SERIOUS HAZARDS OF TRANSFUSION

SHOT

Annual Report 1999-2000

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Affiliated to the Royal College of Pathologists

British Blood Transfusion Society • British Society for Haematology
Faculty of Public Health Medicine • Institute of Biomedical Science
Institute of Health Care Management • NHS Confederation
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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GLOSSARY OF TERMS

AML	Acute myeloid leukaemia
ATM	Automatic telling machine
ATR	Acute transfusion reaction
BCD	Buffy coat derived
BCSH	British Committee for Standards in Haematology
BMS	Biomedical Scientist
BMT	Bone marrow transplant
PHLS/CDSC	Communicable Disease Surveillance Centre of the Public Health Laboratory Service
CMV	Cytomegalovirus
CPA	Clinical Pathology Accreditation
CPAP	Continuous positive airways pressure
DAT	Direct antiglobulin test
DIC	Disseminated intravascular coagulation
DTR	Delayed transfusion reaction
ELISA	Enzyme-linked immunosorbent assay
FFP	Fresh frozen plasma
GLAM	Granulocyte, lymphocyte and monocyte assay
HLA	Human leucocyte antigen
HPA	Human platelet antigen
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
ICU	Intensive care unit
LISS	Low ionic-strength saline
MCA	Medicines Control Agency
MLA	Medical Laboratory Assistant
NBA	National Blood Authority
NBS	National Blood Service
NHSE	National Health Service Executive
PCR	Polymerase chain reaction
PDF	Packed data format
PTI	Post-transfusion infection
PTP	Post-transfusion purpura
RhD	Rhesus D
SDFFP	Solvent-detergent fresh frozen plasma
SNBTS	Scottish National Blood Transfusion Service
TA-GVHD	Transfusion-associated graft-versus-host disease
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenia purpura

1. MAIN FINDINGS AND RECOMMENDATIONS

1. Participation

Of the 426 hospitals eligible to participate, 155 (36.4%) submitted initial reports during the reporting year, an increase of 5.8% over the previous year and an overall increase of 14.3% since the scheme began. A further 150 hospitals sent "Nil to report" cards indicating that they had seen no incidents during the reporting year. Overall participation is only 72% (305/426) this year compared with 77.8% last year. This apparent decrease in participation may be misleading, however, given that response to the "Nil to report" exercise this year was comparatively poor. Only 246 hospitals (57.7% of those eligible) had returned their cards by the time this report went to press and two of these did not give information about participation.

The Health Service Circular 19981224 "Better Blood Transfusion" [1] requires hospital Trusts to participate in SHOT reporting. These figures suggest that participation is not yet universal. A formal mechanism to monitor participation does not yet exist but the Advisory Committee for Clinical Pathology Accreditation is currently addressing how best to incorporate SHOT participation within CPA standards.

Last year we were able to estimate from information gained in the "Nil to report" exercise that 90% of all red cell units issued to hospitals had been received and handled by 64.6% of hospitals eligible to report to the SHOT scheme. However, this year, due to the poor response, all we can say is that of the 246 hospitals who returned cards, 210 gave figures for units transfused which totalled 1,520,249 i.e. 49.3% of hospitals eligible to participate received and handled 55.5% of all red cell units issued to hospitals during the fiscal year 1999-2000.

2. Reports

A total of 291 initial reports was received this year, an increase of 15.5% over the 253 received last year [2] and an overall increase of 72% since the scheme began [3,4]. Once again the largest category remains "incorrect blood component transfused" with 201 reports this year, an increase of 39.6% over last year (144 reports). This year IBCT incidents contributed 69.1% of the total compared to 57.3% last year and 58.9% over the four reporting years 1996-2000. A total of 287 completed reports were analysed this year, including 18 outstanding from last year. 22 reports, for which no questionnaires were returned by the closing date, will be included in next year's analysis.

Recommendations

(i) **In line with Health Service Circular 19981224 "Better Blood Transfusion"[1] systems of Clinical Governance within Trusts should ensure a commitment to SHOT reporting and to changes in practice resulting from SHOT observations and recommendations. It is now time to implement participation in SHOT reporting as a standard for clinical blood transfusion laboratories.**

3. Incorrect blood component transfused ("wrong blood") incidents

A total of 201 cases was reported, 39.6% more than last year, enabling analysis of 200 incidents including 12 brought forward from the previous year. The continued increase in reports in this category (148% since 1996) is disproportionate to the increase in hospital participation and may have a number of explanations including heightened awareness of the importance of reporting, increasing confidence in the anonymity and confidentiality of the scheme, pressure from the Department of Health as a result of Health Service Circular 19981224 [1] and an actual increase in the number of incidents.

There were 39 cases of ABO incompatibility, a somewhat lower proportion than last year and the cumulative four year period (19.5% compared to 24% and 26.5% respectively) which resulted in 2 deaths, one definitely and one probably related to the transfusion and a further 8 cases of major morbidity from the effects of intravascular haemolysis. Over the four years there have been 8 deaths (5 definitely related to transfusion, 1 probably and 2 possibly related) and 54 cases of major morbidity from ABO incompatibility and other red cell incompatibility. Four additional cases of major morbidity this year were attributable to RhD incompatible

cause contributing 16 cases of potential RhD sensitisation over four years of reporting. These figures mask a somewhat larger number of ABO/RhD compatible and Rh D incompatible transfusions given in error which did not result in ill-effects.

This is the fourth consecutive year in which the single most important cause resulting in mis-transfusion was failure of some aspect of the bedside checking procedure immediately prior to administering the transfusion. Contributory factors were similar to those reported previously, for example confusion over patients with the same or similar names, checking remote from the patient's bedside, interruption between completion of the checking procedure and administration of the transfusion and failure to note discrepancies between compatibility and donation labels where a preceding laboratory labelling error had occurred. Unusual circumstances clearly contributed to a small proportion of these incidents but in the majority, no clear explanation for the failures was apparent. Missing wristbands or other formal means of patient identification contributed to bedside errors in 10 instances.

Multiple errors continue to contribute to bedside administration errors in 47% of cases indicating that problems still exist at all levels in the transfusion chain.

As in previous years, the withdrawal of the wrong component from its storage location in the hospital preceded a bedside administration error in a significant proportion of cases and there was a notable absence of formal checking procedures at this point in two thirds, contravening recently published BCSH guidelines.[5]

Failure to request irradiated components for patients at known risk of TA-GVHD, notably those being treated with purine analogues, patients with Hodgkin's Disease and those who had received or were due to receive stem cell transplants occurred in 26 cases and in 1 patient, who survived, a diagnosis of TA-GVHD could not be excluded.

Sampling errors are a small but important cause of ABO incompatibility which will not be detectable at laboratory level if the patient has not been previously grouped or if the laboratory historical record has not been consulted. Phlebotomy errors resulting in mis-transfusion are not confined to blood grouping/crossmatch samples. Erroneous haemoglobin results from wrong samples may lead to unnecessary transfusions.

Laboratory errors, comprising 26.8% of the total, included technical errors, sample transposition and labelling mistakes, in addition to a variety of other procedural errors and selection/issue of inappropriate components. Almost half of these errors occurred out of hours although the available data cannot be used to interpret the significance of this finding.

Unnecessary transfusions were noted on a number of occasions and included anti D immunoglobulin administered unnecessarily in 12 patients for a variety of reasons which included mis-prescribing, sampling error, mis-grouping in the laboratory, misinterpretation of a verbal report and mis-identification at the bedside. Additional examples of unnecessary blood component administration occurred as a result of erroneous haemoglobin results and bedside identification errors.

There were a variety of errors in requesting, selection, issue and administration of blood components. These included failure to appreciate the criteria for irradiation and anti D immunoglobulin administration, the significance of pre-existing red cell antibodies, the correct use of emergency group O red cells and occasionally the issue of the wrong component altogether. Together these suggest a basic lack of knowledge and understanding of transfusion issues amongst individuals responsible for different steps in the transfusion process.

"WRONG BLOOD INCIDENTS ARE WITHOUT EXCEPTION AVOIDABLE ERRORS"

Recommendations

(ii) It is essential that every hospital becomes familiar with and puts into practice existing guidelines in the field of blood transfusion to minimise the possibility of human error.

BCSH guidelines have been published[5] on how to achieve this. They were reproduced in last year's SHOT report[2] and have since been widely distributed to hospitals but as yet there is little evidence that they are having an effect on reducing the number of "wrong blood" incidents.

(iii) Hospitals must ensure that ALL staff handling blood and blood components receive correct training and regular review/retraining

(iv) Existing procedures should be re-examined for flaws which could lead to systems errors and thus inevitable human errors

(v) Hospital Transfusion Committees should be managerially empowered to play a key role in ensuring the safety of the transfusion process.

THE BEDSIDE CHECK IS THE FINAL OPPORTUNITY TO PREVENT A MIS-TRANSFUSION

(vi) Every hospital must have a formal policy for the bedside check which must be rigidly enforced at all times.
This must ensure that blood components are correctly allocated and identified and be capable of detecting preceding compatibility labelling discrepancies and relevant previous transfusion information such as previous group and antibody screening reports. The dangers of staff becoming distracted, even after correct checking, must be recognised and environmental deficiencies which contribute to this should be corrected.

(vii) Every patient should be uniquely identified using a wristband or equivalent.
Retaining wristbands or their equivalent in the operating theatre situation is essential and a formal means of identification should be pursued for all patients in theatre and A+E departments. Reliance should not be placed on familiarity with the patient in the outpatient setting and there should be no exception to the wearing of wristbands.

USE OF INFORMATION TECHNOLOGY AT THE BEDSIDE WILL PREVENT HUMAN ERROR

(viii) Computerised systems are available to ensure safe transfusion at the bedside. Pilot studies have been conducted at a few sites in the U.K. These systems now merit further study and development.
Their potential value beyond the transfusion setting, for example in reducing drug administration errors, should be explored as this will improve their cost effectiveness.

PREVENTION OF ERRORS IN EARLIER STEPS OF THE TRANSFUSION PROCESS

The bedside check, even when computerised, will not detect all errors at earlier steps of the transfusion process so equal importance must be afforded to these other vital steps.

(ix) Individuals responsible for the prescription and request of blood components must be familiar with their correct use and with the special requirements of their patients.
These should conform with BCSH and other guidelines and special requirements should be flagged on the clinical and laboratory records. A new BCSH guideline on the clinical use of red cells is in press and a pre-publication version is reproduced, with permission, in Appendix 11.

(x) Individuals responsible for taking samples for transfusion testing must at all times follow strict procedures to avoid confusion between patients.
The same degree of care should be afforded to the taking of other blood samples as incorrect results from these may lead to unnecessary blood transfusion.

(xi) Blood banks must continue to be vigilant in reviewing procedures, systems and training to prevent sample handling and technical errors.

(xii) **Telephoned requests for blood components must be formally recorded and incorporate all relevant information including special requirements.**
Great care must be exercised when acting on verbal results.

(xiii) **Every hospital should ensure that standards are set for correct collection of blood components from hospital storage sites; this should incorporate formal identification procedures.**
Staff carrying out this important function must be aware of the key role they play in ensuring the safety of the transfusion process and must receive appropriate training in this procedure. Computerised systems exist to improve the safety of this process and can be linked to bedside identification systems for both blood sampling and administration of blood components. These merit further evaluation.

SETTING "WRONG BLOOD" INCIDENTS IN CONTEXT

Recommendations

(xiv) **Basic "epidemiological" research is needed into the timing and location of transfusions in the hospital setting.**

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

4. Immune complications of transfusion

Reports of acute transfusion reactions have remained at the same level as last year (34) with delayed haemolytic transfusion reactions slightly down (from 31 to 28). Cases of transfusion related acute lung injury have increased a little (from 16 to 19) whilst there were fewer cases of post-transfusion purpura (5 reported this year and 10 last year). This is the first year in which no case of transfusion-associated graft-versus-host disease have been reported. As has been the case in each of the previous three years, immune complications do not generally reflect poor practice and cannot be predicted in a particular individual.

Fresh frozen plasma and platelets are both "over-represented" in the acute transfusion reaction group, compared to red cells which are administered much more frequently. It is possible that patients are experiencing life-threatening reactions to components which perhaps they did not require, although it is not the purpose of SHOT to attempt to assess the appropriateness of transfusions. Acute reactions are under-investigated and it is generally unclear why they have occurred. Some may, in fact, have been due to bacterially-infected components or episodes of transfusion-related acute lung injury. Kidd antibodies, undetectable by current methods, remain the major cause of delayed haemolytic transfusion reactions.

Of the 18 new cases of TRALI analysed in this report, there was major morbidity in 12 and death possibly as a result of the transfusion in 6, although in 3 cases the diagnosis of TRALI was in doubt. Transfusions of red cells as well as platelets and FFP were implicated. 57 cases over 4 years, with major morbidity in 43, death definitely attributable to the transfusion in 4 and possibly attributable in 10 makes TRALI the second most common cause of major morbidity/death exceeded only by ABO incompatibility. The difficulty in making a clinical diagnosis of TRALI is highlighted in this report and was hampered by inconsistent investigation.

The small number of cases of PTP this year (5) is probably within year-to year statistical variation. There were no new findings this year, compared to last, with the exception of a single case of refractoriness to platelets due to anti HPA 1b which responded to a combination of HPA selected platelets and intravenous immunoglobulin. The diagnosis of PTP in this case overlapped with that of refractoriness and resulting intracerebral haemorrhage.

No new cases of TA-GVHD were reported this year although it is too early to suggest that universal leucodepletion may be a contributory factor to this apparent reduction. Of the 12 cases of TA-GVHD reported since 1996, none occurred because of failure to provide irradiated components for a patient whose diagnosis

falls within current BCSH guidelines[6] or because of failure of the irradiation process. 5 of the 12 cases arose in patients with B cell malignancy raising the question as to whether such patients should have gamma irradiated components. In view of the partial protection probably provided by leucocyte depletion, however, it would be reasonable to await further SHOT data over the next 2 years to see whether the absence of new cases of TA-GVHD is maintained. However, there are still a number of episodes each year when irradiation is accidentally omitted, usually because of a failure to request irradiated components and TA-GVHD could not be excluded in one of these cases.

Recommendations

(xv) **Clinicians involved in transfusion should be aware that FFP and platelets carry a relatively high risk of inducing a severe adverse event and should be familiar with national guidelines relating to their correct use.**
Relevant points from these guidelines could usefully be included in hospital transfusion guidelines or transfusion laboratory handbooks in order to improve accessibility and compliance.

(xvi) **A guideline on the appropriate investigation of acute transfusion reactions is required and is currently in preparation.**
Symptoms and signs of acute reactions to FFP and platelets may overlap with TRALI or even bacterial contamination incidents, neither of which can be confirmed without proper investigation.

(xvii) **Laboratories should ensure that any antibodies which may be masked by a detected antibody(ies) have been excluded by the use of additional panels and techniques (e.g. enzyme-treated cells).**
Development of screening techniques in order to improve the detection of extremely low levels of Kidd antibodies should be considered by serologists and manufacturers of screening systems.

(xviii) **In patients dependent on platelet transfusion, HPA antibodies may be a cause of refractoriness to random donor platelets.** Investigation of refractory patients should include a search for HPA antibodies if there are poor responses to HLA selected platelets.

(xix) **Patients at risk of TA-GVHD who are receiving shared care between a transplant/oncology centre and their referring hospital should carry a card to indicate their need for irradiated components. (See Appendix 10)**

(xx) **Full reporting of TA-GVHD continues to be important and investigation of suspected cases should be discussed with the nearest UK Blood Service Histocompatibility and Immunogenetics laboratory.**

(xxi) **The question of gamma irradiation of blood components for patients with B lymphoid malignancies should be kept under review.**

5. Transfusion-transmitted infections

Transfusion-transmitted infections are rare, contributing only 1.4% of total transfusion incidents reported this year. Only 4 confirmed cases were recognised during this period all of which were cases of bacterial contamination, with one death as a result of *Enterobacter aerogenes* contamination of platelets. Following investigation of a further 22 incidents of suspected post-transfusion infection, of completed cases, 47% were shown not to be caused by transfusion and in 32% the investigation was inconclusive. Additionally, in Scotland during this year, one confirmed case (a hepatitis B virus transmission from a donor in the early incubation period of acute infection with two infected recipients) was recognised, two incidents were shown not to be caused by transfusion, and one investigation is pending completion. In addition there were 14 cases of post-transfusion reactions suspected, but not confirmed, to be due to bacterial contamination.

The cumulative total of bacterial contamination incidents over the period 1995-2000 is 15 cases, with 5 fatalities, making this by far the largest cause of transfusion-transmitted infections and of transfusion-related deaths in this category. The majority of incidents involved platelets (12/15 cases), generally at least 3 days old,

although complete information is lacking. Bacterial contamination incidents have continued to be reported following the implementation of universal leucodepletion.

Recommendations

(xxii) **Hospitals should consult guidelines and the blood service about the investigation of suspected cases of bacterial contamination of blood components, including the sampling and storage of implicated units.**
The quality of investigation of such reactions is variable. A NBS guidance document entitled *Bacteriological investigation of adverse reactions associated with transfusion* has been agreed in consultation with the PHLS and the Association of Medical Microbiologists (AMM) and has been distributed to blood centres (see Appendix 9)

(xxiii) **Consideration of strategies to prevent transfusion transmitted bacterial infections should be given appropriate priority.**
These include optimising donor arm cleansing procedures and the bacterial testing of blood components, particularly platelets.

(xxiv) **Clinicians should continue to report all cases of suspected post-transfusion infections to their local blood centre.**
Numbers of cases are small and national collation of data needs to continue over several years before a picture of the extent and nature of the infectious complications of transfusion can emerge.

6. Learning from "near miss" events

"Near miss", "close calls" or sentinel ("warning") event reporting schemes are embedded in industries such as aviation, nuclear power and petrochemical processing but are relatively new to the health care setting [7]. The SHOT scheme is still in its infancy with respect to learning from "near miss" data. Collection of this data began on a small scale last year and continued on the same scale this year with a total of 302 near miss reports over the two years, 1998-2000. With approximately 54% (162/302) being sampling errors, failure to follow correct phlebotomy protocols remains the major cause of "near miss" events. The expansion of near miss reporting to include all hospitals from 1 October 2000 should provide valuable additional data to assist hospitals in designing safer systems to reduce the possibility of human error.

7. Priority setting in blood safety

The SHOT scheme has become established as a robust mechanism for the reporting of transfusion hazards. The information gained has been used to make recommendations which will improve the safety of the transfusion process and many of these can be carried out at local level. However, some of the proposals require policy decisions to be taken centrally and as yet the UK lacks a single strategic framework for blood safety which incorporates all relevant expertise, can evaluate conflicting priorities and advise on the implementation of those changes which will be most effective in increasing blood safety.

Recommendations

(xxv) **There remains a need for an overarching approach to decision making in relation to blood safety. A national unified body, with relevant expertise, could prioritise new developments in this field.**

2. FOREWORD: ACTION IS NEEDED TO IMPLEMENT SHOT RECOMMENDATIONS

The Serious Hazards of Transfusion (SHOT) scheme maintains its momentum and the fourth annual report will be launched with an open multidisciplinary educational meeting to maximise dissemination of the SHOT findings and recommendations. The UK Transfusion Services have now given a clear commitment to the ongoing funding of SHOT. This paves the way for further studies of transfusion hazards, in line with the recent NHS initiative to create a new national system for reporting and analysing other adverse health care events, to make sure key lessons are identified and learned. [8]

The 1999 / 2000 reporting year saw increases in both the number of hospitals submitting reports (by 5.8% over the previous year and 14.3% since the scheme began) and the overall number of reports received (by 15.5% to 291). The increase in reports is almost entirely accounted for by 'wrong blood' incidents, from 144 to 201. It is unclear at present whether this represents greater user confidence in the scheme, or a true increase in hospital errors. These cases remain our greatest cause for concern with ABO and / or other red cell incompatibility over the four reporting years causing 8 deaths (5 definitely related to transfusion, 1 probably and 2 possibly related) and 54 cases of major morbidity, some requiring intensive care unit admission. The current report suggests that the British Committee for Standards in Haematology (BCSH) guideline "The administration of blood and blood components and the management of the transfused patient" [5] which gives sound practical advice and can be used as a basis for staff training, has not been put into place in a number of hospital Trusts. Further, despite the NHSE circular 19981224 "Better Blood Transfusion",[1] sent to all Trusts towards the end of 1998, which recommended universal participation in SHOT and implementation of its recommendations by April 2000, this year, only 72% of all hospital Trusts have demonstrably participated in SHOT. Thus, whilst we now have a mechanism (SHOT) in place to monitor transfusion errors, we do not appear to have developed appropriate mechanisms to ensure implementation of change to reduce transfusion errors.

SHOT has repeatedly recommended that virtual elimination of transfusion errors can only be achieved by investment in computer technology. Although not cheap, these systems have wider application in the prevention of drug errors and can potentially link patient/pathology results – allocation of a laboratory test result to the wrong patient can be just as dangerous as a mis-transfusion. Investment in this area may be self-funding in the long term. SHOT held a workshop in September 1999 on 'Improving the Safety of Transfusion at the Bedside', which included demonstrations of several bar code systems designed for the purpose. Following this, individual pilot projects by a few enthusiasts, detailed in this report (chapter 3) suggest that whilst these systems show promise, further development is needed prior to widespread implementation. SHOT's hope that the NHS Executive would take a lead in this area has clearly not come to fruition. It is now timely for the NHS Executive to ensure speedy development of appropriate computerised systems for patient identification.

What new initiatives in blood safety have been implemented since the last SHOT report? A National Blood Service (NBS) guidance document entitled "Bacteriological investigation of adverse reactions associated with transfusion" (see Appendix 9) has been agreed in consultation with the National Association of Medical Microbiologists. Work on other strategies to prevent transfusion transmitted bacterial infections, including methods for donor arm cleansing and testing of blood components for bacterial contamination, continues. A patient information leaflet and card for patients needing gamma irradiated blood components to minimise the risk of transfusion-associated graft-versus-host disease has now been introduced (see Appendix 10). A BCSH guideline on the clinical use of red cell transfusion is in press (see Appendix 11). SHOT has welcomed the recent implementation of national and regional transfusion user groups with their remit to promote safe and effective blood transfusion practice, to disseminate guidelines and to promote education and training. Overall, these groups should provide a powerful framework for improving all aspects of blood safety and complement the SHOT scheme. We are also pleased that the Advisory Committee for Clinical Pathology Accreditation (CPA) is addressing how best to incorporate SHOT participation within CPA standards.

Analysis of 'Near Miss' (for definition see page 96) reports from 22 hospitals, detailed in the third SHOT Annual Report, highlighted that the single major problem area was patient blood sampling, in contrast to blood collection/administration as the major problem identified by analysis of 'wrong blood transfused' incidents. The complementary information from analysis of 'Near Miss' events should provide valuable data to guide a targeted

approach to improvements in transfusion safety. To extend and validate the data from our limited 'Near Miss' study, we invited all hospitals to report 'Near Misses' from 1 October 2000.

The work of SHOT could not proceed without the enthusiasm of hospital staff who take the time to complete report forms and detailed follow-up questionnaires and we would like to thank all participants. SHOT has established that we are able to sustain a robust mechanism for reporting transfusion hazards. However, the reporting of transfusion hazards cannot be seen as an end in itself. The SHOT scheme can only be of value if the information gained is used to guide allocation of resources to implement those changes which will be most effective in the quest for safe blood transfusion.

GRO-C

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3. EXPERIENCE WITH ELECTRONIC SYSTEMS TO CONTROL THE CLINICAL TRANSFUSION PROCESS

Dr Derek R Norfolk, Leeds General Infirmary

Getting "the right blood into the right patient at the right time" is a complex process with much scope for error[9]. Sequential SHOT Reports have highlighted errors in initial blood sampling of the patient, collection of blood from the Blood Bank or satellite refrigerator and the final "bedside" identity check as the root cause of many transfusion accidents. Whilst education, training and dissemination of guidelines are important, humans will always be fallible and the remedy lies in designing safer, error-resistant systems[10,11]. A multidisciplinary meeting held by the SHOT Working Group in September 1999 identified that computerised systems, developed for other industries, could have wide application in the healthcare setting. The 1998/99 SHOT Report called for the increased allocation of resources to develop electronic "positive identification" systems to control the clinical transfusion process. Currently available systems are largely based on barcode reading technologies developed in the commercial sector. In this short report, I review recent experience of developing and evaluating such systems in the UK

Systems to control patient sampling and bedside identification

Although several systems are commercially available or in development, much of the current experience in the UK is with the "I-TRAC" (now "Safe Track") systems developed by IBG-Immucor. This technology uses hand held (Palm Pilot) computer/barcode readers and mini-printers which produce adhesive barcode labels for the blood sample, patient ID bracelet and blood pack. In line with the BCSH guidelines[5] the system requires **all** patients undergoing transfusion to have an identity wristband. The hand-held computers can communicate with the central laboratory processor via wireless infra-red links. At the bedside check there is positive ID of the patient, blood unit and healthcare worker and the system only authorises transfusion if there is complete concordance. The palm pilots can also prompt the nurse to perform appropriate clinical observations during the transfusion and later download the observations to a permanent central record for clinical and audit purposes.

During 2000 this technology was evaluated in at least three UK centres, including Leeds. In early 2001 the system will be piloted at the John Radcliffe Hospital, Oxford (NBS/Oxford/Cambridge collaboration to evaluate clinical transfusion technologies) and Morriston Hospital in Swansea.

The Leeds experience, using an earlier generation of the system, was generally positive. Both patients and nurses in a busy Clinical Haematology Day-Case Unit were enthusiastic about the concept of electronic checking and outpatients were happy to wear ID wristbands. Training was simple and concise – essential in a busy, pressurised setting. Practical problems included difficulties in reading barcodes on curved or twisted wristbands. Patients were quick to propose solutions, such as inserting a credit card underneath the wristband to flatten it and allow first-time reading. The proliferation of barcodes on modern blood bags was an occasional problem. In clinical practice it is essential that barcodes are read at the first attempt or delays and frustration occur. The mini-printer batteries tended to run down during busy sessions. Although nurses found the new system slower and more cumbersome, this was partly due to using it in parallel with conventional checking during the trial. As expected, performance improved with practice and future technical improvements will overcome many of these problems. New developments of this technology include the use of PDF 2-dimensional barcodes that can contain all the demographic information to be compliant with guidelines, reducing the number of scans from 4 to 1. To improve the safety of sample collection a 15 second timer forces the operator to take the scanner and printer to the bedside and produce the label by the patient. These systems will clearly find a place in "routine" practice but further development is needed to facilitate use in acute or emergency settings where multiple units are transfused quickly (and the need for exquisitely good ID procedures is highest). Keys to successful introduction will be reliability and user-friendliness. Training and accrediting clinical staff will be a major challenge given the clinical pressures and high staff turnover in NHS hospitals.

Blood Tracking Systems

It is essential that all hospital Blood Banks have a system to "track" blood components throughout their journey from laboratory to patient via satellite refrigerators or stores in clinical locations. Current guidelines state that blood should not re-enter the system (i.e. be crossmatched for other patients) if it has spent more than 30 minutes outside an accredited blood refrigerator. Most hospitals in the UK have a "paper-based" system whereby staff collecting or returning blood to refrigerators fill in forms to indicate the time of the transaction. Compliance with such systems is often poor and some hospitals have no system at all. In most Trusts many thousands of pounds worth of blood would be wasted annually if there was strict adherence to the principle of only re-crossmatching units with a perfect storage record. Collection of blood from satellite refrigerators is also a major root cause of transfusion accidents. Many hospitals have limited control over (or knowledge of) which types and grade of staff collect or return blood to storage locations. A number of electronic systems to control this process have been developed over recent years, but none has found widespread acceptance in the clinical setting.

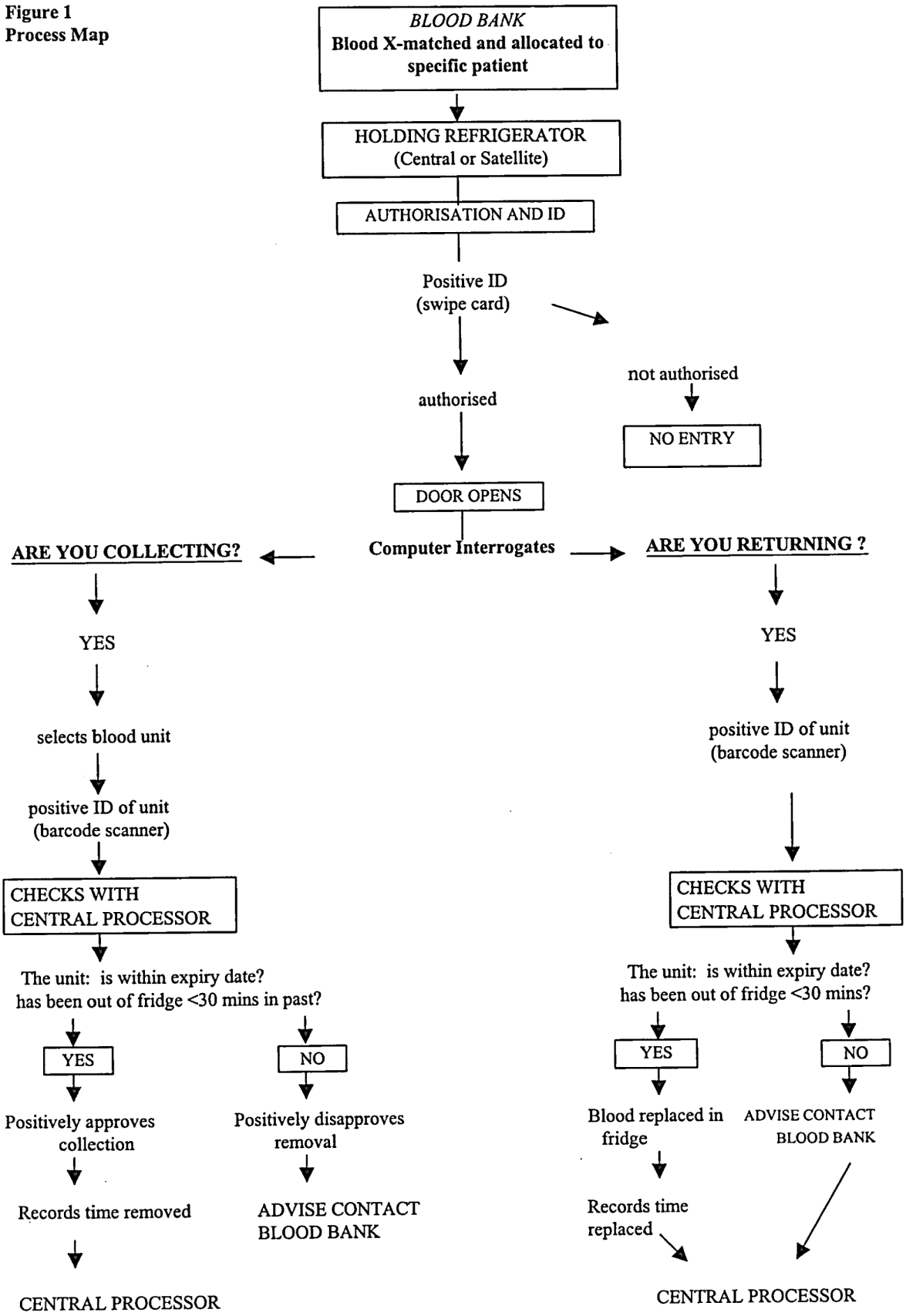
In 2000, the Leeds Teaching Hospitals NHS Trust, one of the largest in the UK and based on 6 sites, was successful in achieving "Modernisation of Pathology" funding from the NHS Executive to commission a comprehensive blood tracking system. The Trust will work closely with the manufacturers in developing a system for hospital use and disseminate their experience with implementation to other NHS users. Our first step was to document the surprisingly diverse groups of clinical and support staff who access blood refrigerators. We then drew up a "process map" of an ideal system (Figure 1) based on positive ID of user and blood units. Key specifications for the new system include computers at each blood refrigerator with touch screen control (similar to "hole in the wall" bank ATMs) linked to the central laboratory processor. Staff accredited to use blood refrigerators will be identified by barcodes incorporated in their security badges. Flatbed scanners, similar to supermarket technology, will read the barcodes on bags removed from or replaced in the refrigerator. All transactions will be monitored by the central processor. Locks on the refrigerator will only allow access to authorised users (with an over-ride for absolute emergencies) and alarms will sound at the refrigerator and Blood Bank if illegal transactions such as removing outdated or mis-stored blood, are attempted. In such instances the system will "ask" (possibly using voice simulation) the user to immediately contact the Blood Bank. The system has to be user-friendly and absolutely reliable in practice with defaults to open the refrigerator-locks in the event of power or computer failure. Our experience with pilot-systems is that all but the most ardent technophobes find the technology acceptable and most find it easier than the previous manual systems. It is already clear that the success of this project will hinge on training, and maintaining the competence of, clinical staff in a busy and complex organisation with high staff turnover. Successful implementation will allow us, for the first time, to define, train and accredit those staff whom we really wish to access blood refrigerators. We also intend to use this initiative to raise the profile of transfusion safety in the Trust. Although the system is commissioned solely for "blood tracking" it will be readily extended to ensuring the correct identity of blood collected from satellite refrigerators (a key SHOT objective) and controlling access to an inventory of "compatible" units as computer-crossmatching is introduced. Indeed, it is possible to envisage systems that will only physically release units known to be safe for an individual patient.

Summary and Conclusions

Computer-based systems, employing technology for positive identification, will soon control the clinical transfusion process "from vein to vein". It is essential that clinical units work closely with manufacturers to develop systems of high clinical utility and acceptability. Transfusion is only one of many exciting possibilities for the use of these technologies to improve the safety of clinical systems. Indeed, transfusion is already a very safe process compared to areas such as drug administration. It seems essential that as multiple electronic ID systems are introduced to the clinical workplace, they share common standards, hardware and computer-links wherever possible. A proliferation of "bespoke" systems with multiple hand-held computers at the Nurses' station could seriously compromise safety and utility. All of those developing systems should communicate effectively and work in collaboration for the benefit of patients and staff alike.

(The views expressed in this review are those of the author and do not imply the endorsement of SHOT for any particular system or commercial organisation).

Figure 1
Process Map



4. AIMS, EDUCATIONAL ACTIVITIES AND PUBLICATIONS

Aims. The Serious Hazards of Transfusion (SHOT) scheme was launched in November 1996. SHOT is a voluntary anonymised 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.

Educational Activities. SHOT continues to receive widespread coverage not only in the UK but also overseas. The following is a list of national and international meetings during 1999 and 2000 at which members of the SHOT team have presented results from the reports as well as giving a broader view of transfusion safety.

1999

January:
- National Haemovigilance Meeting, Athens

March:
- Royal College of Nursing Congress, Harrogate

April:
- Transfusion Nurses Forum, Edinburgh
- British Society for Haematology Annual Scientific Meeting, Brighton

May:
- Blood Transfusion in the Surgical Patient: Lessons from the SHOT reporting system, University of Liverpool
- British Blood Transfusion Society Technology Special Interest Group, Aston University, Birmingham
- Spanish Blood Transfusion Society, Madrid

June:
- Scottish Society of Anaesthetists, Conference Centre, Stirling
- 'Crises in Haematology' Meeting, Royal College of Pathologists, London
- National (Canadian) Transfusion-Transmitted Surveillance System Steering Committee Meeting/CJD Planning Meeting, Winnipeg, Canada

September:
- BBTS Annual Scientific Meeting, Edinburgh
- III^{EME} Congrès National de Securité Transfusionelle et d'Hémovigilance, Lille

October:
- Advancing Laboratory Practice in Haematology, Guernsey

November:
- Launch of the Haemovigilance Scheme for the Republic of Ireland, Royal College of Surgeons, Dublin
- Trasfusione Sicura: la prevenzione dell errore in reparto: Haemovigilance in the UK, Milan
- Vertrouwd en Vernieuwend: Haemovigilance in the UK, Utrecht
- 'Resuscitation Fluids: State of the Art', Royal College of Surgeons, London

2000

February	• European School of Transfusion Medicine, Brussels, Belgium
March	• Le Risque Sanitaire en Europe, Les Systèmes d'Hémovigilance, Paris, France
April	• Institute of Biomedical Scientists Blood Group Serology Conference, Durham, UK
May	• Canadian Society for Transfusion Medicine, Canadian Blood Services and Hema Quebec joint meeting, Quebec, Canada • Pathology 2000, Birmingham, UK • Royal College of Nursing Transfusion Forum Annual Meeting, Bournemouth, UK
June	• 5th Annual Meeting of the European Haematology Association, Birmingham, UK • The SHOT report - is it helpful? Contribution to half day "teach in" at Countess of Chester Hospital, Chester, UK • 32nd Annual Course 'Advances in Haematology', Hammersmith Hospital, London, UK • Advances in Haematology for nurses, Hammersmith Hospital, London, UK
July	• 26th Congress of the International Society of Blood Transfusion, Vienna • WAA/HSANZ/ASBT 2000 Congress, Perth, Western Australia
August	• ISH 2000: World Congress of the International Society of Haematology, Toronto, Canada
September	• BBTS 18th Annual Scientific Meeting, Nottingham, UK • European Haemovigilance Network workshop, Montpellier, France
October	• Royal Society of Medicine / British Blood Transfusion Society joint meeting, London, UK • Royal College of Nursing Study Day on Blood Safety, Oxford, UK
November	• 53rd Annual Meeting of the American Association of Blood Banks, Washington D.C., U.S.A.
December	• Quantifying the risk - the SHOT report. Welsh Blood Service Customer meeting

Publications

Cohen H, Love E, Williamson L, Jones H, Soldan K, Serious Hazards of Transfusion (SHOT): A Scheme for Haemovigilance, International Society of Haematology 2000, Education Program Book, 49-53

Williamson LM, Cohen H, Love EM, Jones H, Todd A, Soldan K. The Serious Hazards of Transfusion (SHOT) initiative. The UK approach to haemovigilance. Vox Sanguinis 2000;78(S2) 291-295

Abstracts

Love EM, Williamson LM, Cohen H, Jones H on behalf of the SHOT Steering Group. The Serious Hazards of Transfusion (SHOT) reporting scheme: outcome of the first three years of reporting, Transfusion Medicine 2000, vol 10, supp 1, 012

Love EM, Williamson LM, Cohen H, Jones H on behalf of the SHOT Steering Group, SHOT Office, Manchester Blood Centre, UK haemovigilance in the UK: what have the first three years of the Serious Hazards of Transfusion scheme (SHOT) achieved? Transfusion 2000, 40, 10S: 44S (AABB Washington)

Love, EM. Williamson LM. Cohen H. 2000 The contribution of "wrong blood" episodes to transfusion morbidity / mortality. Abstract 456, The Haematology Journal, Vol 1, Supp 1, June 2000, p119

Love EM, Williamson LM, Cohen H, on behalf of the SHOT Steering Group. The Serious Hazards of Transfusion (SHOT) scheme: lessons from the first three years, Vox Sanguinis 2000:78/S1/00,0147

5. OVERALL ORGANISATION AND REPORTING SYSTEM

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. A recent welcome addition is a representative from the Institute of Health Service Managers. 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.

In the first three years funding was provided by the blood services of the United Kingdom and the Republic of Ireland supported by generous grants from the British Society for Haematology and the British Blood Transfusion Society. An additional grant from the Department of Health supported the launch of last year's report which coincided with WHO Blood Safety Day. It has now been agreed that future financial support for SHOT will be provided by the four United Kingdom Blood Services on a pro-rata basis according to the number of red cells units issued.

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 as well as public hospitals in Guernsey, Jersey and the Isle of Man are invited to report. Until last year, when its own haemovigilance scheme was launched, the Republic of Ireland also contributed reports.

SHOT invites reports of major adverse events surrounding the transfusion of single or small pool blood components supplied by Blood Centres (red cells, platelets, fresh frozen plasma, methylene blue FFP and cryoprecipitate). It does not cover complications of fractionated plasma products (coagulation factors, albumin, immunoglobulin); as licensed medicinal products, these are already covered by the 'Yellow Card' system of the Medicines Control Agency. Cases in which Anti D immunoglobulin is administered to the wrong patient, however, are reported under the category of Incorrect Blood Component Transfused. Adverse reactions to solvent-detergent treated fresh frozen plasma (SDFFP) are also covered by the "yellow card" scheme. However, for purposes of comparison, complications of treatment with SDFFP should also be reported to SHOT.

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
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
10. autologous pre-donation incidents

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 Blood 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. In Scotland reporting of suspected and confirmed incidents of transfusion-transmitted infection is managed through the Regional Transfusion Centres with information being collated by the National Microbiological Reference Unit. Details of numbers and types of incidents thus reported are provided to NBA/PHLSC CDSC on an annual basis for the purpose of inclusion in the SHOT report.

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 on the 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 or when some clarification is needed, the SHOT staff approach the local contact named on the report form. Once complete, the information in the questionnaire is entered in an anonymised way on to the SHOT database (see Figure 3).

The SHOT staff may offer to visit the reporting clinician, to assist with the completion of the questionnaire.

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

Data are stored in a password-protected database in a secure location.

The help of the IT staff of the National Blood Service Northern Zone is gratefully acknowledged.

Once all the information has been gathered about an event and entered onto the database without patient, staff or hospital identifiers, all reporting forms and other paper records which contain any identifiers are shredded. The questionnaires (which have any possible identifiers removed) are kept in a secure container until data analysis for the report is complete after which they 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.

Limitations of the SHOT system

Reporting to the SHOT scheme is voluntary. We acknowledge that many incidents may go unrecognised or unreported, and that the reports analysed cannot provide a full picture of transfusion hazards.

Following consultation and after assessment of responses to the first report, the questionnaires were revised for use during the second reporting year. It has since become clear that continual revision of questionnaires is required and arrangements have been made to revise and adapt the forms on an annual basis.

Case assessment. Each case is assessed to ensure that it meets the case definition at the top of each chapter. Some reported cases which do not meet these definitions or which are in some other respect not strictly within our remit may be included for educational purposes, but this is made clear in each chapter. Whilst the

questionnaires seek a full picture of each reported transfusion hazard, a critical appraisal is not undertaken by the SHOT co-ordinators with respect to imputability i.e. to say whether an incident is attributable to the transfusion. However, those completing the questionnaires are asked to state their opinion on the presumed cause of the incident and, this year, we have asked reporters of fatal cases to assess the imputability of the transfusion to the death.

'Nil to Report' Card

From the second year of reporting onwards we have tried to ascertain the percentage of hospitals contributing to the SHOT reporting scheme. A 'Nil to Report' card and covering letter is sent to the named consultant haematologist at all hospitals held on the SHOT mailing list (424 in 1997/1998 and 432 in 1998/1999 and 426 in 1999/2000). The consultant haematologist was asked if he/she had reported any adverse events to SHOT during the period 01/10/99 to 30/09/00 or, if no adverse events had been seen, to return the card as 'nothing to report'.

In an attempt to provide a denominator against which transfusion risk could be assessed, we also request information on the number of red cell units transfused per annum from all participating hospitals. In addition the card is used to ask the hospital if it would like to receive a SHOT receipt as proof of participation in the scheme. For this purpose an address label containing the hospital name and address is provided. On returning the 'Nil to Report' card, hospitals requiring a receipt also return the address label which is then used to send a receipt. No records are kept by the SHOT office concerning receipts and, once data from the report cards has been entered onto an anonymised spreadsheet, the cards are shredded. This year we gave hospitals the opportunity to tell us whether they had seen any incidents which they had felt unable to report and why.

The 'Nil to Report' exercise is repeated annually with minor changes to keep all hospitals informed of the latest initiatives in the SHOT reporting scheme and to prompt them to report any adverse events. The results of this exercise are detailed in Chapter 6.

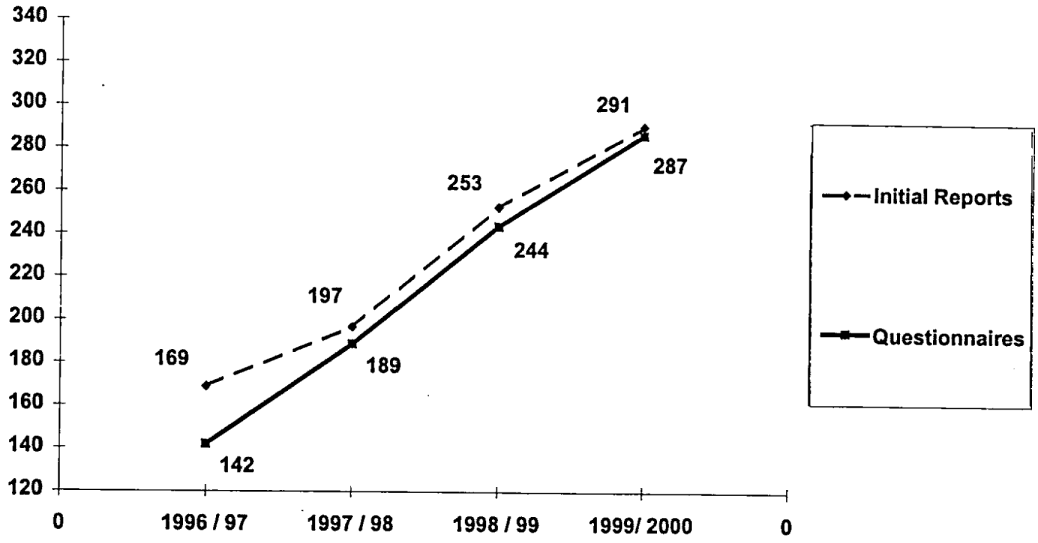
Dissemination of results

Approximately 1500 full reports and 2500 summaries are printed annually and distributed, free of charge, to hospital haematologists and medical laboratory scientific officers in charge of hospital blood banks, chairs of professional bodies and others involved in the practice of blood transfusion. In addition summaries are sent to Trust Chief Executives. A small charge is made for full reports sent to non-NHS agencies and individuals. SHOT reports are made freely available on SHOT's website and those involved in the practice of transfusion medicine are encouraged to make use of the material for educational purposes. In addition members of the SHOT Standing Working Group and Steering Groups are frequently asked to present data at a variety of educational meetings both in the UK and abroad.

Workload and staffing

Since the inception of the SHOT scheme in 1996 there has been a year-on-year increase in the number of reports. There may be any number of reasons for this such as heightened awareness of the importance of reporting, an increase in confidence in the guaranteed anonymity of the scheme, pressure from the Department of Health [1] or perhaps even an increase in the number of incidents occurring although this last reason is purely speculative and is unlikely, in itself, to account for a total increase of 72% in four years. This information is shown graphically is Figure 2

Figure 2
Increases in reporting year by year:



Initial Reports

In the second year there was an increase of 17% over the first and in the third an increase of 28%. The fourth year has seen yet another increase of 15% which is surprising perhaps given that we reported a participation rate of 78% last year. Not all of these reports will go on to produce completed questionnaires for analysis but they still have to be processed in the meantime.

Questionnaires

The numbers of reports which are eventually analysed as valid SHOT reports (whether reported by questionnaire or by letter) has also increased year on year. Year two saw an increase of 33% in analysed incidents, year three was up 29% and year four is up again, this time by 18%.

Consequences

At the same time as having to process an increasing number of reports, with the consequent increase in data handling, the SHOT office continually strives to improve data capture to ensure that it is accurate, consistent and retrievable.
The scheme is now entering its 5th year of reporting and has moved on considerably since the early years both in volume of reports and in its remit. It has been demonstrated clearly that there is a will among professionals in the field for SHOT to take on a wider role in investigating a variety of issues surrounding blood safety. A topical example is in the proposed development of questionnaires to cover cell salvage techniques and acute normovolaemic haemodilution (ANH). Another recent proposal involves the collection of data from all participating hospitals who experience "near miss" events. The volume of data from this project is likely to be much larger than that currently generated by errors which involve actual transfusion. One estimate based on the number of reports received in our smaller study this year puts the figure at approximately 2000 submissions. New and additional projects such as these are an integral part of the evolving nature of the scheme. In addition there is now a need for SHOT to analyse the wealth of data which has accumulated over the first four years and to undertake more in depth analysis of the different error reporting categories, particularly for IBCT. In recognition of this increasing need for resources, staffing levels in the SHOT office have been increased in recent months and currently the office has a staff of four paid employees:

1. The Assistant National Co-ordinator (ANC) whose duties include managerial responsibility for the other staff, the development and enhancement of office procedures and systems including the database, attendance at meetings, conferences etc. and the co-ordination of report writing, the latter task taking up some 6 months of every year.

2. The Data Collection and Management Officer. This is a new post developed with the intention of taking on full responsibility for the maintenance and further development of the SHOT databases. This staff member will also be expected to deputise for the ANC.

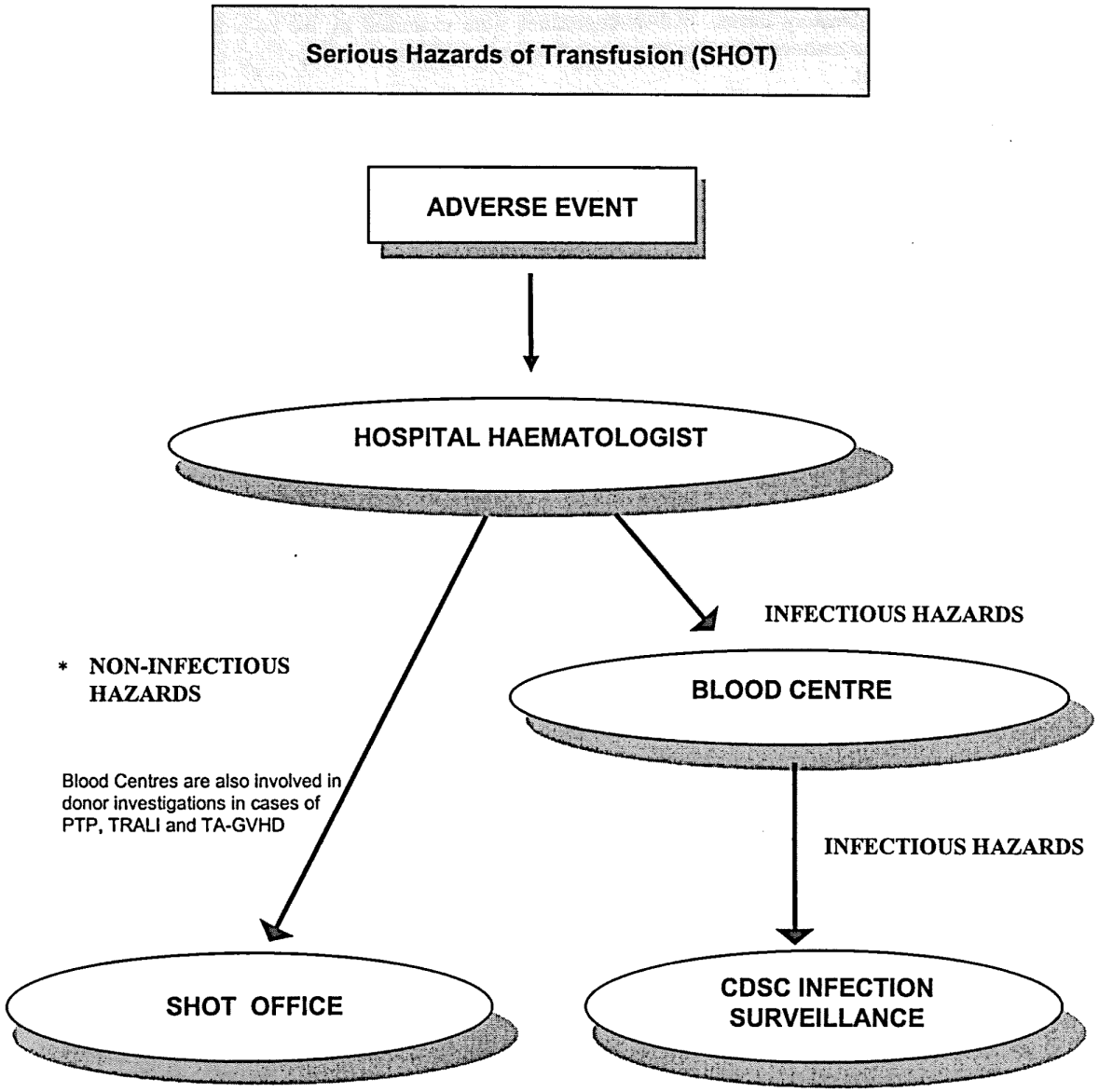
3. The Office Administrator whose role has developed and expanded considerably since the beginning of the scheme. This member of staff handles all the bulk work associated with the clerical processes involved in data collection as well as providing a good secretarial service, conference organisation, and dealing with telephone enquiries.

4. The Administrative Assistant works under the direct supervision of the Office Administrator and relieves her of the more mundane tasks such as photocopying, shredding, filing, basic word processing etc. This is a part-time position but a vital one in ensuring that the office does not grind to a halt under the weight of low level tasks.

The SHOT office welcomes comments and suggestions on ways to improve the service it provides. With more than 400 hospitals eligible to participate in SHOT there is, naturally, a high staff turnover and it would be appreciated if hospital staff could assist with the maintenance of up-to-date mailing lists by notifying the office of changes in personnel responsible for SHOT reporting.

Members of the SHOT Standing Working Group and Steering Group, apart from the SHOT Assistant National Co-ordinator and the National Co-ordinator for infectious hazard reporting (who has a joint paid appointment with the NBS and PHLS) give their time free of charge to SHOT by arrangement with their respective employing authorities.

Figure 3
SHOT reporting system flow chart



- Incorrect blood/component transfused
- Major acute or delayed reaction
- Transfusion-related graft-versus-host disease
- Transfusion related acute lung injury
- Post- transfusion purpura
- Autologous pre-deposit : donor incident

6. OVERVIEW OF RESULTS

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

Incidents submitted to the SHOT reporting scheme are analysed by date of initial report rather than by date of incident. This enables us to carry forward any incident which occurs towards the end of the one reporting year and for which the completed questionnaire arrives after the closing date for that year. The current reporting year, therefore, includes all initial report forms received between the 1st October 1999 and 30th September 2000.

Overview of reports and "Nil to Report" cards

Number of hospitals

Of the 426 hospitals eligible to participate, 155 (36.4%) submitted initial reports during the reporting year. 94 of these hospitals confirmed that they had previously submitted a report when they returned the "Nil to Report" card. The 155 reporting hospitals represents an increase of 5.8% over the previous year and an overall increase of 14.3% since the scheme began. A further 150 hospitals indicated that they had seen no incidents during the reporting year. Combining these 150 with the 155 hospitals which sent reports, participation is now running at a minimum of 72% (305/426 hospitals), compared with 77.8% last year. This apparent decrease in participation may be misleading, however, given that response to the "Nil to report" exercise this year was comparatively poor. Only 246 hospitals (57.7% of those eligible) had returned their cards by the time the report went to press and two of these did not give information about participation.

1999/2000 Nil to Report survey

We asked hospitals to tell us whether they had seen any adverse events of transfusion in any of the standard SHOT reporting categories which they felt they were unable to report. We also asked them to supply one of 5 possible reasons for not reporting: 1) Too time consuming, 2) Confidentiality concerns 3) Peer pressure, 4) Don't think it worthwhile to report 5) Other - please specify. Only 10 hospitals chose to take part in this survey making any results of little value. Nonetheless the 10 responses are reproduced in Table 1 for interest:

Table 1
Responses to the Nil to Report survey

Incident type	Reason for not reporting	No. of cases seen but not reported	Comment
ATR	1	N/A	I don't have enough time to be involved in all febrile NHTRs
TTI	4	2	2 cases of Hepatitis C found in patients transfused in the 1980s but only investigated recently
TTI	5	1	Passed on to local BTS. Assumed they would report
?TTI	5	N/K	Fever with hypotension difficult to identify from laboratory
TRALI	5	0	Poor recognition of a ? common transfusion event
TRALI	5	1	Still under investigation
TRALI	5	1	Confirmatory tests by reference labs took almost 1 year and were sent to consultant who did not pass on the information
Anti D	1		1 anti D given inappropriately
No response	4		We do not think these are serious hazards of transfusion
No response	5		I am sure there are some cases that do not get reported to us.

Number of reports

A total of 291 initial reports were received this year which is an increase of 15% over the 253 received last year. Once again the largest category showing a 39.6% increase remains "incorrect blood component transfused" with 201 reports received this year. The numbers of reports in each category received since the first SHOT annual report are shown in Table 2.

Table 2
Adverse events reported during the four reporting years 1996 to 2000

	1996/97	1997/1998	1998/1999	1999/2000
IBCT	81	110	144	201
ATR	27	28	34	34
DTR	27	24	31	28
PTP	11	11	10	5
TA-GVHD	4	4	4	0
TRALI	11	16	16	19
TTI	8	3	8	4
Unclassified *			7	0
TOTAL	**169**	**196**	**254**	**291**

IBCT: Incorrect blood component transfused
ATR: Acute transfusion reaction
DTR: Delayed transfusion reaction
PTP: Post-transfusion purpura
TA-GVHD: Transfusion associated graft-versus-host-disease
TRALI: Transfusion-related acute lung injury
TTI: Transfusion transmitted infection

* Unclassified refers to 7 incidents analysed last year which we were unable to group in any of our existing categories.

Figure 4
Comparison of incidents reported since reporting began in 1996

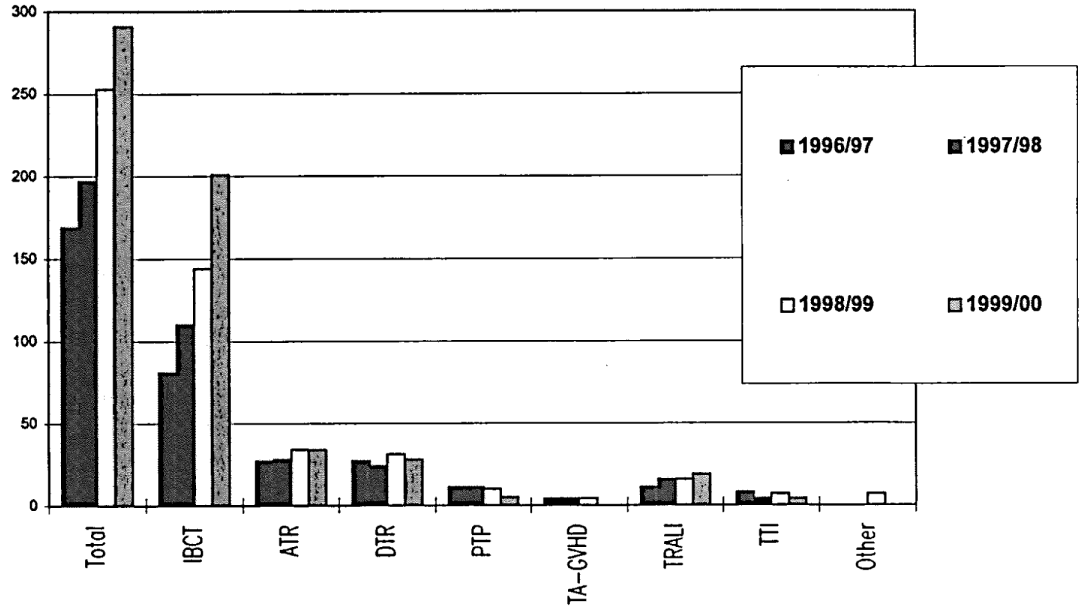
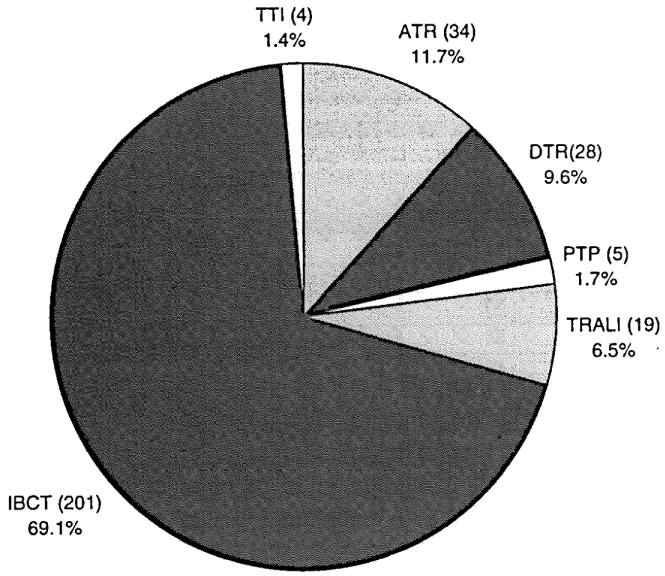


Figure 5
Overview of 291 cases for which initial reports forms were received.



Analysis of questionnaires

A total of 287 incidents (including 4 reported by letter rather than questionnaire) were analysed for this report. 18 of these were outstanding from the previous year. A further 22 initial report forms were received during the reporting period for which no questionnaires were received by the closing date. These will be analysed next year. In last year's report we identified 21 initial report forms for which no questionnaires were received. We have been unable to obtain sufficient information to allow analysis on 3 cases outstanding from last year and these cases will not be pursued further.

Table 3
Summary of completed questionnaires received.

	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI	Totals
Total number of reports received	201	34	28	5	0	19	4	**291**
Questionnaires included in analysis	200 (12)	33 (2)	24 (1)	6 (1)	2 (2)	18	4	**287**
Questionnaires outstanding	13	3	5	0	0	1	0	**22**

These figures include questionnaires outstanding from last year shown in brackets

Figure 6
Overview of transfusion related mortality / morbidity data reported in 287 completed questionnaires.

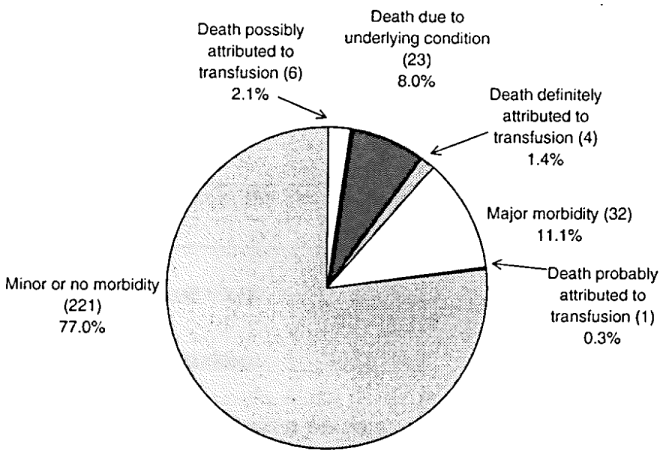


Table 4
Transfusion related mortality/morbidity according to the type of hazard reported in 287 completed questionnaires.

	Total	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI
Death definitely attributed to transfusion	**4**	1	0	0	0	2#	0	1
Death probably attributed to transfusion	**1**	1	0	0	0	0	0	0
Death possibly attributed to transfusion	**6**	0	0	0	0	0	6	0
Death due to underlying condition	**23**	18	2	2	1	0	0	0
Major morbidity	**32**	13	0	1	3*	0	12	3
Minor or no morbidity	**221**	167	31	21	2	0	0	0
Totals	**287**	**200**	**33**	**24**	**6**	**2**	**18**	**4**

Major morbidity was defined as the presence of one or more of the following:

- ◊ Intensive care admission and/or ventilation
- ◊ Dialysis and/or renal dysfunction
- ◊ Major haemorrhage from transfusion-induced coagulopathy
- ◊ Intravascular haemolysis
- ◊ Potential RhD sensitisation in a female of child-bearing potential
- ◊ Persistent viral infection
- ◊ Acute symptomatic confirmed infection (viral, bacterial or protozoal)

* 1 intra-cerebral haemorrhage in association with platelet refractoriness, 2 GI haemorrhage
\# both cases initially reported in the year 1998 / 1999

Figure 7
Calendar days between transfusion incident and initial report to SHOT (n=279)

Excludes 4 TTI and 4 where the date of transfusion was not stated or not known

The median time for return of initial reports was 15 days. This time interval appears to have stabilised during the last three years. The figures for reporting years two and three were 15 and 17 days respectively compared with 30 days for the first reporting year.

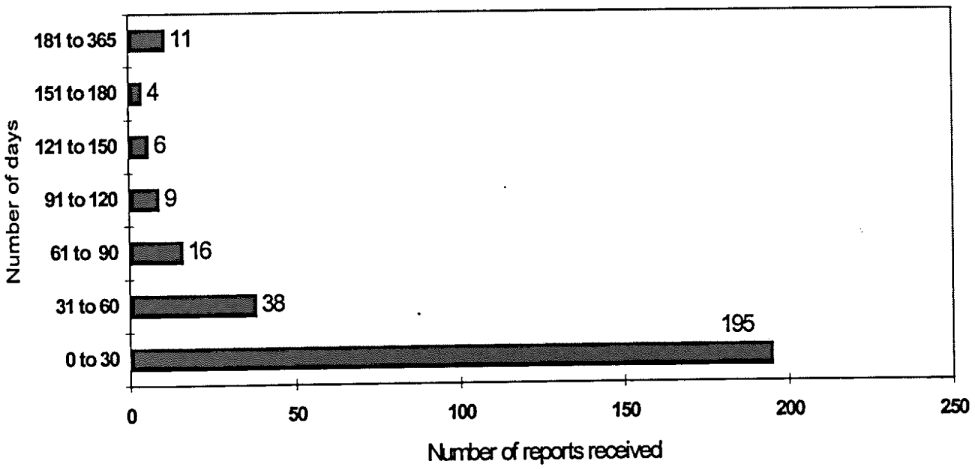
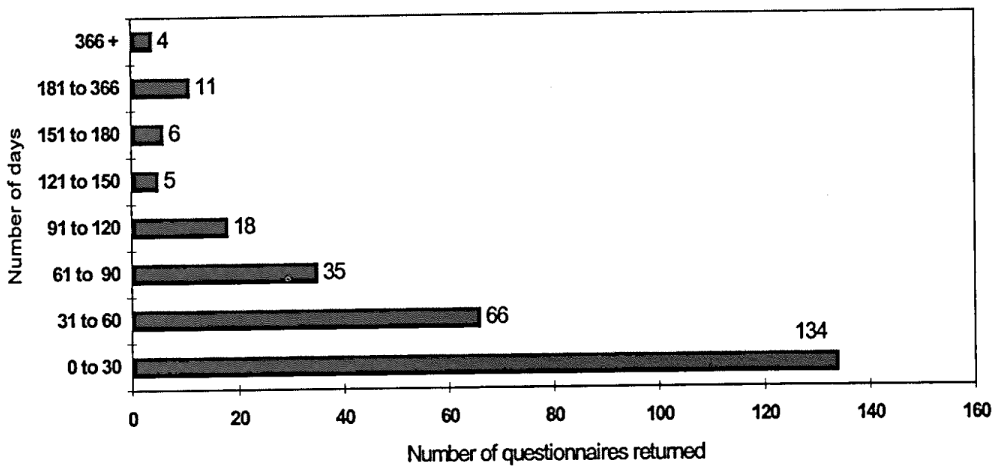


Figure 8
Calendar days between initial report and return of completed questionnaire (n =279)

Excludes 4 TTI, and 4 reported by letter.

The median time between initial report and return of final questionnaire was 33 days. This is high in comparison with earlier years but is partially explained by the fact that due to the increasing number of incidents reported, SHOT office staff have not been able to guarantee sending a questionnaire by return of post.



Overall transfusion activity and patient characteristics

The number of incidents reported needs to be placed in context of the overall numbers of transfusions taking place. Table 5 gives details of total blood component issues from the four UK Transfusion Services (England, Scotland, Wales and Northern Ireland). This information represents components issued during the fiscal year 1st April, 1999 to 31st March, 2000.

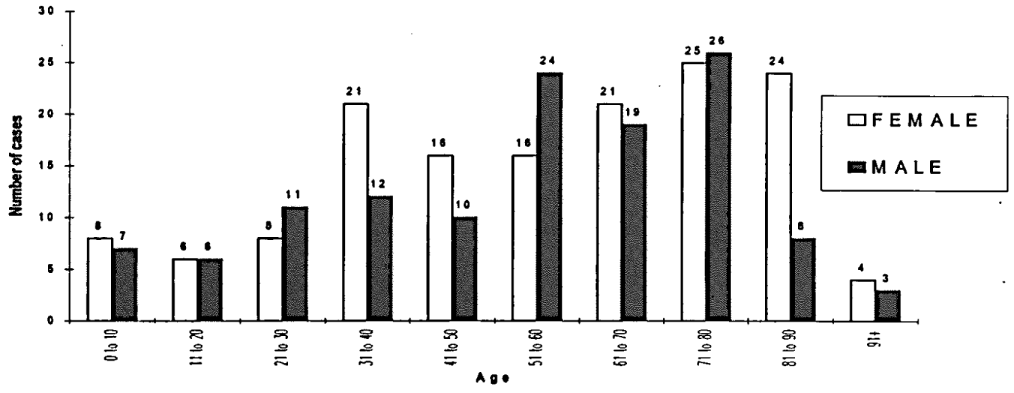
Table 5
Total issues of blood components from the Transfusion Services of the UK in 1999/2000

Red Cells	**2,737,572**
Platelets	**249,622**
Fresh frozen plasma	**365,547**
Cryoprecipitate	**94,114**
TOTAL	**3,446,855**

Last year we were able to estimate from information gained in the "Nil to report" exercise that 90% of all red cell units issued to hospitals had been received and handled by 64.6% of hospitals eligible to report to the SHOT scheme. This year, however, due to the poor response mentioned earlier in this chapter the statistics look less impressive and are given here only for interest. Of the 246 hospitals who returned cards, 210 gave figures for units transfused which totalled 1,520,249 i.e. 49.3% of hospitals eligible to participate receive and handle 55.5% of all red cell units issued to hospitals.

Figure 9
Distribution of patients by age and sex at the time of transfusion (n=275)

Excludes 12 cases where age, date of transfusion, or sex was not stated or not known



	Females (149)	Males (126)	Unknown (2)
Age not known or not stated	2	5	
Date of transfusion not known or stated	3		1
Age range	0 days to 96 years	1 year to 95 years	
Median age	60 years	57 years	

Cumulative data November 1996- September 2000

This year for the first time we are presenting an overview of cumulative totals from 1996 to the current year. This practice will continue in subsequent years.

Initial report forms received:	**910**	**Questionnaires analysed:**	**862**

Figure 10
Initial reports by incident 1996/97 - 1999/00 (n=910)

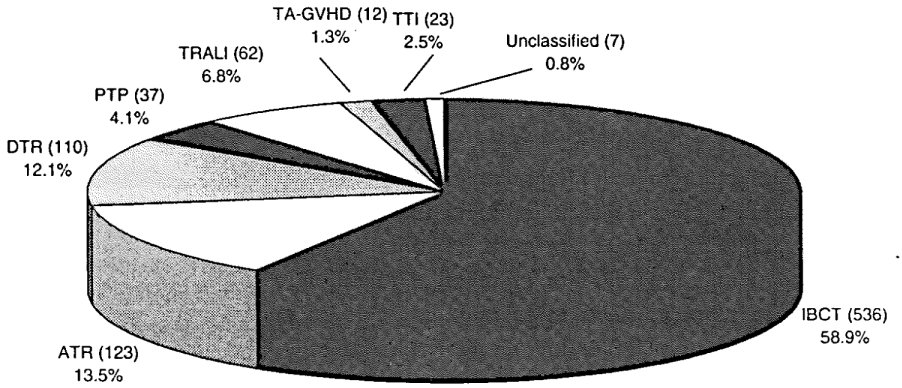


Figure 11
Questionnaires by incident 1996/97 - 1999/00 (n= 862)

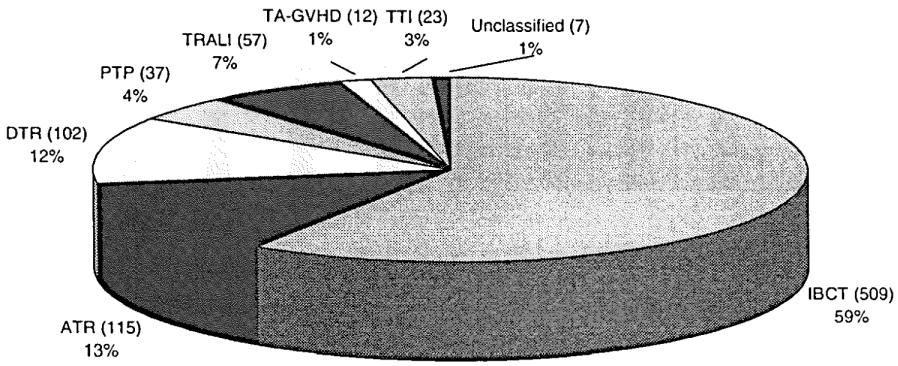
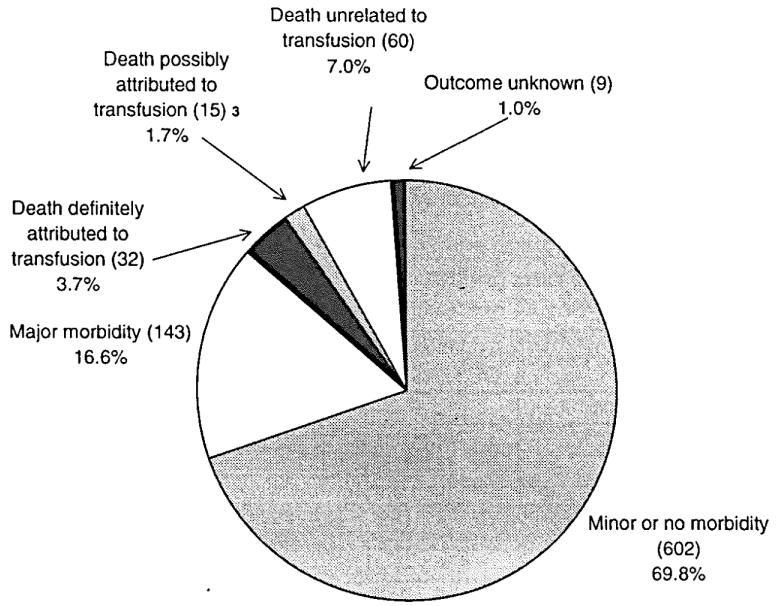


Figure 12
Overall mortality / morbidity figures 1996/97 - 1999/00 (n=862)



NB One slice "Death probably attributed to transfusion" (1) 0.1% is too small to appear on the chart.

Table 6
Overall mortality / morbidity figures by fully analysed questionnaires 1996/97 - 1999/00 (n=862)

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

[1] UC = unclassified incidents from 1998/99 report
[2] This category included for the first time this year
[3] This category not included in the first two years

IBCT cases 1996/97 - 1999/00

Initial report forms received:	**536**	**Questionnaires analysed:**	**509**

Table 7
Mortality / morbidity data for IBCT cases (n=509)

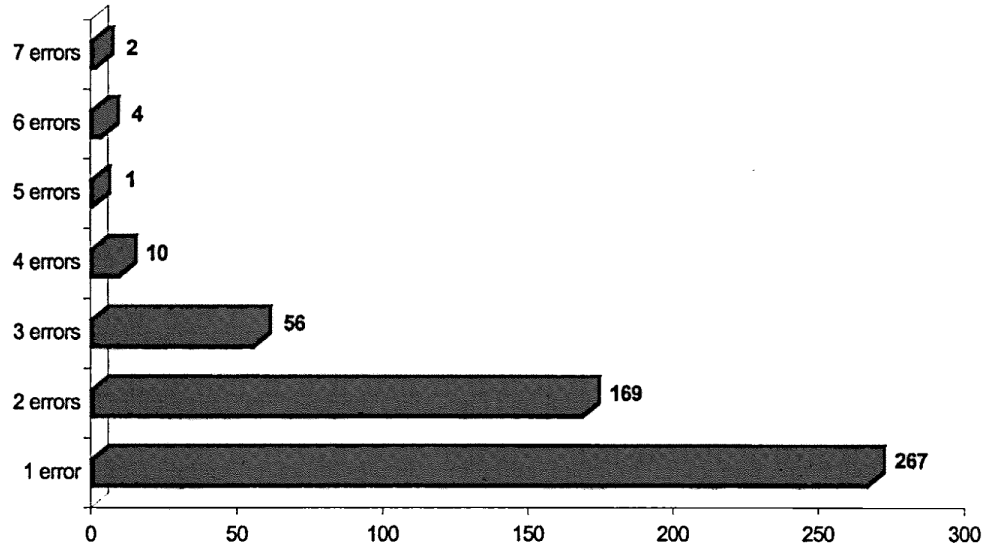
OUTCOME	NUMBER OF CASES
Death definitely attributed to transfusion	5
Death probably attributed to transfusion *	1
Death possibly attributed to transfusion	2
Death unrelated to transfusion	37
Major morbidity	54
Minor or no morbidity	406
Unknown outcome	4
Total	**509**

* This category introduced 1999/2000

Table 8
Outcome of cases of IBCT 1996/97 - 1999/00 (n=509)

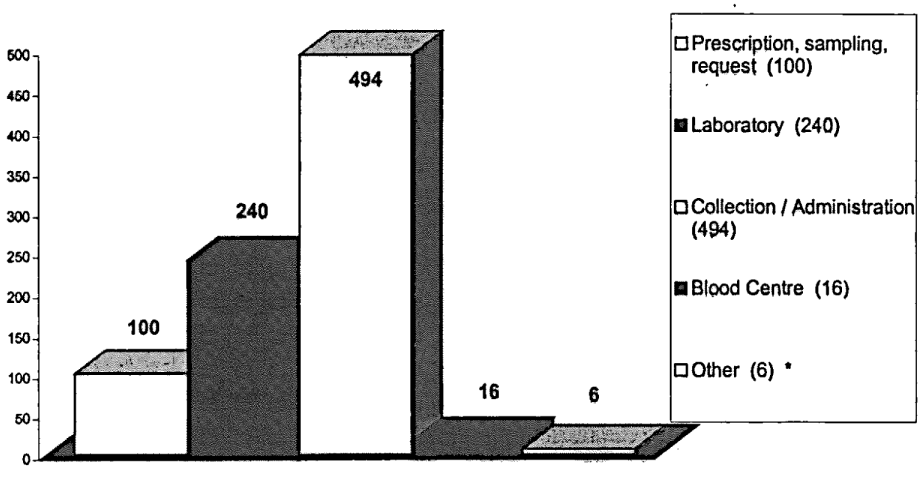
Category	Survived/ no ill effects	Major morbidity	Died unrelated to tx.	Died possibly related to tx.	Died probably related to tx.	Died definitely related to tx.	Unknown	TOTAL
Major ABO incompatibility	85	34	7	2	1	5	1	**135**
RhD incompatible	36	16	4					**56**
ABO / RhD compatible	142		6					**148**
Other red cell incompatibility	23	2	3				1	**29**
Inappropriate transfusion	32		4				1	**37**
Special requirements not met	67	1	4					**72**
Anti D	20							**20**
Blood group not stated	1	1	9				1	**12**
Total	**406**	**54**	**37**	**2**	**1**	**5**	**4**	**509**

Figure 13
Multiple errors in IBCT cases 1996/97 - 1999/00 (n=509 cases, 856 errors)



The average number of errors per case over 4 years is 1.7 and has been consistent each year with averages of 2.3 in year 1, 1.4 in year 2, 1.8 in year 3, and 1.7 in year 4.

Figure 14
Distribution of errors in IBCT cases 1996/97 - 1999/00 (n=509 cases, 856 errors)



* 6 errors in year 4 did not fit in existing categories. 2 errors involved transport between hospitals and 4 errors could not be traced to their source.

Table 9
Laboratory errors and grade of staff 1996/97 - 1999/00
(231 errors in the 203 cases where this information was available)

Error	Total number of errors	State registered BMS, routine, regularly working in blood bank	State registered BMS, on call, regularly in blood bank	State registered BMS, on call, not regularly in blood bank	Other staff	Unstated
Sample transposition	9	5	4	0	0	0
Failure to consult / heed historical record	27	12	5	8	1	1
Incorrect group	70	33	13	20	1	3
Missed antibody screen	7	4	0	2	0	1
Missed incompatibility / crossmatch error	18	6	7	5	0	0
Incorrect labelling of component	21	14	3	2	1	1
Selection / issue of inappropriate component	37	15	8	10	2	2
Failure to clear satellite refrigerator	4	4	0	0	0	0
Failure to irradiate	4	2	2	0	0	0
Clerical error	8	1	2	2	0	3
Other procedural error	25	8	5	9	0	3
Other	1	1	0	0	0	0
Total	**231**	**105**	**49**	**58**	**5**	**14**

Immune complications 1996/97 - 1999/00

Acute Transfusion Reactions

Initial report forms received:	**123**	**Questionnaires analysed:**	**115**

Table 10
Acute reaction types 1996/97 - 1999/00

RED CELLS (57)		FFP (28)	
Haemolytic	14	Pruritis / dyspnoea	1
Non-haemolytic febrile	25	Anaphylactic	15
Hypotensive	2	Allergic	11
IgA antibodies	1	IgA antibodies	1
Anaphylactic	5		
Allergic	5		
Dyspnoea / chest pain / rigors	3		
Other	2		
PLATELETS (30)			
Hypotension / flushing	4		
Haemolytic	3		
Anaphylactic	10		
Allergic	6		
Hypotension	3		
Dyspnoea / chest pain	1		
Difficult to categorise	3		

Delayed Transfusion Reactions 1996/97 - 1999/00

Initial report forms received:	**110**	**Questionnaires analysed:**	**102**

Signs and symptoms of delayed reactions are divided into 4 categories as follows: *

Group 1 (n=16)
Asymptomatic (± positive direct antiglobulin test (DAT) ± spherocytes)

Group 2 (n=20)
Falling haemoglobin (↓Hb) / positive DAT / spherocytes (2 of these parameters)

Group 3 (n=51)
↓Hb + jaundice ± positive DAT ± spherocytes

Group 4 (n=13)
As group 3 + renal impairment

* 2 cases had insufficient data to categorise

100 patients developed 138 newly detectable post transfusion red cell alloantibodies. See Table 11

Table 11
New post transfusion red cell alloantibodies 1996/97 - 1999/00
138 antibodies in 100 patients

Antibody group	Number	Sole antibody
Kidd (Jk)		
Jka	46	27
Jkb	6	2
Duffy (Fy)		
Fya	10	5
Fy3	1	
Kell		
K	11	5
Kpa	1	
Kpb	1	1
Rhesus		
D	4	3
C	4	1
Cw	1	
c	10	5
E	26	7
e	2	1
MNSs		
M	3	
S	3	
Lutheran		
Lua	2	
Lewis		
Lea	1	
Other		
Yka	1	1
Anti B	1	
"private antigen" NOS[1]	1	
Wra	1	1
Unspecified pan-agglutinin	1	
Weak cold agglutinin	1	
TOTAL	**138**	**59**

[1] Not Otherwise Specified

7. INCORRECT BLOOD COMPONENT TRANSFUSED

Definition
This section describes all reported episodes where a patient was transfused with a blood component or plasma product which did not meet the appropriate requirements or which was intended for another patient.

As in all three previous years this category represents the highest number of reports (201 or 69.1% of 291 new reports) and an increase of 39.6% over the previous year. This chapter analyses 184 new questionnaires and 4 explanatory letters plus 12 questionnaires brought forward from last year. Completed questionnaires are still outstanding on 13 new initial reports and will be analysed next year. As in previous years there were a number of incidents where, despite serious errors in the transfusion chain, the right blood did end up in the right patient by good fortune. These incidents do not constitute near miss events as defined in chapter 14 as a transfusion was administered so they are reported here as IBCT incidents. This classification will be reviewed in time for the next (5th) annual report in 2001.

Analysis of reported errors

The questionnaires sought further information about the circumstances and factors which may have contributed to errors and adverse outcomes. The findings are presented in some detail with the use of case studies where appropriate. The aim is to illustrate weak points in the transfusion process in order to help those responsible for training staff or for the review and implementation of transfusion procedures so that areas for improvement may be identified to ensure that the right blood is given to the right patient at the right time, every time.

The data from 200 completed questionnaires are presented.

The following 3 tables give information on the gender and age of recipients and the blood components implicated in the incident.

Table 12
Sex of IBCT patients

Females	=	110
Males	=	88
Unknown	=	2
Total	=	**200**

Table 13
Age of IBCT patients

Age of recipients	
Age range	0 days to 95 years
Median Age	58 years

Table 14
Components implicated in IBCT (207 components in 200 cases)

Components Implicated	Number of cases
Red cells	162
Platelets	24
Fresh Frozen Plasma	6
Anti D immunoglobulin [1]	12
Other [2]	3
Total [3]	**207**

[1] Adverse events to this plasma product are usually reported through the MCA yellow card system, but they are reported here because they fall into the category of either blood derivative to the wrong patient or as a result of RhD typing errors

[2] Two reports of albumin administered incorrectly. One was an outdated product and the other a wrong dosage. The third case involved the administration by a blood centre of unirradiated buffy coats for neutropenic sepsis and from which there were no adverse sequelae.

[3] There were 6 cases in which it was not possible to identify a single component. Five of them involved the use of two products (red cells and platelets) another which included 3 products (red cells, platelets, and fresh frozen plasma). The latter was the result of a grouping error in the hospital blood bank.

The outcome of 200 fully reportable incidents is shown in Table 15

Table 15
Outcome of 200 fully reported incidents

OUTCOME	NO. OF INCIDENTS
Death definitely related to transfusion	1
Death probably related to transfusion	1
Death unrelated to transfusion	18
Major morbidity *	13
Minor or no morbidity	167

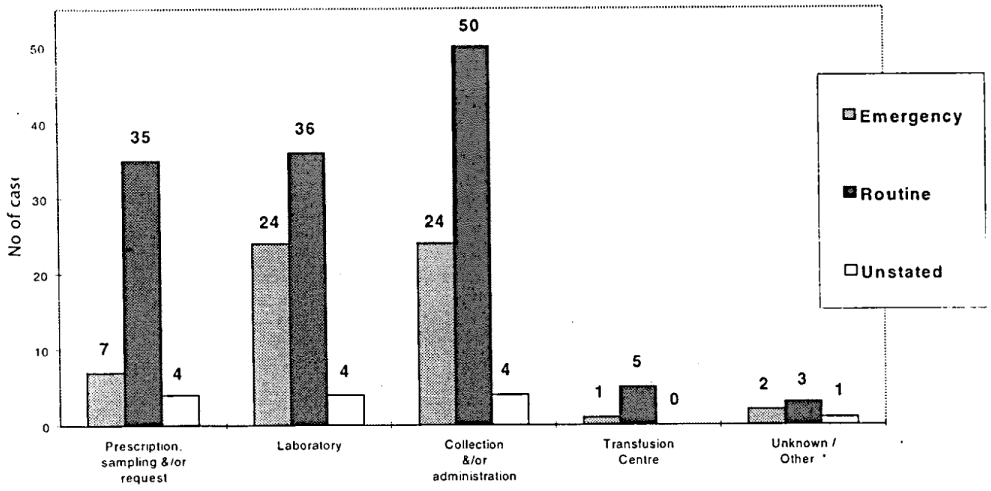
* Major morbidity was classified as the presence of one or more of the following:

- Intensive care admission and/or ventilation
- Dialysis and/or renal dysfunction
- Major haemorrhage from transfusion-induced coagulopathy
- Intravascular haemolysis
- Potential risk of RhD sensitisation in a female of child-bearing potential

Emergency and elective transfusions

Of the 200 completed questionnaires, 129 related to elective and 58 to emergency transfusion. 13 questionnaires did not state whether the transfusion was elective or emergency. Figure 15 shows the distribution of errors relating to emergency and elective transfusions.

Figure 15



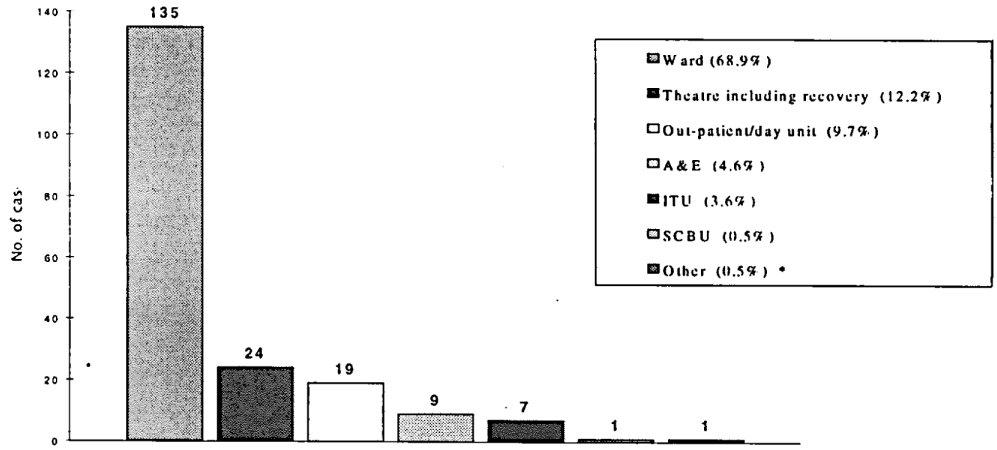
Incidence of errors at the various stages of the process of emergency and elective transfusion (n=200)

* Unknown = 4 cases where it was not possible to determine the source of the error
Other = 2 cases of units being transported from 1 hospital to another out of temperature control

Site of transfusion

The questionnaire asked for information about where the transfusion took place. 194 reports gave information on the site of the transfusion (Figure16). This information is of limited value, however, as no denominator data are available.

Figure 16
Site of transfusion (n=196) [1]

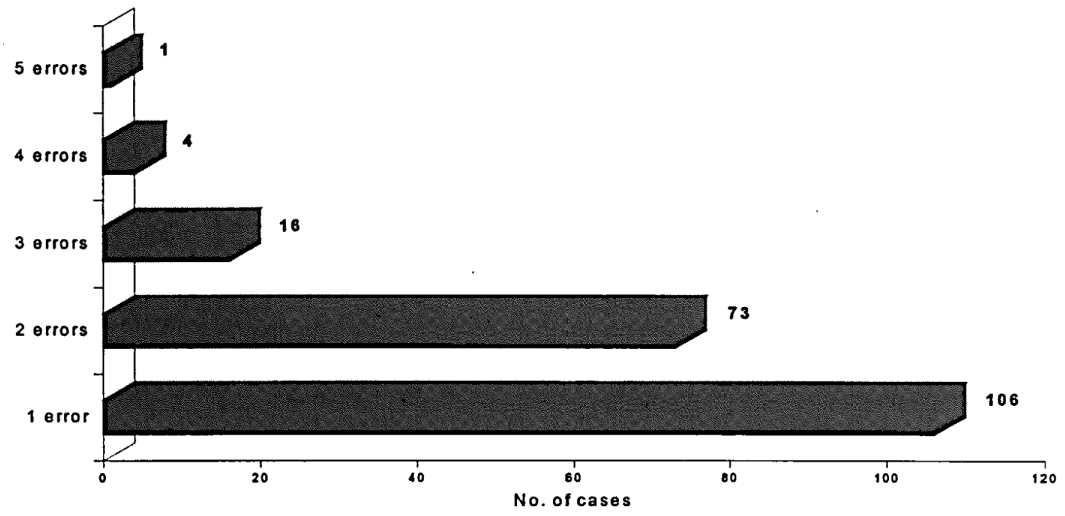


* Other = 1 Anti D given in a G.P. surgery
[1] 2 cases involved transfusions on 2 separate sites

Multiple errors continue to contribute to many "wrong blood" transfusions

In all 3 previous years it has been consistently noted that multiple errors have been implicated in many "wrong blood" incidents. This year is no exception and detailed analysis of 200 completed questionnaires has demonstrated their value in highlighting 94 cases (47%) where multiple errors in the transfusion chain culminated in a "wrong blood" transfusion. This year a total of 321 errors was noted in 200 cases and further detail is shown in Figure 17.

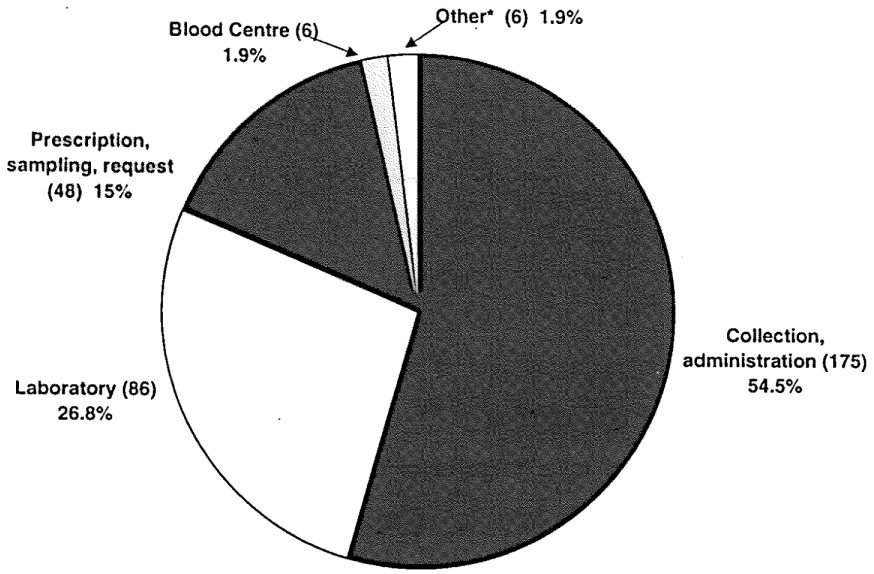
Figure 17
Total number of errors per case (total cases = 200; total errors = 321)



Distribution of errors

The following Pie chart (Figure 18) shows the distribution, according to the main reporting categories, of a total of 321 errors from the analysis of 200 completed reports. A more detailed analysis of the distribution of total errors can be seen in Table16

Figure 18
Distribution of total errors according to the main reporting categories (n=321)



* 6 errors did not fit into existing categories. 2 errors involved transport between hospitals and 4 errors could not be traced to their source.

Table 16
Distribution of procedural failures in terms of total errors (n=321)

Location	Number of errors
Prescription, sampling and request	
Sample taken from wrong patient	7
Details on request form incorrect	3
Details on sample incorrect	4
Prescription of inappropriate and / or incompatible components(s)	2
Inappropriate request	32
Total	**48**
Hospital Blood Bank	
Transcription error	1
Failure to consult / heed historical record	5
Grouping error	19
Missed antibody(ies)	5
Missed incompatibility	1
Selection / issue of inappropriate component	12
Labelling error	5
Failure to irradiate	4
Crossmatch error	6
Crossmatch wrong sample	4
Failure to follow protocol	12
Incorrect serological reasoning	1
Clerical error	4
Technical error	3
Failure to clear satellite refrigerator	1
Failure to detect error made by Blood Centre	2
Other [1]	1
Total	**86**
Collection and Administration	
Collection of wrong component	46
Failure to detect error earlier in the chain	16
Failure of bedside checking procedure	87
Wristband missing or incorrect	14
Inappropriate component selected by clinician	2
General administration error	5
Failure to follow protocol	1
Other [2]	4
Total	**175**
Supplying blood centre	
Inappropriate component supplied	5
Other [3]	1
Total	**6**
Other	
Unable to trace source of error	4
Unit transfused out of temperature control	2
Total	**6**

[1] Computer system not properly evaluated for use
[2] 1 punctured bag, 2 units out of temperature control, 1 Incorrect clinical decision
[3] Breakdown in communication lead to supply of component which was not irradiated and not CMV Neg

The pitfalls of a complex multi-step, multidisciplinary process

Once again we make no apology for pointing out the complexity of the transfusion process the aim of which must always be to ensure that the right patient receives the right transfusion at the right time. Involving, as it does, many individuals and crossing several professional boundaries with different line management accountability, it is hardly surprising, although not excusable, that errors occur from time to time unless the process is very tightly controlled. The following analysis of 321 errors occurring in 200 cases illustrates how events may combine to result in a "wrong blood" incident.

Errors in prescription, requesting of blood components and patient sampling

There were 48 errors in this category occurring in 47 case reports.

Prescription errors

There were 2 errors relating to mis-prescribing which occurred in 2 cases. The first (case study 1), which fortunately had no immediate clinical consequences, clearly illustrates a number of human errors arising in the context of unclear or unsuitable hospital procedures and over-stretched locum medical staff. This case was very thoroughly investigated by a hospital review panel and specific recommendations made to correct deficiencies. The second (case study 2) is possibly a less commonly recognised cause of unnecessary blood transfusion arising as a result of a falsely low haemoglobin (Hb) result.

Case study 1

A catalogue of errors which resulted in the administration of anti D immunoglobulin to the wrong patient or "Extraordinary coincidences do occur"

2 obstetric patients with the same surname were admitted to different wards within a few days of each other. The first woman required anti D immunoglobulin to cover an invasive investigation. This was prescribed by a locum doctor. Later that day the same doctor assessed the second woman and pronounced her fit for discharge. In the meantime the request for anti D was processed in the laboratory from an inadequately completed request form (the ward name, which resembled the patients' surname, had been abbreviated and the name of the consultant in charge of one of the patients was poorly written and thus resembled the name of the other ward!) The anti D was issued to the wrong patient and the attending nurse, noting the absence of a prescription, asked the original doctor to attend to write it up. The doctor did not query the request and was too busy to attend the ward so asked a colleague to help by writing the prescription, as a result of which the blood product was administered. The error was discovered when a nurse on the other ward telephoned the blood bank to enquire why the requested anti D had not been delivered.

Case study 2

Failure to detect an erroneous haemoglobin estimation and to act on the correct result leads to unnecessary blood transfusion

A small volume sample taken from a patient was reported as haemoglobin (Hb) 62 g/dl. A second sample was tested and the Hb found to be 145 g/dl. Laboratory error was considered to have contributed to the reporting of an incorrect result. Despite issuing the second (correct) result in time 4 units of red cells were requested by the clinician who had not looked at the latest result and an unnecessary transfusion of one unit of red cells was given.

Failure to request the appropriate product

In 32 cases there was failure to request the appropriate product. As was shown in last year's report, once again the most common error was failure to request irradiated components for patients at risk, as defined in BCSH guidelines [6] notably 16 patients being treated with purine analogues (15 fludarabine, 1 deoxycoformycin), 4 patients with Hodgkin's disease, 3 patients who had received a bone marrow transplant and 3 due for stem cell harvests. No instances of proven TA-GVHD resulted from these omissions but 1 patient developed skin rash,

fever, diarrhoea, and deranged liver function in association with autologous bone marrow failure. A skin biopsy was compatible with TA-GVHD and the patient responded promptly to steroids. The clinician was reluctant to attribute a firm diagnosis of TA-GVHD.

In 2 cases, patients with previous known red cell antibodies, were transfused with red cells unselected for avoidance of the relevant antigen The first of these cases was a patient with previous anti E and anti cellano, usually abbreviated to anti k. The requesting clinician wrote anti K on the request form. At the time the laboratory computer was down so the historical record could not be checked. On the antibody screening test one cell was weakly positive but the screen and compatibility tests were reported as negative. Wrongly selected (i.e. cellano positive) red cells were transfused without ill effect. The second case was of a patient with previous (but now undetectable) anti Jka identified and issued with an antibody card at another hospital. The receiving hospital on this occasion detected anti c and acted appropriately but, as information from the antibody card was not passed on, failed to request Jka negative red cells.

In 1 case anti D immunoglobulin was inappropriately requested. The blood bank reported that a cord sample was RhD negative. Maternity staff made an assumption, presumably from lack of understanding of the significance of the report, that the mother must also, therefore, be RhD negative and requested anti D. In fact the mother was group A RhD positive.

There was 1 report of a request for homologous blood where autologous was available and 1 failure to request red cells of the appropriate age (< 5 days old) for a neonatal exchange transfusion because ward staff appeared to have been unaware of the guidelines for neonatal exchange transfusion[12] Finally, 1 telephone request made without giving the date of birth and unique patient identity number led to the transfusion of a compatible red cell unit crossmatched from a sample taken from another patient with the same name (case study 3).

Case study 3

Insufficient information on telephoning a request for blood led to the transfusion of a compatible unit crossmatched from a sample from another patient with the same name.

Patient 1 was admitted, crossmatched and transfused without incident. Five days later patient 2, who had exactly the same forename and surname as patient 1 was admitted with a head injury. A sample was taken from patient 2 for group and screen only. The same day patient 1 had a massive G.I. bleed. A telephone request was made to the blood bank for 4 units to be crossmatched for patient 1. The doctor requesting the blood gave only the patient's name but not date of birth or hospital number. The BMS who took the call had just completed the group and screen for patient 2 and, because the name was identical, assumed it was the same person and did not ask the doctor to confirm date of birth or hospital number. At the time the request was made nursing staff expressed surprise among themselves that a further sample was not requested for this patient whose first transfusion had been 5 days earlier but they did not raise the matter with medical staff nor with the blood bank. Two units were then collected from the blood bank by a porter. No formal check was made at this stage. The unit was labelled with details for patient 2 but this was not detected either at collection or at the bedside. Patient 1 received one unit of ABO / RhD compatible blood which had been crossmatched and labelled using another patient's sample. The error was discovered when nurses on the following shift went to the patient to hang the second unit. The patient suffered no ill effects as both patients were group A RhD positive.

Sampling errors

Seven cases involved the taking of samples from the wrong patient.

5 cases involved mis-identification at the time of sampling. In 4 cases the wrong patient was approached for the sample which was subsequently labelled with the intended patient's details. One of these cases in fact resulted from sampling the wrong placenta in a delivery suite (case study 4). In the fifth case the correct sample was labelled with another patient's details. In the sixth incident the only logical conclusion for the cause of an ABO incompatible red cell transfusion was a sampling error at the bedside but this could not be proven. As a result of these 6 errors there were 3 major ABO incompatible transfusions resulting in 2 acute reactions but no other adverse sequelae, 1 case of erroneous administration of anti D, 1 ABO compatible but non-identical red cell transfusion and 1 case where a group O patient was given group B FFP, an acceptable course of action under

certain circumstances. The seventh incident was also an example of sampling from the wrong patient, in this case giving rise to a wrong Hb result (case study 5).

Case study 4

An unnecessary administration of Anti D immunoglobulin following RhD typing from the wrong placenta.

A 28 year old woman who was correctly typed as RhD Negative was given Anti D immunoglobulin when her baby was found to be RhD Positive. The baby's sample, however, had been taken from the wrong placenta. The error was discovered when a fresh sample was sent from the infant (now on the neonatal unit) and was found to be RhD Negative.

Case study 5

An unnecessary transfusion given because the sample for haemoglobin estimation had been taken from the wrong patient.

A young male patient with serious injuries had samples taken for crossmatching, haematology and biochemistry tests. The sample for crossmatching was labelled correctly but the haematology and biochemistry samples were transposed with those of another patient. When the results were received they indicated that the injured patient's Hb was 6.8 g/dl and an immediate transfusion was ordered. The patient was transfused with 1.5 units of red blood cells crossmatched from the correct sample before the phlebotomy error was discovered. The patient's actual pre-transfusion Hb was 10.8 g/dl which increased following the transfusion to 11.9 g/dl.

Labelling errors

There were 7 errors of labelling which involved incorrect details on sample and/or request in 6 cases. 2 errors of mis-spelling of surnames were considered not to have contributed to the eventual "wrong blood transfusions". 2 more errors resulted in "right blood to right patient" despite repeated mis-spelling of a surname in 1 case and entirely the wrong name on the sample in the other. In a further incident where the date of birth was omitted from sample and request form, the correct computer record, which would have revealed previous anti c, was not accessed and the patient was given c positive red cells without adverse effect. The 7th case involved a complex series of four errors resulting in a major ABO incompatible transfusion and is also referred to in the previous section (case study 6).

Case study 6

A sampling error, not detected in the laboratory or at the time of administration, which resulted in a major ABO incompatible transfusion

The first error was the taking of a transfusion sample from the wrong patient and labelling with the intended patient's details. No transfusion history was given on the request form and although the patient had been grouped before, the implementation of a new computer system meant that the old record had not been merged with the new. Correct bedside administration procedure was not followed resulting in the transfusion of <50 ml of group B red cells to a group A patient. An acute reaction (no details available) ensued but no other adverse effects were recorded.

Hospital blood bank errors

Of the 86 laboratory errors noted in 73 case reports, 35 occurred during routine working hours and involved 32 state registered BMSs, 1 supervised MLA and 1 trainee. The 41 errors made out of hours involved 17 BMSs who worked regularly in the blood bank and 24 who did not. In 10 other cases involving 11 errors the grade of staff was not stated. This information is summarised in Figure 19. It can be seen that, as in previous years, errors are neither restricted to inexperienced/unfamiliar staff nor to "out-of-hours" situations. Table 17 gives more detail about the errors and grades of staff involved. Approximately 48% of errors occurred in the "out-of-hours" situation but it is not possible to comment on the significance of this information in the absence of relevant denominator data. This information is currently not sought in questionnaires.

Figure 19
Circumstances under which laboratory errors occurred (n=86)

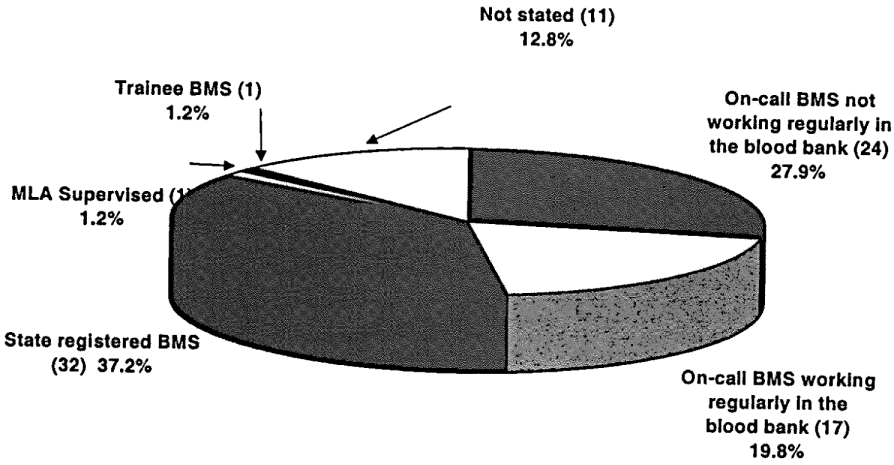


Table 17
Laboratory errors and grade of staff involved (n=86)

Error	Total number of errors	State registered BMS, routine, regularly working in blood bank	State registered BMS, on call, regularly in blood bank	State registered BMS, on call, not regularly in blood bank	Other staff	Unstated
Sample transposition	4	3	1	0	0	0
Failure to consult / heed historical record	5	2	1	1	0	1
Incorrect group	19	6	4	5	1	3
Missed antibody screen	5	2	0	2	0	1
Missed incompatibility / crossmatch error	7	2	2	3	0	0
Incorrect labelling of component	5	5	0	0	0	0
Selection / issue of inappropriate component	12	2	3	5	1	1
Failure to clear satellite refrigerator	1	1	0	0	0	0
Failure to irradiate	4	2	2	0	0	0
Clerical error	5	1	1	1	0	2
Other procedural error	18	5	3	7	0	3
Other [1]	1	1	0	0	0	0
Total	**86**	**32**	**17**	**24**	**2**	**11**

[1] Computer system not properly evaluated for use.

Sample transposition

4 errors fell into this category. 3 resulted in group O RhD positive patients receiving O RhD positive red cells crossmatched using a wrong sample, one of which was serum from a group AB patient. The fourth error, involving two patients with the same name, resulted in major ABO incompatibility with the patient dying from unrelated causes

Failure to consult/act on the historical record

5 errors fell into this category and the details are shown briefly below

- Patient request stated anti K (instead of anti k or anti cellano and anti E). The error was not spotted in the laboratory. There were no adverse sequelae (see earlier).
- A wrong RhD group and failure to check the historical group resulted in unnecessary administration of anti D immunoglobulin
- A sample taken from the wrong patient with failure to check the record resulted in a group A patient receiving group B red cells, fortunately with no ill effects (case study 6)
- A warning on the computer system was ignored and a patient who required irradiated components received unirradiated platelets
- An error in RhD typing resulted in administration of RhD negative red cells to a RhD positive patient and is illustrated below (case study 7).

Case study 7

Mis-grouping, compounded by failure to check the historical record and a wrong unique identifier which was not detected at the bedside

A patient requiring an elective transfusion was sampled correctly. The patient had been grouped before but the transfusion history was not checked in the laboratory. Pre-transfusion testing was reported as group O RhD negative, when in fact the correct group was O RhD positive, with a negative antibody screen. A pre-existing error in the laboratory computer meant that the hospital number was wrong and therefore the wrong hospital number was printed on the pack and issue voucher. This error was not detected at the bedside although the patient's wristband carried the correct identification number. Fortunately this series of errors resulted in the transfusion of compatible red cells.

Grouping, screening and crossmatch errors (n=31)

In this category there were 31 errors occurring in 31 cases.

Grouping errors: RhD

There were 19 errors of grouping. 7 RhD negative patients were grouped as RhD positive and received RhD positive red cells in error. 2 patients died of unrelated causes and 2 were females of child-bearing potential, placed at risk of RhD sensitisation and one of these cases is illustrated below (case study 8):

Case study 8

RhD mis-grouping results in treatment with multiple injections of anti D immunoglobulin

A young female with traumatic amputation of both legs was rapid-grouped as A RhD positive and 2 units of A RhD positive red cells were issued. In the meantime, confirmatory grouping found her to be A RhD negative but was mis-read and entered into the computer as A RhD positive. A further 4 units of A RhD positive red cells was

selected using the computer record but on retesting a grouping discrepancy was noted. Re-grouping confirmed that the patient was in fact RhD negative, thus preventing the issue of more incompatible red cells. Unfortunately the first 2 units had already been transfused resulting in the need to administer a large amount of anti D immunoglobulin over the next three days. Follow-up to check whether RhD sensitisation has occurred has not yet been completed.

6 RhD positive patients were mis-grouped as RhD negative, resulting in the administration of compatible but incorrect red cells to 2 and unnecessary anti D immunoglobulin to 4.

Grouping errors: ABO

The remaining 6 errors involved ABO mis-grouping, of which 5 resulted in major ABO incompatibility although none suffered any serious sequelae. The sixth case was a group B patient with cold haemagglutinin disease who was erroneously grouped as AB (a well-known pitfall of this condition) and was then transfused with group A red cells. The patient survived an episode of intravascular haemolysis.

Screening errors

5 screening errors resulted in one case of missed anti c and 2 of missed anti E. There was one case of missed anti Fya, masked by known anti C and the fifth case, in a patient with known anti E+c, a further antibody was suspected but transfusion preceded identification of anti Jka. None of the patients experienced adverse effects.

Crossmatching errors

Finally there were 7 errors of crossmatching, 5 of which combined with other laboratory errors to result in the transfusion of E positive red cells to a patient with anti E, group AB red cells to a group A patient, K positive red cells to a patient with anti K (case study 9), group A red cells to a group O patient and unselected red cells to a patient with anti C+e. With the exception of the fourth patient who experienced intravascular haemolysis, there were no adverse effects. A further patient was given RhD negative red cells instead of RhD positive and the seventh case involved the inappropriate use of electronic issue for a group A patient who had received a group O renal transplant.

Case study 9

Several breaches in laboratory protocol led to the transfusion of K positive red cells to a patient with anti K

An emergency request was made "out of hours" for red cells for a group O RhD Negative patient with a GI bleed. The on-call BMS crossmatched the sample and found it to be antibody positive. He assumed that the patient had developed anti D, for reasons that were not made clear, and requested that the positive antibody screen be investigated the following day. In fact the patient had developed anti D + K, and one of the units transfused was Kell positive. The BMS, who did not work regularly in the blood bank, failed to discuss the urgency and possible delay for this patient, did not refer the sample to the local Blood Centre and did not inform the consultant haematologist. Furthermore the BMS did not perform the crossmatch correctly and therefore did not detect the incompatibility due to anti K nor did he/she enter the results properly. This elderly patient died from her underlying condition.

Labelling errors (n=5)

4 of these involved placing the label for the intended patient on to the wrong unit. In all 4 cases the error was made by a BMS working during normal working hours and none of the transfusions were in an emergency. Fortunately all these units were ABO and RhD compatible with the patients who received them. The last case was one of "right blood to right patient". The BMS mis-read the patient's name and typed a wrongly spelled version of the name into the computer so that issue labels were incorrect.

Selection / issue errors (n=12)

On 3 occasions date expired units were issued by the blood bank, all of which were issued out of hours, 2 of them in an emergency. 2 cases involved the issue of non-irradiated platelets where irradiated products were

required. 1 of these errors was made by a supervised MLA and the other by a BMS working out of hours who issued them despite a computer warning to the contrary. Similarly there were 2 cases in which laboratory staff failed to issue CMV negative products despite computer warnings. Both these transfusions were routine and the products were issued by a BMS working out of hours who did not work regularly in the laboratory. The remaining cases were 1 unit issued out of temperature control because staff had not noticed a fault on the refrigerator, 1 case of albumin issued as 4.5% concentration when it was, in fact, 20%, 1 unit which was irradiated when the unit was over 14 days old, 1 where a group O RhD positive unit was selected for crossmatch for a group A RhD positive patient, and 1 in which an inexperienced member of the laboratory staff issued a unit crossmatched for another patient mistakenly believing it to be replacement emergency stock.

Failure to clear satellite refrigerator (1)

This error resulted in the transfusion of a unit of red cells with an expiry date 3 days earlier. Prior to this incident the hospital policy was to check satellite refrigerators twice weekly but this has since been changed to daily.

Failure to irradiate (4)

All these cases were failure to irradiate a blood component despite the need for this being detailed on request form and/or there being a warning flag set in the laboratory computer.

Clerical errors (6)

5 of these cases involved incorrect details being entered either onto the laboratory computer or onto issue labels and, in the remaining case, confusion over two patients with the same name led to multiple errors one of which was that the BMS mis-read the name of the ward on a request form and notified the wrong ward that anti D immunoglobulin was available for their patient (case study 1)

Other procedural errors (18)

These were too diverse to cite individually but can be loosely broken down into 4 areas:
1. Failure to follow protocol (12)
2. Technical errors (3)
3. Failure by laboratory staff to detect an earlier error made by the local Blood Centre (2)
4. Incorrect serological reasoning (1).

Errors in the collection and administration of blood components

There were 175 errors in this category occurring in 113 case reports, comprising 54.5% of all errors.

Collection of incorrect component (46)

As in previous years, collection of an incorrect component from its storage site in the hospital remains a significant cause of error. There were 46 incidents in this category and, as in the past, errors were not restricted to specific groups or grades of staff and occurred irrespective of formal checking procedures at the time of collection (Table 18). Failures at this important intermediate stage of the transfusion process continue to set the scene for later failure of the bedside checking procedure. Of note and contrary to recently published BCSH guidelines [5] in 31/46 (67.4 %) of these incidents it was reported that no formal checking procedure was carried out, at the point of collection, by the person responsible for collecting the blood component (Table18).

Table 18
Collection errors according to grade of staff involved and whether or not a formal check was made at this stage (n=46)

GRADE OF STAFF	FORMAL ID CHECK		
	Yes	No	Unknown
Registered nurse	3	11	3
Unregistered nurse	3	4	
Porter	1	10	2
Theatre staff		3	1
Other *		2	
Unknown		1	2
Totals	**7**	**31**	**8**

* 1 midwife, 1 night staff, grade unknown

Failure of bedside checking procedure

The 87 incidents in this category occurring in 86 case reports contributed 27% of errors reported in all categories. 46* preceding errors of collection (45 cases) and laboratory errors (11 cases) were not detected by the bedside check and in 10 cases missing patient identification wristbands contributed to the error. There were 68 bedside mis-identification episodes. Contributory factors included confusion over two patients with the same or similar names (including newborn twins), failure to adequately distinguish between "unknown" trauma victims, checking remote from the patient's bedside and swapping of units of red cells left on bedside lockers even although correct checks had been carried out.

In addition, 18 other bedside administrative errors occurred, including confusion over emergency group O RhD positive and group O RhD negative red cells, transfusion of expired blood components, failure to detect haemolysed red cells, failure to detect a discrepancy between the compatibility label and blood centre donation details as a result of laboratory labelling error and "right blood to right patient" episodes, despite wrong identification details such as unique patient ID and surname. The common factor in all cases was inadequate checking at the bedside.

These "wrong blood" incidents resulted in 25 cases of major ABO incompatibility in which there was 1 death definitely related, 1 death possibly related to the transfusion and 6 cases of major morbidity, 2 of which also involved RhD incompatibility. 1 case of major ABO incompatibility which involved the transfusion of group A platelets to a group O recipient is acceptable under some circumstances but, in this case, involved mis-identity at the bedside.

* In one case a porter was given a unit of red cells crossmatched for another patient in mistake for emergency group O RhD positive red cells. This wrong unit was then stored in an A+E satellite refrigerator from where it was again incorrectly collected by a different member of staff and transfused to the patient despite bearing completely wrong patient ID details i.e. there were 2 separate collection errors involving the same unit.

These incidents are summarised in Table 19

Table 19
Outcome of bedside errors (n=87 in 86 cases)

Category	Survived/ no ill effects	Major morbidity	Died unrelated to tx.	Died possibly related to tx.	Died probably related to tx.	Died definitely related to tx.	Unknown	TOTAL
Major ABO incompatibility[1]	12	6[2]	4		1	1		24
RhD incompatible	5	1[3]	1					7
ABO / RhD compatible[4]	40		4					44
Inappropriate transfusion[5]	7							7
Anti D	5							5
Total	**69**	**7**	**9**		**1**	**1**		**87**

1 Includes 2 cases which were also RhD incompatible
2 Recovered from intravascular haemolysis
3 Potential RhD sensitisation in females of child bearing potential
4 Includes 4 cases of "Right blood to right patient"
5 3 expired units, 1 platelets given instead of cryoprecipitate, 1 platelets not prescribed, 1 expired albumin

Interestingly, in the majority of instances (66/86, 77%) two persons, usually registered nurses, were stated to have performed the check but, as in previous years, errors nevertheless occurred (see Table 20). Recent BCSH guidelines recommend that one member of staff (a doctor or registered nurse) should be responsible for carrying out the identity check of the patient and the unit of blood at the patient's bedside[5]. Since no denominator data is available for procedures not resulting in a mis-transfusion, our data does not allow firm conclusions to be drawn about the relative safety of single or double checking procedures.

Table 20
Grades of staff involved in bedside incidents (n=87)

Grade of staff	Number of cases
Registered nurse & registered nurse	48
Registered nurse & unregistered nurse	8
Registered nurse & doctor	5
Registered nurse and other [1]	3
Registered nurse & unknown	2
Registered nurse only	2
Doctor & doctor	1
Doctor & medical student	1
Doctor & other [2]	3
Doctor & unknown	2
Other only [3]	2
Unstated	10

[1] midwife, theatre orderly, newly qualified nurse awaiting PIN
[2] Operating Department Assistant (O.D.A.)
[3] O.D.A., community midwife

The following selection of case reports illustrate some of the circumstances surrounding collection/ administration errors

Case study 10

The dangers of staff becoming distracted

Two patients on an orthopaedic ward required routine transfusions. Nurse 1 went to collect blood for patient 1 from a satellite refrigerator but was unable to find the prescription form. While this problem was being investigated, nurse 2 decided to proceed with the transfusion for patient 2. Meanwhile patient 1's prescription form was located and brought by nurse 1 along with the unit for patient 1. Nurse 2 checked the unit details against the prescription form but checked no details with the patient. Patient 1's unit was then transfused to patient 2. This B RhD Positive patient received over 100 mls. of A RhD Positive red cells. The error was discovered when the patient developed fever and hypotension and the transfusion was stopped. Fortunately he recovered from the complications of intra-vascular haemolysis. In the investigation which followed this incident nurse 2 said "While I was checking I was thinking about the first patient we had intended to transfuse".

Case study 11

A bed swapping prank results in two "wrong blood" transfusions.

Three thalassaemic brothers were admitted to the same ward. The two younger brothers were prescribed transfusions at the same time. When the blood arrived on the ward the correct protocols were followed for checking the units. Unfortunately the nurses putting up the units then became distracted and, during this time, all three brothers exchanged beds. Two of the boys received blood intended for the other. They were, fortuitously, ABO / RhD compatible and neither patient suffered any ill effects. The error was discovered by the older boy who informed staff that his younger brothers had their bags hung "the wrong way round".

Case study 12

A further demonstration of how incorrect transfusions can still occur even after correct checking procedures.

A unit was collected from the blood bank for transfusion to an in-patient. All checking procedures were performed correctly following which the unit was placed on top of a locker together with another unit for a different patient while pre-transfusion observations were carried out. The incorrect unit was then picked up from the locker and transfused without further checking. This 80 year old man who was group O RhD positive received < 50 mls of A RhD positive blood. He quickly developed fever and rigors and was transferred to the High Dependency Unit for further monitoring. He made a full recovery from the effects of intra-vascular haemolysis.

Case study 13

A fatality as a result of a major ABO mismatch

The patient was a 40 year old woman undergoing elective spinal decompression. An operating department assistant collected a unit of red cells from a satellite refrigerator for use during a routine operation in theatre. The pack was incorrect in all respects; date of birth, name, hospital number, and blood group. The transfusion was then administered by an anaesthetist with the O.D.A. assisting neither of whom checked the unit against the patient. Consequently a whole unit of B RhD Positive blood was transfused to this O RhD Positive patient. She suffered hypotension and other complications. She was transferred to the Intensive Therapy Unit where she later died as a direct result of a major ABO mismatched transfusion

Case study 14

The dangers associated with relying on verbal results

A 31 year old woman suffered a vaginal bleed in early pregnancy (exact gestation not stated). A sample was taken for grouping and the result phoned through to the ward. The patient's group was O RhD Positive but this was mis-heard by the ward staff and interpreted as O RhD negative. As a result anti D immunoglobulin was administered unnecessarily.

Problems with identification wristbands

In 14 cases wristbands were missing although in 4 cases this omission was not considered to have contributed to the mis-transfusion. Analysis of the circumstances revealed that 5 involved outpatients of which 3 were associated with bedside errors and 4 occurred in theatre (3) or the A+E (1) department together comprising 64% of instances. In the 10 cases associated with bedside errors there were 7 ABO/RhD compatible, 1 ABO incompatible and 1 RhD incompatible transfusions.

Inappropriate transfusion episodes

There were 7 of these which can be summarised as follows:

3 expired units
1 expired albumin
1 case of platelets given instead of cryoprecipitate
1 case of platelets transfused but not prescribed
1 case of haemolysed red cells following incorrect storage next to card-ice

Errors originating at the supplying blood centre

6 errors originated at the supplying blood centre

- Breakdown in communication led to product not being irradiated and not supplied CMV Neg
- Failure to irradiate. Blood centre unable to say why.
- Unit supplied not irradiated although blood centre paperwork showed, in error, that it had been.
- Issued 8 pedipacks instead of one adult unit for a 4 year old male
- Incorrect verbal message lead to confusion over requirements for 2 patients
- Supplied group O platelets which had not been checked for absence of high titre anti A,B for a group B child with resultant severe intravascular haemolysis from which the patient recovered.

Errors which did not fit into existing categories

6 errors in 6 cases were difficult to place in the existing error categories.

2 cases involved the transfusion of units which were out of temperature control. In the first of these ward staff at one hospital arranged for a unit of blood to be transported with the patient to another hospital. They did not inform the hospital blood bank and made no appropriate arrangements for the unit to be carried in an insulated box. The second incident was similar insofar as a unit was transported between hospitals without proper temperature control. In this case, however, it was not clear who was responsible for the error.

In 4 cases although it was clear that an error had been made it was not possible to determine how or where the error took place. The first incident resulted in major ABO incompatibility. A group A RhD negative patient received a group AB RhD positive unit in error. There were no errors in collection or administration of the product but clearly an error had been made earlier in the chain. The hospital was unable to determine whether this had been a "sample from the wrong patient" or a grouping error in the laboratory. In a similar case, a group A RhD negative woman received a group A RhD positive unit. She suffered no adverse reactions and, in fact, the error was not discovered until 5 months after the transfusion. For that reason it was not possible to trace the source of the error. The third error occurred when a patient received an unnecessary transfusion as a result of an incorrect Hb level being reported. The presumed cause was that the sample for testing had been diluted during phlebotomy but this was impossible to prove. The last of these cases involved the transfusion in an emergency of 31 units of whole blood. It became apparent during post transfusion testing that one of the units had been ABO incompatible but the cause of this error was never traced.

Outcome

Of the 200 fully analysed cases there were 39 cases of major ABO incompatibility, including 2 cases which were also RhD incompatible. There were 15 cases of RhD incompatibility, 16 cases where other red cell antigen incompatible transfusions were given, and 57 incidents which resulted in ABO and RhD compatible transfusions of which 4 were cases of "right blood to right patient" despite procedural errors.

The remaining cases comprised 38 cases of failure to provide for special requirements (32, non-irradiated, 4 not irradiated and not CMV negative and, 2 not CMV negative), 12 cases of anti D immunoglobulin given in error and 23 cases of an inappropriate or wrong component transfused.

- One patient died as a result of major ABO incompatibility
- One further death was probably related to major ABO incompatibility
- 18 patients died of causes unrelated to the transfusion incident
- 8 patients recovered from the effects of intravascular haemolysis
- 4 RhD negative females of child-bearing potential were exposed to RhD positive red cells
- One patient suffered an autologous bone marrow transplant failure following transfusion of non-irradiated platelets. TA-GVHD could not be excluded.
- 167 patients survived with no lasting effects

The outcome of all IBCT cases is summarised in Table 21

Table 21
Outcome of cases of incorrect blood component transfused (n=200)

Category	Survived/ no ill effects	Major morbidity	Died unrelated to tx.	Died possibly related to tx.	Died probably related to tx.	Died definitely related to tx.	Unknown	TOTAL
Major ABO incompatibility[1]	25	8[2]	4		1	1		39
RhD incompatible	8	4[3]	3					15
ABO / RhD compatible[4]	52		5					57
Other red cell incompatibility	15		1					16
Inappropriate transfusion	22		1					23
Special requirements not met[5]	33	1	4					38
Anti D	12							12
Total	**167**	**13**	**18**		**1**	**1**		**200**

1 Includes two cases which were also RhD incompatible
2 Recovered from intravascular haemolysis
3 Potential RhD sensitisation in females of child bearing potential
4 Includes 4 cases of procedural failure but "right blood to right patient"
5 CMV negative / irradiation

Procedural review

Reporters were once again asked to state whether the incident had been reported to the Hospital Transfusion Committee. Table 22 summarises the responses

Table 22
Hospital Transfusion Committees

Number of responses	Response
12[1]	No response
120	No, but will be discussed at a future meeting
66	Yes
2	No Transfusion Committee in place

1 Includes 4 cases reported by letter only.

It is not possible to analyse these data by numbers of hospitals reporting because of the anonymous nature of the scheme. We cannot, therefore, infer how many Hospital Transfusion Committees are in place. It is interesting to note, however, that this year only 2 reporters stated that their hospital(s) did not have Transfusion Committees. This represents only 1.1% of all those who responded compared with an average of 19.2% in previous years.

We also asked whether the incident had resulted in any changes to policies / procedures. 50 reporters did not respond to this question (but this includes 4 cases reported by letter only), 64 said that no changes had been made and 86 responded positively. A summary of the responses from these 86 reports is given in Table 23 However, of the 114 who said that no changes had been implemented or who did not reply, 56 made other comments which are summarised in Table 24

Table 23
Summary of changes made to policies / procedures (101 changes from 86 incidents)

Number of changes	Summary of change
59	Changes implemented to documentation; collecting; handling; laboratory techniques / procedures; ward procedures / protocols; administration
7	Implementation of new / additional training
13	Review of existing policies / procedures / protocols
2	Recommendation to appoint new / additional staff
4	Upgrade or renewal of equipment
14	Reiteration of existing procedures
1	Hospital Transfusion Committee to be established
1	Committee formed to address problems of patient identification

Table 24
Summary of comments made by reporters who said that no changes had been made or who did not respond to the question (59 comments from 56 reporters)

Number of comments	Summary of comments
12	No changes but re-training / education of staff involved
11	Existing policies / procedure / protocols are adequate
9	Investigation ongoing: changes may result
7	Review pending
5	No changes but ongoing training
5	Reiteration of existing procedures
4	No changes but incident has been / will be reviewed by the Hospital Transfusion Committee
2	No changes but guidelines under review
1	Changes pending
1	Recognise the need for improved communication
1	Software error corrected
1	Changes made to existing procedures

COMMENTARY

- This is the fourth consecutive year in which the single most important cause resulting in mis-transfusion was failure of some aspect of the bedside checking procedure immediately prior to administering the transfusion. (87/321 or 27% of errors). Contributory factors were similar to those reported previously, for example confusion over patients with the same or similar names, checking remote from the patient's bedside, interruption between completion of the checking procedure and administration of the transfusion and failure to note discrepancies between compatibility and donation labels where a preceding laboratory labelling error had occurred. Unusual circumstances (brothers swapping beds after the checking procedure and extraordinary coincidence of wards, patients and consultants with the same or similar names) clearly contributed but in the majority of cases, no clear explanation for the failures was apparent.

- The continued practice of requiring two trained persons to perform the bedside check does not appear to totally prevent "wrong blood" transfusion although in the absence of denominator data it is not possible to draw firm conclusions about the relative safety of single or double checking procedures.

- Multiple errors continue to contribute to bedside administration errors in 47% of cases indicating that problems still exist at all levels in the transfusion chain.

- As in previous years, the withdrawal of the wrong component from its storage location in the hospital preceded a bedside administration error in a significant proportion of cases (approximately 14% of total errors) and there was a notable absence of formal checking procedures at this point in 67% of these, contravening recently published BCSH guidelines [5].

- Together, collection and bedside administration errors account for 54.5% of causes of IBCT

- It is still not universal practice to use unique patient identification wristbands or other formal means of identification at the bedside. In 14 cases absence of wristbands was noted, 64% of these being in the outpatient, theatre or A+E setting and contributing to bedside errors in 10 instances.

- There were 32 failures to request appropriate components for transfusion, of which the most common (n=26) was failure to request irradiated components for patients at known risk of TA-GVHD, notably those being treated with purine analogues, patients with Hodgkin's Disease and those who had received or were due to receive stem cell transplants.

- Sampling errors comprised a small (n=7) but important cause of ABO incompatible and other "wrong blood" transfusions. These are impossible to detect at laboratory level if the patient has not been previously grouped or if the laboratory historical record has not been not consulted.

- Laboratory errors contributed to 26.8% of the total and included 31 errors of grouping, antibody screening and compatibility testing, 5 instances of sample transposition and 5 labelling errors, suggesting technical and/or training problems. These together with a variety of other procedural errors and selection/issue of inappropriate components suggest a need for further training or review of procedures. 48% of laboratory errors occurred out of hours but the available data cannot be used to interpret the significance of this finding. Basic "epidemiological" research into the timing and location of transfusions in the hospital setting is clearly needed.

- Unnecessary transfusions were noted on a number of occasions and with blood safety assuming such importance in the eyes of the public, any such instances must be viewed seriously. Anti D immunoglobulin was administered unnecessarily in 12 patients for a variety of reasons which included mis-prescribing because of apparent lack of understanding or mis-interpretation of RhD grouping results, sampling error, mis-grouping in the laboratory, a verbal report not heard correctly or mis-identification at the bedside. Additional examples of unnecessary blood component administration occurred as a result of erroneous haemoglobin results and bedside identification errors

- A number of errors in requesting, selection, issue and administration of a variety blood components suggest some basic lack of knowledge and understanding of transfusion issues amongst individuals responsible for different steps in the transfusion process. These include criteria for irradiation and anti D immunoglobulin administration, referred to above, the significance of pre-existing red cell antibodies, the correct use of emergency group O red cells and occasionally the issue of the wrong component altogether.

- It remains the case that a factor in some wrong blood transfusions is confusion over telephone messages.

- Phlebotomy errors are not confined to blood grouping/crossmatch samples. Erroneous haemoglobin levels as a result of wrong blood samples may lead to unnecessary transfusions.

- Since publication of the 3rd Annual SHOT Report in March 2000, a BCSH guideline has been published (reproduced in the 3rd Annual Report) on how to achieve safer transfusion at the bedside [5]. It is clear from the foregoing that many of its recommendations have not yet been put into practice.

RECOMMENDATIONS

Although over a year has passed since publication of the BCSH guideline "The administration of blood and blood components and the management of the transfused patient" [5] the number of reports falling into the category of incorrect blood component transfused has risen by 39.6%. The major increase has been in the area of collection from the hospital storage site/bedside administration but an increase in inappropriate requests was also noted. Whether this increase in reporting represents a true increase in incidence of errors or greater willingness on the part of hospitals to report errors cannot be ascertained in this type of hazard reporting scheme. Not all cases were those of transfusion of a blood component to other than the intended recipient or of the incorrect ABO or RhD group. Many involved failure to provide the correct requirements for a given patient or fortuitous issue of the right blood to the right patient despite breaches in procedures. Nevertheless the figures point to significant problems in ensuring the safety of the blood transfusion process, particularly at the point of administration at the bedside. As was stated in last year's report:

"Wrong blood incidents are without exception avoidable errors and the bedside check is the final opportunity to prevent a mis-transfusion"

It is essential that every hospital becomes familiar with and puts into practice existing guidelines in the field of blood transfusion to minimise the possibility of human error.

The complexity of the transfusion process and the difficulties of ensuring compliance with procedures in a large, multi-disciplinary organisation cannot be underestimated. However, the problem of inadequate patient identification procedures in particular may have serious consequences and as this report has shown, extends beyond the confines of the transfusion process itself to involve other blood samples and potentially drug administration (for example anti D immunoglobulin). It is essential that every hospital becomes familiar with and puts into practice existing guidelines in the field of blood transfusion to minimise the possibility of human error. Existing procedures should be re-examined for flaws which could lead to systems errors. Hospital Transfusion Committees should play a key role in this process and should be managerially empowered to do so. As the same types of errors are occurring each year, many of the following recommendations are the same or very similar to those made in previous SHOT reports.

- **Every hospital must have a formal policy for the bedside check which must be rigidly enforced at all times.**
  This must ensure that blood components are correctly allocated and identified and be capable of detecting preceding compatibility labelling discrepancies and relevant previous transfusion information such as previous group and antibody screening reports. The dangers of staff becoming distracted, even after correct checking, must be borne in mind.

- **Every patient should be uniquely identified using a wristband or equivalent**
  Retaining wristbands or their equivalent in the operating theatre situation is essential and a formal means of identification should be pursued for all patients in theatre and A+E departments. Reliance should not be placed on familiarity with the patient in the outpatient setting.

- **Computerised systems are available to ensure safe transfusion at the bedside. Such systems are in operation in other countries, although not on a large scale, and pilot studies have been conducted at a few sites in the U.K. These systems and others such as radiofrequency labels now merit further study and development.**
  Their potential value beyond the transfusion setting, for example in reducing drug administration errors, should be explored as this will improve their cost effectiveness. Currently serious errors in the use of prescribed drugs account for 20% of all clinical negligence litigation and in a recent Department of Health publication it has been recommended that steps should be taken to reduce these by 40% by 2005 [8].

- **Every hospital should ensure that standards are set for correct collection of blood components from hospital storage sites; this should incorporate formal identification procedures.**
  Staff carrying out this important function must be aware of the key role they play in ensuring the safety of the transfusion process and must receive appropriate training in this procedure. Computerised systems exist to improve the safety of this process and can be linked to bedside identification systems for both blood

sampling and administration of blood components. Although such systems are not in widespread use and are still in the process of being developed, as stated above, they merit further evaluation.

- **Blood banks must continue to be vigilant in reviewing procedures, systems and training to prevent sample handling and technical errors.**

- **Individuals responsible for the prescription and request of blood components must be familiar with the special needs of their patients and these requirements must be flagged on the clinical and laboratory records.**
  Recently a card and information leaflet has been developed by the BCSH in collaboration with the NBS for patients requiring irradiated components, particularly those receiving shared care (see Appendix 10). Where appropriate patients should be encouraged to carry these and present them on admission to hospital.

- **Individuals responsible for the prescription and request of blood components must be familiar with their correct use and with the special requirements of their patients.**
  These should conform with BCSH and other guidelines and special requirements should be flagged on the clinical and laboratory records. A new BCSH guideline on the clinical use of red cells is in press and a pre-publication version is reproduced, with permission, in Appendix 11.

- **Individuals responsible for taking samples for transfusion testing must at all times follow strict procedures to avoid confusion between patients.**
  he same degree of care should be afforded to the taking of other blood samples as incorrect results from these may lead to unnecessary blood transfusion.

- Telephoned requests for blood components must be formally recorded and incorporate all relevant information including special requirements. Great care must be exercised when acting on verbal results.

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

Note:

Readers may be interested to note the recent publication of new BCSH guidelines on blood bank computing[13].

8. ACUTE TRANSFUSION REACTIONS

Definition

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

This category accounted for 11.9% of non-infectious hazards reported.
36 initial reports (34 new) were received. 33 completed questionnaires were received. These included 2 cases for which initial notification forms were received in the previous reporting year.

This chapter highlights the main findings from 33 completed questionnaires.

Overall there were 2 deaths in this group, both of which were felt to be unrelated to the transfusion. One death followed FFP administration in a patient with liver disease on ICU, and the second was a patient with myelodysplastic syndrome who was receiving platelets for gastro-intestinal bleeding and who died due to the haemorrhage. One patient required admission to ICU following an anaphylactic reaction to platelets but subsequently made a good recovery and 4 patients were already on ICU at the time of their adverse event. All the remaining patients suffered minor or no morbidity.

Sex (32 reports)

Males	19
Females	13

Age (32 reports)

Age range	1 month - 88 years
Median	52 years

Components implicated (33 reports)

Red Cells (RBC)	11
Fresh frozen plasma (FFP)	9 (2 concurrently receiving red cells +/- platelets; one patient receiving cryosupernatant rather than FFP)
Platelets	13

Leucocyte-depleted components were transfused in at least 18/24 patients who were transfused with red cells or platelets. In a number of the earlier reports (prior to universal leucodepletion) the nature of the component is unclear.

1. Reactions in which red cells were implicated

There were 11 cases and all survived without long term sequelae. The following reactions were seen:

Reaction type	Number of cases
Non-haemolytic febrile	2
Anaphylactic[+]	1
Allergic[++]	2
Dyspnoea and chest pain	2
Haemolysis	4

[+]anaphylactic/anaphylactoid (hypotension with one or more of: rash, dyspnoea, angioedema)
[++]allergic (one or more of: rash, dyspnoea or angioedema **without** hypotension)

Non-haemolytic febrile transfusion reactions (NHFTR)

Most NHFTRs are not regarded as serious sequelae and therefore SHOT does not set out to collect reports of these types of reactions. However, two reports fell into this category and in both cases the reaction began while the transfusion was in progress.

Anaphylaxis

One patient developed a severe anaphylactic reaction during a red cell transfusion. She recovered following steroid, anti-histamine and adrenaline administration. Subsequent investigations showed that she had IgA deficiency with anti IgA.

Allergic reactions

There were 2 apparent allergic reactions in this group. In 1 case, a patient receiving an autologous unit of red cells following a bone marrow harvest developed a rash and fever. The reaction was noted during the red cell transfusion and led to the transfusion being abandoned. The cause of the allergic reaction was not determined.

Dyspnoea/chest pain

Two patients developed acute dyspnoeic reactions during their transfusions. TRALI was queried in each case but then discounted, though the reasons for this are unclear. One red cell unit grew micrococcus and coagulase negative staphylococcus which were felt to be contaminants. Otherwise investigations for TRALI were negative in one case and possibly not carried out in the second case.

Haemolytic Transfusion Reactions

There were 4 patients with evidence of acute haemolysis. In three cases this was due to an identified red cell incompatibility while in the fourth the reaction may have been an exacerbation of autoimmune haemolysis. Details of these cases are given below.

Case 1 This 61 year old male with chronic lymphocytic leukaemia was being transfused as an emergency due to cardiac ischaemia secondary to anaemia. He developed symptoms of intravascular haemolysis within the first 50mls of the red cell unit which had been issued before completion of antibody identification because of clinical urgency. The patient was found to have anti Jkb and this had been known to the Regional Blood Centre but not the hospital laboratory as the patient had been transfused in another hospital previously.

Case 2 A 78 year old female patient with heart disease and recent bleeding was transfused 9 days after a previous uneventful transfusion. She developed dyspnoea and fever during her first unit. Pre-transfusion testing had shown anti c and anti E but post-transfusion testing showed a further antibody which was later shown to be anti Jkb which had presumably been evolving following the earlier transfusion.

Case 3 A 56 year old female patient receiving chemotherapy for breast cancer developed haemoglobinuria, nausea, vomiting and abdominal pain during a routine transfusion. She had had no monitoring of vital signs for 4 hours prior to the reaction. The Junior House Officer (JHO), notified by the nursing staff, saw the patient more than an hour later, having advised continuation of the transfusion, and queried a urinary tract infection. Blood tests confirmed a likely haemolytic event. Anti K was detected 2 months later, although the pre-transfusion and immediate post-transfusion antibody screens were negative.

Case 4 A 68 year old female patient with prolymphocytic leukaemia received a 2 unit red cell transfusion in the community, under the supervision of the Community Rapid Response Team. Two hours after completion of the transfusion she developed chills, fever, haemoglobinuria and back pain. She was brought to A&E where investigations confirmed a probable haemolytic event. Antibiotics were given but blood cultures were negative. Pre-transfusion and post-transfusion testing was negative although she had previously been DAT positive with a non-specific autoantibody. The cause of the haemolytic event remained unclear.

2. Reactions in which fresh frozen plasma (FFP) was implicated

There were 9 reports in this group. One patient was concurrently receiving red cells and another was receiving red cells and platelets. One patient died but this was not felt to be related to the transfusion. The remaining patients survived without sequelae. In all cases, the reactions occurred during the transfusion and were of 2 main types:

Reaction type	Number of cases
Anaphylactic	5
Allergic	4

Anaphylactic/anaphylactoid reactions

There were 5 patients in this category and their reactions were characterised by hypotension with respiratory complications in 3 cases and rash in 2 cases. Two patients were investigated for a possible immunological cause. The first was tested only for HLA antibodies (negative) while the second had more comprehensive investigations (HLA, granulocyte and IgA antibodies - all negative in FFP but weak anti HLA in patient). It should be noted that there is no clear distinction between transfusion-related acute lung injury and anaphylaxis with dyspnoea unless appropriate investigations (performed only in one of these cases) show the presence of potentially implicated antibodies.

One of these patients was given FFP to manage bleeding secondary to a high INR (>20). The guidelines on management of anticoagulation[14] suggest the use of prothrombin complex concentrate may be appropriate in these circumstances but this may not be immediately available in some smaller or more remote hospitals. Currently, only HT-DEFIX (Scottish National Blood Transfusion Service) is licensed for this purpose in the UK.

In the other 4 cases it is difficult to assess whether or not the administration of FFP was appropriate (1 liver disease, 1 prophylaxis before endoscopic retrograde cholangiopancreatography (ERCP), 1 bleeding heavily during cardiac surgery, 1 patient with trauma who had received 3 units of red cells and 2 units of FFP).

Allergic reactions (not anaphylaxis)

Four patients suffered apparent allergic reactions with dyspnoea and rash/pruritis. In one case the patient was receiving cryosupernatant for thrombotic thrombocytopenic purpura (TTP).
Two patients who developed dyspnoea, angioedema and a rash were receiving FFP to reverse a high international normalised ratio (INR) in the absence of bleeding. This is not felt to be an appropriate indication for FFP administration.
A further case appeared to be receiving FFP and red cells in a 1:1 ratio while undergoing re-do cardiac surgery which is generally not considered an appropriate use of this product.
In the majority of cases investigations to identify the cause of the reactions had not been carried out.

3. Reactions in which platelets were implicated

There were 13 cases in this group all of which occurred during the transfusion. One patient died due to a recurrent haemorrhage, unrelated to the transfusion reaction while all the other patients survived without ill effects.

Reaction type	Number of cases
Anaphylactic	7
Allergic	3
Hypotension	2
Dyspnoea/chest pain	1

Anaphylactic reactions were common in this group. As noted above, it can be difficult to differentiate these from episodes of TRALI or sepsis, unless appropriate investigations have been performed.
Selected cases are described in some detail below.

- *Case 1* *This 41 year old male patient with immune thrombocytopenic purpura (ITP) received three pools of platelets to manage bruising. He developed an anaphylactic reaction requiring the administration of steroids, antihistamine and adrenaline and required admission to ICU. It is generally felt that platelets should not be administered in ITP other than to manage significant bleeding.*

- *Case 2* *This 43 year old female patient with acute lymphoblastic leukaemia (ALL) had a cardiac arrest during an anaphylactic reaction to a leucocyte-depleted platelet pool. She made a full recovery following resuscitation. Blood cultures drawn from the patient were negative. No cultures of the pack were performed although the reporter queried a bacterial cause of the reaction.*

- *Case 3* *This 68 year old male patient with Waldenstrom's Macroglobulinaemia developed dyspnoea and chest pain during the transfusion of the first 10mls of an apheresis unit of platelets (leucocyte-depleted). Bacterial cultures of the pack grew coagulase-negative staphylococcus but blood cultures were not performed on the patient. The patient appears to have made a good recovery without antibiotic administration and has subsequently received platelets in Platelet Storage Medium(PSM).*

- *Case 4* *This neonate, thrombocytopenic due to Gram-negative sepsis, developed hypotension and tachycardia with platelet transfusions on 2 consecutive days. No cause for the reactions were identified.*

Response times

In general patients were seen within 5-10 minutes of the reaction developing (24 cases, 72%) and the local haematologist was contacted for advice in 24 cases (72%). The haematologist was not, apparently, contacted in some of the more severe cases, however, and this may have contributed to the under-investigation of many of these events.

Observations

There was a wide range of frequency of nursing observations prior to the onset of the reaction:

Table 25
Frequency of nursing observations

Frequency of observations	Number of cases
5 minutes	1
15 minutes	4
20 minutes	1
30 minutes	5
40-60 minutes	5
>1 hour	1
No information	16
Total	**33**

Reporting to Blood Centres and Hospital Transfusion Committees

This was highly variable, reflecting, perhaps, the wide range of reactions reported.

Table 26
Reporting of reactions to the local Blood Centre, the Hospital Transfusion Committees (HTC) and the Hospital Laboratory

Reported to	Number
HTC	20
Hospital Laboratory	32
Blood Centre	20
Not stated	1

In 5 cases the reporter stated that practice had been changed as a result of the incident. This included 2 patients who were subsequently provided with platelets in PSM, one patient who had a haemolytic transfusion reaction due to an antibody known to the Regional Blood Centre (communication with the Centre has been changed) and one patient (Case 2, above) whose pre-transfusion sample was felt to have been drawn too long before the transfusion ("more than 24 hrs"), resulting in haemolysis due to a developing anti Jkb.

COMMENTARY

- Fresh frozen plasma and platelets both appear to be "over-represented" in the acute transfusion reaction group, compared to red cells which are administered much more frequently. 7-10 units of red cells are transfused for every unit of platelets or FFP and yet FFP and platelets appear to be a more common cause of acute transfusion reactions.

- The SHOT scheme does not specifically attempt to assess the appropriateness of transfusion but it is clear from the details provided that patients are experiencing life-threatening reactions to components which they perhaps did not require.

- Reactions are under-investigated and it is generally unclear why they have occurred. Some of these acute reactions may, in fact, have been due to bacterially-infected components or may have been episodes of transfusion-related acute lung injury.

- Although the local haematologist was informed (or initially involved) in most instances it is surprising that some severe reactions appear not to have been notified to him/her.

RECOMMENDATIONS

- **Clinicians involved in transfusion should be made aware that FFP and platelets carry a relatively high risk of inducing a severe adverse event.**

- **National guidelines are available relating to anticoagulant management[14] and the appropriate use of FFP[15] and also platelets[16] (FFP guidelines currently being updated) but many staff prescribing these may not be aware of their content. Summaries of the more relevant points could usefully be included in hospital transfusion guidelines or transfusion laboratory handbooks in order to improve accessibility and compliance with these.**

- **A national guideline on the appropriate investigation of transfusion reactions is required and is currently under preparation within the NBS and SNBTS.**

- **The local haematologist should be contacted regarding all serious adverse events arising from the transfusion of blood components. These events may have implications for other potential recipients and require timely and appropriate investigation if the cause of the event is to be clarified.**

9. DELAYED TRANSFUSION REACTIONS

Definition

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

Delayed transfusion reactions are defined in this report as those occurring more than 24 hours following a transfusion of blood or blood components. In practice, these are almost invariably delayed haemolytic reactions due to the development of red cell alloantibodies. Excluded from this definition are uncomplicated alloimmunisation episodes which have not resulted in evidence of haemolysis (falling Hb, positive DAT or jaundice) or clinical symptoms. Such reactions are relatively common following red cell transfusions (approximately 1 in 20 transfusions).

This category accounted for 9.8% of non-infectious hazards reported.

28 initial reports were received and 24 completed questionnaires were returned (including one which was initially reported in the previous reporting year). This chapter highlights the main findings from 24 completed questionnaires. One of these cases was a simple serological reaction but, as noted above, reporting of this type of event to SHOT is not required

Sex

Males	11
Females	13

Age

Age range	33-86 years
Median age	62 years

Table 27
Timing of Reaction/Diagnosis in relation to previous transfusion

Days post-transfusion	No. of cases
1-5	1*
6-10	14
11-15	4
16-20	1
>20	1
Not stated	3

* Case 12, see below

Range	3-30 days
Median	8 days

Reactions Reported

There were 2 deaths in this group (cases 7 and 13) which were both due to the underlying disease. In addition, one patient experienced angina secondary to severe anaemia but made a good recovery and a patient who had severe complications following cardiac surgery (case 15) was still recovering at the time of the report. The remaining patients suffered minor, or no morbidity.

All reactions were related to the administration of allogeneic red cells but in 1 patient who seemed to have a clear-cut haemolytic reaction (Case 2) no alloantibodies were implicated. A possible exacerbation of autoimmune haemolysis was suspected. In total 29 new antibodies were noted in the 24 cases.

Six patients had pre-transfusion red cell alloantibodies. A patient with autoimmune haemolytic anaemia (AIHA) who required blood as a matter of urgency (Case 12) was issued with unphenotyped units and was found to have alloanti E on completion of the antibody identification. This patient showed evidence of a transfusion reaction on day 3.

Urgency of Transfusion Requirement

In 19 patients the transfusion was said to be routine and in 5 urgent. Most transfusions were for surgery or bleeding. One patient was transfused for iron deficiency anaemia due to gastritis.

New Post-transfusion Antibodies

Table 28 shows the new post-transfusion antibodies (or antibodies which were later recognised to be present in the pre-transfusion sample) according to antigen specificity and Table 29 gives details of these antibodies for individual patients.

Table 28
New post-transfusion red cell antibodies in 23 patients: according to antigen specificity

Antibody group	Number	Sole antibody
Kidd		
Jka	10	6
Jkb	1	1
Duffy		
Fya	3	2
Kell		
K	1	1
Rh		
c	4	2
E	5	2
SsMN		
S	1	
M	1	
Other		
Anti B[1]	1	
"private antigen" NOS[2]	1	
Wra	1	1

[1] in liver transplant, donor antibody
[2] Not otherwise specified

Table 29
New post-transfusion red cell antibodies in individual patients

ID	Antibody(ies)	Comment
1	Fya	
2	Nil	?AIHA, positive DAT and alloanti E identified pre-transfusion
3	Fya+Jka+anti B	liver transplant (O to B), anti e+S+cold agglutination pre-transplant
4	Jka	
5	Jka	
6	c+E	
7	E	
8	K	Serological reaction only
9	c	
10	Jka	
11	Jka	
12	E	AIHA. Urgency precluded full compatibility testing. Anti E pre-transfusion
13	Wra	
14	Jka	
15	Jka	
16	S+M	Anti C+E+Fya+Jkb+autoanti D pre-transfusion. Sickle cell disease
17	Jka	Anti C+D+E pre-transfusion
18	?private antigen	"non-specific antibody" pre-transfusion
19	Fya	
20	Jkb	
21	c+E	Anti K pre-transfusion
22	c	Nil detected pre-transfusion. History of HDN (not known initially)
23	Jka+E	
24	Jka	Anti D pre-transfusion.

Clinical sequelae

Symptoms and signs could be divided into 4 categories as follows:

- Group 1 Asymptomatic (± positive direct antiglobulin test (DAT) ± spherocytes)
- Group 2 Falling haemoglobin (↓Hb)/positive DAT/spherocytes (2 of these parameters)
- Group 3 ↓Hb + jaundice ± positive DAT ± spherocytes
- Group 4 As group 3 + renal impairment

Group 1
There were 3 patients in this group (cases 5, 8 and 13). Case 13 died of his underlying disease while the other two cases survived without sequelae.

Group 2
There were 5 patients in this group (cases 1, 2, 7, 14 and 17) of whom 3 survived without sequelae, one developed angina (case 2) and one (case 7) died of her underlying disease.

Group 3
There were 15 patients in this group (cases 3, 4, 6, 9, 10, 11, 12, 16, 18, 19, 20, 21, 22, 23 and 24) all of whom survived without sequelae.

Group 4
There was only one patient in this group (case 15) who suffered multiple problems following cardiac surgery, probably exacerbated by the haemolysis, but who was recovering at the time of the report.

The above results are detailed in Table 30

Table 30
Grouping of cases by clinical sequelae of DHTR

Group 1		Group 2		Group 3		Group 4	
ID	Antibody	ID	Antibody	ID	Antibody	ID	Antibody
5	Jka	1	Fya	3	Fya+Jka+anti B	15	Jka
8	K	2	Nil	4	Jka		
13	Wra	7	E	6	c+E		
		14	Jka	9	c		
		17	Jka	10	Jka		
				11	Jka		
				12	E		
				16	S+M		
				18	?to private Ag		
				19	Fya		
				20	Jkb		
				21	c+E		
				22	c		
				23	Jka+E		
				24	Jka		

Analysis of serological information

Antibody screening

Table 31 gives information on the serological methods used for antibody screening in the 24 reported cases.

Table 31
Summary of serological methods used for antibody screening

Screening Method	2 cell screen	3 cell screen	Total
Tube LISS IAT	1		1
Column IAT	9	13	22
Solid Phase	2		2
Liquid Microplate		1	1
Total[1]	**12**	**14**	**26**

1 two respondents recorded more than one technique in the antibody screen questions

This table shows a marked preponderance in the use of column technology for antibody screening in these cases. This is in keeping with the national trend towards increasing use of column technology as shown in the National External Quality Assurance Scheme (NEQAS) for Blood Transfusion Laboratory Practice (BTLP). Antibody screening cells from a large number of suppliers were used with this technology and it is not possible to say if the cells used were always optimal for the column technology selected.

Results were analysed to determine whether or not a 2-cell screen was more likely to be associated with an initially negative antibody screen. This was not the case. 5/12 patients screened using a 2-cell screen had a negative screen compared to 11/14 tested using a 3-cell screen (in 1 case, details were not given). However, as 2-cell screens are more likely to miss antibodies of C^w, Lu^a or Kp^a specificities, none of which were implicated in these events, this result is perhaps not surprising.

In 14 cases the pre-transfusion sample was retested and gave the same result in 13 cases. The exception was the patient with anti Wra which could not have been detected with the screening cells used but which was revealed on further investigation.

Details of some unusual serological cases are given below:

- *Case 3 This 47 year old male patient, Group B, received a liver transplant from a Group O donor (anti B titre 1/4). Pre-transfusion testing showed anti e, S and cold agglutinins but a unit of cross-match compatible, S+ve blood was transfused before investigations were complete. Ten days post-transplant a falling Hb, raised bilirubin and positive DAT were noted. Serological testing showed anti Fya, Jka and anti B in addition to his previously known antibodies. The anti B was presumably of donor origin while the other antibodies are likely to have been produced by the recipient. The reaction noted may have been due to any (or all) of the four antibodies - anti B, S, Fya or Jka.*

- *Case 16 This 33 year old male patient with sickle cell disease received 5 units as an exchange transfusion prior to surgical debridement. Five days later he was noted to be jaundiced, with no rise in the Hb and HbS level of 98% suggesting that any transfused units had been destroyed. Pre-transfusion he was shown to have anti C, E, Fya, Jkb and autoanti D but subsequent testing showed the presence of anti S and anti M in addition. It is possible that these had been responsible for the apparent destruction of the transfused units and may have been present, but missed, at the time of initial testing. Repeat testing of the pre-transfusion sample was not performed*

- *Case 22 This 48 year old female patient received 4 units of red cells for a bleeding duodenal ulcer. At readmission, 8 days later, she was noted to have dark urine, jaundice, low Hb and back pain. Anti c was found in a sample drawn at readmission but the pre-transfusion sample was not available for retesting. The patient advised that her last child had been affected by HDN but this history was not ascertained at the time of first admission.*

Cross-matching

Interval between drawing cross-match sample and transfusion

The interval between sampling and transfusion is shown below for 24 reports

Interval between sampling and transfusion (hrs)	No. of cases
0-47	17
48-71	3
72-96	1
>96	1
Not known	2

In general, the timing of pre-transfusion samples was in keeping with the national guidelines[17]. In one case (Case 24) the time between drawing the sample and transfusion appeared to be inappropriately long (>96 hrs) in view of the history of recent (within 14 days) transfusion.

- *Case 24 This 34 year old female patient was transfused on 2 occasions in one week for anaemia due to liver disease and splenomegaly. Anti D was noted at the time of the first of these transfusions. Six days later a further transfusion was given, matched against a sample drawn more than 4 days before. Jaundice, anaemia and a positive DAT developed. The patient was subsequently shown to have developed anti Jka.*

Cross-matching methods used

The methods used for cross-matching are shown below in Table 32:

Table 32
Cross-matching methods

Method	No. of cases
Electronic issue	
Immediate spin	8
LISS IAT Tube	6
Column	9
Not known	1
Total	**24**

There was no evidence of inappropriate use of the Immediate Spin cross-match. All patients with a positive antibody screen had blood matched by IAT methods.

Reporting to Blood Centres and Hospital Transfusion Committees

19/24 (79%) cases were reported to the Hospital Transfusion Committee while only 11 (46%) were reported to the local Blood Centres. The involvement of the Hospital Transfusion Committee has increased from last year which presumably reflects the increased availability of these committees and greater awareness of their role. It is presumed that the local Blood Centres would have been notified if assistance was required in antibody identification or sourcing of subsequent units of compatible blood.

COMMENTARY

- As in earlier SHOT reports the antibodies responsible for the DHTRs were consistent with those reported in the literature with a preponderance of Kidd - 11/29(41%) of all antibodies, 11/24 (46%) of patients.

- Kidd antibodies, undetectable by current methods, remain the major cause of delayed haemolytic transfusion reactions

- In 1 case (Case 22) the existence of an alloantibody was known historically but not reported to the hospital laboratory. The antibody was not detectable on pre-transfusion testing and, unfortunately there was no sample available for retesting.

- In 3 additional cases it appears that the antibody could have been detected in the pre-transfusion sample (Cases 12, 13 and 16). However, in one case clinical urgency precluded the completion of full testing (Case 12), one implicated antigen would not normally be expressed on screening cells (Case 13 - anti Wra) and in the third case (Case 16) the presence of two additional antibodies (S+M) may have been missed in a patient with multiple antibodies.

RECOMMENDATIONS

- **Transfusions for iron deficiency anaemia (or other medically treatable causes) should be avoided if possible, both because of the risk of primary immunisation and also because of the risk of inducing a secondary immune response with haemolysis. BCSH guidelines on the appropriate use of red cells are due to be published in April and a pre-publication version is reproduced, with permission, in Appendix 11.**

- **Laboratories should ensure that any antibodies which may be masked by detected antibody(ies) are excluded by the use of additional panels and techniques (e.g. enzyme-treated cells).**

- **Historical transfusion details should be sought from all relevant sources (including the patient) and acted upon.**

- **Development of screening techniques in order to improve the detection of extremely low levels of Kidd antibodies should be considered by serologists and manufacturers of screening systems.**

- **Information for patients who may be transfused should include the fact that antibody development is possible and unavoidable.**

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.

Twenty four cases were originally reported (Table 33). There was a duplicate report of 1 case, and 4 others were later withdrawn by the reporter. Of these 4, 2 were re-assigned as cardiac failure/left ventricular overload (cases 18 and 24), 1 as cryptogenic organising pneumonitis (case 6), and 1 as an acute reaction to transfusion (case 10). This illustrates the difficulty in making a clinical diagnosis of TRALI.

There were therefore 19 new cases of TRALI which met the case definition, and completed questionnaires have been received on 18 of the cases, a highly gratifying response. Analysis of these revealed considerable uncertainty about the ultimate diagnosis of the respiratory episode in many of the cases. Two cases (8 and 19) were reported as possibly having adult respiratory distress syndrome, and another (case 22) was reported as either TRALI or cardiac overload. The underlying diagnoses and components given in each case are shown in Table 33.

Of the 19 cases which met the case definition, there were 10 males and 9 females, with an age range of 3-77. Two cases involved children, 1 with acute myeloid leukaemia (AML) and 1 with sepsis/trauma.

The figures quoted in the remainder of this chapter all relate to the 18 cases analysed from questionnaires.

Underlying diagnoses were:-

- haematological malignancy in 7,
- elective surgery in 5
- sepsis/trauma/DIC in 4,
- plasma exchange for TTP in 2.

Components given were:-

- Red cells alone - 2
- Platelets alone - 4
- FFP/cryosupernatant alone -3
- Red cells + platelets - 3
- Red cells + FFP - 3
- Red cells + platelets + FFP - 3.

It was clear which type of component was implicated in the TRALI reaction in only 11 cases, being red cells in 3, platelets in 4 and FFP/cryosupernatant in 4.

Identified risk factors were present in 4 of the 18 patients, with 1 patient each having cardiac failure, fungal chest infection, asthma/sepsis and sepsis/LVF.

The clinical and chest X-ray features are shown in Table 34. Dyspnoea was the only universal feature, with fever in 3 cases (+ rigors in 1), and hypotension in 8. Where measured, all cases had low pO_2, and 5 had high pCO_2. Chest X-ray features were or became abnormal in 11 cases, usually described as 'pulmonary white-out', massive pulmonary oedema, or bilateral pulmonary infiltrates.

Treatment and outcome (see Table 35)

Six patients were already on ICU when transfused, 8 patients required admission to ICU for 1-9 days, and 4 were treated on the ward (1 with Continuous Positive Airways Pressure (CPAP)). Most patients received some form of steroids, +/- anti-histamine, adrenaline, or diuretics.

There were 6 fatalities to which the episode reported as TRALI may have been contributory (cases 2, 4, 9, 13, 16, and 21). Of these, 2 were already extremely ill in intensive care, 2 had haematological malignancies for whom ICU admission was not considered appropriate, and the remaining 2 were admitted to ICU because of the onset of pulmonary symptoms. These were a 68-year old man with lymphoma and a 38-year old woman undergoing plasma exchange for TTP. At post-mortem she was found to have a stenosed coronary artery and massive pulmonary oedema, raising the possibility of left ventricular failure.

Donor characteristics and serology (Table 35)

It is difficult to draw any conclusions from this section, as donor investigations were of variable completeness. In centres which recall donors for fresh samples, or if these are obtained the next time the donor attends, completion of an investigation may take months. In most cases, 1 or more female donors had positive HLA and/or granulocyte antibodies. However, such antibodies are found in >5% of multiparous females, so their presence does not prove that they were the cause of the TRALI episode. Demonstration of a positive-cross match with the patient increases this likelihood, but this was performed in only a minority of cases. The logistics of obtaining donor and patient samples for cross-matching may be complex.

Diagnosis of TRALI (Table 35)

The case definition we have used for TRALI throughout the 4 years of SHOT reporting has not included any requirement for the presence of leucocyte antibodies in donor plasma. Although the original description of TRALI included the observation that such antibodies in the donor were likely to be the cause of the reaction, we took the view that we were unaware of the true extent of acute pulmonary pathology (other than cardiac overload) associated in time with transfusion. We have therefore kept the case definition broad and clinically based. Inevitably this has led to reporting of cases where the diagnosis is uncertain, even after donor serology is completed.

For this year's report, we have therefore attempted to assess the likelihood of each reported case actually being TRALI, taking into account underlying pre-disposing factors, the certainty of the reporter and the donor serology (all available in 18 cases). Of these, 6 emerged as probable, 9 as possible, and 3 as unlikely. There was 1 fatality in the 'probable' group (a 57-year-old man with lymphoma, case 2); 3 in the 'possible' group, and 2 in the 'unlikely' group. There remains, therefore, a wide degree of uncertainty about the diagnosis of TRALI.

COMMENTARY

- TRALI is difficult to diagnose clinically, having no unique features. It is often diagnosed when other causes of acute lung injury have been excluded. In the absence of pulmonary artery wedge pressure data, it is extremely difficult to differentiate from left ventricular failure. Equally, in the presence of risk factors for adult respiratory distress syndrome, it is difficult to define TRALI clinically, except for an association in time with transfusion. Many cases here were of uncertain diagnosis as discussed by the reporter.

- The original description of TRALI required the presence of leucocyte antibodies in the donor, and in most cases, this type of investigation was followed. However, the protocol used for these donors was highly variable. Some centres used archive samples, while others called donors to obtain fresh samples. In some reports, female donors were investigated first, a logical approach. There was also variability in the actual tests performed, and in the interpretation. Many female donors had weak HLA and/or granulocyte antibodies. It was difficult to be sure about the role of those antibodies in the pathogenesis of the cases reported here, since they are present in > 5% of parous donors, and were not always shown to be incompatible with the recipient.

- Seven of 18 analysed cases had haematological malignancies. This may simply reflect the intensive use of plasma-rich platelet concentrates in this group, but more specific risk factors such as radiation damage to the lungs may be important.

RECOMMENDATIONS

- **It would be helpful if suspected cases could be reviewed locally by an anaesthetist before a final diagnosis of TRALI is reached.**

- **Standardised protocols should be developed for investigation of TRALI cases. This will greatly facilitate analysis of suspected cases, and thus increase understanding of the condition.**

Table 33. TWENTY-FOUR CASES ORIGINALLY REPORTED AS TRALI, SHOWING CASES WITHDRAWN DUE TO AN ALTERNATIVE DIAGNOSIS HAVING BEEN REACHED

TRALI	Age/sex	Diagnosis	Reason transfused	Components transfused			Incriminated component
				RBC	Plt	FFP	
1.	53, M	Hairy cell leukaemia	Splenectomy	2	2 pools	0	Plts
2.	57, M	T cell lymphoma, low platelets	Haemorrhage	0	Yes*	0	Plts
3.	50, F	TTP	Plasma exchange	0	0	Yes*	FFP
4.	??, F	Trauma	Emergency, ICU	4	0	8	??
5.	3, F	DIC, ? sepsis	Emergency	0	1 pool	Yes*	??
6.	***Withdrawn Not TRALI***	Onset 5 days after transfusion. Lasted months		'Cryptogenic organising pneumonitis'			
7.	***Same case as 4***						
8.	62, M	Haematological malignancy	Out patient top-up	3	Yes*	0	RBC
9.	55, M	Post allogeneic bone marrow transplant	Anaemia	2	1 apheresis	0	??
10.	***Withdrawn. Now acute reaction***						
11.	26, M	Trauma, sepsis	Haemorrhage	2	0	0	RBC
12.	59, F	AML	Abnormal clotting	4	1	4	??
13.	68, M	Lymphoma	Bone marrow failure	0	1 pool	0	Plts
14.	26, F	*Reporter has informed SHOT that questionnaire will not be submitted.*					

*Number not stated

TRALI	Age/sex	Diagnosis	Reason transfused	Components			Incriminated component
15.	60, M	Elective aortic aneurysm	Peri-operative	8	0	6 + albumin	??
16.	38, F	TTP	Plasma exchange	0	0	9 cryo supernatant	Cryo-supernatant
17.	80, M	Total elbow replacement	FFP - to reverse warfarin	0	0	2	FFP
18.	***Withdrawn. NOT TRALI. Probably left ventricular failure***						
19.	53, M	Oesophago-gastrectomy	Post-op bleeding	12	3	8	??
20.	52, F	Fractures following road accident	Post-op	2	0	0	RBC
21.	5, M	AML, BMT, Cystitis Renal failure	Thrombocytopenia	0	1 pool	0	Plts
22.	58, F	Surgery	???	7 (3 autol; 4 donor) haemodilution trial	0	4	??
23.	77, M	CABG	On ICU	2	1	5	??
24.	38, F **WITH-DRAWN**	TTP **CARDIAC**	Plasma exchange **OVERLOAD**	4	0	4 cryosup	Prob cryo-supernatant

Table 34. CLINICAL & RADIOLOGICAL FEATURES OF CASES REPORTED AS TRALI

	Age, sex, diagnosis	Risk factors	Fever	Hypotension	Rigors	Dyspnoea	Low pO2	High pCo2	CXR
1.	53, M. Hairy cell leukaemia	None	No	No	No	Yes	Yes	No	Perihilar & basal opacities
2.	57, M. T cell lymphoma, low platelets	None	?	Already hypotensive	No	Yes	?	?	Not done
3.	50, F. TTP	None	?	?	?	Yes	?	?	No change
4.	??, F. Trauma	None	?	?	?	Yes	Yes	Yes	??
5.	3, F. DIC, ? sepsis	None	?	Yes	No	Yes	Yes	Yes	??
6.	***Withdrawn. Not TRALI***								
7.	*Same case as 4*								
8.	62, M. Haematological malignancy	None	Yes	Yes	No	Yes	Slight	No	'ARDS'
9.	55, M. Post allogeneic bone marrow transplant	Fungal chest infection + flu	No	Yes	Yes	Yes	Yes	Yes	New changes after transfusion
10.	***Withdrawn. Now acute reaction***								
11.	26, M. Trauma, sepsis	Asthma. Sepsis Already on ICU	No	Yes	No	Yes	Yes	?	??
12.	59, F. AML	None	Yes	Yes	No	?	Yes	?	Pulmonary infiltrates
13.	68, M. Lymphoma	None	Yes	No	No	Yes	Yes	No	Bilat alveolar shadowing
14.	26, F.	*Reporter has informed SHOT that questionnaire will not be submitted.*							

	Age, sex, diagnosis	Risk factors	Fever	Hypotension	Rigors	Dyspnoea	Low pO2	High pCo2	CXR
15.	60, M. Elective aortic aneurysm	Already on ICU	Not stated	Yes	Not stated	Not stated	Yes	Not stated	Not stated
16.	38, F. TTP	None	N/s	N/s	N/s	Yes	Yes	Yes	Massive pulmonary oedema
17.	80, M. Total elbow replacement	None (atrial fibrillation)	N/s	N/s	N/s	Yes	Yes	N/s	White out – No improvement on diuretics
18.	***Withdrawn. NOT TRALI. Probably left ventricular failure***								
19.	53, M. Oesophago-gastectromy	None (hypertension)	No	No	No	Sedated on ICU	Yes	No	R basal atelectasis + white-out
20.	52, F. Fractures following road accident	No	No	N/s	No	Yes	N/s	N/s	???
21.	5, M. AML, BMT, cystitis, renal failure.	Sepsis Mild LVF BMT	N/s	N/s	N/s	Yes	Yes	N/s	???
22.	58, F. Surgery. ? NOT TRALI	None	No	Yes	No	Yes	No	N/s	Pulmonary oedema
23.	77, M. CABG.	Cardiac failure	No	Yes	No	On ventilation	Yes	N/s	Bilateral opacities
24.	38, F. TTP. Withdrawn. Cardiac overload	None	N/s	N/s	N/s	Yes	Yes	Yes	Massive pulmonary oedema

Table 35. TREATMENT, OUTCOME AND DONOR SEROLOGY

	Age, sex, diagnosis	ICU days	Treatment	Outcome	Serology on Donors	Why did reporter consider this TRALI?	Likelihood of case truly being TRALI (SHOT evaluation)
1.	53, M. Hairy cell leukaemia	2 days CPAP on ICU	Methyl pred Antibiotics	Recovered	1 female donor had HLA antibodies. Crossmatch with pt was neg, so inter-donor reaction possible within plt pool.	Acute – 30 mins after transfusion. No LVF No infection	POSSIBLE
2.	57, M. T cell lymphoma, low platelets	None	Hydrocort Antihistamine	Died	2 female donors had positive granulocyte antibodies – one very strong	Onset during transfusion	PROBABLE
3.	50, F. TTP	None	Prednisolone Oxygen	Recovered	1 FFP donor positive –no details given	Onset during transfusion	POSSIBLE
4.	??, F. Trauma	Already on ICU	???	Died	11 donors tested, 4 positive. Two pos in HLA cytotoxicity only (IgM?) Two pos in GLAM only –I weak HLA, 1 wk neutrophil ab.	Onset following transfusion	POSSIBLE
5.	3, F. DIC, ? sepsis	Yes ? days	Dexameth	Recovered	1 female FFP donor had pos granulocyte antibodies	Onset following transfusion	PROBABLE
6.	**Withdrawn. Not TRALI**						
7.	***Same case as 4***						
8.	62, M. Haematological malignancy	Yes ? days	Methyl pred Antibiotics	Recovered	NEGATIVE	Unsure – onset 2 days after transfusion. Had myeloma, renal failure and pneumonia ? ARDS.	UNLIKELY
9.	55, M. Post allogeneic bone marrow transplant	'Not appropriate'	CPAP hydrocort	Died	2/4 positive. 1 wk HLA class II; 1 wk granulocyte antibodies in GLAM. 'Significance of such weak antibodies is unclear'.	Deterioration during transfusion	UNLIKELY
10.	**Withdrawn. Now acute reaction**						

	Age, sex, diagnosis	ICU days	Treatment	Outcome	Serology on Donors	Why did reporter consider this TRALI	Likelihood of case truly being TRALI (SHOT evaluation)
11.	26, M. Trauma, sepsis	Already on ICU	Noradrenaline	Recovered	1 female donor had weak granulocyte and HLA antibodies	Sudden deterioration - after several days stable	POSSIBLE
12.	59, F. AML	No	Oxygen Anti-histamine Oral dexameth	Recovered	14 donors, 4 neg so far	Sudden onset during transfusion	POSSIBLE
13.	68, M. Lymphoma	Yes	CPAP dex	Died	Only female donors tested –all results negative	Sudden onset 10 minutes after transfusion	POSSIBLE
14.	26, F.	*Reporter has informed SHOT that questionnaire will not be submitted.*					
15.	60, M. Elective aortic aneurysm	Already on ICU	Not stated	Recovered	1 donor positive granulocyte antibodies (Not NA system) 1 donor positive HLA antibodies, incl B8 – pt B8 pos. Both donors Xmatch pos with patient.	Sudden onset following transfusion	PROBABLE
16.	38, F. TTP	Yes 1 day	NOT STATED	Died	2/8 donors pos: 1 non-lytic HLA class I antibodies 1 neutrophil + monocyte reactive – not HLA class II.	Sudden onset during transfusion	No WBC in alveoli at post mortem Stenosed coronary artery -?'LVF rather than TRALI' UNLIKELY
17.	80, M. Total elbow replacement	Yes 2 days	frusemide	Recovered	1 donor pos for HLA Ab class II. 1 donor pos for neutrophil specific Ab. No Xmatch done.	Sudden following transfusion. No response to frusemide	PROBABLE

	Age, sex, diagnosis	ICU days	Treatment	Outcome	Serology on Donors	Why did reporter consider this case TRALI?	Likelihood of case truly being TRALI (SHOT evaluation)
18.	**Withdrawn**	**NOT TRALI**	Left ventricular failure		2 male donors only – both neg.		WITHDRAWN
19.	53, M. Oesophago-gastrectomy	Already on ICU	Antibiotic Anti-hist	Recovered	Patient – neg in serum; pos neutrophil-bound IgG 1 donor – No HLA or granulocyte antibodies in serum. Crossmatch cannot be interpreted.	Deterioration following transfusion	POSSIBLE
20.	52, F. Fractures following road accident	ICU – 1 day	Methyl pred + adrenaline	Recovered	1 donor weak neutrophil specific Ab Crossmatch positive.	Sudden onset during transfusion	PROBABLE
21.	5, M. AML, BMT, cystitis, renal failure.	Already on ICU - being weaned off ventilation	??	Died	3 donors negative. 1 donor had non-lytic HLA antibodies by GLAM and ELISA. This donor had previous transfusions and 3 previous pregnancies. No cross-match possible.	Deterioration following transfusion	POSSIBLE
22.	58, F. Surgery	Yes Number of days not stated	None	Recovered with impaired function	14 donors, 5 female. Archive samples inconclusive Fresh donor samples being investigated.	'Clinically may or may not be TRALI'	POSSIBLE
23.	77, M. CABG	Already on ICU - 9 days	???	Recovered	2/10 donors positive -both female donors of FFP. Both had granulocyte antibodies which gave pos crossmatch with pt.	Deterioration during transfusion	PROBABLE
24.	38, F. TTP **Withdrawn**	Yes 3 days	???	Recovered with impaired function	8/9 donors neg. One gave ambiguous results.	Sudden onset following transfusion	**WITHDRAWN-cardiac overload**

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.

Six new suspected cases were reported, all female, ranging from 38-92 years of age (average 65 years). One did not meet the case definition in that no human platelet antigens (HPA) antibodies were found, and so was excluded, leaving 5 definite cases. All five questionnaires were returned and are analysed below. In addition 1 questionnaire was received from a case initially reported last year making a total of 6 to analyse. There was 1 death from unrelated causes in a 92-year old woman; all others made a full recovery.

Summary of cases

All 6 analysed cases had had previous pregnancies, none complicated by clinically apparent neonatal alloimmune thrombocytopenia (NAIT). However, NAIT would not have been a widely recognised condition when many of these pregnancies occurred, more than 20 years ago in 5/6 cases.

In 1 case, the reason for transfusion was not stated, three cases were transfused in association with surgery (removal of renal cell carcinoma, cholecystectomy, and orthopaedic surgery), and two others had haematological conditions (myelofibrosis [MF] and acute myeloid leukaemia [AML]). Both of these patients were profoundly thrombocytopenic (< 10 x 10^9/L) before transfusion. All surgical cases and the MF patient received only red cells. The patient with AML was receiving multiple transfusions of both red cells and platelets, and thus presented as a case of platelet refractoriness. This case is described in detail.

Platelet refractoriness due to HPA-1b antibodies in a patient with acute myeloid leukaemia.

The patient was a 52 year old woman with relapsed AML. During reinduction chemotherapy, during which she received 10 units of red cells and 6 doses of platelets (5 pools and 1 apheresis), she developed refractoriness to random donor platelets. The lowest recorded platelet count was 3 x 10^9/L. HLA antibodies were found and 7 doses of HLA selected platelets transfused. Unfortunately, intra-cerebral haemorrhage developed. She was also found to have HPA-1b antibodies and to be of HPA 1a/1a genotype. She was therefore treated with intravenous immunoglobulin and HPA-1a homozygous platelets, with a good response. The patient completed the remainder of the planned chemotherapy.

Clinical course and serology in the remaining 5 cases

In 2 cases, symptoms developed 5-9 days after red cell transfusion, and in 2 cases the interval was 9-15 days. In all cases, the nadir of the platelet count was < 10 x 10^9/L. In 3 cases, haemorrhage was minor (purpura +/- epistaxis), but 2 patients developed GI haemorrhage, one in association with previous radiation-induced proctitis.

Four confirmed cases had anti HPA-1a, with associated HLA antibodies in 2. The patient with renal cell carcinoma had anti HPA-5b.

All cases were treated with I/V IgG, with the addition of steroids in two. Four patients received platelet transfusions, which were random in 2, and selected antigen negative in 2 (one patient received both random and selected platelets). One patient having orthopaedic surgery, who was aged 92 years, died of unrelated causes. All other patients recovered fully. The platelet count reached a safe level of 50 x 10^9/L in < 7 days in all surgical patients treated with I/V IgG. In the patient with MF, the platelet count recovered in 31 days.

COMMENTARY

- There appears to be fairly full reporting of PTP cases, with 5 new cases this year, compared with 11, 9 and 11 in each of the previous 3 years respectively. This decrease is within year-to-year statistical variation. The platelet reference laboratories in Cambridge and Oxford serve a population of 36 million between them. Each of these laboratories has diagnosed 2 PTP cases this year (information courtesy of Drs M Murphy and W Ouwehand). Assuming equal distribution across the UK (population 58.4 million), these figures lie within the annual expected UK total. It therefore appears that there is not major under-reporting of clinically recognised cases of PTP to SHOT.

- The AML patient is not a typical case of PTP in that she was receiving regular platelet transfusions as well as red cells. She is probably best regarded as a case of HPA alloimmunisation associated with multiple platelet transfusion. The inclusion of this case is a reminder that HPA antibodies can arise *de novo* in patients transfused with platelets. The commonest HPA alloantibody to cause platelet refractoriness is anti HPA-1b arising in an HPA-1a homozygous patient. From an archive of 240 samples from refractory patients, 10 had HPA-1b alloantibodies, with 6 anti Gov[a], 5 with anti HPA-2b, 2 with anti HPA-1a, and 1 each with anti HPA-3a and HPA–5b [18]. This contrasts with fetomaternal alloimmunisation to platelets, in which the commonest antibody is HPA-1a arising in a HPA-1b homozygous woman, with 57/305 cases examined in the same study.

This difference is explained by the fact that 75% of multitransfused patients are at risk of alloimmunisation to HPA-1b, through a combination of being HPA-1a homozygous, and having multiple exposure to HPA-1b through platelet transfusion. Since 25% of individuals carry HPA-1b, there is a random possibility that every platelet pool of 4 donations will contain one which is HPA-1b positive. By contrast, the 75% of pregnant women who are HPA-1a homozygous have only a 1 in 4 chance per pregnancy of being exposed to the HPA-1b alloantigen.

RECOMMENDATIONS

- **In PTP, intravenous IgG results in a beneficial response in most cases.**

- **In patients dependent on platelet transfusion, HPA antibodies may be a cause of refractoriness to random donor platelets. Investigation of refractory patients should include a search for HPA antibodies if there are poor responses to HLA selected platelets.**

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.

No new cases were reported during 1999-00, the first year in which this has happened. Four new cases were reported in each of the previous 3 years. The absence of cases this year is within the limits of statistical variation.

However, 2 outstanding questionnaires were received during 1999-00 concerning cases which were initially reported and included in the figures for 1998-99. These therefore do not appear in this year's figures for new cases but details taken from the questionnaires are reported here for the first time.

Case 1. This was a 67-year old woman with newly diagnosed myeloma, who was transfused with 6 units of leucocyte depleted red cells. The ages of the red cell units were 4 days (4 units), 6 days (1 unit), and 7 days (1 unit). Nine days later, she commenced treatment with combination chemotherapy (adriamycin, carmustine, cyclophosphamide and melphalan).
Approximately 15 days after the transfusions, she developed skin rash, deranged liver function tests, pancytopenia and later diarrhoea. The rash was initially thought to be herpes simplex and later vasculitis. However, a skin biopsy showed a dermal infiltrate of lymphocytes consistent with TA-GVHD. No HLA studies were done. The patient deteriorated, developed renal failure and died 5 weeks after the transfusion.

Case 2. This was a 51-year old man who presented with fever, malaise and weight loss. He developed respiratory failure and was admitted to the ICU in another hospital, where a diagnosis of *Pneumocystis carinii* pneumonia was made. HIV antibody testing was negative. He then developed *Clostridium difficile* infection, associated with gastro-intestinal haemorrhage, which required emergency surgery. He was transfused with red cells at this point. He recovered sufficiently to leave ICU and be transferred to another hospital. There he again became ill with fever, falling blood counts, skin rash and herpes zoster infection. The diagnosis of GVHD was considered, and bone marrow cytogenetics showed 100% female XX cells, demonstrating donor cell engraftment. No HLA studies were done. There was no malignant infiltrate in the marrow. Other investigations revealed low immunoglobulins, a small IgM paraprotein and both T and B cell lymphopenia. An immunological opinion suggested that some form of immunodeficiency was likely, but this could not be characterised. The patient deteriorated and died. No post mortem information is available.

Both of these patients probably had risk factors for TA-GVHD. The first case had a B cell malignancy and combination chemotherapy, while it is likely that the second case had an immunodeficiency state, albeit undefined. To put these into context, Table 36 below summarises the 12 cases of TA-GVHD reported to SHOT during the first 4 years of reporting, including the 2 cases above.

Table 36
Summary of TA-GVHD cases 1996-2000

Year	No. new cases reported	Diagnoses
1996-97	4	• Congenital immunodeficiency • No risk factors • B cell NHL (2 cases)
1997-98	4	• Waldenstrom's macroglobulinaemia • B cell NHL • cardiac surgery • autoimmune thrombocytopenia
1998-99	4	• myeloma (case 1 above) • uncharacterised immunodeficiency (case 2 above) • cardiac surgery (2 cases)
1999-00	0	Nil

Summary:

B cell malignancies	5
Cardiac surgery	3
Congenital/acquired immunodeficiency	2
Autoimmunity	1
No risk factors	1
Total	**12**

COMMENTARY

- The diagnosis of TA-GVHD appears to be correct in both of these newly analysed cases, although it is unfortunate that no HLA studies were done to look for HLA haplotype sharing between donor and recipient. One of the problems with TA-GVHD diagnosis is that the patient may be too leucopenic to perform these investigations. During the next year a standard protocol for TA-GVHD investigation will be developed for use in all National Blood Service laboratories.

- It is interesting that administration of only leucocyte depleted red cells did not prevent TA-GVHD in case 1. It is unclear at this point whether the absence of new cases reported this year relates to the implementation of universal leucocyte depletion or not. Whole blood filtration removes between 3 and 4 logs of total leucocytes. Recent studies measuring leucocyte subsets respectively using flow cytometry and subset-specific mRNA pre-and post-filtration have shown 3.5 $\log_{10}$ removal of CD3 positive T cells [19]. This is likely to have a risk reduction effect, and may be sufficient to remove the risk entirely in patients with normal immune function where a chance donor/recipient haplotype share may be the only pre-disposing factor.

- Neither the diagnosis of myeloma nor any of the chemotherapeutic agents given to the first patient is currently an indication for gamma irradiated blood components. However, this is the fifth case of TA-GVHD in a patient with a B cell malignancy reported to SHOT in 4 years, and again raises the question as to whether patients with B cell malignancies should have gamma irradiated components. In view of the partial protection probably provided by leucocyte depletion, however, it would be reasonable to await further SHOT data over the next 2 years to see whether the absence of new cases of TA-GVHD is maintained.

- None of the 12 cases occurred because of failure to provide irradiated components for a patient whose diagnosis falls within current BCSH Guidelines [6] (or because of failure of the irradiation process). However, there are still a number of episodes each year when irradiation is accidentally omitted, usually because of a failure to request irradiated components. No specific management is required for these patients, other than documentation of the incident, and a high index of suspicion should the patient develop any of the features of TA-GVHD.

RECOMMENDATIONS

- **There was a long delay in obtaining full information about these patients. It would be very much appreciated if questionnaires on TA-GVHD patients could be returned as soon as possible, so that the cases may be reported fully in the year in which they occurred. It continues to be important to have full reporting of TA-GVHD cases.**

- **Investigation of suspected TA-GVHD cases should be discussed with the nearest UK Transfusion Service Histocompatibility and Immunogenetics Laboratory. The exact protocol to be followed will depend on whether or not the patient is leucopenic at the time the investigations are done.**

- **The subject of gamma irradiation of blood components for patients with lymphoid malignancies should be kept under review.**

13. TRANSFUSION-TRANSMITTED INFECTIONS

Definition
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

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 from several weeks to years after the date of the transfusion. Reports of infections transmitted by transfusion in a particular year can therefore accrue over the subsequent year(s). The number of cases ascertained by the end of any period 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 within days 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.
Post-transfusion infections (PTI) may be due to an infected (or contaminated) transfusion or 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, and to reveal any systematic errors or deficiencies in the blood service testing. 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.

A similar collation of reports of cases investigated by blood centres in Scotland found that four post-transfusion infections were investigated during the report year. One post-transfusion HCV infection was found to be not due to transfusion. One post-transfusion Q fever (*Coxiella burnetii*) infection was investigated when a recipient developed acute Q fever confirmed by complement fixation tests. No evidence of *Coxiella burnetii* infection was found in any of the donations given to the recipient (all tested with IgG and IgM ELISAs, followed - if reactive - by immuno-fluorscence tests). One post-transfusion HBV infection is awaiting complete investigation. Two recipients (57 year old male and 30 year old male) developed acute HBV infection 9 months (this recipient was on chemotherapy) and 4 months after transfusion with platelets and red cells respectively from the same

donation. The implicated donation was HBsAg negative by PRISM and Murex and was anti HBc negative and HBV DNA negative by PCR. A donation 8 months later from the implicated donor was anti HBc positive, anti HBs (>1000 IU/l) and anti HBe positive. The probable source of both recipients' HBV infections was concluded to be an HBV infectious, HBsAg negative, donation from a donor in the early incubation period of an acute HBV infection.

Methods

Participating blood centres (see above) 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 in the recipient had been confirmed (by detection of antibody, antigen, RNA/DNA or culture) and there was no evidence that the recipient was infected prior to transfusion, (see exception below) 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).

and c) the case did not involve HCV or HIV infections diagnosed in recipients who had received transfusions in the UK that were not tested for anti HCV (i.e. pre September 1991) or anti HIV (i.e. pre October 1985) respectively. (These cases have been excluded because the blood service is rarely able to conduct follow-up investigation of all donors implicated and these cases do not contribute to knowledge of the current infection transmission risks of blood transfusions.)

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. (PTI report forms are in Appendix 5)

Data received by 31/12/2000 about incidents of transfusion-transmitted infections initially reported by blood centres between 1/10/1999 and 30/9/2000 were included in this report. Data received about incidents reported during the previous four years of the surveillance system are included in a cumulative table.

Unless the investigation was closed due to the identification of a probable source of infection other than transfusion, investigations that were closed without being able to conclusively investigate the source of the post-transfusion infections were classified as post-transfusion infections of undetermined source.

Results

Twenty-six initial reports of post-transfusion infections were made by blood centres during the report year. An additional 14 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 implicated component (i.e. the incidents did not satisfy the criteria for a post-transfusion infection as stated above, but may have been reactions of bacterial origin). Reports were received from 10 of the 17 blood centres participating in the surveillance system. These 10 centres collect approximately 86% of the donations tested by blood centres participating in the surveillance system.
Figure 20 shows the classification of reports during the report year.
Of the 26 post-transfusion infections initially reported by blood centres to the surveillance system between 1/10/1999 and 30/9/2000, 4 (14%) were classified, after appropriate investigation, as transfusion-transmitted infections. Table 37 shows the transfusion-transmitted infections reported to the surveillance system between 1/10/1999 and 30/9/2000 by year of transfusion: all were transfused during the report year.

Figure 20
Classification of post-transfusion infections (and post-transfusion reactions) initially reported between 1/10/1999 and 30/9/2000.

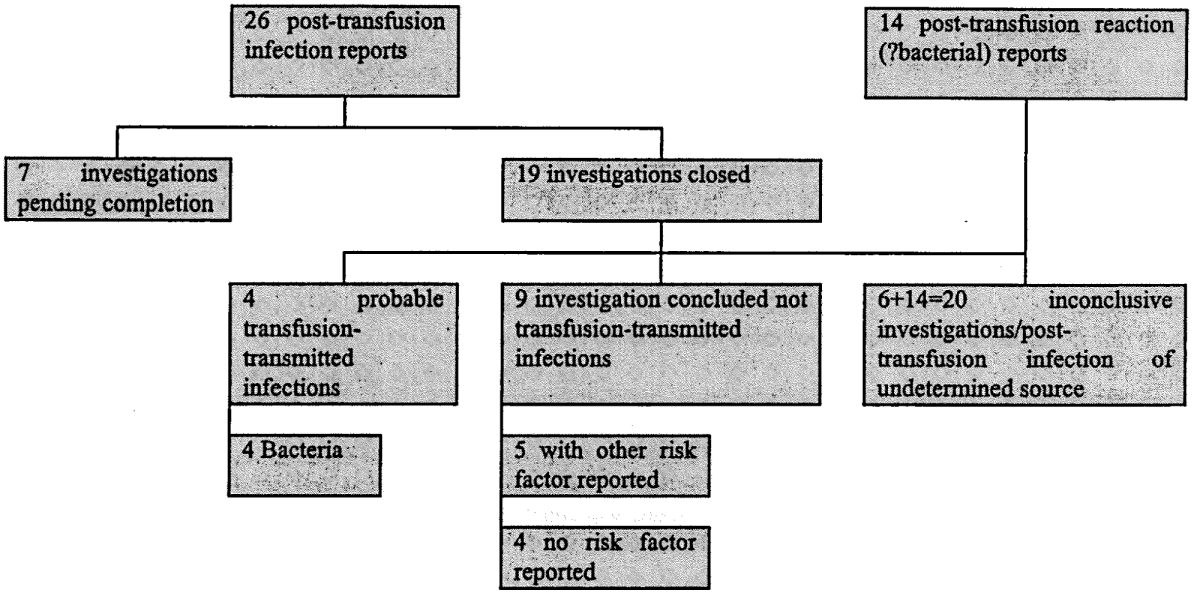


Table 37
Transfusion-transmitted infections reported between 1/10/1999-30/9/2000 by year of transfusion. The number of incidents are shown, with the total number of identified infected recipients shown in brackets.

Year of transfusion	1999	2000 (to end Sept)	Total[b]
Infection			
Bacteria	1(1)	3(3)[a]	4(4)[a]
Total	1(1)	3(3)[a]	4(4)[a]

Notes: [a] Infection was implicated in the death of a recipient.
[b] Additionally, reports in Scotland included one donation shown to have transmitted HBV infection to 2 recipients, transfused during 1999.

Details of transfusion-transmitted infections

A. Infections for which donation testing is mandatory

Hepatitis B virus
No transfusion transmitted HBV infections were reported during this year. One post-transfusion HBV infection reported during the previous year was concluded during this year to be due to transfusion. (See details of case reported in Scotland included in Introduction.)

Hepatitis C virus
No transfusion transmitted HCV infections were reported during this year.

HIV
No transfusion transmitted HIV infections were reported during this year.

B. Infections for which donation testing is not mandatory

Bacteria
Four transfusion-transmitted bacteraemias were reported.

One recipient (83 year old female) felt unwell and flushed after transfusion with a 3 day old apheresis platelet pack. The condition subsequently worsened and the recipient suffered a cardiac arrest and died. *Enterobacter aerogenes* was cultured from the platelet pack. Follow-up swabs of the donor's venepuncture site were culture negative.

One recipient (79 year old female) suffered a bacteraemia after transfusion with 32 day old red cells. Identical isolates of *Staphylococcus epidermidis* were cultured from the recipient's blood and from the red cell pack. The donor was not further investigated.

One recipient (66 year old male) developed rigors and fever after transfusion with a 5 day old pooled platelet pack. Coagulase negative *Staphylococci* with the same antibiotic sensitivities were cultured from the recipient's blood and the platelet pack. The donors were not further investigated.

One recipient (female child) suffered pyrexia, rigors, abdominal pain and vomiting after transfusion with a 5 day old pooled platelet pack. *Staphylococcus epidermidis* was isolated from the recipient's blood and from the platelet pack. The two *Staph epidermidis* isolates had different antibiotic sensitivities reported, however as this apparent inconsistency could not be investigated by further molecular typing (isolates were destroyed), and the other evidence was strong, the recipient's reaction was concluded to be due to transfusion transmission of *Staph. epidermidis*. The donors were not further investigated.

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

Six (21%) post-transfusion infections (3 bacteraemias, 2 HCV infections and 1 CMV infection) were classified as post-transfusion infections of undetermined source due to inconclusive investigation of the transfusion(s) implicated as the source of infection. For nine (35%) post-transfusion infection reports (1 bacteraemia, 3 HBV infections, 3 HCV infections, 2 HIV infections), investigation was completed and no evidence was found to implicate transfusion as the source of infection. A possible source of infection other than transfusion was known for 5 of these infections (HBVx2: invasive medical procedure (one abroad), HCVx1: renal dialysis & previous transfusion, HCV x1: tattoo, HIV x1: sexual risk).

Reporting delay

For the 4 transfusion-transmitted bacterial infections, serious clinical events occurred on the same day as the transfusion. Blood centres were informed of the bacteraemias suspected to be associated with transfusion 4 days, 7 days, 22 days and 54 days after transfusion. The intervals between the blood centre being informed and the completion of the initial surveillance report form (i.e. reporting delay) were 17 days, 37 days, 96 days and 97 days for the 4 bacterial infections. The average interval between transfusion and the initial report (i.e. including all time intervals and reporting delays) was 83 days (N=4:21,59,104, 150).

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. The proportion of post-transfusion infections that are reported each year may be inconsistent as other factors such as testing performed on transfusion recipients, awareness of transfusion as a possible source of infection, reporting of information to blood centres and reporting of information from blood centres to the surveillance centre are all key variables.

Previous year

During the previous reporting year (i.e. 1/10/98 to 30/9/99) 7 transfusion-transmitted infections were reported (see SHOT Annual Report 1998-99 for details of these cases). One post-transfusion HBV infection reported during the 1998-99 year that was awaiting full investigation at the time of the last (i.e. 1998-99) SHOT annual report has subsequently been concluded to have been a transfusion-transmitted HBV infection. A recipient (49 year old female) was tested for markers of HBV infection while receiving dialysis treatment and was found to be negative for HBsAg at the start of her red cell transfusion treatment and to be HBsAg and HBeAg positive four months later. The donor of one of the implicated red cell donations was found subsequently to be anti HBc and anti HBs positive and the archive of the implicated donation was anti HBc negative and had weak levels of anti HBs. The probable source of the recipient's HBV infection was concluded to be an HBV infectious, HBsAg negative donation collected from a donor who was in the early stages of an HBV infection at the time of donating.

The investigations of five post-transfusion infections that were classified as awaiting full investigation in the 1998-99 SHOT report have subsequently been concluded to be not due to transfusion (2 cases of HBV infection) or inconclusive (3 cases: 2 HCV infections, 1 bacteraemia).

Table 38 shows the cumulative number of transfusion-transmitted infections reported by the end of September 2000.

Figure 21 shows the number of reports received by year of report since October 1995.

Table 39 lists some summary details of the 15 bacterial cases reported between October 1995 and September 2000.

Table 38
Cumulative total transfusion-transmitted infections: reported between 1/10/1995-30/9/2000 by date of transfusion. The number of incidents is shown with the total number of identified infected recipients in brackets.

Year of transfusion	pre-1995	1995	1996	1997	1998	1999	2000 (to end Sept)	Total	Deaths
Infection									
HAV	-	-	1(1)	-	-	-	-	1(1)	
HBV	1(1)[b]	1(1)	1(1)	1(1)	1(1)	1(1)	-	6(6)	
HCV	-	-	1(1)	1(1)	-	-	-	2(2)	
HIV[c]	-	-	1(3)	-	-	-	-	1(3)	
Bacteria	-	1(1)	1(1)	3(3)	3(3)[ax2]	4(4)[a]	3[a]	15(15)	4
Malaria	-	-	-	1(1)[a]	-	-	-	1(1)	1
Total[d]	1(1)[b]	2(2)	5(7)	6(6)[a]	4(4)[ax2]	5(5)[a]	3	26(28)	5

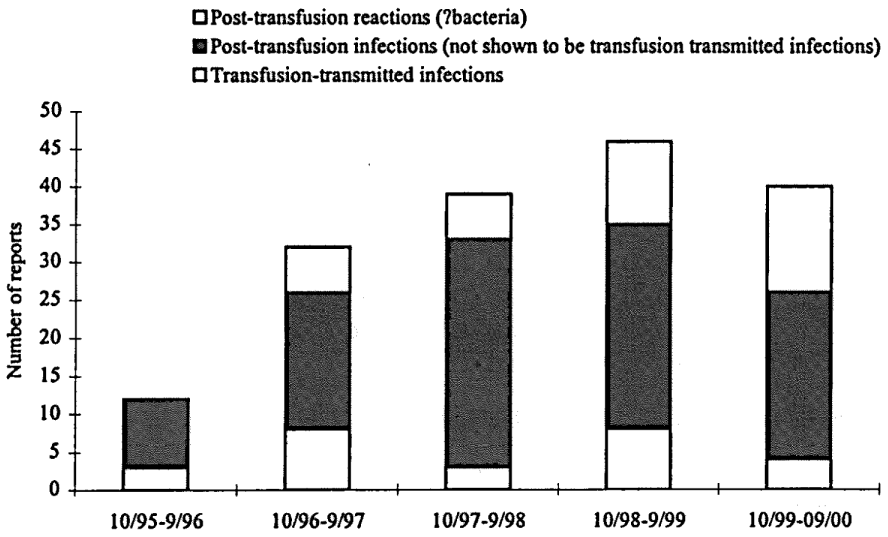
Notes: [a] Infection was implicated in the death of a recipient.

[b] One household member who was caring for the recipient has been diagnosed with acute HBV.

[c] One additional investigation, initially reported during 97-98 and concluded during 98-99, failed to confirm or refute transfusion transmission of HIV infection during the early 1990s. As the patient had received multiple transfusions, and had no other risk factors for infection, transfusion with HIV infectious blood was concluded to be the probable, although unproven, source of infection.

[d] Additionally, reports in Scotland found one probable transfusion transmitted bacteraemia (not fatal), transfused during 1998, and one donation shown to have transmitted HBV infection to 2 recipients, transfused during 1999.

Figure 21
Post transfusion infections (PTI) reports by report year



NB. More reports are pending complete investigation in the most recent report year.

Table 39
Cumulative total transfusion-transmitted bacterial infections: reported between 1/10/1995-30/9/2000.

Year of transfusion	Organism	Component type	Source	Morbidity in recipient
1995	*Bacillus cereus*	Pooled platelets	Donor's arm	Death (other causes)
1996	*group B Streptococcus*	Pooled platelets	Donor's blood	Major morbidity
1997	*Serratia liqufaciens*	Red cells	None identified	Major morbidity
1997	*Bacillus cereus*	Pooled platelets	Donor's arm	Major morbidity
1997	*Escherichia coli*	Apheresis platelets	None identified	Major morbidity
1998	*Staphylococcus aureus*	Pooled platelets	Donor's arm	Death attributed to infection
1998	*Staphylococcus epidermidis*	Apheresis platelets	Donor's arm	Major morbidity
1998	*Escherichia coli*	Apheresis platelets	None identified	Death attributed to infection
1999	*Staphylococcus epidermidis*	Red cells	None identified	Major morbidity
1999	*Staphylococcus epidermidis*	Pooled platelets	None identified	Major morbidity
1999	*Yersinia entercolitica*	Red cells	Donor's blood	Death attributed to infection
1999	*Bacillus cereus*	Pooled platelets	Donor's arm	Major morbidity
2000	*Staphylococcus epidermidis*	Pooled platelets	None identified	Major morbidity
2000	*Coagulase negative Staphylococci*	Pooled platelets	None identified	Major morbidity
2000	*Enterobacter aerogenes*	Apheresis platelets	None identified	Death attributed to infection
15		*12/15=platelets*		*5 fatalities*

COMMENTARY

Transfusion-transmitted infections are rare: only 4 confirmed cases were recognised during this 12-month period of reporting. Investigations of a further 22 cases of post-transfusion infection were reported. Half (47%) of the closed PTI investigations reported during this year have been shown not to be caused by transfusion. For 32% (6) of closed investigations the investigation was inconclusive. Additionally, in Scotland during this year, one confirmed case (a hepatitis B virus transmission from a donor in the early incubation period of acute infection with two infected recipients) was recognised, two incidents were shown not to be caused by transfusion, and one investigation is pending completion.

- Fourteen cases of post-transfusion reactions suspected (but not confirmed) to be due to bacteria were also reported. Conclusive investigation of suspected bacteraemia in a transfusion recipient relies heavily on the collection and handling of relevant samples at the hospital where the transfusion was performed. Absence of evidence of an infection (or toxin), in donations given to recipients who had post-transfusion reactions that were suspected (on clinical presentation) to be due to bacteria does not equate with evidence of absence of a transfusion-transmitted infection (or toxin).

- Cases of transfusion transmitted bacterial infections have continued to be reported following the introduction of universal leucodepletion.

- There were no transfusion transmitted viral infections amongst the concluded reports initially received during this year. One HBV transmission was concluded in a case reported in the previous year. Other reports are awaiting complete investigation and cases transfused during this year may accrue over the next year, and at later stages in the course of the infection.

- One transfusion-transmitted infection from a platelet transfusion (*Enterobacter*) reported during this year resulted in the death of the recipient.

- Numbers of reported cases are small and fluctuations in reports from year to year are to be expected. Also, the reporting system is probably biased towards infections that cause rapid onset of acute disease. However, it should be noted that bacteria account for the majority of reported transmissions by transfusion and the majority of known deaths due to transfusion transmitted infections, not only in this year's cases, but also in the cumulative data since the inception of SHOT.

RECOMMENDATIONS

- **National collation of data arising from these cases needs to continue over several years before a picture of the extent and nature of the infectious complications of transfusion can emerge.**

- **Clinicians should report all post-transfusion infections diagnosed in their patients to the blood service (via their regional blood centre) for appropriate investigation. Blood centres should, in turn, complete an initial report form as soon as possible.**

- **The quality of investigation of transfusion reactions suspected to be due to bacteria is variable. Hospitals should consult guidelines and the blood service about the investigation of such cases, including the sampling and storage of implicated units. (A NBS guidance document entitled *Bacteriological investigation of adverse reactions associated with transfusion* has been agreed in consultation with the PHLS and the Association of Medical Microbiologists (AMM), and distributed to blood centres.) and is reproduced in appendix 9.**

- **Strategies to prevent transfusion transmitted bacterial infections should be given appropriate priority in efforts to reduce the infectious risks of transfusion.**

14. NEAR MISS EVENTS

Definition:
Any error, which if undetected, could result in the determination of a wrong blood group, or issue, collection, or administration of an incorrect, inappropriate or unsuitable component but which was recognised before transfusion took place.

Whilst continuation of the "Near Miss" project, reported last year, was not an official part of the SHOT scheme in this reporting year, 157 reports were submitted from 22 hospitals and the analysis of these is given below.

Incident reporting, even for events detected within the system before results or components are issued, is a valuable audit tool, often having the same root causes as actual transfusion accidents. Complete evaluation of such reports can provide useful management information to identify deficiencies and weak aspects of systems in place, as well as highlight areas of importance within the checking protocols used. All staff should be encouraged to be aware of the need to report "near miss" events and constructive feedback, as an educational aid, is essential[8].

To obtain complete openness within such a reporting system, a culture of "no blame" must prevail as many errors result from deficiency or failure within the systems in use (and are therefore a management issue) rather than from any deliberate individual action. Managers must be aware of the ever present possibility of human error and ensure that systems are sufficiently robust to be able to detect errors before they can affect the patient.

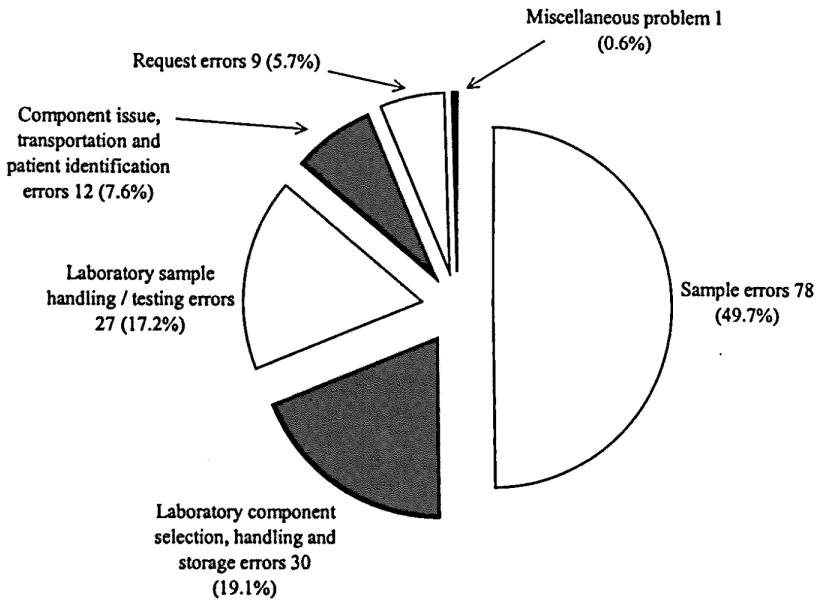
The "Near Miss" reporting process comprises of a single form for different categories of event, with tick boxes to aid rapid recording of details. In the majority of cases no additional contact or information is necessary. The 5 activity areas covered by "near miss"

1. Sample errors
2. Request errors
3. Laboratory sample handling / testing errors
4. Laboratory component selection, handling and storage errors
5. Component issue, transportation and patient identification errors

In addition a single incident was submitted which could not be classified into one of the above categories and this is included as a miscellaneous report.

The following Pie chart shows the number of reports in each category

Figure 22
Categories of "near miss" errors reported (n=157)



Sample errors (78)

Approximately 50% of the total "Near Miss" reports were for this category and highlight the need for increasing awareness, particularly amongst medical staff, of following secure protocols when performing phlebotomy. Samples should be labelled at the bedside, checking the patient wrist band and asking the patient, where possible, to iterate their personal details.

The majority of errors were detected within the laboratory by a discrepant blood group result for the current sample when compared to historical records. Occasionally the person performing the phlebotomy realised the error retrospectively and notified the laboratory of their concerns.

43/78 samples, although labelled as the intended patient, were thought to be from a totally different patient, whilst 34/78 were identified as being from the intended patient but labelled with a different patient's details. In 10 instances it was suspected that patient samples were transposed when labelling was performed after the phlebotomy procedure. Mother and cord blood samples were confused on 6 occasions and all laboratories should be aware of this potential problem and perform appropriate testing to ensure detection of such cases.

The majority of phlebotomy errors were identified as having been made by medical staff, but at least 18 events were attributed to nursing staff and 9 to dedicated phlebotomists. 40% (29/72) of errors were reported as occurring outside laboratory normal working hours.

Although all reports identified the samples as being hand labelled, the use of addressograph labels on the form was a causative factor in some cases. In one instance addressograph labels for another, albeit very similarly named patient, were in the case notes and used on the form, the patient details being copied onto the sample labels. A unit of blood was then transfused to the intended patient, the discrepancy in patient details still not being recognised during the bedside check. It should be noted that, strictly speaking, this incident does not fulfil the criteria for a "near miss" and by SHOT definition fits into the IBCT category as a "right blood to right patient" incident despite serious breaches of protocol.

Several other serious ward / medical record errors or omissions were identified. These included:

- 2 patients with similar names were in the same ward bay and the same incorrect phlebotomy was performed twice by the same medical officer on consecutive days. Neither patient had a wrist band.
- wrist bands were absent on 2 other inpatients involved in separate incidents.
- on 2 occasions it was identified that the wrong patient case notes were being used on the wards, and sample details had been copied from case notes onto the sample labels. Wrist bands were not checked.
- one patient had another similar patient's identification details on the wrist band.
- addressograph labels for incorrect patients were found in the case notes on 3 separate occasions.

Request errors (9)

Incorrect patient identification was provided to the laboratory on 7 occasions when blood components were requested; this was by telephone for 4 requests.

One incident resulted from the wrong patient's addressograph labels being placed in the notes, whilst in another case the 2 copies of the request form bore addressograph labels from different patients, the incorrect patient label being on the top copy.

Laboratory sample handling / testing errors (27)

Laboratory errors were caused by erroneous results attributed to poor technique or procedural failure in 10/27 reports, 7 by incorrect result interpretation and 6 by transcription errors. A clerical error of a wrong ABO blood group was noted on one report from a blood centre. On 3 occasions samples were transposed or wrong bar code labels applied within the laboratory.

No specific problem area or trend could be identified from the reports.

Laboratory component selection, handling and storage errors (30)

An avoidable failure by the laboratory to provide for the special needs of the patient occurred in 12 instances, an incorrect or out of date component was issued in 10 and problems with incorrect storage was reported on 8 occasions.

All 12 reports where the laboratory failed to meet the special needs of the patient were omissions of requirements for irradiated, CMV antibody negative or specially phenotyped components. All were noticed by the laboratory staff before release or detected by the ward bedside checking procedures.

On 6 occasions out of date red cells were issued by laboratories, in one instance 7 days past expiry, and in another by 5 days. The other 4 incorrect issues involved compatible but ABO or RhD mismatched red cells issued in error.

The correct storage of blood components was a concern in 8/31 reports. Blood was placed into a domestic refrigerator on wards in 4 instances, once into the freezer compartment, whilst blood was left on the ward for an excessive time on 3 other occasions before being replaced into a designated blood bank refrigerator

In the remaining report, thermostat failure in a laboratory based blood refrigerator caused the temperature to fall to -5° C, which activated the alarm, however no immediate action was taken resulting in the wastage of 81 units of red cells.

Component issue, transportation and patient identification errors (12)

Blood components were collected for the wrong patient on 10 occasions but detected by the bedside check before transfusion. Portering staff were involved in 9/10 incidents, although 2 of these resulted from the wards using an incorrect addressograph label on the collection slip.

2 problems with transportation of red cells were identified.

- Blood was transferred with a patient from another hospital, left on the ward for 4 hours before being sent to the laboratory
- Blood was transported from an external hospital with no documentation, and with ice inserts instead of 4°C packs

Miscellaneous (1)

A request for platelet transfusion was received for a patient with a platelet count of $5x10^9/l$. Before the transfusion was given a repeat platelet count was performed and was found to be normal. Investigations showed that the original FBC sample had been aliquoted from a biochemistry sample by the nurse who performed the phlebotomy.

COMMENTARY

As in previous "Near Miss" surveys, the problems of incorrect patient identification at phlebotomy comprises the majority of incidents in any single category, with almost 50% of this year's reports being sample errors. Several contributory factors are evident, but all these would be irrelevant if patient identity was fully confirmed at the bedside during phlebotomy and samples labelled at that point.

- Failure to follow correct phlebotomy protocols remains the major cause of "near miss" events. Whilst, in this report, medical staff appear to be associated with the majority, errors are not limited to this group of staff. The particular problem of transposition of mother and baby samples is highlighted.

- A significant number of phlebotomy errors were identified by comparison to laboratory computer records, but it must be recognised that not all can be detected in this way, either because of an identical blood group result or due to the lack of previous testing for that patient.

- Despite recommendations to the contrary in previous SHOT reports [2,3,4] and BCSH guidelines[5,17] the use of addressograph labels continues to give rise to errors. A larger survey, such as the national "Near Miss" project now in place, may provide the data needed to assess if the use of pre-printed labels is a serious problem. Whilst this report focuses on the transfusion process, when wrong addressograph labels find their way into a patient's notes, it is not hard to imagine that this may give rise to errors in other aspects of that patient's management.

- Despite the high degree of automation and computerisation which exists in the majority of hospital blood banks, technical and clerical errors comprised a significant proportion of "near miss" events in this report.

- There were several examples of incorrect handling of components outside the laboratory and of transportation between hospitals, all resulting in wastage of the components The extent of mis-handling of blood components is not clear from this report but the Blood Stocks Management Scheme, which is being introduced this year, may provide more meaningful data.

- It was noted that among the 22 hospitals reporting "near miss" events at least one laboratory in a large hospital did not have a blood bank computer system in place. Several reports from this hospital would have been prevented by computer validation of technical actions. Comparison of current information with the historical record is also facilitated by computerisation.

- Some instances of samples being received unlabelled were reported as "Near Miss" events. As these are rejected at the point of receipt as being unsuitable for acceptance into the laboratory, it is not considered necessary to submit these problems as "Near Miss" reports.

RECOMMENDATIONS

- **Hospital Trusts should ensure that all staff, whatever their background, who carry out phlebotomy are fully trained and competent to do so and that they understand the importance of following correct procedures to avoid sample transposition and ensure complete and accurate labelling.**

- **All staff involved at every stage of the transfusion process must assume responsibility for ensuring that their particular role is fulfilled correctly. Whilst the laboratory historical record is an essential tool in ensuring transfusion safety it cannot be relied upon as a "fail safe" for all instances of sample transposition or cases of incorrect prescribing.**

- **More care is required in the handling of addressograph labels. If these find their way into the wrong set of patient case notes the scene is set for incorrect labelling, not only in the blood transfusion setting but also in other areas of patient management. It is important that BCSH guidelines [5,17] are enforced in order to reduce transfusion errors due to this cause but the problem of mishandling of labels extends beyond staff involved in the transfusion process itself.**

- **Constant vigilance and regular review of competence in the laboratory is essential in order to reduce the risk of technical and clerical errors. These will also be reduced with greater reliance on well designed automated systems and computerisation.**

- **There remains a clear need to educate staff responsible for the handling of blood components as to their correct handling, storage and transport.**

Expansion of the "Near Miss" scheme for 2000- 2001

The small scale scheme already performed attracted significant interest and enthusiasm from many hospitals. Consequently, data is now being accepted from all hospitals in the UK during the forthcoming reporting year to develop a larger, and therefore a more accurate and informative database of near miss events. Near Miss reporting forms, together with instructions for reporters, were sent to all hospitals earlier in the year and as this report went to press the SHOT office had already taken receipt of a substantial number of completed forms.

The work involved in collation, database maintenance and evaluation of data will be significant, but this is an opportunity to see if the small reporting base from previous years is representative of the majority of hospital experiences. The results will be presented in next year's SHOT Report.

15. AUTOLOGOUS PRE-DEPOSIT DONOR INCIDENTS

Definition:
A serious adverse event occurring in the donor in association with an autologous pre-deposit procedure. Serious adverse events were defined as nerve damage, arterial injury, thrombophlebitis, vasovagal attack (four categories of severity), convulsions and cardiovascular events.

Collection of data on autologous pre-deposit donor incidents began in the 1997/98 reporting year.

The questionnaire in appendix 8 gives details of the donor incidents to be reported and the circumstances of the donation.

Only two reports have so far been received in this category and brief details are given in table 40 below. No conclusions can be drawn from these two incidents. Whilst denominator data are not available to be able to assess the scale of autologous pre-deposit procedures in the UK the expectation is that the actual incidence of these events should be higher. This particular aspect of SHOT has not proven popular and further thought and discussion is needed on the best way to acquire this important information as opinions differ on the effects of autologous pre-donation which may place the donor at unacceptable risk [20,21]

Autologous pre-deposit procedures are carried out both in the UK Blood Services and hospitals. Data are already collected by the blood services on all types of donor incidents but the scope of data collection and definitions of serious donor incidents is variable. There is a need for a uniform system of monitoring of serious hazards of donation, which is beyond the scope of the SHOT scheme, and the UKBTS/NIBSC Standing Advisory Committee on the Care and Selection of Donors is planning to address this matter. This will also encompass autologous donor incidents where donors are managed by the blood services. It is still important to try to assess the impact on the donor of an unknown number of autologous procedures being performed in hospitals and therefore it is planned, for the time being, to continue with this category of reporting in SHOT. It is recognised that the questionnaire which has been designed to deal with this is probably over-ambitious and that the category of vasovagal attack in particular needs to be redefined. SHOT welcomes suggestions on how to improve in this area.

Table 40
Information on autologous pre-deposit donor incidents 1999/2000

	Donor 1	Donor 2
Age	67	65
Procedure	Total hip replacement	Total hip replacement
Donation number to which incident related	Second	First
Collection site	Blood Centre	Hospital outpatient dept.
Donor assessed by:	Clinical medical officer	Staff grade doctor
Donation taken by:	RGN	RGN
Complication	Severe faint	Faint

Neither donor had any underlying factor which would be expected to predispose to adverse effects of donation and which would normally constitute a contraindication to autologous pre-deposit.

16. ACKNOWLEDGEMENTS

Once again we are indebted to several individuals and organisations for their continuing help and support. The Steering Group would like to take this opportunity to thank them for their contributions without which the publication of this fourth annual SHOT report would not have been possible.

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All those hospitals who have participated in SHOT reporting

Without your support, SHOT would not be possible

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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.
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 written media communications must be approved by the Steering Group. In urgent situations the Chair and Secretary of the Steering Group may approve written 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. The Steering Group should always include the National Co-ordinator (for non-infectious complications), the Assistant National Co-ordinator, the Chair of the Standing Working Group, a representative from PHLS/CDSC, and a representative from the BCSH Transfusion Task Force. The duration of membership of an individual member will normally be three years, renewable for a further three years subject to agreement of the body which he or she represents.
3. There will be a Chair and Secretary elected from among the members. Each should hold the appointment for three years, renewable for a further three years but with maximum flexibility to allow some overlap with the incoming Chair and Secretary.
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.

6. To seek and maintain funding for SHOT.

7. To maintain links with haemovigilance systems internationally.

Membership and Organisation of Meetings

1. The Standing Working Group will meet as necessary, but not less than four times per year.

2. The membership will be no more than eight, and must always include at least two hospital based haematologists responsible for transfusion, at least one hospital based transfusion technologist, a transfusion nurse, at least two transfusion service consultants and a representative from Serology NEQAS. Duration of membership will normally be three years, renewable for three years.

3. The Chair and Secretary of the Steering Group, the two National Co-ordinators and Assistant National Co-ordinator are also members in their own right.

4. A Chair and Secretary will be elected from among the members. Term of office will normally be three years, renewable for three years.

5. Appointment of new members and renewal of terms of office 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 H Jones**

NAME	REPRESENTING	ADDRESS
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Mr John A Revill (Secretary)	Institute of Biomedical Science	Chief BMS/Laboratory Manager Blood Transfusion Department The Leicester Royal Infirmary NHS Trust Infirmary Square Leicester LE1 5WW Tel: GRO-C Fax: 0116 258 6527 E-mail: jrevill@ GRO-C
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Steering Group Members - Serious Hazards of Transfusion

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Ms P Edkins	Royal College of Nursing Midwifery Society	GRO-C
Dr B Gibson	Royal College of Paediatrics and Child Health	Consultant Paediatric Haematologist Royal Hospital for Sick Children Yorkhill Glasgow G8 8SJ Tel: 0141 201 0391/secretary GRO Fax: GRO-C E-mail: bgibson@ GRO-C
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Dr E M Love	Secretary/ National Co-ordinator SHOT	Consultant Haematologist Manchester Blood Centre Plymouth Grove Manchester M13 9LL Tel: GRO-C Fax: E-mail: elizabeth.love@ GRO-C

Steering Group Members - Serious Hazards of Transfusion

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Steering Group Members - Serious Hazards of Transfusion

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Standing Working Group Members - Serious Hazards of Transfusion

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Dr E M Love	Secretary/National Co-ordinator	Consultant Haematologist/ Lead Clinician Manchester Blood Centre Plymouth Grove Manchester M13 9LL Tel: GRO-C Fax: E-mail: elizabeth.love@ GRO-C
Dr H Cohen	Chair, Steering Group	Consultant Haematologist Department of Haematology A&E Building University College London Hospitals NHS Trust Grafton Way London WC1E 6DB Tel: GRO-C Fax: E-mail: hannah.cohen@ GRO-C
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Standing Working Group Members - Serious Hazards of Transfusion

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Dr A Todd		Clinical Services Consultant Glasgow & West of Scotland BTS Clinical Apheresis Unit Glasgow Royal Infirmary 84 Castle Street Glasgow G4 0SF Tel: GRO-C E:mail: audrey.todd@ GRO-C

SHOT Income and Expenditure Statement

To date the majority of funding has been derived from the four UK Blood Services with support from the Republic of Ireland until March 2000. Generous grants from the British Society for Haematology and the British Blood Transfusion Society have provided vital financial support for the scheme. A DoH grant helped to support the launch of last year's report. Each year it has been necessary to seek renewed funding for SHOT and longer term planning has not been possible. Recently a formal decision has been taken that each of the UK Blood Services will support SHOT on a pro rata basis according to the number of red cell units issued per annum. This now secures the long-term future of the scheme which will be required to submit an annual budget plan to the UK Blood Services. The SHOT budget is "ring-fenced", administered through the NBS Finance Directorate and is subject to NHS audit. The current budget does not include professional medical time, IT or financial services which are provided without charge. SHOT is indebted to Mr Stephen Morgan, Head of Planning and Management Accounting and Mr John Saxton, Financial Controller for their professional services.

	1998/99 Actual	1999/00 Actual	2000/01 Forecast
Income	**£**	**£**	**£**
English Blood Services	36,060	40,459	40,459
Scotland	4,760	6,760	6,760
Wales	4,760	6,760	6,760
Northern Ireland	2,380	4,380	4,380
Republic of Ireland	4,760	4,760	0
British Society of Haematology	0	5,000	5,000
British Blood Transfusion Society	5,000	5,000	5,000
Department of Health	0	0	5,000
Other Income	2,210	2,718	1,807
Total Income	59,930	75,837	75,166
Expenditure	**£**	**£**	**£**
Staff Costs	31,388	33,494	44,332
Travel & Conferences	1,903	2,191	1,479
Rent	1,000	0	1,500
Telephones	0	0	400
Annual Report	17,442	20,895	24,287
Printing, Stationery and Publications	1,715	2,101	1,179
IT Hardware	1,404	0	1,031
Postage	2,823	1,782	1,436
Other	2,018	4,678	6,118
Total Expenditure	59,693	65,141	81,762
Brought Forward	2,962	3,199	13,895
Surplus/(Deficit)	3,199	13,895	7,299

SERIOUS HAZARDS OF TRANSFUSION SHOT

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

The Serious Hazards of Transfusion Group is 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 scheme. We will not enter the identity of the patient in the study database but we will contact you to obtain additional details if necessary

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 transfusion .....hrs

Has your supplying blood centre been informed? **YES / NO**

Incident No.
For SHOT office use only

SERIOUS HAZARDS OF TRANSFUSION SHOT

NATURE OF ADVERSE EVENT

EVENT	(Tick Box) 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		
8. Post Transfusion Viral Infection		
9. Other (describe)		

IF YOU SUSPECT THESE NOTIFY YOUR BLOOD SUPPLY CENTRE IMMEDIATELY!

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 ...../...../.....

..... Tel.Number .....

.....

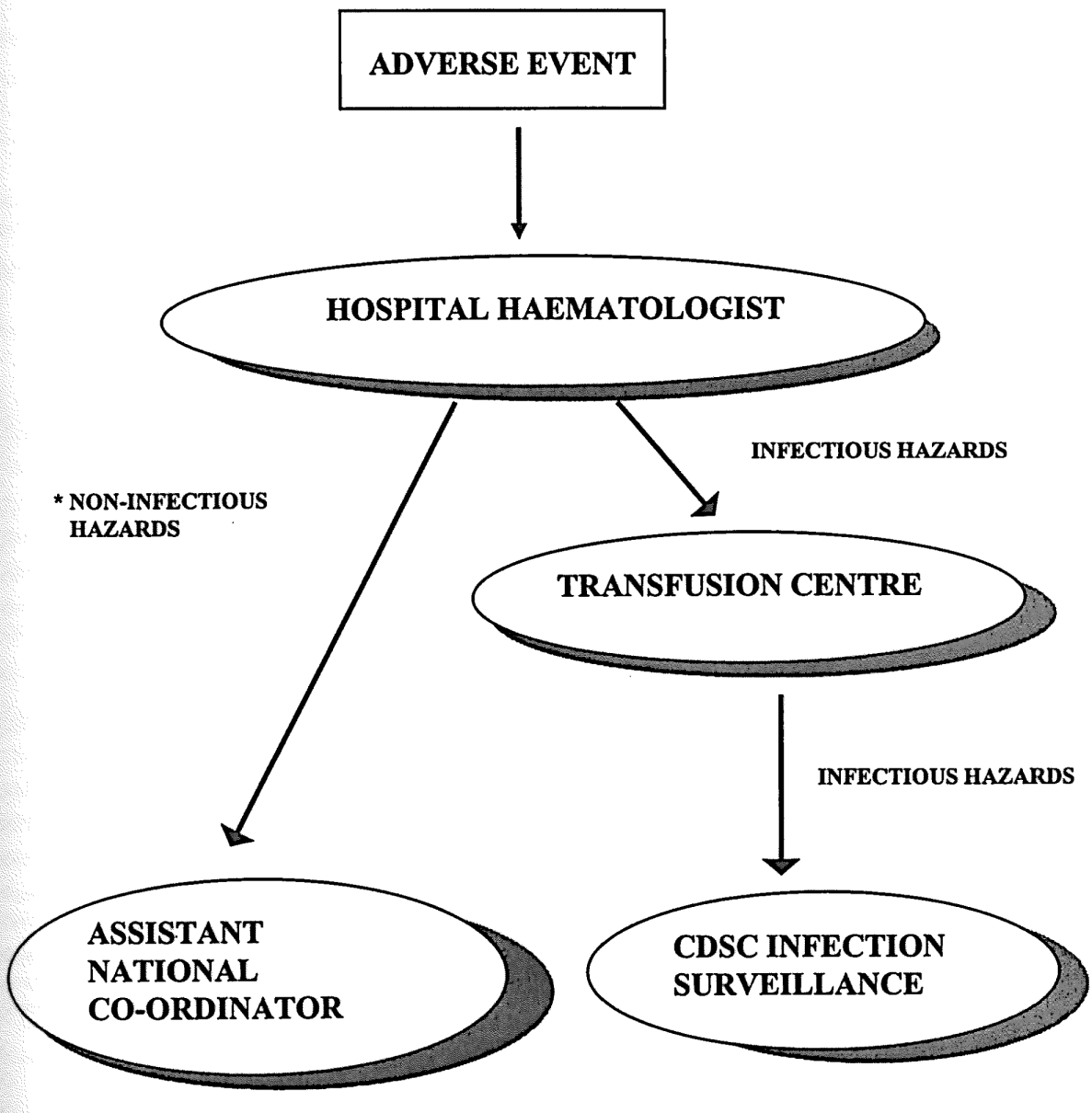
PLEASE SEND REPORT TO

Mrs Hilary Jones
Assistant National SHOT Co-ordinator
SHOT Office
Manchester Blood Centre
Plymouth Grove
Manchester
M13 9LL

Telephone numb GRO-C Confidential Fa GRO-C

SUMMARY OF MAIN FEATURES OF ADVERSE EVENTS AND DIAGNOSTIC TESTS

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.	**Acute haemolytic transfusion reaction**	Dyspnoea, chest pain, fever, chills, ↓BP, ↓urine output, DIC	Haemoglobinaemia/uria, ↓Hb, +ve DAT, serological incompatibility, spherocytes on blood film.
	Anaphylaxis	↓BP, dyspnoea, ± bronchospasm, ± rash	Occasionally severe IgA deficiency with anti-IgA.
3.	**Delayed haemolytic transfusion reaction.**	Unexplained fall in Hb. Jaundice, dark urine.	Urobilinogen in urine, ↑ serum bilirubin, +ve DAT, spherocytes, +ve antibody screen.
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.	



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

SERIOUS HAZARDS OF TRANSFUSION **SHOT**

"NIL TO REPORT" CARD

This card is for cases seen during the period: **01/10/99- 30/09/00**

If you have seen no adverse events please tick "Nothing to report"
If you have reported cases to SHOT in the stated period please tick "Incident(s) already reported". **NB Cards must be returned to SHOT by 29.10.00 for inclusion in this year's report**

Nothing to report ☐
Incident(s) already reported to SHOT ☐

Please complete:
The number of red cell units transfused/annum ☐

"If you would like to receive a receipt as proof of your participation in the SHOT scheme, please return the attached address label with your Nil to Report card which will then be used to send your receipt - thus assuring complete anonymity. Please DO NOT remove the label from its protective backing."

Please turn over ...

In order to gain a more complete estimate of the true frequency of transfusion–related adverse events it is useful to know how many events were recognised but not reported.
*Please indicate any adverse incidents which, for whatever reason, were **not** reported to the scheme:*

Nature of Incident	***IBCT***	***ATR***	***DTR***	***TRALI***	***PTP***	***TA-GVHD***	***TTI***
*No. of **UNREPORTED** cases*							

Reasons for not reporting (tick all that apply)

1) Too time consuming ☐
2) Confidentiality concerns ☐
3) Peer pressure ☐
4) Don't think it is worthwhile to report ☐
5) Other (please clarify

POST-TRANSFUSION INFECTION SURVEILLANCE

SECTION 1: Confirmed post-transfusion infection report

CONFIDENTIAL

Please complete one report for each transfusion recipient **as soon as possible.**

Blood centre to which infection was reported	PTI case code: *(BC prefix)* *(BC case no./code)* ___:_____	Date of 1st report to BC: ___/___/___

Source of report to blood centre(name and institution of notifier)

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

A. PTI information

Reason for diagnosis (please tick):

Hepatitis infection

- Clinical acute hepatitis ☐ 1
- Symptomatic chronic liver disease ☐ 2
- Hepatocellular carcinoma ☐ 3
- Abnormal liver function: routine testing ☐ 4
- HAV/HBV/HCV markers: routine testing ☐ 5
- Other, please specify: 6

HIV infection

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

Other infection

- CMV infection ☐ 11
- Malaria ☐ 12
- HTLV infection ☐ 13
- B19 infection ☐ 14
- Bacteraemia ☐ 15
  Specify species if known _____
- Post-transfusion reaction (PTR) ☐ 16
  (suspected, but not confirmed, to be due to bacteria)
- Other, please specify: 17

Notes & symptoms :

Date of a) onset of symtoms: ___/___/___ **or,** b) diagnosis of sub-clinical infection: ___/___/___

Date of latest report of the recipient and status at that time: ___/___/___

Dead, infection implicated ☐ 1

Dead, no known involvement of the infection ☐ 2

Symptomatic ☐ 3

Asymptomatic ☐ 4

Had the recipient had any other known risk exposures for this infection? yes ☐ 1 no ☐ 2 not known ☐ 9
(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.

	HAV	HBV						HCV			HIV	Other	Lab where tests were performed
Specimen date	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. ___/___/___													

B. Transfusion information

1. Hospital of transfusion: _____

2. Reason for transfusion: _____

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

4. Number and type of units transfused:

red cells	x ☐	cryoprecipitate	x ☐
platelets	x ☐	other	x ☐
whole blood	x ☐	not known	x ☐
FFP	x ☐		

If CMV infection is reported,

4b. How many units were

i) labelled CMV antibody negative ☐

ii) leucocyte depleted ☐

Total number of units = ☐ [= ☐ from this BC + ☐ from other BCs, 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 ☐1 *please attach Section 2&3report forms to the case's file for completion once the investigation is closed.*

No ☐2 Please state reason: _____

_____

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

Please return the top(yellow) copy of this form to:- The Medical Director, (Infection Surveillance) National Blood Authority, Oak House, Reeds Crescent, Watford, Herts., WD1 1QH. Thank you for your help.

[Form code:PTIS 1.02]

Section 2 (NON-BACTERIAL): Confirmed post-transfusion infection donor/donation investigation report

Please complete one form for each PTI case investigated by your blood centre.

Investigation of _____ units from _____ blood centre pertaining to the PTI investigation with the case code ____ : _____
(BC prefix) *(BC case no./code)*

A. Donation/donor information

1. Review of test results and QC test results for original testing of implicated donations:

All checked and found correct ..... ☐1 Error found in testing/labelling/issuing procedures, please specify:_____ ☐2 Checking incomplete, ____ of ____ units un-checked ☐3

2. Infection status of the donor(s)

Please record the results of re-testing the implicated donation(s)/donor(s) in the table below. Use one line to summarise all similar test(s) ie. the same tests and same result(s) on a similar specimen type. Please record re-tests on **archived** samples (and pack residues) from the implicated donations and re-tests on **subsequent** samples (which may be *either* fresh *or* archived subsequent donations, *or* specially bled fresh samples) from the implicated donors separately. Please record results by writing **POS, NEG, EQV** (equivocal) and/or the titre/level (HBsAg, anti-HBc(total) & antiHBs) in each column. An empty cell will be taken as indication that the test was not performed.

		HAV	HBV					HCV			HIV	Other	Lab where tests where performed	Notes
	Number and type of samples (ARCHIVE/SUB.SAMPLE)	anti-HAV IgM	HBsAg	anti-HBc (total)	anti-HBc IgM	HBeAg	anti-HBe	anti-HBs	anti-HCV ELISA(s)	anti-HCV RIBA	HCV RNA	anti-HIV			
1.	☐ x _____														
2.	☐ x _____														
3.	☐ x _____														
4.	☐ x _____														
5.	☐ x _____														

3. Does any donor have a history which suggests exposure to blood borne infection? (eg. a donor's records note past jaundice) yes ☐1 no ☐2 not known ☐9

If **"yes"** please give details, and specify which line(s) of the above table contain this donor's test results:_____

4. Have any of the donors been involved in any other PTI case(s)? yes ☐1 no ☐2 not known ☐9

If **"yes"** please specify which line(s) of the above table contain this/these donor(s) and the other PTI case code(s):_____

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

Please return the top(yellow) copy of this form to:- The Medical Director (CDSC/NBA Infection Surveillance), National Blood Authority, Oak House, Reeds Crescent, Watford, Herts. WD1 1QH. Thank you for your help. [Form code:PTIS 2.02]

3:POST-TRANSFUSION INFECTION SURVEILLANCE

Section 3 (NON-BACTERIAL): Confirmed PTI investigation summary

Conclusion of investigation

Blood centre	PTI case code: *(BC prefix)* *(BC case no./code)* ___:_____

A. Conclusion of this blood centre's investigation

Please tick your conclusion(s) for the investigation of donation(s)/donor(s) at your blood centre. 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 blood centre:

A. Errors were found in compliance with SOP(s) in force at the time of testing/labelling/issuing of the implicated unit(s) ☐ 1

B. ____ donor(s) was(were) found through re-testing of archive samples to have markers of transmissible infection ☐ 2
Please specify the implicated unit type(s):_____

C. ____ donor(s) was(were) found through testing of subsequent samples to have markers of transmissible infection ☐ 3
Please specify the implicated unit type(s):_____

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

D. For ____ donor(s) no sample subsequent to the implicated donation was tested ☐ 4

E. For ____ donor(s) no archive sample of the implicated donation was tested ☐ 5

F. For ____ donor(s) neither an archive sample of the implicated donation, nor a subsequent sample was tested ☐ 6

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

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) ☐ 7

H. Other e.g. the blood centre has been informed of another confirmed source of the recipient's infection ☐ 8
Please specify:_____

B. Actions of this blood centre 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. ____ donor(s) was(were) removed from the panel because confirmed markers of TTI were found in their blood.

B. ____ donor(s) was(were) removed from the panel because of repeated involvement in PTI case investigations.
(Other PTI case code(s):_____, _____, _____)

C. ____ donor(s) was(were) flagged/marked on the donor database as having been involved in a PTI case investigation.

D. ____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 investigation

The recipient's infection **was probably** acquired by transfusion with a unit from the blood service:

A. Errors were found in compliance with SOP(s) in force at the time of testing/labelling/issuing of the implicated unit(s) ☐ 1

B. ____ donor(s) was(were) found through re-testing of archive samples to have markers of transmissible infection ☐ 2

C. ____ donor(s) was(were) found through testing of subsequent samples to have markers of transmissible infection ☐ 3

If B or C is true:

Please specify the implicated unit type(s):_____

Please specify the implicated DONOR type: NEW ☐, REPEAT ☐ - Date of previous donation:____/____/____

Please give the date the recipient was transfused with this unit: ____/____/____

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

D. For ____ donor(s) no sample subsequent to the implicated donation was tested ☐ 4

E. For ____donor(s) no archive sample of the implicated donation was tested ☐ 5

F. For ____ donor(s) neither an archive sample of the implicated donation, nor a subsequent sample was tested ☐ 6

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

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) ☐ 7

H. Other e.g. the blood service has been informed of another confirmed source of the recipient's infection 8
Please specify:_____

NB. Please also complete IDS forms for any HIV/HBV/HCV infected donors detected by this investigation.

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

Please return the top(yellow) copy of this form to:- The Medical Director (CDSC/NBA Infection Surveillance), National Blood Authority, Oak House, Reeds Crescent, Watford, Herts. WD1 1QH. Thank you for your help. [Form code:PTIS 3.02]

Section 2 (BACTERIAL): PTI or PTR donor/donation investigation report

Please complete one form for each PTI case investigated by your blood centre.

Investigation of _____ units from _____ blood centre pertaining to the PTI investigation with the case code _____ : _____
(BC prefix) *(BC case no./code)*

A. Investigation details

1. Samples were obtained from:

The implicated component: ☐1 Other components from the implicated donation: ☐2 The recipient: ☐3 The donor: ☐4 Other: ☐5

please specify: _____ please specify: _____ please specify: _____ please specify: _____

2. Evidence of bacterial infection

Please record the investigations performed and the findings of these investigations

Sample source and type	Investigations performed	Findings

3. Does any implicated donor have a history which may be relevant to the investigation ? (e.g. bacterial illness, skin condition at site of venepuncture for blood donation)?

yes ☐1 no ☐2 not known ☐9

If "yes" please give details: _____

4. Have any implicated donors been involved in any other PTI(bacterial) case(s)?

yes ☐1 no ☐2 not known ☐9

If "yes" please give details: _____

5. Any other information/comments:

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

Please return the top(yellow) copy of this form to:- The Medical Director (CDSC/NBA Infection Surveillance), National Blood Authority, Oak House, Reeds Crescent, Watford, Herts. WD1 1QH. Thank you for your help. [Form code:PTIS(bac) 2.02]

2: POST-TRANSFUSION INFECTION SURVEILLANCE

Section 3 (BACTERIAL): PTI or PTR infection investigation summary

Blood centre	PTI case code: *(BC prefix)* *(BC case no./code)* ___:_____

A. Conclusion *(please complete for all cases)*

Please tick your conclusion(s) for the investigation of this case (A, B C or D), and as many of the statements I - V that are true.

✓	
	A. The recipient's transfusion reaction **was probably** caused by bacteria/bacterial toxins from a transfusion of a blood component from the NBS
	B. The recipient's transfusion reaction **may or may not** have been caused by bacteria/bacterial toxins from a transfusion of a blood component from the NBS
	C. The recipient's transfusion reaction **was not probably** caused by bacteria/bacterial toxins from a transfusion of a blood component from the NBS.
	D. Other: *please specify*

I. The recipient was found to have evidence of bacterial infection likely to have caused their transfusion reaction..... ☐ 1

II. The implicated component was found to have evidence of bacterial infection..... ☐ 2

III. Other components from the implicated donation were found to have evidence of bacterial infection ..... ☐ 3

Please specify the component(s):_____

IV. An implicated donor was found to have evidence of bacterial infection likely to have been transmitted by transfusion ..... ☐ 4

V. The recipient's reaction was probably caused by bacteria from another source ..... ☐ 5

Please specify the suspected source:.....Venepuncture site?.....No(unlikely).. ☐ ...Possible.. ☐ ...Probable.. ☐

Other?_____

Note

B. Summary details of implicated agent and component *(please complete unless transfusion has been shown not to be the cause of the recipients reaction)*

1. Bacteria/toxin found, or suspected, to have caused the transfusion reaction: _____

Bacterial load (if known): _____

2. Component type found, or suspected, to have caused the transfusion reaction: _____

If **RED CELLS** please give details:

Buffy coat depleted?.....YES / NO Leucocyte depleted?.....YES / NO If yes, where? Blood centre ☐ Bedside ☐

If **PLATELETS** please give details:

Recovered ☐

Apheresis ☐ If apheresis, please specify collection apparatus:

Cobe ☐ Haemonetics ☐ Other *(specify)* ☐ _____

Not known ☐

Pooled?.....YES / NO Leucocyte depleted?.....YES / NO If yes, where? Blood centre ☐ Bedside ☐

3. Age of the unit (in days) at time of transfusion: ☐ 4. Volume transfused: ☐

C. Actions of this blood centre 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. ____ donor(s) was(were) removed from the panel because transfusion transmissible infection(s) may be present in their donations / because of repeated involvement in PTI case investigations *(please delete as applicable)*.
(Other PTI case code(s):_____, _____, _____)

B. ____ donor(s) was(were) flagged/marked on the donor database as having been involved in a PTI case investigation.

C. ____ other donation(s) are being investigated.

Other actions following this investigation / notes: _____

Report completed by *(please print name)*: _____ Date ____/____/____
(ie. date investigation was closed by your BC)

Please return the top(yellow) copy of this form to:- The Medical Director (CDSC/NBA Infection Surveillance), National Blood Authority, Oak House, Reeds Crescent, Watford, Herts. WD1 1QH. Thank you for your help.

[Form code:PTIS(bac) 3.02

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, SHOT Office, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, SHOT Office, Manchester Blood Centre

INCORRECT BLOOD/COMPONENT TRANSFUSED

Use this to report all cases where a blood component intended for a named patient was inadvertently transfused to another. Report all such cases, including 'autologous' units, even if there was no ABO incompatibility or haemolysis. Do not report 'near misses' i.e. episodes where an error is discovered before blood is administered.

Incident No.

/	/	0	0	9	9	0

The information you supply is important. It must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choices of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question, simply tick the box(es) which apply or fill in relevant information. Leave blank if not known.

Consultants or junior staff may write to the Serious Hazards of Transfusion Reporting System office, under separate cover quoting the questionnaire number.

All original copies of correspondence will be confidential (to maintain confidentiality it is advised that you do not retain copies of your correspondence with SHOT)

The whole questionnaire will be shredded when data collection is complete.

In case of difficulty, please contact the SHOT office at:

Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL

Telephone: (0161) 251 4208
Fax: (0161) 251 4319

For office use only

DB .....

IDR .....

IRS .....

Comments .....

Serious Hazards of Transfusion Reporting System

Incorrect Blood/Component Transfused
01/10/99 Version 4

A. PATIENT DETAILS			
1.	**Diagnosis and reason for transfusion**		
	a)	Elective surgery - please state type ----------	
	b)	Emergency surgery - please state type ----------	
	c)	Trauma	
	d)	Haemorrhage due to ---------- ----------	
	e)	Malignant haematological disorder	
	f)	Autoimmune haemolysis	
	g)	Anaemia due to ---------- ----------	
	h)	Liver disease	
	i)	Other medical condition - please specify	
	j)	Plasma exchange, please specify diagnosis	
2.	**Was this transfusion**		
	a)	An emergency	
	b)	Routine	
	c)	Unknown	
3.	**Where was the transfusion given**		
	a)	In-patient ward	
	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 ----------	

B. CROSSMATCH SAMPLE AND REQUEST FORM				
4.	**Was the sample taken from**			
	a)	The patient intended for transfusion		
	b)	Another patient		
5.	**Was the sample taken by:**			
	a)	A doctor		
	b)	A nurse		
	c)	A phlebotomist		
	d)	A medical student		
6.	**Were the patient details on the sample**			
	a)	Hand-written		
	b)	On a pre-printed sticky label		
		Was the sample tube pre-labelled	**Yes**	**No**
	c)	Correct in all respects		
	d)	Wrong with respect to name		
	e)	Wrong with respect to date of birth		
	f)	Wrong with respect to hospital number		
	g)	Other (please specify) ----------		
7.	**Were the patient details on the request form**			
	a)	Hand-written		
	b)	On a pre-printed sticky label		
	c)	Correct in all respects		
	d)	Wrong with respect to name		
	e)	Wrong with respect to date of birth		
	f)	Wrong with respect to hospital number		
	g)	Other (please specify) ----------		

C.	BLOOD BANK continued			
8.	Had the patient been grouped before?		Yes	No
9.	Was the current group checked against historical grouping records prior to blood/component issue?			
	a)	Yes - against computerised record		
	b)	Yes - against manual record		
	c)	No - please give reason if available: ---------- ---------- ----------		
	d)	Patient not grouped before		
10.	Has the group on the cross-match sample been re-checked?		Yes	No
11.	Was a sample from the pack bleedline grouped before blood/component issue?		Yes	No
12.	Blood/Components given		Number of units	
	a)	Red Cells		
	b)	Red cells buffy coat depleted		
	c)	Red cells leucocyte depleted		
	d)	Platelets, apheresis		
	e)	Platelets, from buffy coat pools		
	f)	Platelets, from platelet rich plasma		
	g)	Platelets, leucocyte depleted		
	h)	Platelets, HLA selected		
	i)	Fresh frozen plasma: Untreated		
	j)	Fresh frozen plasma: Solvent Detergent		
	k)	Fresh frozen plasma: Methylene Blue		
	l)	Cryosupernatent (Cryo depleted FFP)		
	m)	Cryoprecipitate		
	n)	Granulocytes		
	p)	Other, please state		
13.	Was this unit			
	a)	Autologous		
	b)	From a Transfusion Service donor		
	c)	From a family member		

C. BLOOD BANK

14. Pre-transfusion testing

Was pre-transfusion testing performed?	**Yes**	**No**

If yes, please complete question 14a

If no, please give reason why and then proceed to question 15:

14a Blood Grouping:

Tube		
Microplate		
Column		
Other (specify)---------- ----------		
Please state blood group result obtained		
Was this test performed correctly?	**Yes**	**No**
Was the correct result obtained?	**Yes**	**No**
If not , what was the correct result?		
Was the result recorded correctly?	**Yes**	**No**
Was a method used the routine or rapid method in use in the laboratory? (please circle)	**Routine** **Rapid**	

C.	BLOOD BANK continued		
14	**Pre transfusion testing continued**		
14b	**Was an antibody screen performed**	**Yes**	**No**
	If yes please complete section 14b; if no proceed to question 14d		
	Antibody Screen		
	Was the sample serum or plasma? (please circle) **Serum**	**Plasma**	
	Which screening cells were used? ----------		
	Was it a 2/3/4 cell screen?		
	Which method(s) of screening were used?	(please tick)	
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify) ----------		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify) ----------		
	Was this test performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody screen used in the laboratory? (please circle)	**Routine** **Rapid**	

C. BLOOD BANK continued			
14	**Pre transfusion testing continued**		
14c	**Was the antibody screen positive or negative?** (please circle)	**Positive**	**Negative**
	If positive please complete section 14c & d; if negative, proceed to 14e		
	Please indicate further tests performed:		
	Which panel cells were used? ----------		
	How many panel cells were used? ----------		
	Which methods were employed:		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify) ----------		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify) ----------		
	Were these tests performed in your laboratory? If no, please state where ----------	**Yes**	**No**
	Was this test performed correctly?	**Yes**	**No**
	Was the antibody specificity(ies) identified correctly?	**Yes**	**No**
	Positive - give specificity of antibody		
	Positive - antibody not identified		
	Positive cold auto only		
	Positive enzyme auto only		
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody identification used in the laboratory? (please circle)	**Routine** **Rapid**	
	Would the antibody specificity usually be confirmed at a reference centre?	**Yes**	**No**

C.	BLOOD BANK continued			
14	**Pre-transfusion testing continued . . .**			
14c	Was antigen negative blood selected/used		**Yes**	**No**
	If yes, what was the source? (please circle)	**hospital blood bank**	**transfusion centre**	
	Was crossmatch compatible blood issued with no antigen testing		**Yes**	**No**
14d	**Does your hospital perform donor antigen screening for patients with atypical antibodies**		**Yes**	**No**
	If yes please complete section 14d; if no, proceed to question 15			
	Antigen screening of donor units:			
	Was this performed in your laboratory?	**Yes**	**No**	
	Was this procedure performed correctly?	**Yes**	**No**	
	Were the correct results obtained	**Yes**	**No**	
	Was the result recorded correctly?	**Yes**	**No**	
	Give brief description of methods.....			
14e	**Was crossmatching performed?**		**Yes**	**No**
	If yes, please complete section 14e			
	If no, please give reason and proceed to question 15 : ----------			
	Crossmatch:			
	Which crossmatching methods were used:			
	IAT crossmatch LISS tube			
	NISS tube			
	Column Technology (state type) ----------			
	Other (specify) ----------			
	Was this procedure performed correctly?	**Yes**	**No**	
	Was the correct result obtained?	**Yes**	**No**	
	Was the result recorded correctly	**Yes**	**No**	
	Was this the routine or rapid method of crossmatching used in the laboratory? (please circle)	**Routine** **Rapid**		

C. BLOOD BANK continued

15. Were special requirements in component selection met?

Gamma irradiation	Yes	No	N/A
Leucodepletion	Yes	No	N/A
CMV negative	Yes	No	N/A
Phenotype selection	Yes	No	N/A

Other (please specify) ----------

If special requirements were not met please give reason, if available: ----------

---

Do you have a procedure for ordering components when there are special requirements?	Yes	No

If yes, please give brief details: ----------

---

16. Was the issue label on the blood/component pack

a)	Hand-written	
b)	On a computer-generated label	
c)	Stuck on the pack	
d)	A tied-on tag or luggage label	
e)	Correct in all respects	
f)	Wrong with respect to name	
g)	Wrong with respect to hospital number	
h)	Wrong with respect to date of birth	
i)	No patient-specific label generated	

17. Were the details on the issue voucher/report form

a)	Hand-written	
b)	On a computer-generated form	
c)	Correct in all respects	
d)	Wrong with respect to name	
e)	Wrong with respect to date of birth	
f)	Wrong with respect to hospital number	
g)	Not found	

C. BLOOD BANK continued

18. Grade of staff performing crossmatch and labelling

a)	State Registered blood bank MLSO	
b)	MLA with supervision	
c)	MLA unsupervised	
d)	On call MLSO regularly working in blood bank	
e)	On call MLSO NOT regularly working in blood bank	
f)	Trainee MLSO	
g)	Locum/agency staff	

19. Was the blood/component

a)	Handed over personally from blood bank staff	
b)	Collected from blood bank refrigerator	
c)	Collected from satellite refrigerator	

20. Was the blood/component

a)	**Formally checked for identity with patient**	
b)	**Collected without formal checking**	

21. Grade of staff collecting blood/component

a)	Qualified nurse	
b)	Unqualified nurse	
c)	Porter	
d)	Medical student	
e)	Other (please state) ----------	

22. Was the blood/component collected

a)	The correct pack for the intended recipient			
b)	The wrong pack for the intended recipient with respect to:-			
		Name	Yes	No
		Date of birth	Yes	No
		Hospital number	Yes	No

D. ADMINISTRATION OF BLOOD/COMPONENT

23. Were the two people setting up and checking the transfusion :

a)	A qualified nurse	Person 1	
		Person 2	
b)	An unqualified nurse	Person 1	
		Person 2	
c)	A doctor	Person 1	
		Person 2	
d)	A medical student	Person 1	
		Person 2	
e)	Other	Person 1	
		Person 2	

Please provide local protocol for checking transfusions

24. Was the patient's identity wristband :

a)	Missing			
b)	Correct in all details			
c)	Wrong with respect to	Name	Yes	No
		Date of birth	Yes	No
		Hospital number	Yes	No

25. What was the reason for the error?

a)	Crossmatch sample from wrong patient	
b)	Inappropriate request	
c)	Laboratory error - incorrect group, (please circle) &/or crossmatch, &/or label	
d)	Wrong component collected from storage site	
e)	Misidentity of patient at time of administration	
f)	Other (please describe) ---------- ---------- ----------	

D. ADMINISTRATION OF BLOOD/COMPONENT continued

26. How was the error discovered?

a)	Acute reaction
b)	Delayed reaction
c)	Ward staff detected error (please describe) ----------
d)	Laboratory staff detected error (please describe) ----------
e)	Other (please describe) ----------

E. SEQUELAE

27. State ABO/Rh group of patient

28. State ABO/Rh group of incorrect unit(s) given

29. Was the volume of wrong blood/component given

a)	<50 mls
b)	50-99 mls
c)	100 ml
d)	A whole unit
e)	>1 unit **State number [ ]**

30. What features were there of acute intravascular haemolysis?

a)	None
b)	Fever
c)	Rigors
d)	Haemoglobinuria
e)	Hypotension
f)	Loin pain
g)	Bronchospasm

E. SEQUELAE continued

31. What were the complications of this transfusion?

a)	None	
b)	Ventilatory problems (eg pneumonia, pulmonary oedema)	
c)	Cardiac problems (eg acute LVF, intractable arrhythmias, cardiac arrest)	
d)	Hepatic failure	
e)	Septicaemia	
f)	Renal failure	
g)	Central nervous system failure (eg failure to recover consciousness)	
h)	Progression of underlying condition	
i)	Electrolyte imbalance	
j)	Haematological disorder/coagulopathy	
k)	Other (please specify) ----------	

32 Did the patient require

a)	Dialysis	Yes	No
b)	ITU admission	Yes	No
c)	Already on ITU/dialysis	Yes	No

33 Did the patient :

a)	Survive with no ill effects	
b)	Survive with ill effects, please specify ----------	
c)	Recover from complications of intra-vascular haemolysis	
d)	Die -in the event of death please can you indicate if the death was thought to be:	
	Not related to the transfusion	
	Possibly related to the transfusion	
	Probably related to the transfusion	
	Definitely related to the transfusion	
	Other, please specify : ----------	

F.	PROCEDURAL REVIEW			
34	**Has the case been reviewed by hospital transfusion committee?**			
	a)	Yes		
	b)	No, but will be at a future meeting		
	c)	Hospital does not have transfusion committee		
35	**As a result, have there been recommended changes to transfusion procedures?**		Yes	No
	If yes, please specify: ----------			

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, Manchester Blood Centre

ACUTE TRANSFUSION REACTION (including anaphylaxis)

Incident No.

/	/	0	0	0	0	0

The information you supply is important. It must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choice of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question, tick the box(es) which apply or fill in the relevant information. Leave blank if not known.

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Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL

Telephone: (0161) 251 4208
Fax: (0161) 251 4319

For office use only

DB .....

IDR .....

IRS .....

Comments .....

A.	PATIENT DETAILS			
1.	**Diagnosis and reason for transfusion**			
	a)	Elective surgery - please state type		
	b)	Emergency surgery - please state type.....		
	c)	Trauma		
	d)	Haemorrhage due to		
	e)	Malignant haematological disorder		
	f)	Autoimmune haemolysis		
	g)	Anaemia due to		
	h)	Liver disease		
	i)	Other medical condition - please specify		
	j)	Plasma exchange, please specify diagnosis		
2.	**Did the patient have a previous transfusion history**		**Yes**	**No**
	If yes please give brief details			
3.	**If female, has this patient ever been pregnant**		**Yes**	**No**
4.	**Was this transfusion**			
	a)	An emergency		
	b)	Routine		
	c)	Unknown		
5.	**Where was the transfusion given.**			
	a)	In-patient ward		
	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 & REACTION

6. Interval between end of transfusion and onset of symptoms

a)	Symptoms started while transfusion in progress	
b)	< 2 hours	
c)	2-7 hours	
d)	8-24 hours	
e)	Other (specify in hours)	

7. What components were given in the 24 hours up to and including the time of the reaction, please indicate the number of units and if in your opinion this was the responsible component (tick yes, no or unknown)

	Component	Number of units	Yes	No	Unknown
a)	Red Cells				
b)	Red cells, buffy coat depleted				
c)	Red cells, leucocyte depleted				
d)	Platelets, apheresis				
e)	Platelets, from buffy coat				
f)	Platelets, from platelet rich plasma				
g)	Platelets, leucocyte depleted				
h)	Platelets, HLA selected				
i)	Fresh frozen plasma: Untreated				
j)	Fresh frozen plasma: Solvent Detergent				
k)	Fresh frozen plasma: Methylene Blue				
l)	Cryosupernatent (cryo depleted FFP)				
m)	Cryoprecipitate				
n)	Granulocytes				
p)	Other, please state				

8. Was this unit

a)	Autologous	
b)	From a Transfusion Service donor	
c)	From a family member	

9. If platelet or red cell transfusion, was a filter used at the bedside? Yes / No

10. If yes, please state manufacturer and model of filter.....

.....

B. COMPONENT DETAILS & REACTION continued				
11.	Was this patient treated with ACE inhibitor medication?		Yes	No
12.	Indicate sign(s) /symptom(s)			
	a)	Fever (rise >1°C)		
	b)	Chills		
	c)	Rigors		
	d)	Itching/rash		
	e)	Back pain		
	f)	Chest pain/discomfort		
	g)	Dyspnoea / difficult breathing		
	h)	Dark urine		
	i)	Restlessness		
	j)	Hypotension		
	k)	Other (please specify)		
13.	How often were patient observations recorded before the reaction?		Every	mins
14.	Was a doctor informed?		Yes	No
	If yes, how soon after the reaction		hrs	mins
15.	Did the doctor see the patient?		Yes	No
	If yes, how soon after he/she was informed		hrs	mins
	If no, was advice given by telephone?		Yes	No
16.	What grade was the doctor who first dealt with the problem?			
	a)	Junior house officer		
	b)	Senior house officer		
	c)	Registrar		
	d)	Senior registrar		
	e)	Consultant		
	f)	Staff grade		
	g)	Other		
17.	Was the doctor who gave the advice a haematologist?		Yes	No
	If no, did she/he contact a haematologist for advice about management?		Yes	No
	If yes, how soon after the reaction?		hrs	mins

B. COMPONENT DETAILS & REACTION continued

18.	What type of advice/instructions were given?			
	a)	Continue transfusion as before		
	b)	Continue transfusion at slower rate		
	c)	Stop transfusion temporarily and observe		
	d)	Discontinue transfusion completely		
	e)	Other (please specify)		
19.	Was any medication prescribed?		Yes	No
	If yes, please specify			
	a)	Paracetamol		
	b)	Antihistamine		
	c)	Diuretic		
	d)	Hydrocortisone		
	e)	Adrenaline		
	f)	Other		
20.	Was the transfusion [illegible] done		Yes	No
	If yes, what volume of the unit had been transfused?			mls

C. FOLLOWING THE TRANSFUSION REACTION

21.	Was the unit returned to the transfusion laboratory?		Yes	No
22.	Was [illegible] sample collected?		Yes	No
23.	Were blood samples taken		Yes	No
	Please indicate diagnostic test results where performed		Yes	No	Not done
	a)	Raised urinary urobilinogen			
	b)	Raised plasma bilirubin			
	c)	Falling Hb			
	d)	Haemoglobinuria			
	e)	Deteriorating renal function			
	f)	Positive DAT			
	g)	Spherocytes			
	h)	Evidence of DIC			

C.	FOLLOWING THE TRANSFUSION REACTION		
24.	Was bacteriological culture of the unit performed	Yes	No
	If yes what was the result	Positive, state species	Negative
25.	Was bacteriological culture of the patient performed	Yes	No
	If yes what was the result	Positive, state species	Negative

D.	PRE-TRANSFUSION SEROLOGY		
26.	Pre-transfusion testig		
	Was pre-transfusion testing performed?	Yes	
	If yes please complete section 26a; if no please give reason why and then proceed to question 27		
26a	Blood Grouping:		
	Tube		
	Microplate		
	Column		
	Other (specify).....		
	Please state blood group result obtained		
	Was this test performed correctly?	Yes	No
	Was the correct result obtained?	Yes	No
	If not , what was the correct result?		
	Was the result recorded correctly?	Yes	No
	Was the method used the routine or rapid method in use in the laboratory? (please circle)	Routine Rapid	

D.	PRE-TRANSFUSION SEROLOGY continued		
26.	**Pre transfusion testing continued**		
26b	**Was an antibody screen performed**	**Yes**	**No**
	If yes please complete sections 26b and 26c; if no proceed to section 26d		
	Antibody Screen		
	Was the sample serum or plasma? (please circle)	**Serum**	**Plasma**
	Which screening cells were used?.....		
	Was it a 2/3/4 cell screen?		
	Which method(s) of screening were used?	Please tick	
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microp[illegible]		
	Other (please specify).....		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify).....		
	Was the test performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody screen used in the laboratory? (please circle)	**Routine** **Rapid**	

D.	PRE-TRANSFUSION SEROLOGY continued		
26.	**Pre transfusion testing continued**		
26c	**Was the antibody screen positive or negative? (please circle)**	**Positive**	**Negative**
	If positive please complete section 26c; if negative proceed to section 26d		
	Please indicate further tests performed:		
	Which panel cells were used?.....		
	How many panel cells were used?.....		
	Which methods were employed:		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify).....		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify).....		
	Were these tests performed in your laboratory	**Yes**	**No**
	Was this test performed correctly?	**Yes**	**No**
	Was the antibody specificity(ies) identified correctly?	**Yes**	**No**
	Please give specificity of antibody		
	Positive - antibody not identified		
	Positive cold auto only		
	Positive enzyme auto only		
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody identification used in the laboratory? (please circle)	**Routine** **Rapid**	
	Would the antibody specificity usually be confirmed at a reference centre?	**Yes**	**No**

D. PRE-TRANSFUSION SEROLOGY continued

26c	**Pre transfusion testing continued**			
	Was antigen negative blood selected/used		**Yes**	**No**
	If yes, what was the source? (please tick)	**hospital blood bank**	**transfusion centre**	
	Was crossmatch compatible blood issued with no antigen testing		**Yes**	**No**
26d	**Pre-transfusion was the patient's direct antiglobulin test (please tick)**			
	a)	Positive DAT IgG		
		Complement		
		Both		
	b)	Negative		
	c)	Not Done		
26e	**Does your hospital perform donor antigen screening for patients with atypical antibodies**		**Yes**	**No**
	If yes please complete section 26e; if no proceed to section 26f			
	Antigen screening of donor units			
	Was this performed in your laboratory?		**Yes**	**No**
	Was this procedure performed correctly?		**Yes**	**No**
	Were the correct results obtained?		**Yes**	**No**
	Was the result recorded correctly?		**Yes**	**No**
	Brief description of methods.....			
	.....			
	.....			
	.....			

D. PRE-TRANSFUSION SEROLOGY continued

26f	**Was pre transfusion crossmatching performed?**		**Yes**	**No**
	If yes please complete section 26f; if no proceed to question 27			
	Crossmatch:			
	Which crossmatching methods were used:			
	IAT crossmatch LISS tube			
	NISS tube			
	Column Technology (state type)			
	Other (specify).....			
	Was this procedure performed correctly?		**Yes**	**No**
	Was the correct result obtained?		**Yes**	**No**
	Was the result recorded correctly		**Yes**	**No**
	Was this the routine or rapid method of crossmatching used in the laboratory? (please circle)		**Routine** **Rapid**	
	Interval between taking the crossmatch sample and transfusion			
	a)	0 - 47 hours		
	b)	48 - 71 hours		
	c)	72 - 96 hours		
	d)	> 96 hours (please state)		

27	**Were special requirements in component selection met?**			
	Gamma irradiation	**Yes**	**No**	**N/A**
	Leucodepletion	**Yes**	**No**	**N/A**
	CMV negative	**Yes**	**No**	**N/A**
	Phenotype selection	**Yes**	**No**	**N/A**
	Other (please specify).....			
	If special requirements were not met please give an explanation, if available:			
	Do you have a procedure for ordering components when there are special requirements?	**Yes**	**No**	
	If yes, please give brief details:.....			

E.	POST-TRANSFUSION SEROLOGY		
28	**Was a post transfusion antibody screen performed**	**Yes**	**No**
	If yes please complete 28a and 28b; if no proceed to question 29		
28a	**Antibody screen**		
	Was the sample serum or plasma? (please circle)	**Serum**	**Plasma**
	Which screening cells were used?.....		
	Was it a 2/3/4 cell screen?		
	Which method(s) of screening were used?	(please tick)	
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify).....		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify).....		
	Was this test performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody screen used in the laboratory? (please circle)	**Routine** / **Rapid**	

E. POST-TRANSFUSION SEROLOGY continued

28b	**Was the antibody screen positive or negative?** (please circle)	**Positive**	**Negative**
	If positive please complete section 28b; if negative proceed to question 29		
	Please indicate further tests performed:		
	Which panel cells were used?.....		
	How many panel cells were used?.....		
	Which methods were employed:		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify).....		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify).....		
	Were these tests performed in your laboratory	**Yes**	**No**
	Was this test performed correctly?	**Yes**	**No**
	Was the antibody specificity (ies) identified correctly?	**Yes**	**No**
	Positive - positive specificity of antibody		
	Positive - antibody not identified		
	Positive cold auto only		
	Positive enzyme auto only		
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody identification used in the laboratory? (please circle)	**Routine** **Rapid**	
	Would the antibody specificity usually be confirmed at a reference centre?	**Yes**	**No**

E. POST-TRANSFUSION SEROLOGY continued

29	**Post transfusion was the patient's direct antiglobulin test**		
	a)	Positive DAT IgG	
		Complement	
		Both	
	b)	Negative	
	c)	Not Done	
30	**Was retrospective testing of the pre-transfusion sample performed?**		Yes / No
	Was the same result obtained?		Yes / No
	If no, please give breif details.....		
	.....		
	.....		
31	**Presumed cause of the reaction :**		

F. SEQUELAE

32	**Did the patient require**			
	a)	Dialysis	Yes	No
	b)	Readmission	Yes	No
	c)	Already on RRT dialysis	Yes	No
33	**Did the patient**			
	a)	Survive with no ill effects		
	b)	Survive with ill effects, please specify		
		.....		
	c)	Die -in the event of death please can you indicate if the death was thought to be:		
		Not related to the transfusion		
		Possibly related to the transfusion		
		Probably related to the transfusion		
		Definitely related to the transfusion		
		Other, please specify.....		

Serious Hazards of Transfusion Reporting System — Acute Transfusion Reaction

F.				
34	**Was the reaction reported to any of the following?**		**Yes**	**No**
	a)	Hospital blood transfusion laboratory		
	b)	Hospital transfusion committee		
	c)	Transfusion centre		
35	**As a result, have there been recommended changes to transfusion procedures?**		**Yes**	**No**
	If yes, please specify			

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, Manchester Blood Centre

DELAYED TRANSFUSION REACTION

Incident No.

/	/	0	0	0	0	0

The information you supply is important. It must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choice of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question, simply tick the box(es) which apply or fill in the relevant information. Leave blank if not known.

Consultants or other staff may write to the Serious Hazards of Transfusion Reporting System office, under separate cover, quoting the questionnaire number.

All original copies of correspondence will be confidential (to maintain confidentiality it is advised that you do not retain copies of your correspondence with SHOT).

The whole questionnaire will be shredded when data collection is complete.

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Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL

Telephone: (0161) 251 4208
Fax: (0161) 251 4319

For office use only

DB .....

IDR .....

IRS .....

Comments .....

A. PATIENT DETAILS				
1.	Diagnosis and reason for transfusion			
	a)	Elective surgery - please state type ----------		
	b)	Emergency surgery - please state type ----------		
	c)	Trauma		
	d)	Haemorrhage due to ----------		
	e)	Malignant haematological disorder		
	f)	Autoimmune haemolysis		
	g)	Anaemia due to ----------		
	h)	Liver disease		
	i)	Other medical condition - please specify		
	j)	Plasma exchange, please specify diagnosis		
2.	Did the patient have a previous transfusion history		Yes	No
	If yes please give brief details ----------			
3.	If female, has this patient ever been pregnant		Yes	No
4.	Was this transfusion			
	a)	In emergency		
	b)	Routine		
	c)	Unknown		
5.	Where was the transfusion given ?			
	a)	In-patient ward		
	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 & REACTION

6.	Days between end of transfusion and onset of symptoms				.....days
7.	What components were given prior to the delayed transfusion reaction, please indicate the number of units and if in your opinion this was the responsible component (tick yes, no or unknown)				
	Component		No. of units	Yes	No	Unknown
	a)	Red Cells				
	b)	Red cells, buffy coat depleted				
	c)	Red cells, leucocyte depleted				
	d)	Platelets, apheresis				
	e)	Platelets, from buffy coat pools				
	f)	Platelets, from platelet rich plasma				
	g)	Platelets, leucocyte depleted				
	h)	Platelets, HLA selected				
	i)	Fresh frozen plasma: Untreated				
	j)	Fresh frozen plasma: Solvent Detergent				
	k)	Fresh frozen plasma: Methylene Blue				
	l)	Cryosupernatant (Cryo depleted FFP)				
	m)	Cryoprecipitate				
	n)	Granulocytes				
	p)	Other (please state) ----------				
8.	Was this unit :					
	a)	Autologous				
	b)	From a Transfusion Service donor				
	c)	From a family member				

B. COMPONENT DETAILS & REACTION continued				
9.	Indicate sign(s) / symptom(s)			
	a)	Fever (rise >1°C)		
	b)	Chills		
	c)	Rigors		
	d)	Itching/rash		
	e)	Back pain		
	f)	Chest pain/discomfort		
	g)	Dyspnoea / difficult breathing		
	h)	Dark urine		
	i)	Restlessness		
	j)	Hypotension		
	k)	Jaundice		
	l)	Falling Hb		
	m)	Poor/absent increment follo[illegible] transfusi[illegible]		
	n)	Other (please specify) ----------		
10.	Was any medication prescri[illegible]		Yes	No
	If yes, please specify			
	a)	Paracet[illegible]		
	b)	Antihistamine		
	c)	Diuretic		
	d)	[illegible]ydroc[illegible]isone		
	e)	A[illegible]renaline		
	f)	[illegible]ther ----------		

C. FOLLOWING THE TRANSFUSION REACTION

11.	Was the unit returned to the transfusion laboratory?	Yes	No
12.	Was a urine sample collected?	Yes	No
13.	Were blood samples taken?	Yes	No

	Please indicate diagnostic test results where performed:	Yes	No	Not done
a)	Raised urinary urobilinogen			
b)	Raised plasma bilirubin			
c)	Falling Hb			
d)	Haemoglobinuria			
e)	Deteriorating renal function			
f)	Positive DAT			
g)	Spherocytes			
h)	Evidence of DIC			

D. PRE-TRANSFUSION SEROLOGY

14.	Pre-transfusion testing		
	Was pre-transfusion testing performed?	Yes	No
	If yes, please complete question 14a		
	If no, please give reason why and then proceed to question 15 : ----------		

14a	Blood Grouping:		
	Tube		
	Microplate		
	Column		
	Other (specify) ----------		
	Please state blood group result obtained		
	Was this test performed correctly?	Yes	No
	Was the correct result obtained?	Yes	No
	If not , what was the correct result?		
	Was the result recorded correctly?	Yes	No
	Was the method used the routine or rapid method in use in the laboratory? (please circle)	Routine Rapid	

D.	PRE-TRANSFUSION SEROLOGY continued		
14.	**Pre transfusion testing continued . . .**		
14b	**Was an antibody screen performed**	**Yes**	**No**
	If yes please complete sections 14b and 14c		
	If no proceed to section 14d		
	Antibody Screen		
	Was the sample serum or plasma ? **(please circle)**	**Serum**	**Plasma**
	Which screening cells were used? ----------		
	Was it a 2/3/4 cell screen?		
	Were cells homozygous for major red cell antigens?		
	Which method(s) of screening were used? **(please tick)**		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify) ----------		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify) ----------		
	Was this test performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody screen used in the laboratory? (please circle)	**Routine** **Rapid**	

D.	PRE-TRANSFUSION SEROLOGY continued		
14.	**Pre transfusion testing continued . . .**		
14c	**Was the antibody screen positive or negative? (please circle)**	**Positive**	**Negative**
	If positive please complete section 14c		
	If negative proceed to section 14d		
	Please indicate further tests performed:		
	Which panel cells were used? ----------		
	How many panel cells were used? ----------		
	Which methods were employed:		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microp[illegible]		
	Other (please specify) ----------		
	Enzyme 1 stage [illegible]ain		
	2 stage papain		
	Other (please specify) ----------		
	W[illegible]ase test performed in your laboratory	**Yes**	**No**
	Wa[illegible]s test performed correctly?	**Yes**	**No**
	Was [illegible]e antibody specificity(ies) identified correctly?	**Yes**	**No**
	Please [illegible]ve specificity of antibody		
	[illegible]ositive - antibody not identified		
	Positive cold auto only		
	Positive enzyme auto only		
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody identification used in the laboratory? (please circle)	**Routine** **Rapid**	
	Would the antibody specificity usually be confirmed at a reference centre?	**Yes**	**No**

D. PRE-TRANSFUSION SEROLOGY continued

14c Pre transfusion testing continued . . .

Was antigen negative blood selected/used		**Yes**	**No**
If yes, what was the source? (please circle)	**hospital blood bank**	**transfusion centre**	
Was crossmatch compatible blood issued with no antigen testing		**Yes**	**No**

14d Pre-transfusion was the patient's direct antiglobulin test

a)	Positive DAT IgG	
	Complement	
	Both	
b)	Negative	
c)	Not Done	

14e	**Does your hospital perform donor antigen screening for patients with atypical antibodies ?**	**Yes**	**No**
	If yes please complete section 14e		
	If no proceed to section 15		
	Antigen screening of donor units		
	Was this performed in your laboratory?	**Yes**	**No**
	Was this procedure performed correctly?	**Yes**	**No**
	Were the correct results obtained	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**

Give brief description of methods ----------

D. PRE-TRANSFUSION SEROLOGY continued

14f	**Was pre transfusion crossmatching performed?**	**Yes**	**No**
	If yes please complete section 14f		
	If no proceed to question 15		
	Crossmatch:		
	Which crossmatching methods were used:		
	IAT crossmatch LISS tube		
	NISS tube		
	Column Technology (state type) ----------		
	Other (specify) ----------		
	Was this procedure performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly	**Yes**	**No**
	Was this the routine or rapid method of crossmatching used in the laboratory? (please circle)	**Routine** **Rapid**	
	Interval between taking crossmatch sample and transfusion		
	a) 0 - 47 hours		
	b) 48 hours		
	c) 72 - 96 hours		
	d) > 96 hours (please state)		
15	**Were special requirements in component selection met?**		
	Gamma irradiation	**Yes** **No** **N/A**	
	Leucodepletion	**Yes** **No** **N/A**	
	CMV negative	**Yes** **No** **N/A**	
	Phenotype selection	**Yes** **No** **N/A**	
	Other (please specify) ----------		
	If special requirements were not met please give an explanation, if available: ----------		
	Do you have a procedure for ordering components when there are special requirements?	**Yes**	**No**
	If yes, please give brief details: ----------		

E.	POST-TRANSFUSION SEROLOGY		
16	**Was a post transfusion antibody screen performed ?**	**Yes**	**No**
	If yes please complete section 16a and 16b		
	If no please proceed to question 17		
	Antibody screen :		
	Was the sample serum or plasma? (please circle)	**Serum**	**Plasma**
	Which screening cells were used? ----------		
	Was it a 2/3/4 cell screen?		
	Which method(s) of screening were used?	(please tick)	
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microp[illegible]		
	Other (please specify) ----------		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify) ----------		
	Was the test performed correctly?	**Yes**	**No**
	Was the correct result obtained?	**Yes**	**No**
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody screen used in the laboratory? (please circle)	**Routine** **Rapid**	

E. POST-TRANSFUSION SEROLOGY continued

16b	**Was the antibody screen positive or negative?** (please circle)	**Positive**	**Negative**
	If positive please complete section 16b		
	If negative proceed to question 17		
	Please indicate further tests performed:		
	Which panel cells were used? ----------		
	How many panel cells were used? ----------		
	Which methods were employed:		
	IAT LISS tube		
	NISS tube		
	Immucor Capture Ready Screen		
	Biotest Solid Screen		
	Ortho Biovue		
	Diamed ID		
	Liquid Phase Microplate		
	Other (please specify) ----------		
	Enzyme 1 stage papain		
	2 stage papain		
	Other (please specify) ----------		
	Were these tests performed in your laboratory	**Yes**	**No**
	Was each test performed correctly?	**Yes**	**No**
	Was the antibody specificity(ies) identified correctly?	**Yes**	**No**
	Positive - give specificity of antibody		
	Positive - antibody not identified		
	Positive cold auto only		
	Positive enzyme auto only		
	Was the result recorded correctly?	**Yes**	**No**
	Was the method used the routine or rapid method of antibody identification used in the laboratory? (please circle)	**Routine** **Rapid**	
	Would the antibody specificity usually be confirmed at a reference centre?	**Yes**	**No**

Serious Hazards of Transfusion Reporting System — Delayed Transfusion Reaction

E. POST-TRANSFUSION SEROLOGY continued

17	**Post transfusion was the patient's direct antiglobulin test**			
	a)	Positive DAT IgG		
		Complement		
		Both		
	b)	Negative		
	c)	Not Done		
18	**Was retrospective testing of the pre-transfusion sample performed?**		**Yes**	**No**
	Was the same result obtained?		**Yes**	**No**
	If no, please give breif details ----------			
19	**Presumed cause of the reaction :** ----------			

F. SEQUELAE

20	**Did the patient require:**			
	a)	Dialysis	**Yes**	**No**
	b)	ITU admission	**Yes**	**No**
	c)	Already on ITU / dialysis	**Yes**	**No**
21	**Did the patient :**			
	a)	Survive with no ill effects		
	b)	Survive with ill effects, please specify ----------		
	c)	**Die -in the event of death please can you indicate if the death was thought to be:**		
		Not related to the transfusion		
		Possibly related to the transfusion		
		Probably related to the transfusion		
		Definitely related to the transfusion		
		Other, please specify ----------		

Serious Hazards of Transfusion Reporting System — Delayed Transfusion Reaction

SEQUELAE continued....

			Yes	No
22	**Was the reaction reported to any of the following?**			
	a)	Hospital blood transfusion laboratory		
	b)	Hospital transfusion committee		
	c)	Transfusion centre		
23	**As a result, have there been recommended changes to transfusion procedures?**			
	If yes, please specify:			

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, Manchester Blood Centre

TRANSFUSION - RELATED ACUTE LUNG INJURY

Incident No.

/	/	0	0	0	0	0

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Plymouth Grove
Manchester M13 9LL

Telephone: (0161) 251 4208
Fax: (0161) 251 4319

For office use only

DB .....

IDR .....

IRS .....

Comments .....

A. PATIENT DETAILS			
1.	**Diagnosis and reason for transfusion**		
	a)	Elective surgery - please state type	
	b)	Emergency surgery - please state type.....	
	c)	Trauma	
	d)	Haemorrhage due to	
	e)	Malignant haematological disorder	
	f)	Autoimmune haemolysis	
	g)	Anaemia due to	
	h)	Liver disease	
	i)	Other medical condition - please specify	
	j)	Plasma exchange, please specify diagnosis	
2.	**Was this transfusion**		
	a)	An emergency	
	b)	Routine	
	c)	Unknown	
3.	**Where was the transfusion given**		
	a)	In-patient ward	
	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			
4.	In the 24 hours prior to the onset of symptoms, did the patient receive		State number of units
	a)	Red Cells	
	b)	Red cells buffy coat depleted	
	c)	Red cells leucocyte depleted	
	d)	Platelets, apheresis	
	e)	Platelets, from buffy coat pools	
	f)	Platelets, from platelet rich plasma	
	g)	Platelets, leucocyte depleted	
	h)	Platelets, HLA selected	
	i)	Fresh frozen plasma: Untreated	
	j)	Fresh frozen plasma: Solvent Detergent	
	k)	Fresh frozen plasma: Methylene Blue	
	l)	Cryosupernatent (Cryo depleted FFP)	
	m)	Cryoprecipitate	
	n)	Granulocytes	
	p)	Other, please state	
5.	Was this unit		
	a)	Autologous	
	b)	From a Transfusion Service donor	
	c)	From a family member	
6.	Was the onset of symptoms clearly associated with transfusion of		
	a)	Red cells	
	b)	Platelets	
	c)	FFP	
	d)	Cannot identify	
7.	If platelets or FFP, was the source		
	a)	Apheresis	
	b)	Whole blood	
	c)	Not applicable, other product	

C.	PATIENT OUTCOME		
8.	**Did the patient have pre-existing**		
	a)	Respiratory dysfunction (please specify)	
	b)	Sepsis	
	c)	Cardiac failure	
9.	**Did the patient develop**		
	a)	Fever	
	b)	Hypotension	
	c)	Rigors	
	d)	Dyspnoea	
	e)	↓ pO_2	
	f)	↑pCO_2	
	g)	CXR changes (please specify)	
10.	**Did the patient require**		
	a)	ITU admission	
	b)	Ventilation (specify number of days .....)	
	c)	Neither	
	d)	Patient already on ITU when transfused	
11.	**Specify treatment given**		
	a)	Methyl prednisolone	
	b)	Antihistamine	
	c)	Protease inhibitor eg aprotinin	
	d)	Other (please specify)	

C. PATIENT OUTCOME continued				
12.	Eventual outcome			
	a)	Patient died		
	b)	Full recovery		
	c)	Recovery with impaired respiratory function		
13.	Why did you think that this patient had TRALI rather than ARDS or circulatory overload? Please comment where applicable			
	a)	Sudden onset of symptoms during transfusion		
	b)	Sudden onset of symptoms following transfusion		
	c)	Deterioration of pre-existing symptoms during transfusion		
	d)	Deterioration of pre-existing symptoms following transfusion		
	e)	Comments:		
14.	Were serological investigations of suspected donor(s)			
	a)	Not carried out		
	b)	Negative		
	c)	Positive (state)		
15.	May we contact the reference laboratory performing the serological tests for further information if necessary?		Yes	No
	If yes please state reference laboratory concerned.....			

D.	PROCEDURAL REVIEW			
16	**Has the case been reviewed by hospital transfusion committee?**			
	a)	Yes		
	b)	No, but will be at a future meeting		
	c)	Hospital does not have transfusion committee		
17	**As a result, have there been recommended changes to transfusion procedures?**		Yes	No
	If yes, please specify.....			

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, Manchester Blood Centre

POST TRANSFUSION PURPURA (THROMBOCYTOPENIA)

Incident No .

/	/	0	0	0	0	0

The information you supply is important. It must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choices of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question, simply tick the box(es) which apply or fill in the relevant information. Leave blank if not known.

Consultants or junior staff may write to the Serious Hazards of Transfusion Reporting System office, under separate cover, quoting the questionnaire number.

All original copies of correspondence will be confidential (to maintain confidentiality it is advised that you do not retain copies of your correspondence with SHOT)

The whole questionnaire will be shredded when data collection is complete.

In case of difficulty, please contact the SHOT office at:

Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL

Telephone: (0161) 251 4208
Fax: (0161) 251 4319

For office use only

DB .....

IDR .....

IRS .....

Comments .....

A	PATIENT DETAILS			
1.	**Diagnosis and reason for transfusion**			
	a)	Elective surgery - please state type		
	b)	Emergency surgery - please state type.....		
	c)	Trauma		
		Haemorrhage due to		
	e)	Malignant haematological disorder		
	f)	Autoimmune haemolysis		
	g)	Anaemia due to		
	h)	Liver disease		
	i)	Other medical condition - please specify		
	j)	Plasma exchange, please specify diagnosis		
2.	**Was this transfusion**			
	a)	An emergency		
	b)	Routine		
	c)	Unknown		
3.	**Where was this transfusion given**			
	a)	In-patient ward		
	b)	Out-patient/day unit		
	c)	Intensive care unit		
	d)	[illegible] recovery		
	e)	Accident & [illegible] unit		
	f)	Scene of accident		
	g)	Other (please state).....		
4.	**Number of pregnancies**			
	a)	0		
	b)	1		
	c)	2		
	d)	>2		
5.	**In the case of previous pregnancies, was there any history of previous neonatal alloimmune thrombocytopenia?**		**Yes**	**No**

A	**PATIENT DETAILS continued**		
6.	**Interval between last pregnancy and transfusion**		
	a)	<1 year	
	b)	1-4 years	
	c)	5-20 years	
	d)	>20 years	
7.	**Previous transfusion and interval**		
	a)	No transfusion	
	b)	<1 year	
	c)	1-4 years	
	d)	5-20 years	
	e)	>20 years	
B	**COMPONENT DETAILS**		
8.	**Was the recent transfusion of**		**Number of units**
	a)	Red Cells	
	b)	Red cells buffy coat depleted	
	c)	Red cells leucocyte depleted	
	d)	Platelets, apheresis	
	e)	Platelets, from buffy coat pools	
	f)	Platelets, from platelet rich plasma	
	g)	Platelets, leucocyte depleted	
	h)	Platelets, HLA selected	
	i)	Fresh frozen plasma: Untreated	
	j)	Fresh frozen plasma: Solvent Detergent	
	k)	Fresh frozen plasma: Methylene Blue	
	l)	Cryosupernatent (Cryo depleted FFP)	
	m)	Cryoprecipitate	
	n)	Granulocytes	
	p)	Other, please state	
9.	**Was this unit**		
	a)	Autologous	
	b)	From a Transfusion Service donor	
	c)	From a family member	

C	OUTCOME			
10.	**Did this transfusion result in documented features of an acute transfusion reaction?**		**Yes**	**No**
11.	**Interval between transfusion and onset of clinical symptoms/thrombocytopenia**			
	a)	<5 days		
	b)	5 - 9 days		
	c)	10-15 days		
	d)	>15 days		
12.	**What were the clinical features?**			
	a)	Purpura / bruising		
	b)	Minor haemorrhage (nose, gums, haematuria)		
	c)	GI haemorrhage		
	d)	Lung haemorrhage		
	e)	Intracerebral haemorrhage		
	f)	Incidental low platelet count noted		
13.	**What was the lowest platelet count (x 10^9/ l)**			
	a)	50-100		
	b)	20-49		
	c)	10-19		
	d)	<10		
	Give the pre-transfusion platelet count here			
14.	**Serological investigations - where done?**			
	a)	No platelet alloantibody found		
	b)	Anti-HPA-1a identified	**Yes**	**No**
	c)	HLA antibodies	**Yes**	**No**
	d)	Red cell antibodies	**Yes**	**No**
	e)	Other platelet specific alloantibody identified (please specify)		

C	OUTCOME continued		
15.	**May we contact the reference laboratory performing the serological tests for further information if necessary?**	**Yes**	**No**
	If yes please state reference laboratory concerned		
16	**Treatment given**		
	a) Intravenous IgG		
	b) Random platelets		
	c) HPA-1a negative platelets		
	d) Steroids		
	e) Antihistamine		
17	**Patient outcome**		
	a) Full recovery - days to platelets >50 specify)		
	b) Death from haemorrhage		
	c) Death from other ca		
	d) **Death** -in the event of d th pleas n you indicate if the death was thought to be:		
	Not related to the transfusion		
	Possibly re d to the transfusio		
	Probably relate the tra sion		
	Definitely elated to the transfusion		
	Other, pleas specify.....		

D.	**PROCEDURAL REVIEW**		
18	**Has the case been reviewed by hospital transfusion committee?**		
	a)	Yes	
	b)	No, but will be at a future meeting	
	c)	Hospital does not have transfusion committee	
19	**As a result, have there been recommended changes to transfusion procedures?**		Yes / No
	If yes, please specify.....		

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Mrs Hilary Jones, Manchester Blood Centre

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TRANSFUSION ASSOCIATED GRAFT VERSUS HOST DISEASE

Incident No.

		0	0	0	0

The information you supply is important but must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choice of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question simply tick the box(es) which apply or fill in the relevant information. Leave blank if not known.

Consultants or junior staff may write to the Serious Hazards of Transfusion Reporting System office, under separate cover, quoting the questionnaire number.

All original copies of correspondence will be confidential (to maintain confidentiality it is advised that you do not retain copies of your correspondence with SHOT).

The whole questionnaire will be shredded when data collection is complete.

In case of difficulty, please contact the SHOT office at:

Manchester Blood Centre
Plymouth Grove
Manchester M13 9LL

Telephone: 0161 251 4208
Fax: 0161 251 4319

A. PATIENT DETAILS

1. Diagnosis and reason for transfusion

a)	Elective surgery	
b)	Emergency surgery	
c)	Trauma	
d)	Haemorrhage eg GI	
e)	Anaemic premature neonate (state gestation in weeks)	_____weeks
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)	
n)	Other solid tumour	
o)	HIV related	
p)	Other (please specify).....	

2. Was this transfusion

a)	An emergency	
b)	Routine	
c)	Unknown	

3. Where was the transfusion given

a)	In-patient ward	
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.....	

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 deoxycoformycin)	
	f)	Other (please specify)	
5.	**Patient's HLA type (if known)**		
	A locus		
	B locus		
	C locus		
	DR		
	DP		
	DQ		

B. BLOOD COMPONENT

6.	**In the month prior to syn[illegible] did the pa[illegible]nt receive**		**Number of units**
	a)	Red Cells	
	b)	Red cells [illegible] coat d[illegible]eted	
	c)	Red cells leuc[illegible]cyte depleted	
	d)	Platelets, apheresi[illegible]	
	e)	[illegible]latelets, [illegible]m buffy coat pools	
	f)	[illegible]latelets, f[illegible]m platelet rich plasma	
	g)	Platelets, leucocyte depleted	
	h)	[illegible]latelets, HLA selected	
	i)	Fresh frozen plasma: Untreated	
	j)	Fresh frozen plasma: Solvent Detergent	
	k)	Fresh frozen plasma: Methylene Blue	
	l)	Cryosupernatent (Cryo depleted FFP)	
	m)	Cryoprecipitate	
	n)	Granulocytes	
	p)	Other, please state	

B.	BLOOD COMPONENT continued			
7.	**Are you able to identify which component was responsible for the GVHD?**		Yes	No
	If no, proceed to question 10.			
	If yes, answer questions 8 and 9.			
8.	**Was the component transfused when it was**			
	a)	<5 days old		
	b)	5-14 days old		
	c)	>14 days old		
9.	**Give HLA type of donor if known**			
	HLA-A			
	HLA-B			
	HLA-C			
	HLA-DR			
	HLA-DP			
	HLA-DQ			
10.	**Were the components from**			
	a)	HLA selected donors		
	b)	Family members		
	c)	Autologous		
	d)	From a Transfusion Service donor		
11.	**Was the patient receiving cellular components which were gamma irradiated?**		Yes	No
	If yes, answer questions 12-14			
	If no, proceed to question 15.			
12.	**Was irradiation carried out**			
	a)	In 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		
	c)	10 - 14 days		
	d)	15 - 19 days		
	e)	>19 days		
16.	**Clinical features**			
	a)	Rash		
	b)	Diarrhoea		
	c)	Deranged LFT's		
	d)	Pancytopenia		
	e)	Infection		
17.	**Was the diagnosis based on:**			
	a)	Histology of biopsy (specify tissue)		
	b)	Detection of donor DNA i) In peripheral blood		
		ii) In skin or other tissue		
	c)	Post-mortem histology		
	d)	Other		
18.	**May we contact the reference laboratory performing the histocompatibility tests for further information if necessary?**		**Yes**	**No**
	If yes please state reference laboratory concerned.....			
	.....			
	.....			

D. TREATMENT AND OUTCOME

19.	**Was the interval between onset of symptoms and start of treatment**		
	a)	0 - 3 days	
	b)	4 -7 days	
	c)	8 - 14 days	
	d)	>14 days	
20.	**Did the patient receive as therapy for transfusion-associated GVHD**		
	a)	Methyl prednisolone	
	b)	Immunosuppression	
	c)	Anti-lymphocyte antibodies	
21.	**Patient 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	
	d)	Other (please specify)	

D. PROCEDURAL REVIEW

22.	**Has the case been reviewed by hospital transfusion committee?**			
	a)	Yes		
	b)	No, but will be at a future meeting		
	c)	Hospital does not have transfusion committee		
23.	**As a result, have there been recommended changes to transfusion procedures?**		**Yes**	**No**
	If yes, please specify.....			

SHOT NEAR MISS SURVEY

1. Sample errors

(Errors in phlebotomy or sample labelling which were detected at some stage, but which could have resulted in erroneous results to be issued or components transfused to the wrong patient)

Date of event _____ **Approx. No. of samples tested in Blood Bank per annum** _____

Please return completed form to : SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester, M13 9LL

Sample errors (Please tick **one** box)	**Where collected?** (Please tick **one** box)	**Collected by whom?** (Please tick)	**Where was error detected?** (Please tick)	**Error detected by whom?** (Please tick)	**Was the person involved in collecting or labelling the sample ...**
☐ Sample taken from wrong patient but labelled as per intended patient	☐ Ward	☐ Medical Student	☐ In laboratory before result or component issued	☐ Doctor	☐ A permanent hospital employee
	☐ Clinic	☐ Doctor		☐ Nurse	☐ Locum / Bank/ Agency staff
	☐ Theatre	☐ Nurse	☐ In laboratory after result or component issued	☐ Phlebotomist	**Did the error occur during ...**
☐ Sample taken from intended patient but labelled as per another patient	☐ Phlebo Room	☐ Phlebotomist		☐ Lab MLSO	☐ Routine Working Hours
	☐ Laboratory	☐ Lab MLSO	☐ On ward	☐ GP	☐ On Call Period
☐ Other (Please give details)	☐ GP Surgery	☐ GP	☐ In theatre	☐ Other (Please give details)	**Was the sample labelled with an addressograph label?**
	☐ Other (Please give details)	☐ Other (Please give details)	☐ Other (Please give details)		☐ YES ☐ NO
		NB State Grade (if known)		**NB State grade (if known)**	**How was the error detected?** (Please give brief details below)

SHOT NEAR MISS SURVEY

2. Request errors

(Errors of the request process which, if not detected, could have caused an incorrect or unsuitable component to be transfused)

Date of event _____

Approx. No. of samples tested in Blood Bank per annum _____

Please return completed form to : SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester, M13 9LL

Request errors (Please tick **one** box)	**How requested?** (Please tick one box)	**Requested by whom?** (Please tick)	**Where was error detected?** (Please tick)	**Error detected by whom?** (Please tick)	**Was the person involved in the incorrect request ...**
Wrong component requested ☐	On request form ☐	Medical Student ☐	In laboratory before component issued ☐	Doctor ☐	A permanent hospital employee ☐
Special requirements incorrectly specified which were not previously known to the laboratory ☐	By phone ☐	Doctor ☐	In laboratory after component issued ☐	Nurse ☐	Locum / Bank/ Agency staff ☐
Requested for incorrect patient ☐	By computer (eg order comms) ☐	Nurse ☐	On ward ☐	Lab MLSO ☐	**Did the error occur during ...**
	Personal verbal request ☐	Other (Please give details) ☐	In theatre ☐	Other (Please give details) ☐	Routine Working Hours ☐
	Other (Please give details) ☐		Other (Please give details) ☐		On Call Period ☐
					How was the error detected? (Please give details below)
		NB State Grade (if known)		**NB State grade (if known)**	

SHOT NEAR MISS SURVEY

3. Laboratory sample handling / testing errors

(Any laboratory error which was detected, but could have resulted in the issue of an erroneous report or incorrect component to be transfused)

Date of event _____ **Approx. No. of samples tested in Blood Bank per annum** _____

Please return completed form to : SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester, M13 9LL

Error (Please tick **one** box)	**Reason for error?** (Please tick)	**Person involved?** (Please tick)	**Where was error detected?** (Please tick)	**Error detected by whom?** (Please tick)	**Was the person involved in the error ...**
Incorrect patient details used ☐	Wrong sample used for testing ☐	MLA ☐	In laboratory before result or component issued ☐	MLA ☐	A permanent Blood Bank MLSO ☐
Erroneous result obtained ☐	Clerical error eg transcription error ☐	Trainee MLSO ☐	In laboratory after result or component issued ☐	Trainee MLSO ☐	An MLSO on rotation ☐
Result interpretation error ☐	Technical error eg poor technique, incorrect procedure, failure to follow SOP ☐	State registered MLSO ☐	On ward ☐	MLSO ☐	Locum / Bank / Agency staff ☐
Transcription error ☐	Equipment error or failure ☐	Doctor ☐	In theatre ☐	Doctor ☐	**Did the error occur during ...**
Other laboratory error (Please give details) ☐	IT system software error or deficiency ☐	Other (Please give details below) ☐	Other (Please give details) ☐	Nurse ☐	Routine Working Hours ☐
	Equipment / IT interface error or failure ☐			Other (Please give details) ☐	On Call Period ☐
	Other (Please specify) ☐	**NB State grade (if known)**		**NB State grade (if known)**	**Please give below brief details of the problem**

SHOT NEAR MISS SURVEY

4. Laboratory component selection, handling and storage errors

(Any error of component selection or handling by the laboratory, or component storage problems which, if not detected, could have resulted in the administration of an incorrect, inappropriate or unsuitable component)

Date of event _____ **Approx. No. of samples tested in Blood Bank per annum** _____

Please return completed form to : SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester M13 9LL

Error (Please tick **one** box)	**Where error caused?** (Please tick)	**Person involved?** (Please tick)	**Where was error detected?** (Please tick)	**Error detected by whom?** (Please tick)	**Was the person involved in the error ...**
Avoidable failure by the laboratory to provide for the patient's special needs **eg** CMV neg, irradiated, leucodepleted, incorrect phenotype etc. ☐	BTS ☐	MLA ☐	In laboratory before result or component issued ☐	MLSO ☐	A permanent blood bank MLSO ☐
Incorrect selection of component **eg** out of date or wrong type of component ☐	Laboratory ☐	Trainee MLSO ☐	In laboratory after result or component issued ☐	Doctor ☐	An MLSO on rotation ☐
Incorrect labelling of component ☐	Laboratory based Blood Bank on site ☐	State registered MLSO ☐	On ward ☐	Nurse ☐	Locum / Bank/ Agency staff ☐
Incorrect storage of component ☐	On site remote Blood Bank ☐	Doctor ☐	In theatre ☐	Porter ☐	**Did the error occur during ...**
Other (Please give details below) ☐	Blood Bank in external hospital /ward ☐	Other (Please give details below) ☐	Other (Please give details) ☐	Other (Please give details) ☐	Routine Working Hours ☐
	Other (Please give details below) ☐	**NB State grade (if known)**		**NB State grade (if known)**	On Call Period ☐
					Please give brief details of the problem below

SHOT NEAR MISS SURVEY

5. Component issue, transportation and patient identification errors

(Any error of blood component issue or collection from Blood Bank, component transportation or of patient identification immediately prior to transfusion which, had it not been detected, could have resulted in the administration of an incorrect, inappropriate or unsuitable component.)

Date of event _____ **Approx. No. of samples tested in Blood Bank per annum** _____

Please return completed form to : SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester M13 9LL

Error (Please tick **one** box)	**Where did error occur?** (Please tick)	**Person involved?** (Please tick)	**Where was error detected?** (Please tick)	**Error detected by whom?** (Please tick)	**Was the person involved in the error ...**
Incorrect transportation of component ☐	Transportation within site ☐	MLA ☐	Laboratory after results / component issued ☐	MLSO ☐	A permanent employee ☐
Component issued / collected for incorrect patient ☐	Transportation between sites ☐	Trainee MLSO ☐		Doctor ☐	Locum / Bank/ Agency staff ☐
Error in identification of correct patient at time of transfusion ☐	Laboratory Blood Bank on site ☐	State registered MLSO ☐	Ward ☐	Nurse ☐	**Did the error occur during ...**
Other (Please give details below) ☐	On site remote Blood Bank ☐	Porter ☐	Theatre ☐	Porter ☐	Routine Working Hours ☐
	Ward on site ☐	Doctor ☐		Other ☐	On Call Period ☐
	Theatre on site ☐	Nurse ☐	Other (Please detail) ☐		**Please give brief details below of the problem**
	Blood Bank in external hospital / ward ☐	Other (Please detail)			
	External hospital / ward / theatre ☐				
	Other (Please give details below) ☐	**NB State grade (if known)**		**NB State grade (if known)**	

SERIOUS HAZARDS OF TRANSFUSION **SHOT**

AUTOLOGOUS PRE-DEPOSIT INCIDENT

Use this form to report adverse events following donation of autologous blood. For events associated with the transfusion of blood or blood components, including autologous, please use the yellow reporting form.

Adverse reactions are listed on the back of this form.

Confidentiality of data is fundamental to the success of this scheme. We will not enter the identity of the patient in the study database but we will contact you to obtain additional details if necessary

KEY DETAILS OF ADVERSE EVENT

PATIENT

Surname: **Forename:** **DOB:** **Sex: M/F**

Hospital No: **Hospital:** **Ward/Clinic**

Date of implicated event ...../...../.....

Time of implicated event .....hrs

Incident No. For SHOT office use

ONCE COMPLETED PLEASE SEND REPORT TO:
Mrs Hilary Jones,
Assistant National SHOT Co-ordinator,
SHOT Office,
Manchester Blood Centre
Plymouth Grove
Manchester
M13 9LL

Telephone number GRO-C **Confidential Fax** GRO-C

NATURE OF DONOR INCIDENT

What was the nature of the complication			Please tick as applicable
	a)	Nerve damage	
	b)	Arterial injury, please circle	A[illegible]fistula Pseudoan[illegible]ysm
	c)	Thrombophlebitis	
	d)	Vasovagal attack - please use following criteria	
	(i)	Felt faint: pallor, sweating , light-headedness, ta[illegible]ypnea and/or tachycardia, nausea, air hunger +/- tetany	
	(ii)	Faint: bradycardia, hypotension, loss of co[illegible]iousness	
	(iii)	Severe Faint:-prolonged uncon[illegible]ousness, ([illegible]ore than 5 mi[illegible] and/or prolonged bradycar[illegible]to[illegible] clonic spasms, vomiting, incontinenc[illegible]recurrent fa[illegible]t o[illegible]delayed recovery	
	(iv)	Delayed faint: faint[illegible]ich[illegible]ccur in a do[illegible]r a[illegible]er leaving a blood donation sessio[illegible]	
	e)	Convulsions	
	f)	Cardiova[illegible]ular - [illegible]ase use following criteria	
	(i)	Angina	
	(ii)	Documented arrhy[illegible]mia	
	(iii)	Signi[illegible]t new ECG changes	
	(iv)	Myocardi[illegible]infarction	
	g)	Other	
	h)	Death - state cause	

PATIENT OUTCOME	(Tick Box)
No obvious cli[illegible]cal problem	☐
Morbidity [illegible]ue to the adverse event	☐
Death following adverse event	☐

REPORT MADE BY

Surname ..... Initial & Title .....

Address ..... Date of Report ...../...../.....

..... Tel.Number .....

SERIOUS HAZARDS OF TRANSFUSION REPORTING SYSTEM

National Co-ordinator: Dr Elizabeth Love, Manchester Blood Centre
Assistant National Co-ordinator: Hilary Jones, Manchester Blood Centre

AUTOLOGOUS PRE-DEPOSIT : DONOR INCIDENT

Incident No.

The information you supply is important. It must be accurate if valid conclusions are to be drawn.

Neither the questions nor the choice of answers are intended to suggest standards of practice.

Please enclose a copy of any relevant ward or blood bank records. Any identification will be removed in the Serious Hazards of Transfusion Reporting System office.

For each question, simply tick the box(es) which apply or fill in the relevant information. Leave blank if not known.

Consultants or junior staff may write to the Serious Hazards of Transfusion Reporting System office, under separate cover, quoting the questionnaire number.

All original copies of correspondence will be confidential (to maintain confidentiality it is advised that you do not retain copies of your correspondence with SHOT).

The whole questionnaire will be shredded when data collection is complete.

In case of difficulty, please contact the SHOT office at:

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

A. PATIENT INFORMATION

1.	**Type of procedure donation required for. Please tick as applicable and state procedure**			
	a)	Orthopaedic surgery		
	b)	Cardiac surgery		
	c)	Other vascular surgery		
	d)	Abdominal surgery		
	e)	Other		
2.	**How many donations were scheduled ?(please state number)**		..... units	
3.	**Which donation did this incident relate to? (please state 1st, 2nd, 3rd, etc)**		.....	
4.	**What was the interval between the index donation and the previous donation?**		..... days	
5.	**Has the patient previously been a blood donor?**		**Yes**	**No**
	If yes, have they ever previously experienced any adverse events following donation? please state			
6.	**Age of patient**		.....years	
7.	**Body weight**		.....kg	
8.	**Previous medical history**		**Yes**	**No**
	a)	Good venous access		
	b)	Active bacterial infection		
	c)	Unstable angina		
	d)	Angina at rest		
	e)	Beta Blockers, ACE inhibitors Calcium blockers		
	f)	Severe hypertension - systolic >180mmHg - diastolic>100mmHg		
	g)	Congestive cardiac failure		
	h)	M.I. within last 6 months		
	i)	Aortic stenosis		
	j)	Symptomatic cardiac arrhythmia		
	k)	T.I.A. history		
	l)	Cerebro-vascular accident		
	m)	Severe chronic obstructive airways disease		
	n)	Epileptic attack within last 3 years		

A. PATIENT INFORMATION continued

			Yes	No
8.	**Previous medical history continued**			
	o)	Known to have positive virology markers HBV/HCV/HIV?		
	p)	Hb >110 g/l pre1st collection		
	q)	Did the selection criteria for this patient differ in any way from your formal selection criteria, if so please comment.....		

B. STAFF AND FACILITIES

9.	**Who assessed the patient for fitness? please tick**		
	a)	Surgical team (specify grade)	
	b)	Haematology department (specify grade)	
	c)	Other - please specify.....	
10.	**Who drew the blood? please tick**		
	a)	Consultant	
	b)	Junior doctor	
	c)	Registered general nurse	
	d)	MLSO	
	e)	Other - please specify.....	
11.	**Where did the service take place?**		
	a)	Blood service - static session	
	b)	Blood service - mobile team	
	c)	Hospital premises NHS In-patient / Out-patient	
	d)	Hospital premises private In-patient / Out-patient	
	e)	Other, please state.....	

C. DONOR INCIDENT

12.	**What was the nature of the complication**		**Please describe/ or tick as applicable**	
	a)	**Nerve damage**		
		.....		
		.....		
	b)	**Arterial injury, please circle**	**AV fistula**	
			Pseudoaneurysm	
	c)	**Thrombophlebitis/lymphangitis**		
	d)	**Vasovagal attack - please use following criteria**		
	(i)	Felt faint: pallor, sweating , light-headedness, tachypnoea and/or tachycardia, nausea, air hunger +/- tetany		
	(ii)	Faint: bradycardia, hypotension, loss of consciousness		
	(iii)	Severe Faint:-prolonged unconsciousness, (more than 5 min) and/or prolonged bradycardia, tonic, clonic spasms, vomiting, incontinence recurrent faint or delayed recovery		
	(iv)	Delayed faint: faint which occurred after leaving the blood donation session		
	e)	**Convulsions**		
	f)	**Cardiovascular - please use following criteria**		
	(i)	Angina		
	(ii)	Documented arrhythmia		
	(iii)	Significant new ECG changes		
	(iv)	Myocardial infarction		
	g)	**Other**		
	h)	**Death - state cause**		
		.....		
		.....		
13.	**Was the donation, please tick as applicable**			
	a)	Simple (ie. blood drawn, no volume replacement)		
	b)	Isovolaemic (ie. blood drawn, simultaneous volume replacement)		
	If isovolaemic please state which fluid was used, and the volume			
	.....			
14.	**Was ECG monitoring used during the donation?**		**Yes**	**No**

C. DONOR INCIDENT continued

15.	What was the rest period after donation, please state in minutes			.....mins
16.	What volume of blood was taken, please state in mls			.....mls
17.	Did the incident occur		Yes	No
	a)	During the collection		
	b)	After the collection — At the session		.....hours after
		At home		.....hours after
	c)	Elsewhere, please state where		
18.	Did this incident require hospitalisation		Yes	No
	If yes , what was the length of stay			.....days
	Did this incident require specialist referral		Yes	No
	If yes, please give details			
19.	In your opinion, was the donation responsible for this incident		Yes	No

D. GENERAL SELECTION CRITERIA FOR YOUR CENTRE

20.	What are the eligibility criteria for patients?		
	a)	Age range	.....yrs to .....yrs
	b)	Minimum Hb non pregnant	.....g/dl
	c)	Minimum Hb pregnant	.....g/dl
	d)	Other, please specify	
21.	What are the exclusion criteria (tick whichever applies)		
	a)	Pregnancy	
	b)	Left main coronary narrowing	
	c)	Aortic valve disease	
	e)	Systemic infection	
	f)	Epilepsy	
	g)	Asthma	
	h)	Mininmum weight, please state in kg	.....kg
	i)	Other, please specify	
22.	Does your centre use a standard pre-deposit fitness questionnaire?	Yes	No

D. GENERAL SELECTION CRITERIA FOR YOUR CENTRE

23.	**Minimum interval between donations - please state in days**			.....days
NB. Please enclose any eligibility or exclusion criteria and/or donor fitness questionnaires that your centre uses to assess fitness for autologous pre-donation.				
24.	**Is cardiac arrest equipment on site?**		Yes	No
25.	**Is a cardiac arrest team available on site?**		Yes	No
26.	**By whom are autologous pre-donation clinics staffed?**			state number
	a)	Doctors		
	b)	Nurses		
	c)	Secretary		
	d)	Clerk		
	e)	Donor attendant		
	f)	Other, please specify.....		
27.	**By whom are staff trained? Please tick**			
	a)	Blood transfusion service		
	b)	Hospital (state grade and specialty)		
	c)	Self taught		
28.	**Date service was instituted**			...../...../.....
29.	**Approximate number of donations made at centre per month**			.....
30.	**Approximate number of units transfused per month**			.....

E. BLOOD SAFETY

31.	**Is collected blood tested for transfusion transmissible viruses?**		Yes	No
32.	**If yes, please indicate which - tick yes or no**		Yes	No
	a)	HCV		
	b)	HIV		
	c)	HBV		
	d)	Syphilis		
	e)	Other, please state		