

SERIOUS HAZARDS OF TRANSFUSION

ANNUAL REPORT

2004

Affiliated to the Royal College of Pathologists

British Blood Transfusion Society, British Society for Haematology

Faculty of Public Health Medicine, Institute of Biomedical Science

NHS Confederation, Health Protection Agency Centre for Infections

Royal College of Anaesthetists, Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Royal College of Paediatrics and Child Health

Royal College of Physicians, Royal College of Surgeons, The 4 UK Blood Services

Published 21st November 2005

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ISBN 0 9532 789 7 2

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Glossary of Terms

ALI	Acute lung injury
ATD	Adult therapeutic dose
ATR	Acute transfusion reaction
BBTS	British Blood Transfusion Society
BCSH	British Committee for Standards in Haematology
BMS	Biomedical scientist
BMT	Bone marrow transplant
BSE	Bovine spongiform encephalopathy
BSH	British Society for Haematology
BSMS	Blood Stocks Management Scheme
CEO	Chief Executive Officer
CMO	Chief Medical Officer
CMV	Cytomegalovirus
CNST	Clinical Negligence Scheme for Trusts
CPA	Clinical Pathology Accreditation
CRP	C-reactive protein
DAT	Direct antiglobulin test
DH	Department of Health
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation
DNA	Deoxyribonucleic acid
DTR	Delayed transfusion reaction
ECG	Electrocardiogram
EU	European Union
FBC	Full blood count
FFP	Fresh frozen plasma
HAV	Hepatitis A virus
HBc	Hepatitis B core
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HPA CFI	Health Protection Agency Centre for Infections
HPA CIS	Health Protection Agency Centre for Infections Surveillance
HTC	Hospital Transfusion Committee
HTLV	Human T-cell leukaemia virus
HTT	Hospital Transfusion Team
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
IBMS	Institute of Biomedical Scientists

Glossary of Terms

ICU	Intensive care unit
INR	International normalised ratio
Ig	Immunoglobulin
ITU	Intensive Therapy Unit
IUT	Intrauterine transfusion
JPAC	Joint Professional Advisory Committee
LDH	Lactate dehydrogenase
MB	Methylene blue
MHRA	Medicines and Healthcare products Regulatory Agency
MSBT	Microbiological Safety of Blood and Tissues for Transplantation
MSBTO	Microbiological Safety of Blood, Tissues and Organs
NBS	National Blood Service
NBS/HPA	National Blood Service/Health Protection Agency
NBTC	National Blood Transfusion Committee (England)
NIBSC	National Institute for Biological Standards and Control
NPSA	National Patient Safety Agency
OAS	Optimal additive solution
OIG	Operational Impact Group
PCR	Polymerase chain reaction
PCT	Primary Care Trust
PEG	Polyethylene Glycol
PMETB	Postgraduate Medical Education and Training Board
PTP	Post-transfusion purpura
PTR	Post-transfusion reaction
RNA	Ribonucleic acid
RTC	Regional Transfusion Committee
SABRE	Serious Adverse Blood Reactions and Events
SHA	Strategic Health Authority
SHO	Senior House Officer
SPOT	Specialist practitioner of transfusion
SpR	Specialist registrar
TA-GVHD	Transfusion-associated graft-versus-host disease
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenia purpura
vCJD	Variant Creutzfeldt-Jakob disease
WBS	Welsh Blood Service

1 Keynote Message

Progress in blood safety in the UK

This year is a momentous one for all involved in the provision of blood transfusion, with the implementation of the European Union (EU) Directive on Blood Safety and Quality¹. The Directive was incorporated into UK legislation on 8th February 2005 as the Blood Safety and Quality Regulations, and will be implemented on 8th November. It requires that Blood Establishments and Hospital Blood Banks report to the Secretary of State for Health, 'all serious adverse reactions attributable to the safety or quality of blood', and 'all serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components that may have an influence on their quality and safety'.²

For SHOT this has meant a new working relationship with the Medicines and Healthcare products Regulatory Agency (MHRA), the interim Competent Authority for the Directive. In collaboration with SHOT and the adverse events subgroup of the Operational Impact Group (OIG), MHRA has developed an on-line reporting system, Serious Adverse Blood Reactions and Events (SABRE). This system will fulfil the legislative requirements of the Directive and will also enable on-line submission of SHOT questionnaires - progress that would not otherwise have been possible in the short term. Further information about SABRE can be found on the Joint Professional Advisory Committee (JPAC) website <http://www.transfusionguidelines.org/index.asp?Publication=REGS> and was disseminated in the roadshows and training events organised by MHRA. The combination of expertise and experience of SHOT and MHRA provides a unique opportunity to strengthen haemovigilance in the UK. It is essential that the professional input, the confidence and trust of hospital colleagues and the reporting culture fostered by SHOT over 8 years are preserved and taken forward in the new environment. The EU Directive does not encompass no harm errors in clinical areas, which account for 70% of Incorrect Blood Components Transfused (IBCT) events. It is therefore vital that hospitals continue to report these events to SHOT in order to preserve the safety culture that we have established in the UK and to provide continuity of data for monitoring of the NPSA/NBTC/SHOT initiative outlined below, and other blood safety initiatives.

In addition to the requirement for haemovigilance reporting, the Directive also mandates full traceability of blood components and a quality system in hospital laboratories including documented training and education. Both of these requirements will contribute to 'right blood to right patient' and are most welcome. SHOT strongly supports the recommendation of the Department of Health (DH) OIG http://www.transfusionguidelines.org/docs/pdfs/oig_report.pdf that relevant training should be provided for all staff involved in the transfusion process.

2004 saw a further 19% increase in total reports to SHOT over 2003. The percentage of hospitals reporting incidents increased from 47% to 54%, and, when "near misses" are included, the figure rises to 67%. SHOT welcomed the recommendation of the Chief Medical Officer (CMO) for England in his 2003 Annual Report³ that 'participation in the SHOT scheme should be demonstrably active with reports of adverse events and "near misses" made by all hospitals' and looks to Trust Chief Executive Officers (CEOs) to ensure that this happens. The pattern of reports is consistent with that in previous years, with a 26% increase in reports of IBCT and, encouragingly, a further fall in ABO incompatible transfusions.

In December 2004, a stakeholder workshop was held, organised by the National Patient Safety Agency (NPSA), the CMO's National Blood Transfusion Committee (NBTC) and SHOT, to launch a joint initiative aimed at reducing the incidence of ABO incompatible transfusions by 50% over 3 to 5 years. At the workshop, four initiatives already in use in hospitals were selected for further evaluation and possible roll-out. These were; barcode technology, the 'red label' transfusion wristband system, a photo-id system for regularly transfused patients and a sustained approach to training, with the development of a nationally agreed set of competencies for nurses, midwives and porters handling blood.

The main recommendations made by SHOT this year are identical to last year's, as, although progress has been made, problems continue to exist. The National Comparative Audit carried out jointly by the Royal College of Physicians and the National Blood Service (NBS)⁴ identified deficiencies in patient identification and in monitoring of transfused patients. SHOT sees the outcome of these system failures. The most important contribution that can be made now by Trust CEOs to improve patient safety in this area is to provide support and resource for training and education of all staff involved in the transfusion process. A framework for education has been developed in Scotland <http://www.learnbloodtransfusion.org.uk> and is in the process of being adopted in Wales and by the CMO's NBTC in England.

2004 has also seen the development of other collaborations. Work is ongoing between SHOT and the Blood Stocks Management Scheme (BSMS) to develop a benchmarking system enabling hospitals to compare their adverse event rate against a peer group. Meetings have also been held between SHOT and NPSA to explore the potential benefits of information sharing. Harmonisation within Europe continues to develop, with a successful 7th European Haemovigilance Seminar held in London in February 2005 and ongoing discussions within the European Haemovigilance Network towards standard definitions.

There has been much international interest this year in SHOT data on transfusion-related acute lung injury (TRALI) and on bacterial contamination of platelets in the light of blood service initiatives, (driven by previous SHOT reports), to improve safety in these areas. Reports of TRALI are reduced in comparison with 2003. However, for the reasons outlined in the section on TRALI, we urge caution in interpreting these data, and advise that a longer period of observation is required to assess the impact of male-only Fresh Frozen Plasma (FFP). Similarly, although there has been no confirmed report of transfusion-transmitted bacterial sepsis in 2004, a longer period of observation is needed before the effect of diversion pouches and improved donor arm cleansing can be proven to have significantly and consistently reduced bacterial transmissions.

SHOT continues to recommend that the UK requires an over-arching body to evaluate and prioritise blood safety initiatives. As this report goes to press, a Department of Health review of the DH advisory committee on Microbiological Safety of Blood, Tissues and Organs (MSBTO) is in progress. SHOT awaits the outcome of this review and hopes that it will encompass the role of haemovigilance in improving transfusion safety in the UK.



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2 Main Findings and Recommendations

SUMMARY OF MAIN FINDINGS

Participation

Participation in SHOT is essential if we are to maintain and develop our evidence base for assessment of transfusion risks and continue to improve transfusion safety in the UK. The evaluation of strategies to reduce the risk of TRALI and the joint NPSA/SHOT/NBTC initiative to reduce ABO incompatible transfusion, will rely on continuity of monitoring data. Following implementation of the European Directive on Blood Safety and Quality¹ on 8th November 2005, reporting to SHOT will be integrated with reporting to MHRA, the interim Competent Authority appointed to ensure that the UK fulfils the legislative requirements of the Directive. Integrated reporting will avoid duplication of effort and ensure that the UK continues to maintain a comprehensive picture of transfusion hazards which has demonstrably underpinned the implementation of a number of strategies to improve transfusion safety. The Directive does not encompass no-harm errors in clinical areas, which account for approximately 70% of IBCT. Continued reporting to SHOT of all adverse events, and preservation of the safe environment that has enabled development of a learning culture, are crucial.

With the adoption in 2003 of confidential identification numbers, SHOT is now able to provide every hospital with verification of participation, required in England for the Clinical Negligence Scheme for Trusts (CNST). In 2004, 218/405 (54%) of hospitals reported incidents, compared with 47% last year. When "near misses" are included, this figure rises to 270/405 (67%).

For CNST purposes, a level 2 certificate will be issued to hospitals that submit one or more reports. With implementation of electronic reporting via the SABRE system, it will be possible for hospitals to print a summary of reports submitted and the participation certificate will become obsolete.

Total events reported

539 questionnaires were analysed, plus 1 transfusion transmitted infection (TTI) report received from the NBS/Health Protection Agency Centre for Infections Surveillance (NBS/HPA CIS). A further report of a possible prion transmission has also been included.

This is a 19% increase in total reports over 2003.

Transfusion related mortality

There were 4 transfusion related deaths in which there was certain and conclusive evidence that death was related to transfusion (imputability 3) or where the evidence was clearly in favour (imputability 2). Two were related to IBCT, of which one followed an ABO incompatible red cell transfusion and one was caused by an inappropriate transfusion based on a haemoglobin result from the wrong patient. These cases are further discussed in section 4. One patient died due to TRALI and one death was reported as acute transfusion reaction (ATR) (see Case 2 page 33). For definitions of imputability criteria see Appendix 1.

Incorrect blood component transfused ("wrong blood") incidents

439 reports were analysed, a further 26% increase from 2003. 428 of these were 'no-harm' events in which the patient suffered minor or no morbidity.

In the context of an increase in total reports it is encouraging to note that 2004 saw a further reduction in ABO incompatible transfusions to 23, of which 19 were red cells. See figure 4, page 19.

IBCT reports analysed in 2004 comprised

- 88 (20%) 'wrong blood' events, where a patient received blood intended for someone else or of the wrong ABO group
- 143 (33%) events in which the blood given was not of the appropriate specification, (in 88 of these the component should have been irradiated but was not)
- 29 (7%) pre-transfusion testing errors
- 56 (13%) inappropriate transfusions
- 54 (12%) handling errors.

"Near miss" events

SHOT defines 'near miss' as 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. 1076 near miss reports were received this year plus 387 error logs not included in the analysis.

Again this year patient mis-identification at the blood sampling stage resulting in 'wrong blood in tube' was the most frequently reported event accounting for 491 (46%) reports.

Immune complications

Twenty-three case reports of suspected TRALI were analysed in 2004, of which 13 were considered highly likely or probable (imputability 2-3). Of these 13 cases, FFP was the implicated component in 6, platelets in 4 (3 buffy coat pools, 1 apheresis), red cells in 2 (1 plasma reduced, 1 Optimal Additive Solution (OAS)), whole blood in 1. All 13 implicated donors were female and all had leucocyte antibodies.

There were 34 analysable reports of acute transfusion reactions (ATR) of which 4 were haemolytic, 27 severe allergic or anaphylactic and 3 others.

Forty-three delayed haemolytic transfusion reactions (DHTR) were analysed, a marked increase from last year's 25 reports but consistent with previous years.

There were no reports in 2004 of transfusion-associated graft-versus-host disease (TA-GVHD) or post-transfusion purpura (PTP).

Transfusion transmitted infections

In 2004, 34 reports of suspected transfusion transmitted infections (TTI) were referred to the NBS/HPA CIS from blood centres throughout the UK. Only one report (hepatitis E) was confirmed as a TTI. A further report of a possible prion transmission referred to the surveillance scheme is also included in this year's report.

There were no confirmed reports of bacterial infection by transfused components.

SHOT in patients under 18 years of age

67 of all case reports in 2004 (12%) involved patients less than 18 years of age, 57 of which were reports of IBCT. As last year, there was a disproportionately high incidence (7%) of IBCT reports relating to infants under 12 months of age.

Autologous transfusion

There was one case report of a patient who had pre-deposited autologous blood but received only allogeneic blood.

A report of a series of adverse reactions related to re-infusion of salvaged blood following knee replacement was received from a single hospital. Details can be found in section 7, page 35.

RECOMMENDATIONS

GENERAL RECOMMENDATIONS

The recommendations made in last year's report remain pertinent and have been reviewed and updated to take into account additional developments.

1. Active participation in SHOT must continue

In addition to the legislative requirements of the EU Directive, every serious transfusion reaction and adverse event must be identified, fully investigated and reported to SHOT as recommended in HSC 1998/224⁵, HSC 2002/009⁶ (BBT2) and required in England by CNST. In a questionnaire survey in 2004 of implementation of BBT2 in England and Wales, to which 95% of NHS Trusts and 37% of private hospitals responded, 99% of responding hospitals stated that they participated in SHOT [Murphy M, personal communication]. SHOT received reports of adverse events or "near misses" from only 67% of UK hospitals, suggesting that reporting remains incomplete. Active participation requires thorough and systematic investigation of all errors, immunological reactions and post-transfusion infections, with appropriate involvement of the blood services; essential in order to maintain a comprehensive picture of transfusion risks and to drive improvements. SABRE, the new on-line system for reporting transfusion reactions and adverse events, provides integrated electronic reporting to MHRA and SHOT and is accessible via the websites of MHRA, SHOT and JPAC.

The NPSA's National Reporting and Learning System (NRLS) collects anonymised reports directly from hospital risk management systems and the NPSA provides training and advice in root cause analysis⁷.

Action: Trust CEOs through Hospital Transfusion Committees (HTCs) and risk management structures, consultant haematologists, hospital staff involved in the blood transfusion process

2. An open learning and improvement culture must continue to be developed in which SHOT reporting is a key element

Development of a culture in which there is an appreciation of the potential for error and an emphasis on learning from adverse events is key to participation in SHOT. The EU Blood Directive¹ mandates a regulatory role for MRHA with respect to errors in hospital transfusion laboratories, but does not encompass all clinical errors. Cumulative SHOT data shows that improved reporting of errors, driven by transfusion practitioners within hospital transfusion teams, has led to the development of a reporting culture associated with a fall in ABO incompatible transfusions. This must be encouraged. Fear of criticism or disciplinary action and uncertainty about the consequences of reporting blood transfusion errors leads to under-reporting, and lost opportunities to learn from errors and improve practice.

Hospital management must support the continued development of a learning culture, consistent with that fostered by the NPSA⁷, that recognises that errors arise predominantly as a result of systems failures and very rarely merit a disciplinary approach.

Action: Trust CEOs through risk management structures, staff involved in the blood transfusion process

3. Resources must be made available in Trusts to ensure that appropriate and effective remedial action is taken following transfusion errors

Action: Strategic Health Authorities (SHAs), Primary Care Trusts (PCTs), Trust CEOs through HTCs and risk management structures

4. Hospital transfusion teams (HTTs) must be established and supported

As recommended in HSC 2002/009⁶, hospitals involved in blood transfusion must establish and support a HTT to drive greater vigilance, and hence reporting of errors which may have previously gone unrecognised. The HTT requires clinical leadership, ideally from a consultant haematologist with dedicated sessions, supported by a transfusion practitioner and the blood bank manager. Adequate administrative resources must be made available. A questionnaire survey of implementation of 'Better Blood Transfusion' in England and Wales conducted in April 2004 [Murphy M, personal communication] indicated that 70% of NHS Trusts responding had a HTT that included a Transfusion Practitioner, but only 30% had administrative support.

Action: Trust CEOs through HTCs

5. Hospital transfusion laboratory staffing must be sufficient for safe transfusion practice

Hospitals must ensure that blood transfusion laboratories have adequate numbers of appropriately trained biomedical scientists (BMS) to cover the 24-hour working day, including a core of permanent blood transfusion laboratory staff. National standards should be established for manpower appropriate to the level of workload and this should be subject to inspection.

The initiatives outlined in 'Making the Change'⁸, which include the development of National Occupational Standards for Healthcare Scientists, flexible career pathways, improved status through higher specialist training and a stronger regulatory framework through the Health Professions Council, provide an opportunity to increase and consolidate the workforce and must be implemented.

The EU Blood Directive requirements for implementation of a quality system necessitate urgent review of hospital transfusion laboratory staffing and the appointment of quality managers.

Action: *Trust CEOs, clinical directors of pathology, professional and accrediting bodies*

6. Education and training is of key importance for safe and effective blood transfusion practice. Education in blood transfusion must be included in the curriculum for all clinical staff involved in prescribing and administering blood. Adequate resource is needed in Trusts to ensure that all staff involved in the transfusion chain in hospitals must receive appropriate training, which must be documented. Effectiveness of training should be assessed with assessment based on competency.

i) Blood transfusion must be included in the curriculum for student nurses, medical undergraduates and newly qualified doctors as recommended in the 2003 Annual Report of the CMO for England³. This teaching must include all aspects of blood transfusion safety and should not be confined to basic blood group serology. The web-based toolkit developed in Scotland⁹ provides a suitable framework.

Action: *General Medical Council, Deans of Schools of Nursing and Medical Schools, Postgraduate Medical Education and Training Board, Nursing and Midwifery Council*

ii) Blood transfusion should also be included in the curriculum of specialist trainees, particularly anaesthetists and critical care nurses who may be at the 'front line' of transfusion of vulnerable patients, e.g. unconscious patients in theatres and intensive care units (ICUs) and patients requiring massive blood transfusion.

Action: *Medical Royal Colleges, Universities*

iii) The disproportionate number of errors in transfusion of paediatric patients reflects lack of knowledge by clinical and laboratory staff of their transfusion requirements. The British Committee for Standards in Haematology (BCSH) guideline on blood transfusion in neonates and older children,¹⁰ detailing special requirements for these patients, should be implemented.

Action: *Royal College of Paediatrics and Child Health, Royal College of Nursing, Staff in paediatric units and transfusion laboratories*

iv) An ongoing programme of education and training in blood transfusion is essential for all hospital staff, including consultants and BMSs, involved in the transfusion process and will require additional resource. The education subgroup of the NPSA/SHOT/NBTC initiative is exploring the development of a nationally agreed set of competencies for staff involved in blood administration.

Action: *Local, regional and national transfusion committee network, NPSA/SHOT/NBTC initiative, Trust CEOs*

v) The regional transfusion committee structure, facilitated by the blood services, provides a potential forum for debate and sharing of problems and solutions in a supportive environment with expert clinical input. SHOT reportable incidents should be a standing agenda item for regional BMS forums and specialist practitioner of transfusion (SPOT) meetings. An important role of the Regional Transfusion Committee (RTC) is to support translation of guidelines into local practice.

Action: *RTCs and user groups*

7. Mechanisms must be put in place for appropriate and timely communication of information regarding special transfusion requirements

Poor communication remains an important cause of adverse events. In the longer term, the electronic patient record offers a robust solution, but interim arrangements are required and must be locally implemented and audited. Consideration should be given to the development of a patient-held booklet to record and update special requirements, similar to the 'yellow book' issued to patients on oral anticoagulants.

Action: CMO's NBTC in England and its counterparts in devolved administrations to make recommendations on suitable mechanisms for implementation by Trust CEOs through HTCs, HTTs

8. Appropriate use of blood components must be strenuously promoted and evaluated. This must include monitoring for serious adverse effects of alternatives to transfusion

Appropriate use of blood is an integral part of any blood safety strategy and should be monitored by regular audit. This year, the NBS has seen a 6% reduction in the use of red cells. Guidance on the use of blood components is available on <http://www.transfusionguidelines.org.uk> and in the Handbook of Transfusion Medicine,¹¹ and is revised in accordance with current BCSH guidelines. Attention is drawn to the BCSH guidelines on the use of FFP, cryoprecipitate and cryosupernatant.¹² Continued efforts are needed to ensure that practitioners and patients have ready access to up-to-date, simple, consistent and user-friendly information on best practice.

The potential risk of transfusion transmitted variant Creutzfeldt-Jakob disease (vCJD), and the exclusion of previously transfused donors drive an increased imperative towards appropriate use of blood together with a nationally led and appropriately resourced evaluation of alternatives to allogeneic blood transfusion. It is crucial that there is a parallel initiative on monitoring for serious adverse effects of alternatives to transfusion so that the relative risks of pharmacological alternatives to blood and autologous transfusion are compared with those of allogeneic transfusion.

Action: CMO's NBTC and counterparts to develop action plans, Trust CEOs through HTCs, clinicians administering blood transfusion, hospital transfusion teams

9. Information technology as an aid to transfusion safety should be assessed and developed at national level. A co-ordinated approach is essential

As noted in previous SHOT Reports, we believe that information technology has great potential to improve transfusion safety. The IT Working Group of the CMO's NBTC in England is to be congratulated in getting the needs of the transfusion community firmly on the agenda of bodies such as Connecting for Health, responsible for setting standards and priorities in the NHS IT strategy. Next steps include the development of national standards and specifications for blood tracking systems, currently being undertaken as part of the NPSA/SHOT/NBTC initiative, the adoption of SNOMED codes for transfusion complications, the use of the NHS number as a unique patient identifier and the inclusion of the blood group and transfusion history in the electronic patient record. Communication and co-ordination between initiatives is essential and the NPSA/SHOT/NBTC initiative is playing a pivotal role.

Action: NPSA/SHOT/NBTC initiative, CMO's NBTC IT Working Group, Connecting for Health.

10. Further national initiatives are needed to drive forward blood safety issues in hospital transfusion laboratories

SHOT is delighted that the NPSA/SHOT/NBTC initiative to reduce ABO incompatible transfusions is progressing. However this initiative addresses clinical errors, and cumulative SHOT data indicates that 30% of transfusion errors occur in hospital transfusion laboratories. Consideration should be given to a national initiative to reduce laboratory errors.

Action: CMO's NBTC in England and its counterparts in Scotland, Wales and Northern Ireland to develop action plans in collaboration with relevant professional bodies

11. There is a need for a national body, with relevant expertise and resource, to advise government on priorities for improvements in transfusion safety

Each SHOT report contains specific recommendations. However SHOT has no authority over implementation and cannot monitor compliance. Decision-making pathways are needed to enable data from SHOT to influence blood safety policy and prioritisation of resource allocation for the development, evaluation and implementation of improvements in transfusion safety. The role of the MSBTO Committee is currently under review and the outcome is awaited.

Action: DH

SPECIFIC RECOMMENDATIONS

The following specific recommendations are made in the chapters and are reproduced here.

INCORRECT BLOOD COMPONENT TRANSFUSED

- Training and competency testing of all staff involved in the transfusion process must emphasise the importance of positive patient identification, with particular attention paid to critical care situations.

Action: HTCs

- All newly qualified doctors must receive education in blood transfusion as recommended by the CMO for England. A web-based education package (<http://www.learnbloodtransfusion.org>) is included in the FY1 curriculum in Scotland and should be implemented throughout the UK.

Action: CMO's NBTC, Postgraduate Medical Education and Training Board (PMETB)

- Pending the availability of an effective IT solution, hospitals should take steps to implement robust methods to ensure that the patient's transfusion history including special requirements is kept up to date and accessible to the transfusion laboratory at all times. A patient held booklet is one possible solution.

Action: CMO's NBTC, RTC/HTC network

- The EU Directive requires that hospital transfusion laboratories implement a quality system. Elements of this include ensuring adequate staffing levels, systematic and documented training, validation of methods and change control. This presents an opportunity to drive improvements in practice and must be fully supported, resourced and monitored.

Action: Trust CEOs

NEAR MISS

- All hospitals are encouraged to report "near miss" events as required by HSC 2002/009 (BBT2)⁶ in order to further identify local weaknesses in the transfusion process. All instances of 'wrong blood in tube' must be fully investigated.

Action: HTTs

- Training and education in blood sampling, including the practical aspects of venepuncture and positive patient ID, should be included in the curriculum for medical and nursing students.

Action: CMO's NBTC, Undergraduate Deans of Schools of Nursing and Medicine

- All staff involved in the pre-transfusion sampling, testing and issue of blood must be deemed competent having undergone appropriate training, which must be documented.

Action: Trust CEOs through risk management structures

- Robust systems for noting patients' special requirements should be developed together with a policy of empowering patients to be more aware of their own special needs.

Action: Clinicians, HTCs, HTTs

- Hospital transfusion laboratories must develop and adhere to policies for the timely clearing of satellite refrigerators, required by the Blood Safety and Quality Regulations 2005.²

Action: Hospital transfusion laboratories

- Ward staff at all levels must be trained in appropriate storage of blood components once they have been collected from the blood bank.

Action: Ward managers, HTTs

ACUTE TRANSFUSION REACTIONS

- In the continued absence of a published national guideline for investigation of ATR, SHOT is developing, in collaboration with the BCSH Transfusion Taskforce, a minimum standard for investigation. This will be included in the Toolkit on the SHOT website.

Action: *SHOT, BCSH TTF, HTTs investigating ATRs*

- In the event of a patient death during or immediately following blood transfusion, the possibility of an ATR must be considered and investigated.

Action: *HTCs for inclusion in transfusion policies*

ADVERSE REACTIONS TO POST-OPERATIVE CELL SALVAGE

- Users of post-operative salvage should continue to monitor patients for adverse reactions. Those of sufficient severity to require discontinuation of transfusion should be reported to SHOT together with information on total numbers of procedures.

Action: *HTTs*

DELAYED TRANSFUSION REACTIONS

- Investigation of a suspected DHTR should include retesting of the pre-transfusion sample (where still available) by different or more sensitive techniques. This may involve referral to a reference centre.

Action: *Hospital blood transfusion laboratories*

- Automated systems or changes to indirect antiglobulin test (IAT) technology should be validated using a range of weak antibodies to ensure appropriate sensitivity.

Action: *Hospital blood transfusion laboratories*

- Consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being crossmatched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.

Action: *The CMO's NBTC and its counterparts in Scotland, Wales, and Northern Ireland*

- There is a need for a review, co-ordinated by a professional national body, of how long specimens should be kept post-transfusion. The review needs to consider the relative risks and benefits of storing specimens beyond the time that they are suitable for use in further crossmatching tests.

Action: *British Blood Transfusion Society (BBTS) and BCSH*

TRALI

- Every effort must be made to avoid unnecessary transfusion of plasma rich blood components including FFP and platelets.

Action: *Clinicians administering blood transfusion*

- FFP continues to be associated with risks of reactions including TRALI and should only be used when clinically indicated in accordance with BCSH guidelines.¹² Guidelines for the management of high international normalised ratio (INR)s due to warfarin therapy should also be followed.¹³

Action: *Clinicians administering blood transfusion*

- Transfusion of whole blood should be discouraged.

Action: *HTTs*

- Hospital staff should continue to be aware of TRALI and report possible cases to the local Blood Centre to facilitate investigation. Continued education of all relevant staff about this condition is needed.

Action: *HTTs; clinicians administering blood transfusion*

- Cases should be evaluated early by the consultant(s) involved. A team approach including the haematologist and chest physician and/or intensive care unit (ICU) consultant is recommended. There should be early liaison with the local Blood Centre.

Action: Clinicians administering blood transfusion plus haematologists, chest physicians and ICU consultants

- Serological investigation of suspected TRALI cases must include tests for antibodies to human leucocyte antigen (HLA) Class II, HLA Class I and granulocyte specific antigens.

Action: UK Blood Services

- UK Blood Services should continue to consider strategies to minimise the risk of TRALI from apheresis platelets.

Action: UK Blood Services

TRANSFUSION TRANSMITTED INFECTION

- Efforts to prevent bacterial contamination of blood components should continue. These include
 - Continuation of diversion of the first 20-30 mL of the donation (likely to contain any organisms entering the collection needle from the venepuncture site).
 - Careful attention to adequate cleansing of donors' arms.
 - Adherence to BCSH guidelines (1999)¹⁴ with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion.

Action: UK Blood Services, hospital transfusion laboratories, staff undertaking pre-transfusion bedside checking

- Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria. Attention should be paid to the sampling and storage of implicated units or their residues.

Action: HTTs

- Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately.

Action: HTTs

- UK Blood Service collection teams should ensure donor selection guidelines are adhered to at all times in order to prevent transmission of blood borne infections.

Action: UK Transfusion Services

3 Overview of results 2004

Data in this year's report were collected during the period 1st January, 2004 to 31st December, 2004

Number of hospitals

405 hospitals were eligible to participate in the scheme this year. 270 completed at least one questionnaire for either a full incident or a "near miss" giving an overall participation rate of 67%. Figure 1 shows the numbers of full incidents submitted by hospitals and figure 2 shows a breakdown of whether hospitals reported full incidents, "near miss", both or neither. In future editions we hope to show numbers of reports received measured against numbers of components issued.

Figure 1

Numbers of incidents reported by individual hospitals (excludes "near miss" events)

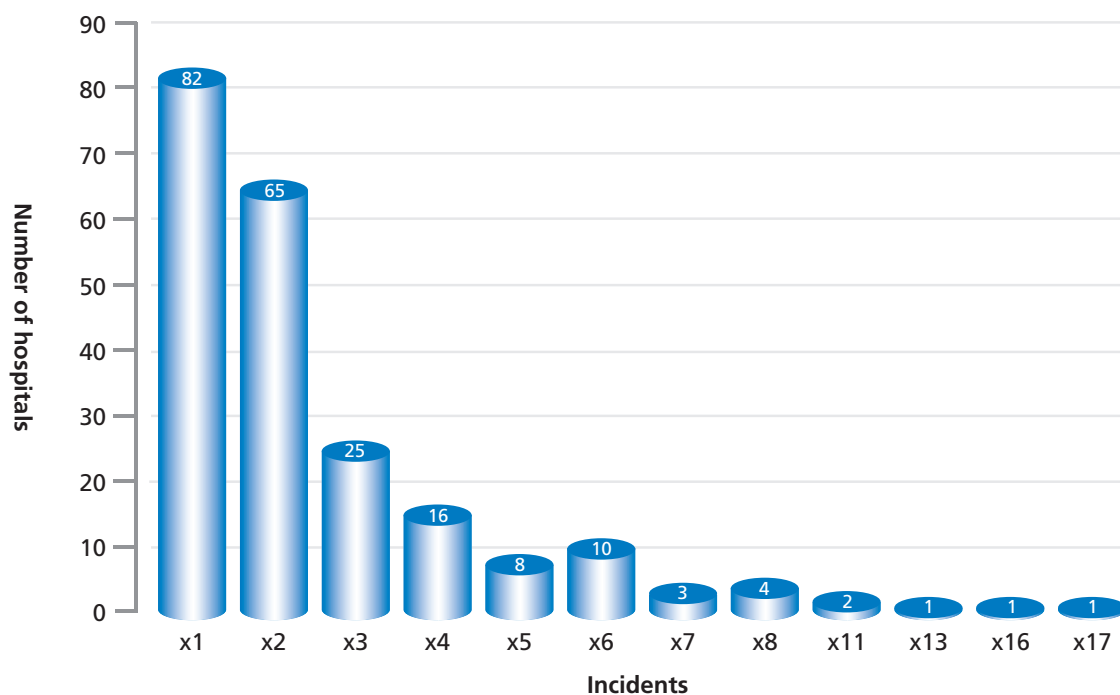
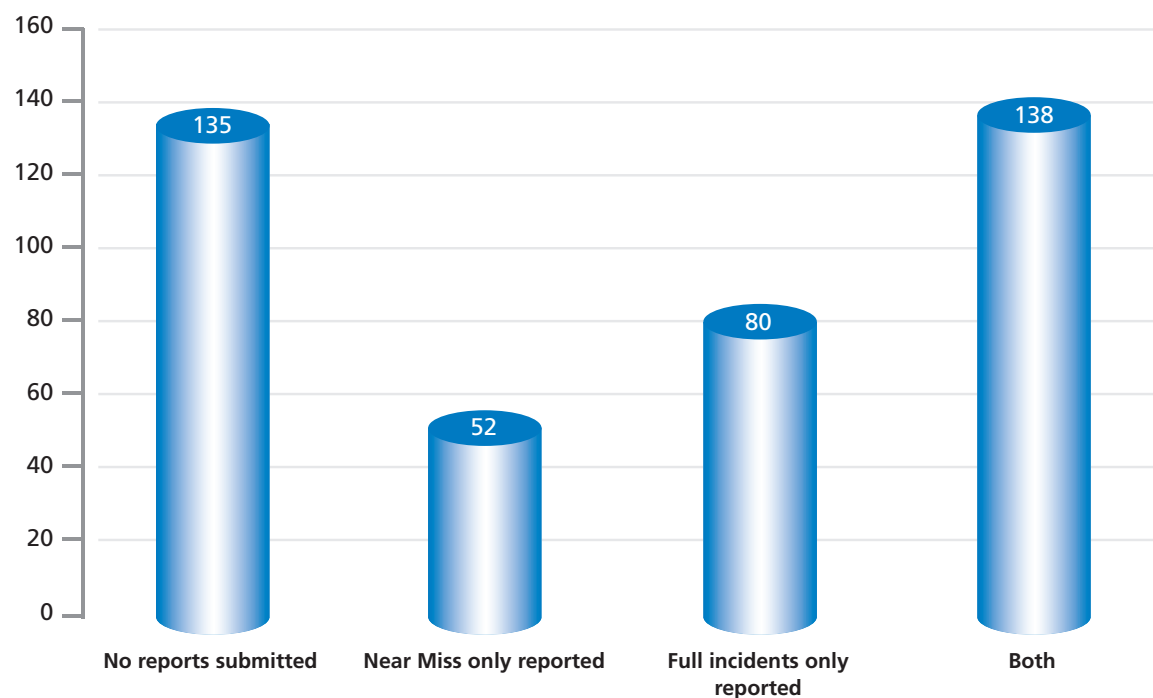


Figure 2**Breakdown of hospital reporting****Non-reporting hospitals**

Of the 135 hospitals that submitted no reports, 5 were high red cell users according to BSMS categories (i.e. use >11,000 units p.a.) and 9 were moderate users (6,000 to 11,000 units p.a.) The remaining 82 for which issue figures are available were in the low user category and included 46 using <1,000 units p.a. No issue figures were available for 39 hospitals that were not registered with BSMS.

Summary of completed questionnaires received.

	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI	Totals
Questionnaires included in analysis	439	34	43	0	0	23	2	541

Overall transfusion activity and patient characteristics

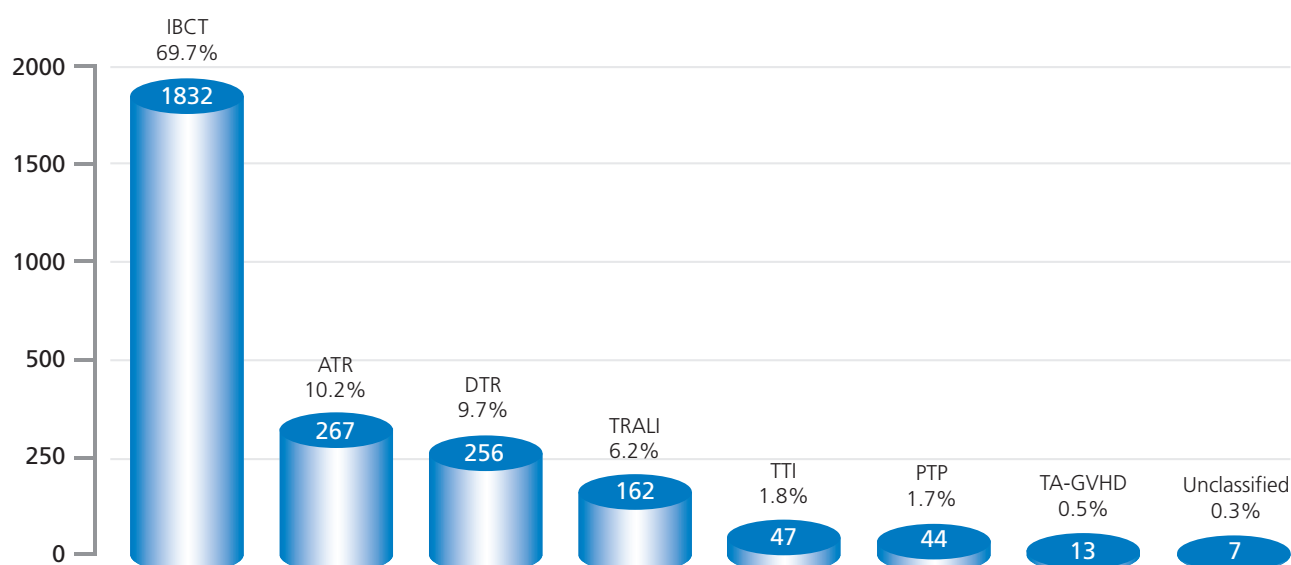
The number of incidents reported needs to be placed in the context of the overall numbers of transfusions taking place. Table 1 below gives details of total blood component issues from the four UK Transfusion Services (England, Scotland, Wales and Northern Ireland). This information represents components issued during the fiscal year 1st April, 2003 to 31st March, 2004. No figures are available for components transfused, however data from BSMS indicates that wastage in hospitals is <5% p.a.

Table 1**Total issues of blood components from the Transfusion Services of the UK in 2003/2004**

Red Cells	2,607,410
Platelets	264,539
Fresh frozen plasma	372,855
Cryoprecipitate	95,417
TOTAL	3,340,221

Figure 3**Cumulative data 1996 - 2004: Questionnaires analysed (n=2628)**

Further cumulative data are available on the SHOT website. We are no longer presenting numbers of initial reports received by SHOT since the majority of those which are not followed up by a completed questionnaire were withdrawn because they did not fit any current SHOT definitions. The numbers of cases which are written off by the SHOT office, having failed to obtain a questionnaire despite regular contact with the reporter are now so rare, that it would be inappropriate and unnecessary to continue to measure them.



4 Incorrect Blood Component Transfused

Definition

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.

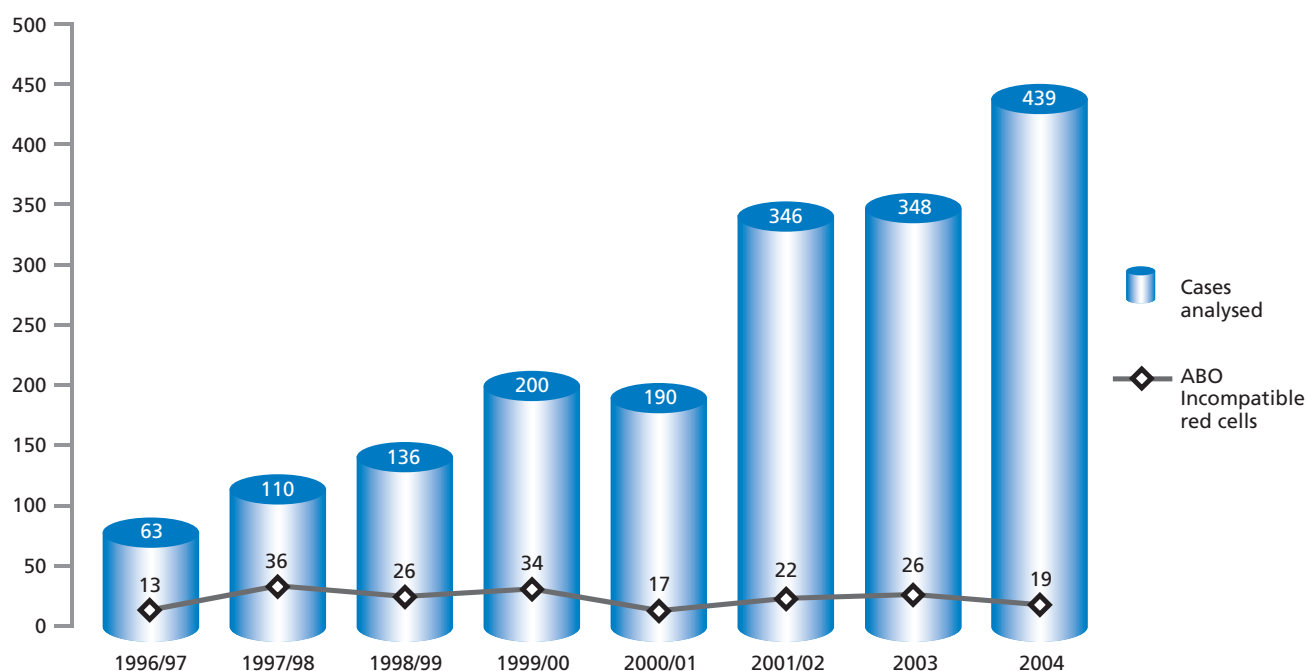
460 completed questionnaires were received.

Twenty-one reports were withdrawn by the analysts, of which 11 were "right blood to right patient" incidents, in which the patient received the intended component despite a serious breach of protocol. These are analysed separately at the end of this section. A further 10 did not meet the criteria for IBCT.

This section describes the findings from 439 analysed cases, a 26% increase from 2003. Reports of IBCT show no sign of reaching a plateau, and it is likely that the appointment of Transfusion Practitioners and establishment of Hospital Transfusion Teams is resulting in increased awareness of errors and improved reporting. Last year we noted an encouraging downward trend in reports of ABO incompatible transfusions in the context of an increase in total reports, - this year sees a continuation of this trend.

Figure 4

ABO incompatible red cell transfusions



Patients

185 males and 254 females.

Ages ranged from 1 day to 98 years.

57 reports (13%) related to patients under 18 years of whom 31 (7%) were infants under 12 months.

Mortality and morbidity

ABO incompatibility

Two patients died following ABO incompatible red cell transfusions, one considered likely (imputability 2) and one possibly (imputability 1) to be due to the transfusion.

Five patients suffered haemolytic transfusion reactions with major morbidity due to ABO incompatibility - red cells in 4 cases and FFP in one. One of these patients (see case 3 below) died from hypostatic pneumonia 6 weeks later, having been immobilised because surgery for a fracture was delayed as a result of the transfusion reaction.

One recipient of an ABO mismatched bone marrow transplant received platelets of their historic group (O) instead of donor group (A) after marrow engraftment, resulting in a haemolytic reaction.

A further 2 patients had mild haemolytic reactions following ABO incompatible red cell transfusions.

Eleven patients received ABO incompatible red cells but suffered no morbidity.

Inappropriate transfusion

Two patients died following inappropriate transfusions given in one case on the basis of a haemoglobin result from a sample from the wrong patient (case 5 below) and in another (case 6) following an incorrect haemoglobin result from a dilute sample. Death was thought to be definitely related to transfusion in the first case (imputability 3) and possibly related in the second (imputability 1).

An infant undergoing cardiac surgery developed severe bradycardia and hypotension following over-rapid platelet transfusion.

Intra-uterine transfusion of blood with too high a haematocrit (wrongly labelled by the blood centre) caused fetal distress in one case.

Other morbidity

There were 2 acute and 2 delayed haemolytic reactions reported due to irregular antibodies not identified in pre-transfusion testing. (anti-K and unknown antibody causing ATRs, anti-Jk^a and anti-Jk^b causing Delayed Transfusion Reactions (DTRs)) These cases are further discussed under 'Failure to provide for special requirements' and 'Other pre-transfusion testing errors' below.

Analysis of reported errors

The IBCT questionnaire requests much detail regarding the circumstances of events and adverse outcomes and this information is used to analyse each case individually and draw conclusions regarding the distribution and types of errors. This section seeks to highlight and illustrate some of the important issues identified from reported incidents.

Types of event and causes

'Wrong blood' events (n=88)

These patients, who received a blood component intended for a different patient or of an incorrect group, represent those at high risk of a potentially life-threatening haemolytic transfusion reaction. Nineteen patients received ABO incompatible red cell transfusions, 4 of which were also D incompatible. Two patients received ABO incompatible FFP and two ABO incompatible platelets.

Patient mis-identification (n=46)

It is notable that 16 of these cases involved patients being treated in critical care situations (ICUs, high dependency units, accident & emergency (A&E) departments and operating theatres).

There were 6 cases in which the sample for pre-transfusion testing was taken from the wrong patient or labelled with another patient's details (wrong blood in tube), and because the patient was not previously known to the laboratory, the error could not be detected.

Case 1

Shirley Bloggs was being seen in the A&E department by a Specialist Registrar (SpR) from the gynaecology ward. He was asked by the A&E Senior House Officer (SHO) to see Lara Croft, and he took Mrs Bloggs' notes with him. The A&E SHO took a sample for crossmatch from Lara Croft, but labelled it with Shirley Bloggs' details taken from the notes by the bedside. The sample was sent urgently to the laboratory, who crossmatched and issued blood for Shirley Bloggs using the sample from Lara Croft, who was group A. Meanwhile the gynae SpR returned to Shirley Bloggs, took a sample for crossmatch, labelled it (correctly) and wrote up the blood prescription. This sample was sent to the laboratory in the routine delivery, - when it arrived and was tested the error was discovered, but by this time Shirley Bloggs, who was group O, had received 4 units of group A blood. She developed acute intravascular haemolysis with renal failure and was admitted to ICU for exchange transfusion, but recovered.

In 40 cases there were errors in blood collection and administration to the patient. In 23 of these the wrong component was collected from the refrigerator and the error was not detected at the bedside, in 17 the blood was correctly delivered to the ward but was given to the wrong patient.

A common feature of these cases, documented in 17 of the 40 reports, is that the blood was 'checked' away from the patient's bedside against a compatibility form, and no wristband or other identity check was carried out. The patient details on the compatibility form will always match those on the blood pack and checking one against the other does not constitute an identity check.

Case 2

Two patients on a haemato-oncology unit were to be transfused. They had similar names (Ron Biggs and Reg Biggins). Reg Biggins' blood was ready for collection and was transferred by an auxiliary nurse to a satellite refrigerator. The blood for Ron Biggs was not yet ready.

An agency nurse was sent to collect blood for Ron. She took no documentation, went to the satellite refrigerator and took a unit of the blood intended for Reg. She then collected Ron's prescription sheet from his bedside and went to the ward office where she and a colleague checked the unit of blood against the compatibility form (as the form was issued with the blood, the details on it matched those on the blood pack). The unit of blood was transfused to Ron without further bedside check. It was fortunately ABO compatible.

Case 3

A porter was sent to the blood bank to collect a unit of blood for Fred Bloggs, whose blood group was AB D negative. He collected the correct unit but delivered it to the wrong ward, where Jane Smith, who was Group O D positive, was being transfused. On seeing the unit of blood, the staff nurse assumed that it was the second unit for Jane Smith. The staff nurse and deputy ward sister checked the unit of blood against the compatibility form away from the patient's bedside and transfused it without a bedside id check. Later that evening the ward where Fred Bloggs was being treated phoned the lab to say that the blood had not arrived. It was not traced until the next morning when the transfusion practitioner found the empty pack. The ward had noticed that Jane Smith had become jaundiced but did not associate this with the transfusion. She developed acute renal failure requiring dialysis from which she recovered, but her planned surgery for a hip fracture was postponed for 4 weeks during which she was immobile. Post-operatively she developed hypostatic pneumonia from which she died.

Other reported cases include; five further examples of blood given to the wrong patient with the same or a similar name, a patient on a renal unit who was not wearing a wristband, an unidentified male admitted to A&E whose blood sample and request form were labelled with a unique id, but blood for a different unidentified male was collected from the refrigerator and transfused, a unit of blood checked against a cardex on the end of the patient's bed but which belonged to a different patient, and two patients in adjacent beds in a haematology day unit who received one another's blood.

Blood delivered by blood service transport direct to clinical areas (n=2)

In a further 2 cases blood was delivered by blood service transport direct to a clinical area in emergency situations and transfused without further checking.

Learning points

- The final identity check when taking a blood sample or administering blood MUST be done at the patient's bedside against a wristband or equivalent form of identification. No other form of checking is acceptable under any circumstances
- The final patient identity check at the bedside must never be omitted, however urgent the clinical situation
- Mistakes can happen even in areas where there is 'one-to-one' care

Wrong ABO group determination (n=18)

Eighteen cases were reported in which there was an error in ABO group determination by a hospital transfusion laboratory. In 5 of these the wrong sample was selected for testing; in 12 the correct sample was tested using a manual method and the result was wrongly interpreted or wrongly recorded. In one worrying case, the BMS took a deliberate shortcut by omitting to perform an ABO group on the current sample, relying instead on a historic group from 3 years previously, which was unfortunately wrong. Six of these 18 patients received ABO incompatible transfusions, one died and one suffered major morbidity.

Laboratory selection and labelling errors (n=22)

In a further 22 cases a wrong blood component was selected by the laboratory, or was mis-labelled. These included 4 cases where compatibility labels were transposed, one resulting in an ABO incompatible transfusion. Five cases involved selection of FFP of a different ABO group from the patient, raising concerns about possible lack of understanding of ABO compatibility of plasma. In 7 cases D positive blood was inadvertently selected for D negative patients.

Learning points

- Manual methods of ABO group determination are not robust and are particularly unsafe in urgent situations
- BCSH guidelines for pre-transfusion testing should be adhered to
- A table of FFP compatibility should be included in laboratory procedures for components

Failure to provide components of appropriate specification or that did not meet special requirements (n=143)

These cases, which in 2004 comprised 33% of IBCT reports, are summarised in Table 2.

Table 2**Special requirements not met**

Special requirement	No of cases
Irradiated component	84
CMV negative component	10
Irradiated and CMV negative	4
Viral inactivated or non-UK FFP for child	9
Antigen negative red cells for pt with known antibody	20
ABO or D mismatched BMT recipient	7
Red cells for IUT, exchange transfusion, neonate	7
HLA matched platelets	1
Pre-deposited autologous red cells	1

As in previous reports, the majority of these cases involved failure to provide irradiated blood components for patients treated with purine analogues or who have undergone stem cell transplantation. Errors and failures of communication in 'special requirements not met' reports occurred at all stages in the transfusion chain. Contributory factors included shared care, out-patient prescribing of purine analogues not notified to the laboratory, provision of incomplete or incorrect patient details such that the transfusion history was not available, inadequate clinical information on request forms, lack of familiarity of special requirements for neonates.

Eighty-four patients (c.f. 81 last year) were put at risk of TA-GvHD by failure to provide irradiated components. Most cases arose from failure of communication between the clinical team and the blood transfusion laboratory, especially where patients were treated in more than one centre.

Seven reports were received of patients who had received ABO or D mismatched bone marrow transplants and were given blood of their historic group instead of the donor group.

In 4 cases, blood unsuitable for neonatal use was given as a matter of expediency in an emergency.

One patient had pre-deposited blood for elective surgery, but when blood was requested out of hours, there was no system in place to alert the laboratory that autologous blood was available.

Three patients suffered adverse reactions as a result of special requirements not being met; one recipient of an ABO mismatched bone marrow transplant (BMT) was given platelets of their historic group (O) after engraftment and suffered a haemolytic reaction; one fetus was transfused with blood of too high a haematocrit (wrongly labelled by the blood centre) and developed signs of distress, one patient with a previously known but currently undetectable anti-Jk^a who did not receive antigen negative blood had a mild delayed transfusion reaction.

Learning points

- Discrepant ABO grouping results must be fully investigated and resolved, taking into account relevant clinical information, before blood is issued
- Consideration should be given to the introduction of a patient held booklet (similar to the anticoagulant booklet) with details of protocols following BMT and other special requirements
- Laboratory IT systems should be updated with new rules when special requirements are introduced (e.g. methylene blue (MB) FFP for patients under 16) and used to flag special requirements

Other pre-transfusion testing errors - incorrect D groups, missed alloantibodies and missed incompatibilities (n=29)

Six cases of incorrect D group determination were reported. One was due to a reagent problem whilst the remaining 5 were related to emergency or out of hours testing. In 4 of these a manual technique was used.

Twenty-three cases were reported in which laboratories failed to identify an irregular antibody or red cell incompatibility in pre-transfusion testing. Three of these involved reference laboratories.

Three patients suffered mild haemolytic reactions. In one patient the antibody screen was positive but identification was not attempted, as this was not required by laboratory policy when testing was done out of hours. Anti-K was identified in the pre-transfusion sample when retrospective testing was carried out following the ATR. In the second case the BMS failed to notice a positive antibody screen and issued blood electronically. The antibody specificity was not recorded. The third case was due to anti-Jk^b - see case 4 below.

Case 4

A positive antibody screen was noted in a patient with a known anti-K. The BMS did not perform an identification panel, but issued K-negative crossmatch compatible blood. The patient developed a haemolytic transfusion reaction, investigation showed an anti-Jk^b detectable in the pre-transfusion sample. Procedures in the laboratory have since been modified and now state that an antibody identification must be carried out on every occasion in patients with known antibodies, consistent with guidelines.

In 5 cases a positive antibody screen was missed - in 1 an on-call BMS failed to read DiaMed cards which were found in the centrifuge the next day.

In a further 5 the antibody screen was found to be positive but the BMS did not attempt identification as this was laboratory policy out of hours and at weekends.

Two cases involved inadequate testing before issuing blood for an infant.

In 9/23 cases testing was done out of hours or at a weekend. It is of concern that there are different standards of testing in some laboratories depending on whether samples are tested during or outside of 'core hours'.

Two cases were reported in which blood was issued electronically without a serological crossmatch despite a positive antibody screen and no antibody identification.

Learning points

- The same standards should apply to pre-transfusion testing in and outside of laboratory 'core hours'
- Laboratory procedures should be consistent with current guidelines
- Maternal results must always be checked before issuing blood for a neonate
- Recommended best practice (included in forthcoming BCSH guideline on Specification and Use of IT Systems in Blood Transfusion Practice) is that all electronic issue procedures should be controlled by computer algorithms to validate appropriateness of actions

Inappropriate transfusions (n=56)**Table 3**

Cause of inappropriate transfusion	Number
FBC sample unsuitable (e.g. from 'drip arm') or from wrong patient	19
Analytical error in haematology laboratory	11
FBC result wrongly transcribed on ward	4
Wrong component given*	6
Transfusion given before haematology results available, on basis of out of date result, or in contravention of instructions	10
Blood components available 'on standby' and given without prescription	3
Wrong dose given (e.g. request for '4 units' of platelets - 4 ATDs issues)	2
Excessively rapid transfusion of platelets to an infant undergoing cardiac surgery	1

*In 1 case, 2 qualified nurses on a surgical ward gave red cells when platelets were prescribed

Case 5

A request for full blood count (FBC) was left on a ward for a phlebotomist. A blood sample was sent to the laboratory, where a Hb of 7.9g/dl was recorded and telephoned to the ward. The haematology laboratory suggested that a repeat sample was required because of the change from the previously recorded level on this patient. No repeat was sent, instead a 3 unit transfusion was prescribed and given. The post-transfusion Hb was 18.7 g/dl. Blood grouping of the pre-and post-transfusion samples revealed that the pre-transfusion sample was from a different patient. The patient was venesected but developed cardiac failure and subsequently died.

Case 6

A frail elderly lady was admitted with a chest infection, dehydration and impaired renal function. Her Hb was within the normal range. Two days later a further sample was taken and the Hb was found to be 7.7g/dl. The result was sent to the ward computer without comment. The biochemistry laboratory realised that the sample was diluted with saline and rejected the results obtained. The sample had been taken from the 'drip arm'.

A 2 unit transfusion was prescribed and given, following which the Hb was 18.0g/dl. Her creatinine increased to 251umol/l. Her renal function continued to deteriorate and she died 5 days later.

Learning points

- Correct procedures must be followed for patient sampling
- A decision to transfuse must be based on clinical assessment as well as laboratory results - look at the patient!
- Blood components must not be given without prescription
- Blood should only be prescribed by a doctor who has undergone training in blood transfusion and has been assessed as competent
- Diagnostic laboratories must carry out checks to identify large changes in parameters ('delta checks') and should not issue unvalidated reports
- Nurses giving blood must be familiar with blood components and the indications for their use

'Unsafe' transfusions (n=54)

Fifty-four patients received potentially 'unsafe' transfusions, including damaged packs (2), units past their expiry (27), or that had been out of temperature control (19). A further 6 were outwith guidelines on sampling intervals for pre-transfusion testing.

Learning points

- Named individuals should be given responsibility for checking of satellite refrigerators and for removal of expired units
- 'Emergency O D negative' blood should be rotated back into main stock before it nears expiry

Adverse events relating to anti-D immunoglobulin (Ig) (n=67)

Sixty-seven events were related to anti-D administration and are summarised in table 4 below.

Table 4

Type of event	Number
Late administration of anti-D Ig	16
Anti-D Ig given to D pos patient	15
Anti-D Ig given to patient with immune anti-D	11
Anti-D Ig given to patient with weak D antigen	10
Anti-D Ig given on basis of incorrect cord group	5
Other	10

There was evidence of lack of understanding by both midwives and laboratory staff of the significance of immune anti-D.

'Right blood to right patient' (n=86)

Eighty-six cases were received (11 re-classified from IBCT) which described episodes where the right component was given to the right patient despite one or more errors in the checking process. These cases do not fit the existing SHOT reporting categories and are, therefore, not included in the total number of incidents received. They do, however, provide some important evidence indicating that serious errors continue to be made which, in these cases, were fortuitously not harmful to the patient.

The 86 cases are summarised in table 5. These identification elements were missing from, or contained errors on, a wide variety of documentation (for example sample tubes, patient notes, wristbands etc.) Similarly the errors were made in different locations (e.g. A&E, hospital blood bank etc.)

Table 5**Right Blood to Right Patient episodes**

Elements which were wrong	Number of incidents
Date of birth	27
Spelling of name	19
Hospital number	17
Date of birth and Hospital number	6
Incorrect Surname	4
Date of birth and address	2
Transposed donation numbers	2
Spelling of name and wrong date of birth	2
A&E number	1
Date of birth, address, and first name	1
Date of birth, hospital number and first name	1
First name	1
Gender	1
NHS number	1
Missing documentation	1

Learning points

- Correct patient identification is crucial in preventing 'wrong blood' incidents. Every patient must have an id wristband or equivalent containing their surname, first name, date of birth and unique id number. For unidentified patients there must be a policy in place stating the minimum identification data set
- All staff should receive training and demonstrate competency in positive identification procedures

COMMENTARY

Notable findings this year were

- Patient mis-identification continues to cause 'wrong blood' events, with approximately one-third of such reports relating to critical care.
- Inappropriate transfusion is a potential cause of death and serious morbidity. In many cases there was inadequate clinical assessment of the patient.
- There has been an increase in reports of failure to provide for special transfusion requirements. This may in part be due to increased awareness of the problem, and increased numbers of patients at risk, and must be addressed.
- Laboratory errors are a cause for concern and in some cases reflect poor standards of practice.
- The reduction in ABO incompatible transfusions is encouraging. (Figure 4)

RECOMMENDATIONS

- Training and competency testing of all staff involved in the transfusion process must emphasise the importance of positive patient identification, with particular attention paid to critical care situations.

Action: HTCs

- All newly qualified doctors must receive education in blood transfusion as recommended by the CMO for England. A web-based education package (<http://www.learnbloodtransfusion.org>) is included in the FY1 curriculum in Scotland and should be implemented throughout the UK.

Action: CMO's NBTC, PMETB

- Pending the availability of an effective IT solution, hospitals should take steps to implement robust methods to ensure that the patient's transfusion history including special requirements is kept up to date and accessible to the transfusion laboratory at all times. A patient held booklet is one possible solution.

Action: CMO's NBTC, RTC/HTC network

- The EU Directive requires that hospital transfusion laboratories implement a quality system. Elements of this include ensuring adequate staffing levels, systematic and documented training, validation of methods and change control. This presents an opportunity to drive improvements in practice and must be fully supported, resourced and monitored.

Action: Trust CEOs

5 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.

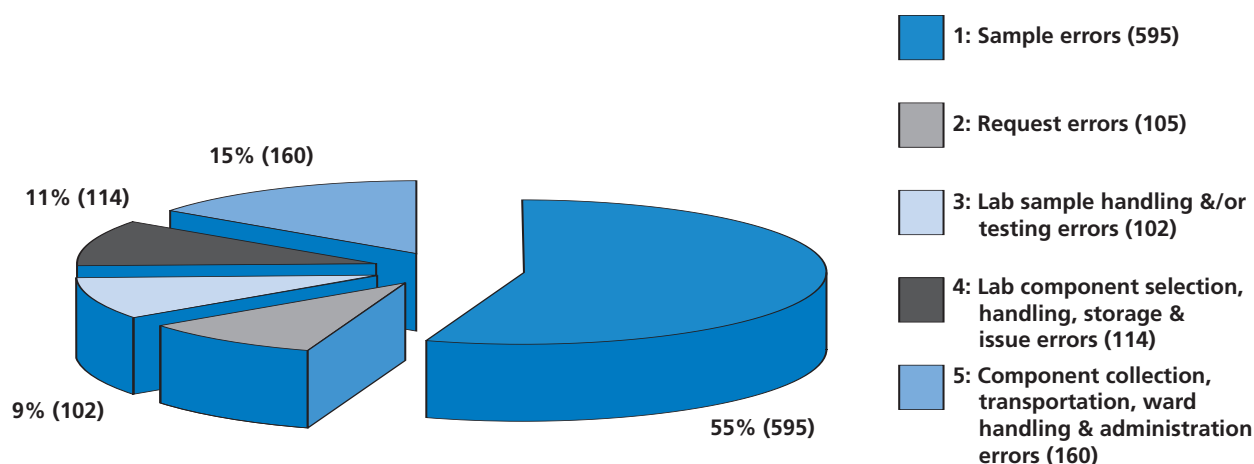
Once again the number of "near miss" incidents reported to SHOT increased from 906 in 2003 to 1076 in 2004. In addition to the 1076 incidents reported on the "near miss" questionnaires, SHOT also received 387 "bulk" reports from two hospitals (244 and 143 reports each). These incidents were submitted by reporters who kept an error log of the numbers of events in each of the 5 categories over a period of time. As no specific details were provided, they are not included in the totals.

Fourteen incidents were withdrawn from the analysis as no originating error could be determined, making it impossible to identify learning points. The majority of these incidents involved a discrepancy between the group of the current sample and the historical record. The historical record was proven to be incorrect by taking a second sample from the patient. The incorrect group recorded in the historical record could have occurred for a number of reasons, for example transcription error, wrong patient being bled or interpretation error.

The categories and numbers of events reported this year are shown in figure 5

Figure 5

Categories and proportions of "near miss" events (n = 1076)



Category 1: Sample errors (595 cases)

Again the most frequently reported "near miss" events were sample errors, comprising 55% of all incidents. There were 230/1076 cases (21.4% of errors) where the sample was taken from the wrong patient but was labelled with the intended patient's details. In 261/1076 cases (24.3% of errors), the sample was taken from the intended patient but was labelled with another patient's details and in 104/1076 cases (9.7% of errors) another error had occurred at the sampling stage. These 3 originating errors arose under a variety of circumstances and a selection of these are given below.

Table 6
Typical sample errors

Error	Number of occurrences
Prelabelled tubes	2
Maternal and cord samples transposed	17
Samples transposed	11
Samples labelled away from bedside	4
Incomplete / inaccurate details on sample	75
Sample taken from drip arm / poor venepuncture	12

In 3 cases the inaccurate details on the sample meant that the patient's historical record was not accessed. The first case involved a sample taken from the intended patient which was labelled with the wrong date of birth and forename. This meant that the antibody record could not be accessed. The second case involved a sample labelled with the wrong date of birth and the third case resulted in a patient having 2 incomplete historical records.

Category 2: Request errors (105 cases)

Request errors comprised approximately 10% of cases. One of the most frequently reported problems in this category was failure to notify the transfusion laboratory of the need for irradiated and/or cytomegalovirus (CMV) negative components. These were, in the majority of cases, prevented from going on to be full incidents by the vigilance of the laboratory staff. There were 11 cases where the request was found to be inappropriate. Five of these cases involved ward staff misreading laboratory results in the patients' notes.

Category 3: Laboratory sample handling and/or testing errors (102 cases)

Approximately 9% of errors fell in to this category. There were 8 cases of failure to investigate fully a positive antibody screen. The majority of these laboratory errors were recognised by the staff involved before the components left the laboratory.

Category 4: Laboratory component selection, handling, storage and issue errors (114 cases)

This category of errors comprised approximately 11% of cases. Forty-four of the 114 cases (4.1% of errors) involved failure by the laboratory staff to heed the request for special requirements. There were 5 cases where the laboratory staff issued Anti-D to D positive women and 1 case of Anti-D being issued to a woman previously sensitised. The inappropriate use of Anti-D is highlighted in the Incorrect Blood Component Transfused section (section 4, page 19) and continues to be an important training issue.

Category 5: Component collection, transportation, ward handling and administration errors (160 cases)

The majority of these cases (55%; 88/160), involved inappropriate storage of the components, with this error comprising 8.2% of errors in all categories. The bulk of these storage errors involved units being stored in inappropriate refrigerators or the storage of expired units due to failure to clear refrigerators. In 1 case a partially used unit was returned to the ward refrigerator and another case involved tape being removed from the door of an out of order refrigerator so that components could be stored in it. There were 42 cases (4% of errors) of the component being collected for the wrong patient. Twenty four of these cases involved porters, one of whom forgot to take his glasses with him to the refrigerator resulting in a failure to check the paperwork properly.

Table 7 below shows the distribution of originating errors and at what stage of the transfusion process the errors occurred.

Table 7

Originating Errors (n = 1076)

Originating error	No. of errors	% of errors
Sample errors		
Sample taken from wrong patient but labelled as per intended patient	230	21.4
Sample taken from intended patient but labelled as per another patient	261	24.3
Other - sample	104	9.7
	595	55.4
Request errors		
Wrong component requested	17	1.6
Special requirements incorrectly specified which were not previously known to the laboratory	30	2.8
Component requested for wrong patient	27	2.5
Other - request	31	2.9
	105	9.8
Laboratory sample handling &/or testing errors		
Incorrect patient details used	8	0.7
Erroneous result obtained	22	2
Result interpretation error	16	1.5
Transcription error	28	2.6
Other - lab sample handling, testing	28	2.6
	102	9.4
Laboratory component selection, handling, storage & issue errors		
Avoidable failure by the laboratory to provide for the patients' special needs	44	4.1
Incorrect selection of component e.g. expired or wrong type of unit	19	1.8
Incorrect labelling of component	20	1.9
Incorrect storage of component	14	1.3
Component issued for wrong patient	5	0.5
Other - lab selection, storage, issue	12	1.1
	114	10.7
Component collection, transportation, ward handling & administration errors		
Incorrect transportation of component	12	1.1
Component collected for wrong patient	42	3.9
Incorrect handling / storage of component	88	8.2
Error in identification of correct patient at time of administration of component	8	0.7
Other - collection, transport, ward handling	10	0.9
	160	14.8

Staff involved in “near miss” incidents

One thousand and twenty seven reports gave information about who was involved in the error, 42 reports were unable to identify staff involved and 7 reports gave no response to this question. The distribution of the staff involved is shown in table 8.

Table 8

Staff involved in incidents (n=1076)

Staff group	Number of incidents involving each staff group	
Medical student	1	(<0.1%)
Doctor	389	(36.2%)
Registered nurse	190	(17.7%)
Midwife	102	(9.5%)
Phlebotomist	56	(5.2%)
State registered BMS	193	(17.9%)
GP	1	(<0.1%)
Unregistered nurse	9	(0.8%)
MLA	10	(0.9%)
Trainee BMS	6	(0.6%)
Porter	33	(3.1%)
BTS staff	5	(0.5%)
Other*	32	(3%)
Unknown	42	(3.9%)
No response	7	(0.7%)

* A breakdown of staff in the “other” category can be found on the website

Sample error is still the most commonly reported event, 595/1076 cases. The majority of these errors involved medical staff (49%), nursing and midwifery staff (33%) and phlebotomists (9%). The number of doctors making mistakes in blood sampling appears disturbing. However the questionnaire from which these data are derived did not provide sufficient detail to confirm these findings. A new version is now in use which should enable us to make a more accurate statement in the future.

It is imperative that all staff groups undertaking venepuncture for pre-transfusion testing should receive training and education and have their competency tested. This is an important clinical governance issue, which should be addressed by senior managers within hospitals and trusts.

Other areas where training and education should be reviewed include; biomedical scientists involved in sample handling, pre-transfusion testing and component selection, staff involved in handling and issue of blood components (20% of errors) and registered nurses and porters involved in collection, transportation and administration practices (15% of errors).

The future of “near miss” reporting

Whilst the number of “near miss” reports have increased by 138% in 4 years, SHOT is aware that only 47% (190/404) of hospitals are regularly participating in the “near miss” scheme. “Near miss” reporting is an important means of gauging practice and providing essential evidence, which can be used to identify deficiencies in the transfusion process. Internal error logging and evaluation can be a valuable audit and educational tool.

Work is ongoing to simplify the current “near miss” questionnaires and provide hospitals with classifications for “near miss” events, in order to improve reporting in this category. If hospitals have any queries about reporting “near miss” events they should contact the SHOT office.

COMMENTARY

- Sample errors continue to comprise over half of all “near miss” incidents reported. The majority of sample errors appeared to involve medical staff (49%) and highlights the need for inclusion of education in blood safety in the medical curriculum at undergraduate and postgraduate levels.
- Failure to notify the transfusion laboratory of the need for irradiated and/or CMV negative components was one of the most frequently reported problems at the request stage.
- Over half the errors at the component collection, transportation, ward handling and administration stages involved inappropriate storage of components.
- Over the last 4 years, the numbers of “near miss” reports submitted to SHOT have increased by 138%. However, SHOT is aware that only 47% of hospitals are regularly participating in the “near miss” scheme.

RECOMMENDATIONS

- All hospitals are encouraged to report “near miss” events as required by HSC 2002/009 (BBT2)⁶ in order to further identify local weaknesses in the transfusion process. All instances of ‘wrong blood in tube’ must be fully investigated.

Action: HTTs

- Training and education in blood sampling, including the practical aspects of venepuncture and positive patient ID, should be included in the curriculum for medical and nursing students.

Action: CMO's NBTC and counterparts, Undergraduate Deans of Schools of Nursing and Medicine

- All staff involved in the pre-transfusion sampling, testing and issue of blood must be deemed competent having undergone appropriate training, which must be documented.

Action: Trust CEOs through risk management structures

- Robust systems for noting patients' special requirements should be developed together with a policy of empowering patients to be more aware of their own special needs.

Action: Clinicians, HTCs, HTTs

- Hospital transfusion laboratories should develop and adhere to policies for the timely clearing of satellite refrigerators, required by the Blood Safety and Quality Regulations 2005².

Action: Hospital transfusion laboratories

- Ward staff at all levels must be trained in appropriate storage of blood components once they have been collected from the blood bank.

Action: Ward managers, HTTs

6 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 Section 4

Forty-seven completed questionnaires were submitted for analysis. Eleven febrile non-haemolytic reactions and 1 drug reaction were withdrawn by the analyst and 1 report was transferred to the TRALI section.

This section describes the main findings from 34 completed questionnaires.

Patients

14 males and 20 females.

Ages ranged from 5 months to 87 years.

3 reports related to patients under 18 years and 1 to an infant under 12 months.

Outcomes and imputability

1 patient died following an acute unclassifiable reaction to red cells; imputability 1 (possibly related).

1 patient died following platelet transfusion, probably from acute pulmonary oedema; imputability 2 (probably related).

1 patient had an acute anaphylactic reaction causing major morbidity (respiratory arrest requiring ventilation) following FFP; imputability 3 (certain beyond reasonable doubt).

Table 9

Components implicated and types of reaction (n=34)

Reaction type	Red Cells	FFP	Platelets	Red cells, FFP and platelets	Totals
Acute haemolytic	4	0	0		4
Anaphylactic*	0	5 (1 MB-FFP)	3	1	9
Allergic**	6	9	3		18
Hypocalcaemia	0	1 (MB-FFP)	0		1
Probable acute pulmonary oedema			1		1
Unclassifiable	1	0	0		1
Total	11	15	7 ***	1	34
Incidence of reports per 100,000 components issued	0.4	4.0	5.8		1.0

* anaphylactic/anaphylactoid is defined as hypotension with one or more of: rash, dyspnoea, angioedema

** allergic is defined as one or more of: rash, dyspnoea, angioedema **without** hypotension

*** 5 were from buffy coat pools, 2 apheresis

Time relationship to transfusion

23 reactions occurred during the transfusion and 11 within 2 hours of completion.

Acute Haemolytic Reactions (n=4)

In every case, a reference laboratory was involved, either in providing antigen matched units or in the subsequent investigation of the reaction.

All patients had a negative pre-transfusion antibody screen. Antibodies reported on post-transfusion testing by reference laboratories were: an anti-Le^a active at ambient temperature, an anti-E detectable only by enzyme technique, an anti-Jk^a detectable by enzyme IAT, (not identifiable until 5 days post transfusion), and an IgM pan-agglutinin reacting at temperatures up to 30°C

Anaphylactic Reactions (n=9)

Six patients were investigated for IgA deficiency, with negative findings. Two patients receiving platelets were also investigated for HLA and platelet specific antibodies, with negative findings.

Mast cell tryptase, which is typically transiently raised in severe allergic reactions, was requested in one patient and was found to be elevated.

One patient with TTP developed a rash and dyspnoea during plasma exchange with standard FFP but subsequent exchanges were uneventful using solvent-detergent treated plasma. The hospital now routinely uses solvent-detergent treated plasma for plasma exchanges (in line with current recommendations from MSBT).

One patient of 18 years had convulsions whilst hypotensive.

A 10 year old girl had experienced a mild allergic reaction during the previous two platelet transfusions but had not been given any pre-medication for the transfusion episode in question, following which she became dyspnoeic and hypotensive. The hospital now pre-medicates patients receiving platelets if they have suffered from a previous allergic reaction.

There were no instances of inappropriate FFP transfusions in this group.

One reaction involved MB-FFP.

Allergic reactions (n=18)

Five patients were investigated for IgA deficiency with negative findings. HLA antibodies were found in one of the 2 platelet recipients investigated.

Two patients received FFP outwith BCSH recommendations.

Deaths associated with transfusion

Case 1

An 87 year old male with multiple myeloma requiring regular red cell support developed rigors, hypotension and neck pain following transfusion of 100ml red cells. He died despite active resuscitation measures.

The unit was confirmed to be ABO identical and pre- and post-transfusion antibody screens were negative. A post mortem examination gave the cause of death as acute coronary insufficiency.

No bacterial cultures of the patient or unit were performed, hence bacterial contamination cannot be excluded.

Case 2

A 62 year old female with disseminated ovarian carcinoma, ischaemic heart disease and thrombocytopenia was transfused with 1 ATD of pooled buffy coat platelets prior to the reinsertion of a nephrostomy tube. Within 2 hours of completing the transfusion she became flushed, hypertensive and started coughing up "pink frothy sputum". She died before any attempts could be made to resuscitate her.

A tentative diagnosis of massive pulmonary embolus was made and the family declined a post mortem. However the clinical findings of a raised blood pressure and the nature of the sputum would favour acute pulmonary oedema.

Hypocalcaemia following MB-FFP transfusion

Case 3

A 5 month old female with pulmonary atresia underwent a Blalock-Taussig shunt operation and received MB treated FFP post-operatively to correct a prolonged prothrombin time. After 100ml plasma had been transfused the infant developed hypotension and bradycardia and was found to have a low ionised calcium of 0.31mmol/l. She made a rapid recovery following intravenous calcium, sodium bicarbonate and adrenaline.

Clinical management and case review

Most patients were seen promptly by a doctor and a Consultant Haematologist was also consulted.

Table 10

Time interval between reaction and medical examination

Time before seen by a doctor	Patients
< 15 minutes	21
< 30 minutes	7
< 60 minutes	2
Unknown	4
Total	34
Haematologist involved	22
Case review	
Reported to HTC	27
Reported to hospital laboratory	31
Reported to blood centre	17

COMMENTARY

- All cases of haemolytic transfusion reactions were referred to their local reference laboratory, in contrast with previous years.
- All reports of anaphylactic reactions were due to FFP or platelets. Although an increased proportion of patients with these reactions is investigated, there is no consistency of approach and a guideline is still awaited for the investigation of ATR.
- The two deaths occurring within hours of transfusion were not attributed to the transfusion by the reporters. However whilst the patients' underlying disease certainly contributed, their transfusions cannot be discounted as contributory factors.

RECOMMENDATIONS

- In the continued absence of a published national guideline for investigation ATRs, SHOT is developing, in collaboration with the BCSH Transfusion Taskforce, a minimum standard for investigation. This will be included in the Toolkit on the SHOT website.

Action: SHOT, BCSH TTF, HTTs investigating ATRs

- In the event of a patient death during or immediately following blood transfusion, the possibility of an ATR must be considered and investigated.

Action: HTCs for inclusion in transfusion policies

7 Adverse reactions to post-operative cell salvage

The increasing implementation of strategies to reduce allogeneic transfusion requires monitoring of their safety alongside haemovigilance. Post operative cell salvage following knee replacement is an effective means of reducing blood use and a number of different devices are available. A cluster of adverse reactions associated with re-infusion of unwashed salvaged blood has been reported this year from a single hospital. Although these reactions do not fulfil the SHOT definitions for severe allergic or anaphylactic reactions we feel that it is important to report on adverse reactions to currently used technology in order to increase awareness and enable better assessment of the relative risks of autologous and allogeneic transfusion.

Post-operative cell salvage devices drain blood from around the surgical site. In the reporting hospital if greater than 100 ml of blood is collected within 6 hours, the unwashed, citrated blood is transfused. This can be repeated up to 12 hours post surgery or until a maximum of 1500ml has been infused.

Adverse reactions during re-infusion were first noticed in mid 2003. The hospital began to systematically document cases in 2004 and have reported 13 reactions occurring out of a total of 811 procedures, giving an incidence of 1.6%. All reactions consisted of gross bodily shaking +/- pyrexia. Transfusion was discontinued in all cases, and the reactions responded promptly to symptomatic treatment. One patient was found to have an irregular pulse and electrocardiogram (ECG) identified ventricular ectopics, however no other postoperative problems occurred and discharge was unaffected in all cases.

Laboratory investigations revealed that the lactate dehydrogenase (LDH) was raised in all 12 cases where it was measured and the C-reactive protein (CRP) raised in 9/12 cases. These abnormalities may have been due to the recent surgery. Blood cultures were performed in 11 patients and were negative. The occurrence of a reaction did not appear to be associated with a particular surgeon, anaesthetist, individual machine used, batch of disposable kit, volume of autologous blood infused, person setting up the transfusion or concomitant drug therapy. Twelve cases involved the Dideco system and one a Suretrans machine.

A literature search revealed that pyrexial reactions have been well documented following postoperative blood salvage and reinfusion after total joint arthroplasty.^{15,16,17,18,19} The reported incidence varies from 1.5%¹⁵ up to 12%^{16,18} and suggested causes include -

- recovery from hypothermia and surgical trauma not associated with transfusion¹⁷
- cytokine release from the wound, again not associated with transfusion²⁰
- intravenous infusion of cytokines present in the salvaged blood^{21,22,23}
- Acrylic monomers used in the cement¹⁸

RECOMMENDATIONS

- Users of post-operative salvage should continue to monitor patients for adverse reactions. Those of sufficient severity to require discontinuation of transfusion should be reported to SHOT together with information on total numbers of procedures.

8 Delayed Transfusion Reactions

Definition

Delayed transfusion reactions are defined as those occurring more than 24 hours following a transfusion of blood or blood components. In practice, these are usually 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.

Forty-four questionnaires were received, one of which was transferred to the Incorrect Blood Component Transfused section. This section describes the main findings from 43 completed questionnaires.

Patients

17 males and 26 females.
Ages ranged from 30 to 88.

Outcomes and imputability

Number of reports: 43
Haemolytic: 42
Non-haemolytic: 1

Five patients died, none thought to be related to the transfusion (Imputability 0).

Fourteen patients were asymptomatic with a positive DAT only.

Twenty-three patients had evidence of increased red cell destruction without renal impairment:

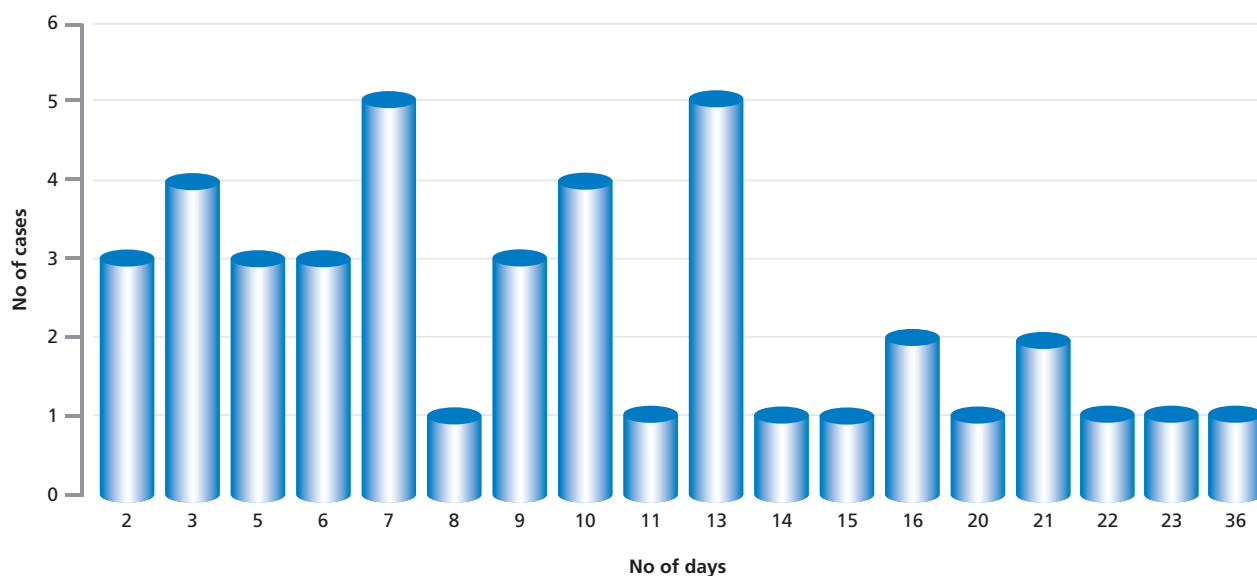
- In 9 cases the only sign was a fall in haemoglobin (spherocytes were noted in one case).
- In 14 cases there was a fall in haemoglobin and a raised plasma bilirubin (spherocytes were noted in 2 cases). Haemoglobinuria was also noted in two of these cases. In one (case 11), an autoantibody had also developed, and it is therefore unclear whether the signs of haemolysis were due to allo or autoantibody, or both.

Five patients had increased red cell destruction and renal impairment; one died unrelated to the transfusion, whilst the other 4 did not suffer any long term morbidity:

- Case 4 had a raised bilirubin and signs of deteriorating renal function 11 days post transfusion; however, it is not clear that the latter was related to the transfusion. This patient was already on the intensive therapy unit (ITU) following redo coronary artery bypass grafting and mitral valve replacement.
- Case 7 had haemoglobinuria, raised plasma bilirubin and deteriorating renal function 13 days post transfusion, and required re-admission to hospital.
- Case 10 was re-admitted 9 days post transfusion with abdominal pain and frequency. On day 10, there was laboratory evidence of deteriorating renal function and disseminated intravascular coagulation (DIC), and the patient had jaundice and dark urine.
- Case 20 required ITU admission with falling Hb, raised plasma bilirubin and deteriorating renal function 13 days post transfusion.
- Case 36 had vomiting and tachycardia, 13 days post transfusion. The plasma bilirubin was raised and there was evidence of deteriorating renal function. However, the imputability is low, with the reaction only possibly related to the transfusion. The patient subsequently but co-incidentally suffered a cardiac arrest and died.

Non-haemolytic reactions

There was a single case report of a non-haemolytic delayed reaction.
See vignette for details (case 12, page 39).

Figure 6**Time relationship to transfusion**

Median = 9 days

Range = 2 to 36 days

Figure 6 shows the interval in days between the implicated transfusion and signs or symptoms of a DHTR. The intervals given are necessarily those when the signs or symptoms were first noted. However, it is likely that some extravascular haemolysis was ongoing during or shortly after the transfusion in those cases where the causative antibody was retrospectively detectable in the pre-transfusion sample, or when the reaction was clinically noted within 48 hours of the transfusion.

Serological findings

25 (60%) of cases developed Kidd antibodies, either singly or in conjunction with other specificities. One patient with sickle cell disease and sepsis had a severe haemolytic episode two days post transfusion, but had no detectable antibodies. Table 11 shows the specificity of new antibodies detected post-transfusion, by blood group system.

Table 11

New specificities by blood group system

Antibody specificity by blood group system	Number of cases	Sole new antibody
Kidd		
Jk ^a	19	14
Jk ^b	6	1
Rh		
C ^w	1	0
E	9	3
c	4	1 (with anti-E)
D	2	0
C	3	0
ce	1	1
Kell		
k	1	1
Duffy		
Fy ^a	7	4
Fy ^b	1	1
MNSs		
S	1	0
M (37°C)	1	0
Other		
Lu ^a	1	0

Techniques Used

Table 12 shows the technology used for antibody screening by IAT.

Table 12

IAT technology used for antibody screening

IAT screening technology	Number of cases	By automation
BioVue	14	14 (100%)
DiaMed	24	16 (67%)
Solid phase	3	3 (100%)
DiaMed/Solid phase	1	no answer

Retrospective testing findings

Retrospective testing was undertaken in 21 (50%) cases; the same result was obtained in 19 of these. In the other 2 cases, anti-Jk^a was retrospectively detected in the pre-transfusion sample. In the first of these, the antibody was detected using additional techniques (PEG and enzyme IAT); in the second, the antibody was detected in the full panel, but not the screen, despite the presence of a Jk(a+b-) cell on the 3-cell screening panel. In both cases the anti-Jk^a was detected by IAT, 3 days post transfusion.

Clinical management and review

21 (50%) of cases were referred to the NBS and 38 (90%) to the HTC. One case was reported to neither.

Vignettes

Case 12

A 48 year old female patient was transfused with 4 units of red cells for menorrhagia. Two days later she suffered from joint swelling and pain, particularly in the knees, and was treated with antihistamines. The presence of anti-IgA antibodies in the patient's serum was confirmed by the reference centre and was the presumed cause of this unusual reaction.

Case 11

A 30 year old, transfusion dependent male patient with β -thalassaemia major received a regular 2 unit red cell transfusion. The patient had known anti-C^w and anti-Kp^a, but the anti-C^w was no longer detectable and, following blood service policy (and national guidelines), crossmatch compatible blood was given. Twenty-one days later, the patient's Hb was lower than expected, although no investigation was undertaken at that time. Forty-one days post transfusion, retesting demonstrated a strongly detectable anti-C^w and a weak auto anti-e, with both specificities present in an eluate made from the patient's red cells. There was further evidence of haemolysis demonstrated by a raised plasma bilirubin.

Although it is not clear whether the allo anti-C^w or the auto anti-e was responsible for the haemolysis, this case raises an interesting point about policies for not selecting antigen negative red cells for patients with antibodies to low incidence antigens, when the antibody is no longer detectable. This is especially pertinent in patients requiring chronic transfusions.

COMMENTS AND RECOMMENDATIONS

No new recommendations are made this year. The recommendations made in last year's report remain pertinent and are restated here.

- Investigation of a suspected DHTR should include retesting of the pre-transfusion sample (where still available) by different or more sensitive techniques. This may involve referral to a reference centre.

Action: Hospital blood transfusion laboratories

- Automated systems or changes to IAT technology should be validated using a range of weak antibodies to ensure appropriate sensitivity.

Action: Hospital blood transfusion laboratories

- Consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being crossmatched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.

Action: The CMO's NBTC and its counterparts in Scotland, Wales, and Northern Ireland

- There is a need for a review, co-ordinated by a professional national body, of how long specimens should be kept post-transfusion. The review needs to consider the relative risks and benefits of storing specimens beyond the time that they are suitable for use in further crossmatching tests.

Action: BBTS and BCSH

9 Transfusion-Related Acute Lung Injury

Definition

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

Twenty-seven cases were reported, of which 3 were withdrawn by the analyst and 1 by the National Medical Co-ordinator on receipt of the report, leaving 23 cases which were analysed and are reported here.

Summary of reported cases

Every case was reviewed by an expert panel including a transfusion medicine specialist, an immunologist and a critical care anaesthetist. As in previous years, cases were classified into four groups, as shown in Table 13

Table 13

Classification of cases

Likelihood	Criteria	No.
Highly likely	Convincing clinical picture and positive serology	10
Probable	Either: a less convincing history and positive serology; or a good history and less convincing or absent serology	3
Possible	Either the clinical picture or serology was compatible with TRALI, but other causes could not be excluded	4
Unlikely	Clinical picture and serology were not supportive of the diagnosis	6

Patients

There were 15 males and 8 females, ranging in age from 7 to 83 years.

3 patients were less than 18 years old.

Patient outcomes and imputability

Two deaths occurred in the 13 highly likely and probable cases. In the first case TRALI was considered likely to have contributed to the patient's death (imputability 2) and in the second case it was considered possible that TRALI had contributed, but other causes could not be excluded (imputability 1).

Of the 4 cases in which TRALI was considered possible, 1 patient died. It was therefore possible that TRALI had contributed to the patient's death, but other causes could not be excluded (imputability 1).

Two of the 6 unlikely TRALI cases died from causes unrelated to transfusion (imputability 0).

Time relationship to transfusion

The definition of TRALI currently used by SHOT includes cases occurring up to 24 hours after transfusion. In 18 of the 23 cases the temporal relationship between transfusion and respiratory symptoms was reported. Of these, the reaction occurred during or immediately after transfusion in 11 cases, and between 1 and 5 hours in 7. Thus all 18 fulfil the Canadian Consensus Conference proposed criterion of acute lung injury (ALI) occurring within 6 hours of transfusion.²⁴

Immunological findings

Donor Antibodies

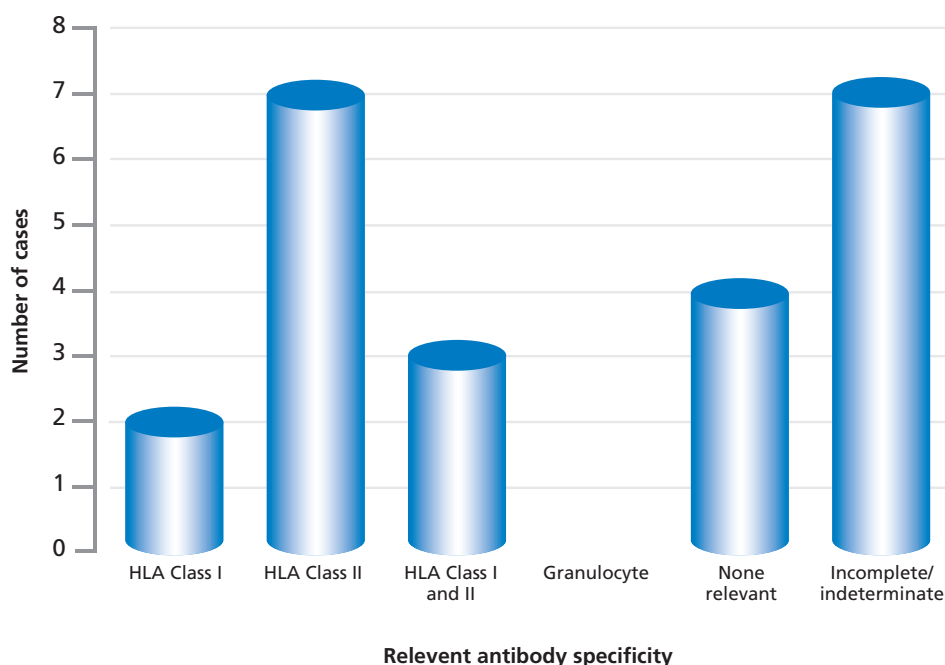
Relevant donor antibodies were identified in 12 of 23 cases. These were either specific antibodies corresponding with patient leucocyte antigens (9 cases) or leucocyte antibodies without identified specificity but with positive donor/patient crossmatch results (3 cases). Of the remaining 11 cases; relevant donor antibodies were excluded in 4 cases, in one case the results were indeterminate and 6 case investigations were incomplete.

The 6 incomplete investigations were due to unavailability of patient sample for crossmatch studies in 4 cases (one of these patients had died); laboratory investigation was halted in the other 2 cases because another cause of the reaction was considered more likely.

Analysis of the results of identification of implicated donor antibodies is shown in the Figure 7.

Figure 7

Implicated donor antibodies



Patient antibodies

One patient had anti HLA Class I antibodies which corresponded with the HLA type of two of the donors who contributed buffy coats to an implicated platelet pool. One of these donors also contributed the plasma to the pool. This donor also had HLA Class I antibodies of undefined specificity but a fresh patient sample could not be obtained for cross match. It was considered that the plasma donor's antibodies were more likely to be of relevance in this case than the patient's antibody because the platelet pool was leucocyte depleted.

Components implicated, serology, and likelihood of TRALI

Of the 13 cases considered to be highly likely or probable, FFP was the implicated component in 6, platelets in 4 (3 buffy coat pools, 1 apheresis), red cells in 2 (1 plasma reduced, 1 OAS), and whole blood in 1. All the implicated donors were female and all had leucocyte antibodies. Incompatibility between donor and recipient was proven in 11 of these cases. It should be noted that no case in which FFP was implicated occurred later than January 2004. The NBS started to select male donors preferentially for the production of FFP from October 2003, but previously issued FFP (with a 12 month shelf life) produced from female donors was not recalled from hospitals.

Buffy coat derived platelets were implicated in three reports of cases assessed as highly likely or probable. In each of these cases the plasma contributor to the platelet pool was a leucocyte antibody positive female. NBS is now suspending 80-90% of platelet pools in male plasma.

Whole blood was implicated in a case that occurred following treatment of a post-partum haemorrhage. This case was considered highly likely to have been TRALI.

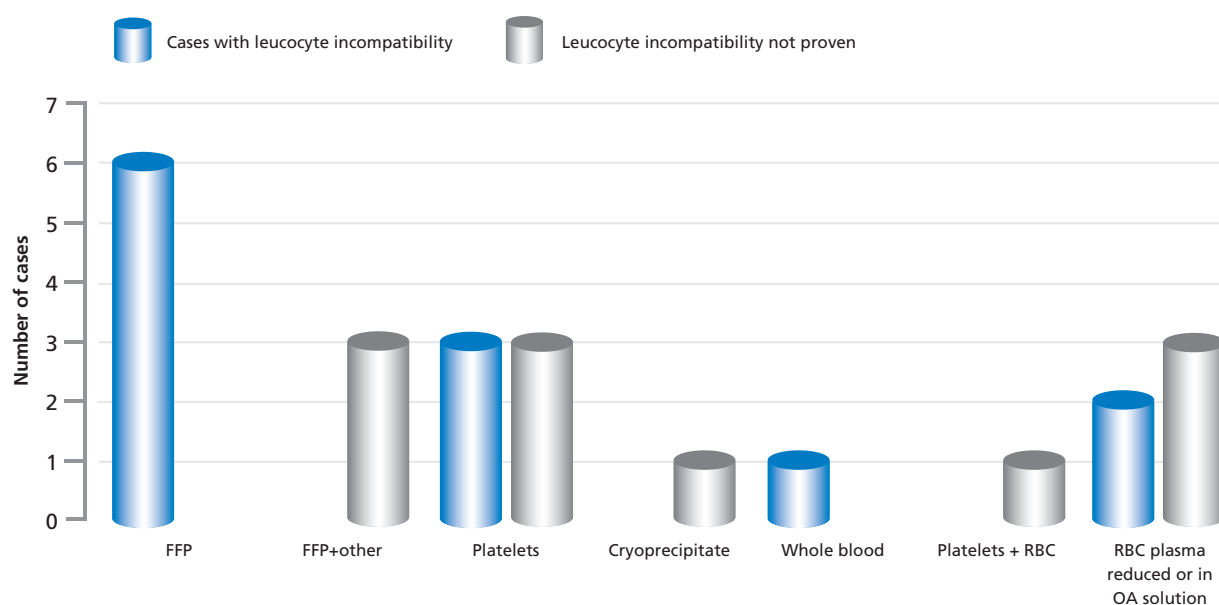
Of the 4 cases considered to be possible, the implicated components were thought to be RBCs in OAS in 1 case, platelets in 2 (1 apheresis and 1 buffy coat pool), and cryoprecipitate in 1. All of the implicated donors were female.

The 6 patients in whom TRALI was considered unlikely all had other risk factors for ALI. Four had received multiple components and 2 red cells only. There was no supporting serology to implicate a particular component.

All cases were analysed according to implicated component and whether leucocyte incompatibility was proven (12 cases) or not (11 cases).

Figure 8

Analysis of components implicated in TRALI



Comparison with previous years

A comparison of case numbers with those from 2003 and 2001/2 is shown in Table 14 (page 43). It should be noted that, because of the time taken to complete serological investigations, many cases are not reported until several months after the event. In 12/23 cases in this report, the clinical event occurred prior to December 2003.

Table 14**3 year comparison of case numbers**

Reporting year	2004	2003	2001-2 (15 months)
TRALI cases analysed	23	36	33
Highly likely	10	20	13
Probable	3	2	5
Possible	4	6	14
Unlikely	6	8	1

COMMENTARY

Fewer cases in total have been reported this year. This fall can be accounted for by a drop in reports attributed either to FFP (from 14 to 6) or platelets (from 10 to 6). This is consistent with the main fall being in highly likely or probable cases, however cases reported in 2004 relate to FFP from female donors issued prior to the introduction of male-only FFP in January 2004. Due to the long lag phase required to complete investigations and the long shelf-life of FFP stored in hospital blood banks, a longer period of observation is required to assess the impact of 'male-only' FFP. The fall in platelet cases may also be attributed to the policy of suspending platelet pools in male plasma as far as possible. No specific steps are currently taken to minimise the risk of TRALI from apheresis platelets.

Donor HLA Class II antibodies were again the most frequently implicated antibodies in cases of TRALI. They were detected in 10 of 12 proven cases of leucocyte incompatibility between donor and recipient.

No suspected case was associated with proven granulocyte incompatibility.

RECOMMENDATIONS

The recommendations made by SHOT last year in relation to TRALI remain relevant.

- Every effort must be made to avoid unnecessary transfusion of plasma rich blood components including FFP and platelets.

Action: Clinicians administering blood transfusion

- FFP continues to be associated with risks of reactions including TRALI and should only be used when clinically indicated in accordance with BCSH guidelines.¹² Guidelines for the management of high INRs due to warfarin therapy should also be followed.¹³

Action: Clinicians administering blood transfusion

- Transfusion of whole blood should be discouraged.

Action: HTTs

- Hospital staff should continue to be aware of TRALI and report possible cases to the local Blood Centre to facilitate investigation. Continued education of all relevant staff about this condition is needed.

Action: HTTs; clinicians administering blood transfusion

- Cases should be evaluated early by the consultant(s) involved. A team approach including the haematologist and chest physician and/or ICU consultant is recommended. There should be early liaison with the local Blood Centre.

Action: Clinicians administering blood transfusion plus haematologists, chest physicians and ICU consultants

- Serological investigation of suspected TRALI cases must include tests for antibodies to HLA Class II, HLA Class I and granulocyte specific antigens.

Action: UK Blood Services

- UK Blood Services should continue to consider strategies to minimise the risk of TRALI from apheresis platelets.

Action: UK Blood Services

10 Transfusion Transmitted Infections

Definition

A report was classified as a **transfusion transmitted infection** if, following investigation: -

- The recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection

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 contain the agent of infection

In 2004, and for the first time since surveillance of TTIs began in 1995, there were no reports of bacterial sepsis resulting from transfused components or of transmission of microbial infections for which blood in the UK is routinely tested. However, one report was made of an incident involving the transfusion of a unit of platelets contaminated with *Staphylococcus epidermidis* from a donor's arm but transmission to the recipient could not be confirmed.

Reports of suspected transfusion transmitted infections

34 reports of suspected transfusion transmitted infections were referred from blood centres throughout the UK (33 in England and Wales, 1 in Scotland) to the NBS/HPA Centre for Infection Surveillance for investigation. Only one report (hepatitis E) was determined to be a TTI according to the above definition.ⁱ Of the 33 remaining reports, in 31 (14 bacteraemia, 1 hepatitis A, 10 hepatitis B, 5 hepatitis C, 1 HIV) transfusion was not implicated as the source of infection. One (hepatitis C) involved a recipient transfused with 143 units during 1993 that could neither be confirmed nor refuted as a TTI, and one (HHV8) is pending complete investigation. All UK blood centres contributed to the scheme.

Case report of transfusion transmitted hepatitis E

A repeat donor reported onset of jaundice 23 days post donation. The archive sample from the donation was tested and found positive for HEV RNA. The platelets and red cells from this donation had been transfused and the recipients were traced and tested; the plasma had been discarded. The platelet recipient (55 year old female) was tested 84 days after transfusion, and had not developed markers for hepatitis E infection. The 65 year old male recipient of the red cell unit tested positive for HEV RNA and HEV IgM two months post-transfusion. He remained asymptomatic apart from mild jaundice and abnormal liver function tests, which may not have been noted if he had not been under surveillance. He became HEV RNA negative three months post-transfusion. No source of the donor's infection was identified. Sequence and phylogenetic analysis showed identity between donor and recipient viruses.

Reports of further incidents

Bacteria

1. A 75 year old female patient with chronic lymphatic leukaemia developed rigors, vomiting and pyrexia following transfusion of a 5-day old pooled platelet unit. The transfusion was terminated and the patient recovered. An identical strain of *S.epidermidis* was isolated from the transfused platelet pack and from the venepuncture site of one of the four contributing donors. However, the organism was not isolated from the recipient following the reaction. This is evidence of bacterial contamination of a platelet pool from a donor's arm and suggests arm cleansing was inadequate. Although transmission to the recipient was not confirmed it would seem likely.

ⁱ For inclusion and exclusion criteria and method of surveillance see SHOT 2003 annual report.²⁷

2. A 5-day old grossly contaminated pooled platelet unit was identified by visual inspection by the hospital before it was issued to the ward for transfusion and 12 hours before it expired. The unit was returned to the blood centre for testing and was found to be contaminated with *Escherichia coli*. This represents a "near miss" incident, i.e. had it not been recognised, transfusion of a bacterially contaminated unit could have occurred. Subsequent testing of the donor found no evidence of *E.coli* on the donor's arm.

Other organisms

1. A report was received of an incident involving the transfusion of a unit of red cells from a donor who was retrospectively found positive for malaria antibodies. In January 2005, an individual with a past history (1986) of treated malaria presented as a blood donor. The individual had previously donated blood in September 2004 and because of a procedural error this donation was not tested for malarial antibodies. The red cells were transfused in October 2004 to an elderly female for treatment of a gastrointestinal haemorrhage. The recipient had died of her underlying disease in January 2005. Although no blood samples were taken in January, earlier samples showed no malarial parasites. Subsequent samples from the donor showed high levels of malarial antibodies but were negative for all other tests, including polymerase chain reaction (PCR). Whilst transmission of malaria is unlikely, this incident emphasises the need for robust procedures to ensure the reliability of discretionary testing.ⁱⁱ

2. In 2004, the National CJD Surveillance Unit reported a case of possible prion transfusion transmission.²⁵ In 1999, an elderly patient received a unit of non leucodepleted red blood cells. The donor developed symptoms of vCJD 18 months after donation and died in 2001. The diagnosis of vCJD in the donor was confirmed at post mortem. The recipient died of causes unrelated to vCJD five years after the transfusion. Autopsy revealed protease-resistant prion protein (Pr^{Pres}) in the spleen and in a cervical lymph node. The patient was a UK resident, so dietary exposure to bovine spongiform encephalopathy (BSE) cannot be excluded. It is uncertain whether the individual would have subsequently developed clinically evident vCJD or posed a risk for iatrogenic transmission. The patient has a different genotype at codon 129 of the prion protein to that found so far in people with vCJD. This may affect estimates of future incidence of vCJD in the UK.

Cumulative data, 1995-2004

Figure 9, page 47, shows the cumulative number of reports of suspected TTI's and post-transfusion reactions made to NBS/HPA Centre for Infections Surveillance since October 1995. Table 15, page 47, shows the cumulative number of reports of TTIs by year of transfusion.

COMMENTARY

- In 2004, and for the first time since surveillance of TTIs began in 1995, there were no reports of bacterial infection by transfused components or of transmission of microbial infections for which blood in the UK is routinely tested. However, one report was made of an incident involving the transfusion of a unit of platelets contaminated with *S.epidermidis* from a donor's arm but transmission to the recipient could not be confirmed.
- The identification of a case of transfusion transmitted hepatitis E in 2004 prompted the insertion into the donor selection guidelines in 2005 of an entry for hepatitis E (<http://www.transfusionguidelines.org.uk/docs/pdfs/tdsg02r3.pdf>). The guideline states that an individual must not donate blood until 12 months after their (or their contact's) recovery from hepatitis E infection. This is compatible with guidelines for other types of viral hepatitis. Prior to this change, general guidance for any individual with a history of hepatitis infection applied.

ⁱⁱDiscretionary testing is testing that is performed on selected donations in addition to routine mandatory testing. This includes testing for malaria, and other infections, where a donor has reported possible travel or other exposure during the pre-donation donor health check, as recommended in the donor selection guidelines. For further information see UK Guidelines at <http://www.transfusionguidelines.org.uk>.

- Post donation information led to the ascertainment of the transfusion transmitted hepatitis E incident in 2004; the recipient was asymptomatic and the transmission may not have been detected had the donor not contacted the blood service about his suspected infection. Although there were unlikely to be any serious consequences following this transmission of hepatitis E, this incident illustrates the importance of post donation information and the need to act upon it.
- Surveillance of TTIs tends to be biased towards ascertainment of acute cases that are clinically apparent. Each year the number of reports received is small and fluctuations are to be expected. However, this year's findings are consistent with the current very low estimated risk of HIV, HCV and HBV infectious donations entering the UK blood supply,²⁶ and with the implementation of the strategy to divert the first 20-30mL of each blood donation in 2002 to reduce the risk of bacterial contamination of components.
- With the report of a second case of possible prion transmission in 2004, evidence to support the transmission of human prion disease through transfusion accumulates. However, in both cases the possibility that the recipient acquired infection through dietary exposure to BSE could not be ruled out. A number of precautions are in place to reduce the risk of transmission through blood transfusion.
- The Standing Advisory Committees (SAC) of the Joint UKBTS/NIBSC Executive Liaison Committee (JPAC) make recommendations to the Guidelines for the Blood Transfusion Services in UK in relation to the prevention of transfusion-transmitted infections. For example, SAC Transfusion Transmitted Infection (SACTTI) regularly reviews the residual risk of transfusion transmitted HCV, HIV and HBV infections to assess the need for additional testing methods, such as HIV RNA testing, HBV DNA or anti-HBc. SAC Care and Selection of Donors ensures donor deferral criteria are optimal in terms of exclusion of donors with behaviour that may put them at high risk of contracting transfusion transmissible infections.

RECOMMENDATIONS

- Efforts to prevent bacterial contamination of blood components should continue. These include
 - Continuation of diversion of the first 20-30 mL of the donation (likely to contain any organisms entering the collection needle from the venepuncture site).
 - Careful attention to adequate cleansing of donors' arms.
 - Adherence to BCSH guidelines (1999)¹⁴ with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion.

Action: UK Blood Services, hospital transfusion laboratories, staff undertaking pre-transfusion bedside checking

- Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria. Attention should be paid to the sampling and storage of implicated units or their residues.

Action: HTTs

- Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately.

Action: HTTs

- UK Blood Service collection teams should ensure donor selection guidelines are adhered to at all times in order to prevent transmission of blood borne infections.

Action: UK Transfusion Services

Figure 9: Reports of possible TTI's in the UK in England and Wales made to NBS/HPA Centre for Infections surveillance, by year of report to 31/12/2004 (Scotland included from 10/98)

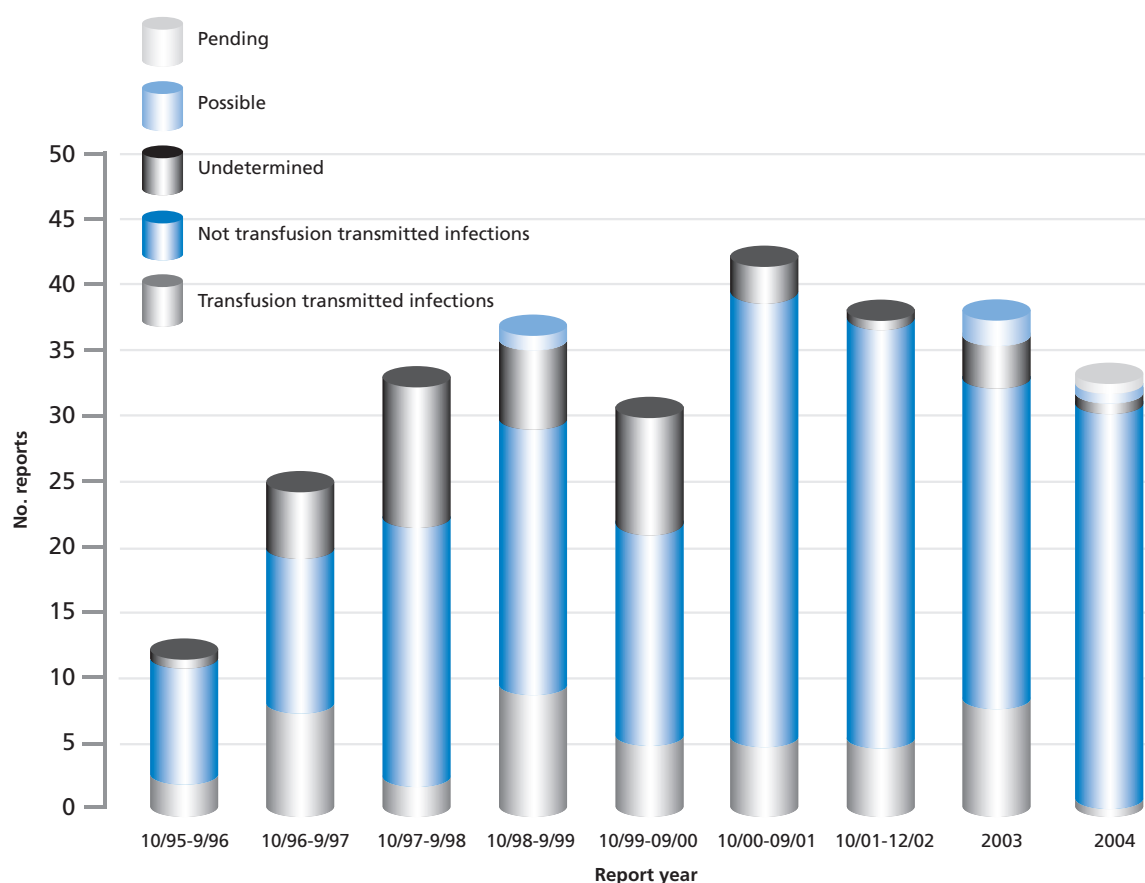


Table 15

Cumulative total of reports of TTI's made to NBS/HPA Centre for Infections surveillance between 1/10/1995-31/12/2004 by year of transfusion and infection. The number of incidents is shown with the total number of identified infected recipients in brackets.

Year of transfusion	Pre 1997	1997	1998	1999	2000	2001	2002	2003	2004	Total	Deaths ^a
Infection											
HAV	1(1)	-	-	-	1 (1)	-	-	-	-	2	-
HBV	3(3) ^b	1(1)	1(1)	2(3)	1(1)	-	1(1)	1(1)	-	10	-
HCV	1(1)	1(1)	-	-	-	-	-	-	-	2	-
HIV ^c	1(3)	-	-	-	-	-	1(1)	-	-	2	-
HEV	-	-	-	-	-	-	-	-	1(1)	1	-
HTLV I	2(2)	-	-	-	-	-	-	-	-	2	-
Bacteria	2(2)	3(3)	4(4) ^{2a}	4(4) ^a	7(7) ^{3a}	5(5)	1(1)	3(3) ^a	-	29	7
Malaria	-	1(1) ^a	-	-	-	-	-	1(1)	-	2	1
vCJD	1(1)	-	-	-	-	-	-	-	-	1	-
Possible prion transmission	-	-	-	1(1)	-	-	-	-	-	1	-
Total ^d	11(13) ^b	6(6)^a	5(5)^{2a}	7(7)^a	9(9)	5(5)	3(3)	5(5)	1(1)	52	8

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

^{2a} Infection was implicated in the deaths of 2 recipients.

^{3a} Infection was implicated in the deaths of 3 recipients.

^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.

11 Acknowledgements

The Steering Group would like to take this opportunity to thank the following individuals and organisations for their contributions without which the publication of this eighth annual SHOT report would not have been possible.

The Blood Transfusion Services of the United Kingdom for funding

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*The Royal College of Pathologists for their support and use of facilities*

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Financial Services - NBS

~~~~~

*Karen Carter - Marketing Services, NBS, for help and advice with the production of the report*

~~~~~

Kirk Beard - NBS, for the provision of data relating to the issue of blood components from the Transfusion Services of the UK

~~~~~

*Rob Hick & Judith Chapman- Blood Stocks Management Scheme, for the provision of data relating to the issue of blood components to hospitals in the UK*

~~~~~

Monty Mythen, Institute of Child Health, London, Marcela Contreras, NBS, Neil Soni, Imperial College Medical School and Cliff Morgan, Royal Brompton Hospital for expert review of the TRALI cases

~~~~~

*Paul Ashford and Ceri Frampton - WBS, for maintenance of the SHOT website*

~~~~~

Amneep Aujalay and Savi Chetty, SHOT Office Personnel

~~~~~

*Angela Allen, Personal Assistant to Dorothy Stainsby*

~~~~~

Christine Smith, Personal Assistant to Hannah Cohen

All hospitals who have participated in SHOT reporting

Without your support, SHOT would not be possible

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13 Appendix 1

Imputability Levels

N/A	Not Assessable	When there are insufficient data for imputability assessment
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or to alternative causes
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component