SERIOUS HAZARDS OF TRANSFUSION

ANNUAL REPORT

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GLOSSARY OF TERMS

AML	Acute myeloid leukaemia
API	Adverse patient incident
ARDS	Acute respiratory distress syndrome
ATR	Acute transfusion reaction
BBTS	British Blood Transfusion Society
BCSH	British Committee for Standards in Haematology
BMS	Biomedical scientist
CAT	Column agglutination technology
CML	Chronic myeloid leukaemia
CMV	Cytomegalovirus
CNST	Clinical Negligence Scheme for Trusts
CPA	Clinical Pathology Accreditation
CPAP	Continuous positive airways pressure
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
DTR	Delayed transfusion reaction
DNA	Deoxyribonucleic acid
EBV	Epstein-Barr virus
EC	European Commission
EDTA	Ethylenediamine tetraacetic acid
ELISA	Enzyme-linked immunosorbent assay
EUB	Effective Use of Blood
FFP	Fresh frozen plasma
FMH	Fetomaternal haemorrhage
GLAM	Granulocyte, lymphocyte and monocyte assay
HAV	Hepatitis A virus
HBc	Hepatitis B core
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency virus
HLA	Human leucocyte antigen
HPA	Human platelet antigen
HTC	Hospital Transfusion Committee
HTLV	Human T-cell leukaemia virus
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
ICU	Intensive care unit
IUT	Intra-uterine transfusion
IVIgG	Intravenous immunoglobulin
LISS	Low ionic-strength saline
MCA	Medicines Control Agency
MLA	Medical laboratory assistant
MSBT	Microbiological Safety of Blood and Tissues for Transplantation

NBA	National Blood Authority (England)
NBS	National Blood Service
NBTC	National Blood Transfusion Committee (England)
NEQAS-BTLP	National External Quality Assurance Scheme for Blood Transfusion Laboratory Practice
NICU	Neonatal intensive care unit
NPSA	National Patient Safety Agency
PHLS/CDSC	Public Health Laboratory Service Communicable Disease Surveillance Centre
PTI	Post-transfusion infection
PTP	Post-transfusion purpura
RBTC	Regional Blood Transfusion Committee
RCOG	Royal College of Obstetricians and Gynaecologists
RhD	Rhesus D
RTC	Regional Transfusion Centre
SDFFP	Solvent-detergent fresh frozen plasma
SHO	Senior house officer
SNBTS	Scottish National Blood Transfusion Service
SOP	Standard operating procedure
SPOT	Specialist practitioners of transfusion
TA-GVHD	Transfusion-associated graft-versus-host disease
TNS	Transfusion nurse specialist
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenia purpura
UKBTS	United Kingdom Blood Transfusion Services
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
vCJD	Variant Creutzfeldt-Jakob disease

1. MAIN FINDINGS AND RECOMMENDATIONS

SUMMARY OF MAIN FINDINGS

Participation and number of reports

In 2000 – 2001, 379/413 (92%) hospitals participated in the SHOT scheme compared with 72% the previous year. There were increases in both the number of hospitals submitting reports (199/413 hospitals eligible to participate; 11.6% increase since the previous year and 25.9% since the scheme began), and the overall number of reports (315 initial reports; 7.5% increase since the previous year).

Incorrect blood component transfused ("wrong blood") incidents

Once again the largest category, showing a 6% increase in number since the previous year (213/315 reports), remains transfusion of the wrong blood. Cumulative data over 5 years show that the largest category of reports is blood transfusion errors with the wrong blood transfused to patients accounting for 61% (699/1148) of cases. The outcome of these was death in 11 patients (5 definitely related to transfusion, 1 probably, and 5 possibly related) and major morbidity, for example conditions necessitating intensive care unit admission (ICU), in 60 as a result of ABO and/or other red cell incompatibility.
This year, of 190 completed questionnaires (cases), hospital blood transfusion laboratories were the sites of the largest category of originating errors (36% of all cases). Thirty six percent of all laboratory errors (100 errors in 80 reports) occurred out of hours. As in previous years multiple errors were implicated in many "wrong blood" incidents. There were 103 cases (54.2%) with multiple errors and 344 errors in total indicating that problems still occur at all stages of the transfusion process and that the final bedside check may fail to detect mistakes made earlier in the transfusion chain. When all errors (344) rather than all cases (190) were analysed, 29% occurred in hospital transfusion laboratories, 35% during bedside administration, 8% during the collection of blood components from the hospital storage site, 7% from other administrative errors, 15% during the prescription, sampling and request of blood for transfusion, 2% at the supplying blood centre and 4% where the origin of the error could not be detected. Thirty-three percent of laboratory errors were in the categories "failure to consult/heed the historical record" and "selection/issue of inappropriate component".

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

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

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

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

"Near Miss" events

All hospitals in the UK have been encouraged to report "Near Miss" events to the SHOT Scheme for the last reporting year. Disappointingly only 121(29%) of hospitals from a possible 413 supplied data comprising 452 reports. Of these, 50% (230/452) were sampling errors indicating that phlebotomy errors remain the major cause of "near miss" events. Selection of blood components by the laboratory, handling and storage errors accounted for 81 cases (18%) with 44/81 related to the incorrect storage of components in clinical areas and 18 where the laboratory issued components without ensuring that special requirements (e.g. irradiated or cytomegalovirus (CMV) antibody negative components) were provided. Cumulative data from 812 reports since 1997 shows that the relative proportions of causes of "Near Misses" are fairly constant. Increased participation by hospitals in this "Near Miss"

reporting scheme would enable a more comprehensive evaluation of incidents from a representative national perspective.

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

Immune complications of transfusion

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

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

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

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

Transfusion-transmitted infections (TTI)

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

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

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

MAIN RECOMMENDATIONS BASED ON FINDINGS

GENERAL RECOMMENDATIONS

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

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

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

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

   - **Transfusion practitioners should be appointed in all hospital Trusts.**
     Transfusion practitioners play a key role in staff training and implementation of safe transfusion practice, as well as in appropriate blood component usage. Currently the majority of those in post are nurses but other clinical staff with appropriate background are not precluded from this role. A structured training programme and professional accreditation should be considered to make the role of transfusion practitioner a more attractive career option. The recently developed Specialist Practitioners of Transfusion (SPOT) group and the Effective Use of Blood (EUB) group in the Scottish National Blood Transfusion Service (SNBTS) provide peer support and the opportunity for shared learning.
   - **More transfusion medical consultant time is needed in hospital Trusts.**
     This will provide a driving force for blood safety improvements and the parallel initiative of appropriate blood usage. This is likely to have training and manpower implications.
   - **Hospital Trusts should ensure that they employ adequate numbers of appropriately trained BMSs.**
     This year hospital blood transfusion laboratories were the sites of the largest category of originating errors (36% of all cases). Errors occurred out of hours in 40.5% (77/190). Hospitals should ensure that they employ sufficient numbers of appropriately skilled BMSs to maintain adequate staffing at all times. The blood transfusion laboratory setting remains one where considerable technical and interpretative skills are essential for patient safety. SHOT data have demonstrated that such skills are not always optimal.

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

6. Use of information technology will reduce the opportunities for human error: a proactive and co-ordinated approach to the development/assessment of new technologies is needed. This should be structured, organised and led at national level.

Despite best efforts, human error is inevitable and cannot be entirely avoided. Thus, new technologies merit vigorous development and assessment to determine whether their implementation could achieve reductions in transfusion error.

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

7. A national unified system with relevant expertise should be developed, to prioritise strategies most effective for blood safety.

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

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

8. Appropriate blood usage should be implemented and alternative strategies to blood transfusion explored.

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

SPECIFIC RECOMMENDATIONS

Incorrect component transfused ("wrong blood")

" Wrong blood" transfusions are without exception avoidable errors

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

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

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

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

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

A single, unique identifying number should be used.

Prevention of errors at earlier steps in the transfusion chain

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

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

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

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

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

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

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

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

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

Setting "wrong blood" incidents in context

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

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

"Near Miss" events

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

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

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

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

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

Immune complications of transfusion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Samples should be referred to the relevant Transfusion Centre.

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

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

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

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

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

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

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

Transfusion-transmitted infections

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

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

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

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

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

2. FOREWORD: SOME PROGRESS BUT MORE IS NEEDED

SHOT has accumulated powerful national data on serious transfusion hazards, and based on these, has made firm recommendations to improve transfusion safety. This 5th reporting year saw an increase in participation to 92% of eligible hospitals compared with 72% the previous year, with an 11.6% increase in the number of hospitals submitting reports. There was a 7.5% increase in reports. The largest category of reports remains 'wrong blood to patient' episodes, 61% (699/1148) over 5 years. Eleven of the 699 patients who received the wrong blood died (5 definitely related to transfusion, 1 probably, and 5 possibly related), and a further 60 suffered major morbidity, for example necessitating intensive care unit admission. It is emphasized that transfusion of the wrong blood was potentially fatal in virtually all 699.

The increased participation probably reflects a) greater user confidence in SHOT b) effective Clinical Governance and c) the requirements of the Clinical Negligence Scheme for Trusts (Appendix 9). Universal participation in SHOT is achievable and would be further encouraged by d) SHOT participation as a standard for Clinical Pathology Accreditation (CPA) – the anticipated inclusion of reference to SHOT participation in the bibliography to the revised CPA standards being a step in the right direction, and e) a "no fault" ethos for error reporting, without fear of disciplinary action and with clear definition of the role of the Health and Safety Executive.

We continue to press for greater emphasis on transfusion issues at hospital level, in particular, the appointment of transfusion practitioners, usually nurses, to help implement improved transfusion practice (Chapter 5). Education and training in blood transfusion should be incorporated in the medical undergraduate curriculum and in induction programmes for junior medical staff. There are 2 new useful teaching resources: a) the Handbook of Transfusion Medicine of the UK Blood Transfusion Services and b) a video from the National Blood Service (NBS), on blood transfusion errors, "The strange case of Penny Allison". Hospitals should ensure that there is sufficient transfusion medical consultant time to provide clinical leadership to drive improvements in blood safety and appropriate blood usage. This is likely to have training and manpower implications.

Notably, in 69/190 case reports (36%) of 'wrong blood to patient' episodes, the originating error was made in the hospital blood transfusion laboratory. Thirty six percent of all laboratory errors (100 errors in 80 reports) occurred out of hours. SHOT data have indicated that the considerable technical and interpretative skills essential for patient safety may be lacking during part of the current working week. Hospitals should ensure that there are sufficient numbers of appropriately skilled biomedical scientists, to maintain adequate staffing at all times. SHOT also recommends a proactive and co-ordinated approach, led at national level, to the development and assessment of new technologies to minimise blood transfusion errors, such as electronic blood/patient identification, remote blood issue and electronic compatibility testing. Some of these systems also have potential to reduce drug errors.

SHOT is collaborating with broader NHS initiatives on hospital errors, particularly the new National Patient Safety Agency (NPSA). Currently, reporting to SHOT by hospitals continues unchanged. "Near Miss" events (452 this year, with 50% of reports describing sampling errors; Chapter 12) are more numerous than those which lead to mis-transfusion. Their analysis should supplement other SHOT findings and will be used to learn where systems need to be redesigned to minimize human error. "Near Miss" data will also be a major source of information to evaluate changes to improve blood transfusion safety. In this 5th reporting year all hospitals in the UK were encouraged to report "Near Miss" events to SHOT. Only 29% of eligible hospitals supplied data, but it is probable that more hospitals experienced "Near Miss" events. Appreciation of the value of collecting such data should encourage increased reporting of these episodes.

The investigation of acute transfusion reactions (ATR) is variable. A forthcoming guideline on this subject from the BCSH is to be welcomed. It is striking that reactions to fresh frozen plasma (FFP) comprise 24% of ATR reports, yet only 11% of components issued are FFP. There is evidence from SHOT reports of misuse of FFP, so as a reminder, the relevant section of the BCSH guidelines on oral anticoagulation is summarised (Appendix 11). None of the FFP related reactions were stated to be due to solvent-detergent (SD) treated pooled FFP. However, very little of this product is used in the UK, so further observation is needed. Once again, this report highlights the difficulty of diagnosing transfusion-related acute lung injury (TRALI), the second largest cause of transfusion-related morbidity and mortality after ABO incompatibility. While there has been improvement in the way these cases are investigated, greater consistency is needed. The UK Blood Transfusion Services are having to prioritise measures to prevent possible transmission of variant Creutzfeldt Jakob Disease (vCJD) by transfusion. Strategies for TRALI prevention must also be considered as part of overall blood safety planning. The report of a fatal case of transfusion-associated graft-versus-host disease (TA-GVHD) this year demonstrates that it cannot always be prevented by current leucocyte depletion processes. Of 13 cases, all fatal, of TA-GVHD reported over 5 years, 6 occurred in patients with B-cell malignancies. BCSH guidelines for irradiation of blood components should be

reviewed to assess whether all patients with B cell malignancies should receive irradiated components, particularly where new and perhaps more aggressive treatment regimes are used.

Transfusion transmitted infection (TTI) led to less than 3% of reported cases, with bacterial contamination responsible for 21/35 reports and 6 fatalities over 6 years. Bacterial contamination is thus the major cause of reported (i.e. generally symptomatic) TTI, a significant cause of death from transfusion, and accounts for more cases of TTI than all reported viral infections combined. It must be noted, however, that SHOT is not well suited to ascertainment of the chronic complications of viral transmissions which may only become apparent after several years. That said, it is appropriate that the past year has seen ongoing evaluation by the Blood Services of methods to minimise bacterial contamination. As the frequency of serious contaminations is greatest for platelet transfusions, specific strategies for platelet preparation and issue are being considered as well as strategies to reduce the frequency of contamination of all blood donations at the time of their collection. It is anticipated that during 2002/2003 there will be changes in the blood collection process to improve the cleansing of donors' arms and to divert the first few mL of blood collected (most likely to contain skin flora) away from the primary pack that is sent for component production. SHOT reports will be one source of information used to evaluate these changes.

SHOT welcomes the new National Blood Transfusion Committee (NBTC) in England, which provides a potentially powerful framework for improving all aspects of clinical transfusion practice, and to support the work of local transfusion committees to promote safe and effective use of blood. It is hoped that the NBTC will oversee a continuing 'Better Blood Transfusion' initiative which should include introduction of the recommendations of a) the Health Service Circular (HSC) 1998/224, to date limited (Appendix 14) and b) the HSC anticipated following the Chief Medical Officers' 'Better Blood Transfusion 2' Seminar. The NBTC will also steer a Royal College of Physicians/NBS national comparative audit of blood transfusion practice. Consideration of appropriate blood usage and its alternatives remains a cornerstone of transfusion safety. BCSH guidelines on red cell transfusion[6] are available. BCSH revised guidelines on FFP and platelet transfusion, as well as on autologous transfusion and alternatives to red cell transfusion, are in preparation. Attention is drawn to the new draft proposal by the European Commission (EC) for a directive covering the collection, testing, processing and distribution of blood, but not its donation or clinical use.[12]

SHOT continues to press for a national unified system with relevant expertise, to prioritise strategies most effective for blood safety. While a national blood safety system is not in place, we are encouraged that discussions have begun regarding a broader remit for the Department of Health's Microbiological Safety of Blood and Tissues for Transplantation (MSBT) Committee. Resource should be allocated for implementation of SHOT's recommended strategies to reduce the major transfusion hazard identified – transfusion of the wrong blood.

Currently, SHOT receives reports on autologous pre-deposit transfusion and SD FFP (covered by the "Yellow card" system of the Medicines Control Agency (MCA), but also included for purposes of comparison in SHOT questionnaires), and this year we include the UK Haemophilia Centre Doctors' report on adverse effects of coagulation factor concentrates (Appendix 15). This broader picture may need to be expanded further. There is currently unprecedented interest in alternatives to donor blood, driven by concerns over vCJD and possible future blood shortages when a vCJD test becomes available. However, the UK is not yet in a position to gauge the risks and benefits of alternatives such as erythropoietin, haemodilution and cell salvage in parallel with risks from donor blood. During the forthcoming year, SHOT will consider how a broader view of the relative risks of donor blood transfusion and its alternatives can be obtained. We will also consider how best to complement the MCA reporting system for hazards from plasma products. The ultimate aim is to provide comprehensive and co-ordinated data – a national haemovigilance 'umbrella' - to inform policy for overall blood transfusion safety.

Finally, we owe SHOT's success to the overwhelming support and enthusiasm of hospital staff who take the time to complete report forms and detailed follow-up questionnaires. We warmly thank all participants.

Hannah Cohen MD FRCP FRCPath
Chair, SHOT Steering Group.

3. FIVE YEARS OF SHOT – WHAT HAS BEEN ACHIEVED?

There can be no doubt that the profile of transfusion practice in the UK has increased during the 5 years SHOT has been in existence. It would of course be greatly exaggerating to say that SHOT alone has been responsible for this– the emergence of variant Creutzfeldt-Jakob disease (vCJD) as a possible transfusion-transmitted disease has greatly focussed minds on to the twin issues of transfusion safety and appropriate blood usage. Nevertheless, SHOT has for the first time provided the UK Blood Services and other decision takers with truly national data on major transfusion hazards. Participation in SHOT is now seen as a necessary professional activity, as reflected in the HSC 1998/1224 and is under discussion as a possible requirement of Clinical Pathology Accreditation. At this five year milestone, it is therefore appropriate to assess what changes to transfusion practice have been implemented, or are being considered, as a direct result of SHOT recommendations.

1. Overview of blood safety

A consistent recommendation of SHOT reports is that the UK needs an overarching organisational and intellectual framework for assessing transfusion hazards and prioritising blood safety initiatives side-by-side. While a single overarching blood safety body for the UK is not yet in place, discussions have begun regarding a broader remit for the Department of Health's Microbial Safety of Blood and Tissues Committee. In addition, a number of separate initiatives have been taken which will help to promote general and specific SHOT recommendations . These include:-

- establishment of a National Transfusion Committee for England, reporting directly to the Chief Medical Officer, with a regional transfusion committee structure.
- creation of a Blood and Tissue Safety Assurance Group within the NBS, with a number of subgroups covering all areas of work. This includes the creation of 2 posts within the Department of Health's Economic and Operational Research division to work on blood safety issues.

2. Transfusion errors

SHOT recommendations on the need for better transfusion training in hospitals may be one reason why the number of transfusion nurses is increasing across the country. Mandatory training in blood sampling and administration has become much more widespread for junior doctors as well as nurses. Recently, the National Patient Safety Agency (NPSA) has been established for England, to collect data on all types of errors and their effects on patients. Useful initial discussions have been held between SHOT and NPSA. Specific actions on prevention of transfusion errors in line with SHOT recommendations have included:-

- a guideline from the British Committee for Standards in Haematology (BCSH) on blood handling and administration.[4]
- a National Blood Service (NBS)-funded project to evaluate 2 current systems for bar-code printed wrist bands and their use in blood components/patient identification.
- funding from Pathology Modernisation funds for implementation of computer-controlled blood refrigerator access throughout an exceptionally large Trust.

3. Immunological complications

These have been neither as frequent nor generally as serious as 'wrong blood to patient' episodes, and therefore have attracted less resource towards their prevention. However, a number of initiatives have begun in line with SHOT recommendations:-

- a BCSH guideline on investigation and management of acute transfusion reaction is in preparation. A disproportionate percentage of acute reactions are to platelets and fresh frozen plasma, and new BCSH guidelines for both components are in preparation to assist in optimal use of these components.
- design of various National External Quality Assurance Scheme exercises designed to assess detection of Kidd antibodies frequently implicated in delayed haemolytic transfusion reaction.
- guidelines from the NBS Clinical Policies Group on investigation and management of transfusion-related acute lung injury (TRALI) and transfusion-associated graft-versus-host disease (TA-GVHD) are in preparation.
- production of a card and leaflet jointly by BCSH and NBS Clinical Policies Group for patients who require irradiated components. For a pre-publication version updated for 2002 see Appendix 13.

- consideration of steps to minimise TRALI risk as part of NBS 'Safer Plasma in Components' project, and funding of a new study to assess the frequency of leucocyte antibodies in blood donors.

4. Transfusion-transmitted infections (TTI)

SHOT data have been helpful in confirming the current rarity of viral transmission, and have done a great deal to focus attention on bacterial contamination as the commonest TTI at the present time. In particular, it has been demonstrated that the skin of donors' arms is the single commonest source of bacteria. Specific actions in line with SHOT findings and recommendations have included:-

- a NBS guideline for the investigation and management of suspected bacterial contamination.
- the NBS has carried out studies into improved arm cleansing techniques with a view to implementation in the next financial year.
- divert pouches, which prevent the first 20-30 mL collected of any blood donation eventually being transfused, are being implemented across the UK. Arm cleansing plus divert pouches together can potentially reduce the bacterial risk by at least 50%.
- Studies of bacterial screening and pathogen inactivation of platelets will be carried out by the NBS in the next 12 months.
- Review of specific steps to further minimise the residual risk of hepatitis B. All cases reported to SHOT in the past 5 years have been as a result of transfusion from donors in the early infectious window period, without any serological markers of hepatitis B, rather than anti-HBc-positive chronic carriers.

5. The international scene

After France, the UK was one of the first countries to establish truly national haemovigilance and members of the SHOT team have been much in demand at international meetings to describe the running of SHOT and the results we have obtained. We have done talks and posters in 18 countries and have been asked to provide advice to Departments of Health in Canada and Australia. The UK currently holds the Chair of the newly established International Society of Blood Transfusion Haemovigilance Group, and it has been especially gratifying to hear that a number of countries are basing their own haemovigilance systems on the SHOT model e.g. Ireland, Denmark, The Netherlands. However, different types of systems also exist e.g. in France, and in Germany, where haemovigilance is run as part of pharmacovigilance.

Within Europe, the Council of Europe 'Guide to the preparation, use and quality assurance of blood components, 7th Edition, 2001'[13] now recommends that haemovigilance be in place in all countries which it covers. In addition, a European Commission (EC) Directive[12] is being drafted which confirms the requirement for national haemovigilance within member states. A voluntary haemovigilance network is already being established across some European countries with the aim of generating standardised haemovigilance data, and SHOT is considering how best to support this initiative within the context of its current reporting systems. The generation of data which can legitimately be compared between countries will be an interesting challenge. This will provide an excellent platform from which comparative data can be generated.

6. Is transfusion becoming safer as a result of SHOT?

It would be wrong to pretend that transfusion in the UK is already safer as a result of SHOT. We are a young scheme compared to other confidential enquiries and practice is often slow to change – especially where funding is needed to improve things. The biggest cause for concern must be the apparently inexorable rise year-on-year in the number of 'wrong blood to patient' cases reported. We have initially attributed this to improved user confidence in the scheme and an increased willingness to report errors. However, we cannot exclude the possibility that errors are indeed becoming more common. SHOT hopes to conduct further studies in this area to see whether staff shortages and pressures both on the ward and in the laboratory could be contributing to transfusion errors.

While other hazards are largely unchanged over the 5 years (although post-transfusion purpura and TA-GVHD have decreased following universal leucocyte depletion), considerable efforts are being put into their further prevention and management. Most importantly, SHOT data provide the basis for a concerted plan of action, so that public funds can be most appropriately used to improve transfusion safety. At a time when UK Blood Services are dominated by issues surrounding vCJD, this is a considerable achievement.

Lorna Williamson, BSc, MD, FRCP, FRCPath

4. FORGIVE AND DON'T FORGET: Using incident reporting to make patients safer

The *Organisation With a Memory*[3] [Department of Health 2000 **www.doh.gov.uk**] should learn how to avoid making the same mistake twice – and it should also be equipped to act, consistently so that it really does not repeat its errors.

The National Patient Safety Agency
The UK's new National Patient Safety Agency (NPSA) [**www.npsa.org.uk**] has issued comprehensive guidance for its pilot scheme: this draws on a wealth of experience from many countries, notably Australia and the US. Recommendation 2 of the present SHOT report encourages Trusts to develop a "no fault" ethos for reporting adverse incidents. As it is planned to develop reporting links between SHOT and the NPSA, this is a useful time for a brief review of some points paraphrased from the NPSA's draft paper on the National Incident Reporting System and how these relate to lessons from the first 5 years experience of SHOT.

The following are some of the key requirements laid down by NPSA for NHS organisations to manage, report, analyse and learn from adverse incidents involving their patients.

- All individuals involved in patient care should know what constitutes an adverse patient incident (API). The definition of an API is: "any event or circumstance arising during NHS care that could have or did lead to unintended harm or unexpected harm, loss or damage" i.e., it includes near-miss events in which no actual harm resulted. Incidents are graded in severity: catastrophic [causing death], major, moderate etc. Acute haemolytic transfusion reaction that does not result in death is given as one example of a major event.

- The incident is reported to and managed by a designated person. There should be a clear policy on handling API. Management is responsible for developing and implementing improvement strategies with prioritised actions to help prevent recurrences and needs to track progress on implementing actions and the effectiveness of the actions taken which should result in demonstrable improvements in patient care.

- For all "category red" [serious] incidents a full root cause analysis should be done [a structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it].

- Aggregate reviews of local incident information are carried out and the significant results communicated to local stakeholders and NPSA.

NPSA stresses that "*Improvement strategies that punish individual clinicians are misguided and do not work. Fixing dysfunctional systems on the other hand is the work that needs to be done".*

How does SHOT fit with NPSA's model ?
SHOT established from the start clear definitions of reportable incidents and has publicised these through its reports, publications, lectures, provision of teaching slides and incorporation into training materials. It is likely that there is a good level of awareness of the programme among NHS staff. Incidents reportable to SHOT since its inception include those causing harm to patients as well as errors in process that lead to patients receiving the wrong blood even if these do not result in harm. The recent extension to include "near miss" reporting is consistent with the NPSA model. SHOT also covers events such as the occurrence of post transfusion purpura or transfusion-related acute lung injury (TRALI) which are essentially unavoidable rare side effects of transfusion of the current generation of blood products.

Responsibility for reporting is assumed by SHOT to rest with the haematologists running hospitals' blood banks and communications are generally addressed to them. However, hospitals may not adopt a consistent approach in assigning formal responsibility for reporting.

SHOT has always endeavoured to analyse the causes of adverse incidents and the resulting information, together with "stories" or case vignettes have been among of the most informative aspects of its reports. However, it is unlikely that any but a minority of events has been subjected to full root cause analysis by a local team as advocated by NPSA.

The annual reports of SHOT include cumulative aggregated information: this, after 5 years is beginning to allow some very preliminary views to be formed about the pattern of events (Chapter 10). However, SHOT recognised from the start that it would have great difficulty in establishing relevant denominators to allow annual incident rates

to be estimated, and that there would be major uncertainties about the completeness of reporting, even with the restricted list of event categories. The much more extensive NPSA operation will experience similar problems.

Who is responsible for implementing improvements?
Establishing the reporting system is clearly a vital step in promoting informed awareness of the scope and extent of the risks to which patients are exposed. It will undoubtedly confirm that risks related to transfusion constitute a tiny proportion of the whole. Wider awareness of the incidence and causes of Serious Hazards of Transfusion should in itself be a stimulus to improve quality systems although it should be noted that 5 years into the SHOT project, it is still too early to have convincing evidence of improvements in most of the risks (Chapter 3). It will require the sustained commitment at a high level of hospitals' management to undertake and maintain a program to improve safety and quality of the clinical transfusion process as a part of the responsibilities of Clinical Governance.

Delivering the comprehensive campaign, envisaged by NPSA, of specific, managed improvements in response to API reports is a major challenge for professionals and management. It is relatively easy to make recommendations (for example) for "better input by fully trained specialists" or "improved monitoring of sick patients at weekends and over holiday periods by sufficiently experienced staff" or "fully integrated assessment of the patient's condition and needs together with a detailed plan for aftercare immediately before discharge from hospital".[14] Recommendations of this sort in another report recently attracted this comment from the editor of the BMJ *"The report makes 198 recommendations, most of which contain the verbs "must" and "should," but declines to prioritise or cost them…This is not good management"*.[15]
For some of the more important problems resulting from flawed processes [such as the transfusion of an incorrect blood component or the misdirection of a vital radiological report], a more profitable approach may be to look for ways of making tasks less complicated and redesigning them so that the safest way of doing it is also the easiest. Some examples of this type of approach are given in Table 1.

Table 1
From: Berwick [Joint Commission of Accreditation of Healthcare Organisations [JCAHO] *Preventing Adverse events in behavioural healthcare: A systems approach to sentinel events.*[www. jcaho.org]

- Simplify: Reduce the number of steps and handovers in work processes. Reduce non-essential elements of equipment, software and rules of procedure.
- Standardise: Limit unneeded variety in drugs, equipment, supplies, rules and processes of work.
- Improve [spoken] communications: Use repetition, standard vocabularies and unmitigated communication.
- Support communications against the authority gradient: Use lessons from "cockpit resource management" Train for team communication.
- Use defaults properly: Design processes so that the safe [route] is the one requiring the lowest energy. Make doing the right thing the easiest thing to do.
- Automate cautiously: Avoid overautomating systems and equipment. Make sure operators can know the true state of the system, can override automation effectively and can maintain proper vigilance. Make the system visible to the user.
- Respect limits on vigilance and attention: When designing tasks and work systems keep in mind stress, workload, circadian rhythm, time pressure, limits to memory. Design for normal human behaviour and capacity.
- Encourage reporting of errors and hazardous conditions: Reward reporting. Build a culture that celebrates the increase of knowledge on the basis of which error rates can be reduced and risks mitigated.

Those concerned with making it safer for patients to receive a transfusion might reflect on the thought that many complexities in procedures have resulted from well-intentioned efforts to improve systems as a result of the investigations of adverse incidents. The safety of patients receiving transfusion might benefit from:

- Review of the current, intricate British Committee for Standards in Haematology guidelines for administration of blood[4] to find ways of making them easier for busy nurses to adhere to.
- Redesign of the current blood pack label with its proliferation of bar codes, multidigit numbers and tiny patient compatibility label (now displaced to the wrong side of the pack). Is this is really fit for the purpose of helping staff get the right blood into the patient, in a busy, ill-lit ward.
- The close involvement of operational clinical staff in the development and introduction of simple, robust systems that give highly dependable support and assistance to practitioners in the daily performance of tasks such as ordering and administering blood or medications.

Brian McClelland, BSc (Hons), MBChB, MRCP, MD – Leiden (cumlaude), FRCP, FRCPath

5. TRANSFUSION NURSES – The Way Forward

Introduction

Blood transfusion nursing is a small but rapidly developing specialty. Over the years, nursing practice in whole blood collection, clinical and therapeutic apheresis and tissue banking has largely been developed within the National Blood Transfusion Services. These initiatives have been developed in response to: identified donor and patient needs, new technologies, or advances in scientific and medical research and in recent years, the associated risks of transmission of infective agents via allogeneic blood transfusion. Yet, hospital based transfusion practice has largely been neglected as part of this developmental process. The SHOT scheme has shown repeatedly that clerical errors are the major cause of transfusion-related morbidity and many unrelated studies have confirmed this fact. These studies demonstrate a clear need for directing change initiatives at the bedside.[16,17,18] Directing practice and educational initiatives to the bedside could ensure optimal provision of care, adequate standards of safety and proper use of resources within the National Health Service. It has been recognised that the transfusion nurse specialist (TNS) is the ideal person to take these initiatives forward.[19,20]

The number of departments employing nurse specialists has been steadily expanding over the last decade, e.g., critical care, tissue viability, infection control.[21,22,23] There is growing consensus concerning the role and responsibilities of the specialist practitioner, including:

- expert practitioner
- educator
- researcher
- consultant/change agent[24,25]

Our aim is to show how the TNS role has been developed within the UK using examples from 2 models, the hospital based nurse and the nurse working as part of the Scottish National Blood Transfusion Service based Effective Use of Blood (EUB) team. Whilst we appreciate that other professionals are currently undertaking this role within the UK e.g., Medical Scientific Laboratory Scientists, and that a number of different job titles exist, for the purposes of this paper we will refer to the TNS.

Expert Practitioner

The expert practitioner role has been defined as:

> *Demonstrating higher levels of clinical decision making, monitoring and improving standards of care through supervision of practice and clinical audit, developing and leading practice, contributing to research, teaching and supporting professional colleagues*.
> (UKCC, 1994; PREP 9:49, 28:10)

As part of a multidimensional role the TNS aims to ensure optimal provision of patient care during the entire transfusion episode. With the drive towards integrated hospital and laboratory information systems, increasingly blood and blood products will be ordered directly via the hospital computing networks. The TNS could be viewed as a crucial link in developing the clinical interface between the hospital transfusion laboratory and the user.

As well as empowering others through their expert knowledge base, skills and demonstrable practice the TNS is the ideal person to contribute to the development of local transfusion guidelines. For example, one of the authors working with her Hospital Transfusion Committee (HTC), has responsibility for writing and implementing a hospital wide multidisciplinary policies and procedural document for adult and paediatric administration of blood and blood products. The EUB team has developed a generic Transfusion Clinical Procedure Manual that can be adapted by Trusts for local use.

The TNS is able to collaborate with other health care professionals in order to plan and provide care for patients who have specific transfusion needs. For example, co-ordinating the management of Jehovah's Witness patients, surgical patients attending pre-admission surgery clinics requesting autologous pre-donation, and patients identified prior to surgery as having atypical antibodies, coagulation problems or anaemia.

Linked to the management of the patient requiring transfusion support is the provision of information for patients and staff. The EUB team has developed a patient information leaflet and the TNSs are currently assessing its acceptability to both patients and staff. Similar leaflets have been developed by the English and Welsh National Transfusion Services. The TNS can ensure that the relevant information is made freely available to staff and patients and that their queries are responded to in a timely and professional manner.

Educator

Providing education is a pivotal role of the specialist practitioner.[24,25,26] It has been a challenge to manage and design a training programme for all staff involved in the transfusion process, from the clinician who prescribes the blood, the porter who collects the product, to the practitioner who has the task of administering it. As well as locally tailored education programmes developed by the hospital based TNS; the EUB team has designed the *Better Blood Transfusion Continuing Education Programme* to assist practitioners involved in the transfusion process to provide consistently high standards of care. This programme has been developed at three levels; Level 1 – *Safe Transfusion Practice* aims to ensure that all practitioners participate safely in the transfusion process and has been implemented in 11 acute NHS Trusts in Scotland. The package is available in a number of formats including face-to-face, self-directed and e-learning formats.

As well as delivering educational programmes the TNS can perform a crucial role in maintaining training records, records of assessment and feedback forms. This allows the TNS to identify any further learning needs and enables managers to target the developmental needs of their staff. A number of national Continuing Professional Development initiatives have also been developed by the TNS, e.g., the educational series on practical procedures for nurses in blood transfusion published in the Nursing Times.[27] Education in conjunction with audit and research initiatives has been shown to lead to improvements in practice.[28,29]

Researcher

'A First Class Service' states that organisations should ensure that:

> '*Quality improvement processes are in place and integrated with the quality programme for the organisation as a whole".*[30]

Working with the identified clinical groups the TNS is ideally placed to implement effective methods for improving clinical practice by facilitating audit and research studies both at a local and national level. Although audit is viewed as integral to improving practice it is only one of the many roles that the TNS will assume when implementing initiatives aimed at improving transfusion practice.

The Specialist Practitioners of Transfusion (SPOT) group, is a national forum whose focus is to provide peer support and education for professionals working in the area of blood transfusion. The members of the forum have developed a standard and audit tool, which is aimed at bench-marking clinical transfusion practice.[31] Supported by a grant from the British Blood Transfusion Society (BBTS), in 2002, 16 TNSs will audit transfusion practices in their hospitals in England and Ireland. By establishing a detailed picture of transfusion practice in these hospitals the TNSs will be able to monitor the impact of their educational and practice developments.

The multi-centre blood use audit and research projects co-ordinated and undertaken by the EUB TNSs in orthopaedic and ICUs have performed an important role in the setting and monitoring of transfusion standards.[32,33] The results of these studies have also allowed the EUB team to identify areas for further development of a clinical research programme in transfusion.

Professional Leader/Change Agent

The TNS role can be viewed as one where the expert practitioner is able to address the more complex aspects of the transfusion process, dealing with patients, relatives, colleagues and students both as a leader and a change agent. As they become expert in a defined area of knowledge and practice there will be opportunities to influence future practice and guideline development by participating in professional working groups, national committees, guideline development groups and haemovigilance schemes. A number of TNSs within the UK currently participate in such forums. The recent publication of the Scottish Intercollegiate Guidelines Network, Perioperative Blood Transfusion for Elective Surgery guideline[34] demonstrates the valuable contribution a TNS can make to the application, development and dissemination processes of an evidence-based guideline. To ensure that the TNS can function as a leader and change agent it is imperative that we develop training and education programmes as well as a developmental structure of nursing grades. This will ensure that the role attracts and retains experienced practitioners.

Job Description/Training

The United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) consultation document, *A Higher Level of Practice*[35] has proposed a number of prerequisites for practising as a specialist practitioner including:

- hold a first level registration qualification,
- spend the majority of their time in practice,
- hold a UK degree or equivalent in nursing or related subject,
- complete a post-registration educational programme in their area of practice.

At present the training and developmental needs of the TNS have largely been developed in response to local needs. However, on reviewing the job descriptions of a number of SPOT members, there appears to be a consensus on the key result areas that are fundamental to the role:

1. To provide education and support relevant to the transfusion process to nursing, medical and support staff, and patients and carers.
2. In association with the HTC, to plan, implement and evaluate clinical audit/clinical effectiveness projects, in relation to blood and blood component use within the Trust.
3. To liaise with local blood bank clinicians and managers in order to implement, monitor and evaluate the effect of interventions aimed at reducing losses and wastage of blood and blood components.
4. To contribute to the development and dissemination of evidence based local transfusion guidelines and policies.
5. To undertake development of a pre-transfusion information and planning service for patients undergoing elective surgery.
6. To assist in the Serious Hazards Of Transfusion reporting scheme and dissemination of the annual report.
7. To assist in the counselling and re-training of staff involved in transfusion errors or near-miss events.
8. To deliver training of staff involved in the care of patients receiving blood components to individualise patient care, in collaboration with the consultant haematologist, based on best practice/current guidelines.
9. To assist in clinical research trials in relation to blood transfusion and alternative therapies, based upon Good Clinical (research) Practice.

The UK Infection Control Nurses Association has promoted the role of their specialist nurse by developing a generic job description, professional core competencies and validating a number of specialist training courses for their members. This is excellent model for the TNS to follow.[36]

Conclusions

The role of the Hospital Transfusion Specialist is still in its infancy; the majority of the 50 UK practitioners to date have been in post for less than two years, however, their contribution to transfusion safety, efficacy and efficiency is just beginning to be realised. By breaking down inter-professional boundaries between doctors, nurses, ancillary staff and Allied Health Professionals, and by acknowledging that the neglect of transfusion education for all professional groups can perpetuate mistakes and bad practice, the existing culture can be changed. The TNS can reduce out-dated and unwitting bad practice provided they are appointed in sufficient numbers and have adequate support, training and recognition.

To meet government directives such as the HSC 1998/224 'Better Blood Transfusion'[2] or the Clinical Negligence Scheme for Trusts, all hospitals should consider employing a TNS. The TNS is already demonstrating the way forward by promoting safe and effective transfusion practice and ensuring that our patients increasing expectations are met.

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6. WHY DO WE MAKE LABORATORY ERRORS AND HOW CAN WE TACKLE THEM?

There are opportunities for error throughout the transfusion chain, from the donor session through to the final transfusion to the patient. Over the first 5 years of reports to SHOT in the category incorrect blood component transfused (IBCT), 28% of errors have occurred in the laboratory compared with only 12% at phlebotomy and request. In contrast, phlebotomy errors are the major cause of 'Near Misses' reported to SHOT; clearly many of these errors are detected by the laboratory, thus preventing incidents of IBCT, whilst others are undetected or even compounded by the laboratory. In addition to IBCT, it is necessary to consider incidents of delayed haemolytic transfusion reaction (DHTR) as potential laboratory errors; frequently, pre-transfusion samples are unavailable for re-testing and those that are available should be tested by a reference centre to confirm the absence of antibodies.

There is a lack of information in SHOT reports concerning by whom and by what technique retesting is performed and it is possible that deficiencies in test systems may go unnoticed. National External Quality Assurance Scheme (NEQAS) results often give an indication of how and why laboratory errors occur; questionnaire data also provide clues.

With few exceptions, ABO grouping is extremely straightforward using IgM monoclonal reagents and most errors are likely to be procedural rather than technical in origin. Virtually all ABO errors noted in NEQAS exercises are due to transcription errors or transposition of samples. Procedures that include manual steps are particularly prone to procedural errors, leading to misgrouping, unless appropriate checks are included at critical points. One of the most effective ways of controlling an ABO test is the reverse group, however, despite clear guidelines to the contrary,[37] 1% of UK laboratories do not include a reverse group even on new patients. Furthermore, the majority of these are using manual systems. British Committee for Standards in Haematology (BCSH) guidelines[37] also recommend that a double check is built into manual ABO grouping procedures, e.g. separating the reading of the forward and reverse group. Checking against historical data is another critical step, often overlooked, resulting in up to 12% of laboratory errors.

SHOT highlights a significant number of RhD typing errors, rarely with any explanation of cause. Procedural errors are again a potential problem, particularly in manual systems, hence the recommendation for duplicate RhD typing.[37] However, questionnaire data reveals 3% non-compliance with this recommendation, even on new patients and in manual systems. Monoclonal IgM reagents have made RhD typing easier to perform but not necessarily to interpret. Reagent selection and use of appropriate controls is of vital importance, as is the understanding of the nature and limitations of the reagents in use. BCSH guidelines[37] recommend that reagents used for patient typing do not detect RhD^{VI}, that an indirect antiglobulin test (IAT) is not used and that, if in doubt, an interpretation of RhD negative should be made pending investigation by a reference laboratory. However, in 99R2, 32 UK non-reference laboratories interpreted a RhD^{VI} as something other than RhD negative; one used a polyclonal IgG reagent, five used IgM monoclonals known to detect RhD^{VI} and seven routinely used an IAT for detection of weak RhD in pre-transfusion testing. Ten participants mistyped a rr direct antiglobulin test positive cell in 00R5, five basing their results on a single weak positive result, using a potentiated anti-D reagent. Anti-CDE has also been the cause of false positive RhD typing; three participants in 01R2 mistyped an r' cell as RhD positive due to misinterpretation of a positive reaction with an anti-CDE reagent.

Fewer incidents of IBCT are reported as being due to antibody screening errors. However, the possibilities that some antibodies detected post DHTR have been missed pre-transfusion due to procedural error, or to insensitive technique or reagent failure, cannot be ruled out. Anti Kidd antibodies are notoriously difficult to detect and often manifest considerable dosage effect; UK NEQAS results (96R0, 98R0) have shown this phenomenon to be particularly marked using column technology, the technology of choice for over 70% of UK laboratories. NEQAS questionnaire data (1997) suggest that 5% of laboratories use screening cells that do not always bear apparent homozygous expression of those antigens known to manifest dosage and the 1998/99 SHOT report[38] described two examples of anti-Jk^a missed due to lack of a homozygous Jk^a cell. Furthermore, 45% of antibodies in patients with reported DHTR are anti-Jk^a or -Jk^b. Another potential cause of false negative antibody screens is the use of reagent red cells not validated for the technique in use. For example Ortho recommend a 3-5% starting cell suspension for use in BioVue cassettes (BLISS addition), however commercial screening cells provided at 3%, will actually vary within limits set by the manufacturer and may actually be lower than 3%. There have been failures to detect some weak antibodies distributed by NEQAS by BioVue users, resolved by increasing the cell concentration to 3-4%. There is also evidence from NEQAS questionnaire data (2000) that antibody screening tests are not being

adequately controlled, with 40% of manual users not including positive controls with every batch of tests and 4% using no positive controls at all.

Antibody identification of antibody mixtures is the biggest source of error in NEQAS exercises. Reasons for this are threefold: firstly, and most importantly, a lack of understanding of the process, highlighted by a theoretical exercise distributed in 2000, in which 46% of respondents recorded a result of anti-M for a reaction pattern that could have been attributable to anti-D+K; secondly, over 50% have access to only a single panel of reagent red cells and thirdly, 20% use an IAT technique only. One third of patients with DHTR reported to SHOT during 1999/2000 had more than one antibody detectable post transfusion and there were two cases of IBCT reported in 1998/1999 due to antibodies not identified in mixtures.

Serological crossmatching inevitably involves manual input even in an otherwise automated laboratory, and is not usually subject to the same critical checks and controls that occur in grouping or screening. There is likely to be an underestimation of transcription and transposition errors in this process, since most of the tests will give negative results. In addition, cell suspensions are likely to be less standardised than for antibody screening and the IAT crossmatch less sensitive than the IAT antibody screen, due to the random zygosity and the length of storage of donor cells. There is also a lack of compliance with guidelines, e.g. it is recommended that a 2-5 minute incubation period is used for 'immediate spin' (IS) crossmatching and that Ethylenediamine tetraacetic acid (EDTA) saline is used to suspend cells, where serum is used. However, 16% incubate for <2 minutes and only 13% of those using serum, utilise EDTA saline. One ABO incompatibility missed by IS has been reported to SHOT and over 5 years crossmatch errors account for about 6.5% of total laboratory errors reported.

A high proportion of transcription (and transposition) errors are made in NEQAS exercises (100% for ABO grouping). Similarly, many of the IBCT incidents are due to non-technical errors, e.g. in the 1999/2000 SHOT report,[9] there were four sample transposition errors, six clerical errors, five labelling errors and six unexplained ABO errors.

IBCT events due to errors originating in the Blood Services are extremely low. There are obvious differences between mass testing of standard donor samples and the case-mix of samples processed in the hospital laboratory. Nevertheless, the low error rate in the Blood Services is likely to be at least in part due to their well regulated and well established quality environment encompassing full automation, comprehensive IT, and quality management systems, which require extensive validation of all processes. In contrast, 8% of hospital blood banks have no computer (October '99), 65% have no automation (May '00) and most have less experience of working with formal quality systems. It is impossible to prevent people from making errors, but steps can be taken to prevent these errors from becoming incidents; wherever possible, manual intervention should be removed from procedures, and where not possible, the consequences should be limited by identifying critical points and implementing double or triple checks. Either way, quality systems must be in place, including written standard operating procedures, with subsequent training and review.

Clues to the reasons for IBCT incidents that do not directly relate to errors seen in NEQAS exercises can be obtained by looking at questionnaire data. For example, a questionnaire distributed to all users of column agglutination technology (CAT) in 1999, revealed an alarming lack of compliance with manufacturers' instructions and a general lack of good laboratory practice. In the former category, 19% reduced the minimum recommended incubation time; up to 7% did not use the recommended diluent and 9% admitted to deliberate non-compliance. In the latter category, 34% did not monitor staff proficiency, 60% did not check the temperature of the incubators and 8% used controls only for new batches of cards/cassettes.

Transcription and transposition errors are preventable. Automation and computerisation can help reduce and perhaps even eliminate some errors, but are not infallible and as they may even introduce new unforeseen sources of error, require extensive validation and revalidation following upgrades. However, they are no replacement for quality systems and continued training and education are essential to maintain the competence and expertise required to ensure safe practice.

Clare Milkins, Scheme Manager, UK NEQAS (Blood Transfusion Laboratory Practice)

7. 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 findings continue to stimulate widespread interest in the UK and abroad. The following is a list of national and international meetings during 2000 and 2001 at which members of the SHOT team have presented results from the reports in the context of a broader view of transfusion safety.

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.** • "Nature has her own doctor in every limb – An autologous transfusion study day", Chichester, UK
December	• **Quantifying the risk - the SHOT report. Welsh Blood Service Customer meeting**

2001

March
- **SHOT Annual launch, London, UK**

April
- **British Society for Haematology Annual Scientific Meeting: invited lecture and oral presentation, Harrogate, UK**
- RCN Blood Transfusion Nursing Forum, Manchester, UK

May
- Baxter Symposium "El impacto clinico de la calidad total en el proceso de la medicina transfusional", Merida, Mexico
- Conference "Hematología 2001", Havana, Cuba

June
- Adverse effects of blood products, AAGBI Workshop, Cambridge, UK
- Postgraduate Haematology Course, London, UK
- Association of Clinical Anaesthetists Update, London, UK
- Interrelación entre Centros de Transfusión y Bancos de Sangre, Madrid, Spain

July
- ISBT Congress, Paris, France

September
- BBTS, Leeds, UK
- CNST Update Seminar, London, UK
- CMO conference on Better Blood Transfusion 2, London, UK
- Hemovigilancia, Lima, Peru

November
- Plenary lecture on Haemovigilance and co-chair, ISBT Regional Congress, Shanghai, People´s Republic of China
- Risk 2001, London, UK
- CNST Update Seminar, Manchester, UK
- Transfusion Medicine meeting, London, UK

December
- Workshop on haemovigilance, Sao Paulo, Brazil
- Workshop on European Haemovigilance, Athens, Greece

Publications 2000

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

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

Publications 2001

Haemovigilance in the UK: 4 years of the SHOT scheme (oral), ISBT Paris July 2001, Transfusion Clinique et Biologique, 2001, 8 Supp 1, S23-005

EM Love, H Jones, LM Williamson et al, Haemovigilance and experience of the Serious hazards of Transfusion (SHOT) scheme in the United Kingdom (UK), Chinese Journal of Blood Transfusion 2001, 14, Supp: 19-23

8. 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 as well as 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 BBTS. It has now been agreed that future financial support for SHOT will be provided by the four UKBTSs 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. The Republic of Ireland also contributed reports up to and including the 1998/1999 report after which it launched its own haemovigilance scheme.

SHOT invites reports of major adverse events surrounding the transfusion of single or small pool blood components supplied by Blood Centres (red cells, platelets, FFP, 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 MCA. 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
11. "Near Miss" events

Reporting of transfusion-transmitted infections

Suspected cases of TTI 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 (PTI) 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 TTI is managed through the Regional Transfusion Centres (RTC) with information being collated by the National Microbiological Reference Unit. Details of numbers and types of incidents thus reported are provided to NBA/PHLS 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 2).

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 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.

Participation Card

From the second year of reporting onwards we have tried to ascertain the percentage of hospitals contributing to the SHOT reporting scheme. A participation card (formerly called the 'Nil to Report' card) and covering letter is sent to the chief BMS at each of the hospitals held on the SHOT mailing list. The number of hospitals eligible to participate varies each year as hospitals close, new ones are built, and Trusts merge but the number this year was 413. The chief BMS was asked if he/she had reported any adverse events to SHOT during the period 01/10/00 to 30/09/01 or, if no adverse events had been seen, to return the card as 'nothing to report'. Formerly cards were sent to the named consultant haematologist but following requests from several hospitals it was decided that laboratory staff might be in a better position to be able to complete and return the card.

In an attempt to provide a denominator against which transfusion risk can be assessed, we also request information on the number of red cell units transfused per annum from all participating hospitals. On returning the participation card to the SHOT office, and once any queries have been resolved with the reporting hospital, a SHOT receipt is sent which can be used to provide evidence to the CNST should this be required.

The participation card exercise is repeated annually with minor changes (sometimes including short surveys) to prompt hospitals to continue to report adverse events. The results of this exercise are detailed in Chapter 9.

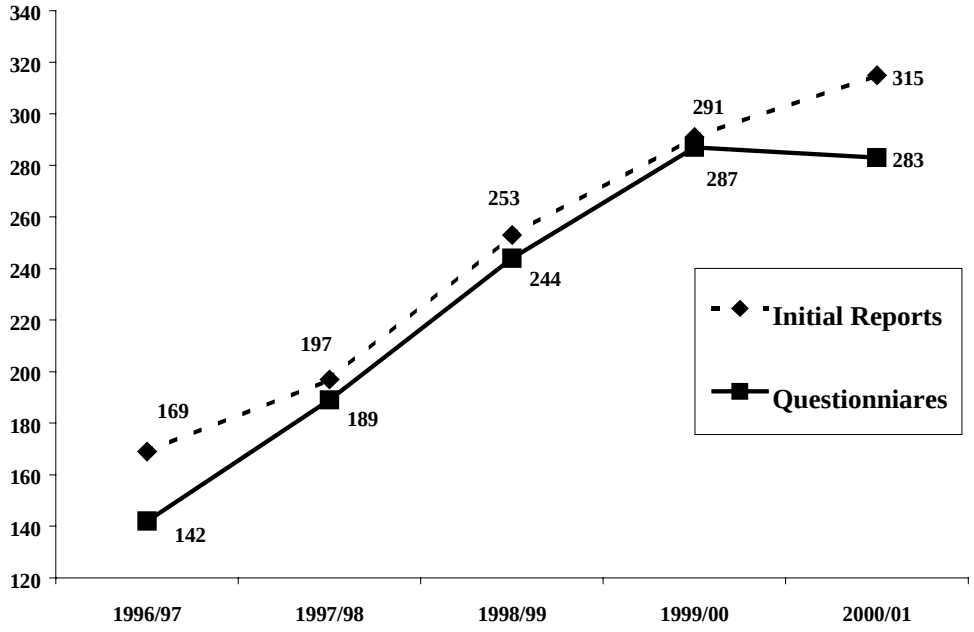
Dissemination of results

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[2] 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 1

Figure 1
Increases in reporting year by year:



Initial Reports

In the second, third and fourth years there were increases in receipt of initial reports of 17%, 28%, and 15% respectively. This year we have seen a further increase of 8%.

Questionnaires

The numbers of reports which are eventually analysed as valid SHOT reports (whether reported by questionnaire or by letter) had, until this year, also increased annually. These increases for years two, three and four were 33%, 29%, and 18% respectively. This year we have experienced greater delays in receiving completed questionnaires which has complicated data analysis. We therefore intend to introduce a more rigid system of follow up which will involve a strictly observed series of letters and phone calls at regular, pre-determined stages to encourage reporters to complete the questionnaires as early as possible. In all cases of non-infectious hazards except TA-GVHD, outstanding cases will not be kept beyond six months unless there are mitigating circumstances. We recognise that investigations for TA-GVHD cases are often time consuming and lengthy and so we propose to wait 12 months before writing outstanding TA-GVHD questionnaires off. In all instances, these end dates will be negotiable but will, nevertheless, form the basis for a structured approach.

SHOT Personnel

Last year staffing levels were increased in order to provide a better service in the light of increasing numbers of reports and to enable further projects to be undertaken. For the moment it is felt that staffing is at its optimal level with 3 full time employees and one half time office assistant. The 4 posts are described here:

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 (DCMO). This post was developed with the intention of taking on full responsibility for the maintenance and further development of the databases as well as the SHOT website. This staff member is also be expected to deputise for the ANC.

3. The office administrator, accountable to the DCMO, 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

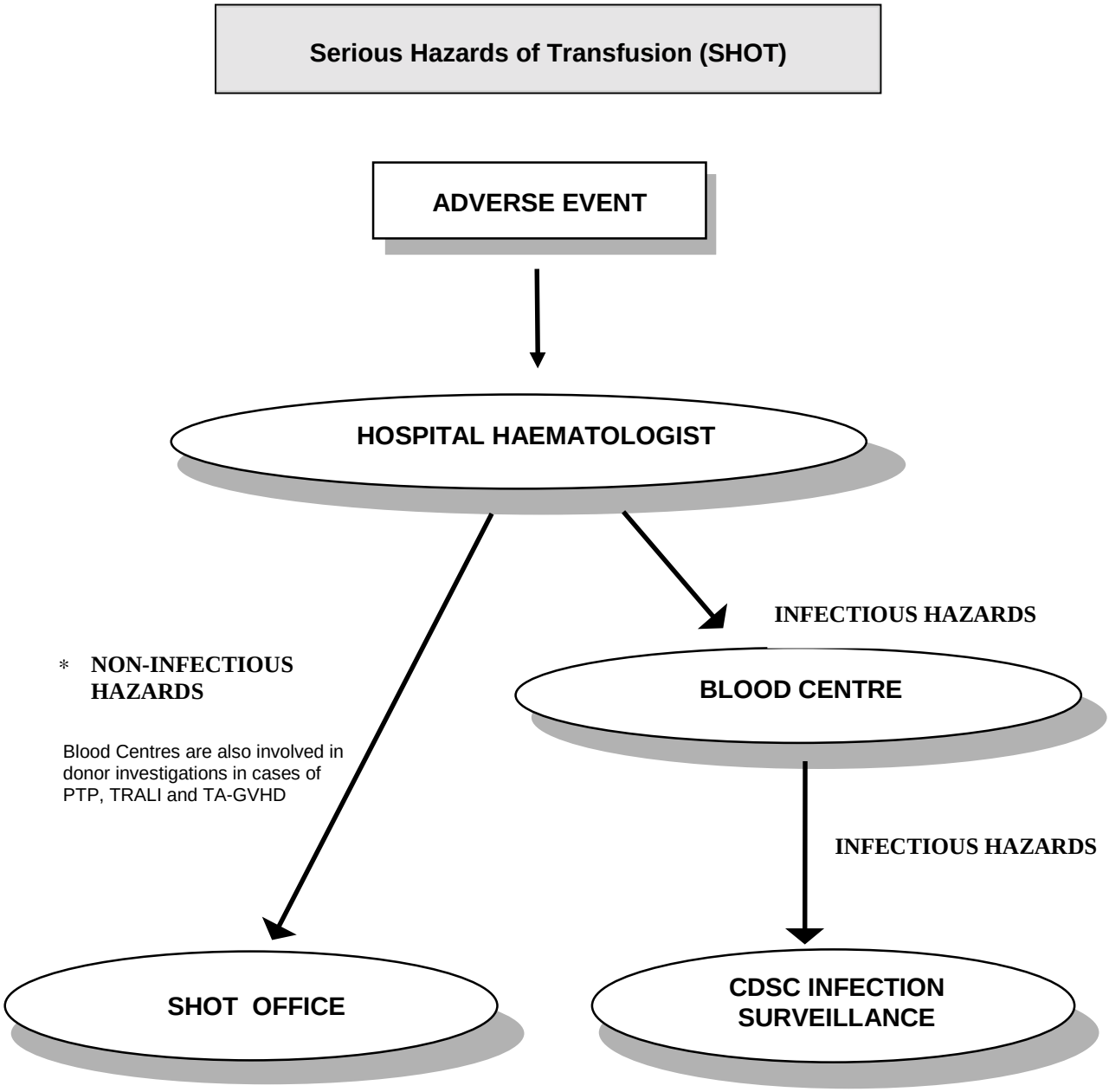
clerical processes involved in data collection as well as providing a good secretarial service, conference organisation, and dealing with telephone enquiries.

4. The administrative assistant works under the direct supervision of the DCMO and relieves the office administrator 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) have given their time free of charge to SHOT by arrangement with their respective employing authorities.

Figure 2
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
◊ Near Miss Events

9. OVERVIEW OF RESULTS 2000-2001

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 2000 and 30th September 2001. This system of reporting has been in place since the second Annual Report.[39] In the first report (1996-1997)[40] the incidents were reported by date of transfusion and that report also included 14 incidents which occurred prior to October 1996 and which were used to pilot the questionnaires.

Overview of reports and participation cards

Number of hospitals

Of the 413 hospitals eligible to participate, 199 (48%) submitted initial reports during the reporting year. 180 of these hospitals confirmed that they had previously submitted a report when they returned the participation card (formerly called the 'Nil to Report' card). This is sent out annually in order to ascertain the extent of participation and to provide some denominator data on blood usage so that numbers of incidents can be set in context. The 199 reporting hospitals represent an increase of 11.6% over the previous year and an overall increase of 25.9% since the scheme began. A further 180 hospitals indicated that they had seen no incidents during the reporting year. Combining these 180 with the 199 hospitals which sent reports, participation is now running at a minimum of 91.8% (379/413 hospitals), compared with 72% last year. The apparent increase in reporting since last year may, however, be misleading since the number of participation cards returned last year was poor in comparison with this year. Last year only 246 hospitals (57.7%) returned their cards while this year we received 360 (87%)

Number of reports

A total of 315 initial reports were received this year which is an increase of 7.5% over the 293 received last year. Once again the largest category showing a 6% increase remains "incorrect blood component transfused" with 213 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 five reporting years 1996/97 to 2000/01

	1996/1997	1997/1998	1998/1999	1999/2000	2000/2001
IBCT	81	110	144	201	213
ATR	27	28	34	34	37
DTR	27	24	31	28	40
PTP	11	11	10	5	3
TA-GVHD	4	4	4	0	1
TRALI	11	16	16	19	15
TTI	8	3	9*	6*	6
Unclassified **			7	0	0
TOTAL	**169**	**196**	**255**	**293**	**315**

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

***** The totals for TTI in years 1998/99 and 1999/2000 appeared in last year's report[9] as 8 and 4 respectively. This was because one case reported in Scotland in 1998/99 and another in 1999/2000 together with a case in 1999/2000 which was pending full investigation at the time of the report were not then included in the totals.
** Unclassified refers to 7 incidents analysed in the 3rd annual report[38] which we were unable to group in any of our existing categories.

Figure 3
Comparison of initial reports of incidents since reporting began in 1996

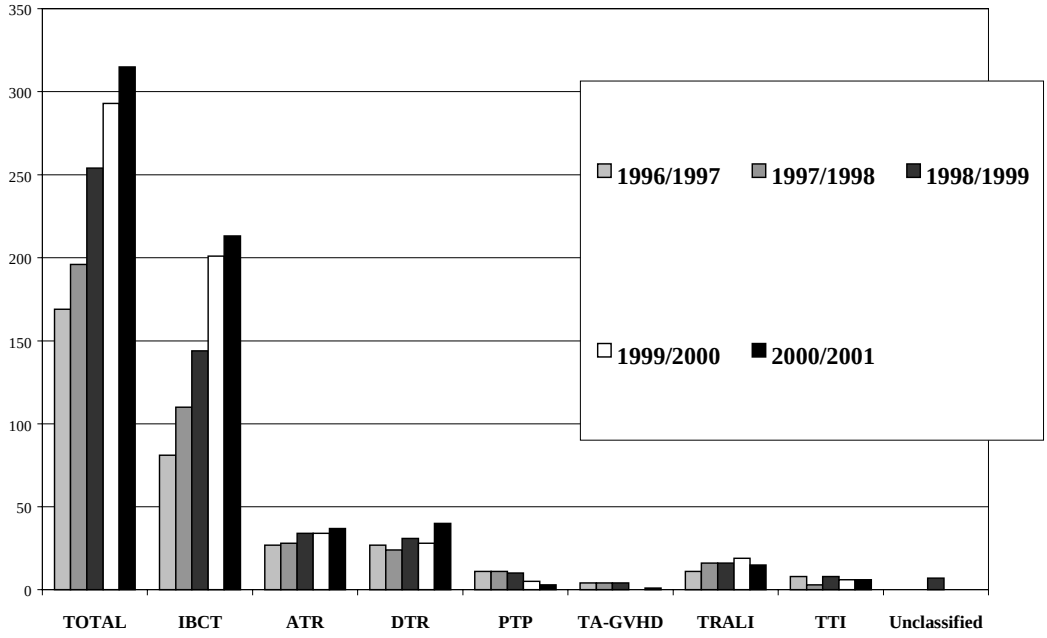
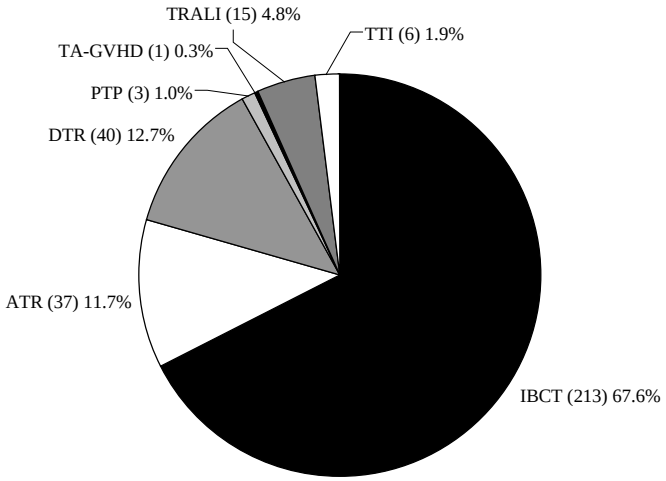


Figure 4
Overview of 315 cases for which initial reports forms were received.



In addition to the 315 initial report forms shown above a further 24 were received which were withdrawn because they were not considered to be valid SHOT reports and 4 which were written off when it became clear, despite extensive following up by SHOT office staff, that the questionnaires would not be returned. Details of the withdrawn cases are summarised in table 3.

Table 3
Initial report forms withdrawn from the analysis

- **12 were withdrawn by the reporter**
- **11 were withdrawn by the SHOT analyst**
- **1 was withdrawn by the SHOT office**

The 12 withdrawn by the reporter

ATR (2) 1 x Insufficient details available in patient notes.
1 x Coroner's report stated that death was not associated with transfusion.

DTR (6) 3 x Eventually proved to be simple alloimmunisation. These patients have developed red cell allo-antibodies following transfusion but without the development of a positive direct antiglobulin test (DAT) or evidence of haemolysis. As this is a recognised complication in 5-6% of patients who are transfused it is felt this should not be regarded as a serious adverse event.
1 x Consultant who originally reported left the authority without following the case up.
1 x Case reported in error due to clerical mistake in the patient's notes.
1 x Later believed not to have suffered a reaction.

IBT (3) 1 x Reporter unable to confirm suspicions that an incorrect transfusion had occurred.
1 x Reported the previous year but reported again in error.
1 x Transpired that no blood had been transfused therefore categorised as "Near Miss".

TRALI (1) 1 x Initial findings of TRALI not confirmed.

The 11 withdrawn by the SHOT analyst

ATR (4) 1 x Reaction to Anti-D.
1 x Reaction to Immunoglobulin.
1 x Case did not fit the ATR definition.
1 x Bacterial case involving a contaminated pack of donor platelets.

DTR (1) 1 x Serological reaction only.

IBT (6) 2 x No blood transfused therefore categorised as "Near Miss".
4 x Clinical decision.

The 1 withdrawn by the SHOT office

IBT (1) Case already reported.

Analysis of questionnaires

Excludes 6 TTI cases

A total of 277 incidents (including 1 IBCT reported by letter rather than questionnaire) were analysed for this report. Fourteen of these were outstanding from the previous year. A further 46 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[9] we identified 22 initial report forms for which no questionnaires were received. We have been unable to obtain sufficient information to allow analysis on 4 cases outstanding from last year and these cases will not be pursued further. Additionally 4 were eventually withdrawn by the originating reporter.

Table 4
Summary of completed questionnaires received.

	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI	Totals
Total number of reports received	213	37	40	3	1	15	6	**315**
Questionnaires included in analysis	190 (10)	31	39 (3)*****	3	1	13(1)	6	**283**
Questionnaires outstanding	33	6	4	0	0	3	0	**46**

These figures include questionnaires outstanding from last year shown in brackets
* One delayed transfusion reaction (DTR) brought forward from last year was carried forward from the ATR section of last year's report.[9] It was reclassified as DTR on receipt of the questionnaire.

Figure 5
Overview of 283 cases for which fully completed questionnaires were received

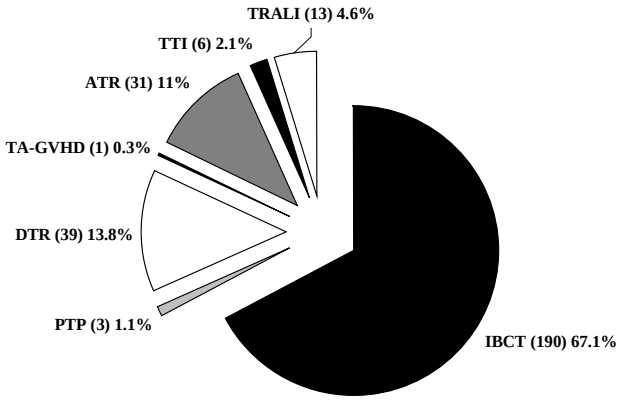


Figure 6
Overview of transfusion related mortality/morbidity data reported in 283 completed questionnaires.

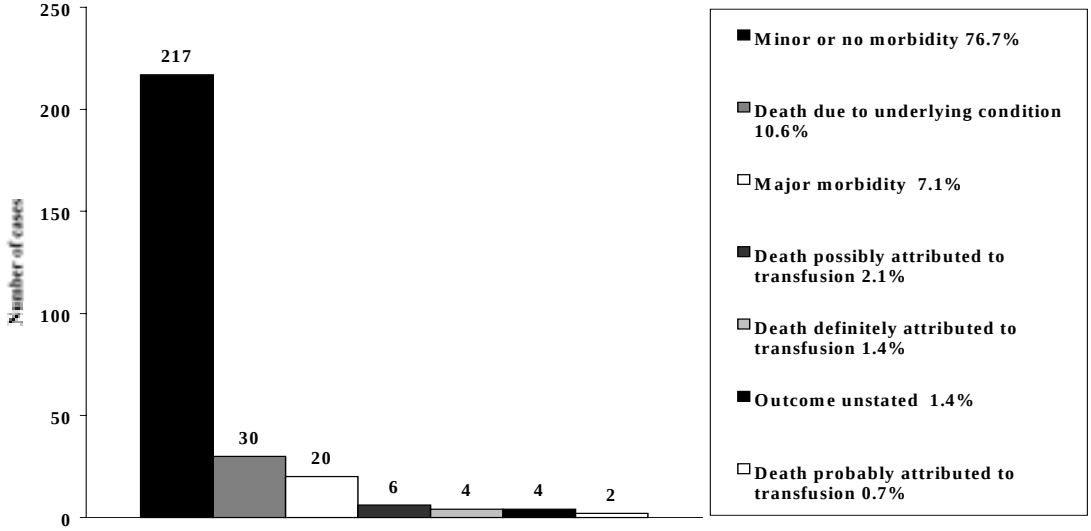


Table 5
Transfusion related mortality/morbidity according to the type of hazard reported in 283 completed questionnaires.

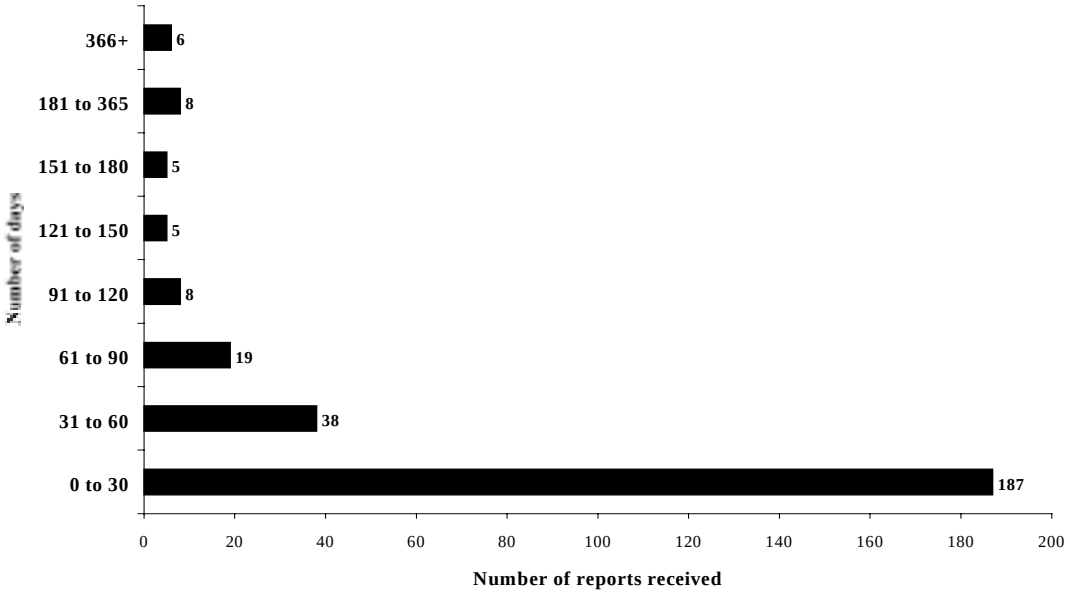
	Total	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI
Death definitely attributed to transfusion	**4**	0	1	0	0	1	1	1
Death probably attributed to transfusion	**2**	0	0	0	0	0	2	0
Death possibly attributed to transfusion	**6**	3	2	1	0	0	0	0
Death due to underlying condition	**30**	19	3	5	0	0	3	0
Major morbidity	**20**	6	0	0	3	0	6	5
Minor or no morbidity	**217**	160	25	32	0	0	0	0
Outcome unstated	**4**	2	0	1	0	0	1	0
Totals	**283**	**190**	**31**	**39**	**3**	**1**	**13**	**6**

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)

Figure 7
Calendar days between transfusion incident and initial report to SHOT (n=276)

Excludes 6 TTI and 1 where the date of transfusion was not stated or not known

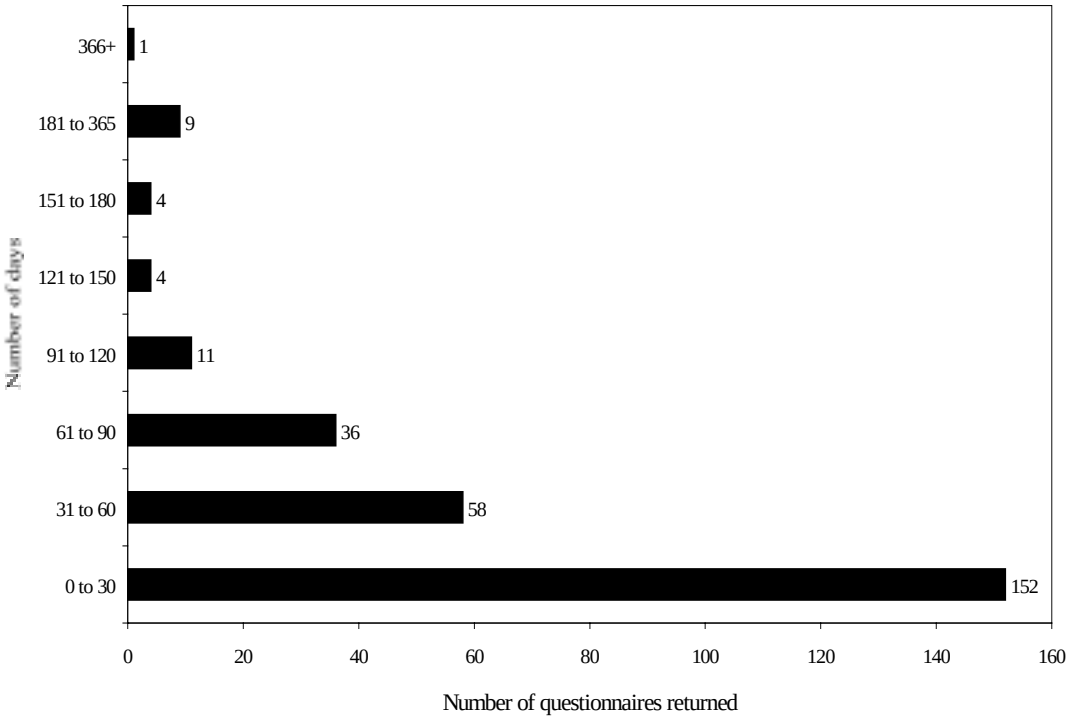


The median time for return of initial reports was 16 days. This time interval appears to have stabilised during the last three years. The figures for reporting years 2, 3 and 4 were 15, 17 and 15 days respectively compared with 30 days for the first reporting year. There were 6 cases which had very lengthy delays between the incident and reporting it. The reasons the reporters gave for this were:

Two IBCT reports were received (1 x 1 year after the transfusion and 1 x 1 year and 4 months after the transfusion) because the reporter was new in post and found 2 cases which should have been reported to SHOT earlier. Three IBCT cases were reported retrospectively when patients were re-admitted. These 3 involved delays in reporting of 1 year, 1½ and 2½ And the last was a PTP case reported 3 years after the event. The reporter stated that the delay resulted from the combined effects of a late report, temporary loss of case notes and the fact that the patient, who was a temporary visitor, had returned home without further local follow up.

Figure 8
Calendar days between initial report and return of completed questionnaire (n =275)

Excludes 6 TTI, 1 IBCT reported by letter, and 1 TRALI not reported on a valid questionnaire



The median time between initial report and return of final questionnaire was 26 days. This is an improvement on last year's median time of 33 days.

Overall transfusion activity and patient characteristics

The number of incidents reported needs to be placed in the context of the overall numbers of transfusions taking place. Table 6 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, 2000 to 31st March, 2001.

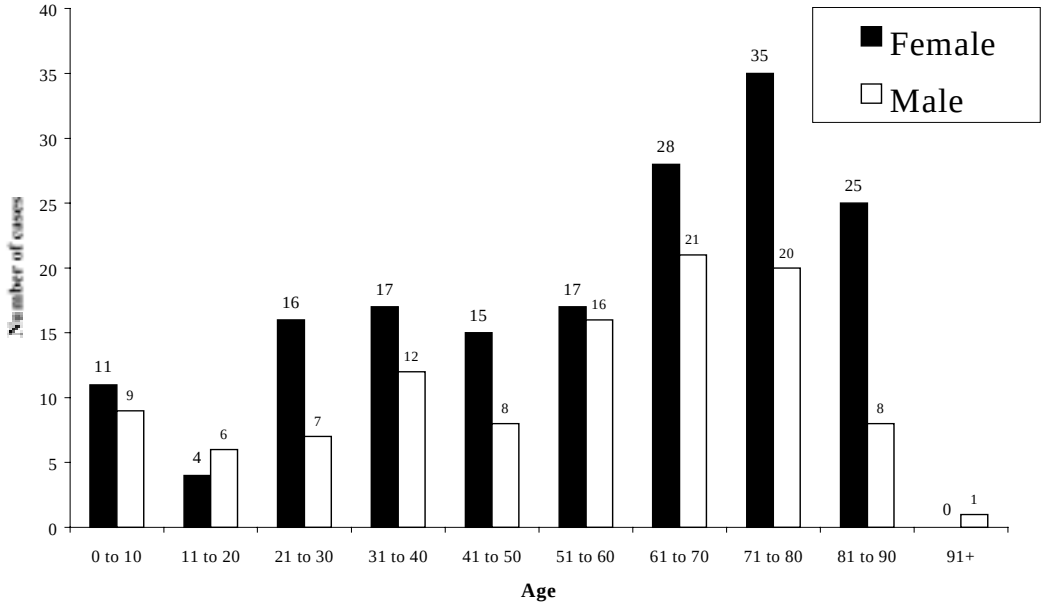
Table 6
Total issues of blood components from the Transfusion Services of the UK in 2000/2001

Red Cells	**2,706,307**
Platelets	**250,259**
Fresh frozen plasma	**374,760**
Cryoprecipitate	**95,456**
TOTAL	**3,426,782**

For the last 3 years, data from the participation cards have been used to determine what percentage of all red cells issued were being received and handled by what percentage of participating hospitals. This year the number of cards returned to the SHOT office increased to 87% (360/413) and in total the number of red cell units transfused was calculated as 2,773,293. Since this figure is higher than the actual number of red cell units issued from the UK Transfusion Services it is clear that the data are unreliable and this casts some doubt on the validity of data concerning red cell usage in previous reports. The reason for this discrepancy is not immediately obvious. It is possible that some reporters mistakenly thought they were being asked for numbers of all blood components transfused. Alternatively it may be that some hospitals gave Trust wide figures without realising that individual hospitals had already submitted their own returns. If meaningful data on red cell usage are to be gathered in future years a thorough review of techniques for soliciting this information is clearly needed.

Figure 9
Distribution of patients by age and gender at the time of transfusion (n=276)

Excludes 1 case where gender was not stated or not known



	Females (168)	**Males (108)**
Age range	1 day to 88 years	1 day to 93 years
Median Age	63 years	58 years

10. CUMULATIVE DATA 1996 - 2001

The accumulated data from 5 years of SHOT reporting now provides a powerful body of evidence on serious transfusion complications in the UK. This chapter summarises that data and should prove to be a useful reference tool for data on overall mortality/morbidity figures as well as more detailed extracts from the full chapters on Incorrect Blood Component Transfused, Acute Transfusion Reaction, Delayed Transfusion Reactions and Near Miss Events. We began collecting non-infectious hazard data in 1996 but that on TTI began one year earlier. For consistency therefore, TTI cases reported in that first year have been excluded from cumulative data. However it is included in Chapter 18.

Initial report forms received:	**1228**	**Questionnaires analysed:**	**1148**

Figure 10
Initial reports by incident 1996/97 - 2000/01 (n=1228*)

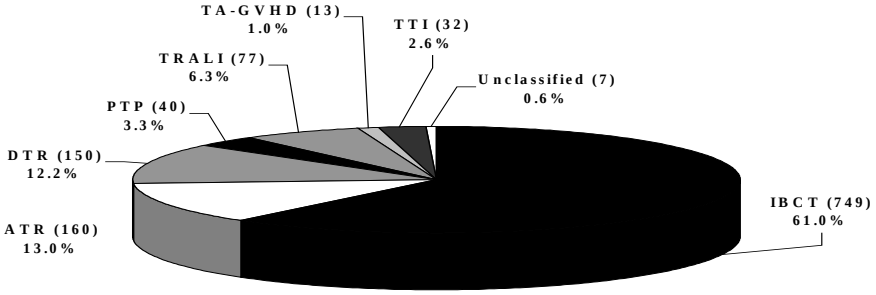
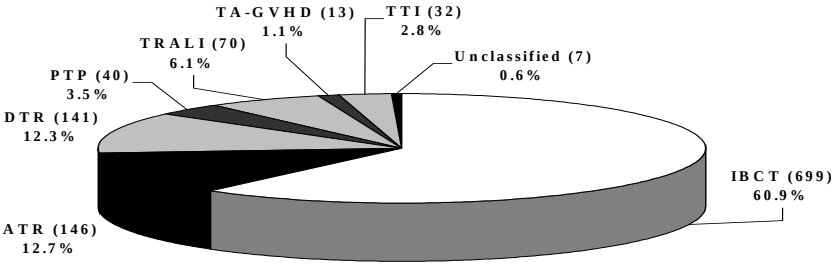


Figure 11
Questionnaires by incident 1996/97 - 2000/01 (n= 1148*)



* The totals of 1228 and 1148 appear, when compared with the charts in last year's report,[9] to show 3 extra cases. This is because 2 TTI cases in Scotland not previously included and 1 case which was pending full investigation at the time of the last report are now included in the overall totals. Please note that this statement applies throughout the report wherever the totals of TTI = 32, Initial Reports = 1228 and Questionnaires = 1148 appear.

Figure 12
Overall mortality/morbidity figures 1996/97 - 2000/01 (n=1148)

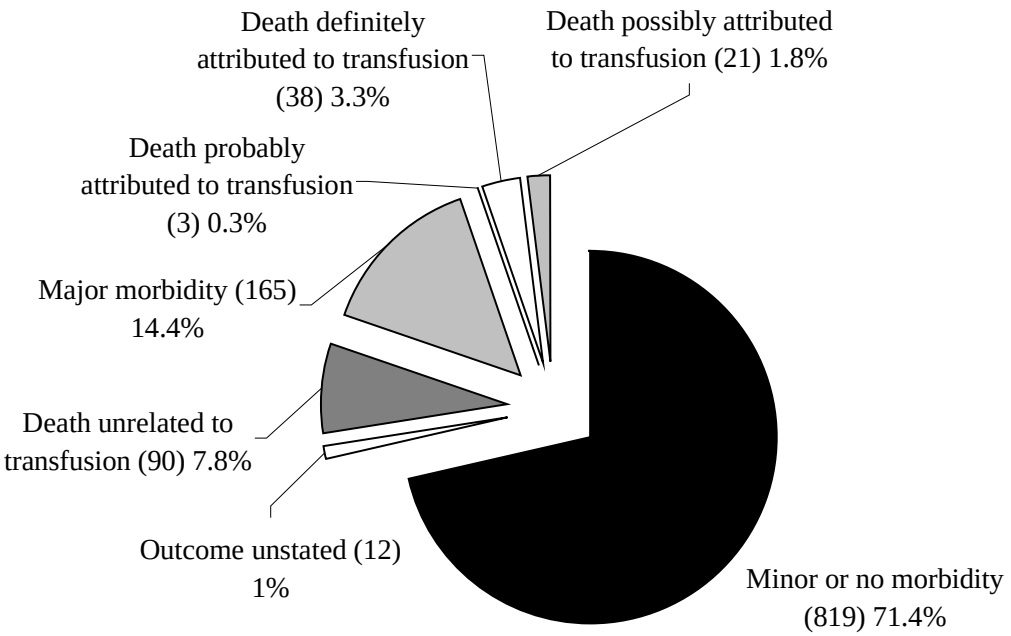


Table 7
Overall mortality/morbidity figures by fully analysed questionnaires 1996/97 – 2000/01 (n=1148)

	Total	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI	UC[1]
Minor or no morbidity	819	566	121	103	24	0	0	0	5
Major morbidity	165	60	3	18	11	0	49	24	0
Death definitely attributed to transfusion	38	5	2	4	1	13	6	7	0
Death probably attributed to transfusion [2]	3	1	0	0	0	0	2	0	0
Death possibly attributed to transfusion [3]	21	5	4	1	1	0	10	0	0
Death unrelated to transfusion	90	56	13	14	3	0	3	1	0
Outcome unknown	12	6	3	1	0	0	0	0	2
Totals	**1148**	**699**	**146**	**141**	**40**	**13**	**70**	**32**	**7**

[1] UC = unclassified incidents from 1998/99 report
[2] This category included for the first time from 1999/2000
[3] This category included for the first time from 1998/1999

Incorrect Blood Component Transfused cases 1996/97 - 2000/01

Initial report forms received:	**749**	**Questionnaires analysed:**	**699**

Table 8
Mortality/morbidity data for IBCT cases (n=699)

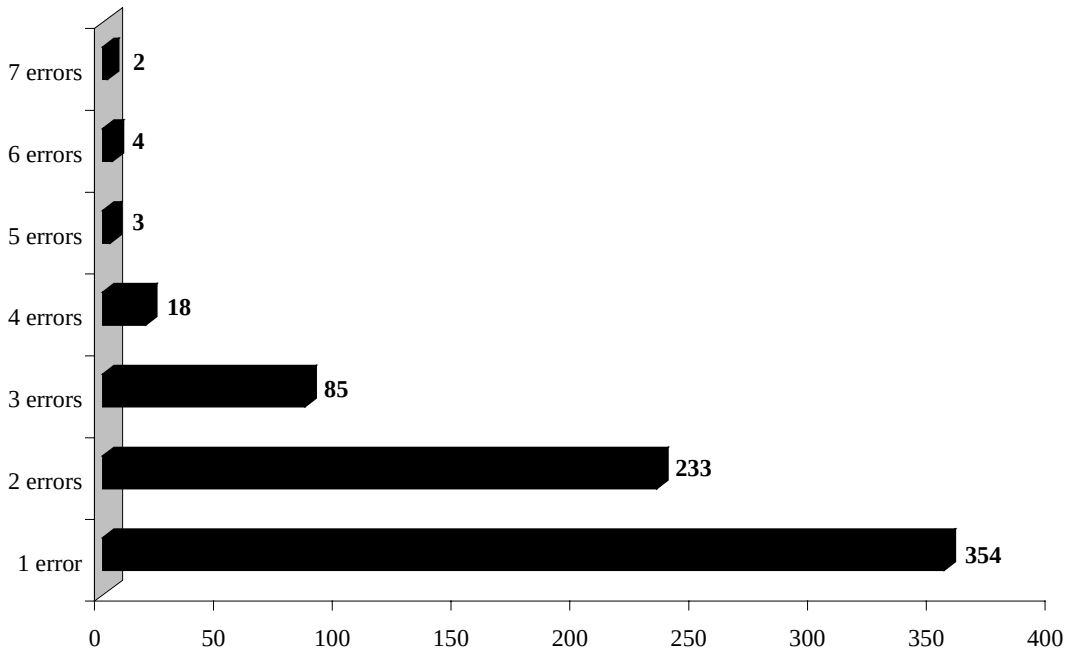
OUTCOME	NUMBER OF CASES
Death definitely attributed to transfusion	5
Death probably attributed to transfusion *	1
Death possibly attributed to transfusion	5
Death unrelated to transfusion	56
Major morbidity	60
Minor or no morbidity	566
Unknown outcome	6
Total	**699**

***** This category introduced 1999/2000

Table 9
Outcome of cases of IBCT 1996/97 – 2000/01 (n=699)

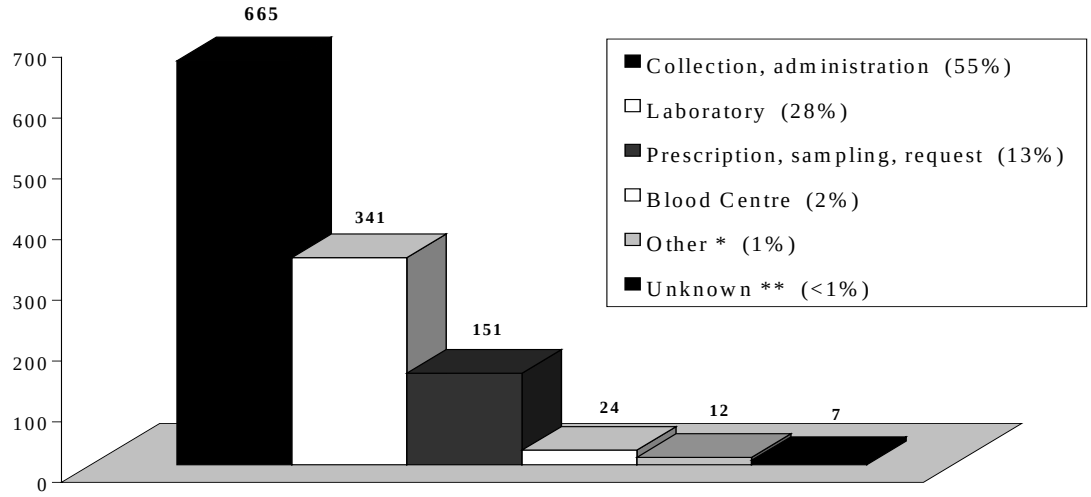
Category	Survived/ no ill effects	Major morbidity	Died unrelated to tx.	Died possibly related to tx.	Died probably related to tx.	Died definitely related to tx.	Unknown	TOTAL
Major ABO incompatibility	102	37	12	3	1	5	1	**161**
RhD incompatible	51	17	5					**73**
ABO/RhD compatible	184		11					**195**
Other red cell incompatibility	29	4	3				1	**37**
Inappropriate transfusion	52		6	2			1	**61**
Special requirements not met	109	1	10				2	**122**
Anti D	37							**37**
Other	1							**1**
Blood group not stated	1	1	9				1	**12**
Total	**566**	**60**	**56**	**5**	**1**	**5**	**6**	**699**

Figure 13
Multiple errors in IBCT cases 1996/97 - 2000/01 (no cases=699, no. errors=1200)



The average number of errors per case over 5 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 years 4 and 5.

Figure 14
Distribution of errors in IBCT cases 1996/97 - 2000/01 (no. cases=699, no. errors=1200)



***** **Other** = Year 4: 2 errors involved transport between hospitals and 4 errors could not be traced to their source. Year 5: 2 cases of expired albumin where it was not possible to determine who was responsible for maintaining stocks, 2 cases of a communication failure between the hospital transfusion laboratory and the ward, 1 case of a patient who had duplicate hospital records but with completely different dates of birth, and 1 case where it is thought that the patient's Hb result was written wrongly in the notes.

****** **Unknown** = Year 5: 4 cases where it was not possible to determine the source of the error, and 3 cases of erroneous Hb results leading to unnecessary transfusions but for which the reason for the invalid result was not known.

Table 10
Laboratory errors and grade of staff involved 1996/97 - 2000/01
(331 errors in the 283 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	**12**	6	4	2	0	0
Failure to consult/heed historical record	**38**	17	8	10	1	2
Incorrect group	**80**	35	15	24	1	5
Missed antibody screen	**14**	6	2	5	0	1
Missed incompatibility/ crossmatch error	**22**	7	9	6	0	0
Incorrect labelling of component	**26**	19	3	2	1	1
Selection/issue of inappropriate component	**57**	26	11	13	3	4
Failure to clear satellite refrigerator	**11**	10	0	0	0	1
Failure to irradiate	**11**	6	3	0	1	1
Clerical error	**16**	5	4	2	1	4
Other procedural error	**38**	14	7	12	0	5
Other	**4**	3	0	0	0	1
Unknown	**2**	1	0	1	0	0
Total	**331**	**155**	**66**	**77**	**8**	**25**

Immune complications 1996/97 - 2000/01

Acute Transfusion Reactions

Initial report forms received:	**160**	**Questionnaires analysed:**	**146**

Table 11
Acute reaction types 1996/97 - 2000/01 (total cases = 148)

RED CELLS (71)		**FFP (35)**	
Haemolytic or Incompatibility*	19	Anaphylactic	18
Non-haemolytic febrile	25	Allergic	14
Hypotensive	3	IgA antibodies	1
IgA antibodies	1	Hypotension	1
Anaphylactic	8	Cardiac Failure	1
Allergic	7		
Dyspnoea/chest pain/rigors	4		
Other (↑BP; jaundice; haemoglobinuria; hypoxia/acidosis in neonate - 1 each)	4		
PLATELETS (40)		**RED CELLS with FFP (combined)(1)**	
Hypotension +/- flushing	8	Hypertransfusion	1
Haemolytic	6		
Anaphylactic	16	**RED CELLS with PLATELETS (combined) (1)**	
Allergic	7		
Chest pain +/- dyspnoea	2	Allergic	1
Generalised pain + hypotension	1		

***** incompatibility = febrile reaction considered to be due to the presence of a red cell antibody (detected in Transfusion Laboratory)

N.B. Cases reported in the first 2 years have been reclassified, where possible, to fit the later definitions of "allergy" and "anaphylaxis"

Delayed Haemolytic Transfusion Reactions 1996/97 - 2000/01

Initial report forms received:	**150**	**Questionnaires analysed:**	**141**

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

Group 1 (n=19)
Asymptomatic (± positive DAT ± spherocytes)

Group 2 (n=33)
Falling haemoglobin (↓Hb)/positive DAT/spherocytes (2 of these parameters)

Group 3 (n=72)
↓Hb + jaundice ± positive DAT ± spherocytes

Group 4 (n=15)
As group 3 + renal impairment

***** 2 cases had insufficient data to categorise

139 patients developed 186 newly detectable post transfusion red cell alloantibodies. See Table 12

Table 12
New post transfusion red cell alloantibodies 1996/97 - 2000/01
186 antibodies in 139 patients

Antibody group	Number	Sole antibody	
Kidd			
Jka	61	39	
Jkb	10	5	
Duffy			
Fya	18	9	
Fy3	1		
Kell			
K	12	5	
Kpa	1		
Kpb	1	1	
Rhesus			
D	6	4	
C	6	1	
Cw	2		
c	10	5	
E	34	9	(1 reacting only by enzyme)
e	3	2	
MNSs			
M	4		
S	5	1	
s	1		
Lutheran			
Lua	3		
Lewis			
Lea	1		
Other			
Yka	1	1	
Anti B	1		
"private antigen" NOS[1]	1		
Wra	1	1	
Chido	1	1	
Unspecified pan-agglutinin	1		
Weak cold agglutinin	1		
TOTAL	**186**	**86**	

[1] Not Otherwise Specified

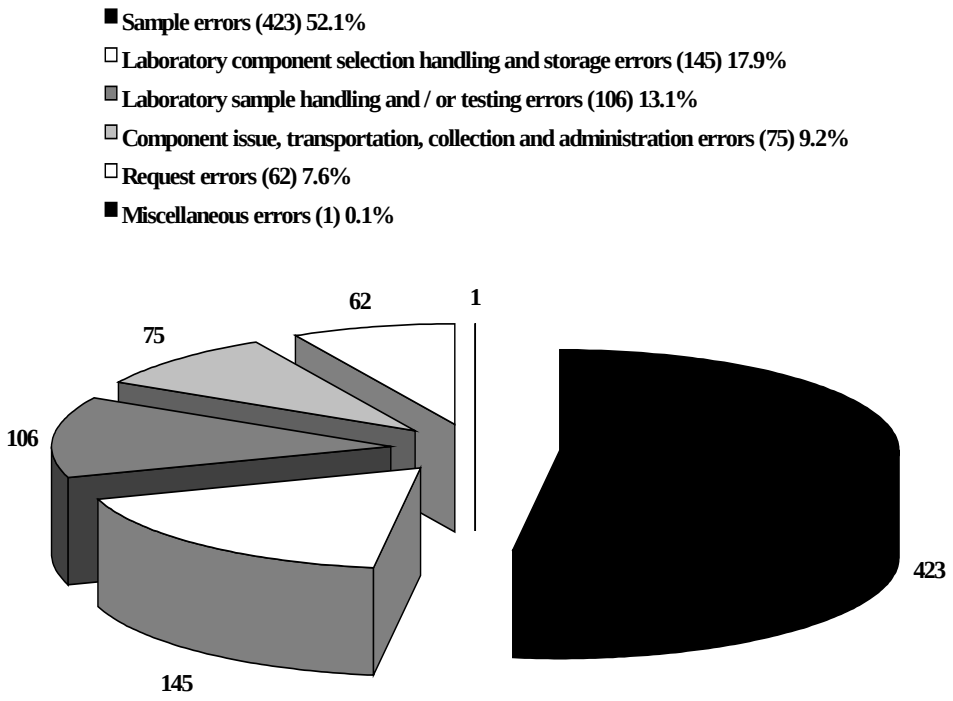
"Near Miss Events" 1997/98 - 2000/01

The Near Miss Scheme was initiated in time for the second reporting year (1997/98)[39] by running a small pilot project involving 4 hospitals over an 8 month period. This was expanded the following year to include 22 hospitals over 7 months and then expanded again in 1999/2000 to include the same hospitals over a 12 month period. This year all UK hospitals have been encouraged to participate. We are presenting here cumulative figures for all Near Miss reports received since the scheme was piloted.

Number of reports received 812

Errors are listed in 6 categories as shown in the key to figure 15

Figure 15
Categories of errors (n=812)



11. 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 four previous years this category represents the highest number of reports (213 or 68.9% of 309 new non-infectious reports and 67.6% of all new reports). This represents an increase of 6% over the previous year. This chapter analyses 179 new questionnaires and one explanatory letter plus 10 questionnaires brought forward from last year. Completed questionnaires are still outstanding on 33 new initial reports and will be analysed next year.

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, to identify areas for improvement and so ensure that the right blood is given to the right patient at the right time.

The data from 190 completed questionnaires are presented.

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

Table 13
Gender of IBCT patients

Female	=	102
Male	=	87
Unknown	=	1
Total	=	**190**

Table 14
Age of IBCT patients

Age of recipients	
Age range	0 days to 94 years
Median Age	56 years

Table 15
Components implicated in IBCT (200 components in 190 cases)

Components implicated	***Number of cases***
Red cells	139
Platelets	31
Fresh Frozen Plasma	9
Anti D immunoglobulin[1]	17
Albumin[2]	4

[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 unnecessary infusion of a blood derivative due to an error earlier in the chain.

[2] Two cases of administration of “expired” albumin, 1 case of albumin being requested for and administered to the wrong patient, and 1 case of 4.5% albumin issued in error instead of 20%. As with anti D, adverse events to albumin would normally be reported through the MCA system.

The outcome of 190 fully analysed incidents is shown in Table 16.

Table 16
Outcome of 190 fully analysed incidents

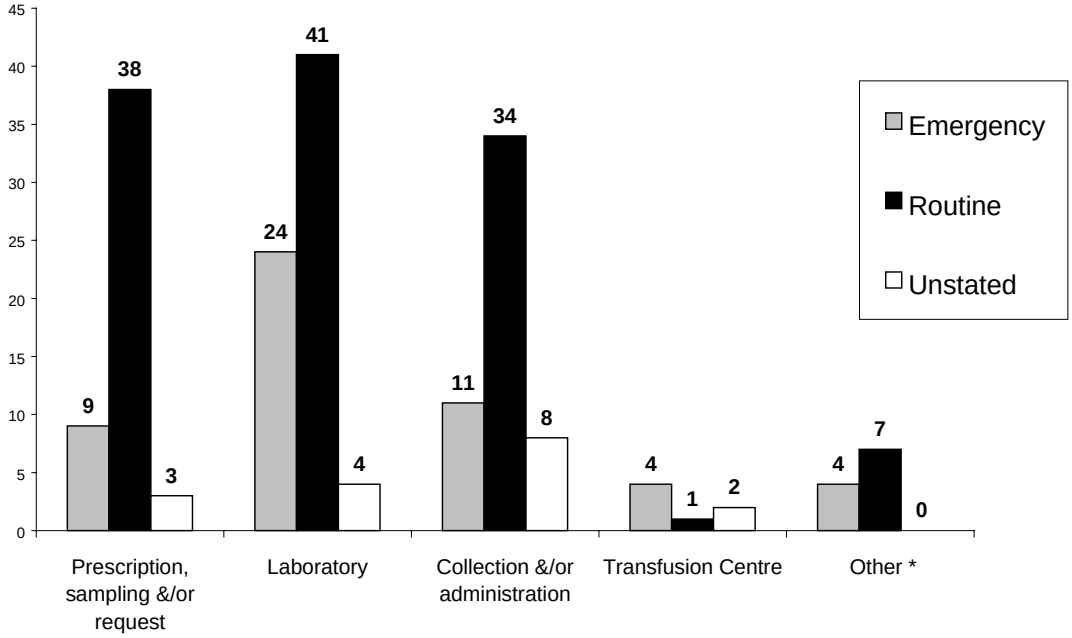
OUTCOME	NO. OF INCIDENTS
Death possibly related to transfusion	3
Death unrelated to transfusion	19
Major morbidity*	6
Minor or no morbidity	160
Outcome unstated by reporter	2

* Major morbidity was classified as the presence of one or more of the following:
- Intensive care admission and/or ventilation
- Dialysis and/or renal impairment
- 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 190 completed questionnaires, 121 related to elective and 52 to emergency transfusions. Seventeen questionnaires did not state whether the transfusion was elective or emergency. Figure 16 shows the distribution of errors relating to emergency and elective transfusions.

Figure 16
Incidence of errors at the various stages of the process of emergency and elective transfusion (n=190)



***** Other = 2 cases of expired albumin where it was not possible to determine who was responsible for maintaining stocks; 1 case of a communication failure between the hospital transfusion laboratory and the ward; 1 case of a patient who had duplicate hospital records but with completely different dates of birth; 4 cases where it was not possible to determine the source of the error; 3 cases of erroneous Hb results leading to unnecessary transfusions but for which the reason for the invalid result was not known.

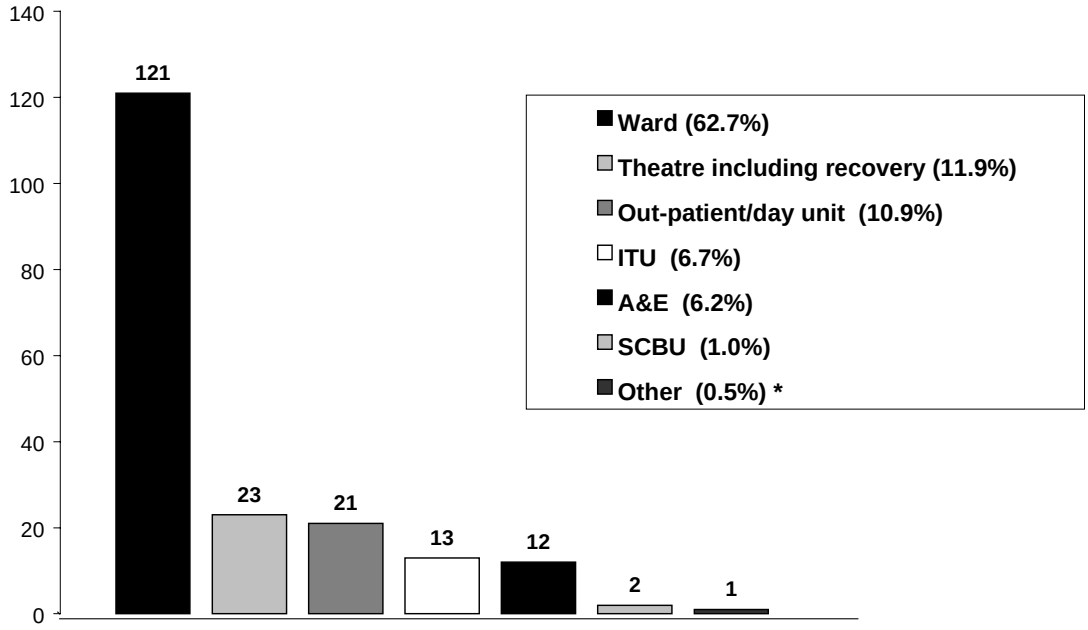
This year, as well as asking whether the error occurred in an emergency or a routine situation, we asked whether the error occurred in or out of normal working hours. There has been some confusion over what was actually meant by "in and out of normal working hours" which we will endeavour to clarify in next year's questionnaire. However the figures are interesting, although of limited value due to the lack of denominator data.

- 88 transfusions took place in normal working hours (46.3%).
- 77 were outside normal working hours (40.5%).
- 6 reporters said that transfusions had taken place both inside and outside normal working hours (3.2%). All these cases involved multiple units.
- 2 reporters stated that they did not know the answer to this question (1.1%).
- 17 reporters did not respond (8.9%).

Site of transfusion

The questionnaire asked for information about where the transfusion took place. One hundred and eighty seven reports gave information on the site of the transfusion (Figure 17). This information is of limited value, however, as no denominator data are available.

Figure 17
Site of transfusion (n=193) #

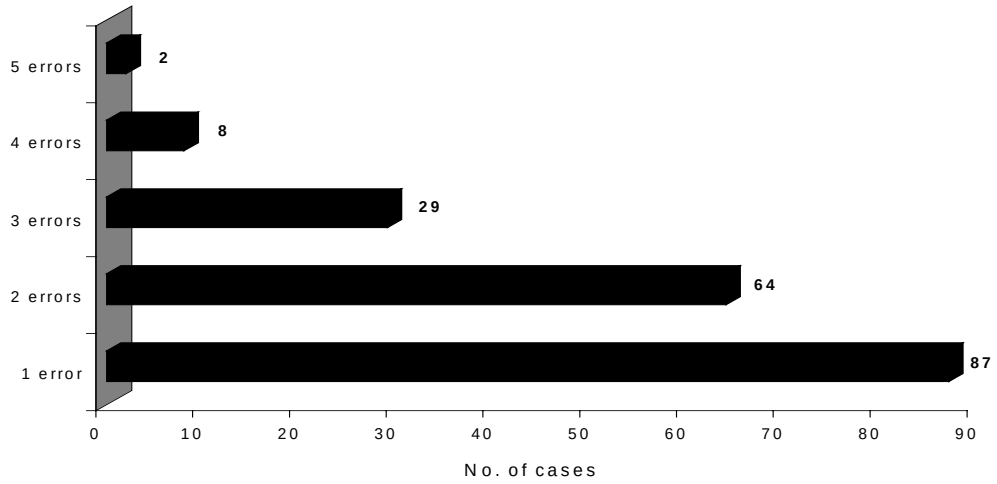


* 1 x during transport to another hospital
\# 6 cases involved transfusions on 2 separate sites

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

In all 4 previous years it has been consistently noted that multiple errors have been implicated in many "wrong blood" incidents and in the 5th reporting year these remain significant. Analysis of 190 completed questionnaires has highlighted 103 cases (54.2%) where multiple errors in the transfusion chain culminated in a "wrong blood" transfusion. This year a total of 344 errors was noted in 190 cases and further detail is shown in Figure 18.

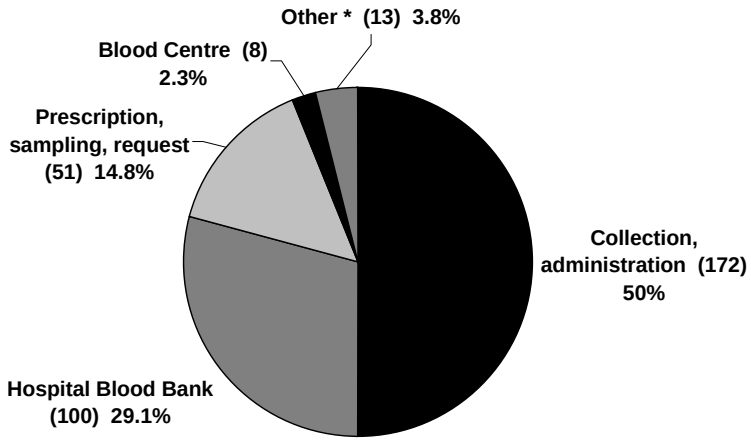
Figure 18
Total number of errors per case (total cases = 190; total errors = 344)



Distribution of errors

The following pie chart (Figure 19) shows the distribution, according to the main reporting categories, of a total of 344 errors from the analysis of 190 completed reports. A more detailed analysis of the distribution of total errors can be seen in Table 17

Figure 19
Distribution of total errors according to the main reporting categories (n=344)



***** **Other** = 2 cases of expired albumin where it was not possible to determine who was responsible for maintaining stocks; 2 cases of a communication failure between the hospital transfusion laboratory and the ward; 1 case of a patient who had duplicate hospital records but with completely different dates of birth; 1 case where it is thought that the patient's Hb result was written wrongly in the notes; 4 cases where it was not possible to determine the source of the error, and 3 cases of erroneous Hb results leading to unnecessary transfusions but for which the reason for the invalid result was not known.

Table 17
Distribution of procedural failures in terms of total errors (n=344)

Each year data emerge which are instructive but which do not fit into pre-existing coding categories. We endeavour to discuss these cases in the text and to take account of the need for new coding categories in subsequent reports. A number of such cases appear in the footnotes to this table, most notably "communication errors" which are discussed separately later in the chapter.

	Number of errors
Prescription, sampling and request	
Sample taken from wrong patient	3
Details on request form incorrect	6
Details on sample incorrect	3
Prescription of inappropriate and/or incompatible component(s)	2
Inappropriate Request	33
Other[1]	2
Unknown[2]	2
Total	**51**
Hospital Blood Bank	
Transcription error	6
Failure to consult/heed historical record	11
Grouping error	10
Missed antibody(ies): Screen error	4
Missed antibody(ies) Identification error	3
Selection/issue of inappropriate component	20
Labelling error	5
Failure to irradiate	7
Crossmatch error	4
Crossmatch wrong sample	3
Incorrect serological reasoning	6
Clerical error	2
Technical Error	5
Failure to clear satellite refrigerator	7
Failure to detect error by Blood Centre	2
Other[3]	3
Unknown[4]	2
Total	**100**
Collection and Administration	
Collection of wrong component	29
Failure to detect error earlier in the chain	38
Failure of bedside checking procedure	82
Wristband missing or incorrect	11
Inappropriate component selected by clinician	7
General administration error	4
Other[5]	1
Total	**172**
Supplying blood centre	
Incorrect group	1
Inappropriate component supplied	4
Other[6]	3
Total	**8**
Other	
Expired albumin given. Not possible to determine who was responsible for maintaining stocks	2
Communication failure between the hospital transfusion laboratory and the ward	2
Patient who had duplicate hospital records but with completely different dates of birth	1
Haemoglobin result probably written wrongly in the notes.	1
Not possible to determine the source of the error	4
Erroneous Hb results leading to unnecessary transfusions but for which the reason for the invalid result was not known.	3
Total	**13**
Total	**344**

[1] 2 x Communication errors
[2] 1 x Possibly pre-transfusion sample diluted with saline; 1 x Sample may have been taken from drip arm;
[3] 1 x Failure to maintain proper stock levels; 1 x Failure to input into computer telephoned special requirements; 1 x Failure to tell Blood Centre of special requirements
[4] 1 x Unable to determine the source of the error within the laboratory; 1 x Possible wrong haemoglobin result given out
[5] 1 x Wrong slip taken to blood bank but unable to determine responsible person
[6] 2 x Transport error; 1 x Did not follow Red Book guidelines in production of component

The pitfalls of a complex, multi-step, multidisciplinary process.

The following analysis of 344 errors occurring in 190 cases illustrates how events combine to result in a 'wrong blood' incident.

Errors in prescription, requesting of blood components and patient sampling

There were 51 errors in this category occurring in 50 case reports.

Sample errors (6)

This year 3 samples were taken from the wrong patient. In 2 cases the sample tubes were handwritten, in one case by a doctor and in the other case by a nurse. The first case resulted in a group O RhD positive patient being grouped as A RhD positive and receiving 8 units of blood, 4 units of FFP and a pool of platelets. The patient survived the complications of intravascular haemolysis. The second case resulted in a group A RhD positive patient being grouped as O RhD positive but there were no adverse sequelae. In the third case the tube was handwritten but prelabelled by a nurse. This resulted in an ABO incompatible transfusion which led to renal failure.
In another case a doctor took a sample when the patient did not have a wristband and put an incorrect hospital number on the sample tube. This led to the laboratory not finding important historical records on that patient.

Case Study 1

Three wrongs make a right

Two patients on the same ward had the same name but different dates of birth and different hospital numbers. A decision was made to transfuse patient A. The sample was labelled with Patient B's details (error 1). As patient B had no historical transfusion record no error could be detected by the hospital Blood Bank and the sample was grouped as O RhD negative. The blood was crossmatched and issued. The nurse collecting the blood for patient A failed to notice the discrepancy in the identification details on the compatibility report (error 2) and when the blood was checked before administration the wrong patient details were also missed (error 3). Serendipitously the right blood was transfused to the right patient.

Errors in Hb estimation (9)

For the first time last year errors in Hb estimation were reported as a cause of unnecessary blood transfusion. This year a further 9 reports were received in this category. These cases have been grouped together as they all led to mis-prescribing of blood but they comprise a number of different errors and therefore do not fall into a single SHOT reporting category:
In two of the cases the patients died possibly as a result of the transfusion. In the first of these the patient was admitted with ischaemic heart disease, an apparent Hb of 80 g/L and symptoms which were at the time attributed to anaemia. The Hb result was released by the laboratory without being validated. Two units of red cells were subsequently transfused resulting in a post transfusion Hb of 140 g/L. The patient developed renal failure and died. It was unclear why the initial Hb result was incorrect although one possibility identified by the reporter was that the original sample was low volume. The second case involved a patient admitted in an emergency with haematemesis. She was given saline and a blood sample taken. Although the patient had no further bleeding following admission the Hb result was given as 72 g/L. Following transfusion of 3 units of red cells her Hb result was 160 g/L. Again it is unclear why the first Hb result was incorrect although it is believed that the sample may have been diluted with saline. This patient suffered fatal cardiac problems post transfusion which may have been a consequence of over–transfusion.

In one case the laboratory result was incorrect and in another case the laboratory phoned the wrong result. In another case the patient was transfused 4 units based on a Hb result obtained, during surgery, from a blood gas analyser. The result obtained was 60 g/L but post transfusion the Hb result was 170 g/L. In one case it was thought that the sample used for testing pretransfusion was probably diluted with saline from a drip arm, the pre-transfusion Hb being 54 g/L whilst the Hb result post a 4 unit transfusion was 182 g/L (see case study 2 below). In a further 3 cases it could not be ascertained whether there had been sampling or laboratory technical errors.
The BCSH Guidelines for the clinical use of red cell transfusions[6] state that the risks of transfusion need to be balanced against the perceived benefits. Consideration of the patients' clinical condition is an essential part of the decision to transfuse red cells or not and is a matter for clinical judgement. Clinicians may underestimate the effectiveness of adaptive mechanisms, particularly with chronic anaemia, relying on the measurement of the Hb concentration alone.

Case Study 2

A diluted sample leads to unnecessary transfusion

The laboratory received a sample for FBC on 23.3.01, Hb was 108g/L. The laboratory received a second sample on 1.4.01, Hb 54g/L. The result was queried with the medical officer who insisted that the sample was correct and that the patient had been bleeding. Four units of blood were requested and transfused. The post transfusion Hb was 182g/L. In retrospect it was realised that the biochemistry department had refused to issue results on the sample received on 1.4.01 and stated that it appeared to be diluted.

Failure to request the appropriate component (33)

In 33 cases there was failure to request the appropriate component. Once again the most common error was failure to request irradiated components for patients at risk as defined in BCSH guidelines.[1] This included 16 cases where the patients were on Fludarabine, and 1 case where the patient was on deoxycoformycin, 6 cases of Hodgkins disease, 2 cases of DiGeorge syndrome, and 5 cases where a neonate had undergone a previous intra-uterine transfusion (IUT). No instances of TA-GVHD resulted from these omissions. Two cases involved omitting to request CMV negative components. 1 case involved an inappropriate request for anti-D.

Interestingly this year, in answer to the question 'As a result of this error have there been recommended changes to transfusion procedures?' 2 laboratories have brought the hospital pharmacy into the procedural chain. In one laboratory the pharmacy informs the blood bank of all patients prescribed purine analogues and will not dispense the drug until they have confirmed that the patient is flagged to receive irradiated components. In another laboratory the blood bank head contacts pharmacy to ensure they have been notified of all patients on purine analogues. Unfortunately in a third case the notification system already in place involved pharmacy and failed.
Another laboratory expressed their frustration at the inability of record systems to identify fetuses as individuals. They felt that a national initiative e.g. allocating a NHS number to fetuses undergoing treatment, would reduce the errors of failure to irradiate blood components for those undergoing IUTs.

Case Study 3

Computer downtime contributes to a wrong blood incident

A 19 year old man with acute lymphoblastic leukaemia required a transfusion of red cells. The request form did not stipulate that the blood should be CMV negative and irradiated. The hospital information systems were being relocated and therefore the historical record could not be accessed. The error was not noticed at the time of administration and only discovered during retrospective update of transfusion computer records.

Case Study 4

Patients should be better informed

A patient with anaemia was admitted to hospital whilst on holiday and required a blood transfusion. Staff were unaware that she had previously been treated with Fludarabine and therefore required irradiated blood components. Had the patient been aware of her previous treatment, and that this information should be passed on, this incident might have been avoided.

Case Study 5

Failure of communication between hospitals places a neonate at risk

An infant who had previously had an IUT was transferred from a tertiary referral centre back to the referring hospital and was transfused with non irradiated red cells as no transfusion history had been given either by the local clinicians or the specialist centre.

Case Study 6

Robust procedures must be in place for autologous donations

A 63 year old lady requested pre-deposit autologous donation for her total knee replacement. Two units were collected at the hospital. The paperwork giving details of the autologous donation was never completed or sent to the laboratory, nor was the laboratory telephoned. On admission for surgery 3 units of allogeneic blood were crossmatched for the patient. Despite the patient's notes having a prominent red label stating that autologous blood had been collected, the first unit of allogeneic blood was given to the patient. The red sticker was then noticed and the patient went on to receive 2 units of her own pre-deposited blood. The Trust concerned has now put a system in place where the nurses at the pre-admission clinic inform the blood bank, one week before surgery when patients have given autologous units.

Case Study 7

Laboratory staff issue platelets of the wrong blood group as they are not informed that the patient has undergone a bone marrow transplant

The blood bank did not know that a group O RhD positive patient with chronic myeloid leukaemia (CML) in blast crisis had previously undergone a bone marrow transplant from a group A RhD positive donor. The laboratory therefore continued to issue O RhD positive platelets, a total of 7 adult doses, until a sample was sent for grouping and a new group was detected from a mixed field appearance.

There was only 1 telephone request error this year, although a telephoned laboratory result culminated in an unnecessary transfusion. It is unclear whether the result was given incorrectly or recorded incorrectly.

Case Study 8

Care must be taken over telephoned requests and nurses must wait for prescriptions to be written

A telephone request for 20% salt poor albumin was made by a house officer. The albumin was issued and labelled according to the patient details given by the doctor. Two nurses checked the albumin on the ward and the infusion was commenced on the patient for whom it was issued although the prescription had not yet been written. One of the nurses contacted the doctor to remind her to prescribe it when the doctor realised that she had requested the albumin for the wrong patient The infusion was stopped immediately, after 45mL had been given.

Hospital Blood Bank Errors

One hundred errors in this category occurred in 80 case reports. This is an increase in laboratory errors of 16.3% over last year and these errors now account for 29.1% (100/344) of total errors. This year the largest number of cases (36% or 69 out of 190), although not the largest number of errors, originated in the hospital blood bank. In many cases errors made within the laboratory cannot be picked up further down the transfusion chain, although in some cases involving 'special requirements' they should be picked up by the staff responsible for administering the transfusion.

Of the 100 laboratory errors 53 occurred during routine working hours and involved 50 state registered BMSs, 1 unsupervised medical laboratory assistant (MLA), 1 locum/agency staff and 1 trainee. The 36 errors made by on-call staff involved 17 BMSs who worked regularly in the blood bank and 19 who did not. In the other 11 errors neither the grade of staff nor the time the errors were made was stated. This information is summarised in Figure 20. Table 18 gives more detail about the errors and grades of staff involved.
36% of laboratory errors occurred outside normal working hours. As stated in last year's report[9] it is not possible to comment on the significance of this information in the absence of relevant denominator data.

Figure 20
Circumstances under which laboratory errors occurred (n=100)

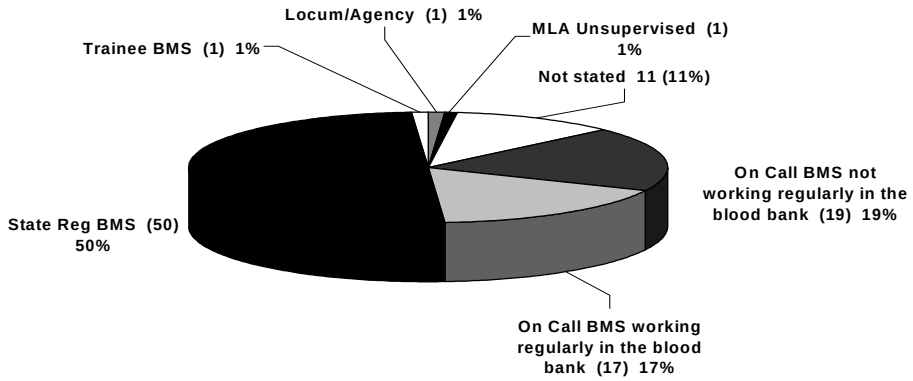


Table 18
Laboratory errors and grade of staff involved (n=100)

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	**3**	1		2		
Failure to consult/heed historical record	**11**	5	3	2		1
Incorrect group	**10**	2	2	4		2
Missed antibody(ies)	**7**	2	2	3		
Missed incompatibility/crossmatch error	**4**	1	2	1		
Incorrect labelling of component	**5**	5				
Selection/issue of inappropriate component	**20**	11	3	3	1	2
Failure to clear satellite refrigerator	**7**	6				1
Failure to irradiate	**7**	4	1		1	1
Clerical error	**8**	4	2		1	1
Other procedural error	**13**	6	2	3		2
Other [1]	**3**	2				1
Unknown [2]	**2**	1		1		
Total	**100**	**50**	**17**	**19**	**3**	**11**

[1] 1 x Failure to maintain proper stock levels; 1 x Failure to input into computer telephoned special requirements; 1 x Failure to tell Blood Centre of special requirements;
[2] 1 x Unable to determine the source of the error within the laboratory; 1 x possible wrong haemoglobin result given out but unable to confirm

The increase in number of laboratory errors is predominantly in the categories:

'Failure to consult/heed historical record'	11 errors this year against 5 last reporting year.
'Selection/issue of inappropriate component'	20 errors this year against 12 last reporting year.
'Incorrect serological reasoning'	6 errors this year against 1 last reporting year.
'Failure to clear satellite refrigerators'	7 errors this year against 1 last reporting year.

These areas will be discussed first.

Failure to consult/heed historical record (11)

This category consisted almost entirely of failure to select irradiated components when the patient records clearly stated that irradiated units were required. In one case the historical record could not be accessed due to computer downtime. It is essential that a record of patients with antibodies or special requirements can be accessed during computer downtime, whether this is in a hard copy format or input into an excel or access file that can be accessed by a PC separate from the blood bank computer system.

Selection/issue of inappropriate component (20)

These errors involved issuing expired components or not selecting the correct antigen negative units for patients with known antibodies. It was of particular concern that some laboratories reporting other errors had not selected antigen negative units for the crossmatch yet did not report this as an error.

Case study 9

Acute renal failure as a result of Fya incompatibility

3 units were requested for a patient who had fallen downstairs and required urgent neurosurgery. The patient was O RhD positive and had an anti-Fy^a. Six units were crossmatched and 3 were found compatible and issued without Fy^a typing. The patient was transfused with all 3 units and then suffered renal failure and required ICU admission, definitely due to the transfusion. The patient recovered with no long term ill effects. The report states that the probable cause of the reaction was a transcription error in the result of the crossmatch and an incompatible unit was labelled as compatible. The laboratory does not seem to have considered the possibility that a crossmatch compatible unit could have been Fy^a positive (weak expression) and missed on the crossmatch. It is possible that the urgency of the situation did not allow for Fy^a typing, but Fy^a typing should have been performed retrospectively.

BCSH guidelines[37] state that 'Blood should be selected which has been tested and found negative for the relevant antigen' when there is a clinically significant red cell antibody. The guidelines do say that ' the recipient's need for immediate red cell support may dictate that pre-transfusion testing is abbreviated', but if this is the case this should be 'stated on the compatibility report.'

Incorrect serological reasoning (6)

This category includes the following examples: two cases where group O FFP was selected for group A patients. A case where RhD positive platelets were supplied by the regional Blood Centre for a RhD negative patient due to a shortage of RhD negative platelets. The hospital was apparently not informed of this. These were then issued to a RhD negative, 8 year old female without anti-D cover, by an unsupervised MLA. This resulted in the individual producing anti-D. All platelets are now issued by BMSs at this hospital. The third case is described below:

Case Study 10

Incorrect serological reasoning and technical errors combine to cause an incompatible transfusion

A 22-day-old baby was transfused with O RhD negative blood, despite a warning on the computer of maternal anti-c+E, because the BMS was of the mistaken belief that maternal antibodies did not persist for long after delivery. The BMS then went on to obtain a false negative antibody screen and a false negative crossmatch, no explanation was given as to the reason for these errors which were detected the following day.

It is of concern that this 22 day old neonate with anti-c+E was transfused routinely for anaemia of prematurity, outside normal working hours.

Clearing main and satellite blood refrigerators (7)

There were 7 errors in this category. Many involving the transfusion of expired units that had not been cleared from the blood bank.

Case Study 11

All blood banks must be cleared regularly

A unit of blood that had expired 2 weeks ago was transfused. It had been left in the blood bank refrigerator when unused previously. The nurses checked the day of expiry but not the month – it expired on 17th October 2000 and it was now the 1st November 2000.
To the question 'As a result of this error have there been recommended changes to transfusion procedures?' The answer was: 'SOPs rewritten to include checking expiry dates, nurses retrained'. Nothing was mentioned about laboratory staff failing to clear the blood bank. It is important that, when reviewing procedures in the transfusion chain, all links are examined.

Grouping errors (10)

There were 10 errors in blood grouping; 4 in ABO typing and 6 in RhD typing. Only 2 laboratories could give an explanation as to how these errors occurred. One was thought to be due to 'splash' when using a microplate method, which led to a false positive RhD type, and in one case the correct result was obtained but entered incorrectly into the blood bank computer.

Case Study 12

A manual transcription error results in transfusion of Rh incompatible red cells

A rapid group, antibody screen and crossmatch were performed for a routine transfusion during normal working hours. The group was performed correctly but a transcription error resulted in the wrong RhD status being recorded with the consequence that group O RhD positive red cells were issued to a group O RhD negative patient. The error was noted on subsequent routine grouping. The patient was transfused with one unit and survived with no ill effects.

Antibody screen errors (4)

There were 4 cases of antibody screen errors. No explanation could be found to account for the false negative antibody screens which resulted in a missed anti-D, a missed anti-c+E and a missed anti-c. RhD negative units were transfused in the first case and there were no adverse events following transfusion of c positive units in the other 2 cases. In 2 of the cases the BMS involved was retrained, and in another the BMS was relieved of on call duties until retraining was complete. All 3 cases occurred out of hours and all 3 errors were picked up on routine retest the following day. The case where anti-D was missed was for a routine colonoscopy yet was tested outside normal working hours. On one occasion the antibody screen was omitted, with no explanation.

Antibody identification errors (3)

These cases included a missed anti-c in the presence of an anti-E. Interestingly this blood was crossmatched for an elective total hip replacement and yet the laboratory obtained the sample too late to send it for antibody confirmation before surgery. Another case involved a missed weak anti-Fy^a in the presence of an anti-Lu^a. Both these errors were picked up by the reference laboratory when samples were sent for confirmation of antibody specificity, which was the usual policy of the laboratories involved. Neither patient suffered any adverse sequelae. The third case is given below:

Case study 13

Antibody identification error leads to a K incompatible transfusion

An on call BMS was asked to crossmatch 4 units for a patient with chronic renal failure and anaemia (Hb 60g/L). The antibody screen was positive and one of the units incompatible. He suspected that the antibody was an anti-S but the units were not S typed prior to issue. He contacted the senior house officer (SHO) and said that 3 units were compatible but one was not and that further investigation would take place the following morning during routine hours. The SHO asked for the compatible units to be issued forthwith. Approximately two hours after starting the first unit the patient exhibited a mild reaction of fever and malaise. This information was conveyed to the BMS and it was suggested that the transfusion should stop and the reaction should be reported and investigated. Investigation during routine hours identified the antibody as anti-K and the unit causing the reaction was K positive. The unit thought to be incompatible was in fact compatible.

This case was thoroughly investigated locally and sound recommendations were made based on BCSH guidelines. There were a number of errors:

1. The BMS did not follow the local procedure for issue of blood where the antibody screen is positive. In such cases the requesting doctor should be informed that compatible blood cannot be guaranteed and that if blood is required urgently it should be discussed with the on call haematologist. The SHO involved confirmed that he was not asked to delay transfusion but would have done so if asked.
2. The BMS did not type the units for the relevant antigen.
3. There must have been a transposition or transcription error during crossmatch as the single incompatible unit was labelled as compatible.

The BMS acknowledged the seriousness of his failure to adhere to written procedures but in mitigation pointed out that the error occurred at 01.40 am whilst he was busy and tired. Again, it is of interest that the transfusion could have waited until the following morning.

Crossmatching errors (7)

These included a case where a patient had known anti-E+K but the BMS failed to select E and K negative units and then obtained a false negative crossmatch by failing to add the plasma to the card IAT test. The patient recovered from the effects of intra-vascular haemolysis. Another case involved the transposition of samples from two patients with the same surname.

Telephoned request errors (1)

One incident involved a doctor telephoning a new requirement for irradiation and the BMS jotting this down on a notepad but forgetting to input it into the computer. As a result the laboratory policy was changed and a ‘Change of Requirements’ form must now be completed and faxed to the transfusion laboratory.

Labelling of blood components errors (5)

Labelling errors occurred, most commonly affecting platelet packs, which may indicate that less care is taken with labelling products that do not require serological testing. The labels for two packs were simply switched. One laboratory has since implemented a policy where 2 members of staff must check the labelling of platelets which, although a solution in normal working hours, may prove difficult out of hours when fewer staff are on duty. In all cases the initial error made by the laboratory was not picked up at the collection or administration stage.

Failure to detect errors made at the regional Blood Centre (2)

There were 2 instances where the blood centre failed to irradiate human leucocyte antigen (HLA) selected platelets and the hospital BMS then also failed to notice that they were not irradiated.
There was one instance where a CMV positive platelet was labelled ‘for neonatal use’, contrary to UKBTS “Red Book” guidelines[41] (see case study 16).

Errors in the collection and administration of blood components (172)

One hundred and seventy two errors occurred in 104 case reports (50% of all errors).

Collection of incorrect component (29)

Table 19
Collection errors according to grade of staff involved and whether or not a formal check was made at this stage (n=29)*

GRADE OF STAFF	FORMAL ID CHECK		
	Yes	**No**	**Unstated**
Registered Nurse	3	6	1
Unregistered Nurse	0	2	0
Porter	2	9	0
Theatre Staff	0	1	0
Other [1]	2	2	0
	7	**20**	**1**

* One reporter did not respond to this question
[1] 1 ODA; 1 doctor; 1 HCA (trained); 1 support worker

This is still a significant area of error but there appears to have been some improvement since last year with 29 errors this year compared to 46 reported last year. This year there are fewer cases in which the hospital is reporting lack of formal ID check at the point of collection. Although we cannot be certain, this could be because more hospitals now follow BCSH guidelines[4] and have a written protocol for collection of blood components that includes a formal ID check. The majority of errors in collection are made by porters and nurses and this presumably reflects the fact that these are the 2 main groups of staff responsible for blood component collection, although this is not certain due to the lack of denominator data.

This year there were 2 errors involving 'flying squad' emergency O RhD negative blood. In one instance 'flying squad' blood was taken and transfused to a neonate rather than the irradiated, crossmatched unit that had been prepared and was in the same refrigerator. In another instance, rather than collecting 2 flying squad units, one unit of O RhD negative blood and one unit of A RhD negative blood were taken. These units were then transfused into a group B RhD positive patient. The patient died from the underlying condition.
On 2 occasions blood crossmatched for maternal use was collected and transfused to her infant. In one case the doctor in charge made a clinical decision to transfuse in a medical emergency although the wrong unit (i.e. maternal) had been collected in error. This clinical decision was not in itself regarded as an error. On another occasion a nurse sent to collect 'flying squad' blood actually collected the blood crossmatched for the mother and it was transfused without any formal bedside check. Although laboratory staff do not feature in Table 19, they were involved in handing over blood components to porters without a formal check in at least 2 cases.

Failure of bedside checking procedure (82)

In one case in this category, a unit of blood was collected for the wrong patient from a satellite refrigerator in an emergency. The unit was checked against the paperwork which accompanied it but at no stage were any details checked against the patient's wristband or notes. The error was discovered approximately half way through the transfusion of group B RhD negative red cells to a group O RhD positive patient. This elderly man was already very ill and it is not clear whether this major ABO incompatible transfusion was partly responsible for his death several days later.

Table 20
Outcome of bedside errors (82)

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	9	1 [1]	3	1	0	0	0	**14**
RhD incompatible	5	0	0	0	0	0	0	**5**
ABO/RhD compatible[2]	28	0	2	0	0	0	0	**30**
Special requirements not met	21	0	1	0	0	0	2	**24**
Inappropriate transfusion	6 [3]	0	0	0	0	0	0	**6**
Anti D	3	0	0	0	0	0	0	**3**
Total	**72**	**1**	**6**	**1**	**0**	**0**	**2**	**82**

[1] Recovered from intravascular haemolysis
[2] includes 2 cases of right blood to right patient
[3] 4 x expired RBCs; 1 x expired platelets, 1 x wrong concentration of albumin

Table 21
Grades of staff involved in bedside incidents (n=82)

Grade of Staff	Number of cases
Registered nurse & registered nurse	51
Registered nurse and unregistered nurse	2
Registered nurse & doctor	1
Registered nurse and unknown	1
Registered nurse only	9
Doctor & doctor	1
Doctor & other [1]	3
Doctor & unknown	1
Doctor only	2
Other only [2]	1
Unstated	10

[4] O.D.A.
[5] Trauma team

This year we have introduced the category 'special requirements not met' for bedside errors (24 cases). This category refers to errors, made earlier in the transfusion chain, which it is felt should have been noticed by those staff performing the bedside check, either because it was written on the prescription, in the notes, or because staff on specialist wards, for example haematology/oncology wards or neonatal intensive care units (NICU), should have been aware of the patient's special requirements in terms of irradiation or CMV status.

If this category is excluded from the total, the number of bedside errors is 58, a reduction on the previous year's total of 87, suggesting, but by no means statistically proving, a reduction in the number of basic patient identification errors. It is interesting to note that many hospitals still have 2 person checking at the bedside, contrary to BCSH guidelines.[4] Without denominator data on the proportion of single versus two bedside checkers, it is impossible to make any further comments on the significance of these findings.

Case study 14

A bedside error highlights inadequate procedures and protocols

Two patients required blood transfusions on the same day. Blood for patient A was removed from a satellite refrigerator and checked in the treatment room by two nurses. One nurse then took the blood to patient B and commenced transfusion without any further checks. Fifteen minutes later an auxiliary nurse noted patient B to be flushed and unwell and summoned assistance. Transfusion was stopped and the patient treated for the transfusion reaction which resulted from transfusion with a group A RhD positive unit to a group O RhD positive patient.
The following issues were noted by the local investigator:

1. The procedure for the administration of i.v. fluids had not been followed and there was no procedure specifically for the administration of blood.
2. Blood had not been checked at the bedside nor had the patient's identity been confirmed against the blood component by either of the 2 nurses involved.

The hospital submitted a copy of their new policy to the SHOT office. It is felt that the document has some weaknesses and serves to highlight how difficult writing local policies can be. The procedure states:

1. 'Check the blood product prescription, the patient's name, date of birth, blood group, unit number of blood and expiry date with two nurses and against the prescription chart.
2. Check the patient's name and date of birth at the bedside on the patient's identity band.' Unfortunately the above statements do not emphasise the most important cross check of the **patient identification** on the **blood component** against the **patient identification** on the **wristband.**
3. Explain the procedure to the patient and obtain their consent – surely this should be done before the blood is brought to the ward so that the blood can be checked at the bedside and commenced immediately following the check. If the patient does not consent the blood could be out of the refrigerator for longer than the requisite 30 minutes.

The policy referenced articles published in 1992 and 1995. We urge staff to review policies based on **recently** published guidelines.[4]

Problems with identification wristbands

In 11 cases wristbands were missing although in 1 case this omission was not considered to have contributed to the mis-transfusion. Analysis of the circumstances revealed that 4 involved outpatients all of which were associated with bedside errors and 5 occurred in theatre together comprising approximately 82% of instances. In the 10 cases associated with bedside errors there were 4 ABO/RhD compatible, 3 ABO incompatible and 2 RhD incompatible transfusions.

Inappropriate transfusion episodes

There were 6 of these of which 4 involved expired red blood cells, 1 expired platelets and 1 wrong concentration of albumin.

Errors originating at the supplying blood centre

There were 8 errors in this category occurring in 7 case reports

- 2 x Transport errors.
- 2 x Failure to irradiate HLA matched platelets.
- 1 x Incorrect RhD typing.
- 1 x Supplied short expiry platelets over Christmas period despite request for longer expiry.
- 1 x Supplied inappropriate product.
- 1 x Did not follow Red Book guidelines in production.

Case Study 15

Failure to give clear delivery instructions initiated a chain of errors

A patient was admitted to A+E with gunshot wounds. The on-call BMS requested 10 units of red cells and 4 adult doses of platelets from the RTC. The blood components were delivered directly to A+E by a taxi driver. The patient had already gone for surgery and a porter took them to theatre where they were transfused to the patient. The on-call BMS contacted the RTC to enquire about the delivery and was told that all the components had already been delivered. The delivery note was tracked down in theatre and the empty packs returned to the blood bank later that

day. All components were transfused not only without any proper identification but also without any laboratory checks or audit trail.

Case Study 16

Erroneous labelling highlights an IT loophole

A unit of paediatric platelets was issued to a hospital. The label stated 'Platelets, apheresis, leucocyte depleted for neonatal use'. However the CMV status was not given on the bag. An inexperienced member of staff issued the unit and it was transfused. Subsequent investigation revealed that the unit was CMV positive and a 'loophole' in the NBS PULSE computer system allowed CMV positive units to be labelled up for neonatal use, contrary to the requirements of the UKBTS "Red Book" guide.[41]

Errors in anti D administration

Errors occurred at all points in the transfusion chain, as with blood components. These errors have been grouped together this year to give an overall picture of mistakes made in anti-D administration.
There were 17 errors in anti-D administration reported this year compared to 12 last year.
Three of these errors were due to laboratory errors in RhD typing and in one additional case it could not be ascertained whether there had been a grouping error or an error in taking the sample, as the sample was no longer available for retest. Further laboratory errors included: failure to check the RhD status of the baby prior to issuing anti-D (2 cases), issuing anti-D when anti-tetanus immunoglobulin was requested; a mistake which went unnoticed by the administering nurse, and issuing anti-D to a 'D^u positive' patient due to incorrect serological reasoning. National recommendations[7] are quite clear on this point: 'Women who have weak expression of the RhD blood group (D^u) do not form anti-D and do not therefore require prophylaxis.'

Two cases involved misidentification or no formal identification of the patient at the bedside resulting in the wrong patients being given anti-D.
Anti-D is often kept on maternity wards or in antenatal clinics. It is administered by the midwife/GP and is then entered retrospectively onto the blood bank computer. A number (6) of communication and clerical errors have arisen in this process including: administering anti-D based on a verbal blood group given by the patient (against the local, written protocol) which was found to be incorrect 5 months later; not checking the blood group prior to administration on 2 occasions; 2 cases where the RhD type of the patient had been handwritten incorrectly in the notes and a case where a 'negative' result was obtained from the laboratory computer but for an entirely different test, not the RhD status.
The final case contained multiple errors:

Case Study 17

Multiple errors resulted in inappropriate anti-D administration

250iu anti-D was requested for a patient who was stated in error to be RhD negative and had suspected abdominal trauma at 34 weeks gestation. The laboratory staff, realising that the requested dose was incorrect, issued a 500iu dose of anti-D, but failed to check the historic group of the patient which was RhD positive, and also failed to request a repeat sample.

This case contains a number of errors: 2 requesting errors (the wrong RhD type and wrong anti-D dose given on the request form); 2 laboratory errors (failure to look up an historic blood group and failure to ask for a sample for fetomaternal haemorrhage estimation (FMH) – which would have been required had the patient been RhD negative). Recommendations[7] are again clear on this point: 'For all events after 20 weeks gestation 500iu anti-D Ig should be given followed by a test to identify FMH greater than 4mL red cells; additional anti-D Ig should be given as required.'

Errors which did not fit into existing categories (13)

There were 13 errors in 11 cases which could not be placed into existing SHOT error categories and they highlight some important issues.

- Two cases involved the infusion of albumin. Although these cases did include a bedside administration error, as the expiry of the albumin should have been checked at the time of infusion, the primary error was in poor stock control and it was impossible to determine who was responsible for maintaining the stock. Stocks of albumin and all blood products must be properly maintained and have a complete audit trail. A written protocol must be in place which clearly defines responsibility for a task.

- Two cases involved communication failures between the ward and the hospital laboratory. The SHOT standing working group is discussing whether 'communication failure' should be a category in subsequent reporting years as poor communication does contribute to a number of IBCT cases.

- One mis-transfusion probably occurred as a result of a Hb result having been recorded incorrectly in the notes, again showing that simple clerical errors can have serious consequences.

- One case involved a patient with duplicate registrations. The sample and request form were correctly labelled and matched the details on the hospital database. However, following computer checks 6 weeks later, it was found that the patient had been registered twice with two different dates of birth. Two members of staff has checked the units at the bedside but had failed to note the incorrect date of birth, which was later than the patient's real date of birth by 25 years. This was a case of right blood to right patient and the patient suffered no ill effects.

- There were a further 7 errors 3 of which involved invalid Hb results leading to unnecessary transfusions but for which the reason for the invalid result was not known and 4 in which the source of the error could not be determined.

Outcome

Of the 190 fully analysed cases there were 26 cases of major ABO incompatibility, including 1 case which was also RhD incompatible. There were 17 cases of RhD incompatibility, 8 cases where other red cell antigen incompatible transfusions were given, and 47 incidents which resulted in ABO and RhD compatible transfusions of which 3 were cases of "right blood to right patient" despite procedural errors.

The remaining cases comprised 50 cases of failure to provide for special requirements (42, non-irradiated, 5 not irradiated and not CMV negative and, 3 not CMV negative), 17 cases of anti D immunoglobulin given in error and 24 cases of an inappropriate or wrong component transfused. There was additionally 1 case where the laboratory issued O RhD positive platelets for a patient who had received a group A RhD positive bone marrow transplant.

- 1 death was possibly related to major ABO incompatibility and two others possibly related to an unnecessary transfusion
- 19 patients died of causes unrelated to the transfusion incident
- 3 patients recovered from the effects of intravascular haemolysis
- 1 RhD negative female of child-bearing potential was exposed to RhD positive red cells and produced anti-D
- 2 patients suffered major morbidity as the result of other red cell incompatibility
- 160 patients survived with no lasting effects
- in 2 cases the reporter did not state the outcome of the patient

The outcome of all IBCT cases is summarised in Table 22

Table 22
Outcome of cases of IBCT (n=190)

Category	Survived/ no ill effects	Major morbidity	Died unrelated to tx.	Died possibly related to tx.	Died definitely related to tx.	Outcome unknown	TOTAL
Major ABO incompatibility [1]	17	3 [2]	5	1			**26**
RhD incompatible	15	1 [3]	1				**17**
ABO/RhD compatible [4]	42		5				**47**
Other red cell incompatibility	6	2					**8**
Inappropriate transfusion	20		2	2			**24**
Special requirements not met [5]	42		6			2	**50**
Anti-D	17						**17**
Other	1						**1**
Total	**160**	**6**	**19**	**3**	**0**	**2**	**190**

[6] Includes 1 case which was also RhD incompatible
[7] Recovered from intravascular haemolysis
[8] RhD sensitisation in female of child bearing potential
[9] Includes 3 cases of procedural failure but "right blood to right patient"
[10] CMV negative/irradiation

Procedural review

Table 23
Hospital Transfusion Committees (n = 190)

Number of responses	Response
4	No response
112	No, but will be discussed at a future meeting
63	Yes
7	No Transfusion Committee in place
3	Unknown
1	No Transfusion Committee but will be discussed

Table 24
Summary of changes made to policies/procedures

Number of changes	Summary of change
46	Changes implemented to documentation; collecting, handling; laboratory techniques/procedures; ward procedures/protocols; administration
16	Implementation of new/additional training
23	Review of existing policies/procedures/protocols
6	Upgrade or renewal of equipment, including computer
12	Reiteration of existing procedures
1	Hospital Transfusion Committee to be established
1	More clinical for vetting of blood components
3	Patients issued with cards highlighting their need for irradiated blood

Table 25
Summary of comments made by reporters who said that no changes had been made or who did not respond to the question

Number of comments	Summary of comments
7	Procedure correct/no changes made but staff retrained
1	Case being reviewed by Hospital Incident Panel, likely to recommend appropriate remedial measures
2	No changes made but SOPs reinforced
5	No changes made but guidelines are under review
3	Reiteration of existing procedures
1	Recognise the need for improved communication
2	No but Transfusion Committee to review
1	Corrective action taken
2	Review pending
1	Equipment fault pending
1	Simple case of hospital procedure not being followed
1	Ongoing problem in a very active haematology unit

COMMENTARY

- This is the fifth consecutive year in which the single most important cause resulting in mis-transfusion was failure of some aspect of the bedside checking procedure (82 out of 344 errors or 23.8%). 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. The most common error in this category is still checking the unit for transfusion away from the bedside, contrary to recent BCSH guidelines.[4] It is not possible to draw conclusions from available data regarding the safety of one or two person checking procedures.

- *Multiple errors in 52.4% of reports indicate that problems still exist at all levels of the complex, multi-step, multi-disciplinary transfusion chain.*

- The withdrawal of the wrong component from its storage location continues to be a problem. The majority of errors in collection are made by porters and nurses and this presumably reflects the fact that these are the 2 main groups of staff responsible for blood component collection, although this is not certain due to the lack of denominator data.

- It is still not universal practice to use unique patient identification wristbands at the bedside. Nine of the 10 instances where wristbands were missing, and were felt to have contributed to the wrong blood incident, were in outpatient departments and theatres.

- There were 33 failures to request appropriate components for blood transfusion of which the most common was failure to request irradiated components for those patients at risk from TA-GVHD. Contributory factors included failure to supply relevant clinical information on request forms and failure of communication between hospitals when transferring patients. In addition it is suggested that supplying patients with important information regarding their treatment might mitigate against errors of this type.

- Laboratory errors contributed 29.1% of total errors. Errors were made both during routine hours (53%) and out of routine hours (36%), with 11% of cases not giving the timing. They affected emergency (34.7%) and routine (59.4%) requests for transfusion with 5.8% of reports not stating the circumstances of the error. Errors were made both by BMSs who work regularly in the blood bank and by those who did not. However, lack of basic denominator data on the timing and location of errors does not allow any further interpretation of these findings. There are still occasional instances of unqualified members of staff issuing blood components. A number of errors are also occurring in the issue of Hb results from haematology laboratories.

- Due to the lack of denominator data no firm conclusions can be drawn regarding the circumstances surrounding laboratory errors. Routine laboratory tests are inherently safer than rapid techniques, which are usually manual and require manual entry of results and thus open up opportunities for transposition, transcription and technical errors. There are a number of instances this year in which rapid techniques were used for routine transfusions, presumably because samples were not sent to the laboratory in a timely fashion. Similarly a number of errors that occurred out of hours were for routine operations. Case 6 in the Delayed Transfusion Reaction chapter (Chapter 14) also falls into this category.

- Some laboratories do not appear to be following BCSH guidelines[37] with respect to pretransfusion testing and may be putting patients at risk. Cases 2 and 38 in the Delayed Transfusion Reaction chapter also appear to fall into this category. This ties in with recent figures from the NEQAS BTLP 'Urgent Antibody Screening and Compatibility Testing Procedures' questionnaire which states that 2% of participating laboratories do not comply with guidelines because they rely entirely on the serological crossmatch to establish compatibility, in urgent situations, with antibody screening taking place retrospectively.

- There was no explanation for the majority of laboratory errors and, as a result, in many cases no changes were made to SOPs. More commonly existing SOPs were simply reiterated to staff or staff were given retraining.

- Thirty one errors (31%) were in the categories 'failure to consult/heed historical record' and 'selection/issue of inappropriate component'.

- Errors in administration of anti-D are a cause for concern with mistakes being made throughout the transfusion process.
- Sampling errors remain a small but significant cause of 'wrong blood' incidents whilst errors in Hb samples contributed to a number of unnecessary red cell transfusions.
- Communication problems, including failure by the NBS to give clear delivery instructions to their drivers, contributed to a number of errors.

RECOMMENDATIONS

As in all four previous years the category of "incorrect blood component transfused" represents the highest number of reports (213 or 68.9% of 309 new reports), an increase of 6% over the previous year. Once again, mistakes in collection from the hospital storage site/bedside administration comprise the majority of errors.
There is some suggestion that the rate of rise of new reports may be slowing down and that procedures for formal identification at the point of collection and at the bedside may have improved. It is tempting to surmise that these apparent improvements have arisen as a result of better education and application of new guidelines. However, as SHOT lacks accurate denominator data on blood transfusion practices, there is no statistical evidence to substantiate this and it remains the case that SHOT data points to continuing significant problems in ensuring the safety of the transfusion process.

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 will come as no surprise that, 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.

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

Existing procedures should be re-examined for flaws which could lead to systems errors. HTCs should play a key role in this process and should be managerially empowered to do so.
In line with the Department of Health publication "An organisation with a memory"[3] positive learning outcomes, such as highlighting and changing unsafe practices, must be sought from analysis of errors.

It is essential that every institution where transfusions are administered becomes familiar with and puts into practice existing guidelines in the field of blood transfusion to minimise the possibility of human error.
Great care must be taken by hospitals when writing local protocols, based on National Guidelines, to ensure that they are accurate, concise, user friendly and readily available for reference by all staff.
Medical and nursing staff working in specialised units, for example haematology/oncology wards and NICU, must be aware of local and national protocols relating to special transfusion requirements for their patients. It is the responsibility of senior staff in these areas to bring special requirements to the attention of junior staff.

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

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

Every patient should be uniquely and positively identified using a wristband or equivalent and there should be no exceptions.
A single, unique identifying number should be used.

Computerised systems are available which will reduce the opportunities for errors at the bedside. Pilot studies of such systems are underway in the UK.
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[3] and in a recent Audit Commission report[5] the Department of Health recommendation that steps should be taken to reduce these by 40% by 2005 was reiterated.

Blood banks must continue to be vigilant in reviewing procedures and systems to ensure that they all meet current guidelines. Ongoing staff training is essential to prevent errors in the laboratory.
Transfusion laboratory computer software should be improved to offer better warnings when the component chosen for issue does not meet requirements. For example when 'irradiation' is in a special requirement field it would be helpful if the system could warn the BMS if the selected unit does not have an irradiated component code. A similar warning would be beneficial when a patient has, for example, anti-K in an antibody field if the selected unit is not K negative. Warnings could also be applied to the issue of anti-D based on values in a 'gestation' field, a 'blood group' field and the 'baby's blood group' field.

Hospital transfusion laboratories must have protocols for the timely removal of expired blood from blood banks.
Checking the expiry date remains an important element of the bedside checking procedure to back this up.

Individuals responsible for the prescription and request of blood components must be familiar with the special needs of their patients. These should conform with BCSH and other guidelines and special requirements should be flagged on the clinical and laboratory records.

1. There must be a clear line of clinical responsibility for ensuring that transfusion records are transferred with a patient when they are moved between hospitals, often a referral centre and a local hospital. This must include records for intra uterine transfusion in which instance a copy of the mother's notes should accompany the neonate.
2. Clinicians must ensure that patients are aware of their own special requirements which should be passed on to any other clinician whom they consult. Cards are now available for patients to carry, which Trusts can obtain from the National Blood Services of England and Scotland. These should be issued to patients by their clinicians at the earliest opportunity. If appropriate, other departments within a hospital may be brought into the process in order to improve safety, for example, pharmacy as the issuers of purine analogues.
3. Registration of fetuses may be something that should be investigated as a means to improving neonatal transfusion safety.
4. Guidelines published on the clinical use of red cell transfusions[6] should be disseminated more widely to prescribing medical staff. Every hospital must also have a robust policy for the prescription and issue of anti-D which must be based upon joint BBTS/RCOG recommendations[7] and must include a requirement for printed confirmation of the RhD status of the patient.

Personnel responsible for taking samples for any laboratory test must at all times follow strict procedures to avoid confusion between patients.
This means that samples should be taken one at a time and labelled at the bedside after positively identifying the patient. Sound phlebotomy procedures must also be followed in order to obtain a true sample, for example avoiding dilution of Hb samples.

Telephoned requests for blood components must be formally recorded and incorporate all relevant information including special requirements.
Great care must be exercised when acting on verbal results. Local written SOPs must be in place for dealing with telephone requests.

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

12. 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.

All hospitals in the UK have been encouraged to report "Near Miss" events to the SHOT Scheme for the last reporting year and simple report forms were issued to all hospital blood transfusion laboratories for this purpose. Disappointingly only 121 hospitals from a possible 413 (29%) have supplied data during this reporting year and this is analysed below. These hospitals supplied 452 reports.

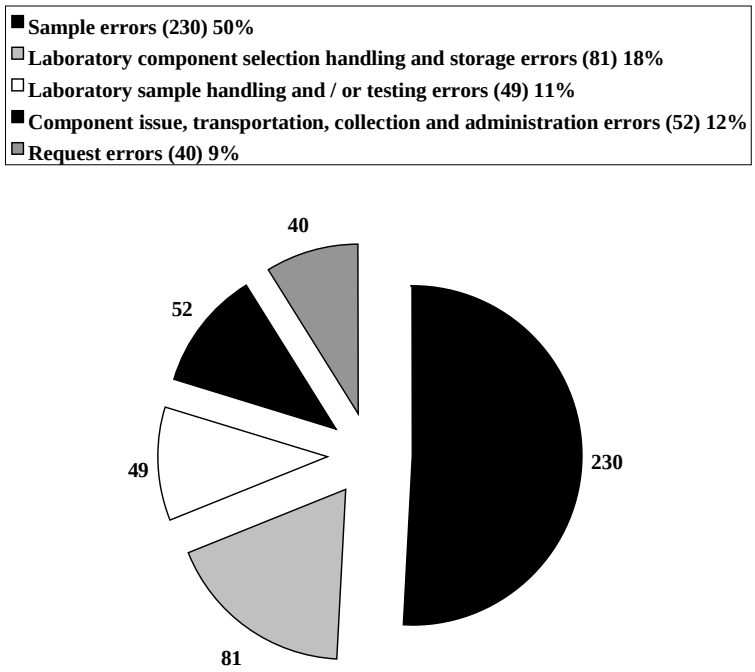
The DoH document "An organisation with a memory",[3] which was the report of an expert group on learning from adverse events in the NHS, recommended that all hospitals should have a system of recording, evaluating and learning from near miss events as these are more frequent than "real" errors, but often have the same root causes.

Whilst error and "Near Miss" reporting are relatively new developments in the NHS, the advantages are now well recognised and all hospitals should have such systems in place as part of an overall risk management strategy. Increased participation of hospitals in this confidential and anonymous "Near Miss" reporting scheme would enable a more comprehensive database to be established to evaluate incidents from a more representative national perspective.

Categories of "Near Miss" events reported (452)

The "Near Miss" reporting process comprises a form for different categories of events, 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 the scheme are described in the key to figure 21.

Figure 21
Near Miss Events October 2000 – September 2001 (n= 452)



Sample errors (230)

As in previous "Near Miss" surveys, errors of phlebotomy and/or sample labelling dominated the reports submitted, comprising 50% of total reports.

Poor practices on 113 occasions resulted in samples being labelled with the intended patient's details but which, because of the finding of a different blood group in historical records, subsequently confirmed on repeat samples, showed that the original sample must have been obtained from another patient. It was also reported that in a further 110 instances the correct patient had been bled but the samples labelled with another patient's details. On 7 other occasions the reason for the blood group discrepancy could not be conclusively identified.

Failure to follow phlebotomy protocols where the patient confirms their identity, the wristband is checked and samples are labelled at the bedside is a serious cause for concern. In 197 cases these errors were detected in the laboratory whilst in 26 cases the person who performed the phlebotomy realised later and notified the laboratory of their concerns. On 7 occasions the errors were not realised until the final bedside check.

Incorrect patient addressograph labels on 17 samples were reported, despite Guideline recommendations that addressograph labels should not be used to label samples.[37] The contribution of incorrect addressograph labels being used on request forms, with subsequent transcription of incorrect details to samples, was not possible to determine, although this problem was reported on several occasions. Addressograph labels for incorrect patients were found in case notes on 2 occasions.

Whilst on 133 occasions medical staff were identified as having taken the sample, at least 82 samples were thought to have been obtained by nursing staff, trained phlebotomists or other staff involved in phlebotomy. This may reflect the increasing role of nurse practitioners in clinical areas and the use of "clinical aides" for general ward functions, including phlebotomy.

Fifty-five samples (24%) were bled at times identified as not in routine working hours, and 10% of sample errors were related to blood collected in A/E Departments.

Request errors (40)

This category comprised 9% of total "Near Miss" reports, and contained 18 instances where components were requested for the wrong patient. On 5 occasions incorrect components were requested, whilst for another 8 patients the need for special requirements was not specified, although these omissions were recognised before transfusion occurred.

Incorrect details given by telephone caused 13/40 errors, with 23 instances of incorrect information being specified on request forms. The majority of errors were made by medical staff.

On 5 occasions red cells were requested for transfusion on the basis of erroneous low Hb results:

- a telephoned result of the white cell count was interpreted as the Hb level
- a misheard telephone result
- a result from a sample collected near to drip site and diluted blood obtained
- mistakenly using pre operative Hb as a basis to order blood in post operative situation
- venepuncture performed using a 60 mL syringe and blood dispensed into bottles with inadequate mixing leading to a false low Hb result

In all these instances over transfusion was prevented by the vigilance of the blood bank BMS in reviewing the need for transfusion.

Laboratory sample handling/testing errors (49)

A variety of sample handling and technical errors, comprising 11% of the total, were reported in this category, mostly involving qualified BMS staff. Clerical or transcription errors caused 14/49 problems, whilst 23 were reported to be caused by poor technique and failure to follow protocols. In 4 instances wrong patient samples were selected for testing.

- Incorrect interpretation of the blood group from visual inspection of column technologies occurred on 2 occasions, whilst 3 errors were caused by automated blood grouping equipment problems. These were:
- a report where 6 RhD negative patients were falsely typed as RhD positive by an automated system utilising column technology.

- a barcode read error resulting in transmission of results to an incorrect patient record.
- an erroneous blood group result of AB was interpreted automatically, cause unknown, and the incorrect group interpretation was then transmitted to the laboratory computer record. The incorrect group was not compared with an existing provisional blood group in the computer record, and the error was not recognised until a further sample was received 2 months later.

On 1 occasion a unit of red cells was issued by a Blood Transfusion Centre as irradiated, but the attached irradiation indicator label showed the unit had not been exposed. This was recognised by the hospital laboratory before use.

An unusual problem was reported as occurring twice on blood donations supplied from the same Blood Centre. Apparently during component preparation the red cell pilot tubing had become separated from the main bag and, contrary to protocols, had been reconnected using a sterile connecting device, unfortunately to the wrong bags. Subsequent crossmatching demonstrated incompatible results due to ABO incompatibility when the red cells in the pilot tubes were found to be group A, whilst the label on the bag was group O, as were the red cells in the bag.

Laboratory component selection, handling and storage errors (81)

Eighteen percent of all events were reported in this category, although 44/81 were related to incorrect storage of components in clinical areas with the potential for damage to the component involved. On 3 occasions platelets were stored overnight in a blood bank refrigerator within theatre areas, and would not have been clinically effective if transfused. All these components were consequently wasted.

There were also 18 instances where the laboratory issued components without ensuring that special requirements e.g. irradiated or CMV antibody negative components, were provided. These avoidable lapses were detected by bedside checks before administration of components.

Three relevant serological problems were reported

- red cells were crossmatched with no problems and issued for use, but at the bedside it was realised the patient had a blood group card stating that they had an antibody capable of causing severe intravascular haemolysis. The patient had been transferred from another hospital with no information provided to the laboratory.
- when blood was being checked at the bedside prior to transfusion, a relative notified ward staff of difficulties at another hospital in providing blood for transfusion. Upon examining the case notes a laboratory report of anti-Vel was found and the blood bank notified. Frozen/thawed Vel negative red cells were provided to avoid a potentially serious haemolytic event.
- red cells were crossmatched with no problems for a patient with anti-D + E. A pyrexial reaction with the first unit caused the laboratory to review the serology when it was realised that one of the units which had been issued but not yet transfused was a r''r (cdE/cde). The anti-E was found to be not detectable in the laboratory testing.

Thirty eight percent of problems occurred outside normal laboratory working hours.

Component issue, transportation and patient identification errors (52)

The collection of components for the wrong patient has been a significant concern in previous SHOT reports, and 20 instances of this problem were reported this year. In at least 8 of these cases red cells were collected for a different patient with the same surname, sometimes despite written details with full identification being taken to the laboratory when collecting blood components. Other problems arose because no details were known by the collector except the patient's surname. These errors were detected by the bedside checking procedures before administration of the red cells to patients. In 3 instances intravenous infusion had been commenced but ward staff realised the error and stopped the infusion before the red cells actually reached the patients.

Lack of correct transportation was recognised on 14 occasions, with poor control of stocks in remote blood banks being reported on 4 occasions. On 2 occasions red cells were inadvertently transported in insulated boxes with dry ice from previous FFP storage, but the partially frozen red cells were detected before use.

COMMENTARY

- Phlebotomy problems are again the single largest group of errors reported (50% of all reports), but because of the increasing numbers of patient records stored on laboratory computer systems, many of these "wrong patient" samples are being detected before results or components are issued. Even so, sample errors involving patients not previously tested or with the same blood group will not be detected, with the potential for ABO mismatch upon transfusion. The control of phlebotomy within hospitals is increasingly no longer the responsibility of the laboratories and appropriate training may consequently be minimal.

- Addressograph labels are still being used in a few hospitals to label samples. Manual transcription of patient details onto samples is thought to ensure improved checking procedures. The use of addressograph labels to identify patients on request forms contributed to several sample and request errors and care must be taken to ensure that the correct labels are used.

- Hand held computer technologies, associated with the scanning of bar coded patient wrist bands and bedside production of sample labels, may be of value in reducing patient identification errors during phlebotomy. These systems are currently being introduced into some hospitals.

- Laboratory staff reviewing pre-transfusion Hb levels prevented four instances of unnecessary transfusion of red cells. Clinical Guidelines for appropriate red cell transfusion requirements have been published,[6] and with the increasing recognition of associated hazards and the possible reduction in future blood supplies, all Hospital Trusts must introduce measures to ensure that the unnecessary transfusion of any blood component is avoided. Laboratory BMS staff should be alert to monitor that requests for transfusion appear appropriate, and refer cases to laboratory clinical staff for advice where necessary.

- The use of automated blood grouping equipment is increasing rapidly and it is interesting to note that 3 instances of errors relating to such equipment have been reported. The frequency of such errors is unknown, but laboratory staff must be aware that automated equipment may have deficiencies or intermittent problems, which could produce rogue results. Guidelines for the validation of equipment have been published.[42]

- On 2 occasions potentially serious intravascular haemolytic incidents were only avoided when it was realised at the bedside that antibodies had been found at previous hospitals, but the information had not been passed onto the laboratory when the patient was transferred. Unfortunately laboratories do not often know of patient transfers and patients are not always issued with blood group cards containing antibody information.

- Wastage of blood components by incorrect handling, storage and transport in clinical areas was a major concern and resulted in disposal of the components involved. This lack of awareness by clinical and ward staff increases the risk of damage or bacterial contamination of components, with potential serious consequences for recipients, as well as being wasteful of a valuable and increasingly limited resource.

RECOMMENDATIONS

- **Strict adherence to phlebotomy protocols is essential with verbal confirmation of patient identity at the bedside, checking of patient wristbands, and the labelling of sample tubes at the bedside rather than remote from the patient. Appropriate training is necessary to ensure that this basic function is performed accurately and reliably.**

- **These basic principles of phlebotomy good practice should be applied to the labelling of all types of blood samples. Erroneous results from a mis-labelled FBC sample, for example, may result in inappropriate transfusion.**

- **With the increasing devolvement of phlebotomy control to clinical areas, clear responsibilities for training must be established and maintained.**

- **BMS staff could usefully monitor the appropriateness of some transfusion requests, referring to laboratory medical staff when necessary.**

- **Lack of knowledge of the care and precautions necessary in the handling, storage and transport of blood components is evident among nursing and medical staff. Education and training is necessary to ensure that maximum benefit to patients is maintained, and that components are not damaged by mishandling or inappropriate storage, thereby possibly comprising patient safety.**

13. 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 11

This category accounted for 11.9% of non-infectious hazards reported and 11.7% of all hazards.
Thirty seven initial reports (all new) were received. In addition a further 7 reports were received which were felt not to fit the definition of ATR or which were subsequently withdrawn by the reporter.
This chapter highlights the main findings from 31 completed questionnaires.

Overall there were 6 deaths in this group, of which one was thought to be definitely due to the transfusion, 3 were felt to be unrelated to, and 2 possibly related to, the transfusion. The remaining patients survived without long-term sequelae other than one patient with ongoing malaise.

Gender (31 reports)

Males	10
Females	21

Age (31 reports)

Age range	1 month - 86 years
Median	65 years

Components implicated (31 reports)

Red Cells	13
Red Cells and Platelets	1 (apheresis platelets)
Fresh frozen plasma	7
Platelets	10 (of which 2 were apheresis units and 8 were pools)

Leucocyte-depleted components were transfused in all patients.

1. Reactions in which red cells were implicated

There were 13 cases and 11 survived, one with persistent debility. Eleven reactions occurred during the transfusion, one occurred within 2 hours of completing the transfusion and one at 8-12 hours. Two patients died, in one case due entirely to the underlying disease and in the second, who had pulmonary complications, the death was probably unrelated to the transfusion. The following reactions were seen:

Table 26

Reaction type	Number of cases
Haemolytic or incompatibility reaction	6
Anaphylactic[+]	2
Allergic[++]	2
Pulmonary oedema	1
Hypoxia + acidosis (neonate)	1
Hypertension	1

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

Haemolytic or Incompatibility Reactions

In 6 cases the reaction was felt to be acute haemolysis or a febrile reaction due to red cell incompatibility (antibody demonstrated).

Case 1
This 20 year-old female had undergone an unrelated bone marrow transplant for acute myeloid leukaemia (AML) 6 months prior to the incident. The donor was Group O and the patient group A. Post-transplant she had received A RhD positive red cells, apparently without incident. Ten days after her most recent Group A transfusion she presented with a Hb of 55 g/L, platelet count of 3 x 10^9/L and a bilirubin of 38μmol/L. Three A positive units were cross-matched at the local Transfusion Centre and she received an apheresis pool of platelets (group and timing not stated). During the third unit she developed dark urine but was otherwise asymptomatic. Subsequently she was shown to have weak anti-A1, strong complement coating and a cold autoantibody. The blood was not given through a blood warmer (ward unaware of cold-autoantibody). The transfused units were apparently shown to have been Group A2 and the ABO mismatch was therefore thought not to be the cause of the haemolysis. Subsequent transfusions through a blood warmer, in a warm environment were effective but the patient died due to a pulmonary embolism $2^1/_2$ weeks later. The reaction has been ascribed to "exacerbation of cold-antibody mediated AIHA". It is not clear if haemolysis due to an incompatible platelet transfusion has been excluded.
There are a number of uncertainties over this case. In view of the time since transplant it would be anticipated that Group A red cells would be incompatible in this patient due to presence of donor anti-A. Indeed she was shown to have anti-A1 which would be consistent with her becoming group O. It is not clear if her "cold autoantibody" may, in fact, have been anti-A of donor origin. It would be surprising if all three red cell units were Group A2 – the frequency of A2 is about 20% and there is therefore a 1 in 125 chance of randomly selecting 3 A2 units. As the group of the platelet unit is not given it is not clear if there may have been a contribution to haemolysis from this – for example if a Group O, high-tire haemolysin unit was given.

Case 2
This 75 year-old female with CML who had required several recent transfusions, received 3 units of red cells and developed fever, rigors, restlessness, vomiting and diarrhoea during the third unit. Initial investigation revealed a raised bilirubin and haemoglobinuria but the patient was allowed home after overnight observation. 5 days later she was readmitted with renal insufficiency, requiring dialysis and remains more frail and less able to manage than previously. Serological investigation revealed no evident cause. The patient was DAT positive (IgG) pre- and post-transfusion. Investigation of pre- and post-transfusion serum (including autoabsorption) revealed only a non-specific autoantibody with no underlying alloantibody. It is presumed that this patient experienced exacerbation of auto-immune haemolysis although it is not clear to what degree haemolysis was apparent before the transfusion.

Case 3
This 25 year-old female with sickle cell anaemia was generally unwell with a Hb of 70 g/L. Two units of red cells were transfused, followed by a further 2 units 9 days later (Hb 40 g/L). Two days later an automated red cell exchange was performed. This raised the Hb to 110g/L but within 5 days her Hb had again fallen to 30g/L. A diagnosis of hyperhaemolytic transfusion reaction was made and a further 2 units were given with steroid and intravenous immunoglobulin (IVIgG) cover. The patient stabilised with this approach. Throughout this period the antibody screen was negative and the DAT remained negative apart from immediately post IVIgG. Fourteen units of donor red cells had been destroyed over a period of 17 days. Acute haemolytic episodes are seen occasionally in sickle cell anaemia patients and may not, in fact, be due to the transfusion per se.

Three patients had haemolytic or febrile reactions which may have been due to red cell incompatibility.

Case 4
This patient developed fever, rigors, dyspnoea and restlessness during transfusion but had no evidence of haemolysis. A positive DAT and anti-Wra was detected in the post-transfusion sample. This antibody is rarely a cause of haemolysis but no other cause was found in this case.

Case 5
This patient experienced a febrile transfusion reaction and was found to have become DAT positive but without evidence of haemolysis. Anti-E had been detected in the pre-transfusion sample but a post-transfusion sample was shown to contain anti-Jk^b in addition. The patient had been recently transfused (2 weeks previously) and the subsequent pre-transfusion sample was drawn less than 48 hrs before the transfusion. The pre- and post-transfusion antibody screen and identification were carried out using the same column technology. The Jk^b status of the units was not stated. Unfortunately the timing of the post-transfusion sample was not given and so it is not clear how rapidly this second antibody appeared.

Case 6
This elderly patient with myelofibrosis and hypersplenism had anti-E and anti-Kp^b detected in the pretransfusion sample and was therefore being transfused with recovered frozen red cells. She was DAT positive but had no recent transfusions. During the transfusion of a second unit of washed, deglycerolised red cells she developed nausea, vomiting and jaundice. The pre-transfusion bilirubin level was not stated and it is not clear how quickly the bilirubin rose to the stated value of 150µmol/L. She presumably had a degree of underlying haemolysis and/or sequestration due to her splenomegaly. A post-transfusion sample, investigated at the RTC, was shown to contain only a weak auto-anti-D in addition to the alloantibodies. The cause of this reaction is, therefore, unclear.

Anaphylaxis

Two patients developed a severe anaphylactic reaction during a red cell transfusion. In one of these cases a transfusion of platelets on the previous day had also caused anaphylaxis (reported to SHOT) but the true nature of this was only recognised when the second event occurred. Investigation revealed only anti-Gm (no additional details supplied by reporter). It is not clear if anti-Gm alone can cause anaphylaxis although this antibody was considered causative by the reporter. Washed red cells and platelets in Platelet Storage Medium have been given on many occasions since without adverse reaction.

Allergic reactions

There were 2 apparent allergic reactions in this group

Pulmonary Oedema

Case 7
This 75 year-old man received 2 units of red cells for bleeding from a gastrointestinal tumour. During the transfusion he developed fever, rigors, back pain and dyspnoea. A chest X-ray revealed pulmonary shadowing (?oedema, ? adult respiratory distress syndrome). He deteriorated and died soon afterwards. Cultures from the pack grew coagulase negative staphylococci, as did post-mortem cultures from the patient but these were felt to be of doubtful significance. The cause of death was given as cardiac failure due to ischaemic heart disease. There were no antibodies detected in the red cell donors although the patient had "a white cell antibody reaction in the serum". The reporter felt that the absence of donor antibodies excluded TRALI although this is not necessarily the case. It was felt, on balance, that this reaction was secondary to a cardiac ischaemic event, resulting in cardiac failure.

Hypoxia and Acidosis in a Neonate

Case 8
This four week old preterm infant (weight and gestation not stated) was transfused with 10-15 mL from the third aliquot from a 3 week-old paedipack. The infant became hypoxic (O_2 saturation 40%) and acidotic, and was managed with an infusion of sodium bicarbonate. No investigations seem to have been performed on the neonate or on the pack, other than a pack pH, which was 6.7. This is not exceptionally low for a unit of stored red cells and would not be expected to lead to acidosis, particularly in the setting of a slow top-up transfusion. In view of the inadequacy of the investigations performed, a transient acute lung injury or bacteraemia cannot be excluded.

Hypertension

Case 9
A 34 year-old female with a gastric tumour became hypertensive during a red cell transfusion in a hospice. The second unit was commenced without managing the hypertension and had to be discontinued after 100mL. The cause of the hypertension was not elucidated.

2. Reactions in which FFP was implicated

There were 7 reports in this group, four reactions occurring during transfusion and 3 within 2 hours of completion.

Table 27

Reaction type	Number of cases
Anaphylactic	3
Allergic	2
Hypotension	1
Cardiac Failure	1

Anaphylactic/anaphylactoid reactions

There were 3 patients in this category. One received FFP prior to undergoing endoscopic retrograde cholangio-pancreatography (no coagulation details given), one received FFP before surgery for haematuria (again no coagulation status given) and a third patient had just completed 2 units of FFP for management of post-cardiac surgery bleeding. The first 2 patients recovered from anaphylaxis with no ill effects but the third patient died 48 hours later from ongoing haemodynamic problems, having been resuscitated with multiple episodes of defibrillation.

Allergic reactions (not anaphylaxis)

Two patients suffered apparent allergic reactions, one with pruritic rash and restlessness and the second with rash, dyspnoea and angioedema. Both patients received FFP for excessive warfarinisation without bleeding (see below).

Hypotension

Case 10
This 56 year-old female patient who was not on angiotensin converting enzyme inhibitors and with no other recognised predisposing cause developed hypotension during plasma exchange for Guillain-Barré Syndrome. The plasma exchange was carried out using hetastarch and FFP as the replacement fluids (in equal volumes). Patients with Guillain-Barré syndrome may have autonomic instability which may be exacerbated during plasma exchange and it is therefore unclear to what extent the FFP administration contributed to the reaction. In addition, it is not clear that FFP was indicated in this case (see below).

Cardiac Failure

A 68 year-old female patient with haematuria due to excessive warfarinisation developed cardiac failure within 2 hours of completing an infusion of 2 units of FFP, presumably due to fluid overload. She recovered without ill effects.

Inappropriate use of FFP

Three patients received FFP for warfarin overdosage (with bleeding in one). One experienced an allergic reaction with angioedema, a second developed a pruritic rash and the third developed cardiac failure. The guidelines on management of anticoagulation[8] suggest the use of prothrombin complex concentrate may be more appropriate in over-warfarinised patients who have life-threatening bleeding but this may not be immediately available in some smaller or more remote hospitals. Currently, only HT-DEFIX (SNBTS) is licensed for this purpose in the UK. In addition, in the absence of life-threatening bleeding, administration of a blood product should not be necessary as these patients can be managed with withdrawal of warfarin and administration of vitamin K, unless there is co-existing liver disease. One patient was receiving FFP (case 10) during plasma exchange for Guillain-Barré Syndrome and became hypotensive. She recovered without sequelae. FFP is not recommended as replacement fluid during plasmapheresis other than in the management of thrombotic thrombocytopenic purpura (TTP). Hypotension can develop during plasmapheresis, even in the absence of FFP use.

3. Reactions in which platelets were implicated

There were 10 cases in this group of which 6 reactions occurred during the transfusion, 3 within 2 hours and 1 haemolytic reaction which is likely to have occurred immediately but which was not recognised for 3 days. Three patients who had reacted to platelets died. However, this was felt not to be due to the transfusion reaction. All other patients in this group recovered without sequelae.

Table 28

Reaction type	Number of cases
Anaphylactic	6
Allergic	1
Haemolytic	3

Cases 11, 12, 13
In each of these three cases a unit of Group O platelets was administered to a Group A recipient and led to a haemolytic transfusion reaction or subsequent cross-matching problems. Two were platelet pools which had not been tested for haemolysin titres and the third was an apheresis unit which had been tested but not designated high-titre anti-A, B. This patient developed renal failure, requiring dialysis and subsequently died from causes that were thought probably unrelated to the adverse event. In each of these cases a Group A unit of platelets was not readily available.

4. Reaction in which a combination of red cells and platelets was implicated

Case 14
A 16 year-old with acute leukaemia, who had received a transfusion of apheresis platelets, closely followed by a transfusion of red cells, developed an extensive itchy rash following 100mL of his first unit of red cells. It was not possible to ascribe this definitely to either of these products.

Response times

In 2 cases no details about the response times (notification of doctor and patient being seen by doctor) were given. In all other cases a doctor was notified within 15 minutes of the reaction occurring or was present at the time. A haematologist was notified or was aware in 25 cases and was not notified in 4 cases (no record in 1). In general, appropriate involvement of medical staff occurred at an early point in the event.

Patient Monitoring

There was a wide range of frequency of nursing observations prior to the onset of the reaction.[4] In 11 cases no details about the frequency of patient monitoring is given. It is not at all clear if this is because no monitoring was performed. One patient seems to have been on only routine 4-hourly observations while the remainder were on continuous monitoring or had observations performed at intervals of 10-60 minutes.
Of the patients who developed anaphylaxis, there is no record of monitoring in 3 cases, one was on only 4-hourly observations while the remainder were on continuous monitoring or 10-60 minute observations.

Investigations

Only 9 patients out of 18 who experienced allergic, anaphylactic or respiratory problems underwent investigation for the presence of white cell antibodies or other alloantibodies. In most cases these investigations seemed to be incomplete ("normal IgA, no platelet antibodies"). Of the 4 patients who had positive results on immunological testing, one had HLA antibodies, one was reported to have IgA deficiency (?tested for anti-IgA) and anti-neutrophil antibodies were demonstrated in a donor of FFP transfused to a recipient who developed angio-oedema. The patient who died as a result of anaphylaxis was initially considered to have suffered from TRALI and investigations of the donors of his FFP showed that one, a female donor, had anti-HLA antibodies only, which did not show specificity for the patient's HLA type. Review of the case by the SHOT Writing Group suggested that this case appeared to be an anaphylactic reaction rather than TRALI.

Reporting to Blood Centres and Hospital Transfusion Committees

The HTC was made aware in 80% of cases which is increased in comparison with previous years, reflecting wider availability of these committees and better awareness of their remit. The transfusion laboratory was notified in all but one case.

Table 29
Reporting of reactions to the local Transfusion Centre, the HTC and the Hospital Laboratory (31 cases)

Reported to	Number
HTC	25
Hospital Laboratory	29
Transfusion Centre	25

In 7 cases the reporter stated that practice had been changed as a result of the incident. In 2 cases this relates to the screening of platelet donations for high-titre haemolysins (threshold changed or testing introduced for pooled platelets). The other changes relate mainly to the transfusion protocols for the individual patients rather than a general change in practice.

COMMENTARY

- In 17/31 cases the reaction was ascribed to platelets or FFP. Platelets may also have been implicated in a patient who also received red cells. As 11 times as many red cells units are issued compared to platelet units and 7 times as many red cell units as FFP units it is apparent that the risk of an acute reaction is significantly higher with the administration of platelets or FFP.

- It is recommended that FFP and platelets should be transfused rapidly and yet it is difficult to justify this on the basis of deterioration of the pack contents. Coagulation factor decline in thawed FFP, for example, affects FVIII and FV levels in the main, yet these are generally not a significant contributor to any observed coagulopathy. Platelets will not deteriorate during a period of a few hours, unagitated, at room temperature. It is accepted, however, that in some circumstances clinical expediency may dictate that a rapid infusion is necessary - for example in the presence of acute bleeding.

- Again, as noted previously, patients have received FFP inappropriately in some cases, particularly for warfarin reversal in the absence of bleeding, and are experiencing life-threatening reactions.

- ABO-incompatible platelet pools and apheresis units are a recognised cause of haemolytic transfusion reactions. Pooled platelets prepared from buffy-coats are suspended in the plasma of one donor. They are, then, just as likely to contain high-titre anti-A or B as an apheresis unit but routine screening for high-titre haemolysins has been introduced only recently in some areas of the UK, in response to the noted haemolytic episodes.

- Under-investigation of acute and delayed adverse events is common and leads to difficulty in ascribing a precise cause.

- The frequency of patient monitoring during transfusion, particularly of platelets and FFP, was very variable and perhaps not carried out in many cases. This is of concern, particularly as these two components are generally infused rapidly and have a relatively high frequency of adverse events as noted above.

RECOMMENDATIONS

- **Patients receiving any blood component must be monitored or observed in such a way that an acute reaction can be detected early. In addition to baseline observations before commencing each transfusion, each patient should be checked after 15 minutes infusion of each new unit or pool.[4]**

- **National guidelines on anticoagulation[8] which include clear guidelines on managing excessive warfarinisation should be circulated more widely, in a form which is accessible to surgeons and clinicians of all grades. It is rarely appropriate to give FFP for this purpose and it is generally sufficient to stop the warfarin and give vitamin K where necessary. Appendix 11 contains a summary of the guidelines on reversal of anticoagulation prior to surgery and in over-warfarinised patients.**

- **Platelet units contributing to pools prepared by the "dry buffy-coat method" should undergo testing of the "plasma donor" for the presence of high-titre haemolysins, similar to that performed for apheresis units. Ideally, however, Group O donors with high-titre haemolysins should not be used as plasma donors in platelet pools. Clinicians should avoid giving Group O platelets to Group A or B recipients unless this will result in a clinically significant delay. A recent entry in "Blood Matters" deals specifically with this topic and is included at Appendix 12.**

- **The feasibility of using only male donors as donors of clinical FFP and plasma for platelet pools should be explored as these will be less likely to have allo-antibodies to any cellular antigens.**

- **More detailed investigation of patients experiencing immune reactions to components would clarify the nature of these reactions and should be considered particularly in cases with anaphylaxis or pulmonary manifestations. However, it is not clear that detailed investigation of other allergic reactions would be cost-effective, unless these are recurrent and causing problems in managing the patient effectively.**

- **The BCSH Transfusion Task Force is drafting a guidelines for the investigation and management of ATR. This will be presented at the next British Society of Haematology meeting in 2002.**

- **The recommendations for appropriate administration rates for FFP and platelets should be revisited in order that clinicians can feel able to infuse these more slowly if the clinical condition permits. This will allow more monitoring of the patient and perhaps early detection of an acute event at an earlier point in the transfusion.**

14. 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. Simple serological reactions (antibody development without a positive DAT or evidence of haemolysis) are excluded.

This category accounted for 12.9% of non-infectious hazards reported and 12.7% of all hazards.

40 new initial reports were received and 3 were carried forward from the previous year. Four additional reports were felt not to fit the definition of a DTR and were withdrawn. This chapter highlights the main findings from 39 completed questionnaires (36 from the current reporting year).

Gender (39 reports)
Males 6
Females 33

Age (39 reports)
Age range 18 - 88 years
Median age 69 years

Table 30
Timing of Reaction/Diagnosis in relation to previous transfusion

Days post-transfusion	No. of cases
1-5	7
6-10	18
11-15	7
16-20	1
>20	4
Not stated	2

Range 2- 30 days
Median 8 days

Reactions Reported

There were 6 deaths in this group of which 5 were reported to be unrelated to the transfusion reaction and one possibly related to the reaction. The outcome of one patient is not known. The remaining patients suffered minor, or no morbidity.

All reactions were related to the administration of allogeneic red cells.
In total 48 post-transfusion antibodies (excluding autoantibodies and enzyme-panagglutinins) were noted in the 39 patients who suffered DHTR. In five patients (cases 2, 5, 6, 27, 28) the causative antibodies were present, and should have been detectable by IAT technique but were not detected before transfusion. In two of these cases no pre-transfusion antibody screen was performed.

A further 2 patients (cases 7, 39) had known pre-transfusion antibodies with additional antibody specificities detectable post-transfusion.

Although the antibody specificities are reported below, this is not intended to imply that these antibodies have been proven to be the cause of the haemolytic reactions. Indeed, in some cases (e.g. anti-Chido, enzyme-only anti-E, cold-antibodies) it seems unlikely or impossible that these were implicated in the haemolysis. In some patients, multiple antibodies developed but it is likely that only one of these was implicated in the haemolysis. Autoimmune haemolysis or drug-induced haemolysis may have been implicated (but not recognised or investigated) in some of these cases.

Urgency of Transfusion Requirement

In 29 patients the transfusion was said to be routine and in 10 urgent. In one case (case 6) pre-transfusion testing had to be performed urgently during elective surgery, as this had not been requested pre-operatively. As a result a detectable pre-transfusion antibody was missed.

New Post-transfusion Antibodies

Table 31 shows the new post-transfusion antibodies (50 in 39 patients) according to antigen specificity and Table 32 gives details of these antibodies for individual patients.

Table 31
New* post-transfusion red cell antibodies in 39 patients: according to antigen specificity

Antibody group	Number	Sole antibody
Kidd		
Jka	15	12
Jkb	4	3
Duffy		
Fya	9	4
Kell		
K	1	
Rh		
Cw	1	
C	2	
D	2	1
E	9	2 (1 reacting only be enzyme)
e	1	1
Lutheran		
Lua	1	1
M,N,S,s		
M	1	
S	2	1
s	1	
Other		
Chido	1	1

* in 6 cases these were probably present pre-transfusion but not detected - either because no screen was done or because the techniques were insufficient or inadequately performed

Table 32
New* post-transfusion red cell antibodies in individual patients

ID	Antibody(ies)	Comment
1	Jk^b	
2	Jk^a	no antibody screen pre-transfusion
3	Jk^a+Fy^a	
4	Jk^a	
5	s	retrospective testing showed this was present but missed in pre-transfusion sample
6	Jk^a	present pre-transfusion but missed
7	Jk^a	Fy^a pre-transfusion
8	Jk^a	
9	Jk^a	
10	M	
11	Jk^a	
12	S	
13	Jk^a	
14	Fy^a	
15	E + enzyme-only C^w	
16	Jk^a	retrospective testing of pre-transfusion sample showed anti-Jk^a by enzyme technique, reacting with homozygous cells
17	E + Fy^a	
18	E + autoantibody	
19	E	
20	Jk^a	
21	Jk^b + Fy^a + E	
22	Jk^a	
23	E + Fy^a	
24	Jk^a	
25	Fy^a	
26	Jk^b	
27	C+ Fy^a	known anti-E pretransfusion, "flying squad" units used without pre-transfusion testing as life-threatening bleed
28	Jk^a	
29	e	
30	Jk^b	
31	D + E + Lu^a	
32	D	
33	Chido	clinical significance dubious
34	E	enzyme-only
35	Fy^a	
36	Jk^a	
37	Fy^a	
38	E + C, + S + enzyme-panagglutinin	M + unidentified antibody pre-transfusion, no cross-match done apparently
39	K	E + unidentified antibody pre-transfusion.

* in 6 cases these were probably present pre-transfusion but not detected -either because no screen was done or because the techniques were insufficient or inadequately performed

Clinical sequelae

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

- Group 1 Asymptomatic (with positive DAT and/or 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. All survived without sequelae.

Group 2
There were 13 patients in this group of whom all survived without sequelae (other than fatigue in 1 case). The outcome for one patient (case 22) was not stated.

Group 3
There were 21 patients in this group of whom 15 survived without sequelae, 5 patients died from unrelated causes and 1 patient's death was "probably not related" to the transfusion reaction. One patient had ongoing jaundice at the time of the report, felt to be due to the transfusion reaction. No other sequelae were felt to be due to the DTR.

Group 4
There were 2 patients who developed renal impairment which was felt to be due to the transfusion reaction. These 2 patients did not require dialysis and recovered without ongoing sequelae.

The above results are detailed in Table 33. There is no clear relationship between the specificity of the antibody and the severity of the reaction.

Table 33
Grouping of cases by clinical sequelae of DHTR*

Group 1		Group 2		Group 3				Group 4	
ID	**Antibody**	**ID**	**Antibody**	**ID**	**Antibody**	**ID**	**Antibody**	**ID**	**Antibody**
6	Jk^a	1	Jk^b	2	Jk^a	29	c	13	Jk^a
8	Jk^a	7	Jk^a	3	$Jk^a + Fy^a$	31	$D+E+Lu^a$	39	K
23	$E+Fy^a$	9	Jk^a	4	Jk^a	32	D		
		14	Fy^a	5	s	33	Chido		
		17	$E + Fy^a$	10	M	35	Fy^a		
		18	E + auto	11	Jk^a	37	Fy^a		
		22	Jk^a	12	S	38	E+C+S		
		24	Jk^a	15	$E + C^w$(enzyme)				
		25	Fy^a	16	Jk^a				
		27	$C + Fy^a$	20	Jk^a				
		30	Jk^b	21	Jk^b+Fy^a+E				
		34	E(enzyme)	26	Jk^b				
		36	Jk^a	28	Jk^a				

*case 19 – severity not stated

There is no apparent relationship between the speed of onset of the reaction and the severity (data not shown). However, it should be born in mind that, in the absence of prospective monitoring, the timing of the onset of signs and symptoms is likely to be extremely inaccurate.

Analysis of serological information

Antibody screening and Cross-match techniques

Table 34 gives information on the serological methods used for antibody screening and cross-matching in the 39 reported cases.

Table 34
Summary of serological methods used for antibody screening and cross-match

Screening Method	No Serological Cross Match	Immediate Spin Cross-match	IAT cross-match	Not stated	Total
Tube LISS IAT			2		2
Column IAT (Diamed)		1	26	1	28
Column IAT (Ortho)	2[a]		4		6
Solid Phase		1	1		2
Not done	1[b]				1
Total	**3**	**2**	**33**	**1**	**39**

[a] 1 patient with anti-M + unidentified antibody in pre-transfusion had no serological cross-matching.
[b] 1 patient issued with blood in emergency without screen or serological cross-match.

Column technology was used for antibody screening +/- cross-matching in 87% of cases. Laboratories are still using IAT cross-matching even for pre-transfusion samples with a negative antibody screen yet this does not appear to be able to prevent the transfusion reactions seen.

Repeat testing of the pre-transfusion sample was performed in 24 cases and revealed the same results in 21. In the three cases in which a different result was obtained, different or additional techniques were used for the repeat testing (enzyme technique; Capture-R rather than LISS-tube; Capture-R in addition to column technology - but in this case the original technique also gave a different result).

In 7 cases the transfusion reaction occurred within 5 days of transfusion (cases 1, 7, 8, 26, 27, 36 and 39). In 5 of these cases the implicated antibody was anti-Kidd (2 $Jk^{b,}$ 3 Jk^{a}) and in one case a weak anti-Kell was detected post-transfusion, reacting only with homozygous cells (Case 39, see below). In one patient (Case 27) the clinical urgency precluded performance of a pre-transfusion antibody screen, which would have revealed the presence of anti-C and Fy^{a}, in addition to her known anti-E.

Details of some unusual serological cases are given below:

Case 2
Details on this case, initially reported in August 2000, are incomplete. However, this 87 year-old female was transfused with 6 units of red cells during elective surgery. She became extremely jaundiced 14 days later, with a positive DAT. It is reported that no pre-transfusion antibody screen was performed (no explanation given) but that the units were cross-matched by IAT techniques. It is not clear if this was an error or if clinical expediency prevented full testing. The post-transfusion sample at 14 days revealed an anti-Jka.

Case 5
This 77 year-old, previously transfused female presented with gastro-intestinal bleeding and required an urgent transfusion of 2 units of red cells. 4 days later she required a further 2 units and 3 days later was noted to have haemoglobinuria, anaemia and jaundice. An antibody screen by column technology had shown no pre-transfusion antibody. A post-transfusion sample, tested using Capture-R and column technology demonstrated anti-s. This was also detectable when these techniques were used to repeat testing on the pre-transfusion sample. The laboratory was using NBS cells for the column technology, with the dilution prepared in-house and it is suggested that the initial cell suspension used may not have been an optimal concentration for the technique used.

Case 6
This 71 year-old female with a previous transfusion history, underwent an elective mastectomy and reconstruction without prior pre-transfusion testing. Routine pre-transfusion testing would have been by use of Capture Ready Screen but as blood was required urgently during surgery a LISS-IAT tube technique was used for screen and cross-match. This revealed no incompatibility. The blood was issued and transfused before the presence of a weak anti-Jka was demonstrated by the routine techniques. Three of the four units transfused were Jk^{a} positive. The patient developed a positive DAT (IgG and C3) and a minor fall in Hb only.

Cases 31 and 32
In 2 cases (Cases 31 and 32), Rh D Negative female patients, aged 70 and 80, were electively transfused with RhD positive units and developed anti-D with the onset of haemolysis at 6 and 8 days, respectively. One had been

previously transfused and the second had had at least one pregnancy. Case 31 had also developed anti-E and anti-Lu[a]. Both recovered without ill-effects.

Case 33
This 77 year-old male was transfused with 5 units of red cells during and after surgery for a fractured neck of femur. He gradually became anaemic again and a further sample taken two weeks post-op was incompatible with all units tested. The only antibody detectable in the post-transfusion sample (at the International Blood Group Reference Laboratory) was anti-Chido. It was confirmed that the pre-transfusion samples had no antibody. Anti-Chido is not known to cause a haemolytic transfusion reaction - this antibody is generally considered to be of no clinical significance when selecting blood for transfusion. There was no evidence of auto-immune haemolysis but a drug-dependant antibody was not investigated in this patient. The patient has not been transfused again and made an uneventful recovery.

Case 34
This 56 year-old female was transfused with a single unit of red cells during elective surgery. She had no previous transfusion history and it is unknown if she has been pregnant in the past. Pre-transfusion serology (IAT by column techniques, IAT cross-match and DAT) were all negative. One month later it was noted that she was anaemic with a positive DAT (IgG). An antibody screen using enzyme techniques in addition to the above showed the presence of anti-E by enzyme techniques only. Two further units of red cells had been transfused before this enzyme-only antibody was detected (by chance these were E-negative). Retrospective testing of the pre-transfusion sample by enzyme techniques could not be done as it had been discarded. It seems unlikely that this antibody had caused the fall in Hb and positive DAT and this may be an incidental finding in a patient who had more significant intraoperative or post-operative blood loss than had been suspected.
A fatal transfusion reaction which was apparently due to an enzyme-only reactive anti-E was presented in last year's report.[9]

Case 38
This 67 year old female was transfused with 4 units of red cells for a gastrointestinal bleed. She had had two transfusions within the preceding month. Pre-transfusion testing of a fresh sample using column technology showed an apparent anti-M plus an unidentified antibody. M-negative blood was given but it is reported that no cross-match was performed (however, it is not clear if this was a mis-understanding of the question on the report form). Nine days later the patient was noted to be jaundiced, anaemic and dyspnoeic. Repeat investigations at this point showed the presence of anti-M, E, C, S and an enzyme-reactive antibody. It seems possible that at least some of these antibodies may have been detectable in the pre-transfusion serum.

Case 39
This 75 year-old female with myelodysplasia had been transfused on several previous occasions, the most recent 10 weeks before the reported incident. A pre-transfusion sample, drawn 5 days before transfusion was shown to contain anti-E and non-specific pan-agglutinins by enzyme and LISS techniques. She became unwell 2 days post-transfusion and was readmitted 10 days post-transfusion with anaemia, jaundice and renal insufficiency. A repeat sample revealed a weak anti-Kell reacting only with homozygous cells. The pre-transfusion sample was unavailable for repeat testing. The patient recovered well.

Cross-matching - timing

Interval between drawing cross-match sample and transfusion

Table 35
The interval between cross-matching and sampling is shown below for 30 reports

Interval between cross-matching and sampling (hrs)	No. of cases
0-47	31
48-71	2
72-96	
>96	4[a]
Not known	1
Not done	1

[a] including one sample sent 53 days before transfusion (pre-admission clinic) and stored frozen - no recent transfusion history

In all cases in which sufficient details were provided, the timing of pre-transfusion samples were in keeping with the national guidelines[37] It was not always possible to ascertain from the questionnaire the timing of an earlier transfusion and the implicated transfusion.

Table 36
Recommended timing of pre-transfusion sampling in relation to most recent transfusion[37]

Timing of previous transfusion	Samples to be taken
3-14 days	max 24hr pre-transfusion
14-28 days	max 72hrs pre-transfusion
28 days - 3 months	max 1 week pre-transfusion

Reporting to Blood Centres and Hospital Transfusion Committees

19 (49%) of cases were reported to the local Blood Centre and 33 (85%) were reported to the HTC. The involvement of the HTC has again increased compared to previous years and presumably reflects the more widespread availability of these committees and clarification of their role.

COMMENTARY

As in previous years, Kidd antibodies feature prominently as a cause of DHTRs in 19 of the 39 patients (49%) and 19/48 (40%) of the "new" post-transfusion antibodies.

In 5 cases it is likely that the antibodies could have been detected pre-transfusion but were missed. In 1 case (case 27) a life-threatening bleed precluded prior testing. In four cases (Cases 2, 5, 6, 38) it appears that the routine screening techniques should have revealed the antibody(ies) but may have been inadequately performed or were omitted. In one of these cases (Case 38) multiple antibodies were present but only one was fully identified before transfusion. Use of enzyme-techniques revealed a very weak antibody in 1 case (Case 16) but this technique is not now commonly used. An additional enzyme-only reactive anti-E (Case 34) seems an unlikely cause of the anaemia and positive DAT in this patient.

In general there is little evidence of inadequate performance of the laboratory techniques but available technology appears to be ineffective in detecting the risk of haemolytic transfusion reactions due to anti-Kidd.

In one case, emergency techniques had to be used because the patient had had no pre-transfusion testing before elective surgery. The techniques selected, or the inadequate performance of them, missed the presence of a clinically significant antibody (anti-s).

As noted in Mollison's text-book "Blood Transfusion in Clinical Medicine"[38], the development of DHTRs in patients with a pre-existing alloantibody which has not been detected in pre-transfusion tests is a recognised phenomenon. In addition, a patient with a relatively low-titre antibody may have an immediate haemolytic reaction which is mild, and therefore not detected, followed by a DHTR as the antibody re-appears in the circulation. The transient disappearance of the implicated antibody is common and may account for some of the failures to detect a clinically-relevant antibody in post-transfusion testing in some of these cases.

RECOMMENDATIONS

- **Attention to timely pre-transfusion testing of surgical patients is essential, especially if there is a history of previous transfusion or pregnancy. Where possible, investigations should be performed within normal working hours in order to make best use of available expertise. Laboratory staff should be given adequate notice of impending surgery and the potential role of pre-admission clinics in facilitating timely pre-transfusion testing should be assessed in each hospital.**

- **In the SHOT report from 1999-2000[9] a need for improved technologies to identify extremely weak Kidd antibodies was identified and this need persists.**

- **Hospital laboratories must take care to avoid missing antibodies which may be masked by another specific antibody or by broadly-reacting non-specific antibodies. Deficiencies in this area were highlighted in a recent "paper" exercise run by the National External Quality Assurance Scheme for Blood Transfusion Laboratory Practice (see NEQAS-BTLP exercise**

00E6).[10] There is a great deal of useful material in this exercise which should be shared with all the BMSs working in transfusion laboratories. Nevertheless, it appears that this problem is a minor contributor to the occurrence of DTRs reported to SHOT.

- **Although 2 patients developed haemolysis due to the development of anti-D post-transfusion, there were no long term sequelae. There is no indication to alter the current policy of administering RhD positive units to RhD negative patients without detectable anti-D, when RhD negative units are in short supply, unless these patients have child-bearing potential.**

- **Laboratories must be aware of the guidelines on pre-transfusion testing and ensure that these are followed by laboratory staff both within normal working hours and in the "out-of-hours" setting.[37]**

- **If a clinically significant red cell antibody is found in a recipient, it is essential that a cross-match is performed, even if phenotyped units are supplied.**

15. 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.

Fifteen new cases were reported, and 12 questionnaires received for analysis. In addition, more complete information (although not the questionnaire) was received on a case initially reported during 1999-2000. There are thus 13 cases analysed in this chapter.
Of these 13 cases, there were 8 females and 5 males. The median age was 60 (range 21-81). In contrast to previous years, there were no cases in children.

There were 4 deaths in which the transfusion was implicated, but as discussed below, in only 2 of these was TRALI considered to be the probable diagnosis.

The underlying diagnoses and transfusion histories of these 14 patients are shown in Table 37. There were 6 patients with haematological malignancies (3 non-Hodgkin's lymphoma, 2 AML, 1 myelodysplasia), 5 having elective surgery (including 2 having cardiac surgery), and 2 with trauma/acute haemorrhage. There were no plasma exchange cases reported, compared with 2 in 1999-2000 and 3 in 1998-1999.

In all cases except 2, symptoms began within 4 hours of the start of the transfusion, and in 9 cases within 1 hour of the start.
In 5 patients the implicated component was red cells, including 4 patients who received no other components. In 2 cases platelets were implicated, and in 4 FFP. In 2 cases it was unclear which component was responsible. This means that 'plasma-rich' components were involved in at least 57% of cases.

Clinical features (Table 38) were classically dyspnoea and hypoxia, with non-specific chest X ray appearances which were not discriminatory from acute respiratory distress syndrome (ARDS) or other forms of acute lung injury.

Treatment and outcome are shown in Table 39. Three patients were already on ICU, and a further 6 required ICU admission. Of these, 1 was not ventilated, 1 received continuous positive airways pressure (CPAP), and 4 were ventilated. In most cases, the duration of ventilation was not reported. Four patients died (31%), and the others recovered from the acute episode, although with impaired respiratory function in one patient. Two further patients died later of underlying malignancy.

Serology In 2 patients (cases 7 and 10), there were HLA and granulocyte antibodies detected post-transfusion without any reported antibodies in the donors. In 9/11 (82%) cases where donors were investigated, either HLA or granulocyte antibodies were found. However, these were confirmed to recognise leucocyte alloantigens, either by cross matching or genotyping, in only 3 cases (5, 6 and 12). In the other cases, cross match was not performed, this being impossible if the patient has died. All serologically positive donors, where their gender was stated, were female. However, the NBS policy for investigating implicated donors involves screening all female donors first. Male donors are tested only if all females are negative. Since 7-12% of female donors have HLA and/or granulocyte antibodies, it is inevitable that positive reactions will be detected in many investigations if large numbers of female donors are involved, and the occasional serologically positive male, previously sensitised by transfusion, may not be detected. In this year's cases, however, most patients were exposed to relatively small numbers of donors. Positive serology in their female donors is therefore less likely to be a chance finding.

Assessment of likelihood of a reported case actually being TRALI
Assessment of the probability of individual cases being due to TRALI is made difficult by the lack of specific clinical features or laboratory markers of TRALI. In this series of cases, the SHOT team took into account the underlying diagnosis, timing between transfusion and symptoms, and donor serology in classifying cases into highly likely, probable, possible and unlikely to be TRALI. This resulted in 3 cases being considered unlikely, 2 possibly, 5 probably and 3 highly likely to be TRALI.

Likelihood of TRALI in relation to outcome

There was no clear correlation between likelihood of TRALI and outcome, although all 3 cases in the 'highly likely' category recovered fully. Of the 5 fatalities, 2 were categorised as probable, 1 as possible and 1 unlikely.

COMMENTARY

- Certain categories of patient continue to feature in TRALI reports, particularly those with haematological malignancies. It is unclear whether these patients have a truly increased TRALI risk, or whether they simply represent heavy users of FFP and platelets. The absence of any plasma exchange cases this year is an interesting observation, coming at a time when there is increasing use of pooled SDFFP for plasma exchange procedures for TTP cases. Continued monitoring will be necessary to assess whether TRALI really is declining in TTP cases. This would be facilitated by national collation of TTP cases.

- There is still variation in the way TRALI cases are investigated. The NBS is producing national guidelines for investigation of suspected cases, and for management of the donors.

- There are no specific clinical or radiological features of TRALI, and no specific diagnostic test. Although the classical description of TRALI involves interaction between donor leucocyte antibodies and the patient's leucocytes, SHOT deliberately chose to use a broad clinically based definition, so as not to exclude transfusion-related pulmonary events in which no donor antibodies were detectable. The International Society of Blood Transfusion Working Group on Haemovigilance, on which SHOT is represented, is working towards an internationally agreed definition for TRALI cases. This will facilitate comparisons between countries, as well as assisting in monitoring the effects of future interventions to reduce the risks of TRALI.

RECOMMENDATIONS

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

Samples should be referred to the relevant Transfusion Centre.

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

- **SHOT is aware that steps to protect against possible vCJD transmission currently have high priority in the UK Transfusion Services blood safety agenda, and that importation of FFP is being considered. In considering sources and type of plasma, TRALI prevention should be taken into account as part of any future strategy for FFP provision from outside the UK. For example, exclusion of female donors from single unit FFP production should be seriously considered.**

Exclusion of female donors should also be considered in relation to the plasma used to suspend pooled platelet concentrates.

Table 37 UNDERLYING DIAGNOSIS AND TRANSFUSION HISTORY OF CASES REPORTED AS TRALI

TRALI Case No.	Age/sex	Diagnosis	Reason transfused	*Components transfused*			Incriminated component	Interval between commencement of transfusion and symptoms
				RBC	Plt	FFP		
1	27, F	Congenital afibrinogenaemia	Trauma, laparotomy	9	-	6 FFP + 10 cryo	?	>48 hrs
2	70, F	Aortic incompetence	Elective valve replacement	2	2	2	?	12 hrs
3	72, F	Non-Hodgkin's lymphoma	Anaemia	-	Yes. Number not stated	-	Platelets	1 hr
4	71, M	Aortic aneurysm	To correct excess warfarin post-operatively	-	-	1 (stopped because of reaction)	FFP	1 hr
5	81, M	Carcinoma rectum	Haemorrhage following anterior resection	4	-	-	Red cells	<12 hrs
6	30, M	Scoliosis	Peri-operative	3	-	-	Red cells	> 4 hrs
7	58, F	Relapsed acute myeloid leukaemia	Anaemic	Yes. Number not stated	-	-	Red cells	Immediate
8	60, M	Acute myeloid leukaemia	Insertion of Hickman line	-	-	4	FFP	<1 hr

Table 37 UNDERLYING DIAGNOSIS AND TRANSFUSION HISTORY OF CASES REPORTED AS TRALI

TRALI Case No.	**Age/sex**	**Diagnosis**	**Reason transfused**	***Components transfused***			**Incriminated component**	**Interval between commencement of transfusion and symptoms**
				RBC	**Plt**	**FFP**		
9	54, F	B cell follicular lymphoma -transformed to high grade	Allogeneic sibling stem cell transplant	2	1 pool	-	Pooled platelets	During infusion
10	53, F	Non-Hodgkin's lymphoma	Liver biopsy - haemorrhage	9	2	-	Red cells	< 1 hr
11	21, F	Ruptured ectopic pregnancy	Laparotomy and salpingectomy	4	-	2	FFP	During infusion
12	74, F	Myelodysplasia	Routine `top-up`	1	-	-	Red cells	70 mins
13	72, M	Coronary stenosis	CABG, oozing from chest drain	2	1 pool	4	FFP	1 hr after commencing FFP

Table 38 CLINICAL AND RADIOLOGICAL FEATURES OF CASES REPORTED AS TRALI

TRALI, Case No.	Age/sex, diagnosis	Risk factors	Fever	Hypo-tension	Rigors	Dyspnoea	Low pO2	High pCO2	Chest x-ray appearances
1	27, F Congenital afibrinogenaemia	Trauma	?	?	?	?	Y	?	Bats wing shadowing. CT scan- possible consolidation
2	70, F Aortic valve surgery	Respiratory dysfunction plus cardiac failure	Y	N	N	Y	Y	Y	Right sided `whiteout` and fluffy shadowing.
3	72, F Non-Hodgkin's lymphoma	Cytotoxic chemotherapy	Y	N	Y	Y	Y	N	Alveolar shadowing, especially upper lobes.
4	71, M Aortic aneurysm	Chronic constructive airways disease	Y	N	Y	Y	Y	N	Not stated.
5	81, M Rectal carcinoma	Sepsis Low albumin	N	Y	N	Y	Y	N	Not stated.
6	30, M Scoliosis surgery	None	N	N	N	Y	Y	N	Not stated.
7	58, F Acute myeloid leukaemia	WBC >100x10^9/L Cytotoxic chemotherapy	N	N	N	Y	Y	N	Diffuse alveolar shadowing.
8	60, M Acute myeloid leukaemia	None	Y	N	Y	Y	Y	N	Intra-alveolar shadowing.

Table 38 CLINICAL AND RADIOLOGICAL FEATURES OF CASES REPORTED AS TRALI

TRALI, Case No.	Age/sex, diagnosis	Risk factors	Fever	Hypo-tension	Rigors	Dyspnoea	Low pO2	High pCO2	Chest x-ray appearances
9	54, F Lymphoma	Pulmonary lymphoma and irradiation to chest; cytotoxics	N	N	N	Y plus respiratory arrest	Y	Y	`White out`. Diffuse shadowing both lungs.
10	53, F Lymphoma	Cytotoxics	N (37.4^{o}C)	N	N	Y	Y (7.9)	Y (5.2)	Bilateral basal shadowing
11	21, F Ruptured ectopic pregnancy	None	Y (39^{o}C)	N	N	Y	9.0 (on 40-60% 0_2)		Widespread bilateral airspace shadowing
12	74, F Myelodysplasia	None (previous fluid overload with transfusion)	Y	N	N	Y `Crackles and wheeze`	Y		Bilateral infiltrates
13	72, M Coronary artery bypass grafting	CABG but no heart failure	N	Y (100/10)	N	On ventilator	Y		'Characteristic of severe ARDS'

Table 39 TREATMENT, OUTCOME AND DONOR SEROLOGY

TRALI Case No.	Age/sex, diagnosis	ICU days	Treatment	Outcome	Serology on donors	Why did the reporter think the case was TRALI rather than ARDS or fluid overload?	Likelihood of case being TRALI
1	27, F Congenital afibrinogen-aemia	Already on ICU	Not stated	Not stated	1 plt donor pos anti-granulocyte. 1 cryo donor pos anti-HLA. 1 cryo donor pos anti-HLA by GLAM assay.	Not stated	UNLIKELY Interval between transfusion/ symptoms too long
2	70, F Aortic valve surgery	Already on ICU	Methyl prednisolone, oxygen, diuretics, fluids	Died	1 apheresis platelet donor – negative.	Reporters think this was probably ARDS	UNLIKELY
3	72, F Non-Hodgkin's lymphoma	0	Oxygen, diuretics	Died	Pending	1) CXR not typical of fluid overload. 2) No response to diuretics. 3) No risk factors for ARDS. 4) Timing in relation to transfusion.	POSSIBLE pending serology
4	71, M Aortic aneurysm	Yes, duration not stated	Inotropes, antibiotics	Died	The FFP donor (gender unstated) had IgG granulocyte antibodies strongly positive by chemiluminescence and by immunofluorescence. Reactions were independent of HNA-1, -2, and -3 antigens.	1) Timing in relation to transfusion. 2) No evidence of fluid overload and poor response to diuretics. 3) No evidence of pneumonia at post-mortem – pulmonary oedema only.	PROBABLE
5	81, M Rectal carcinoma	Yes, duration not stated	Not stated	Recovered	2/4 red cell donors were female. One had HLA non-cytotoxic antibodies, positive by cross-match with the patient's granulocytes and lymphocytes.	Speed and timing in relation to transfusion	HIGHLY LIKELY
6	30, M Scoliosis surgery	No	Oxygen	Recovered	One donor had anti-HNA-1a. Patient's genotype HNA 1a/1b.	1) No risk factors for ARDS. 2) Timing in relation to transfusion. 3) Not fluid overloaded.	HIGHLY LIKELY
7	58, F Acute myeloid leukaemia	No	Oxygen, methyl prednisolone	Recovered, impaired respiratory function	Patient had strong HLA antibodies. 3 donors, all male, all negative for granulocyte and HLA antibodies.	1) No pre-existing symptoms. 2) Timing. 3) No evidence of overload or infection.	POSSIBLE
8	60, M Acute myeloid leukaemia	Yes, 1 day	O_2, methyl prednisolone, antibiotics, diuretics	Recovered (died later of AML)	Patient –strong pos HLA antibodies. HLA type: A2,A3,B15,B44. One female donor –cytotoxic HLA B7 antibodies. Another female donor had non-cytotoxic HLA antibodies. No crossmatch possible.	Rapid onset and recovery in relation to transfusion.	PROBABLE

Table 39 TREATMENT, OUTCOME AND DONOR SEROLOGY

TRALI, Case No.	Age/sex, diagnosis	ICU days	Treatment	Outcome	Serology on donors	Why did the reporter think the case was TRALI rather than ARDS or fluid overload?	Likelihood of case being TRALI
9	54, F Lymphoma	CPAP 2 days	Oxygen, methyl prednisolone	Recovered (died later of NHL)	Three female platelet donors - 1: Anti-HLA A2, A28 2: Anti-HLA B57 Patient HLA A2 positive. No crossmatch possible.	1) Timing 2) No evidence of fluid overload or sepsis.	PROBABLE
10	53, F Lymphoma	Yes, duration not stated	Oxygen, fluids	Recovered	**Patient had granulocyte antibodies by chemiluminescence and immunofluorescence assays, and HLA antibodies by MAIPA only.** The two implicated donors had no pregnancy or transfusion history, so not investigated.	Not stated	PROBABLE
11	21, F Ruptured ectopic pregnancy	Admitted but not ventilated	O_2, frusemide, fluids, dexamethasone, antibiotics	Recovered	Of the 2 FFP donors (both female), one had HLA Class I antibodies, and the other had lymphocyte antibodies. Cross-match positive with patient's lymphocytes and granulocytes.	1) Timing 2) No risk factors for ARDS	HIGHLY LIKELY
12	74, F Myelo-dysplasia	None	Hydrocortisone, frusemide, chlorpheniramine, salbutamol and atrovent inhalers	Recovered (though re-admitted 24-48 hrs later with chest infection)	One female donor, negative by GLAM and Class II ELISA. LCT awaited.	1) Slow transfusion of 260 mL under diuretic cover 2) Poor response to diuretics	UNLIKELY pending further serology
13	72, M Coronary artery bypass grafting	Already on ICU	Oxygen, methyl prednisolone	Died of sepsis/ pneumonia possibly secondary to TRALI	**1 donor pos HLA –17% panel reactivity, IgM only. GLAM negative.**	1) Timing 2) CVP and wedge pressure did not suggest LVF Reporter states death definitely related to transfusion NB. May result in decreased FFP use/change to pooled product	PROBABLE

16. 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.

Only three new cases were reported this year (all female, age range 47-67), a further decrease from the 6 reported last year. To check whether this represented major under-reporting, NBS laboratories undertaking platelet immunology investigations were asked how many PTP cases they had diagnosed during the SHOT reporting year. This confirmed that PTP has remained at a low level, although at least 1 antibody-positive case (anti-HPA-5b) was identified which has not been reported to SHOT. Moreover, 2 of the 3 cases reported this year were not classical PTP cases, as they had also received multiple platelet transfusions.

Case 1 was a 55-year old woman with AML. She had one previous pregnancy with no history of alloimmune thrombocytopenia. She was receiving on-going transfusions of red cells (platelet transfusions not mentioned, and became profoundly thrombocytopenic (platelet count $<10 \times 10^9$/L), and sustained an intracerebral haemorrhage. Anti-HPA-1a was identified, and she was treated with HPA-1a negative platelets and IVIgG. The platelet count reached 50×10^9/L in 11 days.

Case 2 was a 47-year old woman receiving chemotherapy for osteosarcoma. She had 2 previous pregnancies, and had received 16 units of red cells and 16 units of platelets in the preceding year. Ten to fifteen days after a transfusion (component not stated), the platelet count dropped to $<10 \times 10^9$/L, although there was no haemorrhage. Chemotherapy was curtailed because of the thrombocytopenia. HPA-1a and HLA antibodies were identified, and she was treated with random platelets, IVIgG, and steroids. The platelet count reached 50×10^9/L in 10 days.

Case 3 was a 67-year old woman who was transfused because of a gastro-intestinal haemorrhage secondary to oesophagitis. She had had 2 pregnancies, but had never been transfused. Five to nine days after transfusion, she developed purpura/bruising, and the platelet count dropped from 171×10^9/L to $<10 \times 10^9$/L. Anti-HPA-1a was identified, plus platelet autoantibodies and HLA antibodies. She was treated with random platelets, intravenous imunoglobulin and steroids. The platelet count was $> 50 \times 10^9$/L when checked at day 22, and was normal by day 26. The reporter commented that the apparently slow recovery time probably reflected infrequent checking of the platelet count after the acute phase.

COMMENTARY

It seems increasingly likely that the incidence of PTP is decreasing in the era of universal LD. In the first 3 years of SHOT reporting, prior to universal LD, there were a total of 32 reported cases (11, 11 and 10 cases/year respectively). In the 2 years since LD was implemented, the number of reported cases has dropped to 6 and 3 in 1998-99 and 1999-2000 respectively. The most likely mechanism for this reduction is the observed removal of 90% of platelets from red cell components by leucocyte depleting filters. Such filters also reduce the load of platelet microparticles in red cell components. It is of interest that 2 of the 3 cases reported this year, and 2 of 6 cases reported last year were receiving platelet as well as red cell transfusions, and were thus exposed to large amounts of antigen. The role of leucocyte removal in preventing PTP is less clear. The classical description of PTP is of a patient whose primary sensitisation occurred months or years earlier, perhaps by transfusion but more usually by pregnancy. It is rare to know whether the patient developed HPA antibodies at the time of this first exposure. The transfusion which precedes the acute thrombocytopenia thus acts as a secondary immune stimulus, with possibly little or no requirement for donor-derived antigen presenting cells.

RECOMMENDATIONS

- **We would urge hospitals to continue to report PTP cases to help confirm whether its likelihood is reduced by universal LD.**

- **As recommended in the 1998-99 report,[39] the presence of HPA antibodies should be considered in platelet-dependent patients who become refractory to random donor platelets, once HLA antibodies have been excluded as the cause of the refractoriness. In addition HPA antibodies must be sought in HLA alloimmunised patients if there are poor responses to HLA selected platelets.**

17. 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.

One case, which was fatal, was reported during 1999-2000, the first newly reported case in the UK for 2 years.

This case was a 14-year-old girl with relapsed acute lymphoblastic leukaemia (ALL). She was being treated with the UKALL R2 protocol, which does not contain purine antagonists such as fludarabine. Although ALL is not currently an indication for gamma irradiated blood components,[1] all red cells and platelets had been gamma irradiated by the hospital in a specific blood irradiator once the diagnosis was made. The intended midplane dose used was >30 Gy, and radiation-sensitive labels were used on each batch. However, at presentation with relapse, she had received 2 units of red cells and 2 units of platelets which were not irradiated. Just over 2 weeks after receiving these non-irradiated units, she developed all the classical features of GVHD –skin rash, diarrhoea, deranged liver function, pancytopenia and infection. Biopsies of skin and bowel were consistent with the diagnosis, which was confirmed by demonstration of 3 bands on variable number tandem repeat (VNTR) analysis. The patient's HLA type was HLA A3,28; B27,44; DRB1 04,13 B3 01 B4 01; DQ 0302, 0603. Implicated donors were not recalled for HLA typing.

Treatment with methyl prednisolone was commenced within 2 days of the onset of symptoms, and a decision was taken to proceed to stem cell transplantation as 'rescue' therapy. She was pre-conditioned for this using fludarabine, melphalan and CAMPATH but she died of infection the day after stem cell infusion.

COMMENTARY

- This case confirms that current leucocyte depletion processes, even when performed under optimal conditions before blood storage, and with full quality monitoring, cannot always prevent TA-GVHD in susceptible patients. In the 1999-00 SHOT report,[9] a similar case was described of TA-GVHD in a woman with myeloma who had received only leucocyte-depleted red cells. It should be borne in mind that although LD processes are highly consistent, the possibility of an occasional unit failing the LD process cannot be excluded. It is not practical to perform low level leucocyte counting on 3 million components/year, so processes are monitored using statistical techniques. The current UK specification of $< 5 \times 10^6$/unit in 99% of units with >95% statistical confidence reflects this. However, it is possible that LD affords partial protection from TA-GVHD, and may be enough to protect patients with normal immune function whose only risk factor is chance haplotype sharing with the donor. No cases of TA-GVHD in patients have with normal immune function have been reported since universal LD was introduced, compared with 5/12 cases in the previous 3 years. Whole blood filtration reduces the T cell load by > 4.5 logs, and platelet filtration by >3.5 logs.[44] However, the leucocyte load in platelets is already pre-reduced during processing, and the final leucocyte levels in red cells and platelets is comparable.

- Of 13 TA-GVHD cases in the 5 years of SHOT reporting, 6 have occurred in patients with B cell malignancies (3 non-Hodgkin's lymphoma, 1 Waldenstrom's macroglobulinaemia, 1 myeloma, and this case of ALL). These patients now appear to be the most susceptible group not recommended for irradiated components under current BCSH Guidelines.[1]

- The effect of new chemotherapy or immunotherapy regimes on patient susceptibility to TA-GVHD may emerge only with time. However, this may be partly predictable by knowledge of the effects of new therapies on T cell function and number.

- It is not clear whether the hospital intended to treat this patient with irradiated components from the outset, or only once a decision had been taken to embark on the R2 protocol. Either option would have been entirely reasonable within current guidelines (as would a decision not to provide irradiated components at all). However, every year, SHOT receives reports (described in chapter 11) of patients who on occasion failed to

receive irradiated components when these were indicated. Fortunately, no cases of TA-GVHD have resulted from these omissions.

- The investigation and management of this case once symptoms appeared was exemplary. However, it illustrates the fact that there is currently no proven treatment for TA-GVHD.

RECOMMENDATIONS

- **The issue of whether some or all patients with B cell malignancies should receive irradiated components should be again reviewed. In addition, as the current BCSH guideline[1] recommends, each new chemo- or immuno- therapeutic regime should be assessed for the possibility of its causing TA-GVHD. Both of these recommendations might best be achieved by a complete review of the BCSH guidelines.**

- **Hospitals should have systems in place to ensure that patients who need irradiated components always get them. Mechanisms for achieving this include flagging such patients on the hospital computer, and the use of the BCSH/NBS card and leaflet 'Information for patients needing irradiated blood'. (See appendix 13 for a pre-publication version updated for 2002). There may be a role for hospital pharmacies in reminding staff that recipients of purine analogues require irradiated components.**

18. 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 TTI 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.

PTIs 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 NBA and the PHLS CDSC in October 1995. Reported data from England, Wales and Northern Ireland are included in this report.

A similar collation of reports of cases investigated by Scottish blood centres has been in place in Scotland since October 1998.

Methods

Participating blood centres in England Wales and Northern Ireland reported all PTIs of which they had been informed to the NBA/PHLS CDSC infection surveillance system. The criteria for identifying infections eligible for reporting as PTIs 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 PTI, 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 31/12/2001 about incidents of TTIs initially reported by blood centres between 01/10/2000 and 30/09/2001 were included in this report. Data received about incidents reported during the previous five 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 PTIs were classified as PTIs of undetermined source.

Blood centres in Scotland reported all cases to the Microbiology Reference Unit of the SNBTS where they were investigated, and the details and conclusion of each case was then provided to the SHOT system.

Results

Blood centres in England, Wales and Northern Ireland made 38 initial reports of PTIs during the report year. An additional 9 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 PTI as stated above, but may have been reactions of bacterial origin). For three of these 9 reports another cause of the reaction was subsequently confirmed: 1 hypertension, 1 ATR (included in chapter 13), 1 TRALI (included in chapter 15). Reports were received from 8 of the 12 blood centres in England, Wales and Northern Ireland. These 8 centres collect approximately 70% of the donations tested each year in England, Wales and Northern Ireland. Two (5%) PTIs (1 bacteraemia, 1 HCV infection) were classified as PTIs of undetermined source due to inconclusive investigation of the donation(s) implicated as the source of infection. For 21 (55%) PTI reports (8 bacteraemia, 4 HBV infections, 6 HCV infections, 3 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: surgery & liver transplant, HCVx2: occupational contact with blood, HCV x1: travel in India, HIV x1: lived in sub-Saharan Africa).

Blood centres in Scotland reported five PTI investigations during the report year. Three post-transfusion HBV infections and 1 post-transfusion HCV infection were found to be not due to transfusion (one HBV with other source [health care worker] identified). One post-transfusion HBV infection reported during this year (transfused in 1997) is still under investigation. Scottish cases reported since October 1998 are included in the numbers of PTIs and TTIs shown in the tables and figures in this report. (In previous years these cases have not been included in the tables/figures.)

Figure 22 shows the classification of reports during the report year.

Of the 43 PTIs initially reported by blood centres in the UK between 01/10/2000 and 30/09/2001, 6 (14%) were classified, after appropriate investigation, as TTIs. Table 40 shows the TTIs reported between 01/10/2000 and 30/09/2001 by year of transfusion: 4 (3 bacterial contaminations and 1 HBV) were transfused during the report year, and 2 were transfused prior to the report year.

Figure 22
Classification of post-transfusion infections (and post-transfusion reactions) initially reported between 01/10/2000 and 30/09/2001.

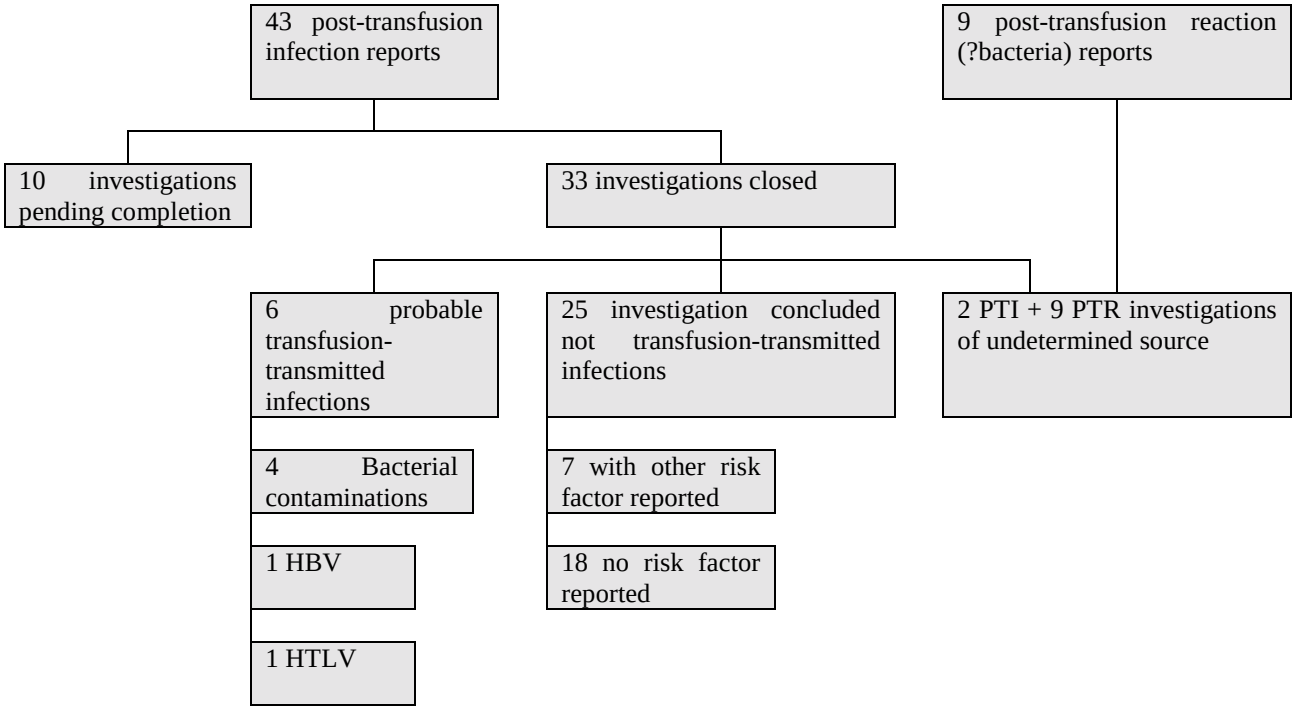


Table 40
TTIs reported between 01/10/2000-30/09/2001 by year of transfusion. The number of incidents is shown, with the total number of identified infected recipients shown in brackets.

Year of transfusion	Pre-2000	2000	2001 (to end Sept)	Total[b]
Infection				
HBV	-	1(1)	-	1(1)
HTLV	1(1)	-	-	1(1)
Bacteria	-	3(3)[a]	1(1)	4(4)[a]
Total	1(1)	4(4)[a]	1(1)	6(6)[a]

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

Details of TTIs

A. Infections for which donation testing is mandatory

Hepatitis B virus
One transfusion transmitted HBV infection was reported during this year. One recipient (50 year old male) was found by routine testing during dialysis treatment to be HBsAg positive and HBV DNA positive 4 months after transfusion to treat anaemia (associated with kidney disease). This recipient, who was immunosuppressed, had not developed any antibodies to HBV by 5 months after the implicated transfusion. The archive sample for 1 unit of red cells transfused to this recipient that had been found to be HBsAg negative at the time of donation was found to be HBsAg positive on re-testing with a different assay and was also found to be HBV DNA positive and anti-HBc negative. Subsequent testing of several samples from the donor indicated that he had suffered a recent HBV

infection and was now immune (HBsAg negative, anti-HBc positive, anti-HBs increasing to >500 iu/L by 7 months post-donation). This donor did not have any risk factors that should – according to guidelines in place at the time - have excluded him from donating blood. The probable source of the recipient's HBV infection was concluded to be an HBV DNA positive, anti-HBc negative, HBV infectious donation, with low level HBsAg, collected from a donor with early acute HBV infection.

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

Bacterial contamination
Four transfusion-transmitted bacterial contaminations were reported.

One recipient (60 year old female) developed fever during transfusion with a 5-day old unit of apheresis platelets during treatment for leukaemia. *Staphylococcus epidermidis* of an identical strain was cultured from the recipient's blood and the platelet pack. The probable source of the recipient's reaction was concluded to be a unit of apheresis platelets contaminated with *Staphylococcus epidermidis*: no source of this contamination was identified.

One recipient (40 year old male) developed fever, rigors and chest tightness after transfusion with a 5-day old unit of apheresis platelets during treatment for thrombocytopenia. *Staphylococcus aureus* with the same antibiotic sensitivities was cultured from the recipient's blood, the platelet pack and swabs from the donor's antecubital skin (there was no growth from nasal and throat swabs from the donor). The probable source of the recipient's reaction was concluded to be a unit of apheresis platelets contaminated with *Staphylococcus aureus* from the donor's arm.

One recipient (57 year old female) suffered a fatal reaction after transfusion with a 4-day old unit of pooled platelets during treatment for severe liver disease. *Bacillus cereus* was isolated from the implicated unit and from arm swabs of one of the four donors (the isolate from the arm swab was of a different strain). No organisms were found by culture of the four related red cell units. The probable source of the recipient's reaction, and death, was concluded to be a unit of pooled platelets contaminated with *Bacillus cereus* from a donor's arm.

One recipient (23 year old male) felt unwell with tightness around the throat and shivering, raised temperature and tachycardia several minutes after the start of transfusion with a 4-day old unit of pooled platelets during treatment for aplastic anaemia. This recipient was on antibiotics at the time and no bacteria were isolated from his blood cultures and he recovered within 2 days. Group B *streptococcus* was isolated from the implicated platelet unit. Culture of throat and arm swabs from the donors of this unit did not isolate any group B streptococcus. The probable source of the recipient's reaction was concluded to be a unit of pooled platelets contaminated with group B *streptococcus*: no source of this contamination was identified.

HTLV
One transfusion-transmitted HTLV-I infection was reported during this year.
One recipient (20 year old female) was traced and tested for HTLV-I infection after the donor of a component of red cells she had been given nine years previously (1991) presented as a patient with adult T-cell lymphoma (ATL) and was found to be infected with HTLV-I. This recipient, who received red cells during treatment for injuries from a road traffic accident, was the only recipient of six possibly infected components who was alive and fit to accept testing. This recipient was found to be positive for antibodies to HTLV-I, and to have weakly positive polymerase chain reaction results. She had had no symptoms of this infection. Neither the recipient nor the donor had any identified risk factors for HTLV-I infection. The probable source of the recipient's HTLV-I infection was concluded to be an HTLV infectious donation that entered the blood supply, in the absence of donation testing for HTLV, from a donor with no identifiable high risk for this infection.

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 PTIs may have been missed and the extent of underreporting of PTIs is therefore unknown. The proportion of PTIs that are reported each year may vary 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 vary.

Previous year

During the previous reporting year (i.e. 01/10/1999 to 30/09/2000) 5 TTIs were reported (see SHOT Annual Report 1999-00[9] for details of these cases).
One post-transfusion bacteraemia reported during the 1999-2000 year that was pending full investigation at the time of the last SHOT annual report has subsequently been concluded to be due to transfusion-transmitted bacteria. The recipient (58 year old male) suffered fatal septic shock after transfusion with a 2-day old unit of pooled platelets. *Staphylococcus epidermidis* (identical isolates) were cultured from the recipient and the implicated unit. Arm swabs of 3 of the donors were also culture positive for *Staphylococcus epidermidis* (but of different isolates). The probable source of the recipient's reaction and death was concluded to be a unit of pooled platelets contaminated with *Staphylococcus epidermidis* from a donor's arm.

The investigations of one post-transfusion HCV infection and one post-transfusion HBV infection (in Scotland) that were classified as pending full investigation in the 1999-2000 SHOT[9] report have subsequently been concluded to be not due to transfusion.
Table 41 shows the cumulative number of TTIs reported by the end of September 2001.

Cumulative data

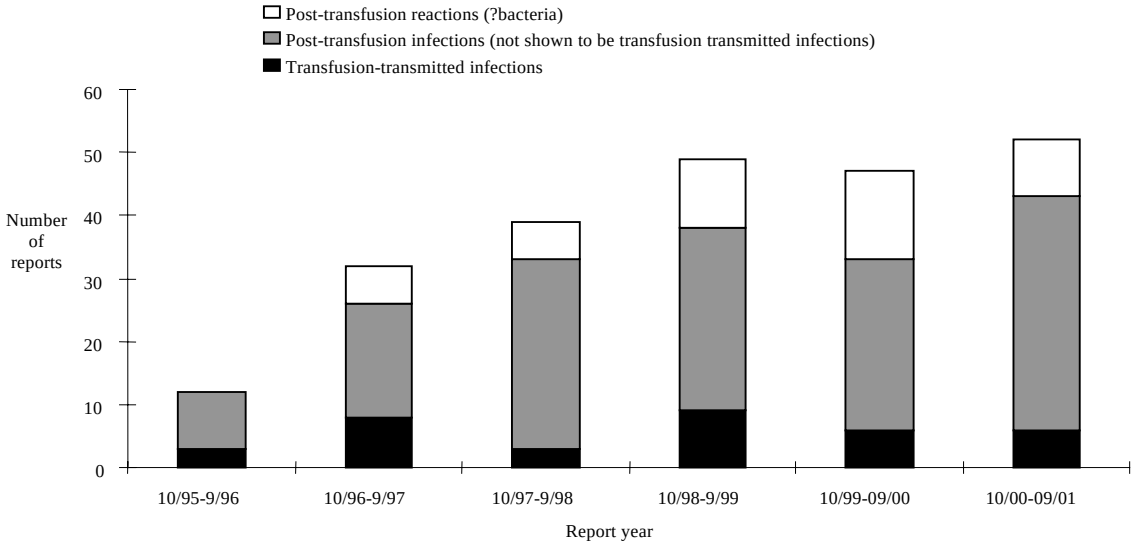
Figure 23 shows the cumulative number of reports received by year of transfusion since October 1995.

Table 41
Cumulative total TTIs: reported between 1/10/1995-30/09/2001 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	2001 (to end Sept)	Total	Deaths
Infection										
HAV	-	-	1(1)	-	-	-	-	-	1(1)	-
HBV	1(1)[b]	1(1)	1(1)	1(1)	1(1)	2(3)	1(1)	-	8(9)	-
HCV	-	-	1(1)	1(1)	-	-	-	-	2(2)	-
HIV[c]	-	-	1(3)	-	-	-	-	-	1(3)	-
Bacteria	-	1(1)	1(1)	3(3)	4(4)[ax2]	4(4)[a]	7(7)[ax3]	1(1)	21(21)	6
Malaria	-	-	-	1(1)[a]	-	-	-	-	1(1)	1
HTLV-I	1(1)	-	-	-	-	-	-	-	1(1)	-
Total	2(2)[b]	2(2)	5(7)	6(6)[a]	5(5)[ax2]	6(6)[a]	8(8)	1(1)	35(38)	7

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 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.

Figure 23
PTI reports by report year (including Scotland from 10/98 onwards)



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

Cumulative data about bacterial contaminations

Table 42 shows a summary of the species of bacteria and the type and age of the implicated components for the 21 transfusion-transmitted bacterial contaminations reported between 01/10/1995 and 30/09/2001.

Table 42
Transfusion-transmitted bacterial contaminations reported in UK between 01/10/1995 and 30/09/2001 by species and component type and age (N=21).

	Platelets Age (in days) at use							Red cells
	1	2	3	4	5	NK	All	
All species	*0*	*1*	*2*	*6*	*4*	*4*	*17*	*4*
Bacillus cereus				3[a]		1	4	
Coagulase negative Staphylococci					1		1	1 (23 days)
Enterobacter aerogenes			1[a]				1	
Escherichia coli			1[a]			1	2	
group B Streptococcus				1		1	2	
Serratia liquifaciens								1
Staphylococcus aureus					1	1[a]	2	
Staphylococcus epidermidis		1[a]		2	2		5	1 (32 days)
Yersinia entercolitica								1[a] (33 days)

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

Six of the 17 contaminated platelet units were collected by apheresis from single donors, 11 were recovered from whole blood donations (each from a pooling of four donations). For 8 of these 21 cases the donors' arms were confirmed by subsequent testing to have been the probable source of the contamination. For some others, investigation of donors' arms was incomplete or inconclusive but the nature of the contaminating organism was suggestive of a skin contaminant that was most likely to have been introduced to the pack at the time of collection. For 2 cases, the donor's blood was concluded to have been the source of the contamination (i.e. endogenous bacteria, so contamination of the pack not preventable by skin cleansing or diversion).

Cumulative data about Hepatitis B virus transmissions

Seven of the 8 transfusion-transmitted HBV infections reported between 01/10/1995 and 30/09/2001 have been concluded to be probably due to infectious blood collected from donors undergoing acute HBV infection, with only one (reported in the first reporting year) due to infectious blood from a donor with later stage HBV infection. This is a change from the pattern observed in earlier collations of transfusion-transmitted HBV infection, for example only 3 of 14 transfusion-transmitted HBV infections reported to the PHLS from 1991 to 1997 were found to be due to donations from donors with acute infection, with the majority being due to donations from donors with chronic infection.[45] This change may have implications for the choice of strategies to further reduce the risk of transfusion-transmitted HBV infection.

COMMENTARY

- Reported TTIs are rare: only 6 confirmed cases were recognised in the UK during this 12-month period of reporting. Investigations of a further 37 cases of PTI were reported. The majority (76%) of the closed PTI investigations reported during this year have been shown not to be caused by transfusion. For two of the closed investigations the investigations were inconclusive.

- Nine cases of post-transfusion reactions suspected (but not confirmed) to be due to bacteria were also reported (in England, Wales and Northern Ireland). Conclusive investigation of a suspected bacteraemia in a transfusion recipient relies heavily on the collection and handling of relevant samples at the hospital where the transfusion was performed. This means that 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 TTI (or toxin). Other causes of the reactions were identified for three of these.

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

- Fifty percent or more of bacterial contaminations are due to skin flora entering the pack at the time of collecting the donation.

- One case of transfusion-transmitted HBV infection was reported this year. The source of the implicated donation in this case – as in 6 of the 7 other cases reported since 01/10/1995 – was a donor with acute HBV infection.

- One case of transfusion-transmitted HTLV-I infection was reported this year. The infection was detected by lookback to the recipients of donations from a donor subsequently diagnosed with symptomatic HTLV-I infection. The identified infected recipient has not had symptoms. Transfusion-transmitted HTLV infection has been previously documented in the UK.[46] LD may have reduced the risk of HTLV transmission by transfusion since these cases were transfused.[47] SHOT is aware that HTLV testing is currently under consideration in the UK with possible tests undergoing evaluation for use for donation testing. This would further reduce the risk of HTLV infection.

- One TTI (*Bacillus cereus*) reported during this year resulted in the death of the recipient. One other investigation that was concluded during this year (reported during the previous year) also found that transfusion-transmitted bacteria (*Staphylococcus epidermidis*) resulted in the death of a recipient.

- Numbers of reported cases are small and fluctuations in reports 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 have accounted for the majority of reported transmissions by transfusion and the majority of known deaths due to TTIs, not only in this year's cases, but also in the cumulative data.

- The absence of any reports of transfusion transmitted HCV (or HIV) infections is consistent with the expected low risk of an HCV infectious donation entering the blood supply in the presence of the current testing of blood donations for both anti-HCV and HCV RNA (and anti-HIV).

RECOMMENDATIONS

- **The cumulative and continuing predominance of bacteria as causing TTIs and infection-related deaths provides strong support for efforts to prevent bacterial contamination of blood components: these include promoting adherence to current BCSH guidelines[4] regarding the visual inspection of units for any irregular appearance immediately prior to transfusion (particularly platelets), as well as evaluating additional or revised strategies to prevent the contamination of donations. Two strategies in particular are currently under investigation and development for implementation: improvements in the disinfection of donors' arms and diversion of the first few mL of blood collected (most likely to contain skin flora) away from the primary pack that is sent for component production. Methods for testing platelets for bacterial contamination are also under consideration.**

- **Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria, including the sampling and storage of implicated units. Cases that are inconclusive due to discard of the implicated pack before sampling continue to be reported. (National guidelines on the investigation of these cases are available at all NBS centres.)**

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

19. 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 autologous pre-deposit donor incidents began in the 1998-99 reporting year. Last year we received only 2 reports and this year there have been 7 reported by 2 hospitals. Whilst data are not available from which 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. No conclusions can be drawn from so few reports. It is clear that this particular aspect of SHOT reporting has not proven popular. However, autologous pre-donation is not without risk[48,49] and an acceptable and practical way of acquiring information on this procedure is urgently needed.

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

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 not optimal and that the category of vasovagal attack in particular needs to be redefined. This was pointed out in last year's report[9] but other priorities have prevented further work on this topic over the past year. SHOT welcomes suggestions on how to improve in this area.

Table 43
Information on autologous pre-deposit donor incidents 2000/2001

Donor ID	Age	Weight (Kg)	Procedure	Donation no. to which incident relates (interval since previous)	Collection site	Donor assessed by	Donation taken by	Complication	Guidelines
01	63		Orthopaedic	1	Hospital OP	Staff Grade	RGN	Faint @ 10 mins	BCSH
02			THR	1	Hospital OP	RGN/BTS nurse	RGN	FF	BCSH
04	66		Orthopaedic	2 (7 days)	Hospital OP	Staff Grade	RGN	Delayed faint @ 60 mins	BCSH
05	61		Orthopaedic	1	Hospital OP	Staff Grade	RGN	FF @ 15 mins	BCSH
06	39	52	Bone marrow donor	3 (5 days)	Hospital OP	BTS Clinical Research Fellow	RGN	Faint – immediate	BCSH
07		79	Bone marrow donor	1	Hospital OP	BTS Clinical Research Fellow	RGN	FF – immediate	BCSH
08	51	54	Spinal surgery	2 (7 days)	Hospital OP	Staff Grade	RGN	FF @ 10 mins	Hb < 110 g/L @ 1st donation

THR = Total hip replacement
OP = Out patient
RGN= Registered General Nurse
FF = Felt faint

All were simple donation procedures and all complication were vaso-vagal episodes with no other sequelae reported. For donor 6, recovery was prolonged and the donor was managed with intravenous saline and oxygen by face mask. All donors satisfied BCSH guidelines for donor selection for pre-deposit procedures[50] with the exception of donor 08 where the Hb level preceding the first donation was < 110 g/L.

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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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