

SERIOUS HAZARDS OF TRANSFUSION

ANNUAL REPORT

1996 - 1997

Affiliated to the Royal College of Pathologists

**British Blood Transfusion Society, British Society for Haematology
Faculty of Public Health Medicine, Institute of Biomedical Science
Public Health Laboratory Service Communicable Disease Surveillance Centre
Royal College of Anaesthetists, Royal College of General Practitioners
Royal College of Nursing, Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health,
Royal College of Physicians, Royal College of Surgeons, UK Transfusion Services**

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by The Serious Hazards of Transfusion Scheme

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1. SUMMARY OF RECOMMENDATIONS

- Request systems for blood and components should ensure prescription, issue and administration of the correct component. These should cover 'special requirements' and telephone requests, and should clarify the respective responsibilities of medical and blood bank staff.
- Pre-labelled tubes for blood grouping/cross-matching should not be used.
- Access to previous transfusion laboratory records containing blood group and irregular antibody information should be available at all times.
- Blood banks should review procedures and systems including enforcement of the current guidelines and standards available, in addition to training to prevent errors of sample handling and technical errors.
- Collection of blood from hospital blood banks is a common source of identification errors. Hospitals should review their current system to ensure that errors in this area can be prevented. Standards should be set for a minimal formal identification requirement when a component is collected. Novel identification systems are available, but have resource implications. These systems merit evaluation and development.
- Hospital systems should ensure that in-patients and out-patients can be identified at the time of both sampling and transfusion, especially in out-patient departments where patient identity is often not available.
- The bedside check is vital in preventing transfusion error. Staff should be vigilant in checking identification details of the component against those of the patient. Every hospital should have a policy for formally checking the identity of the patient against the blood component label at the bedside. Nursing observations during transfusion also show wide variation. National guidelines for the administration and monitoring of transfusion are being developed by the British Committee for Standards in Haematology (BCSH) on behalf of the British Society for Haematology (BSH).
- Blood components should always be administered against a written prescription.
- Consider the use of paracetamol rather than hydrocortisone for the treatment of recurrent non-haemolytic febrile transfusion reactions.
- A national review of the requirements for samples and investigations following acute and delayed transfusion reactions is recommended.
- Hospitals should review crossmatch sampling intervals in the light of BCSH guidelines for pre-transfusion compatibility testing.
- The importance of taking full transfusion and obstetric histories should be stressed.
- Clinicians should consider the possibility of platelet/filter interactions in patients receiving angiotensin converting enzyme inhibitor treatment. Reporting of future cases is encouraged so that a complete picture can emerge.
- In patients with suspected transfusion-related acute lung injury (TRALI), it is always worth informing the supplying Blood Centre. Investigation of implicated donors can then be carried out, and the donors withdrawn if serology is positive.
- Donors implicated in cases of TRALI involving platelets or fresh frozen plasma may not be suitable as red cell donors, as cases involving red cell transfusion have been reported.

- Post-transfusion purpura (PTP) should be considered in any female, parous patient who develops haemorrhagic features with thrombocytopenia after red cell transfusion. As the time of onset is generally > 5 days after transfusion, patients may present after discharge from hospital. Early involvement of a haematologist in cases of unexplained post-operative thrombocytopenia will ensure appropriate diagnosis and treatment.
- In view of the small number of cases of transfusion-associated graft-versus-host disease (TA-GVHD) reported, no firm conclusions can be drawn as to whether current recommendations for TA-GVHD prevention require review. Full reporting of every case is essential to build up a complete picture. The current BCSH guidelines should be widely available for non-haematology staff who may treat at-risk patients.
- Local arrangements for the ordering and administration of blood components should include safeguards to ensure that gamma irradiated components are always given when appropriate. Where patients are being treated on a 'shared care' basis between eg a bone marrow transplant centre and their local hospital, a warning card carried by the patient may be helpful.
- Transfusion-transmitted infection is now rare. National collation of data arising from these cases needs to continue over several years to build up a picture of the extent and nature of the infectious complications of transfusion.
- Clinicians should report all post-transfusion infections diagnosed in their patients to the blood service (via their regional blood centre) for appropriate investigation.
- Hospitals should not destroy blood components implicated in post-transfusion reactions suspected to be due to bacteria, and should consult the blood service about the investigation of such cases.
- Standard protocols for investigating post-transfusion infections should be developed and used.
- Methods and criteria used to exclude those individuals who have risk factors for transfusion transmissible infections from donating blood deserve continuing evaluation and development.
- Each hospital should have a hospital transfusion committee or other appropriate forum to ensure local 'ownership' and dissemination of procedures and guidelines throughout the hospital. This forum should also review all cases of procedural error.
- Currently, several organisations produce recommendations and guidelines aimed at assuring safety in different parts of the transfusion process. A unified body with overall responsibility for transfusion safety could set priorities and direct resources for maximum patient benefit.

2. FOREWORD

Blood transfusion is a widely used therapy in hospital practice, with over 2 million units of red cells issued annually. Nevertheless, there has been a growing awareness among UK transfusion specialists, haematologists and other clinicians that there is little information on the current safety of the whole transfusion process from blood component production in a Transfusion Centre to administration at the bedside. Major policy decisions have had to be reached, and clinical guidelines produced, without a sound basis of epidemiological and statistical information. As suppliers of therapeutic products in the era of HIV, new hepatitis viruses and new variant Creutzfeld-Jacob Disease, Transfusion Services have an obligation to understand the magnitude of patient risk caused by their products. At hospital level, reports from the UK and elsewhere have suggested that errors in patient identification were a major source of transfusion-related morbidity and mortality.

These concerns culminated in the formation, in 1994, of a working group of hospital and transfusion service consultants, to produce proposals for the establishment of a UK-wide surveillance scheme for the reporting of major transfusion-related complications. A number of key questions had to be considered by the working group - was the scheme to be voluntary or mandatory, as in some other countries? What range of complications should be included? How was absolute confidentiality to be maintained? Who should 'own' the scheme, and pay for it?

The efforts of the Working Group finally came to fruition in November 1996, with the launch of the Serious Hazards of Transfusion scheme (SHOT), marked by an editorial in the British Medical Journal. SHOT's remit is to receive and collate confidential reports, sent on a voluntary basis, of transfusion-related deaths and major complications. The details of the scheme as it currently operates, are described on page 10-13, but it is appropriate at this point to acknowledge the tremendous support of the Steering Group established to oversee SHOT's activities. Transfusion is a complicated process, involving staff from a variety of professions and specialties. In recognition of this, the Steering Group includes representation from 8 Royal Colleges and 6 professional bodies, so that all staff who deliver blood components to patients have direct input to SHOT's policies and development.

Our endeavours were greatly helped by the fact that, in a parallel initiative, the Public Health Laboratory was working with the English National Blood Service, to centralise and improve the reporting of post-transfusion infections. This venture, though functionally separate, has been brought under the SHOT umbrella for this report, to provide a co-ordinated approach to publicising post-transfusion complications.

The gestation period of SHOT has been long, but the first year has proved that such a voluntary scheme can yield useful information. New initiatives within SHOT are planned, and we feel confident, that with your support, we can endeavour to maintain and improve the high standard of transfusion safety which the UK currently enjoys. We wish to thank all those of you who took the time and trouble to send in reports. We urge hospitals to help us make future reporting as complete as possible. Only in this way can a complete picture of transfusion risk emerge, and resources be directed to where most benefit will result.

Dr Hannah Cohen, MD FRCP FRCPath
Chair, SHOT Steering Group

3. BACKGROUND

Serious Hazards of Transfusion initiative represents the first moves in the UK towards systematic haemovigilance. This is a broad term which has come to be used for any process by which morbidity and mortality arising from blood transfusion is monitored. A number of approaches to this process are possible, as the variety of systems in use in different countries illustrates^{1,2}. Should reporting be voluntary or mandated by law, and what are the medico-legal implications? What range of complications should be included - fatalities and infection transmissions must obviously be covered, but would inclusion of minor reactions swamp the reporting system? What should be done to monitor 'near miss' events, where an error is discovered in time to prevent transfusion? Which blood derivatives should be included, given that licensed plasma products are already monitored by their licensing body? Should all patients be tested following transfusion for evidence of infection? Should the reporting scheme be 'owned' by the producers, or the users, and who should provide funding? These are only some of the issues to be addressed prior to establishing a haemovigilance system, and the solutions are not necessarily simple.

Nevertheless, the potential advantages of a haemovigilance system have probably never been greater. At this particular time, transfusion in the developed world is probably safer than it has ever been, although patient acceptance of risk in medical care appears to be decreasing. The Chief Medical Officer in England, Sir Kenneth Calman, has formulated a practical way of comparing medical risks with those in real life, which might prove useful in decision making (Table 1, modified from³).

Table 1. Description of Risk of Daily Activities

Term	Absolute Risk of Death in a Year	Example
High	>1:100	Intravenous drug use
Moderate	1:100-1,000	Smoking ten cigarettes a day
Low	1:1,000-10,000	Road traffic accident
Very low	1:10,000-100,000	Playing football
Minimal	1:100,000-1,000,000	Train accident
Negligible	<1:1,000,000	Struck by lightning

Further reductions in the viral risk of transfusion are promised by extremely expensive, well-marketed strategies such as virus inactivation of fresh frozen plasma and nucleic acid testing for viruses as a supplement to serological tests. At the same time, more stringent budgets lead blood bank managers towards multi-skilled or less qualified individuals, with computer cross-matching partially replacing laboratory testing. This, together with increasing pressures on clinical staff and the employment of temporary ward staff, make it increasingly important to establish the relative risks of the recognised complications of transfusion. This will help ensure that future spending can be wisely directed, and the impact of organisational changes on transfusion safety can be monitored.

The clinical transfusion process and its hazards - whose responsibility?

The complexity of the transfusion process has been graphically illustrated by the work of McClelland and colleagues⁴. A large number of people of varying professional training and knowledge are involved in the delivery of a safe unit of blood to a patient. These fall into three broad groups - the UK Transfusion Services, responsible for selection of donors, and for processing and testing of the unit; the hospital blood bank, responsible for component storage, selection and compatibility testing; and phlebotomy/portering/nursing staff responsible for withdrawing the crossmatch sample, delivering blood units from the laboratory to the ward, for administering the transfusion and for monitoring the patient. Medical staff are always responsible for prescribing blood components, although responsibility for ensuring that 'special requirements' are met, such as the need for irradiated, CMV negative, or leucocyte depleted blood is often delegated to the blood bank.

In the United Kingdom, regulation and training of these three bodies of staff is disparately controlled. Transfusion Centres, which in some parts of the UK also provide blood banking services, are required to hold Manufacturers (Specials) Licences from the Medicines Control Agency. Licensing is granted against compliance with Good Manufacturing Practice and the UK Guidelines for the Transfusion Services 'Red Book'⁵, a document produced by the Transfusion Services of the four home nations in collaboration with the National Institute of Biological Standards and Control. Hospital blood banks can now gain accreditation through Clinical Pathology Accreditation, although this is not mandatory, and participate in the NEQAS serology scheme. In addition, the British Society for Haematology Transfusion Task Force produces a series of guideline documents covering both blood bank procedures and blood component prescription, some of which have an impact on manufacturing. Current guidelines include compatibility testing, neonatal transfusion, irradiated components, platelets and fresh frozen plasma⁶⁻¹⁰, while a guideline on leucocyte depletion is nearing completion.

Decisions on microbiological testing of blood are taken at Department of Health level.

All this serves to underline the complex nature of 'responsibility' as applied to the transfusion process, and the need to involve all interested parties in any haemovigilance process. A brief review of the major complications of transfusion will illustrate this point further.

In the eyes of the public and many health care professionals, the major hazard of transfusion is transmission of infectious agents. Transfusion-transmitted viruses, particularly HIV and the hepatitis viruses (HBV, HCV, and more recently HAV and HGV), have been in the news for over a decade, and were primarily responsible for the growing interest in autologous transfusion. Add to that list parvovirus B19 and HTLV¹¹, and transfusion begins to appear a risky process. A recent study from the United States of America, however, demonstrates that the residual risk of HIV from transfusion is extremely low (1 in 500,000) and approximately 1 in 60,000 and 100,000 for HBV and HCV respectively¹². Such risks depend on the background prevalence of viral carriage in the general population, and the testing strategy adopted. It should be noted that screening for hepatitis B core antibodies, HIV p24 antigen and antibodies to HTLV I/II are not mandatory tests in the UK. The addition of genomic detection for viruses to the current testing regime will further shorten the 'window period' during which a donor may be infectious but test negative.

The role of other infectious agents should not be forgotten. Fatal bacterial contamination of red cells occurs rarely but on a regular basis¹³, while increasing attention has been drawn to the problem of bacterial contamination of platelets¹⁴. A recent WHO conference concluded that 'there has been no proven or even probable instance of transmission of Creutzfeldt Jakob disease from human to human by blood transfusion or blood products'¹⁵. A risk assessment is currently under way to examine the likelihood of new variant CJD being present in, and transmitted by, blood products.

Responsibility for preventing transfusion-transmitted infection virtually always lies solely with the supplying Blood Centre. Hospital staff have a preventative role in identifying bacterially contaminated units by inspecting packs for haemolysis. After the first of only two HIV transmissions in 12 years in the UK¹⁶, it was ruled (in Scotland, at least) that responsibility could not be passed back to the donor, even if relevant life-style information was deliberately withheld.

The major cause of non-infectious transfusion fatality and morbidity is ABO incompatible transfusion, usually because blood intended for one patient is inadvertently given to another¹. The frequency of 'wrong blood to patient' episodes has been estimated at 1 in 30,000 transfusions¹⁷. The mortality is minimised by the fact that, by chance, approximately two thirds of such incidents do not result in an incompatible transfusion, and because only 1 in 10 ABO incompatible transfusions are fatal¹⁸. 'Wrong blood to patient episodes' can arise because a cross-match sample is taken from the wrong patient, or labelled wrongly, because ABO grouping of the patient is incorrectly performed or interpreted, or because identity checks at the time of issue or administration of the blood are inadequate¹⁹. American data suggest that the frequency of this complication may be falling²⁰. Other major immediate or delayed reactions may arise from laboratory failure to identify clinically significant red cell antibodies or to provide appropriate antigen-negative blood. Responsibility for this group of hazards lies almost always at the hospital level; ABO incompatibility due to a misgrouped donor unit is now extremely rare.

Other potentially fatal complications of transfusion include transfusion-associated graft-versus host disease (TA-GVHD), transfusion-related lung injury (TRALI) and post-transfusion purpura (PTP). TA-GVHD is preventable by gamma irradiation of cellular components to 25 Gy for susceptible patients. UK Guidelines are available, covering both clinical and manufacturing aspects⁸. Cases could therefore arise because of failure of clinical staff to request irradiated components, or inadequate irradiation procedures by the blood bank or supplier. Occasional cases arising in non-immunosuppressed individuals because of HLA haplotype sharing would be preventable only by universal component irradiation. TRALI arises because of interaction between the patient's leucocytes and strong HLA or granulocyte antibodies in donor plasma²¹. Such antibodies are most commonly seen in multiparous women.

PTP, in which profound thrombocytopenia follows 7-10 days after a red cell transfusion is virtually always seen in parous women, often elderly. The plasma of such patients contains alloantibodies to one or more alleles of the 9 Human Platelet Antigen (HPA) systems, usually HPA-1a²².

The first year of the SHOT initiative has aimed to capture transfusion events relating to these complications. Details of how SHOT is organised are given in the next section of the report.

4. AIMS

The Serious Hazards of Transfusion (SHOT) scheme was launched in November 1996. SHOT is a voluntary anonymous system which aims to collect data on serious adverse events of transfusion of blood components, and to make recommendations to improve transfusion safety.

Through the participating Royal Colleges and professional bodies, SHOT findings can be used to:

- Inform policy within transfusion services
- Improve standards of hospital transfusion practice
- Aid production of clinical guidelines for the use of blood components
- Educate users on transfusion hazards and their prevention.

5. MANAGEMENT OF THE SCHEME

Organisation

The strategic direction of SHOT comes from a Steering Group with wide representation from Royal Colleges and professional bodies representing medical, nursing and laboratory staff. The operational aspects of the scheme are the responsibility of a Standing Working Group, which is accountable to the Steering Group. The Terms of Reference of the Steering and Standing Working Groups, along with the current membership, can be found in Appendix 1. Two national co-ordinators are responsible for receiving and collating reports.

Minutes of Steering Group meetings are sent to the Department of Health for information.

The first two years' funding has come from the Transfusion Services within the United Kingdom and Ireland. A generous grant from the British Society for Haematology is gratefully acknowledged. An income and expenditure statement is presented at Appendix 2. Organisational and funding arrangements will be formally reviewed after two years.

SHOT was affiliated to the Royal College of Pathologists in November 1997.

Scope and Reporting System

Participation in the scheme is entirely voluntary. National Health Service and private hospitals in the United Kingdom and Republic of Ireland as well as public hospitals in Guernsey, Jersey and the Isle of Man are invited to report.

SHOT invites reports of major adverse events surrounding the transfusion of single or small pool blood components supplied by Transfusion Centres (red cells, platelets, fresh frozen plasma, cryoprecipitate). It does not cover complications of fractionated plasma products (coagulation factors, albumin, immunoglobulin); as licenced medicinal products, these are already covered by the 'Yellow Card' system of the Medicines Control Agency.

During the period covered by this report, hospitals have been asked to report the following categories of adverse event:

1. Incorrect blood/component transfused
2. Acute transfusion reaction (including anaphylaxis)
3. Delayed transfusion reaction
4. Transfusion-associated graft-versus-host-disease
5. Transfusion-related acute lung injury
6. Post-transfusion purpura
7. Bacterial contamination
8. Post transfusion viral infection
9. Other post-transfusion infection e.g. malaria

Reporting of transfusion-transmitted infections

Suspected cases of transfusion-transmitted infection are reported using local procedures to supplying blood centres. Blood centre involvement is essential to ensure rapid withdrawal of other implicated components and appropriate donor follow-up. These cases are then reported by blood centres to the National Blood Authority/Public Health Laboratory Service Communicable Disease Surveillance Centre (NBA/PHLS CDSC) post-transfusion infection surveillance system. If the SHOT office is notified directly of an infectious hazard, the hospital haematologist and transfusion centre are approached by the co-ordinator to ensure that all relevant personnel have been informed and that the incident has been reported to NBA/PHLS CDSC.

Reporting of non--infectious adverse events

At hospital level, these are generally reported to the local clinician responsible for transfusion, usually a consultant haematologist. The incident is then notified to the SHOT office yellow 'initial report' form. For some complications, the local blood centre will have been involved in the investigation of the case. On receipt of a report, the assistant national co-ordinator allocates a number to the case, then issues a detailed follow-up questionnaire specifically designed for each hazard.

This enables confidential discussion of an incident between the SHOT office and the reporter if necessary. When incomplete information is received, the SHOT staff approach the local contact named on the report form. Once complete, the information from the questionnaire is anonymously entered onto the SHOT database (see Fig 1).

The SHOT staff may offer to visit the reporting clinician, to assist with the completion of the questionnaire. This service was utilised by one hospital during the year covered by this report.

Confidentiality of data is fundamental to the success of the project.

Data are stored in a password-protected database in a secure location. Once all the information has been gathered about an event and entered onto the database without patient, staff or hospital identifiers, all questionnaires, reporting forms and other paper records are shredded.

SHOT does not provide details of individual cases, or any form of summarised data to any outside person or organisation, other than that provided in this report.

Pre-launch publicity

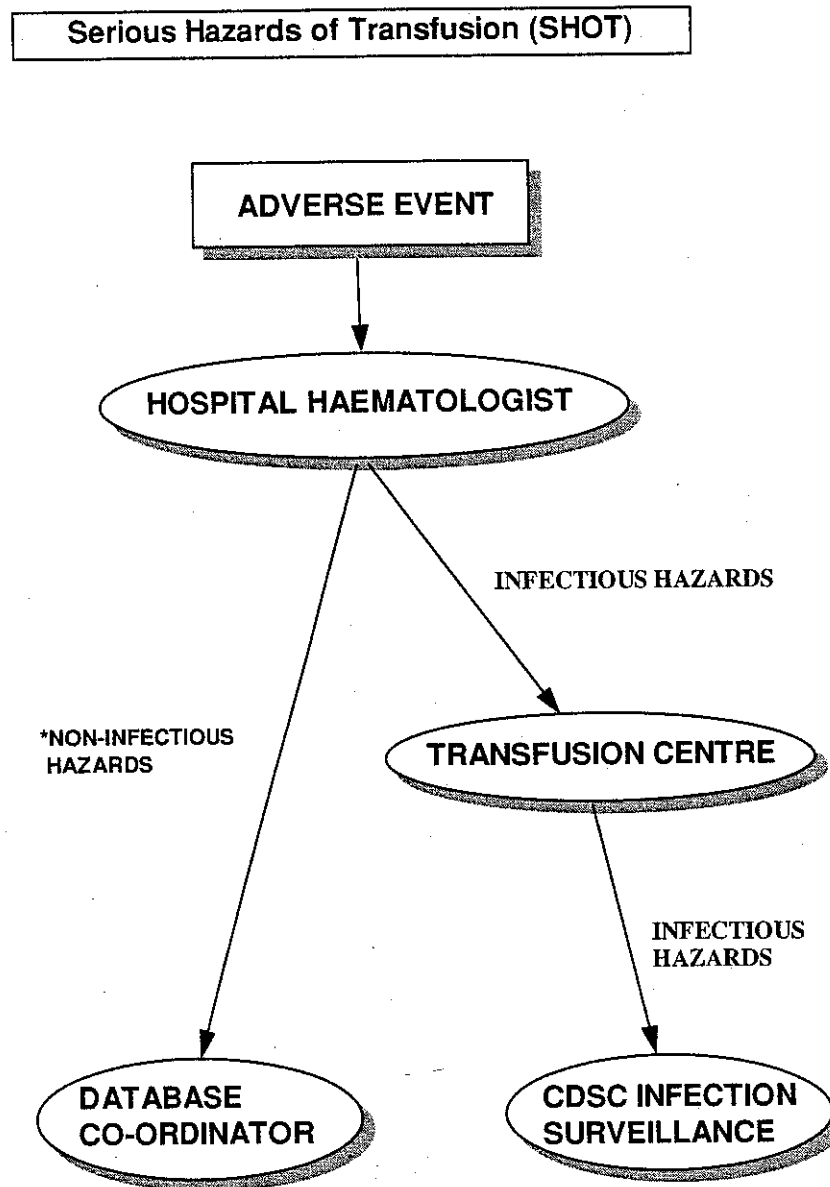
In the months preceding the launch of SHOT, efforts were made to ensure that hospital staff were fully aware of the scheme. A publicity stand was taken to scientific meetings of the British Society for Haematology and the British Blood Transfusion Society, and an information package provided to organisations represented on the Steering Group. The launch in November 1996 was marked by an editorial in the British Medical Journal²³. At that time, all hospital haematologists with transfusion responsibilities and blood bank managers were sent a full information package and a supply of yellow 'report forms'. The mailing list was kindly provided after consultation with the UK Blood Group Serology National External Quality Assurance Scheme.

Limitations of the SHOT system

Reporting to the SHOT scheme is voluntary. We recognise that many incidents may go unrecognised or unreported, and that the reports analysed cannot provide a full picture of transfusion hazards. Due to the anonymity of the scheme, denominator data from reporting hospitals cannot be provided.

The first year of reporting has revealed certain limitations in the questionnaires. These will be revised following consultation and after assessment of responses to this first report.

Figure 1
SHOT reporting system flow chart



- *e.g.
- Incorrect blood/component transfused
 - Major acute or delayed haemolysis
 - Anaphylaxis
 - Transfusion-related graft-versus-host disease
 - Transfusion related lung injury

6. OVERVIEW OF RESULTS

Ascertainment of data

The data in this report are derived solely from the initial report forms, and from subsequent analysis of questionnaires. All questionnaires were examined by the co-ordinator to identify inconsistencies in the information provided and, where these occurred the reporting clinician was contacted for clarification of the event.

The SHOT reporting scheme for non-infectious complications of transfusion was launched on 18th November 1996. The cases analysed in this report occurred between 1st October 1996 and 30th September 1997 and were reported to the system by 31st December 1997. The average time delay from the occurrence of an incident, to receipt of an initial report form was a month. Incidents which occurred during October 1996 are therefore included in the 1996/97 annual report. The report includes 14 incidents which occurred prior to October 1996, which were used to pilot the questionnaires.

Some incidents, (27) initially reported before 30th September 1997 are still under investigation and a questionnaire has not been returned for analysis. These cases will be included in next year's report.

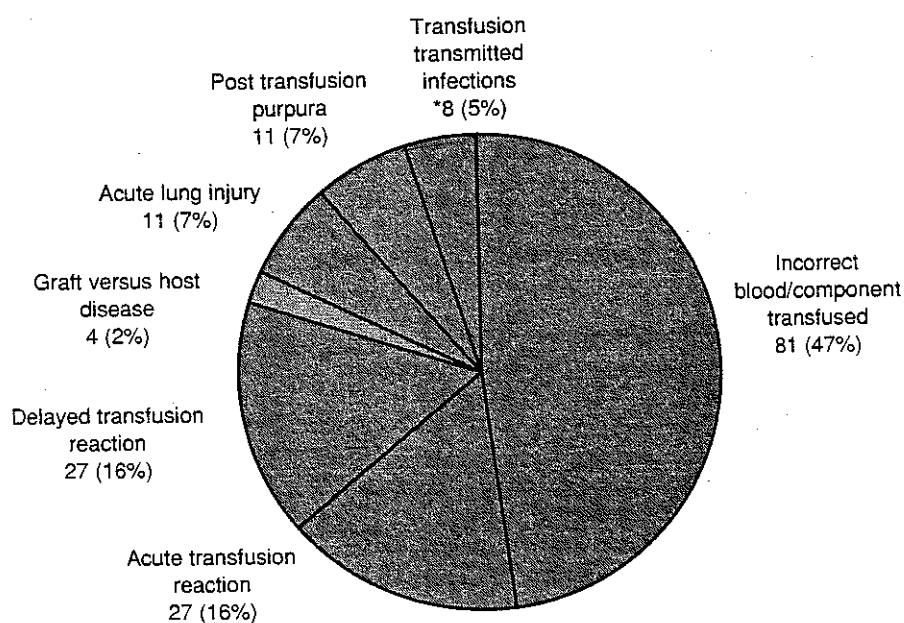
The NBA/PHLS CDSC reporting system for infectious complications of transfusion began on 1st October 1995 and, due to the different nature of infectious complications, uses a different reporting mechanism (see Figure 1 and Chapter 13). This report includes data reported by 31st December 1997 about post-transfusion infection incidents initially reported by blood centres to the system between 1st October 1996 and 30th September 1997.

Overview of reports received

Of the 424 hospitals receiving the SHOT scheme information package, 94 hospitals submitted 169 initial report forms. From these cases, 141 questionnaires have been returned (completed cases).

Figure 2

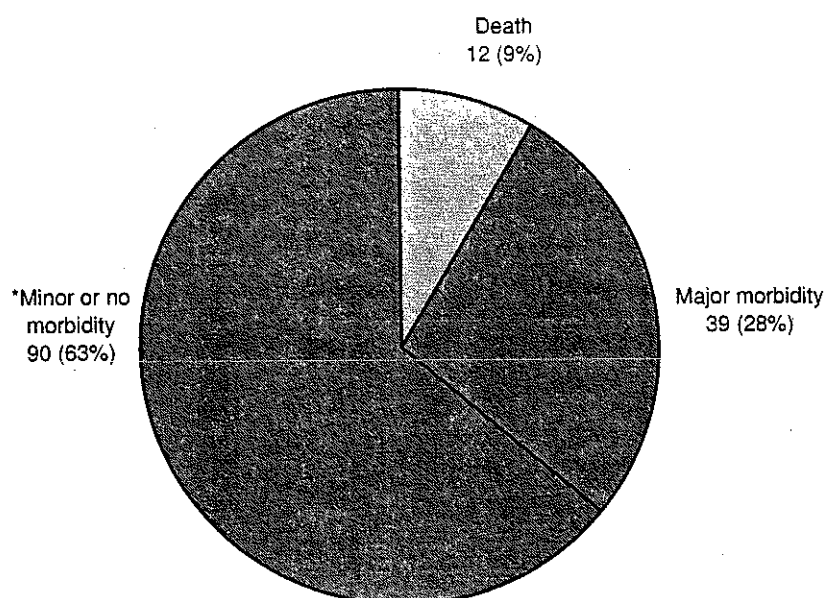
Overview of 169 cases for which initial report forms were received.



*note different reporting system, see Chapter 5.

The following summary refers only to cases for which a completed questionnaire was received.

Figure 3
Overview of transfusion related mortality/morbidity data reported in completed questionnaires (n=141).



* died of underlying condition (n=11)

Table 2
Transfusion-related mortality/morbidity reported in completed questionnaires (n=141).

	Totals	Incorrect component transfused	Major acute transfusion reaction	Major delayed transfusion reaction	Post transfusion purpura	Graft versus host disease	Transfusion related acute lung injury	Transfusion Transmitted Infections
Death attributed to transfusion	12	1	1	2	1	4	2	1
Major morbidity	39	9	1	12	3	0	7	7
*Minor/no morbidity	90	52+	22	9	7	0	0	0

Major morbidity was defined as:

- Intensive care admission and/or ventilation
- Dialysis and/or renal dysfunction
- Major haemorrhage
- Jaundice including intravascular haemolysis
- Persistent viral infection
- Acute symptomatic confirmed infection

At the time of compilation, no reports had been received of deaths in this group.

*Minor/no morbidity seen due to the transfusion: 11 patients in this group died of their underlying condition.

+Includes 3 cases of potential Rhesus sensitisation in young women/girls.

The information in the following figures and tables refers only to the 161 reports of non-infectious hazards reported to the SHOT office. For analysis of transfusion-transmitted infections, see Chapter 13.

Figure 4

Incidence of initial reports by month of event 1996-Sept 1997 (n=161).

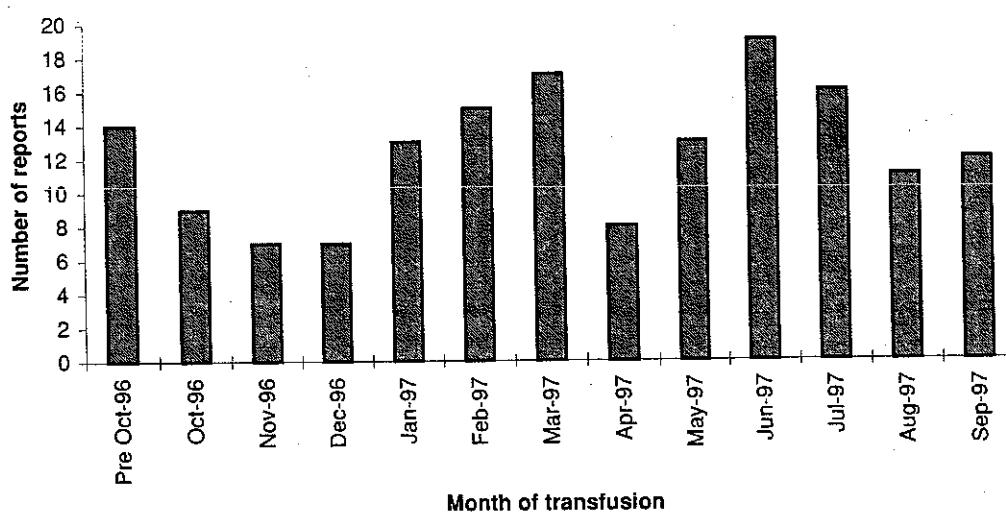


Table 3

Summary of initial reports and completed questionnaires received (n=161)

This includes 14 cases prior to October 1996 comprising of: 3 incorrect blood/component transfused, 3 acute transfusion reaction, 2 delayed transfusion reaction, 2 graft versus host disease, 4 acute lung injury.

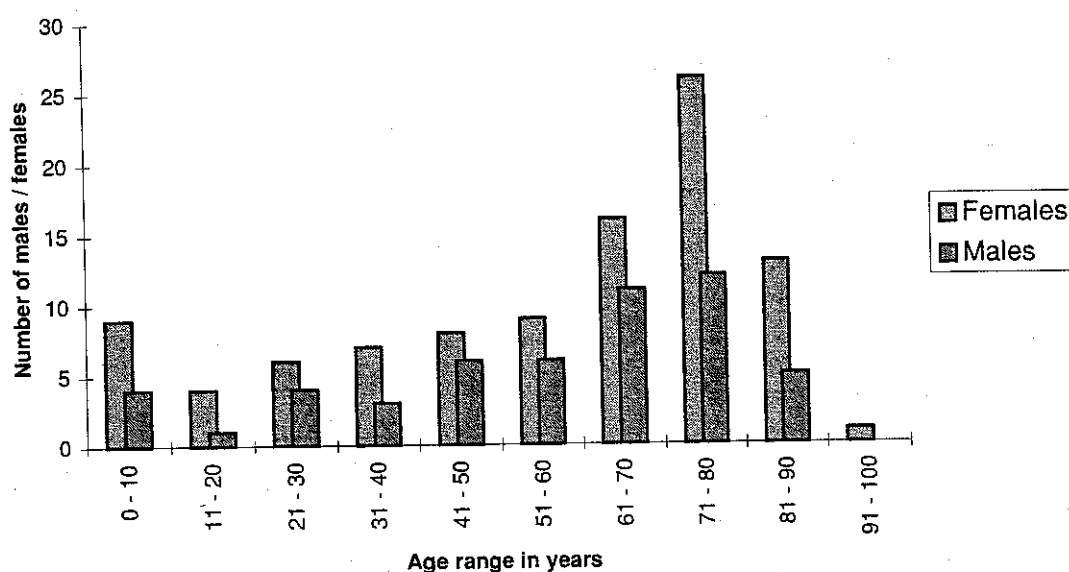
	TOTALS	Incorrect blood transfused	Acute transfusion reaction	Delayed transfusion reaction	Graft versus host disease	Acute lung injury	Post transfusion purpura
Initial reports received	161	81	27	27	4	11	11
Questionnaires received	134	63	24	23	4	9	11
Questionnaires outstanding	27	18	3	4	0	2	0

Table 4
Reasons for questionnaires outstanding.

<u>Pending</u> - receipt expected	
Medical notes unavailable	12
Inadequate staffing to obtain data	5
<u>Case closed</u> - questionnaire will not be submitted	
Medical notes lost	6
Refusal to submit report	4
Total	27

All of the above departments were offered a visit by the SHOT staff to assist with completion of the questionnaire.

Figure 5
Distribution of patients by age and sex at the time of transfusion (n=151)*



*Data excludes 10 cases, 8 where age was not stated and 2 where neither age nor sex was stated.

Males (n=56)

Age unknown 4
Age range 2 weeks - 89 years
Median age 63 years

Females (n=103)

Age unknown 4
Age range 3 months - 92 years
Median age 64 years

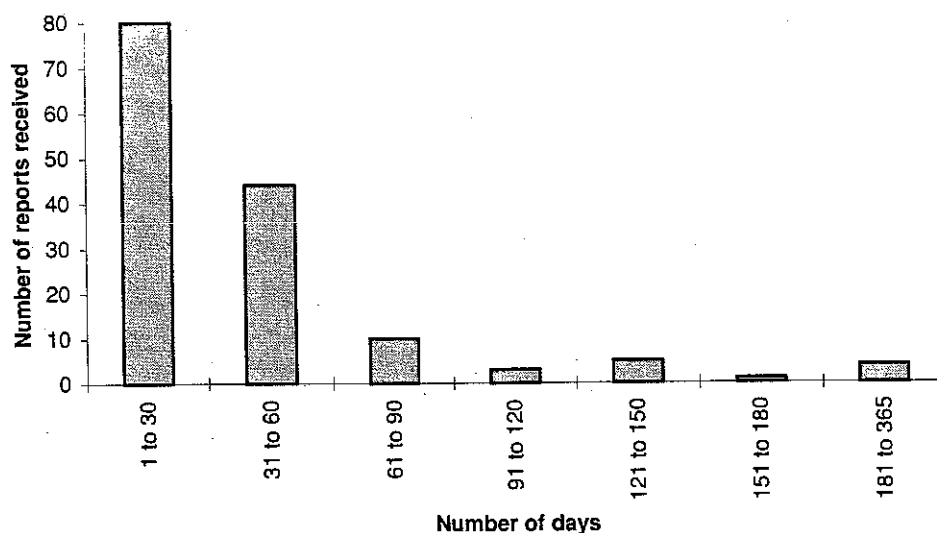
Reporting delays

The following figures summarise the relationship between the time of transfusion and receipt of the initial report form and of the completed questionnaire.

Figure 6

Calendar days between transfusion incident and initial report to SHOT (n=147)*

The median time for return of initial reports was 30 days.

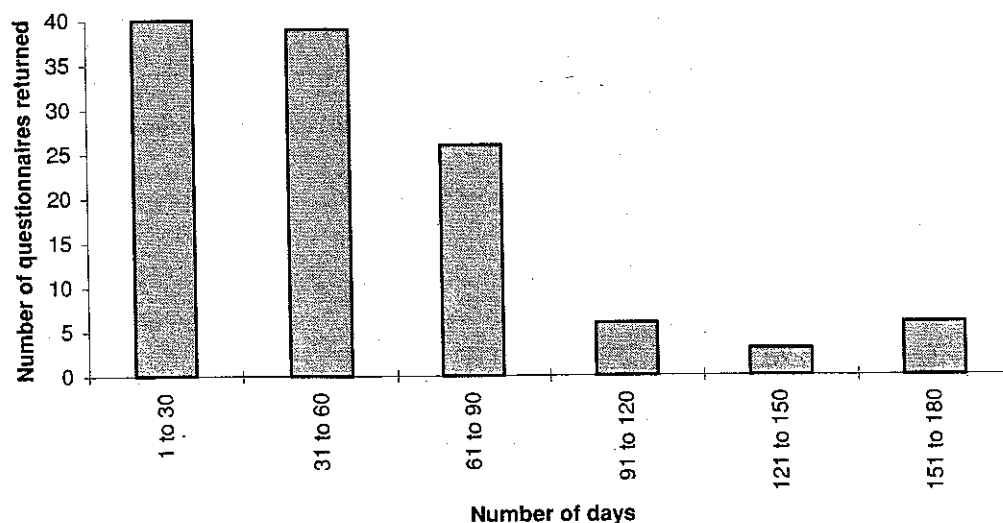


*147 reports: excludes 14 retrospective reports received during the pilot evaluation period prior to October 1996.

Figure 7

Calendar days between initial report and return of completed questionnaire (n=120)*

The median time between initial report and return of final questionnaire was 49 days



*120 reports: excludes 14 retrospective questionnaires received prior to October 1996
10 closed cases where a questionnaire can not be completed (Table 4)
17 questionnaires outstanding on 31/12/97

Information was not sought on the transfusion workload of individual hospitals contributing to the scheme and the voluntary and anonymous reporting nature means that it has not been possible to gain insight into the true incidence of transfusion hazards in the United Kingdom. Table 5 gives details of total blood component issues from the four United Kingdom Transfusion Services in order to give some idea of the context in which hazard reports are taking place.

Table 5

Total issues of blood components from the 4 UK Transfusion Services.

(thousands, to the nearest thousand)	
Red cells	2,430
Platelets	252
Fresh frozen plasma	384

7. INCORRECT BLOOD/COMPONENT TRANSFUSED

Definition. This section describes all reported episodes where a patient was transfused with a blood component which did not meet the intended requirements.

This category produced the highest number of reports ($^{81}_{169}$, 47%). Most episodes involved administration of a blood unit intended for another patient, usually involving a series of mistakes and inadequate adherence to prevailing hospital documented policies and guidelines. In other instances, components with 'special' characteristics was not provided as intended.

81 reports of an incorrect component being transfused were received. Of the 81, 63 questionnaires have been returned.

The data collated from all the returned questionnaires are presented in Appendix 5.i. This chapter aims to highlight common sites of error.

Sex

Males	23
Females	38
Unknown	2

Age (see Chapter 6 for overview).

Age range	3 months - 90 years
Median age	64 years

Components implicated

	<u>No. of cases</u>
Red cells	52
Platelets	6
Fresh frozen plasma	4
Citrate phosphate dextrose adenine (CPDA) anticoagulant solution administered in error.	1

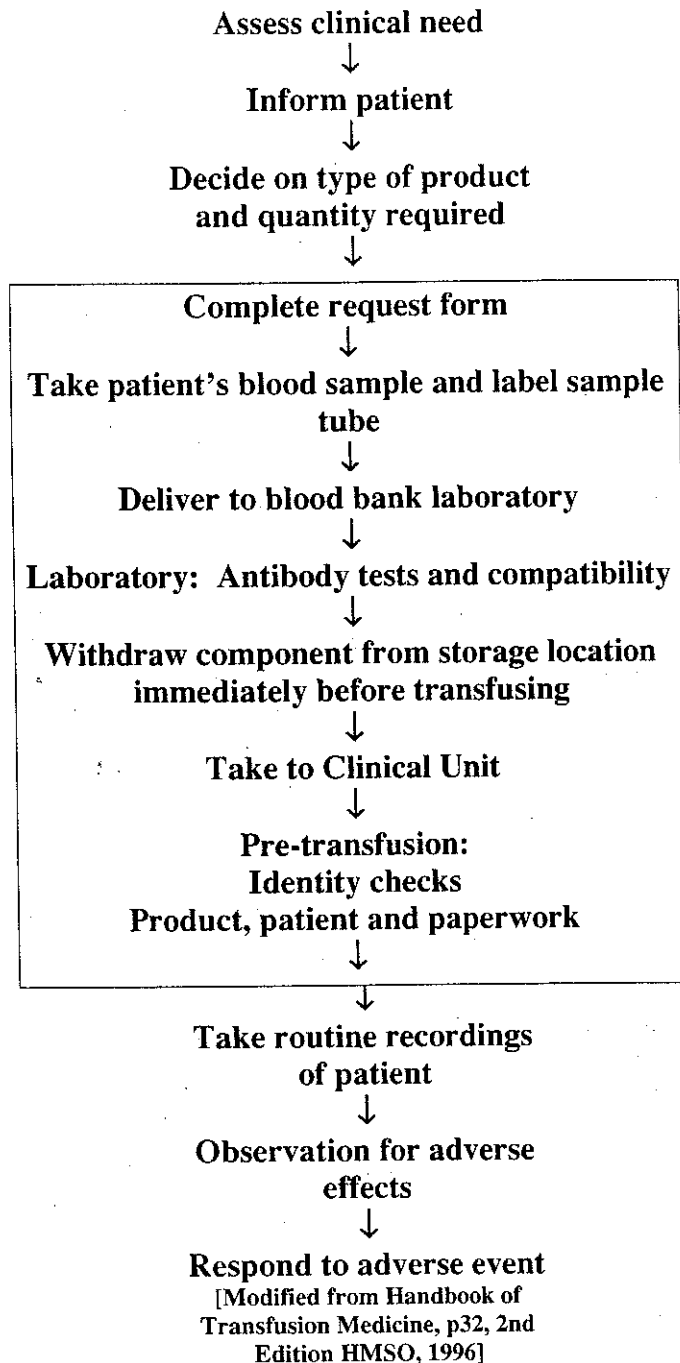
Errors in the clinical transfusion process.

There are many steps in the apparently simple process of requesting, matching, delivering and transfusing blood components. The correct outcome is summed up in a simple slogan:

' Right Blood, Right Patient, Right Time'

A mistake in any of the steps (or its omissions) increases the chance of an incorrect transfusion. Most "wrong blood" incidents result from the combined effect of several errors. Figure 8 illustrates the complexity of the process at hospital level.

Figure 8
Transfusion of Blood Components
Right blood/right patient/right time - essential steps



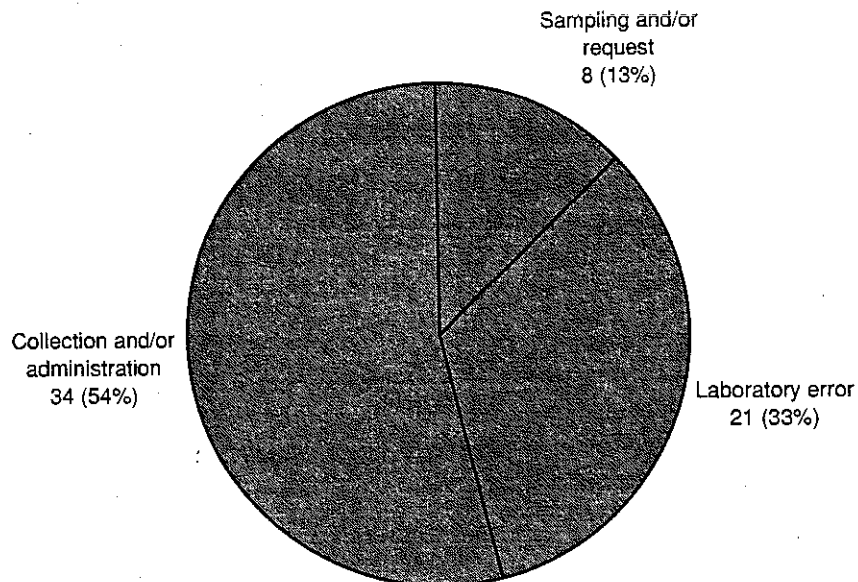
Analysis of reported errors

Where was the error reported to occur?

Errors fell into 3 categories:

1. Requesting blood and/or sampling the patient (8)
 2. Laboratory errors - grouping, cross-matching or labelling (21)
 3. Collection of blood from storage site (usually blood bank) and administration (34).
- The majority of the errors (54%) were attributed to the wrong unit being withdrawn from a blood bank refrigerator to take to the clinical unit, or in the bedside pre-transfusion checks.

Figure 9 Distribution of errors as stated by the reporting clinician (n=63)

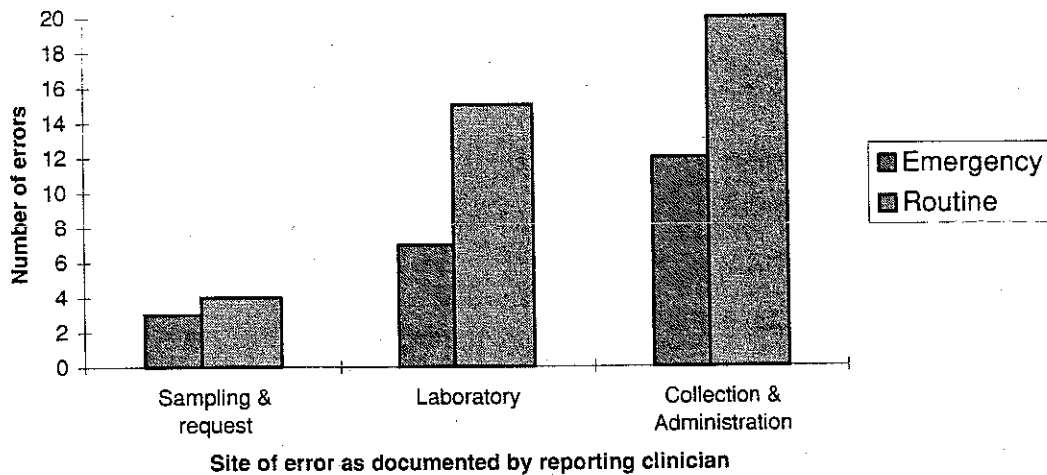


The questionnaire, completed for 63 incidents, sought further information about the circumstances and the factors that may have contributed to these mistakes and adverse outcomes. The findings are presented in some detail as they may help those responsible for training staff or for the review and implementation of transfusion procedures to identify and correct weak points in procedures.

Circumstances - emergency or routine, and site of reported error

Of the 63 complete reports, 39 errors related to routine, non-emergency requests, 22 to emergency requests, and in two this information was not reported.

Figure 10. Incidence of emergency and routine errors in the requesting, laboratory and administration steps of the process.*

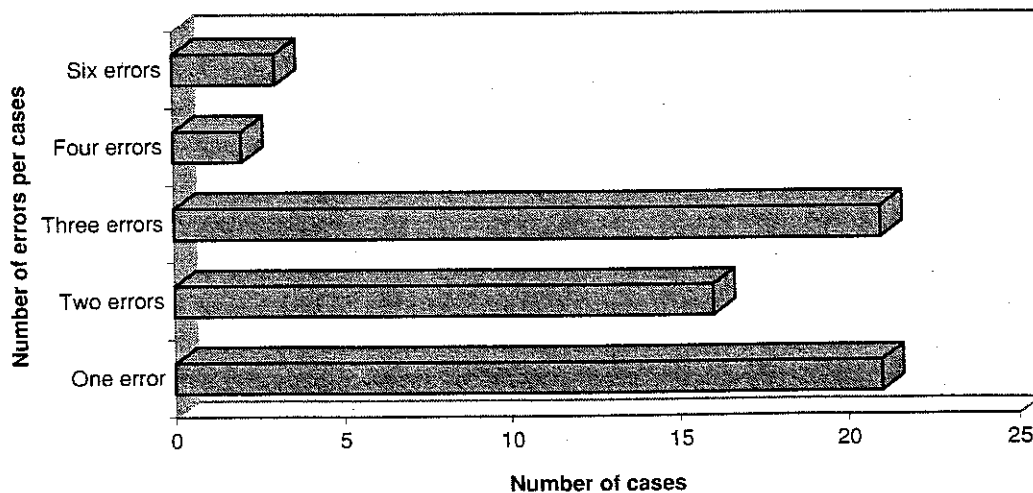


*In 2 cases the priority was not stated

Multiple errors contribute to many "wrong blood" incidents

Clinicians reported the mistake that had been recognised as the cause of the incorrect transfusion. However, analysis of the completed questionnaires showed that this mistake had been preceded by 1 to 5 other errors in the majority (42/63) of incidents. As shown in Figure 11, in the 63 incidents, a total of 142 procedural failures or omissions were identified.

Figure 11 Number of errors per case (n=63)



A sequence of multiple procedural failures or omissions usually precedes transfusion of the incorrect blood component. An accident waiting to happen...

Table 6 shows the site of the initial procedural failure that was identified from analysis of the reports. This gives a sense of the way in which mistakes in the early stages of the process may create the circumstances in which the blood component arriving at the patient's bedside may become 'an accident waiting to happen'. In the 63 incidents, there were 11 errors in blood sampling and request forms, 18 blood bank laboratory errors, and notably, 23 occasions in which the blood was not correctly checked at the final point of withdrawal from storage immediately before setting up the transfusion.

Table 6 Site of first error (n=63)

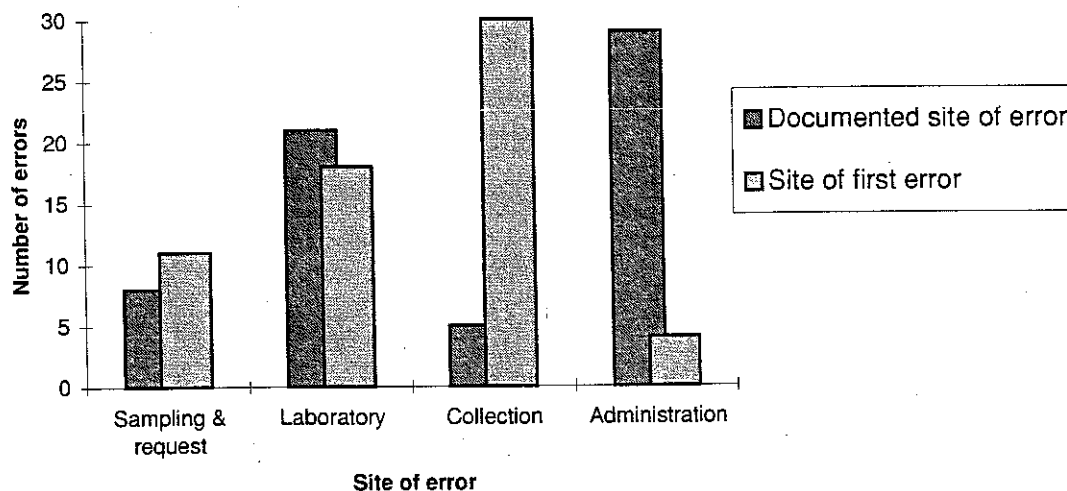
LOCATION	NUMBER OF ERRORS
PATIENT SAMPLING AND REQUEST	
Taken from incorrect patient	2
Details on sample incorrect	1
Details on request form incorrect	8
Total	11
BLOOD BANK LABORATORY	
Historical group not checked	1
Blood incorrectly grouped	7
Blood incorrectly crossmatched	2
Component incorrectly labelled	2
Inappropriate component selected	6
Total	18
COLLECTION OF COMPONENT	
Formal check for identity with patient omitted	23
Incorrect component collected	7
Total	30
ADMINISTRATION OF PRODUCT	
Component not formally checked against patient at bedside	4

This build up of errors is shown graphically in Fig 12.

Figure 12 Site of first error (n=63)

This figure shows the site of error which was recognised by the clinical team, documented and reported to SHOT by the reporting clinician. However, this clearly illustrates the way in which antecedent errors culminate in the transfusion of an incorrect blood component. For example:

- The 34 reported errors at the point of transfusion were preceded by 28 errors in withdrawing blood from its storage site prior to transfusion
- 3 of the laboratory errors were preceded by a sample/request error, 2 of which were telephone requests.



Commentary and recommendations

The following analysis of 63 complete reports of wrong transfusions demonstrates a situation common to complex, multi-step processes which involve many different individuals and which cross professional and managerial boundaries. Delivery of a reliable outcome constitutes a conventional total quality management challenge, with the goal of ensuring that each person involved 'get it right, first time, every time'.

Errors in requesting and cross-match sampling

Transposition of samples at the bedside

There were 2 cases of transposition of compatibility samples at the patient's bedside. One incident, which resulted in a fatality, involved the use of pre-labelled tubes. The second report did not state if pre-labelled tubes were used.

The request and supply of special blood components

There were 5 reports in which the correct component was not requested and/or issued. Three incidents involved the transfusion of non-irradiated components where irradiation was required, and the other 2 cases were where CMV negative components were appropriate but untested components provided. All of these errors occurred when the patient was temporarily away from the specialist unit, or the on-call facility for issue and supply of a requested product took place at a hospital remote from the specialist unit.

Telephone requests

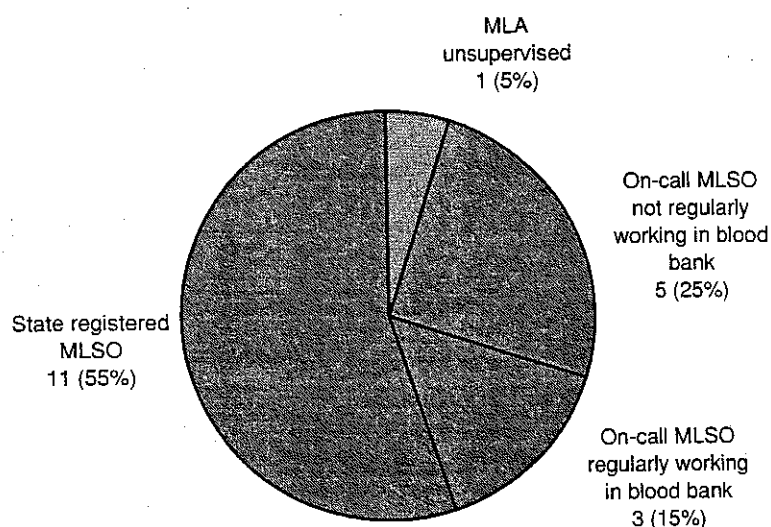
Inadequate information given to the laboratory via telephone requests led to 2 cases of an incorrect component transfused.

Blood Bank Laboratory

Laboratory staff

Laboratory errors were not restricted to either inexperienced staff or on call situations. Of the 21 laboratory errors reported (Figure 13), 12 incidents occurred during routine working hours. Eleven of these involved an experienced blood bank state registered MLSO and 1 an unsupervised MLA. Eight incidents occurred on-call, of which 3 involved regular blood bank staff, and the remaining 5 staff not regularly working in the blood bank.

Figure 13 Grade of laboratory staff and time of error (n=20)*



*In 1 report this was not stated.

Table 7 details the grade of staff, type of error, and whether the incident occurred during routine or on-call hours.

Table 7 Documented laboratory errors (n=21)*

Notes	Error	Total number of errors	State registered MLSO, routine hours, regularly working in blood bank	State registered MLSO, on-call, regularly working in blood bank	State registered MLSO, on-call, not regularly working in blood bank	MLA, Unsupervised routine hours
1	Blood incorrectly grouped	11	7	1	3	
2	Blood incorrectly cross-matched	2		1	1	
3	Component incorrectly labelled	3	1	1		1
4	Inappropriate component selected	5	3	1		

*In 1 case the grade of staff was not stated.

NOTES

1. Incorrect group (n=11)

- 3 errors were due to transposition of samples in the laboratory.
- 1 error was due to the incorrect sample being used to group and crossmatch. This involved a telephone request where only the patient's name was given.
- 1 error occurred due to the omission of the group procedure. The crossmatch was recorded as compatible.
- 2 incidents were due to splash contamination of microplates used for ABO determination.
- 4 cases, where no specific reason for the error was reported, in which
 - Rh positive patient grouped as A Rh positive (1 case)
 - A Rh negative patient grouped as A Rh positive (1 case)
 - Rh negative patient grouped as O Rh positive, (2 cases).

2. Incorrect crossmatch (n=2)

- In the 2 cases that were incorrectly crossmatched, no reason for the error was reported.

3. Incorrectly labelled (n=3)

- 1 case involved a telephone request where only the patients name was given. Due to an incorrect assumption by the member of staff who took the call, the wrong date of birth was entered into the laboratory computer, resulting in misidentification of the patient.
- An incompatible unit was inadvertently labelled with a compatibility label.
- The computer generated compatibility label was attached to an incorrect blood bag.

4. Incorrect selection of component (n=5)

- 1 case involved a group AB Rh positive patient being issued B Rh positive fresh frozen plasma due to incorrect serological reasoning
- 1 case was due to A Rh positive red cells being issued for an A Rh negative female patient of child bearing age.
- 1 case was where a gamma irradiated product was requested but a non-irradiated component supplied
- 2 cases were where autologous blood previously donated by the patient was held in the blood bank, but the laboratory issued compatible donor red cells.

Historical blood bank records not checked

There were 7 cases involving patients who had been grouped previously and whose historical blood bank records were not checked prior to component issue.

In 2 of these cases an ABO incompatible transfusion could have been avoided if current guidelines had been followed⁶. One patient died from sequelae of the transfusion, and the other suffered the complications of intravascular haemolysis.

In 1 incident the historical records of a patient could not be checked at night because computer records were not accessible to the on-call laboratory staff.

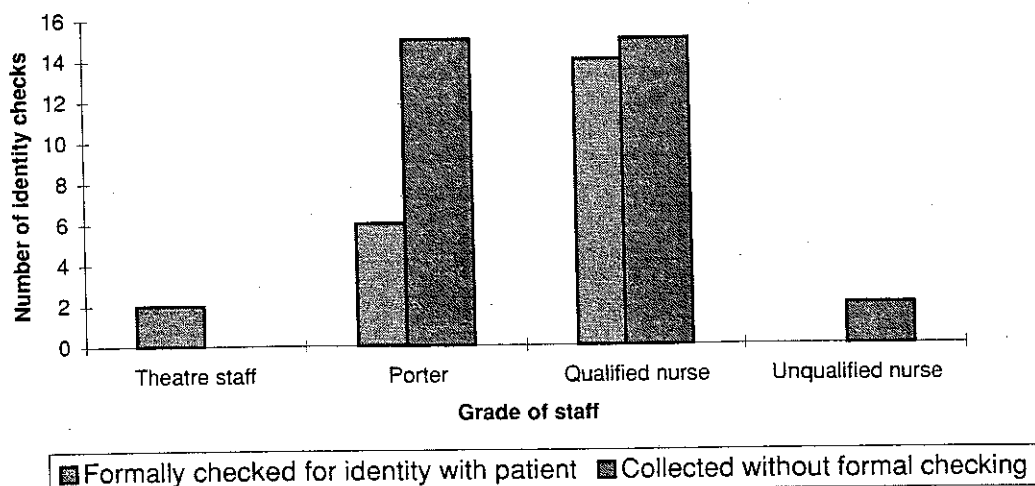
Errors in withdrawal of blood components from storage location immediately prior to transfusion.

Withdrawal of the component from the storage location was a major source of primary error, with 63 reported incidents.

In 14 cases the component was handed over personally from blood bank staff to a porter or member of the clinical unit staff. In 28 cases the component was collected from a blood bank refrigerator and in 19 from a satellite refrigerator. There were 2 cases where the site of collection was not stated.

In 34 incidents the component was not checked at the time of withdrawal for identity with the patient. Of these 34 cases, 19 resulted in the collection of an incorrect component. In these cases it appeared that the grade of staff checking the component did not influence whether a formal check was carried out (Figure 14).

Figure 14. Formal identity check versus grade of staff (n=54) excluding 9 cases where either the grade of staff or the identity check was not stated.



However, even when a formal identity check had been carried out, collection of an incorrect component occurred on 6 occasions (Table 8).

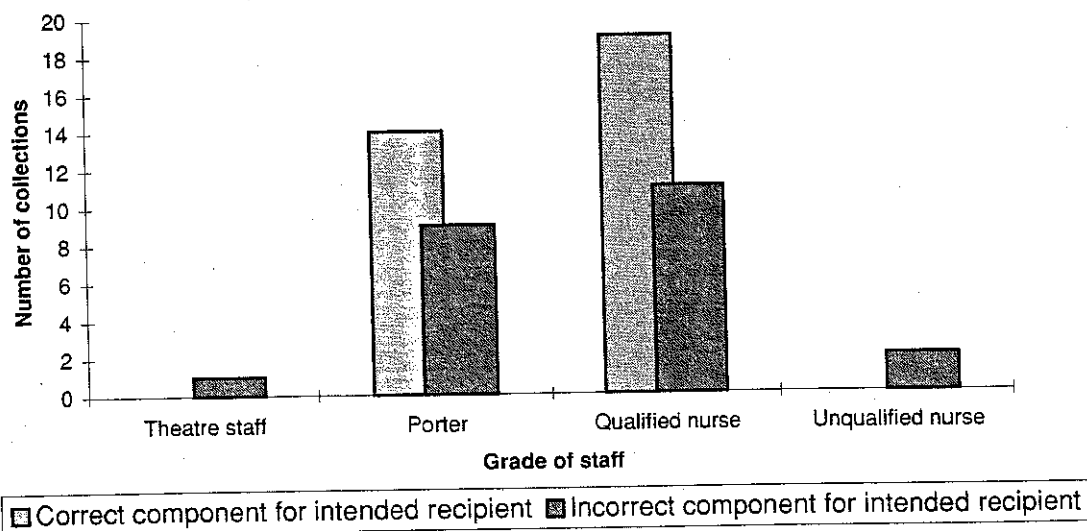
Table 8 Formal check of component at the time of collection versus correct component collected (n=63).

In 7 cases, the data were incomplete.

	Formal check of component	
	Yes	No
Correct component	16	15
Incorrect component	6	19

The incorrect component was collected in 27 cases, including 2 where the presence of a formal check was not stated. In 20 cases the component was incorrect with respect to name, date of birth and hospital number; in 3 cases it was incorrect with respect to date of birth and hospital number; in 1 case it was incorrect with respect to date of birth only. Again it appeared that the grade of staff collecting the component did not influence the reliability of the process (Figure 15).

Figure 15 Withdrawal of correct and incorrect component from storage site: grades of staff involved (n=27)*



*excludes 3 cases which involved the inappropriate collection of components from emergency stock.

NB These figures do not include incorrect components issued where the labelling has been correct for the intended recipient, but due to an error in the laboratory may not in fact be a compatible product for the intended recipient.

Transfusion of blood components - 'bedside' procedures.

There were 34 reported cases where the final bedside check had been omitted. In most of these, two people were reported to have been involved in setting up and checking the transfusion. Table 9 shows the grade of staff setting up the transfusion in these cases.

Table 9 Grades of staff involved in setting up transfusions in which the bedside check was incomplete (n=28)*

Grade of staff	Number of cases
2 Doctors	1
Doctor and qualified nurse	3
Theatre nurse & unknown	1
Qualified nurse & unknown	2
Qualified nurse & qualified nurse	19
Qualified nurse & unqualified nurse	2

* excludes 6 cases where the grade of staff was not reported.

Use of identity wristbands

In 8 incidents where an incorrect component was transfused, the patient had no identity wristband. Three cases occurred in outpatients, 3 on the ward, 1 in theatre and 1 on a day unit.

Recognition of error

Of the 63 incorrect component transfused errors

- 4 were identified due to an acute transfusion reaction. Three of these were ABO incompatible transfusions (2 red cells, 1 FFP) and 1 ABO and Rh incompatible (red cells).
- 2 were identified due to a delayed haemolytic transfusion reaction. Both were ABO incompatible transfusions
- 28 incidences were detected by the laboratory staff
- 2 cases were discovered by junior doctors.
- 1 case was identified by theatre staff
- 1 case was identified by a porter
- 25 incidents were discovered on the ward.

Where transfusion of the incorrect component was not associated with a reaction the error was detected in a variety of ways, for example:

- A trainee doctor in theatre documenting the components transfused retrospectively, noted the discrepancy between the identity of the patient and the red cells transfused.
- Ward staff who were responsible for the intended recipient telephoned the blood bank to inquire when the platelets they had requested would be available. The blood bank had already issued the platelets and traced the error through the portering service to another ward.
- Laboratory staff went to replace the emergency O negative red cells and discovered they were still there, another patient's O negative red cells having been used in mistake for the emergency supply.

Outcome

Out of the 63 cases fully reported, there were 15 ABO incompatible transfusions, 5 Rh incompatible transfusions and 1 ABO+Rh incompatible transfusion (Tables 10 and 11).

- 1 patient died from sequelae of the transfusion. This was an O positive patient who received a whole unit of A positive red cells, and required both intensive care and dialysis.
- 4 patients recovered from the effects of intravascular haemolysis. Three of these were ABO incompatible transfusions and 1 an ABO and Rh incompatible transfusion.
- 1 patient survived with renal impairment. This patient was seriously ill with multiple medical problems at the time of transfusion.
- 1 patient was already on ITU, but suffered with complications of coagulopathy as a direct result of the transfusion.
- Of the 5 documented Rh incompatible transfusions, 4 recipients were female and 1 was male. Three of the females were <50 years of age, including a 2 year old infant.
- In 6 cases the blood group of the patient and/or the incompatible component was not stated, although 1 case was clearly an incompatible transfusion as the recipient required admission to an intensive care unit with haemoglobinuria, hypotension and loin pain after receiving only 50 - 100 mls of incorrect red cells. This patient was documented as having recovered from the effects of intravascular haemolysis.

Table 10 Sequelae of incorrect component transfused according to whether there was ABO and/or Rhesus incompatibility (n=57)*

Sequelae	Asymptomatic	Minor reaction	Major morbidity	Death
ABO incompatible	6	3	5	1
Rh incompatible	2	0	3	0
ABO + Rh Incompatible	0	0	1	0
ABO + Rh compatible	36	0	0	0

*excludes 6 unknowns where the blood group was not stated.

Major morbidity was classified as:

- Intensive care admission and/or ventilation
- Dialysis and/or renal dysfunction
- Risk of Rhesus sensitisation in a female of child-bearing age (or child)

Minor reaction: classified where the patient had suffered symptoms/complications attributed to the transfusion but these did not require ITU admission or dialysis, and the patient recovered rapidly.

Asymptomatic: classified where no symptoms were directly attributed to the transfusion.

Death due to the underlying condition or from other causes are included in this category (n=5)

Table 11 Sequelae of ABO and/or Rhesus incompatible blood transfusions (n=21).

These comprise 1 Rh & ABO incompatible transfusion, 15 ABO incompatible transfusions and 5 Rh incompatible transfusions.

Patient ABO & Rh group	IBT ABO & Rh group	Blood component	Volume IBT Trans-fused	Symptoms/Complications	ITU ventilation and/or dialysis	Outcome
O neg	A pos	red cells	>100 mls	renal failure bronchospasm fever	no	recovered from complications of intravascular haemolysis
AB pos	B pos	fresh frozen plasma	9 units	loin pain falling Hb increase in urea and creatinine	no	recovered from complications of intravascular haemolysis
O pos	A neg	red cells	28 units	rigors	ITU admission	recovered from complications of intravascular haemolysis
O pos	A pos	red cells	1 unit	renal failure haematological disorder	ITU admission dialysis	died from sequelae of transfusion
O pos	A pos	red cells leucocyte depleted	1 unit	anaesthetised	already on ITU	recovered from complications of intravascular haemolysis
O pos	A pos	red cells	50-100 mls	bronchospasm hypotension fever	no	survived with no ill effects
B pos	A pos	fresh frozen plasma	1 unit	none	no	survived with no ill effects
O neg	A neg	red cells	1 unit	marked jaundice	no	survived with no ill effects
A pos	AB pos	red cells	3 units	none	no	survived with no ill effects
A pos	AB pos	red cells	5 units	anaemia jaundice spherocytes (9 days later)	no	survived with no ill effects
A pos	AB pos	red cells	>100mls	none	no	survived with no ill effects
A pos	O pos	fresh frozen plasma	>100mls	coagulopathy	already on ITU	survived with no ill effects
A pos	B pos	red cells	<50 mls	ventilatory problems progression of underlying condition	ITU admission	survived with no ill effects
O pos	A pos	red cells	>100mls	none	no	survived with no ill effects
O pos	A pos	red cells	50-100 mls	none	no	survived with no ill effects
O pos	B pos	red cells	2 units	none	no	survived with no ill effects
A neg	A pos	red cells	2 units	possible Rh sensitisation	already on ITU	survived with no ill effects
A neg	A pos	platelets - apheresis	1 unit	possible Rh sensitisation	none	survived with no ill effects
A neg	A pos	red cells	>100mls	possible Rh sensitisation	already on ITU	survived with no ill effects
O pos	O pos	red cells	<50mls	possible Rh sensitisation	no	survived with no ill effects
O neg	O pos	red cells	<50mls	none	no	survived with no ill effects

Procedural review

Of the 94 hospitals who submitted reports, 18 did not have a transfusion committee or other established forum where the incident could be reviewed. Of the 18, 3 haematology departments were reviewing their local transfusion procedures, 7 had made changes in consultation with the other disciplines involved and 8 had not addressed the situation.

Five hospitals reported that the transfusion committee felt that adequate guidelines were in place, and a change to transfusion policy was not required, although staff education should be implemented.

In 6 of 34 hospitals where the bedside check had been inadequate, the use of identity wristbands had been adopted. In a further case the transfusion policy was under review and in the remaining cases no changes have occurred.

In 34 cases, a review by the transfusion committee was pending at the time of reporting, although in most cases a procedural change had already been introduced where a problem had been identified.

Summary of findings

1. The use of pre-labelled sampling tubes led to one fatality.
2. Request errors were noted, 5 involved the request and supply of 'special components', 2 were telephone requests where inadequate information was given.
3. The historical transfusion record was not always checked prior to component issue.
4. Errors in grouping, crossmatching, labelling and selection of a component have been documented.
5. The most important single contributing cause of incorrect transfusions was the withdrawal of the wrong pack from its storage location (either the hospital blood bank or another storage location).
6. Lack of patient hospital identity wristbands or other formal means of identification led to an incorrect component being transfused on 8 occasions.
7. Two thirds of incorrect component transfused incidents involved multiple errors, culminating in administration of the incorrect unit. The local procedures for the final bedside checks intended to ensure that patients receive the correct blood were frequently not performed, or if performed failed to detect that an incorrect pack had been delivered. This was not prevented by the involvement of staff in the checking procedure.
8. In 1 reported case a component was given to a patient for whom blood transfusion had not been prescribed at all.

Recommendations

1. Pre-labelled sampling tubes should not be used⁶.
2. Request systems for blood and components should ensure prescription, issue and administration of the correct component. These should cover 'special requirements' and telephone requests, and should clarify the respective responsibilities of medical and blood bank staff⁶.
3. Access to previous transfusion records in the laboratory containing grouping information should be available at all times and used as appropriate⁶.
4. Blood banks should review procedures and systems including enforcement of the current guidelines and standards available⁶, in addition to training to prevent errors of sample handling and technical errors.
5. Hospitals should review their current system to ensure that errors in this area can be prevented. Standards should be set for a minimal formal identification requirement when a component is collected. Novel identification systems are available, but have resource implications. These systems merit evaluation and development.
6. Hospital systems should ensure that in-patients and out-patients can be identified at the time of both sampling and transfusion, specifically in out-patient departments where patient identity is often not available.
7. The bedside check is vital in preventing transfusion error, staff should be vigilant in checking identification details of the component against those of the patient. Every hospital should have a policy for formally checking the blood component at the bedside. This is currently being addressed by the British Committee for Standards and Haematology (BCSH) on behalf of the British Society for Haematology (BSH).
8. Blood components should always be administered against a written prescription.

8. ACUTE TRANSFUSION REACTIONS

Definition

Acute transfusion reactions were defined in this report as reactions occurring at any time up to 24 hours following a transfusion of blood or blood components. It excludes cases of acute reactions due to an incorrect component being transfused, as these are covered in Chapter 7.

This category accounted for 17% of non-infectious hazards.

27 initial reports were received (1 fatal) and 24 completed questionnaires were returned.

The data retrieved from the returned questionnaires are shown in Appendix 5.ii.

This chapter highlights the main features of the 24 completed questionnaires received.

Sex

Males	8
Females	16

Age

Age range	1 month - 80 years
Median age	64 years

Components implicated

	<u>No. of cases</u>
Red cells (rbc)	18 (1 also FFP)
Platelets	5
Fresh frozen plasma (FFP)	2 (1 also rbc)

A. Reactions in which red cells were implicated

There were 18 cases including 1 case where FFP was also implicated.

Reactions could be broken down into the following categories:

<u>Reaction type</u>	<u>Number of cases</u>
Haemolytic	6
Non-haemolytic febrile	7
Hypotensive	2
Due to anti IgA antibodies	1
Other	2

Haemolytic reactions and their clinical sequelae.

In 4 cases red cell allo-antibodies were detected for the first time post-transfusion. In 2 of these cases crossmatching was performed on a sample taken four or more days prior to the transfusion in a previously transfused patient. In one case this was undoubtedly a contributory factor but was less clear in the second case. In one case the development of anti-D in a Rhesus D negative patient being transfused with RhD positive red cells was unrecognised because free anti-D was not detected in the pre-transfusion serum. A further case developed a non-haemolytic febrile transfusion reaction and was also found to have red cell allo-antibodies and a positive direct antiglobulin test. In this case the presence of red cell antibodies pre-transfusion had been suspected but transfusion with crossmatch-compatible, unselected red cells was allowed to proceed because it was considered urgent.

Clinical sequelae included one case of exacerbation of pre-existing auto-immune haemolysis (AIHA) and one case of haemolysis presumed to be caused by a cephalosporin-dependent red cell antibody.

Non-haemolytic febrile reactions

Note that the initial SHOT information package did not seek reports of febrile non-haemolytic reactions.

Seven of these were reported. HLA (histocompatibility locus associated) antibodies were found in 4 cases and suspected, but not identified at the time of the report, in 2 cases. In another case the cause was not established. Such reactions are known to be common and not usually serious. The fact that these cases were reported may reflect reactions which were considered more severe than usual.

Hypotensive reactions

There was one reported case in which autologous whole blood, filtered through a negatively charged leucocyte-depleting filter and transfused to a bone marrow donor, was clearly associated with an immediate hypotensive reaction. The transfusion was terminated. The patient was not receiving ACE (angiotensin converting enzyme) inhibitor drugs. Hypotensive reactions to platelets, associated with the use of negatively charged filters and treatment with ACE inhibitors, has been recently recognised (see below) but to our knowledge has not been reported in patients receiving red cell transfusions.

IgA antibodies

The one case reported in this category is worthy of mention because the sole manifestation was pruritis and a skin rash. The patient was subsequently found to be IgA deficient with high titre anti- IgA antibodies. This is the likely cause of the reaction, since such patients are well recognised to experience anaphylaxis during transfusion.

Others

A further three cases were hypertransfusion (1 case), clinical anaphylaxis, cause unknown (1 case) and dyspnoea/restlessness, cause unknown (1 case). In the last case, subsequent transfusion with washed red cells was well tolerated.

B. Reactions in which platelets were implicated

There were 5 cases which fell into 2 groups:

Hypotension/flushing

There were 4 cases in this group, 3 of which involved the use of negatively charged leucodepletion filters as previously described²⁴. In 1 of the cases, the patient was receiving treatment with an ACE inhibitor. A fourth case involved neither the use of a filter nor ACE inhibitor.

Haemolysis

One patient (group A) receiving pooled, buffy coat-derived, group O platelets for a haematological malignancy developed a haemolytic reaction. The group O platelet unit could not be shown retrospectively to have high titre anti A and exacerbation of autoimmune haemolysis could not be ruled out.

C. Reactions in which fresh frozen plasma was implicated

There were only 2 reports in this group, one also involving the use of red cells and resulting in hypertransfusion and the second resulting in pruritis and dyspnoea, cause unknown and probably not fully investigated.

Outcome

The majority of patients reported with acute transfusion reactions survived without sequelae. There was only 1 transfusion-related death, in an elderly female with underlying haematological malignancy and AIHA in whom haemolysis as a result of passive transfer of anti A from group O platelets was thought to be a contributory factor. A further patient, who suffered a reaction as a result of platelet/filter interaction, subsequently died of underlying disease. One patient who was hypertransfused remained seriously ill.

Summary

- In general the reported reactions do not reflect poor practice and cannot be predicted. Procedures for reporting reactions to attendant medical staff and for subsequently seeking more expert advice are generally adhered to although in some cases retraining and/or tightening up of procedures was deemed necessary by hospitals.
- This group of patients who experience acute reactions is commonly treated with a combination of hydrocortisone and antihistamine. Such patients may experience repeated reactions and thus be prescribed repeated doses of hydrocortisone.
- There is wide variation in the frequency with which nursing observations are recorded during transfusions. It is not clear what the optimum type and frequency of such observations should be and this area would benefit from audit and standardisation.
- There is marked variability in the number and types of post-transfusion investigation performed. This may reflect the type of component implicated and the perceived seriousness and cause of the reaction. Lack of data in some cases made it difficult to draw firm conclusions about the cause of the reaction. This is another area which would benefit from standardisation.
- There were four cases where the crossmatch sample was taken four or more days prior to the transfusion. In one case this clearly contributed to the development of acute haemolysis in a patient with an unrecognised delayed haemolytic transfusion reaction. In a second case it was not clear whether the time lag was a contributory factor. In two further cases the delay was not a relevant factor. Recommendations for safe intervals between sampling and transfusion are given in BCSH guidelines for pre-transfusion compatibility testing⁶.
- The majority of reactions were reported to the local Blood Centre but only about 50% of reactions was reported to a hospital transfusion committee. It is not clear whether this reflects simple lack of reporting or the absence of an appropriate forum for reporting.
- There is a new type of reaction, only recently recognised, in which hypotension and flushing is associated with the use of negatively charged bedside leucodepleting platelet filters in patients with reduced ability to break down bradykinin, for example during treatment with angiotensin converting enzyme (ACE) inhibitors²⁴. In this report, a similar reaction occurred in the absence of ACE inhibitor treatment and also in response to filtered whole blood, a feature which to our knowledge has not been previously reported.

Recommendations

- Consider the use of paracetamol rather than hydrocortisone for the treatment of recurrent non-haemolytic febrile transfusion reactions.
- A national review of standards for the type and frequency of nursing observations during transfusion is recommended.
- A national review of the requirements for samples and investigations following acute transfusion reactions is recommended.
- Hospitals should review crossmatch sampling intervals in the light of BCSH guidelines for pre-transfusion compatibility testing⁶.
- A hospital transfusion committee or other appropriate forum for discussion of transfusion-related matters should be set up where one does not exist.
- Clinicians should consider the possibility of platelet/filter interactions in patients receiving ACE inhibitor treatment. Reporting of future cases is encouraged so that a complete picture can emerge.

9. DELAYED TRANSFUSION REACTIONS

Definition

Delayed transfusion reactions were defined in this report as occurring more than 24 hours following a transfusion of blood or blood components. In practice these are almost invariably haemolytic due to the development of red cell allo-antibodies.

This category accounted for 17% of non-infectious hazards reported.

27 initial reports were received (2 fatal) and 23 completed questionnaires were returned.

The data retrieved from the returned questionnaires are shown in Appendix 5.iii.

This chapter highlights the main findings from the 23 completed questionnaires.

Sex

Males	7
Females	16

Age

Age range	25 - 87 years
Median age	68 years

Components implicated

Red cells (rbc)	<u>No. of cases</u> 23
-----------------	---------------------------

In all cases donor (allogeneic) red cells were implicated. The development of 33 newly detectable post-transfusion red cell allo-antibodies was reported in 21 patients.

4 patients were noted to have pre-transfusion red cell allo-antibodies.

In one patient the same antibody (anti Jk^b) found post-transfusion was detected retrospectively in the pre-transfusion sample. Its presence had been suspected pre-transfusion but the urgency of the transfusion left insufficient time for antigen -negative blood to be selected.

A further patient on α -Interferon treatment and with autoimmune haemolytic anemia (AIHA) had pre and post transfusion anti S but it was not clear whether S-negative red cells were selected for the transfusion.

In 2 other patients with pre-existing red cell allo-antibodies (anti E, anti Cw) in whom new allo-antibodies developed it is presumed that appropriate antigen-negative red cells were selected.

Table 12 shows the breakdown of new post-transfusion red cell allo-antibodies according to antigen specificity and Table 13 gives details of these antibodies for individual patients.

Table 12. New post-transfusion red cell allo-antibodies in 21 of 23 patients

Antibody group	Number	Sole antibody
Kidd (Jk)		
Jka	6	5
Jkb	2	
Duffy (Fy)		
Fya	1	
Fy3	1	
Kell		
K	4	1
Kpa	1	
Rhesus		
D	2	1
C	3	1
c	2	1
E	5	1
e	2	1
MNSs		
M	1	
S	2	
Unspecified pan-agglutinin	1	
Total	33	11

Table 13. New red cell allo-antibodies in individual patients

Patient no.	Antibody(ies)
1	D +Jka
2	Jka
3	S+Jkb+Fy3
4	E
5	K+Jkb+Kpa
6	K
7	Jka
8	C+E
9	Jka
10	e
11	Fya+E
12	E+M
13	D
14	E+K
15	Jka
16	C
17	K+C
18	Jka
19	Unspecified pan-agglutinin
20	C+e+S
21	c

Clinical sequelae

Symptoms and signs fell into 3 categories:

- **Group 1** Asymptomatic ($\pm$ positive direct antiglobulin test(DAT)/spherocytes)
- **Group 2** Falling haemoglobin ($\downarrow$ Hb)/positive DAT/spherocytes (2 of these)
- **Group 3** Jaundice/ $\downarrow$ Hb/dark urine $\pm$ positive DAT/spherocytes/renal impairment

Information about symptoms and signs was not complete in all cases so only broad conclusions can be drawn.

Group 1

There were 4 patients in this group. Antibody specificities were all Rhesus (E, C+E, e, c). All survived without sequelae.

Group 2

There were 3 patients in this group. Antibody specificities were D+Jka, Jka and c. All survived without sequelae.

A fourth patient reported solely with a positive DAT and spherocytes developed anti Jka and died from underlying trauma.

Group 3

Of the 14 patients in this group, 13 were recorded with jaundice and of these 6 had evidence of intravascular haemolysis. Five of the 14 patients suffered deterioration in renal function. A total of four patients in this group died, two as a result of combined factors of underlying disease and delayed haemolytic transfusion reaction (DHTR) and two as a result of their underlying condition. The antibody distribution and outcome in this group is shown table 14.

Table 14. Antibody distribution and outcome in Group 3 patients

Patient no.	Antibody(ies)	Outcome
3	S+Jkb+Fy3	Survived
5	K+Jkb+Kpa	Died. Haematological malignancy, AIHA and DHTR
6	K	Died. Underlying immunosuppression
7	Jka	Survived
9	Jka	Survived
11	Fya+E	Survived
13	D	Died. Underlying trauma
14	E+K	Died. Trauma and DHTR
15	Jka	Survived
17	K+c	Survived. Mild renal impairment recovered.
19	Panagglutinin and HLA	Survived
20	C+e+S	Survived
22	Pre-existing S and AIHA	Survived
23	Pre-existing Jkb	Survived

No firm conclusions can be drawn but the more severe DHTRs associated with the development of jaundice, including intravascular haemolysis, and renal dysfunction appeared to be associated with non-Rhesus (particularly Kell and Kidd) and/or multiple antibodies. The 2 deaths in which a DHTR was implicated were in this group.

Summary

- There was no evidence of widespread poor practice. In general delayed reactions as a result of the development of new red cell allo-antibodies could not have been prevented as the antibodies were undetectable at the time of the original crossmatch. In one case where an antibody was suspected pre-transfusion there was insufficient time to investigate and crossmatch-compatible, unselected red cells were transfused. Procedural changes recommended in individual hospitals included access to off-site computer records to enable checking of transfusion history (1 case) and increased emphasis on reporting transfusion and obstetric histories (2 cases)
- The onset of DHTRs ranged from 2 to 15 days (median 7 days) and is similar to that reported in the literature²⁵.
- The antibody types encountered are similar to those previously reported²⁵.
- There was marked variation in the data given for symptoms and signs and the types of samples taken suggesting a need for standardisation.
- One haematologist was keen to draw attention to the association of AIHA and treatment with α -Interferon, recommending that the DAT should be monitored in patients receiving this treatment.
- The crossmatch sample was usually taken within 48 hours of the transfusion and timing did not appear to be relevant to the development of the reaction.
- Over 50% of reactions were reported to the local Blood Centre but there was a low level of reporting to hospital transfusion committees. As with acute transfusion reactions it is not clear whether this reflects simple lack of reporting or the absence of a suitable forum for discussion of transfusion-related matters.

Recommendations

- A national review of the requirements for samples and investigation of delayed transfusion reactions is recommended.
- The importance of taking full transfusion and obstetric histories should be stressed.
- Access to off-site computer records may alert to pre-existing antibody(ies) not detectable at the time of crossmatch.

10. TRANSFUSION-RELATED ACUTE LUNG INJURY.

Definition

Transfusion-related acute lung injury was defined as acute dyspnoea with hypoxia and bilateral pulmonary infiltrates occurring during or in the 24 hours after transfusion, with no other apparent cause.

Nine cases were reported, 2 of which were fatal, with full recovery in the other 7. There were 5 females and 2 males, with a median age of 44 (range 2-69).

The first fatality involved a child of 2 years, who was already very ill following an autologous progenitor cell transplant for acute myeloid leukaemia. This had been complicated by veno-occlusive disease of the liver, leading to haemorrhagic ascites and a small pleural effusion. The child was transfused with platelets, during which he developed fever and rigors, hypotension and dyspnoea, with reduced pO_2 and raised pCO_2 . He was treated with methylprednisolone and required ventilation for 35 days, but subsequently died. Serology revealed a strong HLA-A2 antibody in the serum of 1 of the platelet donors; the patient was HLA-A2 homozygous.

The second fatality was a 44 year old woman with underlying multiple sclerosis, who was transfused with red cells for an elective surgical procedure. During the transfusion, she developed fever, hypotension, and dyspnoea with hypoxia and raised pCO_2 . She was transferred to an Intensive Care Unit, but was moribund on arrival, and did not survive.

Summary

- The implicated blood component was red cells in 3 cases, fresh frozen plasma in 2, apheresis platelets in 1, and pooled platelets in 2 (unidentified in 1). The involvement of red cells in 3 cases is perhaps surprising, as current teaching is that TRALI generally complicates transfusion components containing large volumes of plasma.
- Blood components were given for elective surgery in 3 patients, epistaxis in 1, emergency Caesarian section in 1, and for haematological malignancy in 4, including all 3 recipients of platelets. The relatively young age of this group of patients reflects inclusion of younger haematology patients.
- In 7 cases, the onset of symptoms was during the transfusion, and followed transfusion in the remaining two. Dyspnoea, hypoxia and pulmonary shadowing were universal features. Fever, rigors and hypotension were also seen.
- Steroids in the form of hydrocortisone or methylprednisolone were given in 6 cases, including 1 fatality. Admission to ITU for ventilation was required in 5 cases, including the 2 fatalities described above, for periods of 7-35 days. One patient with mild symptoms received no specific treatment.
- Positive serology on the donor of the implicated unit was obtained in 7 cases. HLA antibodies were demonstrated in donors from 4 cases, granulocyte antibodies in 1 case, and a mixture of HLA and granulocyte antibodies in 1 case.
- In 2 cases, the HLA antibodies were of single specificity, and in 1 fatal case the patient was homozygous for the relevant antigen. One case was highly unusual, in that it involved a platelet pool of 4 donors in which there was inter-donor incompatibility, with the plasma of 1 donor containing a strong HLA antibody reactive with the platelets of another donor. The patient was negative for the relevant antigens, so it is likely that the mechanism here was that of an 'innocent bystander' type.

Recommendations

- In patients with suspected TRALI, it is always worth informing the supplying Blood Centre. Investigation of implicated donors can then be carried out, and the donors withdrawn if serology is positive.
- Donors implicated in cases involving platelets or fresh frozen plasma may not be suitable as red cell donors, as cases involving red cell transfusion have been reported.

11. POST-TRANSFUSION PURPURA

Definition

Post-transfusion purpura was defined as thrombocytopenia arising 5-12 days following transfusion of red cells associated with the presence in the patient of antibodies directed against the HPA (human platelet antigen) systems.

Eleven cases were reported, all female, with an age range of 40-92 years.

There was 1 fatality, an 87 year old women who presented with gastrointestinal haemorrhage due to duodenitis, and who underwent emergency surgery. Her past history included at least 1 pregnancy but no transfusions. She was transfused with red cells peri-operatively without any immediate problems. Between 5 and 10 days later, her platelet count fell to $< 10 \times 10^9$ /litre, and the GI haemorrhage persisted. Her serum was shown to contain strong anti-HPA-1a and weak anti-HPA-3b antibodies. She was treated initially with random platelets, steroids and intravenous immunoglobulin, and switch to selected platelets once the serology was available. She also received intensive plasma exchange, but died due to continuing haemorrhage and myocardial infarction.

Comments

- all cases were female, and all with previous pregnancies. In some cases, the pregnancies were over 30 years previously. There was no past history of neonatal alloimmune thrombocytopenia in any of the cases, but in view of the age of the patients, this may have gone unrecognised at the time. One case had had at least 7 pregnancy losses.
- only one case had been transfused, with her partner's lymphocytes due to multiple pregnancy losses.
- there was a striking predominance of patients with either haemorrhage or anaemia due to gastrointestinal pathology. Only 1 patient was transfused for elective surgery not stated to be for a GI lesion. This association may reflect under-recognition of the condition in patients without pre-existing haemorrhage.
- in 4 of the 11 cases the transfusion was complicated by a febrile transfusion reaction. Thrombocytopenia was usually noted 5-9 days after transfusion, but was not seen till 10 or more days after transfusion in 4 cases.
- in 10/11 cases the nadir of the platelet count was $< 10 \times 10^9$ /l. Patients. All patients except 2 developed new haemorrhagic symptoms, mainly purpura and bruising. In the remaining 2 a low platelet count was an incidental finding. Major haemorrhage was not reported except in patients with pre-existing gastro-intestinal bleeding.
- eight cases involved HPA-1a antibodies, either alone (7) or in combination (with HPA-3b in one case). The remaining 3 cases involved other HPA antibodies either alone (HPA-3a in 1 case; HPA-5a in 1 case) or in combination (HPA-1b+ 2b +3a in 1 case).
- all cases were treated with intravenous immunoglobulin, with the exception of 1 in whom the lowest platelet count was $> 20 \times 10^9$ /l. Additional treatments included steroids (7 cases), transfusion of either random (3) or selected antigen-negative (1) platelets, and apheresis (1).
- with the exception of the fatality described above, all patients recovered to a platelet count of $> 50 \times 10^9$ /l. This took < 7 days in all cases except 1, in whom recovery took 13 days. This was seen in the untreated asymptomatic case with a platelet nadir of $> 20 \times 10^9$ /l, associated with isolated HPA-1a antibodies.

Recommendations

- PTP should be considered in any female, parous patient who develops haemorrhagic features with thrombocytopenia after red cell transfusion. As the time of onset is generally > 5 days after transfusion, patients may present after discharge from hospital. A febrile reaction during the transfusion may indicate that platelet alloantibodies are present, but is neither a specific nor universal finding.
- early involvement of a haematologist in cases of unexplained post-operative thrombocytopenia will ensure appropriate diagnosis and treatment.

12. TRANSFUSION-ASSOCIATED GRAFT-VERSUS-HOST DISEASE.

Definition

Transfusion-associated graft-versus-host- disease was defined as the development of the classical symptoms of fever, rash, liver dysfunction, diarrhoea and pancytopenia occurring 1- 6 weeks following transfusion, without other apparent cause. The diagnosis was usually supported by skin/bone marrow biopsy appearances and/or the presence of circulating donor lymphocytes.

Four cases were reported, all fatal. In each case, the classical features of skin rash, pancytopenia, and deranged liver function appeared in the 4 weeks following transfusion. Treatment was begun within a week of the onset of symptoms in 2 cases, but later than this in the other two. As each case illustrates different points, they will be summarised separately.

The first case was reported retrospectively during the pilot phase of SHOT. The recipient was an 88-year old woman, transfused with red cells for severe epistaxis. Classical GVHD developed 15-20 days later, with death from infection, despite treatment with methylprednisolone. The diagnosis was confirmed on post-mortem histology of skin, bone marrow and liver. She had no risk factors for TA-GVHD, and immunoglobulins and lymphocytes were normal. HLA analysis of post mortem peripheral blood by PCR-SSP was not conclusive, and could not establish whether there was donor/patient haplotype sharing.

The second case was highly unusual. The recipient was a premature neonate, born at 32 weeks and multiply transfused with non-irradiated red cells and FFP over the next month. Investigations revealed an HLA-haplotype share between the infant and one of the red cell donors, and also that the infant was probably suffering from a rare form of severe combined immunodeficiency disease.

The remaining cases were both middle aged men with B cell non-Hodgkin's lymphoma, transfused with non-irradiated red cells. In neither case is patient/donor HLA typing information available to ascertain whether haplotype sharing contributed. In one case, the patient was commenced on fludarabine therapy 12 days **after** the implicated transfusion, just prior to the onset of symptoms.

Comments

- TA-GVHD appears to be a rare complication of transfusion. Guidelines for its prevention by the use of gamma irradiated cellular blood components have been produced by the British Society for Haematology⁸. It should be noted that in addition to the four TA-GVHD cases described above, a number of patients were reported to SHOT who did not receive gamma irradiated components as intended (please refer to Chapter 7).
- Treatment for TA-GVHD is almost always unsuccessful, and death from infection/pancytopenia is the usual outcome.
- It is recognised that occasional cases arise in non-immunosuppressed patients due to random HLA haplotype sharing between donor and recipient. There is no means of preventing these, short of irradiating all cellular blood components.
- Current guidelines do not recommend irradiation of small volume 'top-up' transfusions used to treat the anaemia of prematurity. However, the BCSH guidelines do draw attention to the need to use irradiated components in any infant in whom immunodeficiency is suspected, as the features of the underlying condition and of TA-GVHD itself may be difficult to distinguish.
- Non-Hodgkin's lymphoma is not currently an indication for irradiated components. Although fludarabine therapy is a recognised risk factor for TA-GVHD, previous cases have always involved long term treatment with fludarabine prior to the implicated transfusion.

Recommendations

- In view of the small number of cases reported, no firm conclusions can be drawn as to whether current recommendations for TA-GVHD prevention require review.
- The current guidelines should be widely available for non-haematology staff who may treat at-risk patients.
- Local arrangements for the ordering and administration of blood components should include safeguards to ensure that gamma irradiated components are always given when appropriate. Where patients are being treated on a 'shared care' basis between eg a bone marrow transplant centre and their local hospital, a warning card carried by the patient may be helpful.

13. TRANSFUSION-TRANSMITTED INFECTIONS

Introduction

Infectious complications following transfusion differ from non-infectious complications in several ways that may affect the ascertainment and investigation of incidents. The onset of symptoms related to a transfusion-transmitted viral infection may occur several weeks to years after the date of the transfusion. Reports of infections transmitted by transfusion in a particular year therefore accrue over the subsequent year(s). The number of cases ascertained by the end of any period of time is therefore expected to be an incomplete picture of the infections transmitted during that period. Acute infections, such as bacteraemias, that tend to be clinically apparent and diagnosed soon after receipt of the infectious transfusion, may be relatively complete but chronic viral infections will be underrepresented.

In addition, the occurrence of disease, or the observation of serological markers of infection, in individuals who have donated blood can lead to the ascertainment of transfusion-transmitted infections by tracing and testing of recipients exposed to components collected from donors during potentially infectious periods. Recipients may be asymptomatic at this time and only identified by this investigation.

Infections presenting weeks, months or years following a transfusion are termed post-transfusion infections (PTI). These may indeed be due to an infected (or contaminated) transfusion, but equally, infection may have been acquired from another source. Investigation of markers of infection in an implicated donation, or in subsequent samples from the donors of implicated donations, can confirm transfusion as the probable cause of infection, or identify the need to investigate other possible sources. The blood service must therefore be informed about implicated transfusions so that investigations can be conducted to confirm or refute the suspicion that the implicated transfusion(s) may have been infectious. This is essential to prevent further transmission(s) by other components and/or by chronically infected donors. Such investigations may involve microbiological testing of many donors and may take several months to complete.

A surveillance system to collect standardised information about infections suspected to have been transmitted by transfusion was introduced in the British Isles (excluding Scotland) and the Republic of Ireland by the National Blood Authority and the Public Health Laboratory Service Communicable Disease Surveillance Centre (PHLS CDSC) in October 1995.

Methods

Participating blood centres reported all post-transfusion infections, of which they had been informed, to the NBA/PHLS CDSC infection surveillance system. The criteria for identifying infections eligible for reporting as post-transfusion infections were either: a) the receipt of the transfusion had been confirmed and the infection had been confirmed in the patient (by detection of antibody, antigen, RNA/DNA or culture) and there was no evidence that the recipient was infected prior to transfusion, or, b) the receipt of the transfusion had been confirmed and the recipient had acute clinical hepatitis of no known cause (including no evidence of acute HAV, HBV, HCV, EBV or CMV infection in post-transfusion samples to date). If other possible sources of infection were known for a post-transfusion infection, an initial report was still requested.

Information about the recipient, the recipient's infection and the transfusion(s) implicated as the possible source of infection formed the basis of the initial report. Subsequently, after appropriate investigations had been completed, details about the findings of the investigation, were reported. (The report form is shown in Appendix 4).

A post-transfusion infection was classified as a transfusion-transmitted infection if the following criteria were met at the end of the investigation:

- the recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and, either
- at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection, or
- at least one component received by the infected recipient was shown to have been contaminated with the agent of infection.

Data received by 31/12/97, about incidents of transfusion-transmitted infections initially reported by blood centres between 1/10/96 and 31/9/97, are included in this report. Data received about incidents reported during the previous (first) year of the surveillance system are also briefly described.

Incomplete investigations were classified as post-transfusion infections of undetermined source, unless the investigation was closed due to the identification of a probable source of infection other than transfusion.

Results

Twenty-five reports of post-transfusion infections were initiated by blood centres during the report year. An additional 6 reports were received about post-transfusion reactions that were suspected to be due to bacteria but for which no evidence of bacterial infection (or endotoxin) that could have caused the reaction was sought and found in the recipient or in the implicated component (i.e. although the reaction did not satisfy the criteria for a post-transfusion infection as stated above, it may have been of bacterial origin). Reports were received from eight of the 21 blood centres (between 1-6 cases each) participating in the surveillance system. These eight centres collect approximately 60% of the donations tested by blood centres participating in the surveillance system. One hospital (one clinician) reported two post-transfusion infections.

Of the 25 post-transfusion infections initially reported by blood centres to the surveillance system between 1/10/96 and 30/9/97, 8 (32%) were classified, after appropriate investigation, as transfusion-transmitted infections. None of the 6 post-transfusion reactions suspected to be due to bacteria were clearly shown to be due to transfusion-transmitted bacteria. For 4 of the 6 post-transfusion reactions suspected to be due to bacteria, details about microbiological testing of samples from the recipient were not available. Table 15 shows the transfusion-transmitted infections reported to the surveillance system between 1/10/96 and 30/9/97 by year of transfusion: 4 were transfused during the report year, and 4 were transfused prior to the report year.

Table 15: Transfusion-transmitted infections reported between 1/10/96-30/9/97 by year of transfusion. The number of incidents are shown, with the total number of identified infected recipients shown in brackets.

Year of transfusion	1995	1996	1997 (to end Sept)	Total
Infection				
HAV	-	1(1)	-	1(1)
HBV	-	1(1)	-	1(1)
HCV	-	1(1)	-	1(1)
HIV	-	1(3)	-	1(3)
Bacteria	-	-	3(3)	3(3)
Malaria	-	-	1(1) ^a	1(1) ^a
Total	-	4(6)	4(4)	8(10)

Notes: ^a Infection was implicated in the death of the recipient.

Details of transfusion-transmitted infections**A. Infections for which donation testing is mandatory.****Hepatitis B virus**

One transfusion-transmitted HBV infection was reported. This investigation was initiated because the recipient had acute HBV infection five months after transfusion of three red cell units. One of the donors was found to have markers of resolved HBV infection eleven months after donating the implicated donation. An HBV infectious, HBsAg negative (and anti-HBc negative), donation collected from a repeat donor during acute (asymptomatic) infection was concluded to be the probable source of the recipient's HBV infection.

Hepatitis C virus

One transfusion-transmitted HCV infection was reported. This investigation was initiated because a repeat donor was shown to have seroconverted for anti-HCV between donations. The recipient was traced and tested for HCV infection, seven months after transfusion with a red cell unit from this donor.

The pre-seroconversion donation was subsequently shown by testing of the archived sample to be HCV RNA positive. An HCV infectious, anti-HCV negative, donation collected from a repeat donor during acute (asymptomatic) infection was concluded to be the probable source of HCV infection for the recipient.

HIV

One transfusion-transmitted HIV infection was reported. This investigation was initiated because the recipient developed clinical features consistent with HIV infection, and was found to be anti-HIV positive. This recipient had received over 100 units of red cells and platelets over a seven month period. The archived sample of one donation (giving rise to a platelet unit transfused to the patient), from a repeat donor who had not donated subsequently, was found to be HIV DNA positive. The donor was subsequently found to be anti-HIV positive. An HIV infectious, anti-HIV negative, donation collected from a repeat donor during acute (asymptomatic) infection was concluded to be the probable source of the recipient's HIV infection²⁷. The recipients of the red cells and the fresh frozen plasma produced from the infectious donation were subsequently shown to have also been infected with HIV by transfusion (one recipient had died of non-HIV-related causes by the time of the follow-up).

B. Infections for which donation tested is not mandatory.**Hepatitis A**

One transfusion-transmitted HAV infection was reported. This investigation was initiated after a donor reported HAV infection that developed ten days after donation. The recipient was traced and tested for HAV infection, one month after transfusion with three red cell units. An HAV infectious donation collected from a donor during acute (asymptomatic) infection was concluded to be the probable source of HAV infection for this recipient²⁸. The recipient of the platelets from the implicated donation was found to be non-immune and not infected.

Bacteria

Three transfusion-transmitted bacteraemias were reported.

One recipient developed endotoxic shock after transfusion with a red cell unit. The red cell unit was subsequently found to be haemolysed and was shown to contain *Serratia liquifaciens*. No evidence of infection was found in the donor by arm swabbing and by testing blood for antibodies. The source of the contamination was not identified.

One recipient suffered a bacteraemia after transfusion with a platelet unit. *Escherichia coli* was cultured from the pack and from the patient. No damage to the pack or source of the contamination was identified.

One recipient suffered a bacteraemia after transfusion with a leucodepleted pooled platelet unit. The pack and an arm swab from one of the four donors were both yielded *Bacillus cereus*, serotype H29.

Malaria

One transfusion-transmitted malaria (*Plasmodium falciparum*) infection was reported. The recipient developed cerebral malaria two weeks after transfusion with two red cell units and died within two weeks of diagnosis. One new donor was found to have malarial antibodies when a subsequent sample was tested.

Details of post-transfusion infections not concluded to be transfusion-transmitted infections

Four (16%) post-transfusion infections (1 bacteraemia, 1 HBV infection, 2 HCV infections) were eventually classified as 'post-transfusion infections of undetermined source' due to incomplete investigation of the transfusion(s) implicated as the source of infection. One post-transfusion bacteraemia was classified as "undetermined" because the blood pack was destroyed at the hospital and was therefore not available for testing. For 7 (28%) other post-transfusion infection reports (5 HBV infections, 2 HCV infections), investigation was completed and no evidence was found to implicate transfusion as the source of infection. A probable source of infection other than transfusion was identified for 4 of these infections (HBV: surgery at a time and place associated with other cases, household and sexual contact with infection; HCV: renal dialysis, previous transfusion prior to anti-HCV testing of donations in UK).

Reporting delay

For the 8 transfusion-transmitted infections, the median interval between the transfusion and the diagnosis of the infection in the recipient was 44 days (range 0 days for the three bacteraemias to 224 days for the HCV detected by tracing the recipient after observing seroconversion in the donor). The median interval between diagnosis and blood centres being informed that the infection was suspected to be associated with transfusion was 1 day (range 0 days for the 3 bacteraemias to 98 days for the HBV infection). The median interval between the blood centre being informed and the completion of the initial surveillance report form was 54 days (range 7 days to 194 days). The median interval between the transfusion and completion of the initial surveillance report form was 134 days (range 29 days to 361 days).

Underreporting

The cases ascertained by this surveillance system were diagnosed, suspected to be attributable to transfusion, communicated to the blood service, and reported by a blood centre to the surveillance centre. At any one of these steps, other post-transfusion infections may have been missed and the extent of underreporting of post-transfusion infections is therefore unknown. More widespread testing of transfusion recipients, a heightened awareness of transfusion as a possible source of infection and improved reporting of information to blood centres and from blood centres to the surveillance centre would improve case ascertainment.

Previous year

During the first year of this surveillance system for post-transfusion infections (1/10/95-30/9/96), 15 post-transfusion infections were reported. Five were classified, after investigation, as transfusion-transmitted infections (1 HBV infection, 2 HCV infections and 2 bacteraemias: 1 group B streptococcus and 1 *Bacillus cereus*²⁹). Two post-transfusion infections (1 HBV infection, 1 HCV infection) were classified as post-transfusion infections of undetermined source due to incomplete investigation of the transfusion(s) implicated as the source of the infection. For 8 (53%) post-transfusion infection reports (4 HBV infections, 4 HCV infections), investigation into the case was completed and no evidence was found to implicate transfusion as the source of infection. A probable source of infection other than transfusion was identified for 4 of these infections. Table 16 shows the cumulative number of transfusion-transmitted infections reported up till the end of September 1997.

Table 16: Cumulative total of transfusion-transmitted infections reported between 1/10/95-30/9/97 by date of transfusion. The number of incidents is shown with the total number of identified infected recipients in brackets.

Year of transfusion	1980's (i.e. pre anti-HCV testing)	1995	1996	1997 (to end Sept)	Total
Infection					
HAV		-	1(1)	-	1(1)
HBV		1(1)	1(1)	-	2(2)
HCV	2(2)	-	1(1)	-	3(3)
HIV		-	1(3)	-	1(3)
Bacteria		1(1)	1(1)	3(3)	5(5)
Malaria		-	-	1(1) ^a	1(1) ^a
Total	2(2)	2(2)	5(7)	4(4)	13(15)

Notes: ^a Infection was implicated in the death of the recipient.

Comments

- Reported transfusion-transmitted infections are rare incidents, with only 8 confirmed cases recognised during a 12-month period. One transfusion-transmitted infection (malaria) resulted in the death of the recipient. A further 17 post-transfusion infections could not be clearly linked to a transfusion, as well as 6 post-transfusion reactions suspected to be due to bacteria. Infections transmitted by transfusion between 1/10/96 and 30/9/97 will continue to be ascertained by the surveillance system as diagnoses are made during future years.
- Two of the transfusion-transmitted infections (1 HAV, 1 HCV) were identified by the blood service after the diagnosis of an infection in a blood donor.
- Three transfusion-transmitted infections (1 HBV infection, 1 HCV infection, 1 HIV infection) were due to donations collected from donors during marker negative "window periods" following recent infection. All 3 were in 'repeat' donors.
- Five transfusion-transmitted infections (1 HAV infection, 1 malaria infection, 3 bacteraemias) were due to collection of donations from donors with infections for which no routine testing of donations is performed. One bacteraemia was due to contamination of the blood pack from the donor's arm; two bacteraemias were due to contamination of the blood pack from an unidentified source. The numbers of cases are too small to draw any conclusions about the risks of leucocyte depleted platelet concentrates.
- Thorough investigation of a suspected bacteraemia in a transfusion recipient relies heavily on the collection and handling of relevant samples at the hospital where the transfusion was performed. In 4 of 6 post-transfusion reactions suspected to be due to bacteria reported this year the lack of appropriate samples prevented proper investigation.
- The malaria transmission related to a donor who had been resident in a malarious area as a child. Donor selection criteria have now been amended to exclude such individuals permanently as cell donors, unless they have been shown to be negative for malaria antibodies.
- No reported transfusion-transmitted infections were due to errors in the performance of microbiological testing, or in the release, of blood donations.

Recommendations

- National collation of data arising from these cases needs to continue over several years to build up a picture of the extent and nature of the infectious complications of transfusion.
- Clinicians should report all post-transfusion infections diagnosed in their patients to their supplying blood centre, without delay.
- Hospitals should not destroy blood components implicated in post-transfusion reactions suspected to be due to bacteria, and should consult the blood service about the investigation of such cases.
- Standard protocols for investigating post-transfusion infections should be developed and used.
- Methods and criteria used to exclude those individuals who have risk factors for transfusion transmissible infections from donating blood deserve continuing evaluation and development.

14. FUTURE DEVELOPMENTS - WHERE DO WE GO FROM HERE?

What is the future for transfusion safety?

There has been increasing recognition of the paradox that while the overall risks of transfusion are very small compared with the benefits, a number of different strategies could be pursued to enhance safety even further. A very recent commentary from the USA reminds readers that mistransfusion, leading to ABO incompatibility, is still a far commoner problem than HIV and hepatitis³¹. The recent audit of transfusion undertaken by the Royal College of Physicians³² supports the view that relatively simple and inexpensive measures such as the development of standardised procedures for identity checking of blood components can be implemented.

Many organisations in the UK are involved in production of recommendations and guidelines for different aspects of transfusion. These various strategies compete for scarce resources, and prioritisation is not straightforward. Establishment of a unified body to take an overview of transfusion safety in the UK would help to direct resources most appropriately for maximum patient benefit.

Autologous transfusion

The current SHOT scheme already allows for the reporting of serious hazards associated with the transfusion of autologous blood although very few reports have been received so far. Although guidelines for autologous pre-deposit and haemodilution/red cell salvage have been published^{29,30} the extent of hazards associated with these procedures in the British Isles is not known. In association with the Autologous Transfusion Special Interest Group of the British Blood Transfusion Society, it is proposed to extend the reporting scheme for the collection of data associated with autologous pre-deposit procedures, in the first instance. Other autologous procedures such as peri-operative haemodilution and cell salvage will be included at a later date.

Pilot of 'near-miss' event reporting.

It is recognised that for every transfusion of the wrong blood, many others are prevented by careful checking procedures, despite there having been an error at some point during the transfusion process. Analysis of such 'near-miss' events can shed further light on which procedures require review to ensure safety. To this end, a pilot study in 4 hospitals who will report 'near-miss' events is underway. These errors will be reported in 5 categories:- errors during patient sampling for compatibility testing, errors during ordering of blood/components; technical errors occurring in the hospital blood bank; incorrect selection of components; and errors at the time of withdrawal of units from the blood bank or at the time of transfusion.

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APPENDICES

SERIOUS HAZARDS OF TRANSFUSION SCHEME

TERMS OF REFERENCE

1. AIMS

The Serious Hazards of Transfusion (SHOT) Scheme was launched in November 1996, and aims to collect data on serious sequelae of transfusion of blood components. These will include post-transfusion infections, collected via Transfusion Service/PHLS-CDSC surveillance, and major non-infectious events such as blood being given to the wrong patient. The Scheme will not include fractionated plasma products, which are already covered by MCA procedures for licensed drugs. Reports will be widely distributed. Through the participating bodies, the information obtained will contribute to:-

- a) improving the safety of the transfusion process
- b) informing policy within Transfusion Services
- c) improving standards of hospital transfusion practice
- d) aiding production of clinical guidelines for the use of blood components.

Participation in the scheme is voluntary, and covers both NHS and private hospitals in the United Kingdom and Ireland.

2. ORGANISATION

The scheme's strategic direction comes from a Steering Group with wide representation from Royal Colleges and professional bodies. The operational aspects of the scheme are the responsibility of a Standing Working Group, which is accountable to the Steering Group. Two National Co-ordinators are responsible for receiving and collating reports.

Ownership of the scheme and data generated from it resides with the Steering Group.

The Terms of Reference and membership of the Steering Group and the Standing working Group are shown on pages 64 to 70.

Minutes of Steering Group Meetings are sent to the Department of Health for information.

For the first 2 years of the scheme, funding will come from the Transfusion Services within the UK and Ireland. Organisational and funding arrangements will be formally reviewed after 2 years.

3. CASES INCLUDED.

The Scheme aims to capture data on serious complications of transfusion under the following headings.

Non Infectious

'Blood into wrong patient' (whether ABO incompatible or not, and irrespective of whether harm arises)
Severe haemolysis - acute or delayed
Anaphylaxis
Transfusion-related Graft versus Host Disease
Transfusion-related acute lung injury
Post transfusion purpura

Infectious

Suspected or confirmed cases of microbial transmission
- bacterial, viral or parasitic.

Adverse events associated with transfusions from volunteer donors, family members and autologous transfusions should all be included.

4. CASES EXCLUDED

The Scheme will not include 'near miss' events, defined as cases in which there has been 1 or more procedural errors, but where these have been detected in time to prevent any of the above events occurring. Reporting of 'near misses' to hospital transfusion committees is encouraged.

5. SYSTEM FOR REPORTING

Cases under the above headings should be reported in the first instance to the hospital haematologist responsible for transfusion, who may then report cases confidentially to the National co-ordinator on the Report Form. However, SHOT is not intended to replace or compromise existing local arrangements for forward communication of transfusion problems to supplying transfusion centres.

IN ANY CASE, IT IS ESSENTIAL TO INFORM THE SUPPLYING BLOOD CENTRE URGENTLY OF SUSPECTED CASES OF BACTERIAL SEPSIS OR HEPATITIS/HIV FOLLOWING TRANSFUSION, SO THAT OTHER POTENTIALLY INFECTED COMPONENTS CAN BE WITHDRAWN.

6. QUESTIONNAIRES

On receipt of a report of a non-infectious hazard, the National co-ordinator will follow up the report with a detailed questionnaire. These have been developed to gain relevant information about serious consequences of transfusion.

THIS INFORMATION IS IMPORTANT, AND SHOULD BE COMPLETE AND ACCURATE.

Staff may write to the SHOT office under separate cover if they wish.

7. CONFIDENTIALITY AND LITIGATION

Once all information has been gathered about a case, all hospital identifiers will be removed by the SHOT office before entry to the computerised database. The SHOT office will inform the notifying hospital when this has been done, at which time the hospital may wish to destroy copies of completed SHOT questionnaires.

8. FEEDBACK

Reports will be provided at appropriate intervals which will analyse the findings and make recommendations, but without identification or assessment of individual cases.

9. NATIONAL CO-ORDINATORS

1. Non infectious hazards

Dr E M Love
Mrs S Lowe (Assistant National Co-ordinator)
Manchester Blood Centre
Plymouth Grove
Manchester
M13 9LL
Tel: 0161 251 4208
Fax: 0161 251 4319

2. Infectious

Kate Soldan
Communicable Disease Surveillance Centre
61 Colindale Avenue
London
NW9 5HT
Tel: 0181 200 6868
(ext 4602)
Fax: 0181 200 7868

from whom further information may be obtained.

SHOT Steering Group - Terms of Reference

1. To be the strategic and policy making body for the SHOT scheme, and to ensure that ownership of SHOT, its activities and data remain confidential and firmly within the professional bodies to whom it belongs.
2. Its members bring to the Steering Group the views of the professional body which they represent, and in turn seek endorsement from their professional body for major changes to the scheme.
3. Its members communicate to their professional body information about new SHOT initiatives, and promote SHOT activities through their professional network.
4. To review and oversee the activities of the Standing Working Group from whom regular reports will be provided.
5. To provide financial oversight of SHOT activities, and to be responsible for seeking and maintaining adequate funding.
6. To produce periodic reports to an agreed format.
7. To ensure that recommendations resulting from these reports are disseminated via professional bodies in an open fashion whilst maintaining strict anonymity/confidentiality.
8. The Steering Group may convene one or more Working Parties for specific functions as required.
9. All reports, publications and media communications must be approved by the Steering Group. In urgent situations, the Chair and Secretary of the Steering Group, plus a minimum of 3 other members, may provide media statements without reference to the whole group.

Membership and organisation of meetings.

1. The Steering Group will meet twice every year.
2. Membership will consist of nominated representatives of Royal Colleges and professional bodies as listed below, plus the National Co-ordinator, Assistant National Co-ordinator and the Chair of the Standing Working Group. The duration of membership of an individual member will be decided by the body he/she represents, normally for 3 years. The current membership of the Steering Group is listed on pages 66-68.
3. There will be a Chair and Secretary elected from among the members.
4. The budget will be managed by the National Co-ordinator, who will provide regular financial reports to the Chair.
5. Steering Group minutes will be provided to members of the Standing Working Group, and to the Department of Health for information.

SHOT Standing Working Group - Terms of Reference

1. The primary responsibility of the Standing Working Group is to implement the policy set by the Steering Group, through the work of the National Co-ordinators.
2. To monitor the functionality of the scheme, taking into account feedback from participants on the reporting form and questionnaires.
3. To maintain close liaison with the Steering Group, and to be accountable to it for its activities.
4. To draft detailed proposals for changes and new initiatives for presentation to the Steering Group.
5. To draft reports for presentation to the Steering Group.

Membership and organisation of meetings.

1. The Standing Working Group will meet quarterly or as necessary.
2. The membership will be no more than 8, and must always include at least 2 hospital based haematologists responsible for transfusion, at least 1 hospital based transfusion technologist, and at least 2 transfusion service consultants. The current membership of the Standing Working Group is listed on pages 69-70.
3. The Chair and Secretary of the Steering Group and the National Co-ordinators are also members in their own right.
4. A Chair and Secretary will be elected from among the members.
5. Appointment of new members must be approved by the Steering Group.
6. The Standing Working Group may co-opt members if required, with Steering Group approval.
7. Minutes of meetings will be sent to the Chair of the Steering Group.

Steering Group Members - Serious Hazards of Transfusion

SHOT Office

Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL
Tel: 0161 251 4208
Fax: 0161 251 4319

National Co-ordinator: Dr E M Love

Assistant Co-ordinator: Mrs S Lowe

NAME	REPRESENTING	ADDRESS
Dr H Cohen (Chair)	British Society for Haematology	Department of Haematology St Mary's Hospital Praed Street London W2 1NY Tel. 0171 886 6806 Fax. 0171 886 6809
Mr John A Revill (Secretary)	Institute of Biomedical Science	Chief MLSO/Laboratory Manager Blood Transfusion Department The Leicester Royal Infirmary NHS Trust Infirmary Square Leicester LE1 5WW Tel. 0116 258 6604 Fax. 0116 258 5093
Dr John A J Barbara	British Blood Transfusion Society	Head of Microbiology North London Blood Centre Colindale Avenue London NW9 5BG Tel. 0181 200 7777 Fax. 0181 200 3994
Dr B Gibson	Royal College of Paediatrics and Child Health	Consultant Paediatric Oncologist Royal Hospital for Sick Children Yorkhill Glasgow G8 8SJ Tel. 0141 201 0391 Fax. 0141 201 0857
Professor John S Lilleyman	Royal College of Pathologists	Dept of Paediatric Oncology St Bartholomew's Hospital West Smithfield London EC1A 7BE Tel. 0171 601 8381 Fax. 0771 601 7856
Professor J S P Lumley	Royal College of Surgeons	Department of Vascular Surgery St Bartholomew's Hospital West Smithfield London EC1A 7BE Tel. 0171 601 7838 Fax. 0171 601 8694
Dr D B M McClelland	UK Transfusion Centres	Director Edinburgh Blood Transfusion Centre Royal Infirmary 42 Lauriston Place Edinburgh EH3 9HB Tel. 0131 536 5300 Fax. 0131 229 1069

Steering Group Members - Serious Hazards of Transfusion.

NAME	REPRESENTING	ADDRESS
Mrs Susan Scott	Royal College of Nursing	Adviser in Nursing Practice Royal College of Nursing 20 Cavendish Square London W1M 0AB Tel. 0171 409 3333 Ext 296 Fax 0171 495 6104
Mr D L Economides	Royal College of Obstetricians & Gynaecologists	Consultant Obstetrician/Gynaecologist Royal Free Hospital Pond Street Hampstead London NW3 2QG Tel. 0171 830 2561 Fax. 0171 830 2987
Dr J Bennett	Faculty of Public Health Medicine	Consultant in Public Health Medicine East Sussex Health Authority 3rd Floor, Regency House 95 Ditching Road Brighton BS1 4ST Tel. 01273 681234 Fax. 01273 485400
Dr C G Taylor	Royal College of Physicians	Consultant Haematologist Pembury Hospital Pembury Tunbridge Wells Kent TN2 4QJ Tel. 0181 282 3535 Fax. 01892 824370
Professor E Smith	Royal College of Anaesthetists	Universities Department of Anaesthesia Leicester Royal Infirmary NHS Trust Infirmary Square Leicester LE1 5WW Tel. 0116 258 5291 Fax. 0116 258 4487
Dr M Ramsay	PHLS-CDSC	Consultant Microbiologist PHLS Communicable Disease Surveillance Centre 61 Colindale Avenue London NW9 5EQ Tel. 0181 200 6868 Fax. 0181 200 7868
Dr L M Williamson	Chair, SHOT Standing Working Group	University Lecturer/Hon Consultant National Blood Service University of Cambridge Long Road Cambridge CB2 2PT Tel. 01223 548009 Fax. 01223 548114
Dr Judith Fisher	Royal College of General Practitioners	Consultant in Accident & Emergency Accident & Emergency Department Princess Alexandra Hospital Hamstel Rd Harlow Essex CM20 1QX Tel. 01279 827001

Steering Group Members - Serious Hazards of Transfusion.

NAME	REPRESENTING	ADDRESS
Mr Brian McArdle	Institute of Biomedical Science	Laboratory Manager Department of Haemtology Freeman Hospital High Heaton Newcastle-upon-Tyne Tel. 0191 284 3111 Bleep 3357 Fax. 0191 223 1199

Standing Working Group Members - Serious Hazards of Transfusion

NAME	REPRESENTING	ADDRESS
Dr L Williamson	Chair	Consultant/University Lecturer in Transfusion Medicine National Blood Transfusion Service University of Cambridge Long Road Cambridge CB2 2PT Tel. 01223 548009 Fax. 01223 548114
Dr E M Love	Secretary/National Co-ordinator	Consultant Haematologist/ Lead Clinician Manchester Blood Centre Plymouth Grove Manchester M13 9LL Tel. 0161 251 4200 Fax. 0161 251 4319
Mrs S Lowe	Assistant National Co-ordinator	SHOT Office Manchester Blood Centre Plymouth Grove Manchester M13 9LL Tel. 0161 251 4208 Fax. 0161 251 4319
Dr P Skacel		Department of Haematology Royal Postgraduate Medical School Hammersmith Hospital Du Cane Road London W12 0NN Tel. 0181 740 3144 Fax. 0181 742 9335
Dr A Todd		Clinical Services Consultant Edinburgh Blood Transfusion Service Royal Infirmary 41 Lauriston Place Edinburgh EH3 9HB Tel. 0131 536 5300 Fax. 0131 229 1069
Dr D Norfolk		Consultant Haematologist Department of Haematology Leeds General Infirmary St George Street Leeds LS1 3EX Tel. 01132 923935 Fax. 01132 420881
Dr Roger S Evely		Consultant Haematologist National Blood Service South West Southmead Road Southmead Bristol BS10 5ND Tel. 0117 9507777 Fax. 0117 9592552
Dr H Cohen	Chair, Steering Group	Department of Haematology St Mary's Hospital Praed Street London W2 1NY Tel. 0171 886 6806 Fax. 0171 886 6809

Standing Working Group Members - Serious Hazards of Transfusion

NAME	REPRESENTING	ADDRESS
Mr John A Revill	Secretary, Steering Group	Chief MLSO/Laboratory Manager Blood Transfusion Department The Leicester Royal Infirmary NHS Trust Infirmary Square Leicester LE1 5WW Tel. 0116 258 6604 Fax.0116 258 5093

SHOT Income & Expenditure

The SHOT budget, although separate from National Blood Service funding, is for convenience administered through the Department of Finance, National Blood Service Northern Zone, Bridle Path, Leeds. SHOT is indebted to Mr Stephen Morgan, Director of Finance and Mr John Saxton, Financial Accountant for their services which are freely given.

S.H.O.T. Income & Expenditure Statement

1 October 1996 to 30 September 1997

Income		£
NBS London & S.E. Zone		4,000
NBS Midlands & S.W. Zone		4,000
NBS Northern Zone		4,000
Scotland		3,000
Wales		2,000
Northern Ireland		1,000
Eire		2,000
Total Income		20,000
Expenditure		£
Staff Costs*		13,772
Travel & Conferences		770
Telephones		69
Printing & Stationery		1,098
Postage		99
Office Equipment		310
Computer Hardware		1,583
Total Expenditure		17,701
Surplus/(Deficit) **		2,299

**Carried forward to 1997/98

*The position of Assistant National Co-ordinator has progressed from part-time to full time from 1st September 1997

Please use this form to report adverse events following transfusion of blood and blood components

The Serious Hazards of Transfusion Group has started a project to evaluate a central reporting system for serious adverse events following the transfusion of blood or blood components. Reactions to fractionated products (e.g. albumin, IVIgG) should be notified to the manufacturer and via the CSM "yellow card" system.

Adverse reactions are listed on the back of this form.

Confidentiality of data is fundamental to the success of this project. We will not enter the identity of the reporting person or of the patient in the study database but we will contact you to obtain additional details

KEY DETAILS OF ADVERSE EVENT

PATIENT

Surname: Forename: DOB: Sex: M/F
Hospital No: Hospital: Ward/Clinic

DETAILS OF PRODUCT - INCLUDING AUTOLOGOUS

Please Ring:

Red Cells
Fresh Frozen Plasma
Platelets
Cryoprecipitate
Other (please specify)

Date of implicated transfusion

Time of implicated transfusionhrs

Has your supplying blood centre been informed? YES/NO

Incident No.

--	--	--	--	--	--	--

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NATURE OF ADVERSE EVENT

(Tick Box)

EVENT		Suspected but not confirmed	Certain
1. Incorrect blood/component transfused			
2. Acute transfusion reaction (including anaphylaxis). Incidents occurring < 24hours following transfusion.			
3. Delayed transfusion reaction. Incidents occurring > 24 hours following transfusion.			
4. Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD)			
5. Transfusion-Related Acute Lung Injury (TRALI)			
6. Post-transfusion purpura (PTP)			
7. Bacterial Contamination	<i>IF YOU SUSPECT THESE NOTIFY YOUR BLOOD SUPPLY CENTRE IMMEDIATELY!</i>		
8. Post Transfusion Viral Infection			
9. Other (describe)			

PATIENT OUTCOME

(Tick Box)

No obvious clinical problem ☐
Morbidity due to the adverse event ☐
Death following adverse event ☐

REPORT MADE BY

Surname Initial & Title
Address Date of Report / /
..... Telephone
..... Number

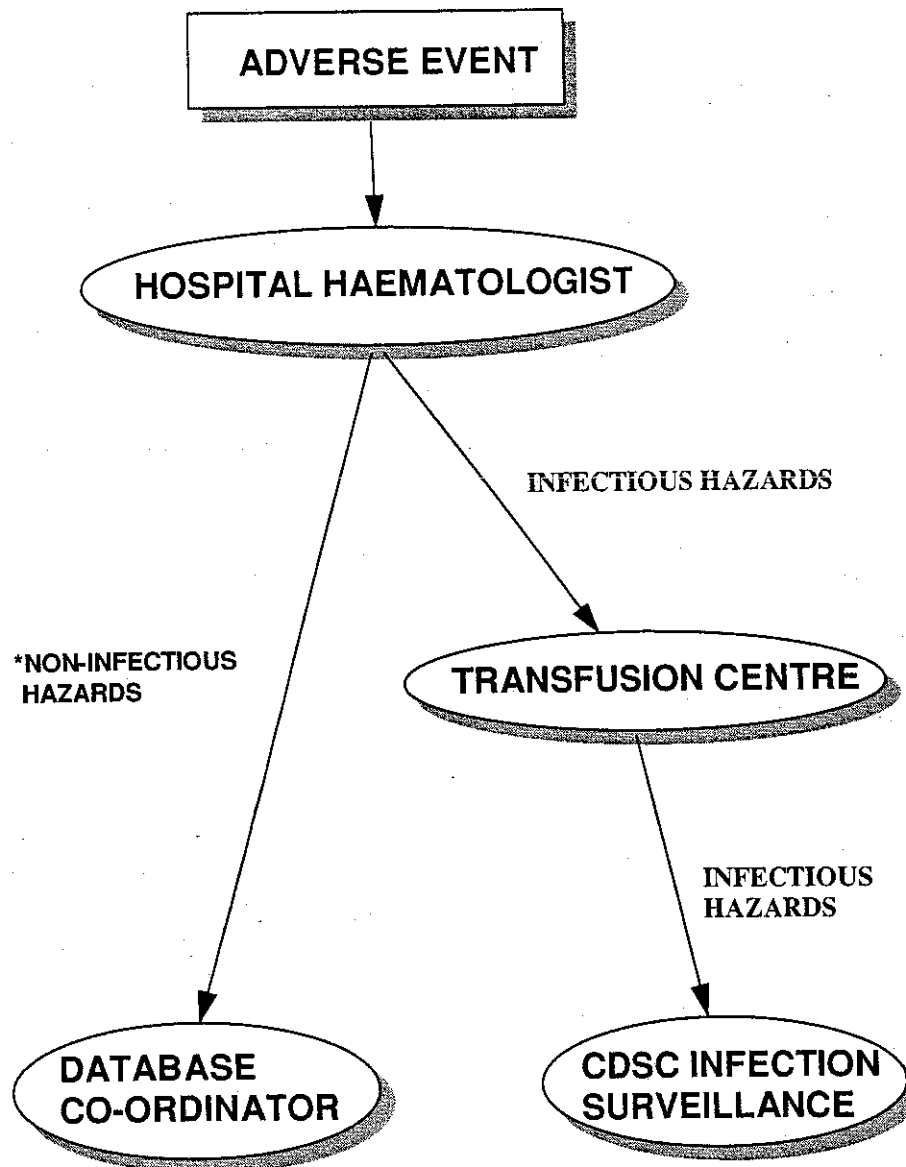
PLEASE SEND REPORT TO

Dr E Love, Medical Co-ordinator, UK Project on Reporting Serious Hazards of Transfusion, SHOT Office, Manchester
Blood Centre, Plymouth Grove, Manchester M13 9LL
[Telephone 0161 251 4208/Confidential Fax 0161 251 4319]

SUMMARY OF KEY FEATURES AND DIAGNOSTIC TESTS FOR ADVERSE EVENTS

Problem	Typical features	Diagnostic Tests
1. Incorrect Blood or component transfused		
ABO incompatible.	May be none - or major collapse as for 2	Check identity and group of patient and unit [inc. Rh(D)]. May have +ve DAT.
ABO compatible.	May be none. As for 2 if patient has atypical red cell alloantibodies.	Check identity and group of patient and unit [inc. Rh(D)]. May have +ve DAT.
2 & 3. Acute or delayed transfusion reaction		
Acute haemolytic transfusion reaction	Dyspnoea, chest pain, fever, chills, ↓BP, ↓urine output, DIC	Haemoglobinaemia/uria, ↓Hb, +ve DAT, serological incompatibility, spherocytes on blood film.
Delayed Haemolytic transfusion reaction.	Unexplained fall in Hb. Jaundice, dark urine.	Urobilinogen in urine, ↑ serum bilirubin, +ve DAT, spherocytes, +ve antibody screen.
Anaphylaxis	↓BP, dyspnoea, ± rash	Occasionally severe IgA deficiency with anti-IgA.
4. Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD)	Progression of fever, rash, ↑liver enzymes, diarrhoea, pancytopenia (1-6 weeks post transfusion)	Skin biopsy + cytogenetic or HLA analysis. DNA analysis (e.g. RFLP, minisatellite probes) to establish presence of third party lymphocytes.
5. Transfusion-Related Acute Lung Injury (TRALI)	Acute respiratory distress (non cardiogenic) Hypoxia, bilateral pulmonary infiltrates.	Anti-leucocyte antibodies in donor or recipient.
6. Post-Transfusion Purpura (PTP)	Immune-mediated thrombocytopenia arising 5-12 days post-transfusion	HPA type patient. HPA antibodies (usually HPA-1a negative with anti-HPA-1a)
7. Reaction to a bacterially contaminated component	Rapid onset of circulatory collapse, fever	REFER TO REGIONAL TRANSFUSION CENTRE URGENTLY
8. Post transfusion viral infection	Depends on virus. e.g. Jaundice, malaise, rash. Weeks to months post transfusion	REFER TO REGIONAL TRANSFUSION CENTRE URGENTLY
9. Other	Any other severe adverse reaction associated with transfusion of a blood component.	

Serious Hazards of Transfusion (SHOT)



- *e.g...
- Incorrect blood/component transfused
 - Major acute or delayed haemolysis
 - Anaphylaxis
 - Transfusion-related graft-versus-host disease
 - Transfusion related lung injury



CONFIDENTIAL

SECTION 1: Post-transfusion infection case report

Please complete one report for each transfusion recipient about which you are informed who has a post-transfusion infection (see notes on the front page of the folder for definition of a PTI case).

BTC to which infection was reported	PTI case code: (BTC prefix) (BTC case no./code) _____	Date of 1st report to BTC: ____/____/____

Source of report to BTC(name and institution of notifier)

Recipient's surname or soundex	Initial(s)	Sex	Date of birth ____/____/____
--------------------------------	------------	-----	---------------------------------

A. PTI information

1. Reason for diagnosis (please tick):

<u>Hepatitis infection</u>	
Clinical acute hepatitis	☐ 10 ₁
Symptomatic chronic liver disease	☐ 11 ₂
Hepatocellular carcinoma	☐ 12 ₃
Abnormal liver function: routine testing	☐ 13 ₄
HAV/HBV/HCV markers: routine testing	☐ 14 ₅
Other, please specify:	☐ 16 ₆

HIV infection

HIV related symptoms, not AIDS	☐ 15 ₇
AIDS	☐ 16 ₈
HIV markers found on routine testing	☐ 17 ₉
Other, please specify:	☐ 10

<u>Other infection</u>	
Symptomatic CMV infection	☐ 18 ₁₁
Symptomatic malaria	☐ 19 ₁₂
Symptomatic HTLV infection	☐ 20 ₁₃
Symptomatic B19 infection	☐ 21 ₁₄
Bacteraemia	☐ 22 ₁₅
Specify species if known	
Other, please specify:	☐ 16

Notes :

--

3. Date of a) onset of symptoms:

____/____/____

or, b) diagnosis of sub-clinical infection:

____/____/____
____/____/____

4. Date of latest report of the recipient and status at that time:.....

Dead, infection implicated..... ☐ 26 ₁	Dead, no known involvement of the infection..... ☐ 28 ₂	Symptomatic..... ☐ 29 ₃
Asymptomatic..... ☐ 27 ₄		

5. Had the recipient had any other known risk exposures for this infection?..... yes ☐ 30₁ no ☐ 31₂ not known ☐ 32₃.
(eg. IDU, sexual/household contact with an infected person, surgery, organ/tissue transplant, fractionated blood product treatment, transfusion abroad)

If "yes", please specify:

6. Infection status of the recipient

Please enter the significant test results (ie. pre-transfusion, post-transfusion and follow up as available) for the recipient's samples in the table below. Please enter POS (positive), NEG (negative) EQV (equivocal) and/or the titre/level as appropriate in each box. An empty box will taken as indication that the test was not performed.

Specimen date	HAV	HBV						HCV			HIV	Other	Lab where tests were performed
	anti-HAV IgM	HBsAg (titre)	anti-HBc (total) (%inhib/level)	anti-HBc IgM	HBeAg	anti-HBe	anti-HBs (titre)	anti-HCV ELISA(s)	RIBA	HCV RNA	anti-HIV		
1. _/_/_													
2. _/_/_													
3. _/_/_													
4. _/_/_													
5. _/_/_													

B. Transfusion information

1. Hospital of transfusion: _____

2. Reason for transfusion: _____

3. Date/period over which transfusion(s) was/were given: _____

4. Number and type of units transfused:

red cells x 35cryoprecipitate x 36

4b. How many units were

platelets x 37other x 38

i) labelled CMV antibody negative

whole blood x 40not known x 41

ii) leucocyte depleted

 42FFP x 43Total number of units = 44 [= 45 from this BTC + 46 from other BTCs, specify: _____

5. Based on the available information about the recipient and the implicated donation(s)/donor(s), ie.A&B above, was an investigation of the donation(s)/donors(s) initiated?

Yes ☐ 47, please attach Section 2: Investigation report form(s) to the case's file(s)No ☐ 48, Please state

reason: _____

Report completed by (please print name): _____ Date ____/____/____

2. POST-TRANSFUSION INFECTION DONOR/DONATION INVESTIGATION REPORT

Section 2: Post-transfusion infection

Please complete one form for each PTL case investigated by your BTC Investigation of units from BTC pertaining to the PTL investigation

[redacted] form for each PTJ case investigated by your BIC.
[redacted] [redacted] [redacted] [redacted]
[redacted] [redacted] [redacted] [redacted]

A. Donation/donor information

1. Review of test results and QC test donations:

PTI case code: (BTC prefix) (BTC case no./code) _____ : _____

results for original testing of implicated

Checking incomplete, 53 of 54 units un-checked

All checked and found correct.

Error found in testing/labelling/issuing procedures, please specify:

.....
Attending/issuing procedures,

[illegible][illegible][illegible]

Does any donor have a history which suggests exposure to one of the above table contain this donor's test results:

4. Have any of the donors been involved in any other PTL case(s)?.....

Date _____

Report completed by (please print name): _____

Report completed by: _____

Welded Haste WDI 10H Thank you for your help.

Form code: PTIS 2.01}



3: POST-TRANSFUSION INFECTION SURVEILLANCE

Section 3: Post-transfusion infection investigation summary

Conclusion of investigation by regarding

BTC

PTI case code: (BTC prefix) (BTC case no./code)

A. Conclusion of this BTC's investigation

Please tick your conclusion(s) for the investigation of donation(s)/donor(s) at your BTC. Please insert the correct number in the space to complete the conclusion where appropriate.

The recipient's infection **was probably** acquired by transfusion with a unit from this BTC:

- A. Errors were found in compliance with SOP(s) in force at the time of testing/labelling/issuing of the implicated unit(s) ☐ 71.
- B. ____ 72 donor(s) was(were) found through re-testing of archive samples to have markers of transmissible infection ☐ 73.
Please specify the implicated unit type(s): _____
- C. ____ 74 donor(s) was(were) found through testing of subsequent samples to have markers of transmissible infection ☐ 75.
Please specify the implicated unit type(s): _____

The recipient's infection **may** have been acquired by transfusion with a unit from this BTC:

- D. For ____ 76 donor(s) no sample subsequent to the implicated donation was tested ☐ 77.
- E. For ____ 78 donor(s) no archive sample of the implicated donation was tested ☐ 79.
- F. For ____ 80 donor(s) neither an archive sample of the implicated donation, nor a subsequent sample was tested ☐ 81.

The recipient's infection **was probably not** acquired from transfusion with a unit from this BTC:

- G. Archived samples or subsequent samples were obtained from all donors; none were found to have markers indicative of possible infectivity at the time of donating the implicated unit(s) ☐ 82.
- H. The BTC has been informed of another confirmed source of the recipient's infection ☐ 83.
Please specify the source: _____

I. Other conclusion, please specify: _____

B. Actions of this BTC as a results of this investigation

Please insert the correct number in the box to indicate the outcome of this investigation for the donor(s) involved.

- A. ____ 84 donor(s) was(were) removed from the panel because confirmed markers of transfusion transmissible infection were found in their blood.
- B. ____ 85 donor(s) was(were) removed from the panel because of repeated involvement in PTI case investigations.
(Other PTI case code(s): _____)
- C. ____ 86 donor(s) was(were) flagged/marked on the donor database as having been involved in a PTI case investigation.
- D. ____ 87 other donation(s) from the infected donor(s) are being investigated ie. look-back at recipients is being conducted.
Please describe any other actions following this investigation: _____

C. Conclusion of case investigationThe recipient's infection **was probably** acquired by transfusion with a unit from the BTS:

- A. Errors were found in compliance with SOP(s) in force at the time of testing/labelling/issuing of the implicated unit(s) ☐ 88.
- B. ____ 89 donor(s) was(were) found through re-testing of archive samples to have markers of transmissible infection ☐ 90.
Please specify the implicated unit type(s): _____
- C. ____ 91 donor(s) was(were) found through testing of subsequent samples to have markers of transmissible infection ☐ 92.
Please specify the implicated unit type(s): _____

The recipient's infection **may** have been acquired by transfusion with a unit from the BTS:

- D. For ____ 93 donor(s) no sample subsequent to the implicated donation was tested ☐ 94.
- E. For ____ 95 donor(s) no archive sample of the implicated donation was tested ☐ 96.
- F. For ____ 97 donor(s) neither an archive sample of the implicated donation, nor a subsequent sample was tested ☐ 98.

The recipient's infection **was probably not** acquired from transfusion with a unit from the BTS:

- G. Archived samples or subsequent samples were obtained from all donors; none were found to have markers indicative of possible infectivity at the time of donating the implicated unit(s) ☐ 99.
- H. The BTS has been informed of another confirmed source of the recipient's infection ☐ 100.
Please specify the source: _____

I. Other conclusion, please specify: _____

Report completed by (please print name): _____

(ie. date investigation was closed by your BTC)

Date ____ / ____ / ____

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

INCORRECT BLOOD/COMPONENT TRANSFUSED

Data Analysis

Number of reports received: 81

Number of questionnaires received: 63

Sex

Males: 23

Females: 38

Unknown: 2

Age

Age range: 3 months - 90 years

Median Age: 64 years

Unknown: 2

Blood centre informed:

Yes: 23

No: 40

A. PATIENT DETAILS		
1.	Diagnosis and reason for transfusion	
	a)	Elective surgery 16
	b)	Emergency surgery 7
	c)	Trauma 3
	d)	Haemorrhage due to 9
	e)	Malignant haematological disorder 13
	f)	Autoimmune haemolysis
	g)	Plasma exchange 1
	h)	Other (please specify) 10
		Anaemia 1
		Transfusion not prescribed for this patient 1
		Pre-operative top up for diabetic patient 1
		Platelet transfusion for ITP 1
		Obstructive jaundice, systemic lupus erythematosus 1
2.	Was this transfusion	
	a)	An emergency 22
	b)	Routine 39
	c)	Unknown 2
3.	Where was the transfusion given*	
	a)	In-patient ward 38
	b)	Out-patient/day unit 4
	c)	Intensive care unit 9
	d)	Theatre, including recovery 14
	e)	Accident & emergency unit 2
	f)	Scene of accident
	e)	Other please state.....

* 2 patients theatre and ward
1 A&E and ITU
1 A&E and theatre

B. CROSSMATCH SAMPLE AND REQUEST FORM				
4.	Was the sample taken from			
	a)	The patient intended for transfusion		53
	b)	Another patient		2
		Unknown		5
		N/A		3
5.	Was the sample taken by:			
	a)	A doctor		32
	b)	A nurse		2
	c)	A phlebotomist		16
	d)	A medical student		1
		Unknown		9
		N/A		3
6.	Were the patient details on the sample			
	a)	Hand-written		46
	b)	On a pre-printed sticky label		4
		Unknown		12
		N/A		1
	c)	Was the sample tube pre-labelled	Unknown 36	Yes 2 No 25
	d)	Correct in all respects		62
	e)	Wrong with respect to name		
	f)	Wrong with respect to date of birth		1*
	g)	Wrong with respect to hospital number		1*
	h)	Other (please specify)		
		* Same patient		

B. CROSSMATCH SAMPLE AND REQUEST FORM continued					
7.	Were the patient details on the request form				
		Unknown	9		
		N/A	1		
		Other	4		
	a)	Hand-written	38		
	b)	On a pre-printed sticky label	11		
	c)	Correct in all respects	58		
	d)	Wrong with respect to name			
	e)	Wrong with respect to date of birth	1*		
	f)	Wrong with respect to hospital number	1*		
	g)	Other (please specify)Incorrect request.	4		
* same patient					
C. BLOOD BANK					
8.	Had the patient been grouped before?	Unknown 1	Yes 41	No 21	
9.	Was the current group checked against historical grouping records prior to blood/component issue?				
	a)	Yes - against computerised record	27		
	b)	Yes - against manual record	4		
	c)	No	7		
	d)	Patient not grouped before	21		
		Unknown	4		
10.	Has the group on the cross-match sample been re-checked?	Unknown 8	N/A 1	Yes 41	No 13
11.	Was a sample from the pack bleedline grouped before blood/component issue?	Unknown 6	N/A 3	Yes 8	No 46

C. BLOOD BANK		
12.	What was the extent of the crossmatch?	
	a) Routine technique (describe)	40
	b) Rapid technique (describe)	8
	c) Computer crossmatch	
	d) No crossmatch - issued by group alone	7
	Unknown	5
	N/A	3
13.	Was the issue label on the blood/component pack	
	a) Hand-written	4
	b) On a computer-generated label	54
	Unknown	2
	c) Stuck on the pack	56
	d) A tied-on tag or luggage label	3
	Unknown	2
	e) Correct in all respects	58
	f) Wrong with respect to name	
	g) Wrong with respect to hospital number	1*
	h) Wrong with respect to date of birth	2*
	i) No patient-specific label generated	3
* Represents 2 patients		
14.	Were the details on the issue voucher/report form	
	a) Hand-written	8
	b) On a computer-generated form	49
	c) Correct in all respects	55
	d) Wrong with respect to name	
	e) Wrong with respect to date of birth	2*
	f) Wrong with respect to hospital number	1*
	g) Not found	
	Unknown	2
	Not issued	4

C. BLOOD BANK continued				
15.	Grade of staff performing crossmatch and labelling			
	a)	State Registered blood bank MLSO	38	
	b)	MLA with supervision		
	c)	MLA unsupervised	1	
	d)	On call MLSO regularly working in blood bank	11	
	e)	On call MLSO NOT regularly working in blood bank	7	
	f)	Trainee MLSO		
	g)	Locum/agency staff		
		Unknown	6	
16.	Was the blood/component			
	a)	Handed over personally from blood bank staff	14	
	b)	Collected from blood bank refrigerator	28	
	c)	Collected from satellite refrigerator	19	
		Unknown	2	
	d)	Formally checked for identity with patient	22	
	e)	Collected without formal checking	34	
		Unknown	7	
17.	Grade of staff collecting blood/component			
	a)	Qualified nurse	30	
	b)	Unqualified nurse	2	
	c)	Porter	22	
	d)	Medical student		
	e)	Other (please state) Theatre Staff	2	
	e)	Unknown	7	
18.	Was the blood/component collected as far as the label indicated			
	a)	The correct pack for the intended recipient	36	
	b)	The wrong pack for the intended recipient with respect to:-	27	
			Name	Yes 20 No
			Date of birth	Yes 24 No
			Hospital number	Yes 23 No
There were 3 incidents of emergency issue/supply abuse				

C.	BLOOD BANK continued			
18.	Was the blood/component collected as far as the label indicated			
		20 incorrect due to Name, DOB and Hosp Number,		
		3 incorrect due to DOB and Hosp Number		
		1 incorrect due to DOB only		
D.	ADMINISTRATION OF BLOOD/COMPONENT			
19.	Blood/Components given			
	a)	Red Cells		47
	b)	Red cells buffy coat depleted		3
	c)	Red cells leucocyte depleted		3
	d)	Platelets apheresis		4
	e)	Platelets from buffy coat pools		1
	f)	Platelets leucocyte depleted		1
	g)	Fresh frozen plasma		4
	h)	Cryoprecipitate		
	i)	Granulocytes		
	j)	Other CPDA		1
	NB	One patient received both red cells and red cells buffy coat depleted in error		
	20.	Was this unit		
a)		Autologous		
b)		From a Transfusion Service donor		62
c)		From a family member		1
21.	Were the two people setting up and checking the transfusion			
	a)	A qualified nurse	Person 1	49
			Person 2	40
	b)	An unqualified nurse	Person 1	
			Person 2	3
	c)	A doctor	Person 1	4
			Person 2	4
	d)	A medical student	Person 1	
			Person 2	
	e)	Other	Person 1	1
			Person 2	
		Unknown	Person 1	9
			Person 2	16

D. ADMINISTRATION OF BLOOD/COMPONENT continued					
22.	Was the patient's identity wristband				
	a)	Missing	8		
	b)	Correct in all details	55		
	c)	Wrong with respect to:			
			Name	Yes	No
			Date of birth	Yes	No
	Hospital number	Yes	No		
23.	What was the reason for the error?				
	a)	Sample & request errors	8		
	b)	Laboratory group/crossmatch/label errors	21		
	c)	Collection of blood/component from blood bank or satellite refrigerator +/- misidentity of patient at time of administration	34		
24.	How was the error discovered?				
	a)	Acute reaction	4		
	b)	Delayed reaction	2		
	c)	Ward staff noticed discrepancy of identity	32		
	d)	Laboratory staff noticed discrepancy of identity	25		
	e)	Other (please describe)			

E. SEQUELAE				
25/6		State ABO/Rh group of patient and incorrecct units given - see table		Unknown 4
Patient	ABO group	Rh group	ABO group of IBT	Rh group of IBT
1	A	NEG	A	POS
2	A	NEG	A	POS
3	A	NEG	A	POS
4	A	NEG	O	NEG
5	A	POS	A	NEG
6	A	POS	A	POS
7	A	POS	A	POS
8	A	POS	A	POS
9	A	POS	A	POS
10	A	POS	A	POS
11	A	POS	A	POS
12	A	POS	A	POS
13	A	POS	A	POS
14	A	POS	A	POS
15	A	POS	AB	POS
16	A	POS	AB	POS
17	A	POS	AB	POS
18	A	POS	B	POS
19	A	POS	O	NEG
20	A	POS	O	POS
21	A	POS	O	POS
22	A	POS	O	POS
23	AB	POS	B	POS
24	B	POS	A	POS
25	B	POS	B	POS
26	B	POS	B	POS
27	B	POS	O	POS
28	O	NEG	A	NEG
29	O	NEG	A	POS
30	O	NEG	O	NEG
31	O	NEG	O	NEG
32	O	NEG	O	POS
33	O	NEG	O	POS
34	O	POS	A	NEG
35	O	POS	A	POS
36	O	POS	A	POS
37	O	POS	A	POS
38	O	POS	A	POS
39	O	POS	A	POS
40	O	POS	B	POS
41	O	POS	O	NEG
42	O	POS	O	NEG
43	O	POS	O	POS
44	O	POS	O	POS
45	O	POS	O	POS
46	O	POS	O	POS
47	O	POS	O	POS
48	O	POS	O	POS
49	O	POS	O	POS
50	O	POS	O	POS
51	O	POS	O	POS
52	O	POS	O	POS
53	O	POS	O	POS
54	O	POS	O	POS
55	O	POS	O	POS
56	O	POS	O	POS
57	O	POS	U	U
58	U	U	O	NEG
59	A	POS	A	POS

E. SEQUELAE		
27.	Was the volume of `wrong` blood/component given	
	Unknown	2
	a) <50 mls	4
	b) 50-99 mls	5
	c) >100 mls	7
	d) A whole unit	17
	e) >1 unit (State number)	28
	In the 28 cases where > 1 unit was transfused	
	2 units	9
	3 units	5
	4 units	4
	5 units	1
	9 units	1
28.	28 units	1
	Unknown quantities, but > 1 unit	7
	What features were there of acute intravascular haemolysis?	
	a) None	55
	b) Fever	2
	c) Rigors	2
	d) Haemoglobinuria	1
	e) Hypotension	2
	f) Loin pain	3
	g) Bronchospasm	3
	NB 4 patients had a combination of symptoms	
	Unknown	2

E. SEQUELAE continued		
29.	What were the complications of this transfusion?	
	a) None	53
	b) Ventilatory problems (eg pneumonia, pulmonary oedema)	1
	c) Cardiac problems (eg acute LVE, intractable arrhythmias, cardiac arrest)	
	d) Hepatic failure	
	e) Septicaemia	
	f) Renal failure	2
	g) Central nervous system failure (eg failure to recover consciousness)	
	h) Progression of underlying condition	2
	i) Electrolyte imbalance	
	j) Haematological disorder/coagulopathy	2
	k) Other (please specify)	
	Anaemia	1
30	Jaundice	4
	3 patients had a combination of complications	
	Unknown	1
	Did the patient require	
	a) Dialysis	1
31	b) ITU admission	4
	NB 1 patient required both dialysis and ITU admission	
	Already on ITU	10
	Neither ITU admission or dialysis	49
31	Did the patient	
	a) Survive with no ill effects	51
	b) Survive with ill effects, please specify	1
	c) Recover from complications of intra-vascular haemolysis	4
	d) Die of sequelae of transfusion	1
	e) Die of underlying condition	5
	f) Die as a result of D +E	
	Unknown	1

F. PROCEDURAL REVIEW					
32.	Has the case been reviewed by hospital transfusion committee				
	a)	Yes	11		
	b)	No, but will be at a future meeting	34		
	c)	Hospital does not have transfusion committee	18		
33.	As a result, have there been recommended changes to transfusion procedures?		12 Unknown	31 Yes	20 No
	If yes, please specify				

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

ACUTE TRANSFUSION REACTION (including anaphylaxis) DATA ANALYSIS

Data Analysis

Number of reports received:	27		
Number of questionnaires received:	23		
Males:	7		
Females:	16		
Age range:	1 month - 80 years (2 unknown)		
Median age:	64 years		
Blood centre informed:	Yes: 20	No: 2	Unknown: 2
Components implicated	No. of cases		
Red Cells (rbc)	18 (1 also FFP)		
Platelets	5		
Fresh frozen plasma (FFP)	2 (1 also rbc)		

A. PATIENT DETAILS		
1.	Diagnosis and reason for transfusion	
	a)	Elective surgery, please state type 4
	b)	Emergency surgery, please state type 2
	c)	Trauma
	d)	Haemorrhage due to 1
	e)	Malignant haematological disorder 8
	f)	Autoimmune haemolysis 1
	g)	Plasma exchange (specify diagnosis)
	h)	Other (please specify)1 Bone marrow donor - autologous transfusion post harvest 8 1 to cover angiogram, 4 anaemias, 1 thalassaemia, 1 sickle cell
2.	Concomitant Drug Therapy (please specify)..... 14 (14 patients were on concomitant drug therapy, 1 patient unknown, 8 not stated as this question was added to our questionnaire in July, I will break down the drugs for the annual report)	
3.	Was this transfusion	
	a)	An emergency 4
	b)	Routine 12
	c)	Unknown 8
4.	Where was the transfusion given.	
	a)	In-patient ward 13
	b)	Out-patient/day unit 1
	c)	Intensive care unit 3 *
	d)	Theatre, including recovery 2 *
	e)	Accident & emergency unit
	f)	Scene of accident
	e)	Other (please state) SCBU 1

* Transfusion given in theatre and ITU

B. COMPONENT DETAILS							
5.	Interval between end of transfusion and onset of symptoms						
	a)	Symptoms started while transfusion in progress	18				
	b)	< 2 hours	2				
	c)	2-7 hours	2				
	d)	8-24 hours	1				
	e)	Other (specify in hours)					
	f)	Unknown	1				
6.	Could you identify which unit was responsible? (I will show a breakdown of the responsible products for the annual report)		<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> <tr> <td>17</td> <td>7</td> </tr> </table>	Yes	No	17	7
Yes	No						
17	7						
7.	Components given prior to reaction (number of units) *						
	a)	Red Cells	25				
	b)	Red cells buffy coat depleted					
	c)	Red cells leucocyte depleted	1				
	d)	Red cell pedipack	1				
	e)	Platelets apheresis	2				
	f)	Platelets from buffy coats	1				
	g)	Platelets from buffy coat pools	4				
	h)	Platelets leucocyte depleted					
	i)	Fresh frozen plasma	2				
	j)	Cryoprecipitate					
	k)	Granulocytes					
	l)	Other - 1 cell saver, 1 whole blood	2				
NB Questions 7 & 8 and 9 & 10 were causing great confusion, and most clinicians answered the first two, we have re-phrased the question and deleted the duplicity to avoid confusion.							
8.	Was this unit						
	a)	Autologous	1				
	b)	From a Transfusion Service donor	23				
	c)	From a family member					

* Some patients received a combination of one or more products

B. COMPONENT DETAILS				
9.	If platelet or red cell transfusion, was a filter used Out of 37 cases where a filter could have been used		Yes 12	No 13 Unknown 13
10.	If yes, please state make and manufacturer of filter Pall PKL x 2, Pall PL100 x 4, Pal x 2, Pal PXL 2KLE x 1, Sepacell x 2, 1 Pall RCXL 2KLE NB. this is another question that was added to the questionnaire at a later date			
11.	Indicate symptoms			
	a)	Fever (rise >1°C)		11
	b)	Chills		3
	c)	Rigors		9
	d)	Itching/rash		3
	e)	Back pain		3
	f)	Chest pain/discomfort		4
	g)	Dyspnoea / difficult breathing		10
	h)	Dark urine		7
	i)	Restlessness		5
	j)	Hypotension		6
	k)	Other (please specify)		
		Abdominal pain		2
		Anaemia		1
		Cyanosis		2
		Falling haemoglobin		1
		Flushed skin		1
		Jaundice		1
		Nausea		1
		Shoulder pain		1
		General deterioration		2
		Tingling at transfusion site		1
		Pallor/clammy		2
12.	How often were patient observations recorded before the reaction? Every minutes			
		Unknown		6
		Immediately - 0 to 5 minutes		4
		6 - 15 minutes		6
		16 - 30 minutes		4
		31 - 45 minutes		1
		46 - 60 minutes		2
		61 - 120 minutes		1

B. COMPONENT DETAILS continued					
13.	Was a doctor informed?		Yes	No	Unknown
			22		2
	If yes, how soon after the reaction?		hrs		mins
	Unknown		1		
	Immediately - 0 to 5 minutes		15		
	6 - 15 minutes		2		
	16 - 30 minutes		1		
	31 - 45 minutes				
	46 - 60 minutes		3		
14.	Did the doctor see the patient?		Yes	No	Unknown
			21	1	2
	If yes, how soon after he/she was informed		hrs		mins
	Unknown		3		
	Immediately - 0 to 5 minutes		12		
	6 - 15 minutes		4		
	16 - 30 minutes		1		
	31 - 45 minutes				
	46 - 60 minutes		1		
If no, was advice given by telephone?		Yes		No	
		1			
15.	What grade was the doctor who first dealt with the problem?				
	a)	Junior house officer	4		
	b)	Senior house officer	7		
	c)	Registrar	6		
	d)	Senior registrar	2		
	e)	Consultant	2		
	f)	Staff grade	2		
	g)	Other - Unknown	1		

B. COMPONENT DETAILS continued					
16.	Was the doctor who gave the advice a haematologist?		Yes 5	No 18	Unknown 1
	If no, did she/he contact a haematologist for advice about management?		Yes 17	No 1	
	If yes, how soon after the reaction?		hrs		mins
	Unknown		6		
	Immediately - 0 to 5 minutes		3		
	6 - 15 minutes		3		
	16 - 30 minutes		3		
	31 - 45 minutes				
	46 - 60 minutes				
	61 - 120 minutes		1		
	> 120 minutes		1		
	17.	What type of advice/instructions were given?			
a)		Continue transfusion as before	2		
b)		Continue transfusion at slower rate			
c)		Stop transfusion temporarily and observe	3		
d)		Discontinue transfusion completely	14		
e)		Other (please specify)	Unknown	1	
			Transfusion had already been completed	1	
			Give patient washed platelets next transfusion	1	
			To give patient prophylactic hydrocortisone and piriton prior to further transfusion of FFP	1	
			Administer platelets of patient group rather than group 0	1	
18.	Was any medication prescribed? *		Yes 17	No 7	
	If yes, please specify				
	a)	Paracetamol	2		
	b)	Antihistamine	11		
	c)	Diuretic	2		
	d)	Hydrocortisone	11		
	e)	Adrenaline	3		
	f)	Other	Antibiotics	2	
			Cryoprecipitate/ FFP/Haemocel	1, 1, 1	

* Some patients were on multiple therapy

B. COMPONENT DETAILS continued					
19.	Was the transfusion abandoned?			Yes 20	No 4
	If yes, what volume of the unit had been transfused?				
	Unknown			4	
	0 - 50 mls			6	
	51 - 100 mls			7	
	101 - 250 mls			1	
	251 - 500 mls			1	
	18 units (hypertransfused)			1	
20.	Was a subsequent transfusion given?			Yes 12	No 12
		If yes,			
	a)	State component			
	b)	And number of units			
	c)	How soon after the previous unit was abandoned?		hrsmins	
	d)	Was the subsequent unit tolerated well?		Yes	No
		<u>a</u>	<u>b</u>	<u>c</u>	<u>d</u>
		Platelets - apheresis + red cells	multiple	14 days	Y
		Platelets - apheresis	1	unknown	Y
		Red cells	1	2 hr 30	Y
		Red cells	2	immediately	Y
		Red cells	2	23 hrs	Y
		Red cells	2	1 day	Y
		Red cells	3	unknown	Y
		Red cells	3	4 - 5 hours	Y
	Red cells	3	8 days	Y	
	Red cells	4	1 day	Y	
	Red cells	8	6 hours	Y	
	Red cells - leucocyte depleted	8	6 hours	Y	

C. FOLLOWING THE TRANSFUSION REACTION						
21.	Were blood samples taken?		Yes 19		No 2	Unknown 3
	If yes, how soon after the reaction?					
	Unknown		3			
	0 - 30 minutes		7			
	31 - 60 minutes		3			
	61 - 120 minutes		1			
	121 - 240 minutes		1			
	< 24 hours		2			
	3 days		2			
22.	Was the unit returned to the transfusion laboratory?		Yes 14		No 5	Unknown 5
	If yes, how soon after the transfusion of the unit was abandoned?					
	Unknown		2			
	0 - 60 minutes		10			
	12 - 24 hours hours		2			
23.	Was a urine sample collected?		Yes 7		No 12	Unknown 5
	If yes, how soon after the reaction?					
24.	Diagnostic test results.		Yes	No	Unknown	Not done
	a)	Raised urinary urobilinogen	1	1	11	11
	b)	Raised plasma bilirubin	3	3	12	6
	c)	Falling Hb	5	6	11	2
	d)	Haemoglobinuria	3	4	11	6
	e)	Deteriorating renal function	4	5	11	4
	f)	Positive DAT	6	7	9	2
	g)	Spherocytes	1	4	13	6
	h)	Evidence of DIC	2	8	12	2

D. PRE - TRANSFUSION SEROLOGY		
25.	Was a <u>pre</u>-transfusion antibody screen	
	a)	Not done 1
	b)	Done on a 2-cell panel 8
	c)	Done on a 3-cell panel 11
	d)	Done by gel techniques 7
	e)	Done by tube enzyme 3
	f)	Done by tube antiglobulin technique 9
	g)	Other 3
	h)	Negative 19
	i)	Positive - Give specificity of antibody 2 = anti wra 1 = known anti c, anti M, anti kpa, anti Le(a) 3
	j)	Positive - Antibody not identified
	k)	Positive cold auto only
	l)	Positive enzyme auto only 1
26.	<u>Pre</u>-transfusion was the patient's direct antiglobulin test	
	a)	Positive DAT IgG 3 Complement Both 2
	b)	Negative 11
	c)	Not Done 8
27.	Was the crossmatch	
	a)	Immediate spin only) Crossmatch A 2
	b)	Immediate spin + LAT) 6
	c)	None) 12
	d)	Unknown) 4

D. PRE - TRANSFUSION SEROLOGY continued.

27.	Was the crossmatch		
a)	Done by gel techniques)	Crossmatch B	6
b)	Done by tube techniques)		7
c)	None)		7
d)	Unknown)		4
28.	Interval between taking the crossmatch sample and transfusion		
a)	0 - 47 hours		9
b)	48 - 71 hours		
c)	72 - 96 hours		2
d)	> 96 hours (please state)		4
e)	Not done		4
f)	Unknown		5

E. POST-TRANSFUSION SEROLOGY

29.	Was a post-transfusion antibody screen		
	a)	Not done	3
	b)	Done on a 2-cell panel	5
	c)	Done on a 3-cell panel	11
	d)	Done by gel technique	7
	e)	Done by tube enzyme	4
	f)	Done by tube antiglobulin technique	7
	g)	Other (please specify)	3
	g)	Negative	13
	h)	Positive, please give specificity of antibody 1 = anti E anti Jka 1 = anti c, anti M, anti kpa, anti Le(a) (as pre- transfusion) 2 = anti D 1 = anti E, Jkb, Fya 1 = anti wra (as pre-transfusion) 1 = anti Jkb Fy3 NB Awaiting results form Blood Transfusion Centre	7 1
	i)	Positive - Antibody not identified	
	j)	Positive cold auto only	1
	k)	Positive enzyme auto only	

E. POST-TRANSFUSION SEROLOGY continued					
	I)	Give interval between end of transfusion and sample being taken			
		Unknown	8		
		Not done	3		
		0 - 5 minutes	3		
		6 - 10 minutes	2		
		11 - 15 minutes			
		16 - 30 minutes	2		
		31 - 60 minutes	2		
		> 60 minutes	3		
30.	Post-transfusion was the patient's direct antiglobulin test				
	a)	Positive	IgG	7	
			Complement		
			Both	2	
	b)	Negative		12	
	c)	Not done		3	
31.	Presumed cause of the reaction				
	Please refer to chapter 8				
F. SEQUELAE					
32.	Did the patient				
	a)	Survive with no ill effects		20	
	b)	Survive with ill effects, please specify		2	
		Hypertransfusion - ITU with pulmonary oedema and ventilated			
		Jaundice			
	c)	Die of sequelae of transfusion			
	d)	Die of underlying condition		1	
	e)	Die as a result of C + D		1	
33.	Was the reaction reported to any of the following?		Unknown 4	Yes 20	No
	a)	Hospital blood transfusion laboratory		20	
	b)	Hospital transfusion committee		8	
	c)	Transfusion centre		18	

F.	SEQUELAE			
34.	As a result, have there been recommended changes to transfusion procedures?	Unknown 8	Yes 5	No 11
	If yes, please specify DAT's performed on all patients who are RhD -ve and have been transfused with RhD+ve blood. A proforma is being introduced to facilitate collection of clinical and laboratory data. Review of numbers of platelets in platelet pools. assessment of alternative filters. The SHO was not aware of correct procedures for reporting and monitoring transfusion reactions, he has now been advised on the correct procedures. The staff nurse who reported the reaction, was aware of the management of a suspected transfusion reaction. Advised that this patient should receive washed red cells for further transfusions. Review of the use of filters in autologous blood transfusion			

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

DELAYED TRANSFUSION REACTION DATA ANALYSIS

Data Analysis

Number of reports received:	27		
Number of questionnaires received:	23		
Males:	7		
Females:	16		
Age range:	25 - 87 years (1 unknown)		
Median age:	68 years		
Blood centre informed:	Yes: 13	No: 9	Unknown: 1
Components implicated	No. of cases		
Red cells (rbc)	23		

A. PATIENT DETAILS		
1.	Diagnosis and reason for transfusion	
	a)	Elective surgery 6
	b)	Emergency surgery 4
	c)	Trauma 3
	d)	Haemorrhage due to: Fractured neck of femur Epistaxis Post-operative haemorrhage following trans-urethral resection of prostate 3
	e)	Malignant haematological disorder 2
	f)	Autoimmune haemolysis
	g)	Plasma exchange (specify diagnosis)
	h)	Other (please specify) Anaemia 2 Liver malignancy 1 Sickle cell anaemia 2
2.	Concomitant drug therapy (please specify) 10 patients were on concomitant drug therapy 13 unknown	
3.	Was this transfusion	
	a)	An emergency 6
	b)	Routine 14
	c)	Unknown 3
4.	Where was this transfusion given.	
	a)	In-patient ward 17 *
	b)	Out-patient/day unit
	c)	Intensive care unit 3
	d)	Theatre, including recovery 4 *
	e)	Accident & emergency unit 1*
	f)	Scene of accident
	g)	Other, please state.....

* One patient was transfused in theatre and on the ward

* One patient was transfused in accident & emergency and in theatre

B. COMPONENT DETAILS			
5.	Days between end of transfusion and onset of symptoms		
	1 - 5 days		6
	6 - 10 days		10
	11 - 15 days		3
	Unknown		4
6.	Could you identify which unit was responsible?		Yes
	(I will show a breakdown of the responsible products for the annual report)		No
	7		14
7.	Components given prior to the reaction (number of units)		
	a)	Red Cells	20
	b)	Red cells buffy coat depleted	6
	c)	Red cells leucocyte depleted	
	d)	Platelets apheresis	
	e)	Platelets from buffy coat pools	1
		Platelets from buffy coats	1
	f)	Platelets leucocyte depleted	
	g)	Fresh frozen plasma	5
	h)	Cryoprecipitate	1
	i)	Granulocytes	
	j)	Other, please specify Unknown	1
	NB	Some patients had more than one component prior to the reaction	
NB Questions 7 & 8 and 9 & 10 were causing great confusion, and most clinicians answered the first two, we have re-phrased the question and deleted the duplicity to avoid confusion.			
8.	Was this unit		
	a)	Autologous	
	b)	From a Transfusion Service donor	23
	c)	From a family member	

B. COMPONENT DETAILS continued					
9.	Indicate symptoms & signs of the delayed transfusion reaction.				
	a)	Fever (rise $>1^{\circ}\text{C}$)	2		
	b)	Chills			
	c)	Rigors	2		
	d)	Itching/rash			
	e)	Back pain	1		
	f)	Chest pain/discomfort			
	g)	Dyspnoea / difficult breathing	2		
	h)	Dark urine	8		
	i)	Restlessness	1		
	j)	Jaundice	15		
	k)	Hypotension			
	l)	Falling Hb	14		
	m)	Poor/absent increment following transfusion.	3		
	n)	Other, please specify		1	
		General deterioration in condition		1	
		Bilirubin 82, LDH 823		1	
		Positive DAT		1	
		Developed irregular antibodies		2	
		Spherocytes on film		1	
		Problems finding compatible blood		3	
	o)	None			
	NB	Some patients had a combination of symptoms (I will illustrate in a table)			
10.	Was any medication prescribed?		Unknown 2	Yes 1	No 19
	If yes, please specify				
	a)	Paracetamol			
	b)	Antihistamine			
	c)	Diuretic			
	d)	Hydrocortisone			
	e)	Adrenaline			
	f)	Other Antibiotics	1		

B. COMPONENT DETAILS continued				
11.	Was a subsequent transfusion given?		Unknown 1	Yes 15 No 7
	a)	If yes, see table state component		_____
	b)	and number of units		_____
	c)	How soon after the previous transfusion.?		_____ days
	d)	Was the subsequent transfusion tolerated well?		Yes No
Incident	Component	Number of units	Component interval	Component tolerated
1	Red Cells	3	4 days	Y
2	Red Cells	1	1 day	N
3	Fresh Frozen Plasma	13	1 day	N
3	Platelets HLA Selected	1	1 day	N
3	Red Cells-buffycoat	23	1 day	N
4	Platelets-apheresis	1	8 days	Y
4	Red Cells	3	8 days	Y
5	Red Cells	2	6 days	Y
6	Red Cells	4	14 days	Y
7	Red Cells	2	13 days	Y
8	Red Cells-buffycoat	2	15 days	Y
9	Red Cells	4	8 days	Y
10	Red Cells	14	6 days	N
11	Red Cells	3	5 days	N
12	Red Cells	3	5 days	Y
13	Red Cells	3	9 days	Y
14	Red Cells	2	13 days	Y
15	Red Cells	3	4 days	Y
C. FOLLOWING THE TRANSFUSION REACTION				
12.	Were blood samples taken?		Yes 18	No 4 Unknown 1
	If yes, how soon after the reaction?			
	Unknown			4
	<24 hours			3
	1 - 7 days			8
	8 - 14 days			3
13.	Was the unit returned to the transfusion laboratory?		Yes 3	No 17 Unknown 3
	If yes, how soon after the transfusion of the unit was abandoned?			
	Unknown			2
	3 hours			1

C. FOLLOWING THE TRANSFUSION REACTION continued						
14.	Was a urine sample collected?			Yes	No	Unknown
				4	14	5
	If yes, how soon after the reaction?					
	Unknown			2		
1 - 7 days			2			
15.	Diagnostic tests results where performed		Unknown	Yes	No	Not Done
	a)	Raised urinary urobilinogen	13	3	4	3
	b)	Raised plasma bilirubin	6	14	3	
	c)	Haemoglobinuria	11	6	3	3
	d)	Deteriorating renal function	10	5	8	
	e)	Positive DAT	1	20	2	
	f)	Spherocytes	9	5	7	1
	g)	Evidence of DIC	15	3	4	1
D. PRE - TRANSFUSION SEROLOGY						
16.	Was a <u>pre</u> -transfusion antibody screen					
	a)	Not done				
	b)	Done on a 2-cell panel			6	
	c)	Done on a 3-cell panel			16	
	d)	Done by gel techniques			11	
	e)	Done by tube enzyme			4	
	f)	Done by tube antiglobulin technique			9	
	g)	Other (please specify)				
		microplate antiglobulin			1	
		12 panel using saline, enzyme and antiglobulin tube technique			1	
		pre modified enzyme in microtitre plate			1	
	h)	Negative			16	
	i)	Positive - Give specificity of antibody				
	anti K			1		
	anti S			1		
	anti E			1		
	anti Cw			1		
	anti C3d			1		

D. PRE - TRANSFUSION SEROLOGY continued			
	j)	Positive - Antibody not identified	1
	k)	Positive cold auto only	
	l)	Positive enzyme auto only	1
17.	Pre-transfusion was the patient's direct antiglobulin test		
	a)	Positive IgG	2
		Complement	
		Both	1
	b)	Negative	8
	c)	Not Done	12
18.	Was the crossmatch		
	a)	Immediate spin only	3
	b)	Immediate spin + IAT	9
	c)	None	10
	d)	Electronic	1
	e)	Done by gel techniques	4
	f)	Done by tube techniques	17
	g)	None	1
	h)	Electronic	1
19.	Interval between taking the crossmatch sample and transfusion		
	a)	0 - 47 hours	18
	b)	48 - 71 hours	3
	c)	72 - 96 hours	
	d)	> 96 hours (please state) 120 hours (5 days)	
	e)	unknown	2

E. POST-TRANSFUSION SEROLOGY

20.	Was a <u>post</u> -transfusion antibody screen		
a)	Not done		
b)	Done on a 2-cell panel	6	
c)	Done on a 3-cell panel	15	
d)	Done by gel technique	11	
e)	Done by tube enzyme	4	
f)	Done by tube antiglobulin technique	3	
g)	Other (please specify)		
	microplate antiglobulin	1	
	12 panel using saline, enzyme and antiglobulin tube technique	1	
h)	Negative	1	
i)	Positive	21	
	Antibody Group	Number	Sole antibody
	Kidd (JK)		
	Jka	6	5
	Jkb	2	
	Duffy		
	Fya	1	
	Fy3	1	
	Kell		
	K	4	1
	Kpa	1	
	Rhesus		
	D	2	1
	C	3	1
	c	2	1
	E	5	1
	e	2	1
	MNSs		
	M	1	
	S	2	
	Unspecified pan-agglutinin	1	

E. POST-TRANSFUSION SEROLOGY continued			
20.	Was a <u>post</u>-transfusion antibody screen		
	j)	Positive - Antibody not identified	
	k)	Positive cold auto only	
	l)	Positive enzyme auto only	1
	m)	Give interval between end of transfusion and sample being taken:	
		Unknown	8
		< 7 days	5
		7 - 14 days	7
		>14 days	2
21.	<u>Post</u>-transfusion was the patient's direct antiglobulin test		
	a)	Positive IgG	12
		Complement	3
		Both	6
	b)	Negative	2
	c)	Not done	
22.	Presumed cause of the reaction		
	Please refer to chapter 9		

F.		SEQUELAE							
23.	Did the patient								
	a)	Survive with no ill effects				16			
	b)	Survive with ill effects, mild renal impairment				1			
	c)	Die of sequelae of transfusion							
	d)	Die of underlying condition				4			
	e)	Die as a result of C + D				2			
24.	Was the reaction reported to any of the following?				None	Unknown	Yes	No	
					1	1	21		
	a)	Hospital blood transfusion laboratory				21			
	b)	Hospital transfusion committee				9			
c)	Transfusion centre				15				
25.	As a result, have there been recommended changes to transfusion procedures				No	Yes	Unknown		
					17	3	3		
If yes, please specify									
1) This patient had been transferred from another hospital, we now have access to their computer to check up on the patients previous transfusion history.									
2) Subsequent information from the patient suggests that she had a child who suffered HDN.									
3) Increase emphasis on reporting of previous transfusion histories.									
4) local practice to monitor DAT and to genotype red cells, of patients on alpha interferon.									

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

TRANSFUSION - RELATED ACUTE LUNG INJURY

Data Analysis

Number of reports received:	9
Number of questionnaires received:	9
Males:	4
Females:	5
Age range:	2-69
Median age:	44
<u>Component implicated:</u>	
Red cells	3
Platelets	3
Fresh frozen plasma	2
Not identified	1
Blood Centre informed	

A. PATIENT DETAILS		
1.	Diagnosis and reason for transfusion	
	a)	Elective surgery 3°
	b)	Emergency surgery (C/S = Caesarian section) 1 (C/S)
	c)	Trauma
	d)	Haemorrhage 1*
	e)	Malignant haematological disorder 4#
	f)	Liver disease
	g)	Other medical condition (please specify) Other medical condition (please specify) ° 1 case also had multiple sclerosis *nose bleed in patient with alcohol withdrawal/chlormethiazole infusion # 1 case had autologous stem cell transplant for relapsed AML, complicated by veno-occlusive disease of the liver/haemorrhagic ascites
	h)	Plasma exchange (specify diagnosis)
2.	Was this transfusion: Unknown 6	
	a)	An emergency 1
	b)	Routine 2
	c)	Unknown
3.	Where was the transfusion given: Unknown 6	
	a)	In-patient ward 3
	b)	Out-patient/day unit
	c)	Intensive care unit
	d)	Theatre, including recovery
	e)	Accident & emergency unit
	f)	Scene of accident
	e)	Other please state.....

B. COMPONENT DETAILS												
* can't identify which component involved Implicated component	4. In the 24 hours prior to the onset of symptoms, did the patient receive											
	CASE		1*	2	3	4	5	6	7	8	9	
	a)	Red cells	8	6*	0	0	2*	3	0	3*	0	5
	b)	Platelets	4	0	0	1* pool	0	5 pool	5*	0	4*	5
	c)	Fresh frozen plasma	0	2	4*	0	0	4*	0	0	0	3
	d)	Cryoprecipitate	0	0	0	0	0		0	0	0	0
	e)	Cryosupernatant	0	0	0	0	0		0	0	0	0
5.	Was this unit: Unknown 3											5
	a)	Autologous										
	b)	From a Transfusion Service donor										4
	c)	From a family member										
6.	Was the onset of symptoms clearly associated with transfusion of											
	a)	Red cells										3
	b)	Platelets										3
	c)	FFP										2
	d)	Cannot identify										1
7.	If platelets or FFP, was the source: Unknown											2 (FFP)
	a)	Apheresis										1 (plts)
	b)	Whole blood										3 (2 plts, 1 FFP)
	c)	Not applicable, other product										3

C. PATIENT OUTCOME			
8.	Did the patient have pre-existing:		
	a)	Respiratory dysfunction (please specify) .. 1 - small pleural effusion 1 - AML - hypoxia - ? sepsis/pneumocystis	
	b)	Sepsis	2
	c)	Cardiac failure	0
9.	Did the patient develop		
	a)	Fever	7
	b)	Hypotension	4
	c)	Rigors	5
	d)	Dyspnoea	9
	e)	↓ pO ₂	9
	f)	↑ pCO ₂	
	g)	CXR changes (please specify) ' ARDS ' - 1 , effuse 1 , a/v infilt (hitch) 1 , a/v infilt/oedema 1 , diffuse shadowing 1 , basal/mid-zone shadowing 1 , bilat shadowing 1 , casol R mid/lower zones 1 , bilat infilt 1	9
10.	Did the patient require		
	a)	ITU admission	5 (1 moribund on arrival)
	b)	Ventilation - number of days:- 7, 13, 35, unknown.	4
	c)	Neither	4
	d)	Patient already on ITU when transfused	0
11.	Specific treatment given None 1		
	a)	Methyl prednisolone 3 patients received steroids in the form of dexamethasone/hydrocortisone	3 (with ventⁿ)
	b)	Antihistamine	2
	c)	Protease inhibitor eg aprotinin	0

C. PATIENT OUTCOME continued		
12.	Eventual outcome	
	a)	Patient died 2
	b)	Full recovery 7
	c)	Recovery with impaired respiratory function 0
13.	Why did you think that this patient had TRALI rather than ARDS?	
	a)	Sudden onset of symptoms during transfusion 6
	b)	Sudden onset of symptoms following transfusion 1
	c)	Deterioration of pre-existing symptoms during transfusion 2
	d)	Deterioration of pre-existing symptoms following transfusion 0
14.	Were serological investigations on suspected donor(s)	
	a)	Not carried out 0
	b)	Negative 0
	c)	Positive (component) 1 - (red cell) 3 donors tested; 2 neg, 1 weak HLA antibodies 2 - (red cell) 9 donors tested; 2 pos for granulocyte antibodies 3 - (FFP) 4 donors tested; 1 HLA - B8 + ? B15 4 - (platelets) anti-HLA-A2 + A28 → A2 / A28 pos platelet in pool (interdonor incompatibility) 5 - (RBC) 2 donors tested; 1 strong granulocyte +HLA antibodies 6 - (FFP) 1 donor tested ; HLA antibodies 7 - (platelets) 4 donors tested; strong anti-HLA-A2; recipient HLA-A2 homozygous 8 - (red cells) strong IgG HLA antibodies in patient's serum ? passive transfer from transfusion; no data on donor serology. 9 - (platelets) donor serology awaited.

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

POST TRANSFUSION PURPURA (THROMBOCYTOPENIA)
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Data Analysis

Number of reports received:	11
Number of questionnaires received	11
Number of fatalities	1
Males:	0
Females:	11
Age range:	40-92 years
Median age:	66 years
Blood Centre informed:	Yes: 10 No: 0 Not stated:1
Component responsible:	Red cells in all cases.

A PATIENT DETAILS			
1.	Diagnosis and reason for transfusion		
	a)	Elective surgery *1 'top-up' prior to gastrectomy	2
	b)	Emergency surgery	3*
	c)	Trauma	0
	d)	Other	0
	e)	Haemorrhage *3 of the 5 also had emergency surgery	5*
	f)	Malignant haematological disorder	
	g)	Other medical condition 1 pneumonia, 1 anaemia, 1 anaemia (gastic ulcer), 1 anaemia (?G1 loss)	4
	h)	Autoimmune haemolysis	0
	i)	Plasma exchange (specify diagnosis)	0
2.	Was this transfusion		
	a)	An emergency	3
	b)	Routine	3
	c)	Unknown	5
3.	Where was this transfusion given. Unknown		
	a)	In-patient ward	5
	b)	Out-patient/day unit	
	c)	Intensive care unit	
	d)	Theatre, including recovery	
	e)	Accident & emergency unit	
	f)	Scene of accident	
	g)	Other (please state).....	
4.	Number of pregnancies		
	a)	0	0
	b)	1	1
	c)	2	5
	d)	>2 *1 with at least 7 miscarriages	5*
5.	In the case of previous pregnancies, was there any history of previous neonatal alloimmune thrombocytopenia?		
			Yes 0 No 5

Not stated/unknown : 6

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Susan Lowe, Manchester Blood Centre

TRANSFUSION ASSOCIATED GRAFT VERSUS HOST DISEASE

Data Analysis

Number of reports received:	4
Number of questionnaires received:	4
Number of fatalities	4
Males:	3
Females:	1
Age range:	2 weeks-88 years
Median age:	57
Blood Centre informed:	Yes: 4 No:0
Component responsible: cases	Red cells in all

A. PATIENT DETAILS			
1.	Diagnosis and reason for transfusion		
	a)	Elective surgery	1 (+ B cell lymphoma)
	b)	Emergency surgery	
	c)	Trauma	
	d)	Haemorrhage eg GI (epistaxis) 1	1
	e)	Anaemic premature neonate (state gestation in weeks)	32 weeks 1
	f)	Exchange transfusion	
	g)	Malignant disorder of bone marrow (please specify).....	
	h)	Allogeneic bone marrow/PBSC transplant	
	i)	Autologous bone marrow/PBSC transplant	
	j)	Solid organ transplant	
	k)	Aplastic anaemia	
	l)	Hodgkin's disease	
	m)	Non Hodgkin's lymphoma (specify B or T cell)	2 (both B cell)
	n)	Other solid tumour	
	o)	HIV related	
	p)	Other (please specify)	
2.	Was this transfusion		
	a)	An emergency	
	b)	Routine	2
	c)	Unknown	
3.	Where was the transfusion given		
	a)	In-patient ward	1
	b)	Out-patient/day unit	
	c)	Intensive care unit	1
	d)	Theatre, including recovery	
	e)	Accident & emergency unit	
	f)	Scene of accident	
	e)	Other please state.....	

A. PATIENT DETAILS continued				
4.	Concurrent drug/radio therapy			
	a)	Myeloablative chemotherapy (please specify)		
	b)	Total body irradiation		
	c)	Local irradiation		
	d)	Immunosuppressive therapy		
	e)	Purine analogues (fludarabine* cladribine, 2 deoxycorformycin)	*1 - commenced 11 days after transfusion	
	f)	Other (please specify)Neonate antibiotics.....		
5.	Patient's HLA type (if known)			
	Neonate		Female (88, PM analysis)	1 unknown 1 awaited
	A locus	2, 23	1, 2	
	B locus	44. 72 BW 4,6	7, 60 (40) BW 6	
	C locus	W4		
	DR	51, 53, 15, 4	103, 9 (3, 15) ? donor	
	DP	6, 8		
	DQ			
B. BLOOD COMPONENT				
6.	In the month prior to symptoms, did the patient receive			
	a)	Red cells	all 4: 3, 3, 7 and 9 units	
	b)	Red cells, buffy coat depleted	1 (neonate)	
	c)	Red cells, leucocyte depleted		
	d)	Platelets, made from pooled buffy coats		
	e)	Platelets, made by platelet rich plasma method		
	f)	Platelets, apheresis		
	g)	Platelets, leucocyte depleted		
	h)	Platelets, HLA selected		
	i)	Fresh frozen plasma		
	j)	Cryoprecipitate		
	k)	Other. Please state approximate quantities of each.		

B. BLOOD COMPONENT continued					
7.	Are you able to identify which component was responsible for the GVHD?			Yes	No - 1 awaited
	If no, proceed to question 10.			1	
	If yes, answer questions 8 and 9.			2	
8.	Was the component transfused when it was (1 awaited)				
	a)	<5 days old			1
	b)	5-14 days old			2
	c)	>14 days old			
9.	Give HLA type of donor if known				
	Neonatal case		Female (88)	Not stated	Awaited
	HLA-A	1, 2	Not identified		
	HLA-B	44, 57			
	HLA-C				
	HLA-DR	7, 11, 52, 53			
	HLA-DP				
	HLA-DQ	7, 9			
10.	Were the components from				
	a)	HLA selected donors			
	b)	Family members			
	c)	Autologous			
	d)	From a Transfusion Service donor			4
11.	Was the patient receiving cellular components which were gamma irradiated?			Yes	No
				0	4
	If yes, answer questions 12-14.				
If no, proceed to question 15.					
12.	Was irradiation carried out				
	a)	By the transfusion centre, in a blood irradiator			
	b)	By the hospital, in a blood irradiator			
	c)	By the hospital, in radiotherapy equipment			
13.	Was the intended midplane dose				
	a)	15 - 20 Gy			
	b)	21 - 25 Gy			
	c)	26 - 30 Gy			
	d)	>30 Gy			
14.	Is the procedure quality controlled by				
	a)	Radiation sensitive labels on every pack			
	b)	Radiation sensitive labels, 1 per batch			
	f)	Other (please specify)			

C. CLINICAL FEATURES AND DIAGNOSIS			
15.	Interval between transfusion and onset of symptoms		
	a)	<5 days	
	b)	5 - 9 days	1
	c)	10 - 14 days	1
	d)	15 - 19 days	1
	e)	>19 days	1
16.	Clinical features		
	a)	Rash	4
	b)	Diarrhoea	2
	c)	Deranged LFT's	4
	d)	Pancytopenia	4
	e)	Infection	3
17.	Was the diagnosis based on:		
	a)	Histology of biopsy (specify tissue): skin	3
	b)	Detection of donor DNA i) In peripheral blood	3
		ii) In skin or other tissue	
	c)	Post-mortem histology - skin, liver, bone marrow	1
	d)	Other	
D. TREATMENT AND OUTCOME			
18.	Was the interval between onset of symptoms and start of treatment		
	a)	0 - 3 days	1
	b)	4 - 7 days	1
	c)	8 - 14 days	2
	d)	>14 days	
19.	Did the patient receive as therapy for transfusion-associated GVHD		
	a)	Methyl prednisolone	4
	b)	Immunosuppression	
	c)	Anti-lymphocyte antibodies CAMPATH + ALG	1
	d)	Other (please specify) The neonatal case also received G-CSF and an HLA matched sibling bone marrow transplant.	

D. TREATMENT AND OUTCOME continued		
20.	Outcome	
	a)	Death from infection
	b)	Death from haemorrhage
	c)	Death from other causes (please specify)
	d)	Survived with normal bone marrow function
	e)	Survived with impaired bone marrow function
		3 (1 following bone marrow transplant)
		1 -cardiac arrest secondary to sepsis.