees within their region. Further information about these committees will be made available through the *Better Blood Transfusion* website.

- The National Blood Transfusion Committee provides national support and advice on national *Better Blood Transfusion* initiatives
- Regional Transfusion Committees have a role to engage with HTCs in assisting in the safe and effective use of blood and alternatives to transfusion

National Blood Service

29. Other supporting arrangements for Trusts Hospital Transfusion Committees for *Better Blood Transfusion* include the Hospital Liaison Service provided by the National Blood Service (through its Link Consultants, Hospital Liaison Managers and Transfusion Liaison Nurses).

Recommendations requiring further work

30. The need for further work to support the *Better Blood Transfusion* initiative was highlighted at the CMOs conference. Several of the following areas are already in initial development and will be placed on the *Better Blood Transfusion* website when progressed.

- Consideration of a national transfusion episode record. Consideration should also be given to the development of a standard format for reporting of transfusion incidents and errors in Trusts. Future examples of these will be available through the *Better Blood Transfusion* website.
- Explore the application of new technologies to improve the safety and effectiveness of transfusion practice.
    - Development of electronic systems to improve the safety of the process of transfusion and to monitor the appropriate use of blood. Examples of studies in this area will be made available through the *Better Blood Transfusion* website.
- Development of a tool for assessing the 'resources' required to implement *Better Blood Transfusion* at Trust level (e.g. the bed numbers/case-mix/specialties/blood use parameters required to help inform the 'critical mass' for an HTC and the make-up in 'sessional' time of a HTT)
- Development of national training and educational materials
- Continued development of patient information leaflets
- Systematic review and research into the clinical and cost-effectiveness of transfusion practice including alternatives to donor blood transfusion

Abbreviations

CMO	Chief Medical Officer
CNST	Clinical Negligence Scheme for Trusts
CPD	Continuous Professional Development
HA	Health Authority
HSC	Health Service Circular
HTC	Hospital Transfusion Committee
HTT	Hospital Transfusion Team
NBS	National Blood Service
NBTC	National Blood Transfusion Committee
PCT	Primary Care Trust
RTC	Regional Blood Transfusion Committee
SHOT	Serious Hazards of Transfusion
vCJD	Variant Creutzfeld-Jakob Disease

REPORT FOR ADVISORY COMMITTEE ON BLOOD SAFETY
3 OCTOBER 2002

1 vCJD

(a) Position Statement

An updated Position Statement on behalf of the UK Blood Services has recently been prepared by one of its expert Working Groups. This is enclosed for information.

(b) Planned Precautionary Measures

Following direction from the respective Departments of Health the four UK Blood Services are planning to import fresh frozen plasma from the United States for use in neonates and children born after 01 January 1996. This plasma will be pathogen inactivated using methylene blue treatment.

NIBTS is planning to obtain the required amount of imported plasma via the Scottish BTS. There have been some difficulties in sourcing this plasma but it is now anticipated that finished product will be available for issue by March 2003.

The English National Blood Service has similar plans. As an interim step the NBS has recently started to provide methylene blue treated, UK plasma for the same target patient groups ie until imported plasma becomes available. NIBTS has provided methylene blue treated plasma for neonates only since 1998 but does not plan to extend this for the other target group until imported plasma becomes available.

Note: It will be helpful if DHSS PS can provide clarification as to whether it will be mandatory for clinicians to use only

imported plasma for the target group of patients referred to.

(c) Future Precautionary Measures

Future precautions could involve the following:

(i) Extension of importation for other patient groups (adults) or other blood components, e.g. red cells.

(ii) Exclusion of blood donors with a history of blood transfusion (or possibly high risk surgery) or using selected blood (from untransfused donors) for target patients (neonates or children).

(iii) Screening blood test for vCJD if this becomes available.

It should be noted that implementation of (ii) or (iii) above is likely to create significant problems with blood supplies, hence the importance of promoting better transfusion practice.

2 HIV and Blood Transfusion

All blood donations are, of course, screened for HIV antibody. There are no known, proven cases of HIV transmission by blood components (as opposed to coagulation concentrates) in Northern Ireland.

There has been a noteworthy increase in HIV antibody positive blood donors recently, ie two positives detected in 2002 following an 11 year period during which no positives were detected. Scotland has experienced a similar increase, i.e. 6 positives in 2002 to date following previous 2 year period when only 1 positive was detected.

If this is the start of a sustained increase in HIV positives in the blood donor population the risk of HIV transmission by blood transfusion could increase (from donations during the 'window period'). The 'window period' can be reduced by testing for HIV RNA (in addition to HIV antibody). This test can be done (by the Scottish BTS) on the same blood samples provided for hepatitis C RNA testing. This was carried out for a period recently on a pilot basis but was subsequently discontinued. There may be a case for reviewing the position.

3 **HTLV I/II Testing**

The four UK Blood Services plan to introduce routine testing for antibody to human T cell leukaemia virus (HTLV) on mini pooled blood samples. NIBTS is contracting with SNBTS for such testing – the same samples as for hepatitis C RNA testing will be used. This is planned to commence routinely by October/November 2002

4 **Bacterial Contamination**

The UK Surveillance Scheme (SHOT) has shown that bacterial infection is the most common, serious transfusion transmissible infection. This is caused by bacterial contamination and subsequent growth of bacteria in blood components – most commonly originating from the donor arm. The commonest component involved is platelet concentrate, relating to the requirement for 20-24°C storage. Various preventative initiatives are being developed within the UK Blood Services and all are at various stages of implementation. The position in NIBTS is as follows:

(i) Sample diversion (first 20-30mls of blood is directed for samples) – implemented June 2001.

(ii) Enhanced arm cleansing – will be piloted for platelet pheresis donors by October 2002.

(iii) Bacterial testing (automated culture) of platelet concentrate – is being carried out on a pilot basis on approximately 70% of all platelets since June 2001.

A fourth approach, involving a newly licensed pathogen inactivation system (for platelet concentrates) is under consideration by the UK Blood Services.

Note: It would be of value to have an agreed approach at hospital level for the investigation of suspected bacterial infection from contaminated blood.

W M McClelland

16 September 2002

9#02

Subject: Creutzfeldt-Jakob Disease
Date prepared: Update: 15th August, 2002
Prepared by: vCJD Working Group (chair Marc Turner) of the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI)

UK BTS POSITION STATEMENT

Background

Creutzfeldt-Jakob Disease (CJD) is one of a group of diseases called Transmissible Spongiform Encephalopathies. All of these diseases have a very long incubation period, cause severe and irreversible damage to the central nervous system and there are so far no treatments

Sporadic CJD, was first described in the early 1920s, occurs throughout the world and affects around one person per million per year with an average age of onset of 65. Patients experience a rapidly progressive dementia with death within around six months. Other forms of the disease have since been described, including Kuru which was endemic in the Fore people of Papua New Guinea in the 1950s and transmitted through cannibalistic funeral rites. There are also rare familial forms of CJD due to inherited genetic abnormalities. In addition, transmission of CJD has occurred during medical care through neurosurgical instruments, corneal and dura mater grafts and cadaveric-derived pituitary growth and follicular stimulating hormones. Despite epidemiological case control, look back and surveillance studies over the last twenty years, there have been no confirmed cases of CJD transmission by blood component or plasma product transfusion. However, as a precautionary measure, UK Blood Services apply agreed UK and European exclusion criteria (in line with WHO recommendations) to exclude anyone in a risk category from donating blood.

UKBTS Criteria for excluding blood donors who have, or who could have had, contact with CJD:

Obligatory: Permanently exclude individuals with CJD or other prion associated disorder.

Permanently exclude anyone identified at high risk of developing a prion associated disorder.

This includes:

Recipients of dura mater grafts.

Recipients of corneal or scleral grafts.

Recipients of human pituitary derived extracts such as growth hormone or gonadotrophins

Individuals at familial risk of prion-associated diseases. This includes individuals who have had two or more blood relatives develop a prion-associated disease and individuals who have been informed they are at risk following genetic counseling.

Exceptions:

Individuals who have had two or more blood relatives develop a prion-associated disease whom, following genetic counseling, have been informed that they are not at risk. This requires confirmation by the Consultant with responsibility for donors.

Variant Creutzfeldt-Jakob Disease

A different form of Creutzfeldt-Jakob Disease (variant CJD) was first identified in 1996. Unlike sporadic CJD, the new disease affects younger people (a median age of 29, range 14-74 years old). Clinical presentation is also different. Variant CJD patients show signs of behavioral disorder, depression and anxiety followed by problems with sensation and co-ordination leading to progressive dementia and death over a period of six months to two years. The clinical, epidemiological, neuropathological and experimental data all point to variant CJD being the same strain of disease as Bovine Spongiform Encephalopathy (BSE) and a different strain of disease from those seen in sporadic CJD. To date there have been just over 120 definite and probable cases of variant CJD in the UK, 1 case each in the Irish Republic, Italy and Hong Kong and 5 in France. The eventual number of individuals within the UK population likely to develop variant CJD remains uncertain; current estimates range up to 140,000. It is therefore not known what number of current or past blood donors may develop variant CJD in the future. It is also not known whether infectivity is present in the peripheral blood of any individuals who have been infected by the variant CJD agent and if it is, whether it will prove to be transmissible by blood transfusion. In view of these uncertainties the UK blood services have taken a number of precautionary measures. These include:

- Withdrawal and recall of any blood components or plasma derivatives made from a blood donation from any individual who later develops variant CJD (announced December 1997).
- Import of plasma from countries other than the UK for fractionation to manufacture plasma derivatives (announced May 1998, completed October 1999).
- Leucodepletion of all blood components (decision announced July 1998, completion Autumn 1999).

Questions and Answers

- *Is the UK blood supply safe?*

At present it remains uncertain how many UK blood donors may be incubating variant CJD and it is unknown whether the disease is transmissible by blood transfusion or not.

- *What is the risk that a patient could get variant CJD from a blood transfusion in the UK?*

We do not know. It is uncertain what proportion of UK blood donors may currently be incubating the disease, whether they have infectivity present in their peripheral blood and if so, whether the disease will prove to be transmissible by blood transfusion. To date there is no evidence to suggest that any case of CJD, sporadic or variant is due to receiving a transfusion. However it is known that variant CJD is different from sporadic CJD in that it

involves the peripheral immune system. Also, the prevalence of variant CJD in the UK donor population could be higher than that of sporadic CJD. The absence of evidence that sporadic CJD is transmissible by transfusion cannot be assumed to be evidence of absence of risk of variant CJD transmission. The Department of Health has carried out a risk assessment to help inform potential precautionary blood transfusion policy decisions. The UK blood services and the CJD surveillance unit are collaborating in a joint study which is designed to examine whether there is a relationship between blood transfusion and development of vCJD, but this is a long term study and it is unlikely to reveal any useful information for some years.

- *Are there any additional donor selection criteria that can be applied?*

Within the UK no additional donor selection criteria have emerged from risk assessment thus far. Other countries, including the USA, Canada, New Zealand, Australia, Hong Kong and several European countries including Germany, Switzerland, Austria and Eire have taken the precautionary step of excluding blood donors who have spent more than a defined period in the UK between 1980 and 1996. Many countries currently apply a cumulative residence period of 6 months.

- *Will you continue to use UK blood donors?*

At present, all blood components (i.e. red cells, platelet and clinical plasma) are derived from UK blood donors. It is most unlikely that it would be feasible to obtain the amount of blood we require from non-remunerated, non-UK blood donors. Even if it were possible to source blood from other countries, this could increase the risk of exposure to other infectious agents, would be very difficult to implement for certain categories of component with short shelf lives and could precipitate critical blood shortages. The issue is therefore one of balance of risks. On the 15th August the Department of Health announced that, within the next 9-12 months methylene blue inactivated FFP from unremunerated donors will be imported from the United States for neonates and children born after 1st January, 1996.

In view of the recent data demonstrating transmission of BSE and scrapie by blood transfusion in a sheep model, consideration is also currently being given as to whether donors who themselves have received blood transfusions since 1980 should be deferred from donation. In the UK it is estimated that this would lead to a donor loss of between 5-8%.

- *Is there a blood test available for variant CJD?*

No. The types of tests that are used to screen blood donations for viruses cannot be applied to variant CJD because it is a different type of disease. Several international groups of research workers are working to try to develop a blood test, but it is currently unclear whether this will be possible and, if so, what the time frame is likely to be.

- *Can blood donors contract variant CJD from giving blood?*

Blood donations are taken through disposable needles and equipment so it is not possible for anyone to contract variant CJD by blood donation. Demand for blood is rising and the UK BTSs have a duty to supply hospitals with the blood components needed for patient care. This can only be achieved with the help of blood donors and their continued support is vital.

- *Will universal leucodepletion reduce the risk of transmission of variant CJD?*

Universal leuodepletion was announced by the UK government in July 1998 and implementation was completed by the Autumn of 1999. In patients with sporadic CJD and in animal models where infectivity has been found in the peripheral blood, a large proportion has been associated with the white blood cells. Leucodepletion removes all but a very few white cells, and it is hoped that leucodepletion will reduce the level of infectivity in the peripheral blood (if present) to below the threshold for transmission. However this is unproven.

- *Are plasma derivatives likely to be infectious?*

As of October 1999, all plasma products including Factor VIII and Factor IX, immunogloblins and albumin are derived from donors outwith the UK. Therefore, there should be no further risk to patients receiving plasma products provided donors in other countries are not harboring variant CJD. The risk to patients who received plasma products before October 1999 is uncertain. The UK BTSs have engaged in research on the ability of the plasma fractionation processes to remove prions. These studies have shown that there are steps during each manufacturing process which remove prions. Similar studies have been performed by other non-UK organisations with similar results. However, the starting level of infection in plasma from UK donors remains unknown. The risk from UK plasma derived plasma products is likely therefore to have been very low, but we cannot yet assume that the risk was zero.

- *Should UK patients continue to accept blood components?*

Blood transfusions should only be given when it is essential to the health or survival of the patient. In these circumstances the benefits of blood transfusion outweigh the uncertain risk of transmission of variant CJD. In some circumstances alternatives are available which could reduce the exposure to blood components. BTS clinicians are continuing to work with colleagues throughout the National Health Service in establishing and implementing guidelines for the appropriate use of blood. It is a priority for the UK Chief Medical officers and the medical community in the UK to ensure that patients are treated with blood transfusion only when there is a real need.

- *Is any treatment available for CJD?*

There is no treatment currently available for *CJD*. Ongoing research suggests that there are a number of drugs which could be of value in prevention of transmission or treatment of disease during the early pre-clinical phase of the disease or with the onset of clinical problems. However, some of these do have significant side effects and at present none are of proven efficacy in preventing the transmission or progression of disease.

- *Optimal blood usage?*

Optimising blood usage is an urgent priority both in terms of minimising any unnecessary exposure of patients to blood transfusion and also in order to reduce the demand on the blood supply at a time when there may be significant reduction in the donor base.

The Scottish Intercollegiate Guidelines Network (SIGN) have produced guidelines on peri-operative blood transfusion for elective surgery. Their recommendations are graded A, B, C and D to indicate the strength of the supporting evidence. Good practice points are provided where the Guideline Development Group wish to highlight specific aspects of accepted clinical practice.

Details of the evidence supporting these recommendations and their application in practice can be found in the full guideline, available on the SIGN website; www.sign.ac.uk. These guidelines were issued in October 2001.

1. Deciding whether or not to Transfuse

   The decision to transfuse any patient for given indication must balance the risks of not transfusing, influenced for example by disease prognosis, against the risks of transfusion, influenced for example by the probable duration of patient survival and the incubation time of known infective agents.

   D) Given the potential risks, however small, each allogeneic transfusion must have a valid, defined and justifiable indication.

   ⇒ The indication for each transfusion should be documented in the patient's records.
   ⇒ In a haemo-dynamically stable patient, one unit of concentrated red cells should be transfused at a time, allowing the benefit of each to be assessed at 24 hourly intervals.

   B) Transfusion of leucodepleted allogeneic blood should not be limited by concerns over increased cancer recurrence or perioperative infection.

   D) All surgical and anaesthetic units should have protocols;
   ⇒ To prepare anticoagulated patients for all types of surgery
   ⇒ For deep venous thrombosis prophalaxis in the perioperative period.

2. Avoiding Procedural Error

D) The British Committee for Standards in Haematology collaborative guidelines for the administration of blood and blood components and management of transfused patients should be implemented in all Scottish hospitals where transfusion takes place.

   ⇒ A final check of the patient's wrist identity band against the identity given on the blood component to be transfused is essential for safe practice.

3. Haemoglobin Transfusion Thresholds

   The transfusion threshold is the haemoglobin value at which transfusion will normally be indicated, under stable conditions, and in the absence of other clinical signs or symptoms of anaemia.

⇒ A transfusion threshold should be defined as part of an over all strategy to provide optimal patient management.
⇒ The transfusion threshold should be viewed as the haemoglobin value below which the patient should not fall during the perioperative period, particularly in the context of ongoing or anticipated blood loss.

4. Preoperative Threshold

⇒ All patients undergoing major elective surgery should have a full blood count performed prior to surgery, to avoid short term cancellation and to allow those patients presenting with anaemia to be investigated and treated properly (eg iron therapy).

C) Where possible, anaemia should be corrected prior to major surgery to reduce exposure to allogeneic transfusion.

5. Intraoperative Thresholds

There is no indication that thresholds should differ during this period, but the use of Intraoperative transfusion must reflect the ongoing rate of surgical bloodloss, continuing haemodynamic instability and, anticipating perioperative bleeding.

6. Post Operative Thresholds

B) Transfusion is required at haemoglobin values less than 70 grams/l.

C) Patients with cardiovascular disease are those expected to have a high incidence of covert cardiovascular disease (eg elderly patients or those with peripheral vascular disease are likely to benefit from transfusion when their haemoglobin level falls below 90g/l.

D) Transfusion is unjustified at haemoglobin values less than 100g/l.

7. Predicting the need for Transfusion

Nine risk factors which predict the need for allogeneic transfusion have been identified;

⇒ Low preoperative haemoglobin/haematocrit, either before intervention or on day of surgery
⇒ Low weight
⇒ Small height
⇒ Female sex
⇒ Age over 65 years
⇒ Availability of Preoperative Autologous Blood Donation (PABD)
⇒ Estimated surgical blood loss
⇒ Type of surgery
⇒ Primary or revision surgery.

8. Blood Sparing Strategies

Blood sparing strategies should be considered for all patients who may require a transfusion (Mercuriali's formula may be used to identify these patients) and who have consented to transfusion.

⇒ All patients undergoing major blood losing surgery, and who have consented to transfusion, must have as a minimum provision a blood specimen grouped and screened by their hospital bank.

9. Preoperative Autologous Blood Donation

B) Preoperative Autologous Blood Donation (PABD) can be used to reduce allogeneic blood exposure, although it does increase the total number of transfusion episodes.

D) PABD should be offered only when it is possible to guarantee admission and operative dates.

C) PABD should be targeted to :

⇒ Men who present with haemoglobin 110/145 grams/l
⇒ Women who present with haemoglobin 130-145g/l
⇒ PABD can be used safely in elderly populations with diverse comorbidities.

- Any patient undergoing surgical procedures currently served by a Group Screen policy as unsuitable for preoperative donation.
- Patient undergoing primary hip and knee surgery with a presenting haemoglobin less than 140g/l should be discouraged from autologous donation.

10. Erythropoietin

⇒ Erythropoietin use should be targeted to patients aged under 70 years old who are scheduled for major blood losing surgery and who have a presenting haemoglobin less than 130g/l.

D) Erythropoietin can be used for patients with objections to allogeneic transfusion for surgery that involves major blood loss.

- If Erythropoietin brings about a less than 0.50 rise in the patient's Haematocrit, a 50 ml Venesection should be undertaken.

11. Combining the assigned brand and Erythropoietin

B) In fit patients undergoing major surgery, Erythropoietin can be used :

⇒ In combination with Autologous blood collection to reduce allogeneic transfusion
⇒ To obtain multiple Autologous red cell donations while maintaining an adequate day of surgery haemoglobin.

12. Acute Normovolaemic Haemodilation (ANH)

ANH is potentially most useful for a patient meeting all of the following criteria:

⇒ Substantial anticipated blood loss
⇒ A relatively low target haemoglobin (intra operatively and post operatively)
⇒ A relatively high initial haemoglobin

ANH should be limited to patients with a haemoglobin level sufficiently high to allow 1000ml of blood to be removed, and in whom a relatively low target haemoglobin is deemed appropriate.

- ANH should only be implemented where the logistics of blood removal and replacement can be undertaken without detracting from patient care. Hospitals considering ANH must address organisational issues, including the provision of appropriate support to the anaesthetist.

Autologous blood should be labelled and stored according to the British Committee for Standards in Haematology blood transfusion guideline, with particular care being taken where Autologous blood transfusion is initiated post operatively.

13. Blood Ordering Equations

Blood ordering schedules require the ordering of blood to the likelihood that the transfusion will be required. Taking into account the type of operation and an individual patient's risk factors.

C) All hospitals should use a maximum surgical blood ordering schedule to provide concentrated red cells.

When ordering blood, all nine factors determining the risk and degree of transfusion should be taken into account Mercuriali's formula.

14. Mercuriali's Formula

Expected Blood Loss	=	Preoperative Red Cell Volume	-	Post Operative Red Cell Volume	+	Red Cells Transfused

- *Preoperative Red Cell* volume is influenced by :
  preoperative haemoglobin, weight, height, sex

- *Postoperative Red Cell* volume is influenced by :
  post operative target haemoglobin, height, weight, sex, age, medical history.

- *Red Cells Transfused* is partly determined by the potential use of blood sparing strategies such as salvage, PABD, ANH.

15. Cardiac and Orthopaedic Surgery

Aprotinin and Antifibrinolitics

B) The use of Aprotinin or Tranexamic Acid is recommended for patients undergoing Cardiac Surgery which carries a high risk of transfusion (eg repeat Cardiac operations, multiple valve replacement, thoracic Aortic operations, patients on preoperative aspirin therapy and procedures which anticipated long bypass times).

- Aprotinin may be considered to reduce blood loss in hip and knee arthroplasties, but its use should be restricted to :

- procedures with an increased risk of high blood loss (eg bilateral and revision)
- circumstances where other blood conservation techniques are not appropriate (eg treatment of Jehovah's Witnesses)

- Tranexamic Acid can be used to reduce blood loss and transfusion requirements in patients undergoing knee replacement surgery, when other blood conservation techniques are inappropriate and where major blood loss is anticipated.

16. Cell Salvage

C) Reinfusion of washed shed mediastinal blood may be used to reduce allogeneic transfusion in cardiac surgery.

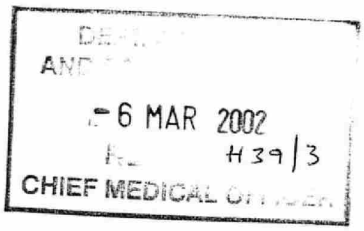
B) In Orthopaedic surgery, unwashed post operative salvage using drains should be considered in patients in whom a post operative blood loss of between 750ml and 1500mls is expected (eg bilateral joint replacement).

B) In Orthopaedic surgery, washed intra-operative salvage should be considered in patients in whom an intra-operative blood loss of more than 1500mls is anticipated (eg major pelvic, spinal or uninfected revision surgery).

B) Cell salvage using either unwashed or washed red blood cells may be considered as a means of significantly reducing the risk of exposure to allogeneic blood in Orthopaedic surgery.

FROM: MARGARET MARK (DR)

DATE: 6 March 2002



CMO

You requested me to consider the SIGN Guidelines on Perioperative Blood Transfusion for Elective Surgery. These Guidelines do address aspects of blood transfusion practice, which were not addressed by the CREST Guidelines issued in February 2001, particularly in respect of autologous blood transfusion.

GRO-C

MARGARET MARK (DR)
Medical Officer

DRAFT FOR CMO'S SIGNATURE – PREPARED BY DR M MARK

To Medical Directors of HSS Trusts to forward to

the Chairpersons of Hospital Transfusion Committees

and all Consultants in Surgical Specialties

Dear Colleague

SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK/CLINICAL GUIDELINES ON PERIOPERATIVE BLOOD TRANSFUSION FOR ELECTIVE SURGERY

I enclose a copy of the Perioperative Blood Transfusion for Elective Surgery Guidelines and Quick Reference Guide, which have been published by the Scottish Intercollegiate Guidelines Network (SIGN) in October 2001. These include recommendations on deciding whether or not to transfuse, avoiding procedural error, and transfusion in cardiac and orthopaedic surgery. The recommendations are graded A, B, C and D to indicate the strength of the supporting evidence and good practice points [√] are provided where the Guideline Development Group wish to highlight specific aspects of accepted clinical practice. Details of the evidence supporting these recommendations and their application in practice can be found in the full guidelines available on the SIGN website: www.sign.ac.uk.

These guidelines complement the CREST published guidelines for blood transfusion practice in Northern Ireland in February 2001. These included guidelines for red cell transfusion, the management of massive haemorrhage and the use of blood components in obstetrics and neonatal transfusion. The CREST guidelines are available from Mrs Angela Lowry, CREST Secretariat, Room 517, Dundonald House, Upper Newtownards Road, Belfast and on the CREST website: www.n-i.nhs.uk/CREST.

Both these sets of guidelines are of relevance to Northern Ireland practitioners who use blood. It is strongly recommended that these guidelines are used by those involved in the use of blood to modify their practice, where appropriate.

Yours sincerely

HENRIETTA CAMPBELL (DR)

Chief Medical Officer

NI SURVEY OF BLOOD TRANSFUSION PRACTICE

A survey was conducted in August 2001 to provide feedback on the Trusts' experience on implementing the actions requested in the Circular HSS (MD) 3/99 entitled "Better Blood Transfusion".

Information was collected on a number of issues including Hospital Transfusion Committees (HTCs), participation in the Serious Hazards of Transfusion (SHOT) Scheme, protocols for safe use of blood, staff training, audit, autologous transfusion, information given to patients and methods of improving blood transfusion.

RESULTS

There was a 100% response rate; 13 Trusts had a Blood Transfusion Service and all of these had a Hospital Transfusion Committee (HTC); 4 of these were chaired by a consultant anaesthetists, 3 by a haematology consultant, 2 by a nephrologist, 2 by a consultant physician, 1 by a A&E consultant and 1 by a consultant neonatologist.

There was a considerable range in the units of red cells transfused in hospitals.

Table 1: Number of Red Cells Transfused

No of Red Cells Transfused	< 1000 Units	1,000-5,000 Units	5,000-100,000 Units
Number of Trusts	3	6	2

HTCs Activity

All but one HTC met regularly, with 50% meeting at least 4 times yearly. The one HTC that had not met was in a small district hospital with a low use of blood.

Safety

All Trusts participate in the Serious Hazards of Transfusion (SHOT) Scheme. 4 Trusts involved in Blood Transfusion have unconditional CPA accredited haematology laboratory services, 5 have conditional accreditation, 2 have had accreditation withdrawn (mainly due to lack of a haematologist), and 2 have not applied for accreditation.

Guidelines

The process of transfusion

Numbers of Trusts with protocols for the process of transfusion are shown in Table 2.

Table 2: Number of Trusts with the following protocols for the process of transfusion.

Blood sample collection for compatibility testing	Collection of Blood from Refrigerator and delivery of clinical areas	Checking and Administering Blood	Investing at the Management of Adverse Events associated with Transfusion
13 (100%)	10 (77%)	13 (100%)	11 (84%)

Protocols for the Use of Blood

National guidelines produced by the British Committee for Standards in Haematology (BCSH) exist for all areas of transfusion practice. Trusts were asked to report to. protocols for use of blood. (Table 3)

Table 3: Number of Trusts with the following protocols for the use of blood

Name of Protocol	Total Number of Trusts	
Maximum surgical blood order schedule (MSBOS)	11	85%
Emergency Transfusion	7	54%
Massive Transfusion	11	11%
Use of red cell transfusions	8	61%
Use of platelet transfusions	3	23%
Use of fresh frozen plasma	4	31%
Management of warfarin overdose	2	15%

Other protocols in place were:

1) Use of Blood in Obstetrics
2) Neonatal Transfusion
3) In house surgical blood order schedule
4) Use of uncrossmatched blood
5) Use of HPPF/Albumen
6) Group and hold for surgical/gynae
7) Sample identification.

Training

Replies showed there was considerable variation in training (Table 4)

Table 4: Number of Trusts with Staff Training in Blood Transfusion Procedures

	Sample Collection	Blood Collection	Administration of blood	Investigation and Management of Adverse effects of Transfusion
Portering Staff	N/A	5 (38%)	N/A	
Phlebotomists	10 (77%)	N/A	N/A	
Nursing Staff	11 (85%)	9 (69%)	11 (85%)	9 (69%)
Medical Staff	8 (61%)	7 (54%)	9 (69%)	8 (61%)

No hospitals had a Haemovigilance (Transfusion) Nurse.

Audit

Audits of Blood Transfusion Practice had been carried out at all blood users over 5,000 units. 11 Trusts had undertaken a number of audits.

The following audits had been carried out:

- Audit of transfusion guidelines against practice:
    1. Request for blood transfusion and the collection of blood samples for retransfusion testing.
    2. Section B: collection of blood or blood components from the hospital blood bank.
- Audit on the use of irradiated blood products.
- Usage of O Rhs Negative blood
- Audit Units ordered against transfused in orthopaedics
- Albumin
- Compliance with maximum blood ordering schedule.
- Anti Thrombin III use.
- Completion of pretransfusion request forms.
- Audit of documentation of transfusion in anaesthetics.
- Use of blood components in obstetrics
- Outcomes following 2 different transfusion regimes
- Procedural audits looking at transfusion documentation
- Blood usage
- Audit of Quality of Blood Transfusion Process at Ward level in the Trust.
- Audit of massive blood transfusion – in conjunction with Crest.
- Crest Guidelines Audit
- Compliance with blood tariff.

Autologous Blood Transfusion

Only 2 Trusts had undertaken this – as a pre deposit donation.

The number of units transfused was very small - < 20 units in each Trust.

Information To Patients

Only one Trust provided a patient information leaflet on blood transfusion to patients.

Respondents Were Asked To Indicate The Best 3 Ways Of Improving Blood Transfusion Practice In Hospitals.

The most frequent responses were:

- Appointment of Haemovigilance (Transfusion) Nurses
- Education of doctors, anaesthetists, surgical trainees, nurses
- Haematologists who are "Hospital Tranfusionists"
- Effective Transfusion Committees.
- Dedicated blood porters bank/air tube system
- HTCs to include nurses
- More blood bank biomedical scientists
- Computerised blood tracking system/electronic blood issue
- Multidisciplinary/multiprofessional audit of all aspects of transfusion
- Bar coded patient identification scheme

Conclusions

All 13 Trusts in NI providing a blood transfusion service have a Hospital Transfusion Committee with a range of specialities chairing these. All but two reasonably active, meeting at least twice and some meeting at least 4 times a year. The two that meet infrequently do not have a consultant haematologist at present.

All Trusts participate in SHOT.

There was considerable activity on the development and review of guidelines and education and training.

There were a considerable number of ongoing audits being undertaken.

Very little progress had been made towards the development of autologous transfusion in any form.

Very little information is given to patients about transfusion. NIBTS reports little demand for pre-deposit autologous transfusion. It is considered that if this option was better known by patients requiring elective surgery they would wish to consider it.

Suggestions for improving blood transfusion focused on effective HTCs, the appointment of Haemovigilance nurses, education and training and participation in audit.

RESULTS OF A QUESTIONNAIRE SURVEY IN RELATION TO THE IMPLEMENTATION OF THE HEALTH SERVICES CIRCULAR 1998/224 '*BETTER BLOOD TRANSFUSION*'

Report prepared by M.F.Murphy, C.Edbury and C.Wickenden

The Health Services Circular *'Better Blood Transfusion'* (HSC 1998/224) details the action required of NHS Trusts and clinicians to improve transfusion practice. It was issued on 11th December 1998, and its requirements were based on recommendations of a symposium held by the UK Chief Medical Officers on *Evidence-based Blood Transfusion* held in London on 6th July 1998.

There was only limited information on the implementation of the recommendations of the HSC 1998/224 as its review date of December 2001 approached, for example:-

- a survey carried out by the UKBTS/NIBSC Joint Guidelines Committee's Standing Advisory Committee on Information Technology found that 84.5% of 317 hospitals indicated they had a Hospital Transfusion Committee (HTC)
- 305/426 (72%) of hospitals surveyed participated in the Serious Hazards of Transfusion (SHOT) scheme in 1999/2000

It was agreed by the Department of Health that a questionnaire survey should be carried out to inform a second UK Chief Medical Officers' symposium on *'Better Blood Transfusion'* in October 2001. A questionnaire survey about the implementation of HSC 1998/224 *Better Blood Transfusion* was sent by the Chief Executive of the National Blood Service in August 2001 to all Chief Executives in hospitals where blood is transfused. It was sent to Chief Executives in hospitals because they were considered to be responsible for overseeing the implementation of the recommendations in the HSC 1998/224 '*Better Blood Transfusion'*.

132 NHS Trusts and private hospitals sent returns, a response rate of only 41% possibly reflecting the mode of distribution of the questionnaire. Hospitals who did not respond to the questionnaire were provided with another opportunity to do so in early 2002 by direct mailing to hospital Blood Bank Managers; a further 88 hospitals sent returns giving a total of 220 returns and an overall response rate of 69%.

There was a considerable range in the units of red cells transfused in the hospitals who responded to the questionnaire with 15.5% of hospitals transfusing less than 1000 units/year,

and 7.7% of hospitals transfusing over 20,000 units/year. However, the majority (51.4%) of hospitals transfused between 5,000 and 20,000 units/year. 161 (73%) of hospitals had CPA accreditation for laboratory transfusion.

The HSC 1998/224 '*Better Blood Transfusion*' states that from March 1999 all hospitals where blood is transfused should participate in the Serious Hazards of Transfusion (SHOT) scheme and have HTCs to oversee all aspects of blood transfusion.

Participation in SHOT

211/220 (96%) hospitals reported participation in SHOT. Those hospitals that reported non-participation were low volume users (<1000 units/year). Those who were not sure about their participation or did not answer the question were low volume users with one exception.

Establishment of HTCs

200/220 (91%) of hospitals responding to this survey have HTCs. However a significant minority of 20 (9%) hospitals do not; 65% of the hospitals without HTCs had a blood usage of <5,000 units/year. 56% of hospitals' HTCs met 3 or more times in the year 2000/01, and the remainder of HTCs met twice or less.

The HSC 1998/224 '*Better Blood Transfusion*' states that from March 2000 all hospitals where blood is transfused should have agreed and disseminated protocols for the process of blood transfusion, based on guidelines and best practice supported by in-house training of staff.

Protocols for the process of transfusion

The majority of hospitals responding to the survey (>97%) have protocols in place covering blood sample collection for compatibility testing, the collection of blood from blood transfusion refrigerators and its delivery to clinical areas, and checking and administering blood. A minority (4%) of hospitals do not have or are unsure whether they have a protocol for the investigation and management of adverse events associated with transfusion. Hospitals lacking one or more of these protocols number 11 (5%). The lack of protocols does not seem to relate to low usage of blood – 8 of the hospitals lacking at least one protocol used between 5,000 and 20,000 units/year, and none of these hospitals had a Transfusion Nurse.

Training

The response to this question was quite poor with failure to respond varying between 15% and 48% suggesting that respondents' knowledge of the training provided by their hospital is poor. The response to this question was particularly poor in relation to training provided to medical staff.

Categories in which more than 70% of hospitals could positively confirm training were:-
Sample collection - phlebotomists
Blood administration - nurses

There were a number of categories in which less than 50% of hospitals were able to positively confirm training:-
Blood Collection - porters
Sample collection – medical staff
Blood collection – medical staff
Blood administration – medical staff
Adverse events – medical staff

30 (14%) of the hospitals responding to this survey indicated that they had a Transfusion Nurse. This agrees with information from the Transfusion Nurses Forum that there are at present about 45 Transfusion Nurses in England.

The HSC 1998/224 '*Better Blood Transfusion*' states that HTCs should promote best transfusion practice through local protocols based on national guidelines. National guidelines produced by the British Committee for Standards in Haematology (BCSH) exist for all the areas of transfusion practice that hospitals were asked to respond to in the questionnaire i.e. implementation of a maximum surgical blood order schedule (MSBOS), emergency and massive transfusion, use of red cell and platelet transfusions, use of fresh frozen plasma and the management of excessive anticoagulation with warfarin.

Protocols for the use of blood

Similar to the responses to the previous question on training, large numbers of hospitals were unable to answer the questions on HTC approved protocols. Only in the case of MSBOS and the usage of FFP were more than 50% of hospitals able to confirm the existence of an approved protocol. There were low rates (around 31-37%) in the case of protocols for the use of red cell transfusions and the management of excessive anticoagulation with warfarin.

The HSC 1998/224 '*Better Blood Transfusion*' states that HTCs should lead multi-professional audit of the use of blood components, focusing on specialities where demand is high.

173 (79%) hospitals had carried out at least one audit since 1999, but 47 (21%) hospitals had not carried out any audits since 1999. 48 (22%) hospitals had carried out 4 or more audits in that time. Audits were most frequent amongst the hospitals with medium and high use blood usage, and those with CPA accreditation.

The HSC 1998/224 '*Better Blood Transfusion*' states that from March 2000 all hospitals where blood is transfused should have explored the feasibility of autologous blood transfusion. In particular, they should have considered the introduction of peri-operative cell salvage.

The usage of autologous transfusion varied with specific type of autologous transfusion; 41 (19%) hospitals in the case of acute normovolaemic haemodilution, 82 (37%) in the case of cell salvage and 113 (51%) for pre-deposit. It was striking that hospitals were unable to accurately estimate the number of units involved for any of the types of autologous transfusion – only in the case of pre-deposit autologous transfusion were more than 50% of hospitals able to answer this question.

Although 113 (51%) hospitals indicated they undertook pre-deposit autologous transfusion, only 13 (6%) used more than 20 units. The same was true for acute normovolaemic haemodilution (only 4% of hospitals reported the use of more than 20 units). In the case of cell salvage, 18 (8%) hospitals reported the transfusion of more than 100 units.

The HSC 1998/224 '*Better Blood Transfusion*' did not make specific recommendations about providing patients with information about blood transfusion, except in the case of cell salvage. However, the provision of information about blood transfusion for patients who may receive one can be considered to be good practice.

112 (50%) hospitals indicated that written information is provided for patients about blood transfusion. Only 17 (8%) hospitals estimated that more than 50% of transfused patients received written information about transfusion.

The final question asked respondents to indicate what they considered would be the best 3 ways of improving blood transfusion practice in hospitals.

Total number of hospitals responding to this question: 186. The most frequent responses were:-

Increased education and training	108
Appointment of a Transfusion Nurse	86
Electronic bedside checking/patient identification procedures	54
Better attendance at Hospital Transfusion Committees	27
Consider alternatives to transfusion	16
Improved systems for data collection and audit	26
Improve communication between the Hospital Blood Bank and other departments	14
Standardisation of procedures and indications for transfusion	11
Implementation of Maximum Surgical Blood Order Schedule	5
Introduction of Cell Salvage	4

Other suggestions included:-

Greater accessibility to advice
Expansion of autologous transfusion service
Increased consultant sessions and more involvement by clinicians
Make personnel more informed about transfusion hazards and protocols
Proper funding for transfusion departments
Ensure enough staff resources
NBS publications to be made available to independent sector users including guidelines
Better policy on post-operative transfusion so that unused units can be returned to stock quickly
More information for patients including risks/benefits of transfusion
National seminars for prescribers
Expand accreditation of transfusion laboratories to cover all aspects of the process
Adherence to blood transfusion schedules/policies
Greater availability of SHOT reports

The initial results of the questionnaire survey were presented at the UK Chief Medical Officers' symposium on *'Better Blood Transfusion'* in October 2001. The discussions at the symposium will result in the development of further recommendations on blood transfusion practice in the form of a second Health Services Circular on *'Better Blood Transfusion'*.

1. MAIN FINDINGS AND RECOMMENDATIONS

SUMMARY OF MAIN FINDINGS

Participation and number of reports

In 2000 – 2001, 379/413 (92%) hospitals participated in the SHOT scheme compared with 72% the previous year. There were increases in both the number of hospitals submitting reports (199/413 hospitals eligible to participate; 11.6% increase since the previous year and 25.9% since the scheme began), and the overall number of reports (315 initial reports; 7.9% increase since the previous year).

Incorrect blood component transfused ("wrong blood") incidents

Once again the largest category, showing a 6% increase in number since the previous year (213/315 reports), remains transfusion of the wrong blood. Cumulative data over 5 years show that the largest category of reports are blood transfusion errors with the wrong blood transfused to patients accounting for 61% (699/1148) of cases. The outcome of these was death in 11 patients (5 definitely related to tra[illegible]n, 1 probably, and 5 possibly related) and major morbidity, for example conditions necessitating intensive care unit admission (ICU), in 60 as a result of ABO and/or other red cell incompatibility.

This year, of 190 completed questionnaires (cases), hospital blood transfusion laboratories were the sites of the largest category of originating errors (36% of all cases). Thirty six percent of all laboratory errors (100 errors in 80 reports) occurred out of hours. As in previous years multiple errors were implicated in many "wrong blood" incidents. There were 103 cases (54.2%) with multiple errors and 344 errors in total indicating that problems still occur at all stages of the transfusion process and that the final bedside check may fail to detect mistakes made earlier in the transfusion chain. When all errors (344) rather than all cases (190) were analysed, 29% occurred in hospital transfusion laboratories, 35% during bedside administration, 8% during the collection of blood components from the hospital storage site, 7% from other administrative errors, 15% during the prescription, sampling and request of blood for transfusion, 2% at the supplying blood centre and 4% where the origin of the error could not be detected. Thirty-three percent of laboratory errors were in the categories "failure to consult/heed the historical record" and "selection/issue of inappropriate component".

Twenty six cases (14% of all "wrong blood" incidents) of ABO incompatibility resulted in 1 death which may have been related to the transfusion and 3 cases of major morbidity as a result of intravascular haemolysis. Three sampling errors resulted in two cases of major ABO incompatibility resulting in intravascular haemolysis in both and renal failure in one. Although only a small proportion of errors, these are critical as they will not be detectable subsequently if the patient has not been previously grouped or the historical record not consulted.

Seventeen reports of Rhesus D (RhD) incompatible transfusions resulted in 1 case of RhD sensitisation in a female of child-bearing potential. This cause has contributed 17 cases of risk of major morbidity over 5 years. As in previous years these figures mask a larger proportion of ABO compatible and Rh incompatible transfusions, given in error, that did not result in any ill effects. There were 17 errors involving the administration of anti-D.

There were 37 cases of failure to irradiate cellular blood components for patients known to be at risk of transfusion-associated graft-versus-host disease (TA-GVHD). Thirty of these originated at the point of prescription and a further 7 as a result of laboratory errors. Fortunately there were no reports of TA-GVHD in this group of patients.

A small number (9) of wrong haemoglobin results, following suspected sampling errors or poor communication, resulted in unnecessary blood transfusions and two deaths possibly attributable to over-transfusion.

"Near Miss" events

All hospitals in the UK have been encouraged to report "Near Miss" events to the SHOT Scheme for the last reporting year. Disappointingly only 121(29%) of hospitals from a possible 413 supplied data comprising 452 reports. Of these, 50% (230/452) were sampling errors indicating that phlebotomy errors remain the major cause

of "near miss" events. Selection of blood components by the laboratory, handling and storage errors accounted for 81 cases (18%) with 44/81 related to the incorrect storage of components in clinical areas and 18 where the laboratory issued components without ensuring that special requirements (e.g. irradiated or cytomegalovirus (CMV) antibody negative components) were provided. Cumulative data from 812 reports since 1997 shows that the relative proportions of causes of "Near Misses" are fairly constant. Increased participation by hospitals in this "Near Miss" reporting scheme would enable a more comprehensive evaluation of incidents from a representative national perspective.

"Near Miss" events are likely to be more numerous than those which ultimately lead to mis-transfusion and analysis of these should be used to learn where systems are flawed so that they can be re-designed to minimise the possibility of human error.

Immune complications of transfusion

Seventeen out of 31 cases of acute transfusion reaction (ATR) were related to platelets or fresh frozen plasma (FFP), with patients noted to be receiving FFP inappropriately. Incomplete investigation of acute adverse events was common and led to difficulty in ascribing a precise cause. The frequency of patient monitoring during transfusion, especially of platelets and FFP, was variable. Delayed haemolytic transfusion reactions (DHTR) occurred in 39 patients with 19/39 (49%) due to Kidd antibodies. In 5 cases it is likely that the antibodies could have been detected pre-transfusion but were missed. There is little evidence of inadequate performance of the laboratory technology but some techniques appear to be ineffective in detecting all the weak Kidd antibodies that will lead to a haemolytic transfusion reaction.

Among the 13 cases of transfusion-related acute lung injury (TRALI) analysed this year there were 3 deaths and 6 cases of major morbidity. Certain categories of patients continue to feature in TRALI reports, particularly those with haematological malignancies. Seventy cases of TRALI over 5 years have resulted in 18 deaths (6 definitely, 2 probably and 10 possibly attributable to the transfusion) and 49 cases of major morbidity. It is important to note that red cells as well as FFP and platelets have been the sole implicated component in some of these cases. The diagnosis of TRALI is a difficult one, particularly in patients with pre-existing cardiopulmonary problems, even in the presence of donor leucocyte antibodies. During the last 2 years we have attempted to assess the likelihood of each case reported actually being TRALI. This has resulted in 5/31 cases considered not to be due to TRALI although they are included in the figures above. Despite the uncertainty surrounding the diagnosis of TRALI, it appears to be the second largest cause of transfusion-related morbidity and mortality after ABO incompatibility.

The reduction in cases of post-transfusion purpura (PTP) and TA-GVHD during the past 2 years compared to the previous 3 years may reflect the benefit of universal leucodepletion (LD) of blood components (see table 2). However one fatal case of TA-GVHD this year demonstrates that current levels of leucodepletion cannot always prevent TA-GVHD. Of the 13 cases (all fatal) of TA-GVHD reported to SHOT over 5 years, 6, including this year's case, have occurred in patients with a variety of B-cell malignancies. These patients now appear to be the most susceptible group not recommended for irradiated components under current British Committee for Standards in Haematology (BCSH) guidelines[1]. Each year SHOT receives a number of reports of cases of failure to provide irradiated components where guidelines recommend their use. No definite cases of TA-GVHD have resulted from these errors although in one case (last year) this diagnosis could not be excluded.

In general, immunological reactions were not investigated with the same rigour as were transfusion-transmitted infections (TTI). There was no consistency in the way that these cases were investigated and classified locally. The BCSH is producing a guideline on this although it is still at an early stage.

Transfusion-transmitted infections (TTI)

Of 43 cases of possible TTI reported during this 12 month period, there were 6 confirmed cases. As in previous years, the largest category was bacterial contamination (4 cases). One case was due to hepatitis B virus (HBV) and one to human T-cell leukaemia virus-I (HTLV-I). It must be noted, however, that SHOT is not well suited to ascertainment of the chronic effects of viral transmission that might only become apparent after several years. All 4 bacterial contamination incidents, including a fatal *Bacillus cereus* infection, were caused by contaminated platelet transfusions.

Cumulative data over 6 years (infectious hazard reporting predates that of non-infectious hazards by 1 year) shows that TTIs account for less than 3% of total hazards reported. Bacterial contamination is by far the most common cause in this category (21/35 reports). Of these 21 cases, 6 proved fatal; 17/21 were due to platelet contamination resulting in 5 fatalities with the remaining cases attributed to contaminated red cells (1 fatality). In 38% (8/21), the donor's skin was the probable source of the contamination and in a number of other cases incomplete investigation precluded this conclusion although the nature of the organism was suggestive of skin contamination.

The second commonest cause of reported TTI has been hepatitis B virus infection (HBV) with 8 cases reported over 6 years, 7 of which have been due to donations collected during the early infectious " window period", from donors without serological markers of HBV. This is a change in pattern from earlier observations on transfusion-transmitted HBV in the UK when the majority of transmissions were due to donations from donors with chronic HBV infection who had undetectable hepatitis B surface antigen at the time of testing but were shown retrospectively to have antibodies to hepatitis B core (HBc) and to HbeAg. This may have implications for the choice of strategies to further reduce the risk of transfusion-transmitted HBV as the effectiveness of additional tests (e.g. testing for anti-HBc and/or HBV DNA) depends on the prevalence of these markers.

MAIN RECOMMENDATIONS BASED ON FINDINGS

GENERAL RECOMMENDATIONS

1. **All Trusts where blood is transfused should participate in SHOT.**
   Participation in SHOT is an essential prerequisite for informed recommendations to improve transfusion safety. In line with HSC 1998/224 'Better Blood Transfusion'[2] which states that all hospitals where blood is transfused should participate in the SHOT scheme, Clinical Governance within Trusts should ensure a commitment to SHOT reporting and to change in practice resulting from SHOT observations and recommendations. Participation in SHOT should be implemented as a standard by Clinical Pathology Accreditation (CPA) for clinical blood transfusion laboratories.

2. **Trusts should develop a "no fault" ethos for error reporting.**
   In line with "An Organisation with a Memory"[3] and the new National Patient Safety Agency (NPSA), error reporting should be encouraged, without fear of disciplinary action. It is only by highlighting errors that we can learn from them and change unsafe practices. Trusts should develop 'Near Miss' reporting as a basis for ongoing internal review.

3. **Training, with ongoing review, of all staff involved in blood transfusion, in the systems and procedures for blood handling and administration should be implemented in all Hospital Trusts.**
   Approximately 52% of 'wrong blood transfused' cases occurred because the wrong blood was collected from the hospital blood bank or satellite refrigerator or because of failures in bedside checking procedures.
   - Trusts should put into place the BCSH guidelines on blood handling and administration[4], and, develop a commitment to the training of all staff handling blood. This will form part of the essential requirements for the Clinical Negligence Scheme for Trusts (CNST) (Appendix 9) which comes into effect in April 2002.
   - Specific education/training in blood transfusion safety should be incorporated in the undergraduate medical curriculum and in induction programmes for junior medical staff (detailed in the Foreword).

4. **Hospital Trusts should employ appropriate numbers of trained nurses, biomedical scientists (BMS) and doctors to enable safe and effective blood transfusion practice.**

   - **Transfusion practitioners should be appointed in all hospital Trusts.**
     Transfusion practitioners play a key role in staff training and implementation of safe transfusion practice, as well as in appropriate blood component usage. Currently the majority of those in post are nurses but other clinical staff with appropriate background are not precluded from this role. A structured training programme and professional accreditation should be considered to make the role of transfusion practitioner a more attractive career option. The recently developed Specialist

Practitioners of Transfusion (SPOT) group and the Effective Use of Blood (EUB) group in the Scottish National Blood Transfusion Service (SNBTS) provide peer support and the opportunity for shared learning.

- **More transfusion medical consultant time is needed in hospital Trusts.**
  This will provide a driving force for blood safety improvements and the parallel initiative of appropriate blood usage. This is likely to have training and manpower implications.
- **Hospital Trusts should ensure that they employ adequate numbers of appropriately trained BMSs.**
  This year hospital blood transfusion laboratories were the sites of the largest category of originating errors (36% of all cases). Errors occurred out of hours in 40.5% (77/190). Hospitals should ensure that they employ sufficient numbers of appropriately skilled BMSs to maintain adequate staffing at all times. The blood transfusion laboratory setting remains one where considerable technical and interpretative skills are essential for patient safety. SHOT data have demonstrated that such skills are not always optimal.

5. **Existing procedures should be re-examined for flaws which could lead to systems errors. Hospital Transfision Committees (HTC) should be managerially empowered to play a key role in this process to ensure the safety of transfusion practice and appropriate blood component usage.**

6. **Use of information technology will reduce the opportunities for human error: a proactive and co-ordinated approach to the development/assessment of new technologies is needed. This should be structured, organised and led at national level.**
   Despite best efforts, human error is inevitable and cannot be entirely avoided. Thus, new technologies merit vigorous development and assessment to determine whether their implementation could achieve reductions in transfusion error.

   - **Electronic blood/patient identification** would provide positive patient identification. This technology also has the potential to reduce drug errors, [5] as well as to ensure pathology results and special dietary requirements are attributed to the right patient.
   - **Remote issue**, a means of electronically controlling the release of blood for patients, could ensure the audit trail, reduce collection errors and may be particularly applicable in the many Trusts that have centralised blood banks serving several hospital sites.
   - **Modernisation of hospital blood banks** with automated grouping and electronic compatibility testing could reduce laboratory errors and enable better use of BMSs. These technologies should complement and not replace BMSs.

7. **A national unified system with relevant expertise should be developed, to prioritise strategies most effective for blood safety.**
   A consistent recommendation of SHOT reports is that the UK needs an overarching organisational and intellectual framework for assessing transfusion hazards and prioritising blood safety initiatives side-by-side. While a single overarching blood safety body for the UK is not yet in place, discussions have begun regarding a broader remit for the Department of Health's Microbiological Safety of Blood and Tissues (MSBT) Committee. In addition, a number of separate initiatives have been taken which should help to promote general and specific SHOT recommendations . These include:-

   - establishment of a National Blood Transfusion Committee (NBTC) for England, reporting directly to the Chief Medical Officer, with a Regional Blood Transfusion Committee (RBTC) structure linked to the NBTC. See Appendix 10.
   - creation of a Blood and Tissue Safety Assurance Group within the English National Blood Service (NBS), with a number of subgroups covering all areas of work. This includes the creation of 2 posts within the Department of Health's Economic and Operational Research division to work on blood safety issues.

8. **Appropriate blood usage should be implemented and alternative strategies to blood transfusion explored.**
   BCSH guidelines on red cell transfusion[6] should be implemented. BCSH revised guidelines on FFP and platelet transfusion, as well as on autologous transfusion and alternatives to red cell transfusion are in preparation. The new English NBTC and RBTC structure provides a potentially powerful framework for improving all aspects of blood safety and supporting the work of HTCs to promote safe and effective use of blood.

SPECIFIC RECOMMENDATIONS

Incorrect component transfused ("wrong blood")

" Wrong blood" transfusions are without exception avoidable errors

The bedside check is the final opportunity to prevent a mis-transfusion

- **Every hospital must have a formal policy for the collection of blood components from storage sites and these must incorporate formal identification procedures.**

- **Every hospital must have a formal policy for the bedside check which must be rigidly enforced at all times.**

This must ensure that blood components are correctly allocated and identified and be capable of detecting preceding compatibility labelling discrepancies and relevant transfusion information such as previous group and antibody screening reports. The dangers of staff becoming distracted, even after correct checking, must be borne in mind

- **Every patient should be uniquely and positively identified using a wristband or equivalent and there should be no exceptions.**

A single, unique identifying number should be used.

Prevention of errors at earlier steps in the transfusion chain

Whether or not new information technology developments are used at the bedside and when collecting blood components from their storage sites, the importance of earlier, vital steps in the transfusion chain must not be ignored as not all errors will be detectable by the bedside check.

- **Individuals responsible for the prescription and request of blood components must be familiar with the special needs of their patients.**

Special requirements should conform with BCSH and other guidelines and should be flagged on the clinical and laboratory records. Guidelines published on the clinical use of red cell transfusions[6] should be disseminated more widely to prescribing medical staff. Every hospital must also have a robust policy for the prescription and issue of anti-D immunoglobulin which must be based upon Joint BBTS/RCOG[7] recommendations and must include a requirement for printed confirmation of the RhD status of the patient.

- **Personnel responsible for taking samples for any laboratory test must at all times follow strict procedures to avoid confusion between patients.**

This means that samples should be taken one at a time and labelled at the bedside after positively identifying the patient. Sound phlebotomy procedures must also be followed in order to obtain a true sample, for example, avoiding dilution of samples taken for Hb measurement.

- **Blood banks must continue to be vigilant in reviewing procedures and systems to ensure that they all meet current guidelines.**

Ongoing staff training is essential to prevent errors in the laboratory.

- **Telephoned requests for blood components must be formally recorded and incorporate all relevant information including special requirements.**

Great care must be exercised when acting on verbal results. Local written standard operating procedures (SOP) must be in place for dealing with telephone requests.

Setting "wrong blood" incidents in context

- **Baseline data on the timing and location of transfusions in the hospital setting are needed.**

The confidential and anonymised nature of the SHOT scheme makes it difficult to place errors in the overall context of transfusion activity in the UK, apart from very broad estimates of the incidence of hazards as a proportion of total blood components issued. The lack of denominator data makes meaningful interpretation of, for example, out-of-hours errors impossible. With the increasing sophistication of blood bank information technology, it is now possible to collect such data and this could be of value in designing improved systems to increase the safety of the blood transfusion process.

"Near Miss" events

- **Strict adherence to phlebotomy protocols is essential.**

This includes verbal confirmation of patient identity at the bedside, checking of patient wristbands and the labelling of sample tubes at the bedside rather than remote from the patient. Appropriate training is necessary to ensure that this basic function is performed accurately and reliably.

- **Basic principles of phlebotomy good practice should be applied to labelling of all samples.**

Erroneous results from a mis-labelled FBC sample, for example, can result in inappropriate transfusion

- **Clear responsibilities for training of all staff who take blood samples must be established and maintained.**

Immune complications of transfusion

- **Patients receiving any blood component must be monitored or observed in such a way that an acute reaction can be detected early.**

In addition to baseline observations before commencing each transfusion, each patient should be checked after 15 minutes infusion of each new unit or pool, in accordance with BCSH guidelines.[4]

- **To help minimise exposure to FFP, national guidelines on anticoagulation which include the management of excessive warfarinisation,[8] should be circulated more widely.**

Guidelines should be presented in a form which is accessible to surgeons and clinicians of all grades. It is rarely appropriate to give FFP for this purpose. Key points from the guidelines are summarised in Appendix 11.

- **Group O platelet pools should undergo testing of the "plasma donor" for the presence of high-titre haemolysins, similar to that performed for apheresis units.**

Clinicians should avoid giving Group O platelets to Group A or B recipients unless this will result in a clinically significant delay. See Appendix 12 for NBS guidance on this subject.

- **More detailed investigation of patients experiencing serious immune reactions to components would clarify the nature of these reactions and should be considered particularly in cases with anaphylaxis or pulmonary manifestations.**

The United Kingdom Blood Transfusion Services (UKBTS) are able to provide such reference services.

- **Attention to timely pre-transfusion testing of surgical patients is essential, especially if there is a history of previous transfusion or pregnancy.**

Where possible, investigations should be performed within normal working hours in order to make best use of available expertise. Laboratory staff should be given adequate notice of impending surgery and the potential role of pre-admission clinics in facilitating timely pre-transfusion testing should be assessed in each hospital.

- **There is a need for improved technologies to identify very weak Kidd antibodies.**

This was identified in last year's SHOT report.[9]

- **Hospital laboratories must take care to avoid missing antibodies which may be masked by other allo- or auto-antibody(ies).**

Deficiencies in this area were highlighted in a recent "paper" exercise run by the National External Quality Assurance Scheme for Blood Transfusion Laboratory Practice (see NEQAS-BTLP exercise 00E6).[10]

- **Confirmation of the diagnosis of TRALI by demonstrating a positive cross-match between donor serum and the patient's leucocytes should be attempted in all cases where recovery samples can be obtained from the patient.**

Samples should be referred to the relevant Transfusion Centre.

- **To assess the significance of the high numbers of haematology patients represented in TRALI reports to SHOT, better epidemiological data are required to understand patterns of usage of blood components in different specialties.**

Exclusion of female donors should be considered from plasma to be used for FFP and to suspend platelet concentrates.

- **Hospitals should continue to report PTP cases to help confirm whether the incidence of this complication is reduced by universal leucodepletion.**

- **BCSH guidelines for irradiation of blood components should be reviewed to assess whether all patients with B cell malignancies should receive irradiated components.**

In addition, as the current BCSH guideline recommends,[1] each new chemo- or immuno- therapeutic regime should be assessed for the possibility of it causing TA-GVHD.

- **Hospitals should implement systems to ensure that patients who need irradiated components always receive them.**

Mechanisms for achieving this include flagging such patients on the hospital computer, and the use of the BCSH/NBS card and leaflet 'Information for patients needing irradiated blood'. For a pre-publication version updated for 2002 see Appendix 13. It may be possible for hospital pharmacies to play a role in this area.

Transfusion-transmitted infections

- **Strategies should be developed to prevent the transfusion of bacterially contaminated donations, in particular platelets.**

The cumulative and continuing predominance of bacteria as a cause of clinically apparent TTIs and infection-related deaths is of concern. Improved methods of arm cleansing and diversion of the first few mL of the donation (most likely to contain skin flora) away from the primary pack sent for component production are two measures which have been shown to reduce contamination risk. Additional measures such as bacterial screening of platelets and pathogen inactivation of platelets should also be evaluated[11]. Recommendations in BCSH guidelines[4], regarding the visual inspection of units for any irregular appearance immediately prior to transfusion (particularly platelets), should be followed.

- **Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria.**

This should include sampling and storage of implicated units. Cases that are inconclusive due to discard of the implicated pack before sampling continue to be reported. (National guidelines on the investigation of these cases are available at all NBS centres.)

- **It would be appropriate for blood services to review the residual risk of transfusion-transmitted HBV infection and assess whether additional donor screening for HBV would bring benefits in terms of blood safety.**