Annual Report 2007

Affiliated to the Royal College of Pathologists

The Steering Group comprises members representing the following professional bodies

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 Surgeons

Royal College of Physicians, the four UK Blood Services

SERIOUS HAZARDS OF TRANSFUSION SHOT

Published 7th July, 2008

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1. Foreword

It is 8 months since the last (2006) SHOT Annual Report was published in November, 2007. The Annual Report has been brought forward for two main reasons – firstly, to publish each year's data earlier in the year, and secondly, to be in line with the requirements of the EU Blood Directive[1] and the Blood Safety and Quality Regulations (BSQR) 2005[2], which require that annual adverse incidents report summaries are sent by the Competent Authority to the EU Commission by 30th June of the following year.

The issues surrounding education and training raised in the 2006 report are emphasised by the findings for 2007, and hence some of the recommendations in this report echo those in last year's report. Action must now be taken to ensure that doctors acquire appropriate levels of knowledge and skills in transfusion medicine to practise safely. Notably, there remains evidence that junior doctors are making critical decisions without adequate basic knowledge or experience. In this report it is stressed that this is not only a training and competency issue, but a professional matter, and responsibility lies with the individuals themselves as well as with their employers. Failures of bedside checking continue to allow accumulated errors to translate into 'wrong blood to patient' episodes. Although mortality is low this year, there is avoidable major morbidity. It is anticipated that the training and competency assessment required by the National Patient Safety Agency Safer Practice Notice (NPSA SPN) 14[3], which is to be fully completed by November, 2010, will reduce errors in phlebotomy, blood component collection and administration.

The anti-D chapter describes a large number of delays and omissions of giving routine antenatal anti-D, as well as unnecessary administration. This has uncovered a knowledge gap in midwives and junior obstetric doctors which needs to be rectified. Unified national guidelines are required, and appropriate education for involved personnel. The SHOT symposium on 7th July, 2008, will begin to address this with a session on anti-D: this will include the rationale for its use.

The SHOT-initiated National Transfusion Laboratory Collaborative has produced evidence-based recommendations. These are around laboratory automation and staffing numbers, skill mix and qualifications, and include both short- and long-term recommendations. It is imperative that appropriate resource becomes available to correct the current deficiencies, which are increasing risk for patients. Further updates on this initiative will be available via the SHOT website (www.shotuk.org) and Newsletters.

Cases in this report involve, among many other issues, the blood administration process, point of care testing (POCT) and warfarin reversal. SHOT draws attention to the British Committee for Standards in Haematology (BCSH) guidelines, which indicate that prothrombin complex concentrate (PCC), rather than fresh frozen plasma (FFP), is the product of choice for the reversal of oral anticoagulation (warfarin) in patients with major bleeding[4]. In the absence of major bleeding PCC (or FFP if PCC is not available) could be used for warfarin reversal for emergency surgery. New BCSH guidelines on POCT and blood administration are currently in draft form.

Participation in SHOT and Medicines and Healthcare products Regulatory Agency (MHRA) adverse event reporting, which is mandatory, remains incomplete with a substantial number of hospitals, including high blood users, not sending reports. Action is required by the Department of Health (DH) in partnership with MHRA and SHOT to elucidate the obstacles to reporting, and facilitate universal participation.

SHOT is pleased to report that the Near Miss pre-transfusion testing pilot took place in April, 2008, with excellent uptake, and is now being analysed. More details are in the Near Miss chapter on page 114. In addition the Cell Salvage adverse events pilot is underway, in collaboration with the UK Cell Salvage Action Group (see page 110). Details of the results of both of these pilots will be found in future Newsletters.

Developments in the SHOT team

Since the last report in November, 2007, SHOT has embarked on a team building process starting with a new Operations Manager, Mr David Mold, who will join SHOT during summer 2008. One of his initial tasks will be an option appraisal process of potential IT systems to support SHOT's data input, storage and analysis, encompassing past, current and future SHOT data. Two further new appointments, a clinical incidents specialist and a laboratory incidents specialist, are planned.

SHOT in the context of European haemovigilance and legislation

SHOT is now entering its second decade of reporting, as one of the longest established haemovigilance systems in the world. At the present time haemovigilance systems are being initiated in Europe in response to the EU Blood Directive[1], as well as further afield, and SHOT continues to be used as a model in their development.

Across the 28 EU member states there is now a legal commitment and imperative to submit data on Serious Adverse Events and Serious Adverse Reactions (SAEs and SARs) to the EU Commission by 30th June, 2008 for the reporting (calendar) year 2007. A great deal of work has been undertaken in individual countries and within EU-based working groups in order to co-ordinate and streamline this process. The Working Group on Haemovigilance, a subgroup of the Competent Authority Blood and Blood Components Committee has produced a guidance document entitled 'A Common Approach for the definition of reportable serious adverse events and reactions as laid down in the Blood Directive 2002/98/EC and Commission Directive 2005/61/EC'. There are a number of areas in which there have been differing interpretations of the scope of the directive. The document has addressed these as far as it has been possible to achieve a consensus, but clarification of some aspects of reporting remains challenging. The guidance document is in late draft form and will be circulated in advance of the deadline for reporting. The membership of the working group on haemovigilance consists largely of professional haemovigilance experts and some representatives of Competent Authorities from countries with effective embedded haemovigilance systems. This group includes representation from the UK, Netherlands, Ireland, France, Malta, Belgium, Spain, Greece and Germany. The group has also liaised closely with the European Haemovigilance Network (EHN), which provided a document suggesting a reporting framework.

Once all haemovigilance data for the EU has been collected, a process of collation and some analysis will take place within the EU. The haemovigilance subgroup will be involved in this process, including members of SHOT and MHRA from the UK. In addition the EHN may become involved in the analysis of data from across Europe.

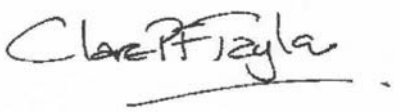
SHOT and MHRA

SHOT continues to work with MHRA through the Blood Consultative Committee and its Adverse Events subgroup (chaired by the National Medical Co-ordinator for SHOT, Dr Clare Taylor). This group has a particular focus on reconciliation of annual data between SHOT and MHRA. SHOT continues to collect a wider scope of data than MHRA, extending into the professional and clinical arenas of transfusion practice. An analysis of this data and recommendations arising from it continue to form a major part of SHOT's Annual Report. In its regulatory role, MHRA's emphasis is upon the quality management system (QMS) in place in blood establishments and hospital blood banks, and its legislative remit extends to the point where blood bank responsibility ends. This point varies between hospital Trusts, depending upon local arrangements and managerial responsibilities. The criteria for reporting adverse reactions are the same for both SHOT and MHRA. Interpretation of cases including severity levels and imputabilities are discussed between SHOT and MHRA prior to EU reporting.

Safety of Blood Tissues and Organs Committee (SaBTO)

The newly established advisory committee on Safety of Blood Tissues and Organs has replaced the previous advisory committee MSBTO (Microbiological Safety of Blood Tissues and Organs). SaBTO is an advisory, non-departmental public body and advises ministers of the UK government and the devolved administrations as well as the UK Health Departments on the most appropriate way to ensure the safety of blood cells, tissues and organs for transfusion and transplantation. SaBTO will advise across the broader area of safety. Its inaugural meeting, under its chairman Mr John Forsythe (also a non-executive director of NHSBT), took place in January, 2008. SHOT has a nominated contact person (Dr Clare Taylor) who will attend the committee when appropriate.

SHOT will continue to produce first-class haemovigilance data to enable informed, evidence-based decision making on prioritisation of action and resources to improve patient safety, at both hospital and national level.



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2. Introduction

This year's report has augmented the format of previous SHOT Annual Reports. Each chapter commences with a grid showing the basic numbers of cases and relevant details for that category of report. This allows essential figures including mortality and morbidity rates and the number of paediatric cases to be extracted quickly from the report. It is anticipated that this will be helpful to readers and for those preparing educational sessions. Recommendations are at the end of each chapter, followed by a tabulated list of active previous recommendations with notes on any specific initiatives taking place to address them. This is the same formula that was applied last year to the overall main recommendations and the tabulated update of previous recommendations.

Paediatric data are included in all the relevant chapters, and there is also a short section summarising the paediatric cases for easier reference for readers with a specific interest (page 112). In addition there is a separate analysis of IT-related IBCT cases and laboratory-related IBCT cases following the main IBCT chapter. The data are documented in the main IBCT section but discussed in more detail in these two stand-alone sections.

There is a short chapter on cases relating to autologous blood transfusion (page 110) and for the first time a short chapter on TACO cases (page 108). These may both increase in size and scope in future years as TACO becomes a separately defined reporting entity, and cell salvage reporting may increase as a result of the cell salvage pilot which is commencing in June, 2008. This year the data in both these short chapters are also included in the totals in the main chapters: i.e., TACO cases are also in the IBCT chapter, and autologous transfusion cases in the ATR and IBCT chapters.

The report finishes with a discussion on corrective and preventative actions (CAPA), and how they may be developed and best utilised, because it became clear on analysing the data that there were variations in the approach and usefulness of this exercise from hospital to hospital.

Reporting categories

This year IBCT categories have been broken down as follows:

- Administration of wrong blood
- Wrong blood in tube
- Inappropriate or unnecessary transfusion
- Handling and storage errors
- Special requirements not met – Cytomegalovirus (CMV) negative / Irradiation
- Special requirements not met – other
- Additional laboratory errors

In the next phase of development of online reporting the questionnaires will be made more user friendly and will reflect the categories above. In the meantime the existing IBCT questionnaires will continue to be used during 2008, with the addition of the TACO questionnaire. 'Inappropriate or unnecessary transfusion' data will be collected in a separate category, as the issue is not that an incorrect blood component has been transfused but rather that the correct blood component has been transfused in an incorrect fashion. This also applies to handling and storage errors which will be separated out from this chapter in future SHOT reports.

What to report to SHOT

The SHOT team still regularly come across reporters who are unsure whether an incident is reportable to SHOT or not. The outline of what is reportable is as follows:

- All reactions in patients are reportable (see Table 1)
- Adverse events arising anywhere in the hospital transfusion process, including all laboratory, clinical and bedside errors, as long as the component is ultimately transfused to a patient
- When a report is sent where no component is transfused, this is a SHOT Near Miss, and will be stored as such in the database; SHOT plans to analyse these reports in the future, in conjunction with data from the Near Miss pilot

SHOT therefore advises that reporters continue to answer 'Yes' to 'Do you wish SHOT to have access to this report?' on the SABRE new report page for all SAE and SAR reports.

Table 1
Active reporting categories for 2008 and what to report to SHOT

Term	Definition	What to report
IBCT (Incorrect or inappropriate blood component transfused)	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	This category currently includes: 'Wrong blood' events where a patient received a blood component intended for a different patient or of an incorrect blood group, including components of an incorrect group given to BMT/SCT or solid organ transplant patients Transfusion of blood of inappropriate specification, or that did not meet the patient's special requirements
Inappropriate or unnecessary transfusions	These are cases in which the intended transfusion is carried out, and the component itself is suitable for transfusion and for the patient, but where the decision making is faulty	Prescription of components that are not required, or where another component or therapy would have been more clinically appropriate, or prescription at an incorrect dose or rate, or for an inappropriate indication
Handling and storage errors	Transfusion of a correct component to an intended patient, when handling or storage errors may have rendered the component less safe for transfusion	'Unsafe' transfusion where there were handling or storage errors such as a component out of temperature control, or delay in completion of transfusion
Near Miss events	Any event 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	The first phase of the 2008 pilot has now been completed, with a further phase due in September, 2008. Results will be publicised once analysis is complete Always ticking 'report to SHOT' on the SABRE reporting page ensures laboratory collection of Near Miss data as well as full reports
Acute transfusion reaction	Reactions occurring at any time up to 24 hours following a transfusion of blood or components, ***excluding*** cases of acute reactions due to an incorrect component being transfused, haemolytic reactions, TRALI, transfusion-associated circulatory overload (TACO) or those due to bacterial contamination of the component	These include: **Isolated febrile –** rise in temperature >1^{0}C +/- minor rigors and chills **Minor allergic – skin +/- rash** **Anaphylactic/anaphylactoid –** hypotension with 1 or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hrs of transfusion **Severe allergic reaction** – severe allergic reaction with risk to life occurring within 24 hours of transfusion, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress **Hypotension** – a drop in systolic and/or diastolic pressure of >30mm Hg occurring within 1 hour of completing transfusion, provided all other adverse reactions have been excluded together with underlying conditions that could explain hypotension **Febrile with other symptoms/signs** – rise in temperature >1^{0}C, with no features of an allergic reaction, but with 1 or more of myalgia, nausea, change in blood pressure or hypoxia

Haemolytic transfusion reaction: *Acute*	Acute HTRs are defined as fever and other symptoms/ signs of haemolysis within 24 hours of transfusion; confirmed by a fall in Hb, rise in LDH, positive DAT and positive crossmatch	Cases with relevant features (see definition) should be reported together with results of all laboratory investigations and antibody identification results if available
Haemolytic transfusion reaction: *Delayed*	Delayed HTRs are defined as fever and other symptoms/ signs of haemolysis more than 24 hours after transfusion; confirmed by 1 or more of: a fall in Hb or failure of increment, rise in bilirubin, positive DAT and positive crossmatch not detectable pre-transfusion Simple serological reactions (development of antibody without positive DAT or evidence of haemolysis) are excluded	Cases with relevant features (see definition) should be reported together with results of all laboratory investigations and antibody identification results if available Cases will be included with no clinical or laboratory features as long as DAT is positive
TRALI	Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion, not due to circulatory overload or other likely cause	Suspected cases should be discussed with a blood service consultant, and reported if there is a high index of suspicion, even if serological investigation is inconclusive
Post-transfusion purpura	Thrombocytopenia arising 5-12 days following transfusion of red cells associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) systems	Cases where the platelet count drops more than 50% following transfusion should be investigated and reported if complete or partial serological evidence is available
Transfusion-Associated Graft-Versus-Host Disease	Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion; the condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host	All cases where diagnosis is supported by skin/bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the patient's blood and/or affected tissues Cases with very high index of clinical suspicion
Transfusion-transmitted infections	Include as a TTI 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 ***plus either*** at least 1 component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection ***or*** at least 1 component received by the infected recipient was shown to contain the agent of infection	Cases of bacterial transmission from blood components, where cultures from the patient's blood match cultures from the component bag and/or from the donor Transmissions of viruses, whether routinely tested for by the blood services or not Transmissions of other agents such as prions, protozoa and filaria
Anti-D events	Events relating to administration of anti-D immunoglobulin	Reports in this section include: ■ Omission or late administration ■ Anti-D given to a D positive patient or a patient with immune anti-D ■ Anti-D given to mother of D negative infant ■ Anti-D given to wrong patient ■ Incorrect dose given ■ Anti-D given which was expired or out of temperature control
TACO (Transfusion-associated circulatory overload)	Any 4 of the following occurring within 6 hours of transfusion: ■ Acute respiratory distress ■ Tachycardia ■ Increased blood pressure ■ Acute or worsening pulmonary oedema ■ Evidence of positive fluid balance	A new questionnaire has been developed, which is not yet available online but can be utilised in paper form for 2008. This will be sent out from the SHOT office on receipt of a SABRE notification which fits the definition

What is reportable to MHRA

Details can be found in the guidance documents to SABRE on the website[5]. The outline of what is reportable is as follows:

- All serious adverse reactions – the same reactions as for SHOT
- All serious adverse events signalling a process failure or failure in the QMS occurring within the responsibility of the Blood Establishment or Hospital Blood Bank or their staff, regardless of whether the component was transfused

Adverse events involving only clinical staff are not reportable to MHRA, but are reportable to SHOT, comprising the largest subgroup of SHOT reports.

In the IBCT chapter of this SHOT report, aspects of reporting to SHOT and MHRA are highlighted to help reporters understand the areas of congruence and the differences between the requirements of SHOT and MHRA reporting.

Definitions

Imputability

In addition to the definitions of the reporting categories in the SHOT Report as shown in Table 1, it is important to clarify the use of the term 'imputability' and also to standardise the definitions of mortality and major morbidity. MHRA defines imputability as 'the likelihood that a serious adverse reaction in a recipient can be attributed to the blood component transfused'.

0	=	excluded/unlikely – the evidence is clearly in favour of attributing the reaction to other causes
1	=	possible – the evidence is indeterminate for attributing the reaction to the blood or to alternative causes
2	=	likely/possible – the evidence is clearly in favour of attributing the adverse reaction to the blood or the blood component
3	=	certain – there is conclusive evidence beyond reasonable doubt attributing the adverse reaction to the blood or blood component

Imputability must not be confused with severity. A very mild reaction such as a pyrexia with no associated symptoms occurring during a platelet transfusion may have an imputability of 3. Conversely an apparently 'severe' reaction may be associated with co-morbidities and may have little to do with the transfusion in progress at the time and therefore have an imputability of 0 or 1.

Transfusion-related mortality

- Death directly and solely caused by the transfusion reaction
- Death in which the transfusion reaction contributed, which may not have occurred at that time had the reaction not taken place

These categorisations are made jointly by the reporter and the SHOT expert analyst. Inevitably such assessments may be a matter of informed opinion and there are times when it is an extremely hard judgement to make.

The term 'imputability' could also be applied to a death that was attributable or likely to be attributable to a transfusion reaction. However, this adds a layer of complexity and potential confusion. For instance a reaction of low imputability, if severe, could still have a strong relationship to mortality, i.e. the death could have a high imputability. It has therefore been decided that SHOT will not use the term imputability in relation to death but only in the same context that it is used by the MHRA in accordance with the EU Blood Directive[1].

Major morbidity

The current categories of major morbidity used by SHOT are:

- Intensive care admission and/or ventilation
- Dialysis and/or renal impairment
- Major haemorrhage from transfusion-induced coagulopathy
- Evidence of intravascular haemolysis
- Potential risk of D sensitisation in a woman of childbearing age
- Persistent viral infection
- Acute symptomatic confirmed infection
- Reaction resulting in a low or high haemoglobin level of a degree sufficient to cause risk to life without immediate medical intervention

The last category of major morbidity has been introduced this year after examining the reports made to SHOT in 2007 and following detailed discussion and analysis by the Steering Group and Standing Working Group.

3. Summary of Main Findings and Cumulative Results

Data analysed for this report were collected between 1st January, 2007 and 31st December, 2007.

Participation

At the end of 2007 there were 308 registered hospital users of SABRE, of which 255 (83%) have (since November, 2005) submitted at least one report for to SHOT. All SABRE notifications are automatically sent through to SHOT as long as the 'send to SHOT' box is ticked. In practice, as a result of close liaison between SHOT and the SABRE team at MHRA, there are no reports that are not reported to SHOT if they are appropriate. For a number of reasons, not all of these incidents go on to be included in the final analysis. They may not fit any of the current SHOT definitions, for example, or they may be withdrawn at some stage by the reporter if additional information comes to light which casts doubt on the validity of the incident.

For the 2007 Annual Report, a total of 561 incidents which fitted the current reporting definitions were included. A further 549 incidents were submitted to SHOT via SABRE that were either Near Miss incidents or which, on review, did not fit current definitions and were withdrawn. This total of 1,110 incidents, which includes 'SHOT only' reports not copied to MHRA, were sent from 212 different reporters (69%). A further insight into low participation is that the 114 cases reported in the ATR category were sent from just 55 hospitals.

There were 1,042 reports submitted to MHRA during 2007, of which 930 are currently considered relevant to reporting under the Blood Safety and Quality Regulations (BSQR)[1]. The exclusions are largely those which are entirely clinical. All relevant reports have been shared with SHOT. From the MHRA perspective, there were 25% of registered reporters who did not send reports in 2006, and the numbers appear similar on analysis of 2007 data at MHRA.

Non-participation in haemovigilance is a matter of great concern as for both professional and regulatory reasons it is imperative that all hospitals participate in the scheme. Whilst some small users may genuinely have no adverse incidents to report, larger institutions carrying out effective haemovigilance are bound to find that some events or reactions have taken place.

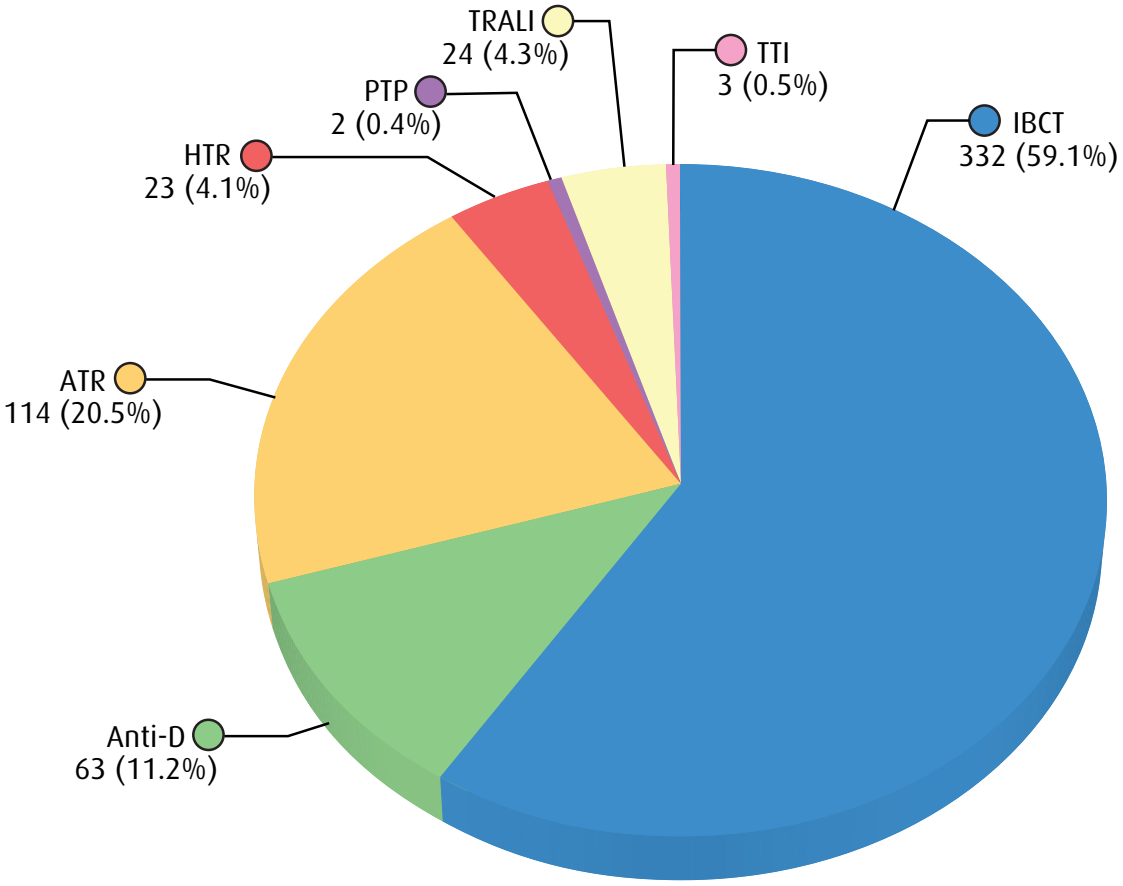
Numbers of questionnaires completed

The total number of questionnaires reviewed is 561, representing an increase from 531 last year of 5%. This year, for the first time, cases of anti-D have been counted separately from IBCT and are reported in a separate chapter. These figures are shown in Table 2 and Figure 1.

Table 2
Summary of reports reviewed

IBCT	Anti-D	ATR	HTR	TRALI	PTP	TA-GVHD	TTI	Totals
332	63	114	23	24	2	0	3	561

Figure 1
Cases reviewed n = 561
[Before 2006, the HTR category was referred to as Delayed Transfusion Reactions]



Numbers of components issued

The total number of blood components issued from the transfusion services of the UK continues to decrease. Table 3 shows data from 1999-2007, demonstrating a steady decrease in issues of red cells from UK Blood Services and resulting in a total decrease of 18% over 7 years. FFP issues have decreased by 16% over the same period. Platelet usage has increased by just 2%, whereas cryoprecipitate usage has increased by 24%.

Table 3
Yearly summary of issues by the four UK Blood Services 1999/2007

Year	Red blood cells	Platelets	FFP	Cryoprecipitate
1999/2000	2,737,572	249,622	365,547	94,114
2000/2001	2,706,307	250,259	374,760	95,456
2001/2002	2,679,925	251,451	385,236	88,253
2002/2003	2,678,098	251,741	377,381	92,768
2003/2004	2,607,410	264,539	372,855	95,417
2004/2005	2,428,934	258,528	313,019	102,719
2005/2006	2,316,152	259,654	320,852	106,139
2006/2007	2,235,638	255,474	306,444	116,672

Table 4 shows the breakdown of issues of different components by the four UK Blood Services in the 2006–7 financial year. Data obtained from Octapharma Limited (quoted with their permission) show that in addition to the 306,444 units of FFP issued from the blood services a further 42,000 units of 200 mL of Octaplas™ were used within UK hospitals. At present there are no cases of adverse events relating to Octaplas™ knowingly received at SHOT. In future years reporters will be specifically asked which type of FFP the adverse event relates to.

Table 4
Total issues of blood components from the transfusion services of the UK in the financial year 2006–2007

	Red blood cells	Platelets	FFP	Cryoprecipitate	Total
National Blood Service	1,864,271	217,401	260,159	100,738	2,442,569
Welsh Blood Service	96,317	8,321	13,141	2,699	120,478
Scottish National Blood Transfusion Service	218,025	23,343	24,166	8,915	274,449
Northern Ireland Blood Transfusion Service	57,025	6,409	8,978	4,320	76,732
TOTAL	**2,235,638**	**255,474**	**306,444**	**116,672**	**2,914,228**

Figure 2
Cumulative numbers of cases reviewed 1996–2007 n = 4334
[Before 2006, the HTR category was referred to as Delayed Transfusion Reactions]

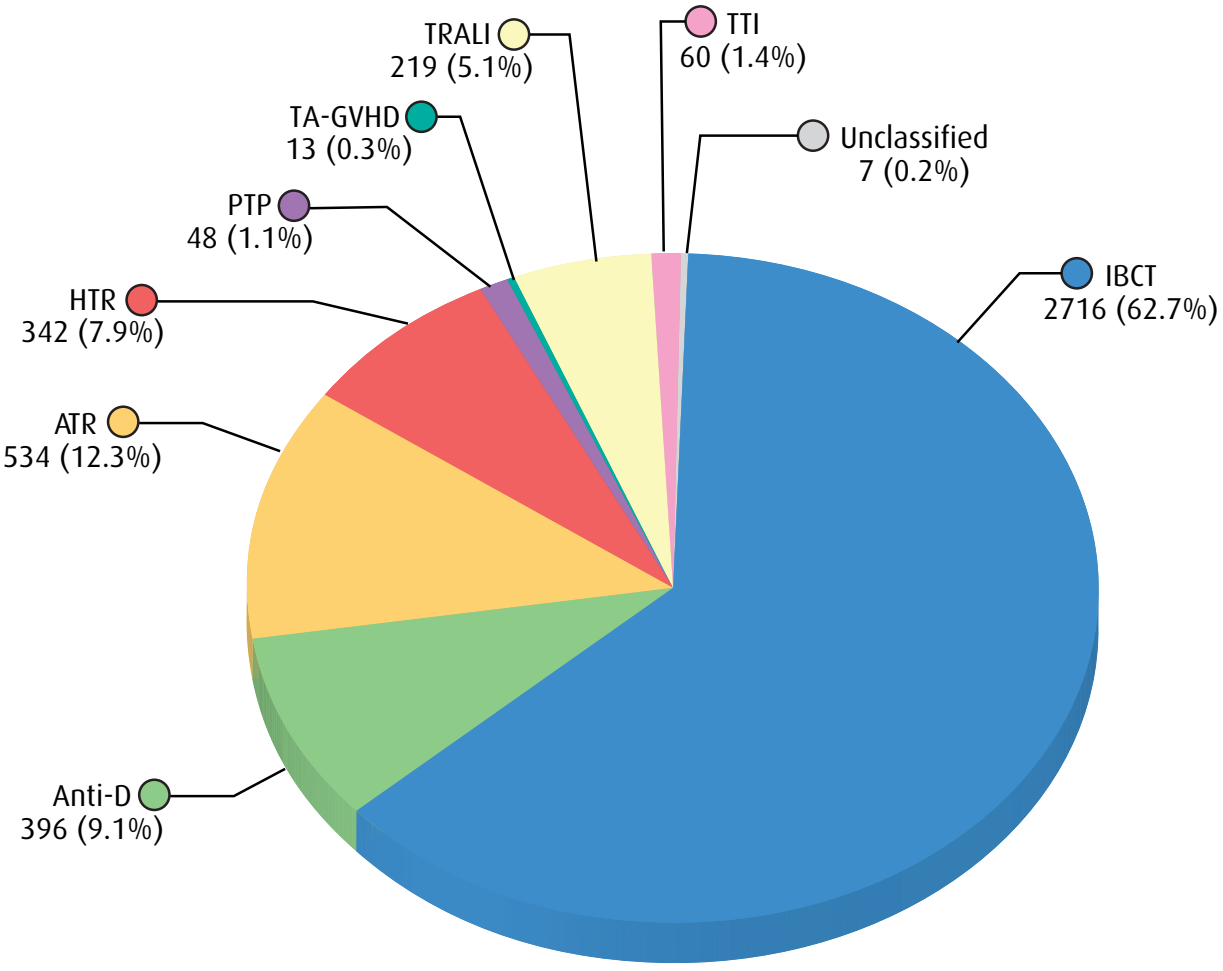


Figure 3
Comparison of report types 1996–2007
[Before 2006, the HTR category was referred to as Delayed Transfusion Reactions]

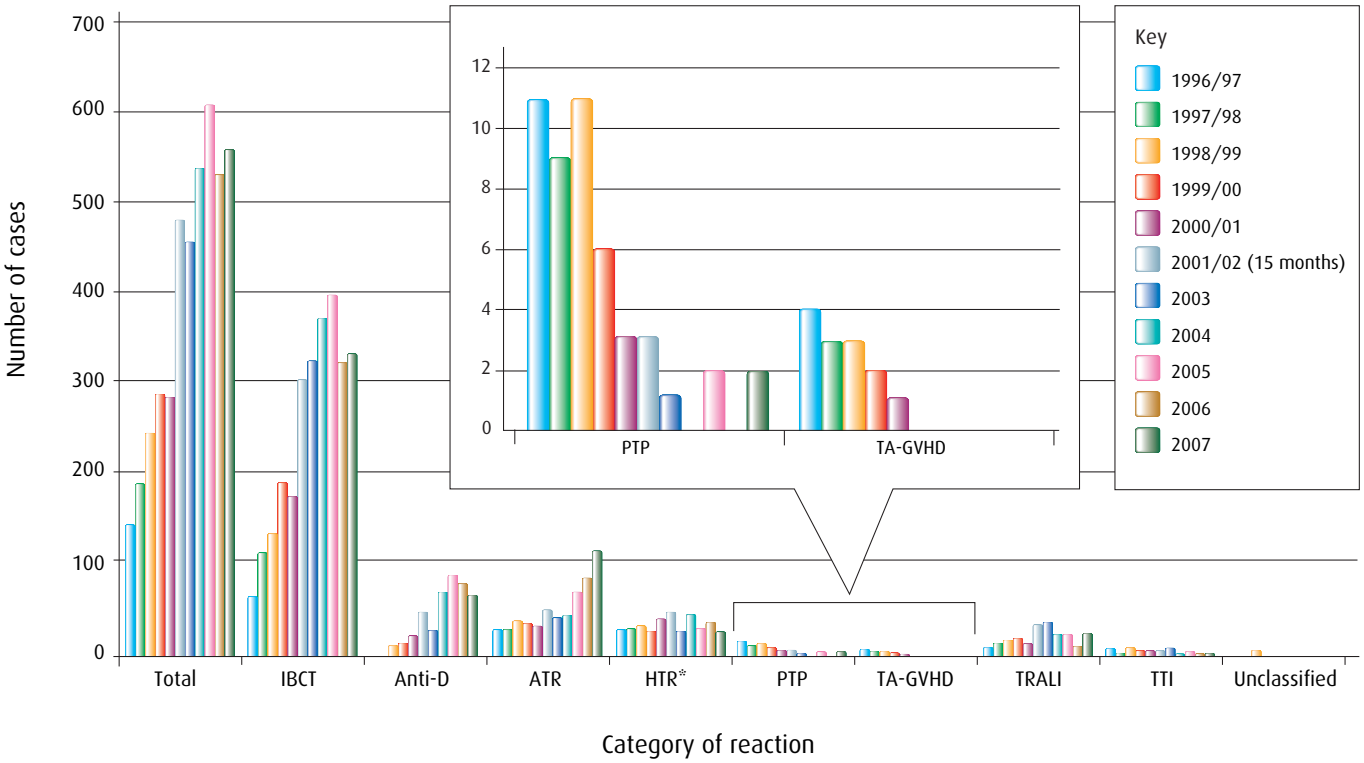


Table 5
Cumulative mortality / morbidity data 1996–2007

	Total	IBCT	Anti-D	ATR	HTR *	PTP	TA-GVHD	TRALI	TTI
Death in which transfusion reaction was causal or contributory	**115**	24	0	14	10	2	13	40	12
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	**376**	107	24	22	34	13	0	133	43
Minor or no morbidity as a result of transfusion reaction	**3821**	2907	39	495	296	33	0	46	5
Outcome unknown	**15**	11	0	3	1	0	0	0	0
TOTAL **	**4327**	**3049**	**63**	**534**	**341**	**48**	**13**	**219**	**60**

* The HTR category was known as 'Delayed Transfusion Reaction' (DTR) until 2006 and did not include acute reactions.

** Excludes 7 cases from 1998–99 that were not classified.

OVERVIEW OF 2007 RESULTS

Transfusion-related mortality

There was 1 death reported during 2007 probably attributable to transfusion. This occurred as a result of a case judged to be probable TRALI, and is described as Case 1 on page 94.

There were 3 cases in which the patient died and the transfusion reaction was considered to be contributory. One of these occurred as a result of an acute transfusion reaction (Case AA1 on page 73) and involved an 8-month-old female infant who suffered an anaphylactic/anaphylactoid reaction following the transfusion of FFP. A further 2 cases in which a transfusion reaction was considered to be contributory are reported in the HTR chapter, Cases D15 and D20 on page 86.

Therefore, the 2007 report, with 1 probable transfusion-related death, has the lowest reported mortality rate from blood transfusion since SHOT reporting began in 1996.

Incorrect blood component transfused

There were 332 events analysed in 2007 (excluding anti-D related cases which are in a separate chapter on page 65). This is comparable to last year's figure of 323 IBCT cases.

The total number of blood components issued from the blood transfusion services of the UK for the financial year of 2006–2007 fallen to 2,914,228. Allowing for the decrease in component usage, the reporting rate has actually increased to 11.4 cases per 100,000 components transfused in 2007, compared with 10.6 in 2006. The cases have been subdivided as shown in detail in the summary of IBCT results in Table 8 (page 27); Table 6 compares the amalgamated subcategories for 2006 and 2007.

Table 6
Direct comparison between IBCT subcategories in 2006 and 2007

Type of event	Number 2006	Number 2007
'Wrong blood' events where a patient received a blood component intended for a different patient or of an incorrect group	54	46
Other pre-transfusion testing errors (excluding erroneous Hb)	28	20
Blood of the incorrect group given to recipients of ABO or D mismatched PBSC, bone marrow or solid organ transplant	8	5
Transfusion of blood of inappropriate specification or that did not meet the patient's special requirements	108	93
Inappropriate or unnecessary transfusions	51	50
'Unsafe' transfusion where there were handling or storage errors	74	118
Total	**323**	**332**

In 96 of the 332 IBCT cases (29%) the error originated in the laboratory and these are discussed in a separate section on laboratory errors on page 51. Thirty-three per cent of the wrong blood errors in 2007 originated in the laboratory.

There are no transfusion-related deaths (definite or contributing to mortality) arising from IBCT in 2007. There were 12 ABO-incompatible red blood cell transfusions given during 2007, 9 as a result of clinical errors including 1 phlebotomy error (wrong blood in tube), and 3 as a result of laboratory errors.

Two main themes emerge this year from the IBCT chapter. The first is the failure of bedside checking procedures which would have prevented wrong blood being administered in all the clinical cases reported this year. The second is once again the prominence of knowledge gaps and lack of training and education in junior doctors, which has been instrumental in the large number of cases in the 'inappropriate and unnecessary transfusion' section (page 35).

Anti-D events

There were 63 anti-D events reported this year compared with 77 in 2006. Twenty-four of these satisfied the SHOT definition of major morbidity in that there was potential for sensitisation of a woman of childbearing age to the D antigen. In addition to these 24 cases in which anti-D was delayed or omitted there were another 35 cases in which anti-D was inappropriately administered, resulting in unnecessary exposure to a human blood product.

Transfusion-related acute lung injury

Thirty-six cases of suspected TRALI were received in this reporting year, of which 12 were withdrawn on further analysis. Of the 24 cases analysed, 8 were considered to be highly likely to be TRALI and a further 4 to be probable TRALI. The remaining 12 cases were possible or unlikely. There was 1 case of mortality directly related to a probable case of TRALI. There were no deaths in which a TRALI reaction contributed to death but there were 15 cases of major morbidity.

TRALI investigations were completed in 18 of the 20 cases put forward for full investigation (4 of the 24 analysed cases were not investigated following a decision by the expert TRALI panel). Of the 18 cases where investigations were completed, concordant donor leucocyte antibodies were found in 11 (61%). Seven of these were associated with human leucocyte antigen (HLA) antibodies, 3 with human neutrophil antigen (HNA) antibodies and 1 with both.

The increased number of TRALI cases investigated this year is partly due to some having been carried over from 2006, because they occurred late in the reporting year and final reports of investigations were not received until 2007. However, the mortality rate, equal to 2006, is again the lowest since reporting began in 1996 and is likely to be related to the change to preferential use of male plasma.

Other immune complications

There were 115 cases of acute transfusion reaction reported during 2007. This represents another increase in the number of reports, this time of 35%, since the previous year. There was also a 25% increase between 2005 and 2006. This is likely to be due to the effect of the new Blood Safety and Quality Regulations which came into force in 2005, bringing a requirement to report all serious transfusion reactions to the Competent Authority. Since the definition of 'serious' remains rather grey, there has generally been an increased tendency to report reactions. There were 27 anaphylactic or anaphylactoid reactions, 12 severe allergic reactions, 2 hypotensive reactions, 21 febrile reactions with other symptoms/signs, 37 minor allergic reactions and 16 isolated febrile reactions.

There were no cases of definite transfusion-related mortality but 1 case in which the transfusion reaction contributed to the death of the patient. There were 5 cases of major morbidity.

Cases of transfusion-associated circulatory overload (TACO) have not been included in the ATR chapter. Those that have occurred this year are included in the IBCT category, as they are related to inappropriate transfusion. They have also been discussed in a separate TACO chapter (page 108). When the 2008 data are reported, cases of TACO will comprise a separate category and be included in a separate chapter.

There were 23 cases of haemolytic transfusion reaction reported this year, which is a decrease compared with 2006. Three of these were acute haemolytic transfusion reactions, of which 1 was a clear case of major morbidity relating to intravascular haemolysis following an ABO-incompatible platelet transfusion. There were 20 delayed haemolytic transfusion reactions and in 2 of these the reaction was thought to have contributed to the death of the patient. There were 4 additional cases of major morbidity in this group.

In 2007 there were 2 cases of post-transfusion purpura, neither of which suffered mortality or major morbidity. Both of the confirmed cases were in females, 1 associated with HPA-1a antibodies and 1 with HPA-1b antibodies. These figures continue the sustained decrease in the number of cases of PTP which has been observed since the introduction of universal leucodepletion in 1999.

There were no cases of transfusion-associated graft-versus-host disease in 2007.

Autologous blood transfusion

There were 3 cases associated with autologous blood transfusion, 2 are included in the ATR chapter and 1 in the IBCT chapter. These are also discussed together in a separate chapter on page 110.

Transfusion-transmitted Infections

During 2007, 25 reports of suspected transfusion-transmitted infection were made from blood centres throughout the UK. Three proven cases are reported in this 2007 SHOT report, whereas 21 cases were concluded as not transfusion-transmitted infection and 1 case is still awaiting completion of the investigations. The 3 proven cases all relate to transfusion-transmitted bacterial infection, and interestingly 2 of these related to red cell packs and just 1 to platelets. There have been no further reports of transmission of vCJD by blood transfusion.

Near Miss events

Near Miss data have not been collected during 2007. A pilot of pre-laboratory Near Miss errors relating to phlebotomy and sample labelling is underway at the time of writing. A chapter in this report (page 114) outlines the classification of Near Miss events into the pre-transfusion testing phase, the testing phase and the collection and blood administration phase of the transfusion process. The potential barriers in place to prevent error are also discussed.

4. Key Message and Recommendations

KEY MESSAGE

Education and training

There are two themes which have emerged this year from the IBCT data. The first is the failure of bedside checking procedures that would have prevented the wrong blood administration in all the clinical cases reported this year. The second is, like last year, the prominence of knowledge gaps and lack of training and education in junior doctors; this has been instrumental in the large number of cases of inappropriate or unnecessary transfusion (page 35).

There have been consistent reports in the IBCT category of events that relate to failures of training and education ever since the first year of SHOT reporting in 1996.

Recommendations on education and training have been made repeatedly in SHOT reports as shown in the list of past recommendations on page 22. In the last SHOT Annual Report in November, 2007, the first and second of the 3 main recommendations were respectively related to the training of junior medical staff and the training of other healthcare personnel involved in the transfusion chain.

Competency assessment

The NPSA Safer Practice Notice (SPN 14) 'Right Patient Right Blood' issued on 9th November, 2006, has addressed this issue. It states that all staff, medical or non-medical, qualified or unqualified, from consultants to medical laboratory assistants (MLAs), operating department assistants (ODAs) and portering staff must be trained and competency assessed before they are permitted to perform a role in the blood transfusion pathway. This includes: obtaining a venous blood sample, organising the receipt of blood/blood products for transfusion, collecting blood/blood components for transfusion, preparing to administer a transfusion of blood components to patients and administering a transfusion of blood components.

An updated statement issued by NPSA (3rd April, 2008) sets deadlines of May 2009 for 50% competency assessment to be completed and of November 2010 for full training and competency of all involved personnel to be completed. The statement also clarifies that self-assessment is not acceptable and that all competencies must be observed for all types and grades of staff. The competency assessments should be carried out every 3 years. The NPSA has provided a toolkit to assist with this process, available on http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/notices/blood-transfusions.

Many hospitals and Trusts have found delivery of training and competency assessment to a huge number of diverse staff a very daunting prospect and a large drain on resources, which are already limited. In order to reduce the assessment burden it is necessary to prioritise the training of personnel and to evaluate mechanisms for reducing the overall number of staff requiring training and observed competency assessments. In many Trusts there are thousands of staff who could potentially be involved in the transfusion process and who could therefore legitimately require the training. Identification of key groups to be involved and key groups who can be excluded, and subsequent prioritisation of training, is crucial for this initiative to be delivered smoothly.

Some hospital Trusts have developed and changed their systems in order to circumvent the need to train and assess large numbers of staff. Strategies have included the following:

- Medical/nursing staff in larger Trusts working in clinical disciplines where blood components are rarely given have not been trained and competency assessed in blood component administration; arrangements can be made on the rare occasions when blood transfusions must be given, for trained and assessed staff to be brought across from other areas to complete the process appropriately.

- In some hospitals a decision has been made that general portering staff should not be included in the training and should not be permitted to collect blood components from the blood bank or from satellite blood fridges at any time. This requires that there are sufficient numbers of trained nursing or theatre staff available to carry out this

task. However, some Trusts have identified a subset of porters who are dedicated to this role and who are trained and accredited, thereby reducing the overall number of staff requiring training and assessment.

- It is possible to employ a system in which only laboratory staff, including MLAs who have been trained and competency assessed, will remove blood from the issue fridge and sign it out. This blood is then handed across a counter to the individual collecting, who therefore does not require to be trained and assessed in blood component collection. This intervention has worked very well in both small and large Trusts, but requires adequate staffing levels within the blood bank. It also requires that the issue fridge is only accessible from within the blood bank and that there are no satellite fridges to which untrained staff have access.

In terms of cost-effectiveness it may be worthwhile in some Trusts to invest in a lockable/barcode protected issue fridge, and satellite fridges that allow access only to trained and accredited personnel. This automatically releases only the correct unit of blood on presentation of the patient's details and the details of the member of staff collecting. However, this solution, although reducing the risk of error, does not reduce the burden of training and competency assessment, as involved staff have to be trained in this process. Nevertheless, this system has been particularly effective in reducing errors in hospitals with large numbers of satellite fridges where monitoring of the audit trail, especially with regard to traceability and the cold chain, can be particularly difficult.

In each Trust a risk assessment will need to be carried out in order to finalise the best solution for any individual hospital. Individual differences between Trusts and the services they provide will inevitably preclude a 'one size fits all' solution.

Professional responsibility

It is of concern that, by concentrating on the many issues surrounding the training and competency assessment of unqualified staff in the transfusion chain, the ultimate and overriding responsibility of the professionals involved may be being overlooked. Only professionally qualified staff can be held accountable and responsible for the work that they carry out. It is also a professional responsibility for individual staff to ensure that they have adequate knowledge, skills and understanding to perform the tasks that are required of them. It is through the knowledge and vigilance of professional staff that errors in transfusion can be prevented, whether at the time of the decision to transfuse and the prescription of components, or in the laboratory, or at the time of blood administration at the bedside. Unqualified staff (i.e. not medical, nursing or scientific staff) cannot be held ultimately responsible for ensuring that the correct component is transfused to a patient.

If properly conducted, the bedside check of patient identification against the intended component would prevent the vast majority of wrong blood episodes. Staff performing bedside checks must take full responsibility for ascertaining the identity of the patient and for ensuring that the unit that they transfuse is the correct unit and bears the correct details of the patient. They must also be certain that the specification of the unit and the manner of its transfusion are all in accordance with the prescription and clinical indication as documented by the medical staff.

Medical staff must possess sufficient knowledge, skills and understanding to assess the patient fully and to make a competent decision regarding the necessity to transfuse, the correct component and the rate of transfusion required. Only junior doctors who have sufficient knowledge to prescribe blood appropriately, effectively and safely should be permitted to do so. Doctors must satisfy themselves that any laboratory results they use to inform the transfusion decision relate to the correct patient, and have been correctly documented.

It is also a medical responsibility to document the details of the transfusion in the notes, together with the clinical indications of transfusion and intended outcome. The transfusion rate and any specific caveats relating to the patient must also be documented, together with any follow-up actions required from other staff. Effective handover is essential when going off duty.

The prescribing of the component on the prescription sheet is only the final end-point in a complex decision making process in which a large number of variables need to have been taken into account. Who finally prescribes the blood component is therefore a much less important issue than the level of knowledge and skills of the personnel involved in the decision making process.

Medical education

Training and assessment of competency in practical tasks is a very important part of maintaining transfusion safety; however, appropriate knowledge, skills and understanding for professionals involved in the transfusion process must not be sidelined by the need to deliver competency training. Only those professional staff who have received suitable education and achieved adequate knowledge and skills should be taking on the responsibility of safe clinical transfusion practice regardless of whether or not they have shown competency according to the NPSA criteria.

Following concerns raised in the previous (2006) SHOT Annual Report, and the main recommendations made that year, SHOT has been in discussion with the National Blood Transfusion Committee (England) (NBTC) and its Royal Colleges and Specialist Societies subgroup regarding a strategy to improve the level of knowledge of transfusion medicine in trainee doctors and nurses in all disciplines. A unified curriculum is necessary for junior medical staff in training grades in all hospital specialities, and completion of the required module should be mandatory before a certificate of completion of specialist training (CCST) can be achieved. A more basic curriculum needs to be developed for Foundation Year (FY) 1 and FY2 doctors; this should also be mandatory before progression to a specialist trainee doctor post can take place. The Royal Colleges of Nursing and of Midwives need to incorporate transfusion education into the curriculum as a requirement before registration can take place.

Conclusion

In this SHOT Annual Report many cases demonstrate a remarkable lack of understanding of the reasoning behind the decision making process in transfusion. Underpinning knowledge and familiarity with transfusion protocols has also been found to be absent. A large number of cases are still process failures but there are also cases showing a worrying disregard for protocol and an offhand attitude to bedside checking. There are still patients receiving blood without a prescription and patients with no identification receiving components. Blood is being prescribed following a decision based on incorrect results or poor or absent clinical reasoning. Transfusion medicine education must be formally incorporated into the core curriculum of the medical and nursing Royal Colleges, and should be mandated for qualification or career progression. If qualified, educated and competent staff take full responsibility for ensuring patient safety, the type of cases described in this 2007 SHOT report and its predecessors could be consigned to history.

RECOMMENDATIONS

SHOT general recommendations this year focus once again on the education of junior doctors, and the need for qualified, trained and competent staff to be responsible for transfusion safety, both in the laboratory and in the clinical arena.

These recommendations have been made after consultation with stakeholders to ensure support for their implementation.

Following the main recommendations, there is a table of active general recommendations from previous years, together with details of any ongoing initiatives to address them. At the end of each chapter there are specific recommendations, together with a tabulated list of active recommendations from previous years.

Main recommendations

- **Transfusion medicine must be part of the core curriculum for doctors in training**. This could be delivered as a 2-stage process: a basic level of working knowledge should be mandatory for FY1 and FY2 doctors, and a higher level for specialist trainees in all clinical hospital disciplines. Progression to the next stage of a hospital career would require this to be signed off as completed.

  Action: NBTC, General Medical Council (GMC), Postgraduate Medical Education and Training Board (PMETB), Royal Colleges, Deaneries.

- P**rofessional, accredited staff must take responsibility for transfusion safety in the laboratory and in clinical practice.** Trusts must ensure that the skill mix of staff is appropriate, so that specialised transfusion personnel are available at all times. Transfusion practitioners and biomedical scientists (BMS) should be encouraged to obtain qualifications in transfusion medicine and this should be facilitated by employers.

  Action: NBTC, National Transfusion Laboratory Collaborative (NTLC), British Blood Transfusion Society (BBTS), Institute of Biomedical Scientists (IBMS), Hospital Trust Chief Executive Officers (CEOs)

- **Obstetricians and midwives must be familiar with the national guidance for routine antenatal anti-D prophylaxis and the rationale behind it.** National guidance regarding all anti-D prophylaxis should be standardised. There is a need for clear and unambiguous advice to ensure that all hospitals are able to develop local guidelines which reflect national consensus.

  Action: NBTC, NHS Blood and Transplants (NHSBT) Appropriate Use of Blood Group, BCSH, Royal Colleges of Midwives, Obstetricians and Gynaecologists, General Practitioners (GPs), HTCs and HTTs.

- **Participation in Haemovigilance must be improved as it is mandatory in the UK and the rest of Europe.** Figures from both SHOT and MHRA show that a substantial number of hospitals, including some high users, are not sending reports. This is in breach of European and UK legislation. Trusts with difficulties in meeting this requirement should seek assistance from the UK haemovigilance bodies, the DH, or the Blood Transfusion Services (BTS).

  Action: DH, MHRA, SHOT, Hospital Trust CEOs, Hospital Transfusion Committees (HTCs), Hospital Transfusion Teams (HTTs), BTS

Active general recommendations from previous reports: update

Year first made	Recommendation	Target	Progress
2006	Inclusion of transfusion medicine in core curriculum for junior doctors	**NBTC, JRCPTB, Royal Colleges, Academy Postgraduate Education Committee**	Royal Colleges and Specialist Societies subgroup of NBTC have instigated review of current curricula
2006	Speciality accredited laboratory and clinical staff in all hospitals	**Hospital CEOs, NTLC, BBT network, RCN, BBTS**	National Transfusion Laboratory Collaborative has delivered recommendations to DH
2006	Comprehensive reporting to SHOT by all hospitals	**Hospital CEOs, SHOT, Consultants with responsibility for transfusion, HTT, HTC**	No change in figures for 2007 – but too early to see effect
2005	Right patient – Right Blood – NPSA safer practice notice (SPN 14) as a result of a joint initiative with SHOT and NBTC	**Trust CEOs**	Reduction in reports of ABO-incompatible transfusions. Rolling out the introduction of competency assessments for clinical staff. Update from NPSA has allowed more time (till November, 2010)
2005	Appropriate use of blood components	**Consultant haematologists with responsibility for transfusion, HTTs, HTCs**	Overall reduction in red cell usage >15% in last 5 years nationwide. NCA platelet audit showed widespread inappropriate use of platelets and non-adherence to guidelines

2004	The RTC structure 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 SPOT meetings. The RTCs should support translation of guidelines into local practice	**RTCs and user groups**	NBS hospital liaison teams focused support on RTCs in 2005 RTCs setting up working groups in 2006. Realignment at RTCs with SHA regions in 2007
2003	The NBTCs and counterparts should take a proactive lead in driving forward blood safety issues in hospitals	**NBTCs**	NBS regional hospital transfusion teams active in each region Parallel initiatives in Scotland, Wales and NI; educational tools developed
2002	HTTs must be established and supported	**Trust CEOs**	Survey in 2004 (M Murphy and C Howell) showed 70% of Trusts had HTT but only 30% were supported; 2006 survey by MM/CH stated 97% Trusts had an HTC and 96% a TP
2002	Blood transfusion should be in the curriculum of specialist trainees, especially anaesthetists and critical care nurses	**Medical Royal Colleges, Universities**	Royal Colleges and specialist societies subgroup of NBTC established 2007
2002	Blood transfusion must be in the curriculum for student nurses, medical undergraduates and newly qualified doctors	**GMC, PMETB, undergraduate deans, NMC**	An education subgroup of the NBTC was established in 2007; SNBTS training package www.learnbloodtransfusion.org.uk endorsed in Scotland, Wales and NI
2002	Blood transfusion should only be prescribed by authorised clinicians		Endorsed by CMO Annual Report 2003
2002	SHOT recommendations must be on the clinical governance agenda	**Trust CEOs, Trust risk management committees and HTCs**	No mechanisms for monitoring
2001	An open learning and improvement culture must continue to be developed in which SHOT reporting is a key element	**Trust CEOs**	Philosophy supported by NPSA. SHOT has developed a training tool for root cause analysis
2001	An ongoing programme of education and training for all staff involved in transfusion	**NBTCs and network, Trust CEOs, NPSA/NBTC/SHOT initiatives**	Mandated by NPSA SPN 'Right Patient, Right Blood'. Also a requirement of NHSLA standards. An educational tool is available at www.learnbloodtransfusion.org.uk, developed by SNBTS
2001	Appropriate use of blood components must be strenuously promoted and evaluated. This must include monitoring for serious adverse effects of alternatives to transfusion	**NBTC, Trusts CEOs**	Successive BBT initiatives promote this. NBS Appropriate Use Group and Patients Clinical Team active. Red cell usage has fallen by >15% since 2000
2001	Transfusion practitioners should be appointed in all Trusts	**Trust CEOs**	Requirement of BBT2 now appointed in 75% of hospitals (National Comparative Audit organisational audit 2005)
2001	More transfusion medical consultant time is needed in hospital Trusts		Requirement of BBT2, but national shortage of consultant haematologists

1999	All institutions where blood is transfused must actively participate in SHOT	**Trust CEOs**	Requirement of BBT and NHSLA. Murphy and Howell survey indicated that 99% of responding hospitals (95% of NHS Trusts) participate; 69% reported events or Near Misses in 2005
1999	Education in blood transfusion must be included in the curriculum for all clinical staff involved in prescribing and administering blood. All staff involved in the transfusion chain in hospitals must receive appropriate training, which must be documented. Effectiveness of training should be assessed by competency assessment	**NBTC, NPSA, Royal Colleges, JRCPTB**	
1997	There is a need for a national body with relevant expertise and resource to advise government on priorities for improvements in transfusion safety	**DH**	MSBTO reviewed by DH; new committee SaBTO created, inaugural meeting 2008

5. Incorrect Blood Component Transfused (IBCT)

Definition

The category Incorrect Blood Component Transfused (IBCT) comprises all reported episodes where a patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or that was intended for another patient.

DATA SUMMARY

Total number of cases	**332**	*Implicated components*		*Mortality / morbidity*	
		Red cells	**257**	Deaths due to transfusion	**0**
		FFP	**13**	Deaths in which reaction was contributory	**0**
		Platelets	**27**	Major morbidity	**7**
		Other (cryo)	**4**		
		unknown	**31**		

Gender		*Age*		*Emergency vs. routine Core hours vs. out of core hours*		*Place of transfusion*	
Male	**156**	<16 years	**22**	Emergency	**83**	A & E	**5**
Female	**158**	<1 year	**11**	Routine	**209**	Theatre	**10**
unknown	**18**	<4 weeks	**12**	Not known	**40**	ITU/HDU/Recovery	**15**
						Wards	**129**
		Total	**45**	In core hours	**108**	Community	**2**
				Out of core hours	**74**	Other	**0**
				Not known/applicable	**150**	Not known	**171**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)		
In how many cases was failure or absence of IT a factor?	**25**	See section 5.2
In how many cases was a transfusion possibly unnecessary or inappropriate?	**49+**	See page 35

Reports of IBCT

This year 352 IBCT questionnaires were received. Seventeen reports were withdrawn during the course of analysis because they did not meet the criteria for the categories currently included in IBCT. An additional 3 cases were 'right blood to right patient' incidents in which the patient received the intended component despite a serious breach of protocol. These have been included in a separate section (page 63) and are not included in the total. There is 1 report of an adverse event relating to autologous blood transfusion on page 48, and there are 2 reports of adverse reactions relating to cell salvage in the ATR chapter; these are discussed together in a section on adverse incidents in autologous transfusion on page 110.

There are separate chapters discussing laboratory-related IBCT reports and the role of IT errors and problems in IBCT cases. These are also included in the total number of IBCT cases. Anti-D related reports have not been included in IBCT this year and have been separated into a discrete chapter on page 65.

This section describes the findings from 332 analysed IBCT cases. There are text boxes associated with some cases listing corrective actions taken at the hospitals concerned. Some of these represent excellent practice. The issues surrounding identification of useful corrective actions are discussed in a separate section on page 116.

Figure 4
IBCT and ABO incompatible cases 1996–2007

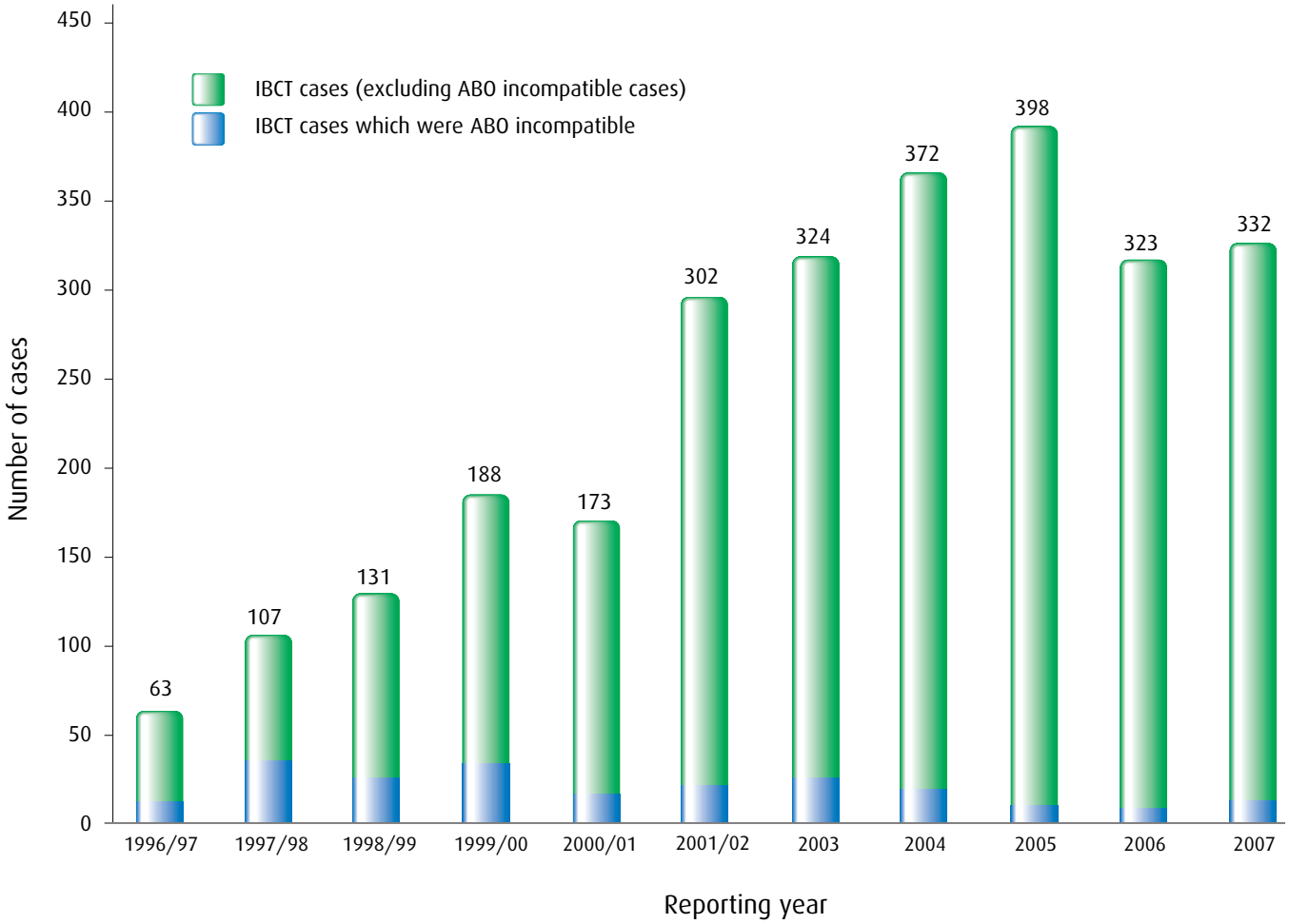


Table 7 shows the number of IBCT reports expressed as per 100,000 components issued in each year from 2003 to 2007 (excluding anti-D cases).

Table 7
IBCT reports 2003–2007

Year	Number of IBCT reports	Reports per 100,000 components
2003	324	9.5
2004	372	11.1
2005	398	12.8
2006	323	10.6
2007	332	11.4

Mortality

There are no fatal cases from IBCT this year.

Major morbidity

There were 7 cases of major morbidity, 4 from ABO incompatibility (Cases 1-4), 2 from inappropriate transfusion causing TACO and cardiac failure respectively (Cases 11 and 12), and 1 from over-transfusion causing a dangerously high Hb (22 g/dL) requiring venesection (Case 14).

ABO-incompatible transfusions n = 14

There were a total of 14 ABO-incompatible transfusions, 10 as a result of clinical errors (including 1 phlebotomy wrong blood in tube (WBIT) error) and 4 as a result of laboratory errors. One of the administration errors related to platelets, and 1 of the laboratory errors to FFP, leaving 12 cases of ABO-incompatible red cell transfusion.

D-incompatible transfusions n = 7

Three D-incompatible transfusions were given as a result of clinical errors (including 1 from a WBIT phlebotomy error), and 4 occurred as a result of laboratory error. Of the laboratory cases, 1 involved platelets and the remaining 3 related to red cells.

Table 8
Summary of IBCT results

Type of event	Number of cases	
Administration of wrong blood		**24**
• ABO incompatible	9	
• D incompatible	2	
• Compatible wrong blood	10	
• Incorrect component type	3	
Wrong blood in tube		**7**
• ABO incompatible	1	
• D incompatible	1	
• Incorrect Hb	4	
• Compatible	1	
Inappropriate or unnecessary transfusion		**50**
• Based on wrong Hb	28	
• Based on POCT INR/plt count	2	
• Haem/coag lab errors	3	
• Poor knowledge and prescribing	17	
Handling and storage errors		**118**
• Technical administration errors	15	
• Transfusion of expired red cells	12	
• Excessive time to transfuse	57	
• Cold chain errors (incl. 20 lab-related)	34	
Special requirements not met – CMV/irrad		**76**
• Clinical errors and omissions	49	
• Laboratory errors and omissions	25	
• Blood Service errors and omissions	1	
• Unclassifiable	1	
Special requirements not met – other		**17**
• Laboratory related cases	15	
• Clinical related cases	2	
Additional laboratory errors (including ABO- and D-incompatible)		**40**
• Wrong blood issued	15	
• Wrong ABO/D type for SCT patient	5	
• Pre Tx errors – testing	5	
• Pre Tx errors – procedural	15	
TOTAL		**332**

Each of these sections will be discussed in detail in the following pages.
Overall assessment of primary errors in the 332 IBCT events revealed that there were 96 errors originating in the laboratory and 235 primarily clinical errors plus 1 blood establishment error.

There was an approximately equal male: female ratio among the reported cases.

Of the settings in which blood components were transfused, 82 cases were regarded as having occurred in emergency settings and 208 in routine settings. In a further 16 cases this information was not known. In 26 of the 332 cases no answer was given.

Table 9
Broad indications for component transfusions

Indication for transfusion	Cases
Elective surgery	26
Emergency surgery	13
Trauma	9
Bleeding from various causes (this included 21 gastrointestinal bleeding from various sites)	47
Bone marrow failure	36
Haemolysis	2
Anaemia from various causes	148
Not given	51

The question about the time the IBCT episode took place was poorly answered in questionnaires with the section left blank in 148 questionnaires out of 332 (45%). Of the remainder, 109 took place between 8 a.m. and 8 p.m., 38 between 8 p.m. and midnight and 37 between midnight and 8 a.m.

ADMINISTRATION OF WRONG BLOOD n = 24

There were 24 cases in which blood components were administered to the wrong patient as a result of clinical errors and omissions. Of these 23 involved nursing and midwifery staff and 1 involved medical staff. Only 1 paediatric patient was involved, an infant 8 weeks of age. There were 12 cases involving female patients and 12 involving male patients.

Nine ABO-incompatible transfusions resulted from these errors of which 1 was both ABO and D incompatible. In addition there were 2 cases of transfusion of D positive blood to D negative patients because of administration errors. One of the ABO-incompatible transfusions caused an immediate reaction with risk to life requiring emergency exchange transfusion; 3 caused immediate reactions with symptoms and signs of intravascular haemolysis; and 2 more caused a less dramatic reaction. In the remaining 3 cases there was no reaction. None of the patients involved in the ABO-incompatible transfusions were children.

Only those cases resulting in a transfusion reaction need to be reported to MHRA via SABRE. The relevant 6 cases were reported to MHRA, but in addition another 14 were also reported to MHRA which were not required to be.

There were 15 cases in which there was an error in the collection of the component from the storage site, i.e. the blood bank refrigerator, satellite refrigerator or the agitator. Of these 15 cases, 8 of the errors in collection were made by a registered nurse or midwife, 3 by porters, 1 by an unqualified nurse, 2 by junior doctors and 1 by a healthcare support worker.

ABO-incompatible transfusions n = 9

There were 9 cases in this group. Seven of the 9 involved collection of the wrong unit from the storage site. This incorrect unit was then transfused to the patient for whom the transfusion was intended. The remaining 2 cases involved a correct unit of blood being collected for a patient requiring transfusion but transfused to a different patient on the ward by the nursing staff.

Major morbidity n = 4

One case suffered a severe immediate reaction with threat to life, requiring red cell exchange.

Case 1

Two ABO-incompatible units transfused resulting in need for red cell exchange transfusion

A man with metastatic prostate cancer presented in the Emergency Department (ED) with a Hb of 5.3 g/dL and gastrointestinal bleeding. Two units of blood were collected by a registered nurse from the issue fridge and commenced via two cannulae. The patient became pyrexial with rigors, loin pain and hypotension and 1 hour after starting the transfusion the nurse called the doctor who stopped the transfusion: by this time most of both units was transfused. The doctor found that the red cell units were for a different patient, and that the units were incompatible, the patient being O D positive and the two transfused units B D negative. The patient received immediate supportive care and further advice was sought from the haematology consultant. A red cell exchange of 4 units of correct ABO/D group red cells took place. The patient suffered worsening renal impairment, and was later discharged to a hospice.

In 3 cases there were documented symptoms and signs of immediate intravascular haemolysis:

Case 2

Classic patient ID error involving two similar patients in adjacent beds: multiple errors

Two male patients with similar names were in adjacent beds with acute epistaxis. Patient A was awaiting a platelet transfusion, and patient B had had a red cell crossmatch requested. Patient B was stable with an Hb of 8.7 g/dL and the junior doctor decided not to transfuse overnight. Platelets were written up for patient A. The laboratory called to say that blood was available for patient B and a healthcare support worker, who had never been to the blood issue fridge, was sent to collect a unit, which she left in the treatment room. Nurse 1 (unqualified) set up a saline infusion on patient A, awaiting platelets, and found he had no wristband, so she made one from the notes and drug chart and attached it to patient A. She then fetched the red cell unit crossmatched for patient B, and commenced the transfusion without any bedside checks at approximately 19.00. Patient A felt unwell, but observations were apparently stable, although documentation only shows recordings at 12.40 and 19.55. At 19.15 patient A complained of back spasm, palpitations and feeling unwell and had pinpoint pupils. Nurse 1 checked that the blood was running and reassured the patient. She went on a break handing over to nurse 2. At 19.45 nurse 2 was called to patient A, who was purple in the face and shaking uncontrollably. She noticed that blood was running instead of platelets and stopped the transfusion. She then noticed that the unit was labelled for patient B in the next bed. She called the junior non-specialist doctor who gave a verbal prescription for IV hydrocortisone and piriton and came to see the patient. Observations were satisfactory apart from a pulse of 125bpm. By 20.30 patient A was a little better. The junior non-specialist doctor was unable to persuade the medical specialist trainee doctor to attend. By 22.00 the transfusion co-ordinator had informed the haematology consultant and transfusion BMS of the error and investigations were initiated, as well as IV fluid and frusemide.

Corrective actions reported from involved hospital Trust

- Raise awareness of blood/platelet transfusion procedures at senior nurses' meeting, and via the risk group, and governance structure.
- Highlight wristband identification policy to all admitting areas and ward nursing staff. Re-audit compliance with policy.
- Continue with training programme of all clinical staff involved in the transfusion process. Only trained personnel to be permitted to collect and administer blood and monitor patients undergoing transfusion.
- Education of all relevant staff in the recognition of transfusion reactions and in appropriate intervention, investigation and documentation.
- Involvement of medical director and clinical directors in the training of specialist trainee doctors and junior doctors, including cascading via grand round and clinical governance structures.

Case 3

Red cell units 'checked' at nurses' station

An 84-year-old male patient was awaiting top-up transfusion for anaemia due to prostate cancer. A unit for another patient had also been collected from the issue fridge. Units were checked at the nurses' station. A nurse then took 1 unit and commenced the transfusion on one of the patients without performing any bedside checks. This patient who was O D positive thus received a unit of blood intended for another patient which was A D negative. He developed fever, haemoglobinuria, hypotension and loin pain which resolved with full recovery.

Case 4

Second unit of a routine transfusion administered without checks

A nurse removed a red blood cell unit from a satellite blood fridge without checking the patients ID details or signing the blood register. The 75-year-old male patient, group O D positive, was still finishing the first unit of a 2 unit transfusion for myelodysplastic syndrome (MDS). The nurse left the second unit in the treatment room and subsequently forgot that she had not checked the unit against the prescription form or compatibility label and put it up without checking the patient's ID wristband. At approximately 21.40, after the blood had been running for 15 minutes, the patient developed rigors and pyrexia, and the transfusion was stopped. The unit was found to be for a different patient with the same first name. Piriton and hydrocortisone were given, and salbutamol as the patient became wheezy. Haemoglobinuria was observed. The patient made a full recovery.

Minor morbidity n = 2

Two patients suffered a mild reaction from the incompatible units with full recovery. There was no reported evidence of intravascular haemolysis.

Case 5

Worrying lack of comprehension of reasons for standard procedures, and disregard for consequences

A patient receiving a red cell transfusion complained of severe back pain, and then developed rigors. The deputy nursing sister attended the patient, noticed it was the wrong blood, took it down and bleeped the junior non-specialist doctor. The ward then phoned blood bank requesting a further unit of blood for another patient as the first had been 'wasted'. Only when the blood bank manager asked for the bag was it revealed that the unit had erroneously been given to the wrong patient. The blood bank manager contacted a consultant haematologist who went to see the patient immediately. The sticky label from the blood bag tag had been removed from the medical notes, and the name had been crossed out on the blood bag label. The bag of blood had been thrown into the sharps bin and was retrieved by consultant haematologist. The nurse who put up the blood admitted she had not performed any bedside checks.

Case 6

Red cells administered by doctors in theatre without checking

A 69-year-old man was in theatre undergoing emergency repair of an abdominal aortic aneurysm. A junior doctor collected an incorrect unit of group A D positive blood from the theatre fridge. The identity of the unconscious patient, who was group O D positive, was not checked against the unit of blood. It was administered by an anaesthetist. The patient developed renal failure postoperatively, which resolved but may in part have been due to the incompatible transfusion.

ABO-incompatible transfusions with no reaction n = 3

Case 7

Two units of ABO-incompatible red cells given despite 'checks'

Patients A and B were in adjacent beds and both were crossmatched. Patient A (an 84-year-old female patient, group A D negative) was prescribed 3 units of red cells for anaemia. Patient B (group AB D negative) was also crossmatched for 2 units of red cells, but the blood had not been prescribed. The registered nurse who went to collect blood for patient A took patient B's blood in error. The unit was then taken to the ward when it was 'checked' by 2 trained nurses prior to being transfused but the error was not detected. The 15 minute observations were performed, but the patient did not display any signs or symptoms of a transfusion reaction. When the first unit was completed it was fated via the computer system (EU Directive traceability). The next unit was collected, and the same error was repeated. Again the check by 2 qualified staff on the ward failed to detect the error and the second unit of patient B's blood was given to patient A. It was unclear what documentation was used in the collection process and where the final check occurred. The 15 minute observations were not performed for the second unit. The error was detected when the transfusion was complete.

There was 1 case of ABO incompatibility in which platelets were given to a patient instead of FFP, but there was no adverse reaction.

Case 8

Lack of understanding about different component types

Four units of FFP were requested for a 68-year-old female patient on warfarin who had a haematoma following access to an AV fistula. An unqualified healthcare support worker was sent to collect the FFP but she removed a unit of stock platelets from the platelet agitator instead. These had not been issued for a patient and therefore had no patient labels attached. A second agency support worker came to collect the second unit of FFP and instead removed a second unit of stock platelets from the platelet agitator. This unit had expired at midnight the night before. The patient was O D positive and both bags of platelets were A D positive. Both of these units were checked by 2 staff nurses and were transfused before the error was detected. Both nurses noticed that the units bore no patient labels but still proceeded with the transfusion. There was no untoward reaction.

In one remaining case in which there was no reaction, the patient received less than 50 mL of blood. The transfusion was stopped when the error was noted because the patient asked whether the blood was irradiated or not.

Case 9

Well-informed patient averts possible catastrophe

No patient identification was taken to the blood fridge, and as a result the wrong unit of red cells was removed by a registered nurse and taken to the ward for an 81-year-old female patient with chronic lymphocytic leukaemia (CLL). On the ward another nurse administering the transfusion assumed that the checks had been completed, and because of this assumption no bedside checks were performed. The patient received non-irradiated group A D positive red cells, instead of irradiated O D positive red cells. The error was noticed when the patient asked whether the unit was irradiated. Consequently <50 mL was transfused.

D-incompatible blood n = 2

There were 2 cases in which D positive blood was given to D negative patients, owing to bedside errors in which blood was not given to the patient for whom it was intended.

Case 10

Simultaneous transfusion of two patients leads to wrong unit being transfused

Blood for two patients was delivered, in two separate blood transport boxes, to the nursing station by the porter, where the units were 'checked'. One unit was taken out of each box and transfused to the appropriate patient. After the first patient, a 19-year-old man with chronic renal failure and a post-op Hb of 5.2 g/dL, had received the first 2 units of blood, an unqualified nurse collected a third unit for him. However, she did not check that she picked up the correct unit from the blood box. She then put the unit up and commenced the transfusion. A few minutes later, a qualified staff nurse responsible for the second patient went to get the second unit from the transport box and found the unit missing. It was then discovered that patient 1, group O D negative, was receiving the unit of blood intended for patient 2, group O D positive.

Errors identified for corrective action at the involved hospital

- **Qualification for transfusion:** student nurses were giving blood transfusions but they are not qualified to do so
- **Supervision:** the qualified nurses on the ward did not notice the students nurse's actions
- **Checking and traceability:** it was found that the registered nurses had checked that the blood in each box was for the two patients and then signed the traceability/compatibility labels and left the units in the boxes, from where they would be taken one at a time for transfusion

Case 11

Unit checked against crossmatch report

An intensive therapy unit (ITU) staff nurse took the incorrect patient's crossmatch report as identification to collect 2 units of red cells from the issue fridge. The units collected matched units on the report, and therefore were wrong for the intended patient. Once back at the ward the units were checked, again using the crossmatch report, and not the patient identification band. Thus 2 units of O D positive red cells were transfused to an O D negative male patient in error.

The NPSA Safer Practice Notice, SPN 14, advises that compatibility forms should be phased out as this prevents the erroneous practice of checking units against compatibility forms instead of patient ID. However, the above case clearly demonstrates an equivalent error involving a crossmatch report form (which is the paper report sent to the ward from the lab when the elective crossmatch has been performed). This highlights the need for sufficient depth of education regarding the reasoning behind protocols, as training to the protocol alone does not avoid errors.

Commentary on administration of wrong blood to patient

There are a number of themes common to the above cases, many of them highlighting that not only are training and competency essential for safe collection and administration of blood components, but that levels of knowledge and understanding are required for the following of protocols to be performed safely. Staff need to understand the process and the rationale for it in order to act appropriately when situations deviate from 'normal'.

There are three particular areas of concern highlighted by these 11 cases, many of which recur in other sections of this chapter.

Errors in following process for collection of components:

Poor knowledge and recognition of different component types
Failure to act appropriately on discovering an 'unlabelled' component
Deployment of unqualified staff to collect components
Use of inappropriate documentation, or no documentation, to collect component

Failures of bedside checking procedure:

No checking done at bedside
Persistent misunderstanding that 'checking' can be performed remotely from the patient's side
Checking against paper documents being substituted for cross-checking against the patient's ID wristband

Non-recognition of a transfusion reaction:

Lack of understanding of the imperative to monitor patients receiving blood components
Failure to recognise a transfusion reaction, due to insufficient knowledge or experience
Not acting appropriately when a patient suffers a reaction, due to lack of appreciation of the potential seriousness

All of these cases would have been prevented by following the proper process for carrying out a bedside check of patient ID and component details. However, in order for this to take place universally, it must be carried out by staff with levels of knowledge and skill that allow them to appreciate the rationale behind this imperative. Competency assessment for blood component collection and administration is essential also, but this should not be used as a way of allowing staff with insufficient knowledge or experience to undertake this critical task. Nursing and medical staff must take responsibility and are professionally accountable. Staff should not undertake tasks for which they themselves feel poorly prepared.

Wrong blood transfusions which happened to be compatible n = 10

There were a further 10 cases in which blood intended for a different patient was transfused and in which, by chance, there was no ABO or D incompatibility and thus no reactions took place.

There were 6 instances in which the correct blood had been collected for the patient from the storage site but once it was on the ward it was checked away from the patient and then subsequently given to the wrong patient. In one pair of cases two patients were given each other's red cell units, fortunately of the same group. These cases highlight weaknesses in the training of staff in the blood checking process, in that staff still carry out the so called 'check' remotely from the patient. It must be made clear that full, safe checking of a component is impossible without the patient. Blood cannot be checked away from the patient and must not be checked against compatibility forms or other paper documentation. Components must always be checked against the patient's wristband and the patient's verbal account of their name and date of birth.

Case 12

'Helpful' nurses and doctor administer platelets to the wrong patient

Platelets arrived in ITU and the nursing sister took them to a patient's bedside. This was not the bedside of the patient to be administered platelets. Finding the patient unconscious and without an ID bracelet she went to write a wristband. Two other nurses saw the platelets and checked them by asking other staff if it was the correct patient. Finding the platelets were not written up for that patient, they asked the doctor to prescribe them, which he did. The platelets were then given to this patient, who did not require them, instead of another patient on the unit. There was no adverse reaction.

Case 13

Lack of understanding of possible consequences of actions

Two qualified nurses checked a unit of blood at the nurses' station and a nurse then walked into a 6 bedded bay and connected it to the wrong patient with no bedside check. The nurse then realised her mistake, disconnected the giving set from the wrong patient and reconnected it directly to the right patient. A senior colleague queried her actions as she had used a fluid giving set, not a blood giving set. The nurse was sent away and the senior nurse changed the giving set as she was unaware of the previous mistake. The rest of the transfusion was then administered (to the right patient). The patient who had received a part unit of wrong blood was not monitored and nothing was documented in the notes.

There were 2 cases in which units were mistaken for 'flying squad' blood and removed from controlled temperature storage, and given in an emergency situation to a patient. However, in both these cases the blood removed from the storage site was not flying squad blood but had been crossmatched for another patient.

Case 14

After 'losing' the flying squad blood, units crossmatched for another patient are taken and transfused

During a massive obstetric haemorrhage emergency O D negative blood was collected from a satellite fridge and taken to theatre, but 'lost'. An anaesthetist went back to the satellite fridge and collected 2 more units of red cells which were in fact crossmatched for another patient. These were transfused before it was realised that they were not the emergency O negative units. The patient was B D positive and received O D positive blood with no clinical consequences.

There are 2 cases in which the wrong unit was collected from controlled temperature storage by portering staff and the bedside check failed to detect that the unit was not for the intended patient and it was transfused.

Case 15

A porter collects blood without adequate documentation

During the night, a unit of blood was collected for top-up transfusion of an 85-year-old female patient by a porter who was given only the patient's name. He collected blood for another patient in error, whose name differed by only one letter. The date of birth and the hospital number were not checked as the porter did not have them. On the ward, 2 nurses checked the blood against the compatibility form – which matched the unit. They did not check the patient's wristband or the prescription sheet. The whole unit was transfused and the error identified only when the next unit was put up. The unit transfused was group O D positive and the patient was group A D negative. There was no adverse outcome.

Errors and omissions identified at the hospital

- It was not appropriate that this routine top-up transfusion was taking place overnight
- The portering controller was not given the patient's full name, hospital number and date of birth for collecting blood products
- The porter failed to check even the limited details given adequately
- The nursing staff did not check that the porter had collected the correct unit, and did not follow the hospital policy for the checking of blood products, which is for single nurse checking
- In addition they did not check the medical notes or prescription chart, nor the patient ID (verbally or wristband)

Incorrect component type given to correct patient n = 3

There were 3 cases in which the patient had more than 1 component type available and the wrong component type was collected and transfused despite a correct prescription. In 2 of these cases red cells were transfused where platelets had been prescribed, although the red cells were for the same patient. In both cases the wrong component, i.e. red cells, were collected by nursing staff from the issue refrigerator instead of collecting platelets from the agitator as per the prescription.

Case 16

Confusion regarding components results in unwanted red cell transfusion and delayed surgery

A 77-year-old man had prophylactic platelets written up prior to spinal decompression surgery. Night nurses erroneously collected red cells which were also available for the same patient as they were crossmatched for the morning list. Two units of red cells were transfused over 30 minutes each, and no platelets. In the nursing notes the transfusions were documented as platelets, and it seemed that the staff were unfamiliar with the different types of blood component. The surgery had to be delayed in the morning when the day staff discovered the error.

In 1 case platelets were given instead of FFP. In this example the platelets were collected erroneously by the porter instead of FFP and the bedside check did not detect this discrepancy. The report also suggests that the transfusion of FFP was not clinically indicated.

Case 17

Porter collected platelets instead of FFP

An 8-week-old female child with severe metabolic disorder and sepsis required blood component support. Both platelets and FFP were available in blood bank. The porter was asked to collect FFP but took platelets. Nurses performing the bedside check did not notice the error and transfused the platelets resulting in the platelet count rising from 90 to 126 x 10^9/L.

The case above raised the issue as to whether non-clinical staff can safely be trained to collect different components which are superficially similar. It is perhaps unreasonable to expect non-clinical staff to be responsible for making this differentiation.

WRONG BLOOD IN TUBE ERRORS n = 7

In these cases an incorrect patient was bled either for haemoglobin estimation or for a group and save/crossmatch sample and all cases resulted in incorrect or inappropriate transfusion. One case resulted in ABO-incompatible transfusion and another in D-incompatible transfusion. Four cases resulted in the wrong patient being transfused as the haemoglobin was actually that of another patient. There was 1 case in which a D group was actually that of another patient but was in fact compatible.

Case 1

Phlebotomy error results in ABO-incompatible transfusion

An 83-year-old female patient who was previously unknown to the hospital had a routine sample sent requesting a crossmatch of 2 units of red cells. The sample grouped as A D positive and two compatible units were issued and transfused to the patient. The patient suffered no transfusion reaction and was discharged home. She was readmitted 6 weeks later for recurrent anaemia. A sample sent requesting a further 2 unit crossmatch, grouped as O D positive' this was confirmed on a repeat sample. It appears that on the initial admission the patient received 2 units of incompatible (A D positive) blood as a result of a phlebotomy error.

Case 2

D-incompatible blood given as a result of a phlebotomy error

A 58-year-old male patient was grouped as O D negative and transfused 2 units of O D negative blood. Six weeks later a second sample was grouped as O D positive. A third sample was taken to confirm the patient's blood group as O D positive.

In 4 of these cases the phlebotomy had definitely been carried by a junior hospital doctor and in a fifth case this was probably the case although it is not entirely clear from the report.

In all these cases the recipients were adults.

INAPPROPRIATE or UNNECESSARY TRANSFUSION n = 50

There were 50 cases in this category, of which 37 were reported to SHOT only and 13 were reported to MHRA via SABRE. In fact none of these cases were reportable to MHRA, as even the laboratory-related errors were related to the haematology laboratory rather than the transfusion laboratory.

In 47 of the 50 cases the junior doctor was at the root of the problem, although in 6 of these cases this was not categorically stated in the report but was implied by the narrative. However, this still leaves 41 out of 50 cases where a junior doctor was directly implicated in an inappropriate or unnecessary transfusion.

[There are 2 cases which have been included in the blood administration section as they concerned nursing staff transfusing a greater quantity of blood than was prescribed. They are less apposite here as the main theme in this section is poor decision making rather than error.]

Three cases involved patients under 4 weeks old at the time of the inappropriate transfusion. An additional one was under a year old. Four further cases were in patients between 1 and 16 years old; in 1 case the patient was 18 years old.

In 17 cases recipients were male and in 31 cases female (in 2 cases gender was not recorded).

Eighteen cases were emergencies, 27 were routine, 3 were unknown and 2 were unrecorded.

Transfusions based on wrong haemoglobin result n = 28

Table 10
Inappropriate transfusion based on incorrect haemoglobin value

Cause of falsely low Hb value	Cases
Falsely low Hb due to phlebotomy from drip arm	5
Hb from massively haemodiluted patient	1
Erroneously low Hb from Hemacue/point of care testing/blood gas analyser	4
White cell count mistaken for Hb	6
Transcription error from telephoned Hb result	4
Albumin value misinterpreted as Hb	1
Hb value misread from computer screen	1
Poor sampling technique resulting in clots, stasis in syringe, etc.	6
TOTAL	**28**

Drip arm (and haemodilution) n = 6

There were 5 cases reported in which an inappropriate decision to transfuse was based on a falsely low haemoglobin level because the sample was taken from a drip arm. In an additional sixth case the patient was described as 'haemodilute', apparently resulting in a falsely low Hb estimation.

Case 1
Falsely low Hb from a drip arm results in unnecessary transfusion

A patient had a full blood count (FBC) performed at night and was found to have a Hb of 5.5 g/dL. 4 units of red cells were ordered and issued and 1 unit was transfused. A further sample was sent later the same morning and found to have a Hb of 11.1 g/dL. No further units were transfused, and the original sample was rechecked and the result of 5.5 g/dL confirmed. On investigation, it emerged that the original sample was taken from a drip arm and was therefore diluted. The patient suffered no immediate harm.

In many of these cases there was a lack of engagement by the junior doctor with the results. Taking stock of the change in haemoglobin from the previous sample and evaluation of the clinical condition of the patient might have prevented some of these unnecessary transfusions.

Erroneous Hb result from POCT equipment n = 4

These cases include results from blood gas analyser and Hemacue™ devices – a result not of malfunctioning of the equipment but of poor training and unfamiliarity. There were 4 cases in this group relating to erroneous haemoglobin. [Two further POCT errors are reported separately as they apply to platelet and international normalised ration (INR) results.]

Case 2

Hb of 3 g/dL not queried by medical staff

A 74-year-old male patient in recovery post hip replacement was drowsy, hypotensive and tachycardic. A haemoglobin estimation from a blood gas analyser was 3 g/dL. A FBC sample was sent to the laboratory, but in the interim 1 unit of 'flying squad' (uncrossmatched group O D negative) blood was commenced. The new Hb result from the laboratory was 11.2 g/dL and recovery staff informed of this result advised medical staff to discontinue the transfusion. The patient suffered no apparent ill effects as a result of the over-transfusion or uncrossmatched unit.

Unnecessary transfusion based on transposed Hb and white cell count (WCC) results n = 6

This category comprises 6 cases in which as a result of misreading of laboratory reports or miswriting of results, the white cell count was taken to be the haemoglobin. The patient was thus transfused on the basis of what was apparently a low haemoglobin but which was actually the white cell count.

Case 3

White cell count mistaken for Hb resulting in unnecessary transfusion

A 70-year-old woman presented in ED looking very pale and had fainted at home. Full blood count run on a POCT analyser in ED showed a WBC of 7.9x10^{9}L, which was mistaken for the Hb, and a 2 unit transfusion was prescribed. The error was identified when the post-transfusion Hb was 16.3 g/dL. The patient was informed of the error, but she stated that she was happy as she felt much better.

Transcription errors n = 6

There were a further 6 cases of transcription errors. Four of these involved telephoned results written down in the ward. In 2 cases the source of the alleged telephoned result could not be traced. In a further case an albumin of 6 g/L was incorrectly supposed to be the patient's haemoglobin and the patient was transfused unnecessarily. In the fourth case the haemoglobin result was written in the wrong set of notes and a patient who did not require transfusion was given red cells in error.

There is also an incident in which the decision to transfuse a patient, made on a ward round and jotted in junior doctor's notebook, was later transcribed into a wrong patient's notes. In the final case a doctor admitted she had misread the results from a computer screen and ordered blood for a patient who did not need it.

Case 4

Danger of poorly documented telephoned results

Routine blood tests were performed on a 64-year-old male patient on ITU following an emergency laparotomy during which 3 units of packed cells had been given. Biochemistry results were phoned to ICU, and an albumin of 6 g/L reported, but a nurse documented this result as a Hb of 6 g/dL. Four units of blood were then transfused on the basis of this result. In fact the pre-transfusion (preoperative) Hb had been 10.4 g/dL, and post transfusion it was 17.6 g/dL.

Poor sampling technique leading to erroneously low haemoglobin level n = 6

Case 5

Difficult phlebotomy results in falsely low Hb

A sample was taken with great difficulty from an elderly female patient with a hip fracture, giving a Hb of 3.6 d/dL. The BMS phoning the result stated that it was a very small sample and that it should be repeated. This was communicated to a second doctor, but, finding the patient to be tachycardic and pale, he prescribed 3 units of red cells. Later another doctor also prescribed 3 more units, plus FFP and platelets. On review the patient had signs of pulmonary oedema and was therefore given frusemide. A repeat Hb taken a few hours later was 12.6 g/dL.

This case is typical of this group in which difficulties in phlebotomy encountered by junior doctors resulted in haemodilute samples, partially clotted samples or samples that were in a syringe for such a long time that settling of the red cells took place.

Inappropriate or unnecessary transfusion of FFP and platelets based on POCT results n = 2

Case 6

FFP transfused on basis of erroneous INR even though repeat lab test result was available

An 84-year-old man admitted postoperatively with a retinal bleed was tested using a point-of-care coagulation device on the ward. An INR of 6.1 was recorded and a venous sample was sent to the laboratory for confirmation. Four units of FFP were requested urgently and prescribed, and subsequently a normal INR of 1.1 from the venous sample was recorded in the patient's medical notes. The FFP was nevertheless transfused inappropriately 9 hours later despite normal coagulation screen and no evidence of active bleeding.

Case 7

Bizarre results from ED not queried

A 76-year-old female patient was admitted with a dislocated knee. FBC processed POCT equipment in ED, produced a platelet count of 67 x 10^9/L. The accompanying Hb was 24 g/dL. The anaesthetic junior doctor ordered some platelets, and did not discuss the peculiar results with the haematology team. The BMS did not query the request in the light of Trust protocols for platelet transfusion. The junior non-specialist doctor prescribed the platelets to run over 2 hours. A normal count was later obtained from the main laboratory.

In the cases above, as in the previous ones, there appears to be a failure to query the veracity of the results based on the clinical picture, or to view the results as a whole, including WCC, platelets and indices as well as accompanying chemistry results. All of these may appear very abnormal in a situation such as Case 7. Full evaluation of the patient is essential and there must always be awareness that results can be incorrect.

Haematology and coagulation laboratory errors (i.e. not transfusion laboratory) n = 3

In 2 cases a patient prone to platelet clumping in ethylenediaminetetraacetic acid (EDTA) was transfused platelets unnecessarily on account of this. In both cases the laboratory had issued a report showing a low platelet count. In 1 case the caveat was added to – that there was clumping and that a citrated sample should be sent to check the platelet count more accurately. However, the junior doctor still prescribed platelet prophylaxis on the basis of this erroneously low count.

In another case an INR was performed on a partially clotted sample and this was not spotted in the laboratory. The patient was therefore given FFP unnecessarily on the basis of her erroneously high INR result.

BMS staff in the hospital transfusion laboratory should certainly feel able to query requests, but frequently results such as these are from separate laboratories, geographically separate from the transfusion laboratory, and the results cannot be easily checked.

Transfusions based on poor basic knowledge and prescribing n = 17

Inappropriate transfusion based on lack of knowledge or understanding n = 4

These are cases in which there is some confusion or lack of certainty among junior doctors as to what exactly they need to order or what their patient really requires. In 1 case platelets and cryoprecipitate were ordered when the patient really needed FFP. In another case a doctor seemed unclear as to the reasoning behind asking for a group and save, or asking for crossmatch. Having requested the latter, the doctor was uncertain as to whether this led to transfusion.

Case 8

Junior doctor uncertain of implications of group and save (G and S) or crossmatch

After some instructions from her consultant, a junior doctor requested an urgent '2 unit crossmatch' on an 85-year-old female patient with a suspected bowel perforation admitted at 05.00. The Hb was not available. Later the laboratory rang the admitting ward to tell them the blood was ready, and the nurse contacted the doctor to inform her and to remind her that the blood had to be prescribed. The doctor was very busy so the ward sent a support carer to meet her to complete the documentation. The nurse commenced the transfusion at 07.05. At 09.00 the patient's consultant stopped the transfusion as he knew the Hb was 13.9 g/dL. The intention had been to request an urgent G and S to cover a possible bleed but the patient was not to be transfused until further results were available. The junior doctor was confused between a 'crossmatch' and 'group and save' request.

In the case below a patient was given platelets unnecessarily, owing to lack of familiarity with the guidelines for platelet transfusion prior to insertion of a Hickman line. This resulted in the junior non-specialist doctor transfusing platelets against the advice of the haematology consultant.

Case 9

Disagreement about necessity of prophylactic platelets

A 47-year-old man with acute lymphoblastic leukaemia (ALL) was booked for insertion of a Hickman line. Platelet cover was on standby and the consultant haematologist instructed that platelets were not to be given if the count was > 50 x 10^9/L. The platelet count was 57 x 10^9/L, but the radiologist would not insert the Hickman line without platelets being transfused prior to the procedure. The patient was returned to the ward where the junior non-specialist doctor prescribed the platelets against the consultant's advice and outside of national guidelines. The patient returned to X-Ray where the line was inserted.

Finally there is a case in which there was inappropriate use of emergency group O D negative blood when in fact the patient was crossmatched and blood was available for them in the same refrigerator. There had clearly been lack of communication or handover regarding what components were available for the patient, and the patient was taken to theatre without the personnel involved checking the status of laboratory requests.

Case 10

Emergency blood given in haste by a junior doctor

A 28-year-old man required a repair to an arterial laceration in the anticubital fossa. A surgical junior doctor demanded 2 units of O D negative emergency blood. In fact the patient's group was known and 4 units had been crossmatched and were already available in the same refrigerator.

Excessive volume of components prescribed (or given) n = 13

In this group of cases excessive quantities of components were given as a result of lack of communication, and insufficient knowledge and experience of the junior doctors who required guidance for prescribing appropriately. There were no incorrect or misleading laboratory results influencing decision making.

Two cases (Cases 11 and 12) resulted in severe life-threatening transfusion-associated circulatory overload (TACO), while a third (Case 13) resulted in dangerously high haemoglobin levels requiring venesection.

There are 13 cases in which doctors (junior and senior) prescribed excessive volumes of components often because of miscalculation of the required dose for the patient. Omitting to check the baseline haemoglobin or to monitor Hb following transfusion was a contributory factor in several cases. In 2 of these cases there was major morbidity with serious risk to life caused by TACO. In 2 additional cases excessive volumes (in excess of what was prescribed) were given to patients by nursing staff. These are not included in the totals here and are discussed on pages 42 and 43, as they are administration errors not decision making or prescription errors.

Table 11
Excessive transfusion of components n = 13 [+2]

Inappropriate/unnecessary transfusion with correct results available	Cases
Excessive red cells prescribed Hb not checked	5
Excessive red cells prescribed for small patient	5
Excessive volume of FFP prescribed	1
Excessive volume of cryoprecipitate given	1
Excessive volume of platelets transfused	1
[Excessive volume red cells given (not prescribed) see administration errors]	*[2]*

Case 11

Involvement of too many personnel in decision to transfuse

A 20-month-old girl on regular dialysis for end stage renal failure attended for routine haemodialysis and her father reported that she had been unwell. A consultant commenced dialysis urgently and, as the Hb was 5.0 g/dL, requested 2 units of blood to be given during dialysis. The dialysis was completed before the blood was ready so a decision was made by a second consultant to give 250 mL of blood slowly over 6 hours. This message was conveyed between the dialysis unit nurse and the ward nurse by the patient's father. The notes were later collected and a third and fourth nurse set up the transfusion. Observations were done by the fourth nurse. No pre-transfusion observations were done. At 5, 20 and 35 minutes into the transfusion the patient was hypertensive, tachypnoeic and irritable; her oxygen saturations were unrecordable. The nurse thought this was normal for the patient. The transfusion was completed in 1 hour (not 6) and a fifth nurse then realised that the patient's extremities were blue. A sixth nurse administered oxygen while an anaesthetist was called who performed emergency intubation. The patient was transferred to paediatric ITU where she underwent sedation, high-frequency oscillatory ventilation and haemofiltration. The patient made a full recovery.

The transfusion of this child involved two consultants, the father of the patient and 6 nurses. Owing to changes of plan and no single person taking charge of the management of the patient, the child was transfused too late, when she was already off dialysis, and much too fast, causing life threatening TACO. The transfusion had also initially been prescribed over 6 hours, which is outside guidelines (which state a maximum of 4 hours). Nurses need to be assigned to specific patients and maintain responsibility for and control over all nursing tasks associated with that patient's care. Handover must be effective and structured, and a patient's care should not be taken over by new staff on an *ad hoc* basis. Lack of continuity of care has been an increasing problem in medical care in recent years, as the European working time directive has required shorter days and the implementation of shift systems for junior doctors. As a result, detailed handover between doctors as they change shift is essential, as well as full documentation in the medical notes regarding treatment decisions and including instructions for planned interventions.

Case 12

Misunderstanding and lack of knowledge leads to excessive preoperative platelet transfusion

An 81-year-old man was preoperatively transfused with 4 units of platelets within a 4 hour period. The patient developed cardiac failure, the operation was cancelled, and medical intervention was necessary. In fact the orthopaedic specialist trainee doctor had written in the notes 'Arrange 4 units of platelets'. The junior non-specialist doctor assumed this meant to order and transfuse 4 units of platelets prior to surgery. When ordering, the junior non-specialist doctor was advised by a BMS to seek a haematology opinion as the order appeared inappropriate. This advice was not sought.

This case is somewhat akin to Case 8 (above) in that a junior doctor, unfamiliar with the transfusion process and the jargon that goes with it, had not grasped the fact that blood components ordered to cover surgery are not necessarily transfused beforehand. The senior doctors (consultant and specialist trainee doctor) assumed a level of knowledge which the junior non-specialist doctor just did not have.

In the following case a patient with chronic iron deficiency anaemia was massively over transfused over a period of 3 months. The cause of his iron deficiency was not given in the report.

Case 13

Repeated transfusions for iron deficiency resulting in Hb of 22 g/dL

Four units were requested for an 85-year-old male patient with chronic iron deficiency anaemia. Between 29/01, when his Hb was 6.3 g/dL, and 23/04, 24 units of packed cells were transfused on 8 separate occasions, 2 or 4 at a time, with no Hb check. On 09/05 the Hb was 22 g/dL. In addition platelets were 98 x 10^9/L, INR 1.5, APTR 1.4 and fibrinogen > 8 g/L. The patient was subsequently venesected and by 24/05 Hb was 15.3 g/dL and platelets 307 x 10^9/L.

This patient subsequently required venesection. This case shows once again a lack of understanding by successive junior doctors seeing the patient: they did not realise that the Hb should be monitored before prescribing further transfusion. The decision to transfuse was not reviewed, and the junior doctors seeing the patient regularly on the day ward or in outpatients did not sufficiently understand the nature of the condition, or the purpose of the treatment, to question the appropriateness of continuing regular transfusion. Once again this raises issues of continuity of care, documentation of decisions and instructions for handover.

In the following 2 cases the size of the patient was not taken into account when the transfusion was prescribed. One was a very small adult and the other a 2-year-old child.

Case 14

Small anaemic patient over transfused

A 79-year-old female patient with CMV colitis weighing 41.5kg had a Hb of 6.7 g/dL. She was given a 4 unit red cell transfusion resulting in a post-transfusion Hb of 18.1 g/dL.

Case 15

Junior doctor unfamiliar with paediatric prescribing protocols

A 2-year-old girl was admitted with peritonism, possibly due to ruptured appendix (later found to be a ruptured kidney tumour). Hb was 6.7 g/dL and the surgical team decided to transfuse, writing a dose of 15 mL/kg in the notes. The junior non-specialist doctor wrote up 2 units and the child was given 2 adult bags over 6 hours. Hb was 18.6 g/dL post transfusion.

In the case below there was a combination of a possibly erroneously low haemoglobin result combined with a small patient, and an excessive volume of red cells was prescribed and transfused without any further checking. Junior doctors need to be aware of transfusion algorithms based on a mL/kg calculation for smaller patients. They also need to realise that there are very few instances, except where there is active haemorrhage, in which 4 units of red cells need to be given so rapidly. The patient below, with a Hb of 7.3 g/dL, only required a single unit.

Case 16

Small adult patient with low Hb

An 18-year-old male patient weighing 35kg, with a probable chest infection, received a 4 unit red cell transfusion based on an Hb result of 7.3 g/dL. The doctor prescribed 2 units of red cells. The patient was then referred to a medical team and another junior doctor prescribed a further 2 units of red cells making a total of 4 units. Post transfusion the Hb was 18.4 g/dL. Both samples were rechecked and correct. Investigation revealed that the initial sample was taken by a junior doctor in ED using a syringe during a difficult cannulation. The red cells may have settled in the syringe before the sample tubes were filled, giving an inaccurate result. No IV fluids were in progress at the time. No adverse reaction or ill effects were noted from the transfusion.

The final case reveals not only a lack of awareness of national guidelines on reversal of warfarin[4] but also poor clinical acumen leading to high volume fluid transfusion, which is clearly in itself potentially dangerous.

Case 17

A case of TACO after use of FFP to reverse warfarinisation

A 61-year-old male patient with an INR of 6.0 required warfarin reversal prior to elective surgery. He was given Vitamin K 5 mg and 4 units of FFP over 160 minutes. Without any further INR being performed he then received another 3 units over 45 minutes, at which point he became unwell with rigors, chills, wheeze and a temperature of 38.3°C. His oxygen saturation on air was 80%. He was managed with diuretics and oxygen. The planned surgery was performed the following day.

HANDLING AND STORAGE ERRORS N = 118
[Previously reported as 'unsafe' transfusions]

Technical administration errors n = 15
There were 15 cases in which there were technical administration errors.

Table 12
Types of technical error in administering transfusion

Type of error	Number of cases
Leaking component bag sealed with surgical tape and transfusion continued	4
Blood given through solution giving set	5
Frusemide added directly to blood in bag	1
Completely unlabelled platelets transfused	1
Transfusion in community given by patient's mother	1
Inappropriate prescription of cryoprecipitate administered by a syringe	1
Volume of red cells administered in excess of what was prescribed	2

These cases highlight a need for personnel involved in blood administration to understand fully the reasons behind the various steps of the blood administration protocol. These are the kind of mistakes that are made when personnel do not fully appreciate the potential dangers to patients, for instance of unfiltered blood being transfused, of blood being contaminated by a penetration of the sterile bag, or by inadequate monitoring being carried by an untrained person. It therefore underscores the need for education of nursing staff in transfusion, going beyond training and competency.

Case 1
Leaking FFP bag fixed with sticky tape
A 43-year-old male patient was undergoing emergency laparotomy for internal bleeding. During administration of FFP, an operating department practitioner observed leakage from pack. The cause was unclear, possibly a faulty port or a spiked bag. He applied surgical 'Sleek' tape to the pack to prevent further leakage, and the transfusion continued.

The above example is one of 4 cases where surgical tape was used to stem leakage of a component bag. In no cases was there any appreciation of the possible consequences of contamination of the component.

The next case below is one of 5 in which a solution giving set was used to administer a red cell transfusion instead of a blood giving set with an integral in-line filter.

Case 2
Erroneous use of solution giving set
An experienced agency nurse used a normal solution giving set instead of a blood giving set with an in-line filter for transfusion of packed red cells.

There were 2 cases in which nursing staff administered a greater volume of red cells than had been prescribed: in 1 case this was in part owing to the transfusion instructions being verbal, in an emergency. In the other a lack of continuity of care between shifts contributed to but did not fully explain the error.

Case 3
Excessive transfusion follows misinterpretation of verbal instructions
A 48-year-old male patient was in resuscitation with a major gastrointestinal (GI) haemorrhage. Five units of blood arrived and a verbal order for 2 units was given by the doctor, who then wrote them up on a prescription chart. The senior nurse asked the doctor if he wanted the blood given through the rapid transfuser, and he confirmed that 'all the blood can go though it'. Five units were transfused instead of the intended 2 units.

Case 4

Excess red cells are administered to an infant despite correct dose calculation and prescription

A 3-month-old baby with a rhabdomyosarcoma received 171 mL of red cells over 7 hours. The child had been prescribed only 80 mL over 3 hours, and her Hb consequently rose from 7.4 to 15.3 g/dL. The error was caused partly by a failure to include the 71 mL given during the night shift to the volume given during the morning. However, the day staff still transfused yet another additional 20 mL for which no rationalisation could be made.

In a final case the component (cryoprecipitate) was administered in an inappropriate fashion, via a syringe, but fortunately there were no complications. The reporter commented that it was also likely that the cryo was given without any valid clinical indication as it was 'the only component which the patient would accept', all other components being refused.

Transfusion of expired red cells n = 12

There were 12 cases in which expired blood was given to patients. This raises issues regarding who is responsible for making sure that this does not happen. The various reports place the responsibility with different personnel in different hospitals. The final checking at the bedside should confirm that blood is within date for transfusion and therefore it is the ultimate responsibility of personnel trained in blood administration to be certain that blood is safe for transfusion. In some hospitals there appears to be an increased assignment of responsibility to the blood bank or hospital transfusion team to ensure that no expired blood is available in any issue fridges or satellite fridges. However it is very difficult in practice for hospital blood banks to clear expired blood from fridges as blood expiry time of the majority of red cell units is midnight. Many of these cases occur between midnight and 9 a.m. before the daily round of satellite fridges by the laboratory MLA or BMS to remove all expired units. It is reasonable that the hospital transfusion laboratory should be responsible for checking satellite fridges each working day morning, to remove unused and expired blood. However the onus is on the clinical staff administering the component to perform the final check at the bedside.

Case 5

Expired red cells transfused

Two units of blood were issued in response to a request for urgent crossmatch for an anaemic 87-year-old female patient. One of the units was due to expire that day at midnight. It was decided to defer transfusion until the following day. The expiry date was not checked either at collection or at the bedside and the patient received over 100 mL of expired blood before the error was noticed. The unit had not been removed from the issue fridge by the lab at 09.00.

Excessive time taken to complete administration of blood component n = 57

There were 57 cases in this category all of which relate to nursing and midwifery staff except for 3. Of these 3 cases there were 2 in which a junior doctor wrote up the blood to be given at the rate of each unit over 6 hours, and there was 1 case in which a consultant wrote up 4 units of blood over 8 hours each. In both these cases the prescription was clearly outside of guidance which states that red cell transfusion should be completed within 4 hours of leaving controlled temperature storage (CTS)[6].

Of the 57 cases, 1 case was of a transfusion taking place in the community, 2 were taking place in ICU, 1 in ED and 1 in an operating theatre. The vast majority therefore were taking place in inpatient wards.

Thirty-eight cases were routine transfusions and 8 were stated to be emergency transfusions. In 11 cases this information was not available. Thirty-eight of the 57 patients were women and 15 were men, whereas in 4 cases their gender was not stated. There were no children under 4 weeks, but there were 3 children under 1 year and 2 children under 16.

In the majority of cases there was no special reason why the blood component was given over a long period of time. Sixteen of the 57 cases were of red cell transfusions that took more than 6 hours to be completely transfused to the patient from the time that they left CTS. In 7 cases there were 2 units transfused to the same patient, which were each given over more than 6 hours.

There were 3 cases in which additional reasons were quoted as to why the blood took a long time to be administered. In 3 of these cases there were problems with the cannula not being fully patent, and the blood ran slowly. One of these was the only case involving platelets. In addition there was 1 case in which the blood inside both the giving set and the bag was found to be clotted. This bag was cultured and was found to be negative for micro-organisms.

However, in all these cases full adherence to protocols for blood component administration, including monitoring of the patient and performing observations, as well as checking the transfusion rate and any problems with the cannula, would have meant that all of these slow transfusions could have been avoided. It was noted in the National Comparative Audit[7] that the monitoring of the patient undergoing transfusion was poor in many hospitals.

It is interesting to note that of these 57 cases, 27 took place out of hours, which is clearly disproportionate compared with the number of transfusions overall which take place out of hours[8].

Table 13
Breakdown of times of transfusions that took excessive time to run

Time period	Number of cases
8 a.m. to 8 p.m.	27
8 p.m. to midnight	16
Midnight to 8 a.m.	11
Not recorded	3

Forty-two of these cases were reported as 'SHOT only' reports, which is appropriate. Fifteen were also reported to MHRA via SABRE, which is unnecessary as these are entirely clinical blood administration problems.

Cold chain errors n = 34

[20 of these 34 cases involve lab errors and are discussed again in the lab section on page 51]

There are 34 cases in this group, 10 of which were reported to SHOT only, of which 5 may have had relevance for MHRA as there was a laboratory responsibility involved. Of the 22 that were reported to MHRA only 8 possibly had laboratory relevance.

Table 14
Cold chain errors n = 34

Type of error	Number of cases
Alarm related	7
Delivery or transfer of components	7
Inappropriate storage of component	20
Returned to stock when should have been discarded	*8*
Returned to satellite fridge when should have been discarded	*5*
Storage in inappropriate fridge (e.g. drug fridge)	*3*
Storage of inappropriate material in blood fridge	*1*
Inappropriate storage of FFP and platelets	*3*
TOTAL	**34**

Problems related to alarms at CTS sites n = 7

There are 7 cases relating to alarms: 3 of these were alarm failures on a platelet agitator, 1 related to a satellite fridge with no alarm fitted, 1 related to a main Blood Bank stock refrigerator where the door was left open and there was no response to the alarm when it was activated, and 2 related to overheating of refrigerators in the rooms which were very small and therefore prone to elevations of temperature. Once again the alarms were not correctly set and the patients were transfused with units which had been out of temperature.

Case 6

No alarm on refrigerator at satellite site

Three units of red cells stored at a satellite site prior to transfusion were transfused over 2 days. Subsequently the temperature data were downloaded for the satellite fridge and showed that the storage temperature was above 6°C for 1 hour during the period that 2 of the units transfused were in situ. On investigation it was discovered that the satellite fridge did not have an alarm.

Case 7

Alarms activated by door being left open were ignored

FFP that had not been stored in appropriate conditions was administered to a patient. The FFP had been defrosted according to guidelines and placed into the out-of-hours blood bank fridge for possible use within 24 hours of thawing. During this period the temperature in the blood bank fridge rose to 9°C due to the door not being closed properly between 01.00 and 06.00. Temperature alarms were activated and switchboard contacted the BMS in blood bank to report the alarms. However, due to the recent move to a new laboratory building, the member of staff in blood bank was not aware that the alarms were from the blood bank refrigerator, and did not check the cause.

Problems with delivery and transfer of blood components n = 7

Seven cases related to delivery and transfer standard operating procedures (SOPs) for blood stocks arriving at hospitals. In 2 cases platelets were delivered by a Blood Service courier directly to a clinical area, without going being received in the blood transfusion laboratory for entry into stock. In 1 case red cells were left in an inappropriate area by a courier resulting in a prolonged period out of temperature control. There were another 4 cases in which red cells transported with a patient between two hospital sites were out of temperature for an excessive period in a transport box prior to transfusion to the patient.

Inappropriate storage of component n = 20

There were 8 cases in which blood was returned to stock having been out of temperature control for more than 30 minutes. It was then re-released from stock and transfused to either the same patient or another patient.

There were 5 cases where clinical staff returned units of red cells to a satellite refrigerator after it had been out of controlled temperature storage for more than 30 minutes. These units were then stored in a satellite refrigerator for variable lengths of time before being used for patients later the same day or in ensuing days.

Case 8

Blood out of CTS for prolonged periods, returned to issue fridge and later transfused

A unit of red cells was removed from the fridge and returned twice prior to transfusion. On the first occasion it was out of controlled temperature storage for 20 minutes, and on the second occasion for 50 minutes. On each occasion the unit was signed back into the issue fridge but not placed in the quarantine box, nor was the laboratory informed of its return as per the local policy. On the third occasion the blood was removed and transfused to the patient.

There were 3 cases in which blood units were stored in an inappropriate ward refrigerator intended for the storage of drugs rather than in the controlled temperature satellite blood refrigerator. This blood was later transfused. There was also 1 case in which microbiological samples (swabs, etc.) were stored alongside components in a satellite blood refrigerator. Blood from this refrigerator was then transfused to a patient.

One case concerned platelets which a porter returned to a refrigerator rather than the platelet agitator. He was then asked to collect them again for the same patient when they were finally required. He collected them from the stock refrigerator in Blood Bank and they were transfused to the patient.

There were 2 cases in which thawed FFP was stored at room temperature for several hours before being transfused.

SPECIAL REQUIREMENTS NOT MET – CMV and IRRADIATION n = 76

There were 76 cases in which the special requirements relating to CMV negative blood and irradiated blood were not met. Of these, 49 cases related to failure of the clinicians to inform the laboratory of the necessary requirement for irradiated or CMV negative components. Another 25 cases were where irradiated and CMV negative blood components were not issued appropriately for a patient as a result of laboratory errors and omissions. There were 2 additional single cases.

Special requirements not met – Clinical errors and omissions n = 49

Of the 49 cases in this group, in 43 the report stated this was a medical (doctor) error or omission and in 1 case it implied that the oncology nurse was responsible for issuing the correct order for blood component requirements. In 5 cases the responsibility was unclear. In 3 cases there was also a system in place for the pharmacy to inform the hospital blood bank about prescriptions for fludarabine and other purine analogues, and this system was also implicated as having failed to inform the blood bank in these 3 cases. Forty-six of the 49 cases relate to irradiated products and 3 relate to CMV negative products.

Case 1

Nurses, doctor and patient all omit to inform laboratory of special requirements

A request form for blood components for a patient with CLL on fludarabine was completed by a haematology nurse, and checked and signed by a junior doctor who also prescribed the components. The need for irradiated blood was not indicated on the request form or the prescription. The patient did not present their alert card at the time of sampling or prior to the transfusion. The medical staff are responsible for informing the transfusion lab when a patient is first prescribed fludarabine.

Of the 46 clinical omissions to request irradiated blood the indications for irradiation were as follows:

- 12 Hodgkin's disease
- 19 Prescription of fludarabine or other purine analogues
- 9 Stem cell transplant (or conditioning prior to stem cell transplant)
- 3 Neonate post-intrauterine transfusion (IUT)
- 1 Neonate with possible DiGeorge syndrome
- 1 Neonate for truncus arteriosus surgery
- 1 Unknown/unstated indication

Case 2

Lack of information regarding neonate following IUT

An on-call request for a 1 unit crossmatch on a 4-week-old male infant stated 'Rh incompatibility Anaemia Hb 5.5' as the indication for transfusion. The sample grouped as O D negative and the BMS on duty rang the requesting hospital, but no further history was available, though there was a record of the blood group as O D negative, with maternal antibodies. Red cells were crossmatched and issued. The following day the local blood centre called to inform the hospital transfusion laboratory that the child had received IUT for maternal anti-D and required irradiated components. The patient's blood group was later confirmed as O D positive by the International Blood Group Reference Laboratory (IBGRL). The blood grouped as O D negative due to the previous IUT. No clinical information had been passed on to laboratory at either site, and therefore special requirements were not met.

In 9 of these reports there was a clinical situation involving shared care with another hospital, and the need for special requirements was not communicated by the treating hospital to the supporting hospital. In 1 of these 9 cases the patient and their family spoke no English, making it very difficult to obtain a clear history of the condition and its treatment. A proforma discharge letter should be used in these situations, which would help to ensure that transfusion requirements are communicated.

Case 3

Discharge letter from tertiary referral centre omitted vital transfusion information

A 3-year-old boy was undergoing treatment for medulloblastoma on a shared care basis between the tertiary referral centre and a local paediatric department. Initial requests made for the patient by doctors at the local hospital did not specify the need for irradiated CMV negative cellular blood components. Later conflicting requests prompted a telephone call to the tertiary centre when the need for irradiated CMV negative components was confirmed. The discharge letter from the tertiary centre did not contain information concerning transfusion support and local medical staff did not seek advice.

Case 4

'Hodgkin's Disease' is insufficient information to ensure issue of irradiated components

Red cells were requested for a 75-year-old man stating 'sepsis, low Hb' on the initial request form and 'Hodgkin's Disease' on a subsequent one. A unit of non-irradiated cells was transfused initially. No request for irradiated components had been received and the diagnosis of Hodgkin's was not picked up by the BMS on duty. The laboratory manager noticed the omission by chance the following morning.

In most hospitals it is a well defined responsibility of the clinicians to communicate the special transfusion requirements of their patients to the transfusion laboratory. Some hospitals have also developed a system in which prescription of purine analogues results in an automatic communication from the pharmacy to the laboratory regarding the need for irradiated products. Hospital transfusion laboratory staff will be aware of many of the indications for special requirements, but cannot be expected to discern the need from handwritten requests that may use acronyms, be illegible or not be filled in at all.

Special requirements not met – laboratory errors and omissions n = 25

There were 25 cases in this group, of which 21 related to a special requirement for irradiation, 3 to CMV negative requirements and 1 to both.

These will be discussed in detail in the separate laboratory chapter on page 51.

Special requirements not met – blood service errors and omissions n = 1

There was 1 case in which the blood service was requested to send CMV negative blood for a patient but sent blood untested for CMV in error.

Case 5

Incorrect information from blood service

CMV negative platelets were ordered from the blood service for a 61-year-old female patient with acute myelocytic leukaemia (AML). When they arrived there was no label stating the CMV status, so the hospital laboratory telephoned the Blood Centre requesting verbal and written confirmation that the platelets were CMV negative. This was received by fax and the platelets were then issued and transfused. The matter was subsequently investigated by a hospital liaison manager who discovered that in fact the unit had not been CMV tested.

Special requirements not met – miscellaneous n = 1

There was 1 unclassifiable case in this section in which a number of factors relating to a consultant's decision and the IT system resulted in a patient receiving non-irradiated blood.

Case 6

Clinical decision regarding IT implementation impairs accessibility to key data

A 70-year-old female patient had been treated with autologous peripheral blood stem cells (PBSC) for breast cancer and had required irradiated products since 1997. The hospital changed IT systems in 2005, and all special requirement flags were transferred. Owing to the complexity of this process, the consultant haematologists made a decision to transfer to the new system only irradiation flags since 2000. When this patient returned for blood, there was no legacy data on the new IT system, so the lab did not issue irradiated blood. The requestor did not ask for irradiated components. The error was noticed by a nurse who knew the patient had had a PBSC and made the connection, but by then 1 unit had been transfused.

SPECIAL REQUIREMENTS NOT MET – OTHER n = 17

There are 17 cases in this group, of which 15 were laboratory related and 2 clinical related. The laboratory-related cases will be discussed in more detail in the laboratory section of this chapter.

Clinical cases n = 2

The 2 cases which related to clinical errors or omissions were as follows:

A stem cell transplant patient had moved from one hospital to another, and the new laboratory was not informed of the blood group status following the stem cell transplant.

Case 1

Patient's mother alerts clinicians to changed ABO group

A 6-year-old boy who was A D positive had an ABO mismatched stem cell transplant (SCT) from an O D positive donor. One month later he was transfused with A D positive red cells as no information had been communicated to the hospital transfusion laboratory. When group A D positive red cells were again issued the next month, the child's mother informed the nursing staff that he should have O D positive blood. There was no adverse reaction.

The second case relates to a patient with anti-U antibody.

Case 2

Unnecessary transfusion of incompatible blood

A maternity patient (para 13) was known to have anti-U and was anaemic prior to caesarean section. U negative units were ordered from the frozen blood bank, but in the interim the clinicians requested that incompatible units be made available in the labour ward fridge in case of emergency. These incompatible units were recalled when U negative units arrived and were issued, but were not returned. The patient was transfused following delivery by CS and an incompatible unit still in the labour ward blood fridge was used despite the compatibility form clearly stating that the blood was incompatible. She received < 100 mL of red cells and suffered rigors and flushing, and the transfusion was stopped.

Owing to a plethora of problems relating to understanding, communication and logistics, incompatible blood was given to the patient even after U negative blood was made available. The report did not state the pre-CS haemoglobin, nor the degree of blood loss, so it is not possible to make a comment about the appropriateness of this transfusion. It is possible that the presence of a rare antibody and the difficulty in obtaining red cells for this patient paradoxically resulted in an increased likelihood of a decision to transfuse.

Local review by staff involved and HTC members revealed the following causes of error:

- Failure of labour ward staff to return recalled units on request by transfusion laboratory
- Poor handover in BT department – staff were not aware that incompatible units had been issued, recalled and not yet returned
- Labour ward staff did not check fridge and return units routinely next day, as per their agreement
- Failure of ward staff to use compatibility slip in the checking process as per transfusion procedure

The last bullet point is of interest. The compatibility slip was the only document on which the fact that the blood was incompatible was clearly stated. Many hospitals have now removed the compatibility slip from the blood administration process as a measure to enforce effective patient ID checking. In this case the compatibility slip may have been the one possible barrier to the error.

Autologous transfusion n = 1

There was 1 case involving autologous transfusion – where a patient was over transfused with autologous blood. This is also discussed on page 110 together with other cases related to autologous transfusion.

COMMENTARY

The number of IBCT reports (excluding anti-D reports, dealt with elsewhere) has remained static this year. It remains of concern that there may have been a fall off in reporting since the implementation of the Blood Safety and Quality Regulations in 2005.

There has been no further fall in the number of ABO-incompatible red cell transfusions, although it is encouraging that there were no fatalities this year. Cases are still occurring in which a transfusion reaction is not recognised as such when a patient becomes unwell. Further reductions in morbidity and mortality arising from ABO incompatibility will correlate with levels of education and awareness in front line clinical staff. After 10 years of reporting there are still very basic collection, identification and monitoring errors. Although technical solutions may help to overcome this, and competency assessments clearly have an important role to play, these interventions must not be seen as an alternative to appropriate knowledge and educational levels for staff performing critical tasks. Twenty-three of 24 cases of administration of wrong blood to patients in the clinical setting were carried out by nursing and midwifery staff, reflecting the fact that usually blood component administration is performed by this group of staff. However, Case 6 of the ABO-incompatible transfusions was the result of error by two doctors in theatre (see page 31).

This year, as in previous years, there are a large number of incidents arising because junior doctors who may have received no specific training or education in blood transfusion are performing tasks they do not understand, neither on a physiological basis, nor in terms of the reasons for the required steps involved. Four or 5 of the 7 cases leading to mis-transfusion of a patient because of 'wrong blood in tube' related to phlebotomy error by junior doctors – a disproportionate number given that this is not a core task. Inappropriate and unnecessary transfusion involved junior doctors in 46 of the 49 reported cases, and involved errors at all stages of the patient evaluation, including result interpretation, decision making and the prescribing process.

There has been a decrease in some of the handling and storage errors this year, which may be the result of increasing awareness because of the focus of BSQR on this area. While many more cases are being reported of red cells taking more than 4 hours to be transfused from the point of leaving CTS, there has been a decrease in reports of components out of temperature control and expired units transfused.

The number of reports of patients not receiving blood with the appropriate special requirements has remained static. Irradiation continues to be the most commonly missed special requirement, the majority of cases relating to haematology and oncology patients (40/46 clinical omissions of special requirements). The failure to request irradiated components in patients receiving purine analogues is the most common single category (19/46 clinical cases). New BCSH guidelines are currently in preparation.

RECOMMENDATIONS

New recommendations from this year

- Participation in SHOT and MHRA reporting should be scrutinised carefully, as there is evidence from both databases that reporting is patchy, with some Trusts that are high component users still not reporting. Reporting rates in the UK are still relatively low compared with some comparable countries, and the different reporting patterns may be rewarding to study.

  Action: SHOT, MHRA, DH

- Education of doctors and nurses involved in transfusion must continue beyond basic training and competency to a level where the reasoning and rationale behind protocols and practices is understood. Transfusion medicine needs to be a mandatory part of the curriculum to achieve CCST in all hospital specialties, and should be incorporated into the nursing and midwifery curriculum.

  Action: NBTC, Royal Colleges, Specialist Training Committees, GMC

- Only staff who are qualified to make a decision to transfuse, to prescribe, and to administer and monitor transfusions should be performing these tasks.

  Action: Hospital Trust CEOs, HTCs and HTTs, NPSA, NBTC, Royal Colleges, Specialist Training Committees

- Staff involved in blood component issue and administration must be aware of their professional accountability and responsibility, and should not carry out tasks unless they consider themselves competent to do so. Effective and comprehensive handover between different staff shifts or teams is part of this professional responsibility.

  Action: GMC, Medical Professional's insurance schemes, e.g. the Medical Defence Union (MDU) and Medical Protection Scheme (MPS), Nursing and Midwifery Council (NMC), IBMS

- The importance of irradiation, and the rationale behind it should be emphasised during teaching of junior haematology and oncology doctors. This education is part of the curriculum for specialist trainees, but the junior pre-specialist doctors in these areas may remain ignorant despite being frequently called upon to order components.

  Action: Hospital Trust CEOs, Medical Schools, Deanery

- Systems are in place in some Trusts for pharmacy to inform the hospital transfusion laboratory of prescriptions for purine analogues. Such systems work well and best practice can be shared. Assessment and feasibility studies of such arrangements should be carried out in hospitals with high usage of these agents.

  Action: Hospital Trusts, Hospital liaison networks, Better Blood Transfusion (BBT) network, SHOT Transfusion Practitioner network, BCSH

5.1 IBCT Events Originating in the Hospital Transfusion Laboratory

There are a total of 121 cases in which the primary error arose in the laboratory. Of these, 96 events are a subset of the 332 IBCT events reported in 2007. They have all been referred to at the beginning of that chapter and in the relevant sections, but they are discussed in more detail here.

Laboratory errors from the anti-D chapter are also included in this table, to allow a complete picture of laboratory errors, as is one case from the HTR chapter where sample age was probably a contributory factor in the delayed haemolytic transfusion reaction (DHTR). However, these cases are not discussed in this section, but in their own chapters.

Table 15
Summary of laboratory-related errors n = 121

Type of error	Number of cases from this chapter	Number of cases from anti-D chapter	Number of cases from HTR chapter
Wrong Blood	**15**		
Wrong sample selected	3		
ABO grouping error	4		
D grouping error	3	10	
Incorrect component selected	3		
Incorrect labelling	1		
WBIT which should have been detected	1		
Wrong group selected for SCT patient	**5**		
Wrong ABO group	4		
Wrong D group	1		
Other pre-transfusion testing errors	**20**		
Testing errors	5		1, Case D6, sample age was a factor
Procedural errors	15	11	
Special requirements not met	**36**		
Irradiated component	21		
CMV negative component	3		
CMV negative and irradiated	1		
Phenotyped component	6		
MB treated FFP	3		
IgA deficient cells	1		
Correct component (cryo issued instead of FFP)	1		
Incorrect dose of anti-D issued		2	
Handling and storage errors	**20**		
Alarm related	7		
Non-clearance of fridge	4		
Issued blood known to be out of CTS	4		
Expired components used	3	1	
Other	2		
TOTAL	**96**	**24**	**1**

Wrong Blood Incidents n = 15

This year 'wrong blood' incidents resulted from laboratory errors in 15 cases. One case involved a baby <1 year old, the remaining cases were in patients over 16 years of age. None of the errors caused adverse reactions. Twelve of the cases occurred 'out of hours', 5 classed by the reporter as being during a 'shift' system and 7 during 'on call' systems. Three of the errors were made by staff who normally work in blood transfusion while 7 errors were made by staff who did not work regularly in transfusion; 1 error was made by a locum staff member and in 1 case the staff details were not stated.

The 15 errors were:

- 3 cases where the wrong sample was selected for test. These errors resulted in group A FFP being transfused to a group B recipient; group A D positive red cells to a group A D negative female recipient (see Case 1); and group O red cells to a group A recipient.
- 4 errors in ABO grouping. One case resulted in group B D negative red cells being transfused to a group A D negative recipient, fortunately with no adverse reaction. In the second case a group A patient was typed as AB but was transfused group A red cells because AB red cells were not routinely held at the hospital. In the third case group A red cells were provided for a group AB patient (see Case 2). No details were provided in the fourth case.
- 3 errors in D typing. These resulted in transfusion of D positive red cells, in 1 case, and D positive platelets in another, both to D negative males. In the third case D negative red cells were given to a D positive recipient.
- 3 cases of incorrect component selection. In 1 case D positive red cells were selected for a D negative elderly female, in another group O red cells were selected for a group A recipient and in the third case group O FFP was selected for a group A recipient. This third case was human error and occurred during computer downtime so that the usual warning flags were not available.
- 1 case of incorrect labelling where the wrong platelet unit was selected and labelled for a patient. Fortunately the platelets were of the right specification for the patient to whom it was transfused.
- 1 case where the primary error was in sampling i.e. WBIT, but the laboratory failed to find the error and prevent a mis-transfusion, see Case 3.

All of the ABO grouping errors were made while providing blood urgently. Three of the 4 cases involved manual methods: 1 error was regarded as incorrect interpretation of the group and 2 as transcription errors. In the fourth case an automated group was performed but required manual interpretation – a mixed field reaction was incorrectly interpreted by the BMS.

All of the D typing errors were made using manual methods. In one case the patient was typed as D negative but was actually a weak D. The incubation time for the test was shortened and the test was not repeated with further anti-D reagents as per the SOP. The second was a recording error and the third error was a missed a mixed field (MF) reaction using microplate technology.

Case 1

SOPs are in place for good reasons

A laboratory mix up of two samples resulted in a 33-year-old group A D negative female patient receiving some group A D positive blood. When the error was discovered in the laboratory the ward was contacted and the transfusion was stopped after approximately 20 mL of blood. Anti-D was given. Investigations revealed that pressure owing to staff shortages was the main contributory factor for the breach in laboratory policy, which states that samples are to be opened, checked and labelled one at a time.

Case 2

The power of suggestion

A patient was admitted to hospital B, having been transfused at hospital A, and a verbal message was given to blood bank that the patient was group A D positive. The BMS on call obtained mixed field reactions and manipulated the blood group results to reflect a group A D positive blood group. The patient was transfused group A D positive blood and plasma as a result. The patient was grouped wrongly by blood bank a further 11 times as a result of misleading information on the computer. Finally a senior BMS grouped the patient and recognized that this patient was actually group AB D positive.

Case 3

Question a changed blood group

A patient had been grouped as O D negative by the laboratory on two previous occasions. On the third occasion the sample grouped as O D positive. The BMS repeated the group on that sample, which was correct, and changed the group of the patient on the computer. The BMS had not realised that the sample was from a different patient.

COMMENTARY

The number of laboratory errors contributing to 'wrong blood' events has decreased this year from 25 to 15 and the reduction in ABO typing errors reported last year has continued, see Table 16. The number of D typing errors also remains low. This continued reduction in the types of error with potentially the most serious outcome is encouraging, although it is interesting that this reduction has occurred at the same time as the commencement of MHRA inspections. This trend may represent a genuine improvement in practice as a consequence of more stringent regulation, or could potentially be the result of under-reporting since the BSQR came into effect.

Table 16

Laboratory errors resulting in wrong blood events 2003–2007

Year	Total no of cases	Wrong sample tested	Interpretation / transcription errors	Other	ABO-incompatible transfusions	Sequelae
2003	17	8	9		7	2 major morbidity
2004	18	5	12	1	6	1 death 1 major morbidity
2005	22	9	12	1	9	1 AHTR
2006	6	2	3	1		No morbidity
2007	7	3	4			No morbidity

This year there have been two errors involving mixed field reactions. This mirrors errors seen in National External Quality Assurance Scheme (NEQAS) BTLP exercises over the years. In NEQAS the overall detection rate of a 50:50 MF reaction has improved in successive exercises, from 13% in exercise 99R2 and 20% in 02R2 to the current rate of 41% in 06R9. NEQAS evidence shows that laboratories using CAT and automation are significantly more likely to detect an MF reaction ($p = <0.001$ for each factor independently). However, once a mixed field reaction is detected it must then be correctly interpreted, after obtaining a thorough clinical and transfusion history. NEQAS exercise 06R9 provides a concise method for investigation of an ABO MF reaction. Clearly training and competence assessment of ABO/D typing must include this phenomenon.

Previous SHOT reports have detailed that manual techniques carry greater risk of error. This year all the ABO and D typing errors have involved manual techniques or manual interventions in automated methods.

This year all the ABO errors were made while providing blood for urgent cases and the majority, 12 out of 15 cases, of 'wrong blood' incidents have occurred out of routine hours.

Learning Points

- Manual processes are more prone to error. During process validation ensure that manual procedures and interventions are kept to a minimum and that appropriate checks are in place at weak, manual points of a process.
- Competency assessment in ABO/D typing should include detection and interpretation of mixed field reactions.

The following learning point from a previous report remains pertinent:

- Training and competency assessment in the laboratory must cover basic manual checking procedures to ensure that these are second nature at a time when automation and computerisation will have lessened experience and practice in these basic skills.

Wrong ABO or D type blood issued for SCT recipients n = 5

There were 5 cases this year where blood of the wrong ABO or D type was given to recipients of mismatched bone marrow/cord/stem cell transplants. Three of the 5 cases involved children under 1 year of age, 1 a child under 16, and 1 an adult. Four of the errors occurred during routine hours and 1 out of hours on a shift system.
In 4 cases group A red cells were transfused when O was the group of choice, and in 1 case D positive components were transfused when D negative should have been provided.

There were a number of causes: 1 case involved communication breakdown between the laboratory and the clinicians and it was difficult to ascertain the root of the problem; 4 cases were clearly laboratory errors including the following:

- bone marrow transplant (BMT) protocol not followed
- computer alert bypassed
- computer flags misunderstood and overridden
- incomplete data entered on computer

Other pre-transfusion testing errors n = 20

Three of the 20 cases involved children under 1 year of age, and the remaining cases were in adults over 16 years of age. Twelve of the cases occurred out of hours, 6 classed by the reporter as being during a 'shift' system and 6 during 'on-call' systems. Six of the errors were made by staff who normally work in blood transfusion while 6 errors were made by staff who did not work regularly in transfusion.

The 20 errors can be arbitrarily split into:

- Testing errors, i.e. the correct tests were performed but incorrect results obtained, either by poor performance of the test, transcription error or incorrect interpretation
- procedural errors, i.e. incorrect test selection

Testing errors n = 5

There were 5 examples of testing errors, 2 of which led to transfusion reactions.
One example of missed incompatibility in a crossmatch led to a haemolytic transfusion reaction (Case 4): imputability 3.

Case 4
Haemolysis owing to missed antibody reaction
A patient had a known anti-K and anti-Co^{b}. The laboratory issued K negative, crossmatch compatible blood as per NHSBT advice (Co(b-) units are not routinely supplied). At the end of transfusion of the first unit (after 1 hour 25 min) patient had rigor, tachycardia and haemoglobinuria (although there was some haemoglobinuria prior to transfusion). The unit was returned to the transfusion laboratory, with fresh samples. The unit was incompatible with both pre- and post-transfusion samples, presumably due to anti-Co^{b} as units confirmed O D positive, K negative, direct antiglobulin test (DAT) negative. The laboratory can only assume that plasma had not been added to the original crossmatch tests as the antibody reaction was strong. The patient was sent home to return the following day for reassessment.

A transcription error took place in a 3 unit manual, indirect antiglobulin test (IAT) crossmatch, after identifying an anti-Kpa, where 1 unit was incompatible and 2 units were compatible. This resulted in transfusion of the incompatible unit. A transfusion reaction was reported by medical staff, which led to discovery of the error (Case 5): imputability 3.

Case 5

Erroneous selection of incompatible unit by BMS

A sample was tested and the antibody screen was positive: the antibody was correctly identified as anti-Kpa. The BMS issued red cell components, which were transfused. The doctor then telephoned 2 days later to inform blood bank that the patient had had a transfusion reaction. Repeat samples were requested. On re-crossmatching the units using pre and post samples, 1 of the red cells issued was found to be incompatible – the BMS had selected the incorrect unit.

There were 2 missed weak reactions in manual antibody screens (an anti-K and anti-E), one of these errors was not repeatable, the other was due to plasma being added before the cells when performing a manual Diamed IAT column technique.

There was 1 interpretation error when an anti-Jka was missed in the presence of anti-K + anti-C

Procedural errors n = 15

There were 15 examples of procedural errors:

- Three cases where tests were performed on samples that were not properly labelled according to local protocol: 2 undated samples and 1 having an addressograph label
- Three cases where the sample used for compatibility testing was too old (there is an additional case here, D6 from HTR, see Table 25)
- Three cases involving babies: failure to test maternal sample before issuing blood to a baby, failure to link mum and baby when maternal antibodies were present, failure to obtain a fresh sample for pre-transfusion testing when the baby was over 4 months old
- Two cases where a positive antibody screen result was missed and the crossmatch performed without antibody identification/selection of antigen negative units or IAT crossmatch. The patients had anti-K and anti-K+C, respectively
- One case where the blood was issued before the group and screen was complete (Case 6)
- Two cases where staff failed to exclude other clinically significant antibodies in the presence of a known antibody. In 1 case a weak anti-Jka was missed and the units issued, although serologically compatible by IAT, were not Jka typed; fortunately there was no adverse reaction. In the second case serologically compatible red cells were also issued and when further tests were carried out there were no further antibodies detected
- One example of electronic issue of red cells when there was no current sample in the laboratory

Case 6

Blood issued before group and screen complete

The BMS did not complete pre-transfusion testing of a patient with known atypical antibodies and issued blood. The antibody panel was not done although blood had been transfused since the last identification. The BMS left a note for day staff to ask if a panel should have been performed. It was reported that the BMS was put under pressure by medical staff as the patient required blood urgently. The right blood was transfused as no further antibodies were found on investigation.

COMMENTARY

Errors in pre-transfusion testing continue to occur although the number of errors are down from last year (28 in 2006). Non-observance of protocols still occurs but it is unclear from many reports whether this is due to lack of knowledge, poor training or 'slips' that have occurred. Clearly, both from these pre-transfusion testing errors and those errors occurring in the 'wrong blood' section, there is a particular problem with error rates 'out-of-hours'. Again, whether this is due to problems with training staff who work 'out-of-hours' or because staff working 'out-of-hours' are more tired or under more stress is unclear. The NTLC has started work to try to gain better understanding of why errors are occurring and why a greater percentage are occurring 'out-of-hours' nationally. Local review of errors is also vital to understand local factors contributing to error and to identify useful corrective measures. Laboratory information systems must provide as much guidance as possible, in the form of prompts and warnings, for example on sample age and outstanding work. Systems must provide easy solutions to problems such as linking mothers and babies.

Learning Points

- Laboratories must ensure that robust systems are in place for highlighting 'outstanding' work on a patient, for example positive antibody screen awaiting identification, group and screen not complete.
- Competency-based training for laboratory staff must include staff who work out of hours, both those staff who do not work routinely in transfusion and those who do, and must apply to locum members of staff.
- A laboratory quality system, as required by the Blood Safety and Quality Regulations, must include internal incident reporting mechanisms and appropriate, documented, corrective actions.

Failure to provide components of appropriate specification or that did not meet special requirements n = 36

Laboratory errors accounted for 36 cases in this category: by far the most common error was failure to provide irradiated components (21 cases) when required. The other cases were failure to provide: CMV negative (3), CMV negative and irradiated (1), phenotyped components (6), MB treated FFP (3), washed or immunoglobulin IgA deficient red cells (1), and in 1 case cryoprecipitate was provided when FFP had been requested.

Six of the 36 cases involved children under 1 year of age, a further 5 cases involved children under 16 years of age and the remaining 25 cases were in adults. Interestingly, in this category of error, more errors were made during routine hours: 23 cases occurred during routine hours and 8 cases out of hours, 5 classed by the reporter as being during a 'shift' system and 3 during 'on-call' systems. In 5 cases the time of the error was not given.

COMMENTARY

Issuing blood that does not meet the special requirements of the patient continues to be a major source of error and this type of error is not decreasing. A number of these errors occur due to patients having multiple numbers during hospital visits so that their complete history is not available.

Laboratory computer systems must provide bold warning flags. However, warning flags must be set correctly in the first instance and this is a source of error. The procedures for adding flags to a patient's laboratory record must be robust. Warning flags must always be set against the patient not a sample.

Learning Points

[These learning points are also applicable to the errors occurring in blood issue for SCT patients]

- Transfusion laboratories must have thorough search strategies when looking for patient histories in order to find and reconcile multiple entries for a patient – see the section on laboratory errors related to IT.
- A laboratory quality system must include process validation. The process of recording special transfusion requirements within the transfusion laboratory should be validated and must be kept as simple as possible.
- Competency assessment of staff working in the transfusion department must include competencies in the provision of blood for specific groups of patients and in understanding the importance and use of 'special requirement' flags.

Handling and storage errors n = 20

Some of the errors in this category were due to problems with satellite blood fridges and in many of these cases it was difficult to ascertain responsibility for the error. The 20 errors attributed to the laboratory in this category were as follows:

Blood fridge not cleared	4
Alarm failure of blood fridge or platelet incubator	4
Failure to react to a blood fridge alarm	1
Blood fridge/platelet incubator failure – no alarm	2
Component known to be 'out of temperature control' but transfused	4
Cold chain incomplete	1
Incorrect thawing of cryoprecipitate	1
Blood components used past their expiry	3

Case 7

The laboratory must be involved in validation of equipment following a move

A blood fridge was relocated into a small room where the size of the room contributed to a rise in temperature of the surroundings. The fridge could not cope with the ambient rise and the temperature increased to over 6°C. The incident was noticed only when the chart recorder was returned to the blood transfusion laboratory. In addition, when the fridge was relocated the temperature alarm was incorrectly fitted and not tested at the time of fitting. A patient was transfused with blood that had been stored at too high a temperature. No adverse symptoms were reported by the patient or nurse following the transfusion. Staff were retrained on temperature monitoring, the alarm was refitted and tested and the room has been ventilated, which has reduced the ambient temperature to acceptable levels.

COMMENTARY

Errors continue to occur in the storage and handling of blood. As laboratories continue to improve their quality management systems (QMS) in line with the Blood Safety and Quality Regulations (2005) the number of these errors should fall. The management of satellite fridges should be tightly controlled by a written SOP/SLA/technical agreement. This must very clearly specify responsibilities and must be comprehensive. It must contain a thorough protocol for managing a blood bank fridge move to include change control. Staff must be trained and competent in these tasks before being permitted to carry them out. Documentation, risk assessment of the move and validation and temperature mapping of the fridge post move must be included.

A QMS should include regular alarm testing to cover appropriate responses to the alarm as well as testing that the alarm is functioning correctly. The system should also cover safe partitioning of blood. Having well labelled, defined areas of storage for quarantined blood, for example, should help to prevent reissue of inappropriately stored blood.

Learning Points

- Ensure implementation and monitoring of a comprehensive quality system covering blood component handling and storage to meet the requirements of the Blood Safety and Quality Regulations.

SHOT has, for many years, been advocating improved IT to help prevent transfusion errors. This year, there have been 2 cases reported where a BMS has overridden electronic blood tracking systems to allow the transfusion of expired components. This is a training and knowledge issue. All staff should have signed and competency assessed training in these systems, and they must also fully understand the rationale for the system and have sufficient knowledge to support their safe use of the system.

Case 8

FFP issued despite warning from electronic tracking system

FFP was issued on request, but was not used within 24 hours of thawing. It was taken out of the issue fridge 9 hours later despite warnings from the electronic blood tracking system which were overridden by a BMS. The unit was transfused to the patient. No adverse effects were noticed.

Case 9

BMS overrides warning from electronic tracking system

Cryoprecipitate was issued on request, but was not used within 4 hours of thawing. It was taken out of the issue fridge the next day despite warnings from the electronic blood tracking system which were overridden by a BMS. The unit was then given to the patient. No adverse effects were noticed.

RECOMMENDATIONS

New recommendations from this year

- Laboratories must develop a robust quality system in line with the Blood Safety and Quality Regulations. This should include:
  - task-based training and competency assessment for all staff in the transfusion laboratory
  - a robust quality incident reporting system which encompasses root cause analysis and CAPA
  - documented change control
  - defined communication systems for staff at handover periods and following implementation of change.

Action: Trust CEOs, HTCs, HTTs

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2006	The National Transfusion Laboratory Collaborative aims to improve standards, staffing levels, knowledge, competency and skills in hospital laboratories, and should be supported	**National Transfusion Laboratory Collaborative, stakeholder professional bodies, Trust CEOs**	Recommendations are under consultation by stakeholders
2005	Better laboratory practice – improved staffing levels, appropriate skill mix, competency assessment, safe on-call structures	**Trust CEOs**	National Transfusion Laboratory Collaborative started – see above
2005	Avoid Blood Transfusion outside core hours	**Trust CEOs, consultant haematologists with responsibility for transfusion together with HTCs and HTTs**	National Comparative Audit was done; national figures now available and, where recommendations followed, participants able to benchmark locally against national performance
2004	The EU Directive requires that hospital transfusion laboratories implement a Quality System; this presents an opportunity to drive improvements in practice and must be fully supported, resourced and monitored	**Trust CEOs**	Considerable progress has been made in this area, and a toolkit and examples of advice and good practice is available at www.transfusionguidelines.org

2004	Further national initiatives are needed to drive forward blood safety issues in hospital transfusion laboratories	**NBTCs, with relevant professional bodies**	Identified as a key recommendation in 2005; launch of National Transfusion Laboratory Collaborative in 2007 aimed at improving laboratory practice
2003	Hospital transfusion laboratory staffing must be sufficient for safe transfusion practice	**Trust CEOs**	
2000–2001	Establish protocols for timely removal of blood from blood banks to prevent transfusion of expired units	**Trust CEOs**	Considerable progress has been made with these recommendations, as Trusts seek to comply with the requirements of the BSQR and NHS Litigation Authority risk management standards
2000–2001	Labs must be vigilant in reviewing procedures and systems against current guidelines. Ongoing staff training is essential		
1999–2000	Labs must vigilant in reviewing procedures and systems and training to prevent sample handling and technical errors		
1998–1999	Hospitals must develop unambiguous protocols for the management of satellite refrigerators and their stock		
1998–1999	Labs must be vigilant in reviewing procedures and systems and training to prevent sample handling and technical errors		

5.2 IBCT Errors Relating to IT Systems

Problems with IT systems (or their incorrect use) continue to cause IBCT incidents. In 2007 there were 25 reported incidents (compared with 27 in 2006) that led to the transfusion of an incorrect component.

Table 17
IBCT errors relating to IT systems

Error	Reports	Non-irradiated component transfused	Antigen positive unit transfused	Non-CMV neg unit transfused	Wrong group after SCT	Electronic issue error	Other
Failure to consult historical record	6	6	0	0	0	0	0
Historical record not identified[1]	3	2	1	0	0	0	0
Ignored warning flag	3	0	0	0	1	1	1 (outdated FFP issued)
Failure to update warning flags	3	0	1	0	1		1 (failed to issue IgA deficient unit)
Computer system 'down'	3	1	0	1	0	0	1 (inappropriate FFP group)
Data not transferred from old system	3	1	2	0		0	0
Electronic blood tracking system errors/misuse	2	0	0	0	0	0	1 (wrong blood taken from fridge in emergency[2]) 1 (outdated component issued[3])
No links between transfusion labs in same hospital group	1	1	0	0	0	0	0
Pharmacy computer error[4]	1	1	0	0	0	0	0

[1] In two cases there were multiple hospital numbers and the wrong laboratory records were accessed. In the third case an Emergency ID number did not link to the laboratory information management system (LIMS) records on the same patient.

[2] During an episode of obstetric haemorrhage, a midwife accessed the blood fridge by pressing the 'Emergency Button' and took out two units of O D positive red cells rather than the emergency O D negative stock.

[3] An outdated component was issued because of failure to update the tracking system's Management System.

[4] The automated alert to the blood transfusion laboratory when purine analogues were prescribed was inadvertently deleted during an upgrade of the pharmacy computer system.

COMMENTARY

A significant proportion of IBCT events originating in the hospital transfusion laboratory could be prevented by appropriate use of existing IT technology and development of systems to overcome common errors (see below).

The majority of IT-related errors (15/24) stemmed from failure of laboratory staff to consult, locate or heed historical records that indicated the need for special blood components or to ensure 'computer flags' were updated.

In 8 of the 11 cases where details of the laboratory staff involved were available, a BMS who worked regularly in the transfusion laboratory was responsible for the error. Six of the 8 cases occurred in normal 'core' hours and 2 during a night or evening shift. Several of these cases involved multiple systems errors, especially omission by clinical staff to indicate special requirements such as irradiated components.

Locum BMSs were involved in 2 of the 3 cases where warning flags on the laboratory information system were ignored or overridden. In the third case, a BMS on shift who did not work regularly in the transfusion laboratory selected the wrong ABO group for red cell support after a bone marrow transplant.

Patients continue to acquire multiple hospital ID numbers and case records. 'Emergency ID numbers' allocated to acute admissions increase the risk of failure to identify historical records.

In one case, two transfusion laboratories in the same hospital group had separate laboratory information systems with no shared database. A patient was known by one of the laboratories to require irradiated components after purine analogue therapy but was admitted to the other hospital.

IBCT errors continue to occur because historical data on special requirements are not transferred when new laboratory information systems are installed.

RECOMMENDATIONS

Based on current incidents and previous SHOT Reports:

- Frequent reconciliation of multiple computer records on the same patient is important for safe practice (a clear historical trail of all amendments to the records must be maintained to comply with BSQR). This should be a routine laboratory process that can be performed by appropriately trained and competency-assessed staff.
- The problem of multiple hospital numbers and case records could be reduced by routine use of the unique NHS Number as a primary patient identifier in line with the recommendation from the NPSA SPN 24[9]. However, this change must be carefully managed because not all current LIMS can use the NHS number as a primary identifier and there is the potential to lose access to historical records with unintended adverse consequences.
- When laboratory IT systems are 'off-line', non-essential transfusions should be avoided. Robust manual back-up procedures and recovery plans must be in place and tested.
- Laboratory IT systems should be designed to ensure that 'warning flags' are prominently displayed, preferably on the opening screen. Where appropriate (e.g. criteria for electronic selection) it should not be possible to override or bypass flags.
- Staff must be trained in appropriate search strategies to ensure that all relevant records are accessed. Work is required to develop *appropriate* and effective search strategies, perhaps co-ordinated by the BCSH Transfusion Task Force.
- Transfusion laboratories should have direct access to the hospital Patient Administration System (PAS) and the ability to review haematology results online (ideally on the same screen).
- When new laboratory IT systems are installed, patient data from the old system should be transferred to the new system. Wherever possible this should be done electronically to avoid transcription errors (see SHOT Annual Report 2005).
- Most failures to consult the historical record or the use of inappropriate search strategies were made during normal working hours by BMSs who work regularly in the transfusion laboratory. This problem is clearly not confined to 'on call' or rotating staff. Laboratories must ensure that all staff (including locums) using the IT systems have appropriate training, updates and documented competency assessment.
- The increasing use of routine computer alerts from pharmacies to transfusion laboratories has great potential to ensure that appropriate patients receive irradiated components. However, these systems must be robust, comprehensive and timely.
- As noted in previous SHOT Annual Reports, the development of IT links between transfusion laboratories, or access to an electronic patient record (EPR) containing accurate and up-to-date transfusion data, would significantly reduce the number of IBCT due to failure to meet special requirements. This would also impact on delayed haemolytic transfusion reactions caused by blood group alloantibodies that have fallen to undetectable levels. The UK Connecting for Health project has the potential to meet these needs but the question of how and when transfusion data are entered on the EPR must be resolved.
- All laboratories using electronic selection to issue red cells must ensure that their operating procedures are consistent with national guidelines and followed by laboratory staff[10]. The computer algorithms in use must prevent issue outside the guidelines.

- IT systems to support transfusion safety, monitoring and traceability outside the laboratory (e.g. blood-tracking systems and bedside ID systems) should integrate with laboratory systems and processes. Laboratory staff should understand the working of these systems and be able to provide support and advice to clinical areas on a 24/7 basis. All clinical staff using these systems must be trained and competency-assessed. This is crucially important in clinical areas, such as operating theatres and delivery suites, where rapid access to emergency blood stocks is essential.

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
1998	IT as an aid to transfusion safety should be assessed and developed at national level	**NBTC IT WG, NPSA/NBTC/SHOT initiative, CfH**	Co-ordination now achieved between NBTC, NPSA, CfH; national standard specification under development; implementation is dependent on central funding through CfH or by individual Trusts

Development of laboratory IT systems to reduce SHOT incidents

The failure of laboratory staff to notice or heed 'computer flags' for special transfusion requirements, such as irradiated components or the use of methylene blue fresh frozen plasma (MB-FFP) for patients under 16 years of age, could be reduced by development or reconfiguration of LIMS. This requires close collaboration between users and manufacturers to increase the contribution of LIMS to transfusion safety. Examples of such developments include the following:

- As well as exhibiting warning flags on the opening screen, LIMS could use data on component irradiation that is embedded in the barcode attached at the processing blood centre. An additional warning flag could be generated, at the point where blood is reserved for the patient, if an attempt is made to issue a non-irradiated component. Clearly, this must be an alert, rather than preventing appropriate issue of non-irradiated components in an emergency.

- Linkage between the component barcode and the patient's date of birth could produce an additional alert to ensure methylene-blue treated, non-UK derived fresh frozen plasma (MB-FFP) is reserved for patients under 16 years of age in line with Department of Health guidance.

- There were 23 episodes of 'right blood to right patient' (page 63) that were due to the transposition of issue labels, between units selected for the same patient. The introduction of systems capable of automatically printing the donation number in a barcode on the laboratory-generated issue label, combined with a further step where the donation number and product code on the pack and laboratory issue label are electronically reconciled at reservation, would prevent these errors.

5.3 Right Blood to Right Patient

As in previous years reporters have been given the opportunity to separately submit incidents where the right blood was transfused to the right patient despite one or more errors that should have led to the unit being rejected. These incidents do not fit the definition for IBCT but are, nevertheless, instructive. They are not included in the overall numbers of IBCT cases. Two cases were identified as Near Misses and removed from the 'Right blood to right patient' (RBRP) section; both cases involved transposition of component labels that were identified by staff in the clinical area during the checking procedure.

Table 18
Right blood to right patient episodes n = 65

Elements that were wrong on blood packs, documentation, identity bands, etc.	Number of incidents
Name alone or with other elements	15
DOB alone or with other elements	12
Transposed labels on 2 units	23
Hospital or NHS number	10
Blood establishment labelling error	1
Miscellaneous	
Incorrect address used	2
'Issue' documentation missing during final bedside checking procedure	1
Group O fresh frozen plasma supplied to group A patient	1

If the correct checking procedures had taken place all these errors could have been prevented. Table 19 shows where the error(s) should have been detected but were not or were ignored.

Table 19
Checking procedure(s) that failed to detect the error(s)

Checking Procedure	Number of incidents
Laboratory + bedside check	30
Sampling + bedside check	15
Sampling + laboratory + bedside check	11
Collection + bedside check	2
Patient registration + bedside check	2
Laboratory + collection + bedside check	3
Laboratory	1
Blood establishment + laboratory + bedside check	1

The number of transposed label errors reported in the RBRP category has increased from 9 in 2006 to 23 in 2007, a 144% increase. The majority of these episodes appeared to be non-emergency transfusions; in 1 case (and 1 Near Miss case) the cause of the error began with a printer problem requiring the reprinting of the issue labels.

The majority of reports suggested the main actions taken following investigation were reiterating policy and procedure, +/- retraining of staff, usually in the clinical area, despite the primary error occurring in the laboratory. Overall, fewer than 10/23 reporters stated that any process or procedural recommendations had been implemented, i.e. corrective actions were not being carried out. In the areas where recommendations had been implemented, these included changes to the local policy – for example, including the pack label number in the collection check, and changes to local SOPs such as initialling the pack label prior to issue.

In the patient detail error reports, only a few reporters described the implementation of recommendations that included redesigning the request form to prevent date of birth errors and ensuring all agency staff completed their transfusion training before being deemed competent to administer transfusions. One reporter indicated that an audit of bedside practice was underway.

Two cases where corrective actions have taken place showing good practice

Case 1

Transposition of red cell labels

Two units were requested and issued for 1 patient. Following crossmatch, the 2 compatibility labels were printed and were placed on the 2 units, but they were transposed so the wrong labels were attached to each unit. One unit of red cells was transfused; the error was not picked up during the final patient / component check at the bedside. The error was detected when the second unit was collected. A change was made to the local laboratory SOP to ensure the numbers on the unit and the label are double-checked before affixing the label to the bag. Prior to issue the label is initialled to indicate that the unit / label numbers match.

Case 2

Units transfused in spite of incorrect date of birth on labels

Two units of red cells were transfused to a patient, despite the date of birth on the bag being incorrect. The error was not picked up until the pre-transfusion check was carried out for the third unit using the correct patient identification procedures. The primary error occurred during the admission process. On review, this error highlighted the need to the check the patient identification details on the addressograph labels prior to any use. The local policy has been amended.

Learning Point

- It is important when reviewing any incident that investigators examine the events leading to the error to determine if improvements to the process, procedure or system can be made.

6. Adverse Events Relating to Anti-D Immunoglobulin

Definition

An adverse event relating to anti-D administration may be defined as any reaction due to anti-D when administered, or any serious adverse event relating to the prescription or administration of anti-D which has the potential to cause harm to the mother or foetus immediately or in the future.

DATA SUMMARY

Total number of cases	**63**

Implicated Components	
Red cells	**0**
FFP	**0**
Platelets	**0**
Anti-D	**63**

Mortality / morbidity	
Deaths due to transfusion	**0**
Deaths in which reaction was contributory	**0**
Major morbidity	**24**

Gender	
Male	**0**
Female	**63**

Age	
<16 years	**2**
<1 year	**0**
<4 weeks	**0**

Emergency vs. routine Core hours vs. out of core hours	
Emergency	
Routine	
Not known	**63**
In core hours	**0**
Out of core hours *	**2**
Not known	**61**

Where transfusion took place	
A & E	**0**
Theatre	**1**
ITU/HDU/recovery	**0**
Wards (clinics)	**58**
Community	**4**
Other	**0**
Not known	**0**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)		
In how many cases was failure or absence of IT a factor?	**6**	
In how many cases was a transfusion possibly unnecessary or inappropriate?	**35**	

* 2 were possibly out of core hours but it was not possible to tell definitively from the questionnaire.

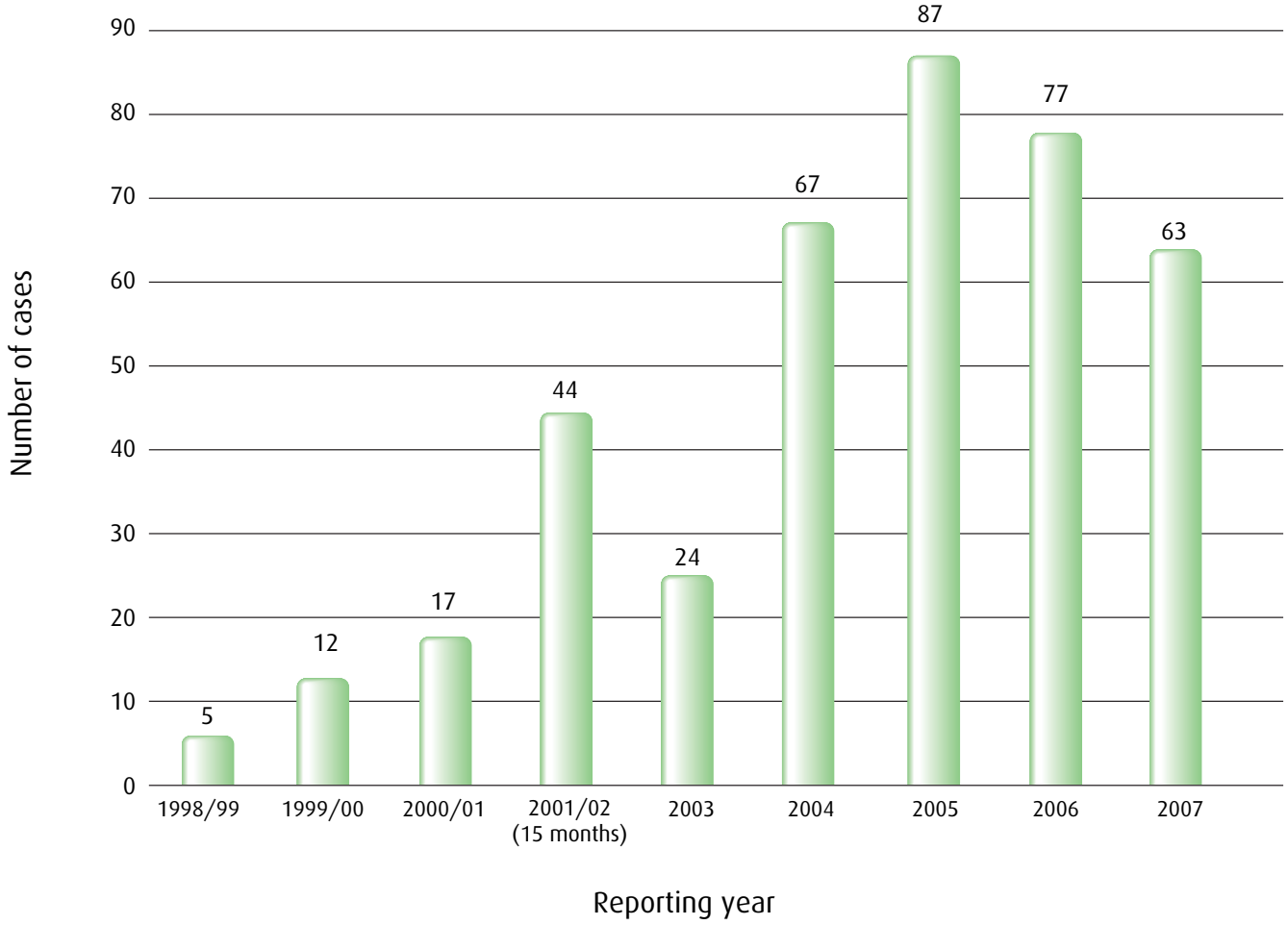
Reporting categories

- Omission or late administration of anti-D immunoglobulin
- Inappropriate administration of anti-D immunoglobulin to:
  - a D positive patient
  - a patient who already has immune anti-D
  - a mother of a D negative infant
  - a different patient from the patient for whom it was issued
- An incorrect dose of anti-D immunoglobulin according to local policy
- Administration of expired, or otherwise out of temperature control, anti-D immunoglobulin

Mortality and morbidity

There are no data in the reports this year to indicate any mortality or degree of morbidity resulting from errors relating to anti-D immunoglobulin although, in 24 cases where anti-D was administered late or omitted altogether, there is the potential for sensitisation of the patient to the D antigen, which satisfies the current SHOT definition of major morbidity.

Figure 5
Anti-D cases 1998 to 2007



In the reporting year 2007, 63 events relating to anti-D immunoglobulin administration occurred. These are summarised in Table 20 below.

Of most concern were 24 cases in which administration of anti-D Ig following potentially sensitising events was delayed or omitted, placing the patient at risk of developing an immune anti-D, and 35 cases where anti-D was inappropriately administered, resulting in unnecessary exposure to a human blood product.

Table 20
Errors in cases involving anti-D Ig administration

Type of event	Cases	Primary *(All)* Errors		
		Midwife / Nurse	Laboratory	Doctor
Omission or late administration of anti-D Ig	**24**	22 *(24)*	2	-
Anti-D Ig given to D positive patient	**17**	3 *(5)*	11	3
Anti-D Ig given to patient with immune anti-D *(In 4 reported cases, there was no actual error involved)*	**6**	*(1)*	2	-
Anti-D Ig given to mother of D negative infant	**6**	-	6	-
Anti-D given to wrong patient	**6**	5 *(5)*	-	1
Wrong dose of anti-D given	**2**	*(2)*	2	-
Anti-D Ig expired or out of temperature control	**1**	*(1)*	1	-
Other *(anti-D Ig administered instead of anti-tetanus globulin)*	**1**	-	-	1
Total cases	**63**	30 *(38)*	24 *(24)*	5 *(5)*
Total errors: Primary / *(All)*		59 *(67)*		

Omission or late administration of anti-D n = 24

In 22/24 cases the primary error was by a midwife or nurse. Three cases occurred in the community (including one in which the midwife went to the wrong hospital to collect the anti-D) and 21 in a hospital setting. Lack of communication and poor documentation were common features – failure of the maternity discharge checklist was noted in 10 cases. In 1 case the laboratory did not telephone results to the ward, which was compounded by the clinical area not chasing the result, and in 4 cases there was significant delay because the original samples had been inadequately labelled.

In 1 case, anti-D was not administered in response to a sensitising event because the patient was due to receive routine antenatal anti-D prophylaxis (RAADP) a week later. The anti-D had been correctly issued in response to the sensitising event by the laboratory, but was returned unused by the ward. This case highlights the real need for targeted education around RAADP, where the principle is to administer anti-D in response to sensitising events regardless of recent or planned administration of prophylactic anti-D in the third trimester.

These cases, as in last year's report, emphasise the need for clear protocols and delineation of responsibilities within care pathways.

Anti-D Ig given to D positive patients n = 17

These cases resulted from variation in D group determination, poor documentation or communication, or misunderstanding of the laboratory report. Variation in D-typing of patients with weak D antigen, as commented in previous reports, may be unavoidable, as technologies differ in their sensitivity, but it is important that D type is determined by the most robust routine method available.

- Two patients had been tested as D negative at booking and received anti-D, but were confirmed as weak D positive later in the pregnancy.
- Two patients received anti-D for sensitising events on the basis of testing performed at other hospitals, but were subsequently found to be D positive.
- One patient was clearly flagged as a weak D on the LIMS, but this hazard flag was ignored by a BMS, who issued anti-D on request.
- A patient was on record as D positive, but this result was ignored by a BMS who had been asked to perform a Kleihauer test because the patient was known to have anti-C^w, and who then issued anti-D on request.
- In 1 case a midwife had recorded the D type incorrectly, and then insisted on anti-D being issued even though the patient's record on the LIMS clearly showed she was D positive.

One patient was mistyped as D negative by a Blood Service reference laboratory, and there were 2 further errors in hospital laboratories involving 'emergency' manual techniques which were later contradicted by routine automated testing. There was no comment made by reporters as to whether the non-routine processing of post-natal samples was appropriate in these cases.

In 1 case a patient testing as D negative at booking was confirmed as weak D by a reference laboratory after administration of the 28-week RAADP anti-D. However, the final laboratory report failed to give advice as to future treatment, so the 34-week RAADP dose was administered as well, from stock held in the maternity department. This case again highlights the need for education around the subject of anti-D, including interpretation of results, and also the need for a review of standard comments issued by reference laboratories to make them more relevant to the end-user.

In 6 cases, and also in 1 separate case where anti-D was administered instead of anti-tetanus immunoglobulin, the anti-D was stored in a batch either in the maternity department or at a GP surgery. In 2 of these cases, the patients informed the clinician that they were D negative on the basis of remembering they had received 'injections' in previous pregnancies. In all 6 cases no check was made on the D type of the patient prior to injection of anti-D (Case 1).

Better Blood Transfusion 3[11] requires anti-D to be subject to the same rigorous patient identification, recording and traceability requirements as all other blood components and products, and remote batch issue cannot come close to compliance with this.

Case 1

Anti-D administered with no blood group check

Having been told by the patient's husband that his wife was D negative, the consultant ordered anti-D from the pharmacy rather than blood bank, and proceeded to administer it without any grouping checks being made. The patient was in fact D positive.

Anti-D Ig given to patients with immune anti-D n = 6

There was 1 case in which anti-D was issued to a patient who was on record as already having anti-c+D. The mother and cord request made no mention of the antibodies, and the BMS did not check the LIMS prior to issue of the immunoglobulin.

In 1 case anti-D was issued on the basis of a historical group and screen result. When the current sample was tested, the patient was found to already have a strong immune anti-D.

In 4 cases women who had been tested at booking and found to have no antibodies, and who had no subsequent record of receiving prophylactic anti-D, were found to have immune anti-D at 28 weeks in the group and screen sample taken immediately before RAADP was administered.

These are not errors, as National Institute for Clinical Excellence (NICE) recommendations were clearly being followed to the letter (see commentary below), but it is interesting that hospitals have reported what appear to be genuine sensitisations prior to 28 weeks gestation as adverse events. One hospital has felt it necessary to alter its procedure by taking the second group and save sample a full week before planned administration of the anti-D, resulting in extra clinic commitment for both patients and midwives. However, it should be noted that in 1 of these cases the positive antibody screen was reported by the laboratory as 'post-injection of anti-D', even though there was no evidence that the patient had received prophylactic anti-D prior to the current sample.

There were no clinical sequelae reported in any of the babies following late development of anti-D in the mothers during the pregnancy. Data on subsequent pregnancies would be of interest.

Anti-D Ig given to mothers of D negative infants n = 6

These 6 cases were exclusively laboratory errors, 3 involving errors in transcription of cord D typing results, 2 involving testing errors where the laboratory SOP was not followed, and 1 where the anti-D was issued in error by a BMS not normally working in transfusion.

Case 2

Transcription error results in unnecessary administration of Anti-D

Mother and cord samples were correctly tested, both as D negative. The BMS then incorrectly transcribed the maternal result onto the request card as D positive. When the ward telephoned the laboratory to ask for the results, a second BMS assumed that the D positive result belonged to the cord, and issued anti-D on that basis.

Anti-D given to the wrong patient n = 6

These were exclusively clinical errors due to misidentification of the patient prior to administration of anti-D. The implication is that 6 patients who *should* have received anti-D did not, though none of the reports state whether or not the correct patients were eventually administered their immunoglobulin, and whether it was within the appropriate time frame.

Case 3

Anti-D given to wrong patient owing to lack of ID check

Anti-D was issued by the laboratory for a named patient scheduled to attend antenatal clinic. The ampoule of anti-D was clipped to the wrong patient's notes by a midwife in clinic and was administered by a second midwife, along with other medication, without any further checks being made.

Laboratory errors n = 24

Laboratory errors accounted for 24 (36%) of the reported errors in this section.

In 2 errors anti-D was issued to mothers of D negative babies by laboratory staff who did not regularly work in transfusion. In 6 cases, historical results or hazard flags in the LIMS should have prevented the issue of anti-D, but these were ignored or overridden by the BMS on duty at the time of request.

There were 3 cases where the wrong dose, according to local policy, or an expired vial, of anti-D was issued, and these were compounded by failure to detect the error at the bedside prior to administration. In 1 of these cases, a 2500iu vial was issued instead of a 250iu dose, and in 1 case 500iu was issued instead of 250iu.

COMMENTARY

Many of the cases in this year's report involve failure to follow basic clinical protocols and laboratory SOPs, and these serve to highlight the need for targeted education to all groups of staff regarding the appropriate administration of anti-D immunoglobulin, related blood tests, and the significance of antenatal antibodies in general. This need is all the more pressing in the light of the proposed withdrawal of NHSBT from routine antenatal testing, meaning that some hospitals will have to formulate plans for taking it back 'in house', with all the implications of interpretation and advice which that entails.

The development of nationally agreed, robust laboratory SOPs and clinical care pathways, is essential for the safe administration of a blood product around which there is evidently still confusion and variation in practice, and where the laboratory is often the first port of call for advice to the clinical area.

The use of RAADP is increasing as the recommendations of NICE[12] are being adopted. The BCSH guidelines for blood grouping and antibody testing in pregnancy[13] provides guidance on appropriate follow-up and further investigation where low levels of anti-D are detected in these patients.

Current NICE guidance advises that anti-D be administered at 28 weeks gestation, immediately after the second group and screen sample is taken and before the results are available. This is to minimise the impact of the RAADP programme on patient and staff time and resources. It must be appreciated that this carries the risk of inappropriate administration if the D group determination at booking was incorrect or a weak D unresolved, or if the patient has developed an immune anti-D in the intervening weeks.

If there is any doubt as to the true D status of a patient, or whether anti-D detected in an antibody screen is of immune or prophylactic origin, and these questions cannot be quickly resolved, then prophylactic anti-D should be administered rather than place the patient at risk by withholding it.

RECOMMENDATIONS

New recommendations from this report

- D-typing should be performed by the routine methodology available in the blood bank, not by emergency techniques which may not be as robust.

  Action: Trust CEOs, consultant haematologists with responsibility for transfusion, HTCs, HTTs

- Trusts should comply with the requirement in Better Blood Transfusion 3[11]: 'Ensure the use of anti-D immunoglobulin follows the same rigorous patient identification, recording and traceability requirements as all other blood products and components.'

  Action: Trust CEOs, consultant haematologists with responsibility for transfusion, HTCs, HTTs

- Obstetricians and midwives must be familiar with the national guidance for routine antenatal anti-D prophylaxis and the rationale behind it. National guidance regarding all anti-D prophylaxis should be standardised. There is a need for clear and unambiguous advice to ensure that all hospitals are able to develop local guidelines which reflect national consensus.

  Action: NBTC, NHS Blood and Transplants (NHSBT) Appropriate Use of Blood Group, BCSH, Royal Colleges of Midwives, Obstetricians and Gynaecologists, General Practitioners (GPs), HTCs and HTTs

- There should be clinical follow-up and retesting in 6 months of patients in whom anti-D administration has been delayed or omitted. The outcome should be reported to SHOT as well as internally within the Trust.

  Action: Trust CEOs, consultant haematologists with responsibility for transfusion, HTCs, HTTs

Recommendations still active from previous years

Year first made	Recommendation (previously Learning Points)	Target	Progress
2005	Laboratories undertaking antenatal serological testing should have clear protocols based on BCSH Guidelines including algorithms for repeat testing in cases where there is uncertainty whether anti-D is passive or immune	**Trust CEOs consultant haematologists with responsibility for transfusion HTCs, HTTs**	Improving safety of anti-D prophylaxis has been highlighted as an area for action in BBT3 'SHOT in Obstetrics' (2008) downloadable from SHOT website Several educational symposia aimed at midwives and junior doctors have taken place A multidisciplinary working party formed under the NHSBT Appropriate Use of Blood group will examine issues around guidelines and training later in 2008
2005	Laboratory reports should provide clear and unambiguous advice on the need for repeat testing and prophylactic anti-D administration		
2005	Senior, experienced laboratory staff should take responsibility for interpretation of results and issue of anti-D		
2005	The introduction of RAADP should be supported by education of doctors, midwives and laboratory staff regarding the appropriate administration of anti-D, related blood tests and the significance of antenatal antibodies	**Royal Colleges of Midwives, Obstetricians and Gynaecologists, GPs, consultant haematologists with responsibility for transfusion, HTCs, HTTs**	
2005	Increase safety of routine anti-D prophylaxis.	**Royal Colleges of Midwives, Obstetricians and Gynaecologists, GPs, HTTs**	

7. Acute Transfusion Reaction (ATR)

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, haemolytic reactions, TRALI or those due to bacterial contamination of the component.

DATA SUMMARY

Total number of cases	**114**	*Implicated components*		*Mortality / morbidity*	
		Red cells	**51**	Deaths due to transfusion	**0**
		FFP	**20**	Deaths in which reaction was contributory	**1**
		Platelets	**40**	Major morbidity	**5**
		Other (salvaged red cells)	**2**		
		(cryoprecipitate)	**1**		

Gender		*Age*		*Emergency vs. routine Core hours vs. out of core hours*		*Where transfusion took place*	
Male	**62**	<16 years	**7**	Emergency	**21**	A & E	
Female	**52**	<1 year	**2**	Routine	**87**	Theatre	
		<4 weeks	**0**	Not known	**6**	ITU/HDU/recovery	
						Wards	
				In core hours	**86**	Community	
				Out of core hours	**26**	Other	
				Not known	**2**	Not known	**114**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)		
In how many cases was failure or absence of IT a factor?	**N/A**	
In how many cases was a transfusion possibly unnecessary or inappropriate?	**6**	**(FFP)**

Current category definitions

- **Isolated febrile**
  - rise in temperature >1^{0}C with or without minor rigors and chills
- **Minor allergic**
  - skin irritation with or without rash
- **Anaphylactic/anaphylactoid/severe allergic reaction**

  Anaphylactic/anaphylactoid reaction:
  - Hypotension with 1 or more of: rash, dyspnoea, stridor, wheezing, angioedema, pruritus, urticaria, during or within 24 hrs of transfusion

  Severe allergic reaction:
  - A severe allergic reaction with immediate risk to life occurring during or within 24 hours of transfusion, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress
- **Hypotension**
  - a drop in systolic and/or diastolic pressure of >30mm Hg occurring during or within 1 hour of completing transfusion, when all other categories of adverse reactions have been excluded together with underlying conditions that could explain hypotension
- **Febrile with other symptoms/signs**
  - rise in temperature >1^{0}C, with no features of an allergic reaction, but with 1 or more of myalgia, nausea, change in blood pressure or hypoxia

Analysis

Of the 124 questionnaires received, 10 were withdrawn because symptoms were due to underlying disease or other cause, leaving 114 cases. The number of reports continues to rise. This may be due to improved haemovigilance. However, if the increase is sustained in the future, possible factors contributing to this will need to be examined. It is worth noting that the reporting rate is very variable, with many large hospitals reporting no reactions, yet some small hospitals report several. There is no geographic pattern to this.

The median age of patients is 59 (range 35 days to 88), which is considerably younger than last year (72). There were 62 male and 54 female patients.

Figure 6
ATR cases 1996 to 2007
[Totals include cases of Acute Haemolytic Transfusion Reaction (AHTR) to 2006]

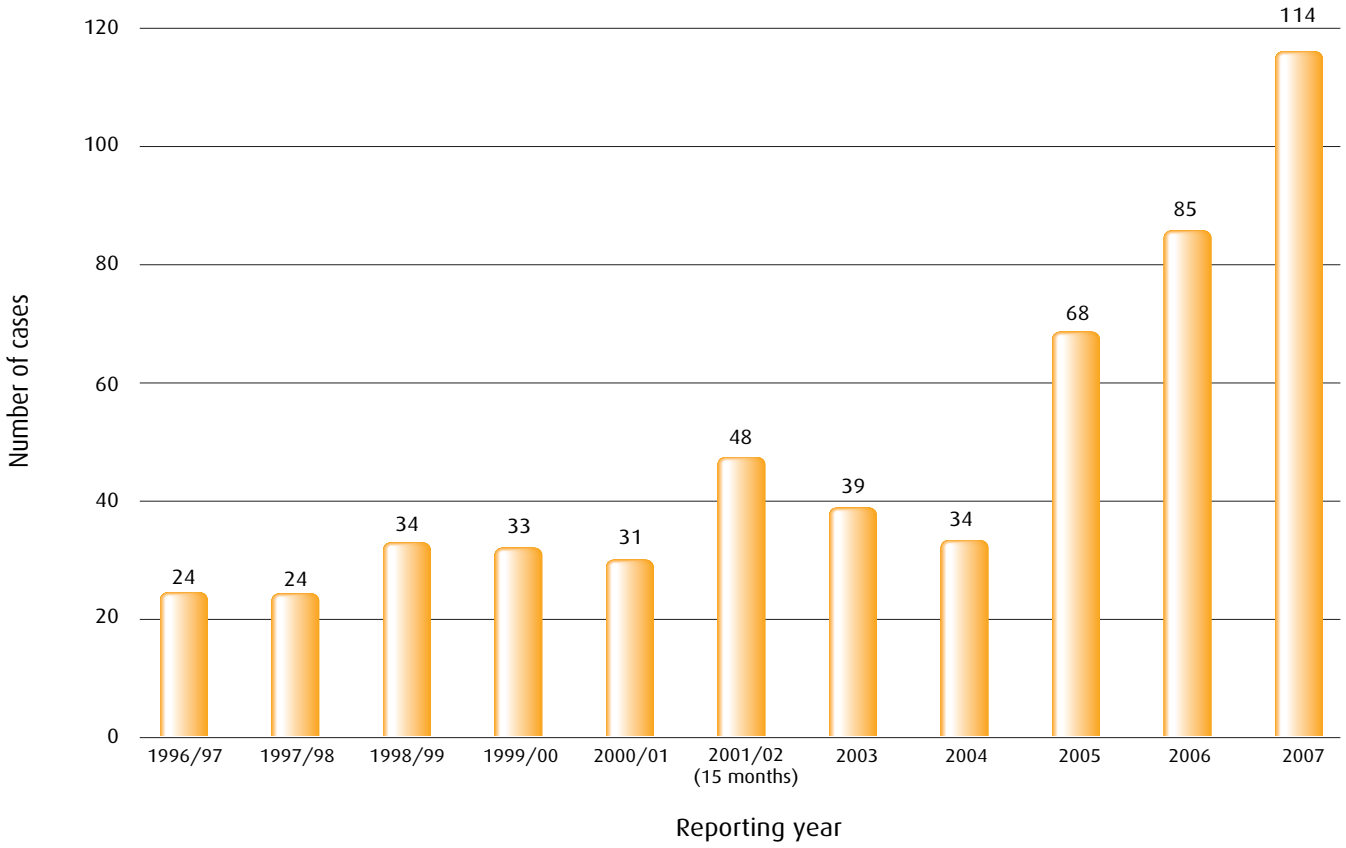


Table 21
Components implicated

Reaction	RBC n = 51	Salvaged RBC n = 2	Platelets apheresis n = 19	Platelets buffy coats n = 21	FFP * n = 20	Cryo ** n = 1	Total n = 114
Isolated febrile	12	1	3				**16**
Minor allergic	14		4	12	7		**37**
Severe allergic	2		4	1	5		**12**
Anaphylactoid	6		6	7	7	1	**27**
Hypotension	1	1					**2**
Febrile with other symptoms / signs	16		2	1	1		**20**
Total	**51**	**2**	**19**	**21**	**20**	**1**	**114**

* All FFP cases related to standard FFP

** Two pools of cryoprecipitate were transfused

Mortality

Two patients in this series died, and their details are given below.

Case AA1 apheresis platelets

An 8-month-old female infant was already very ill with cardiac problems and sepsis, and was prescribed apheresis platelets because of a postoperative platelet count of 11. She received the first unit of 61 mL over 20 minutes without problems. Ten minutes after starting the second unit, having received 14 mL, she became flushed and developed profound hypotension and reduced oxygen saturation, and later died. The clinical team decided that the anaphylactic/anaphylactoid reaction had accelerated what was likely to be inevitable clinical deterioration.

Case AA2 FFP

A 38-year-old male patient with peritonitis received 4 units of FFP to correct deranged clotting prior to emergency surgery. At the end of the fourth unit, he developed symptoms suggestive of an anaphylactic/anaphylactoid reaction, notably angioedema, dyspnoea with oxygen saturation of 90% and a fall in diastolic blood pressure of 20 mm Hg. The patient required ventilation and later died. Later, E. Coli was isolated from the patient's blood cultures. The referring team state that the death was not due to a transfusion reaction, and it cannot be stated that these symptoms were in any way related to the transfusion.

Major morbidity

There were 2 cases of major morbidity with imputability 2, with 1 of them due to an anaphylactic/anaphylactoid reaction and 1 due to a severe allergic reaction. These are described later in the text (Cases AA6 and SA1).

There were also 3 cases of major morbidity with imputability 1.

Anaphylactic/anaphylactoid reactions (AA)

There were 27 cases, including 2 deaths, described above, and 3 cases of major morbidity.

Case AA3 apheresis platelets

A 24-year-old male had ALL with sepsis and platelets of 3 x 10^9/L. He collapsed with profound hypotension 10 minutes after a transfusion of irradiated CMV negative platelets, and was given respiratory support on ITU for 10 days, after which he made a complete recovery. TRALI was excluded after full investigations. Mast cell tryptase was normal. Serum IgA was low but no IgA antibodies were detected. HLA antibodies were negative. Washed platelets were subsequently given with no problems.

Case AA4 RBC

A 65-year-old female received the first unit of red cell transfusion for chemotherapy-associated anaemia. Seventy minutes after the start of transfusion, having received 150 mL, her blood pressure dropped from a baseline of 121/54 to 70/40. She developed supraventricular tachycardia which required cardioversion and treatment with adenosine, with successful outcome.

Case AA5 RBC

A 5-week-old female infant was being investigated for possible tracheomalacia. She had had a previous transfusion, and had received 9.6 mL of the implicated unit when she became pale, sweaty, bradycardic, hypotensive and tachypnoeic. In view of the deterioration, she was transferred to a specialist unit. The clinical picture was very complex, but an anaphylactic/anaphylactoid reaction cannot be excluded.

Case AA6 cryoprecipitate

A 65-year-old female patient received 2 pools of cryoprecipitate at the end of surgery to investigate a pelvic mass. Within 30 minutes she developed a rash and nausea, and her blood pressure became unrecordable. She was reintubated and taken to ITU. Investigations proved negative.

Table 22
Clinical features of remaining 22 cases of anaphylactic/anaphylactoid reactions

Case No.	Component type	Rash	Angioedema	Dyspnoea O_2 sats (%) where recorded	BP	Impaired consciousness or collapse	Interval from starting transfusion in minutes
AA7	Buffy coat platelets	√	√	√	>30 mm Hg drop		15
AA8	Buffy boat platelets	√			'profound'		<5
AA9	Buffy coat platelets	√		√	?		5
AA10	RBC			√	30 mm Hg drop		5
AA11	FFP			√	80/55 (40 mm Hg drop in systolic)		?
AA12	FFP	√		√ sats normal	68/30 (40 mm Hg drop)		5
AA13	FFP		√	√	dropped		20
AA14	RBC			√ sats 80	70/42 (50 mm Hg drop)		5
AA15	RBC			√ sats 95 as ventilation adjusted	?	ventilated	15
AA16	Buffy coat platelets	√		√ sats 85	slight		60
AA17	Buffy coat platelets	√			60 mm Hg drop systolic		60
AA18	Buffy coat platelets	√		ventilated	65/40		15
AA19	Apheresis platelets	√		√ sats 42	Profound drop		10
AA20	Buffy coat platelets			√ 79%	>30 mm Hg drop		10
AA21	Apheresis platelets	√			>30 mm Hg drop		25
AA22	Apheresis platelets	√			> 30 mm Hg drop		?
AA23	RBC			√ 90%	28 mm Hg drop systolic		40
AA24	FFP	√		√ 82%			2
AA25	FFP	√	√		40 mm Hg drop in diastolic		15
AA26	FFP	√	√		> 30 mm Hg drop		30
AA27	Apheresis platelets	√		ventilated	70 mm Hg drop		90

Severe allergic reactions (SA)

Twelve severe allergic reactions were reported, with 1 case of major morbidity.

Case SA1 buffy coat platelets

A 69-year-old female patient with myelodysplasia received 1 pool of buffy coat derived platelets prior to total knee replacement. Fifteen minutes later she developed angioedema with a fall in her oxygen saturation to 86% on oxygen. She was treated with continuous positive airway pressure (CPAP) for 3 days, with slow resolution of her symptoms.

One case involving a major reaction is discussed in the section on reactions with coincidental red cell antibodies (Case AB4).

Table 23
Clinical features of the remaining 10 cases with severe allergic reactions

Case no.	Component type	Rash	Fever/ Rigors	Dyspnoea	Hypoxia, sats	Angioedema	Time from starting transfusion (minutes)
SA2	Apheresis platelets	√		√	√ sats 'dropping'	√	35
SA3	Apheresis platelets	√		√	√ 95%	√	5
SA4	FFP			√	√ 86%		25
SA5	FFP	√	√	√	√-not stated		60
SA6	FFP	√		√	√ 84%		?
SA7	Apheresis platelets			√	√ 92%		5
SA8	RBC		√	√	√ 81%		90
SA9	Apheresis platelets			√	?		
SA10	FFP	√		√	√ 90%		45
SA11	FFP		√	√	√ 80%		20

Hypotension

There were 2 reports of hypotension in the absence of other features suggestive of anaphylactic/anaphylactoid reactions.

Case H1 RBC

A 63-year-old male patient was planned to have 2 units of red cells for cancer-related anaemia. Within 15 minutes of starting the first unit, he complained of chills, nausea and feeling faint. His blood pressure fell from 120/71 to 88/58. He recovered without any treatment.

Case H2 autologous

An 82-year-old male patient underwent vascular surgery with intraoperative cell salvage. His systolic blood pressure dropped by 40 mm Hg, and vasoconstrictors were administered. The transfusion team decided that the reaction was related to incomplete cell washing. Further details are given in the autologous section below.

Febrile reactions with other symptoms or signs

There were 20 reports, 16 with donated red cells, 2 with apheresis platelets, and 1 each with FFP and buffy coat platelets. Five of these cases became hypertensive. Oxygen desaturation was described in only 1 case.

Isolated febrile and minor allergic reactions

There were 37 reports of minor reactions, and 16 of isolated febrile reactions.

Autologous red cells

There were 2 reports of reactions to salvaged red cells. These are discussed on page 110.

Case AR1

See Case H2 above.

Case AR2

A 64-year-old male patient, who had previously been transfused on two occasions, had 600 mL of blood collected via a Bellovac drain after knee replacement. The report states that the blood was reinfused over 4 hours and 30 minutes. The patient then developed an isolated febrile reaction. No investigations were performed.

Paediatric cases

There were 7 cases in patients under the age of 16. Two of these occurred in infants under the age of 1. One was an anaphylactic/anaphylactoid reaction to apheresis platelets in a 35-day-old female infant with multiple cardiac problems. This reaction was considered to have possibly contributed to her death (Case AA1). The other was an anaphylactic/anaphylactoid reaction to red cells in an 8-month-old female infant who had significant co-morbidity (Case AA2). These cases are described in the earlier section dealing with anaphylactic/anaphylactoid reactions. The other 6 reactions were in children aged between 1 and 12, with 5 of the cases being minor allergic reactions, and 1 being a severe allergic reaction, described below (Case P1). Five of the cases were due to platelets (2 to apheresis platelets, and 3 to buffy coat platelets).

Case P1 apheresis platelets

A 7-year-old boy with T-cell ALL received two paedi-packs of apheresis platelets. The first was transfused without problems, but towards the end of the second unit he developed angioedema, rash and tachycardia, and became hypertensive and hypoxic. He was treated with oxygen, hydrocortisone and piriton, and his symptoms resolved. Culture of the unit was negative. HLA antibodies were not demonstrated.

Acute transfusion reactions in which post-transfusion antibodies were demonstrated (AB)

There were 4 cases in which patients had symptoms consistent with acute transfusion reactions, but who were also shown to have low titres of alloantibodies in the post-transfusion sample. The first 2 of these cases were first reported as ATRs, but the other 2 were initially reported as haemolytic transfusion reactions. None of these cases had clinical or laboratory evidence of acute or delayed haemolysis, and it was felt that the alloantibodies were not the cause of the acute reactions, hence their inclusion here.

Case AB1

A 64-year-old male patient, with no past history of transfusion, received 1 unit of red cells because of postoperative bleeding. Within 2 hours of stopping the transfusion, he developed a temperature rise of more than 1.5°C and rigors. Serological investigation of pre- and post-transfusion samples using 5 different panels gave varying but inconclusive results. The samples were referred to a reference centre, and a high-titre, low-avidity anti-Rodgers antibody was demonstrated.

Case AB2

A 66-year-old man developed pyrexia (temperature rise >1.5°C) and rigors during the second unit of a transfusion. Blood had been electronically crossmatched according to BCSH guidelines. Serological investigation of the post-transfusion sample showed he had developed a positive direct antiglobulin test, and a positive serological crossmatch with the second unit. Further referral to a reference centre revealed that the patient had developed anti-Wr^a. There was no rise in bilirubin, and no laboratory evidence of haemolysis.

Case AB3

A 74-year-old female patient with pancytopenia, who had not previously been transfused, received the first of a planned 3 red cell units. After receiving 80 mL she developed back pain, dyspnoea, pyrexia, rigors, vomiting and raised blood pressure. The symptoms responded promptly to steroids and antihistamine. Pre- and post-transfusion samples showed a strong positive direct antiglobulin test with IgG and C3d. She was shown to have an auto-anti-Fy^a in the pre- and post-transfusion samples, and an allo-anti-S in the post-transfusion sample. There was no significant rise in bilirubin or other evidence of haemolysis.

Case AB4

A 37-year-old female who was known to have detectable HLA antibodies, and who was receiving pre-transplant conditioning for a bone marrow transplant, received 2 units of group A red cells without problems. Two weeks later she received another transfusion and developed a severe allergic reaction within 5 minutes of starting the first unit. Serological investigations showed that she was group A2 and had probably developed a weak anti-A1 after the previous transfusion. There was no increase in bilirubin and serum haptoglobin remained stable. The reference laboratory advised that the weak anti-A1 was a coincidental finding.

Investigations

- **Bacteriological investigation of patient's blood and transfused component**
  This was performed in 60 cases, with either negative findings or growth of a species unlikely to be of clinical significance. The majority of reports in which bacteriology was not performed were related to minor allergic reactions, but it was also not performed in 7 isolated febrile reactions, and 7 febrile reactions with other symptoms and signs.
- **HLA/HPA investigations**
  These were performed in 14 cases, 6 of which were severe allergic reactions or anaphylactic/anaphylactoid reactions. Positive results were obtained in 7 cases.
- **Serum IgA and IgA antibodies**
  These were performed in 22 cases. Two patients had low serum IgA, and 1 patient was found to have positive IgA antibodies.
- **Mast cell tryptase (MCT) assays**
  These were only performed in 4 cases, and no abnormal results were found.
- **Red cell serological investigations**
  Eight patients had red cell serological investigations, including two patients who were initially referred as having haemolytic transfusion reactions. Post-transfusion antibodies were identified in four cases, described above.

DISCUSSION

Use of FFP

Twenty of the case reports were associated with infusion of FFP, in all cases the standard product provided by UK blood services. There were 6 reports associated with inappropriate use of FFP. In all 6 of these cases, FFP was given for warfarin reversal. SHOT draws attention to BCSH guidelines which indicate that prothrombin complex concentrate (PCC), rather than FFP, is the product of choice for the reversal of oral anticoagulation (warfarin) in patients with major bleeding[4]. In the absence of major bleeding, PCC (or FFP if PCC is not available) could be used if warfarin reversal is required for emergency surgery.

Management of acute transfusion reactions

The majority of cases received some form of treatment for their transfusion reaction. Forty-five patients received both hydrocortisone and an antihistamine, 19 cases were reported as receiving an antihistamine, and 12 as receiving hydrocortisone alone. Other drugs that were used include paracetamol (21 cases), adrenaline (12 cases, all of which were anaphylactic/anaphylactoid or severe allergic reactions) and salbutamol (8 cases – 6 of which were anaphylactic/anaphylactoid or severe allergic reactions). It is of interest that there were 3 reports of patients receiving pethidine for management of rigors. This is a treatment that appears to be being used more frequently. There is a specific indication for the use of pethidine to manage transfusion reactions in patients who are receiving intravenous amphotericin[14], but, outside this specific recommendation, the evidence base for this treatment is unclear.

COMMENTARY

- Acute transfusion reactions continue to be an important and largely unpredictable hazard of transfusion.
- The number of reports has risen yet again, with a total of 114 reports, compared to 85 in 2006.
- This chapter is based on case reports from 55 hospitals. Notably 9 transfusion teams, including some from small hospitals, reported 54 (46%) of the above cases. This suggests that the number of reports received does not accurately reflect the prevalence of this type of reaction.
- Classification of acute transfusion reactions remains problematic, with many reports not fitting into currently accepted categories. Current categories for classification can be found in the SHOT toolkit[15]. Standard definitions for surveillance of non-infectious adverse transfusion reactions will be published by the International Society for Blood Transfusion (ISBT). BCSH guidelines on the management of acute transfusion reactions are being produced.

- There are four cases (AB1-4) who had evidence of a post-transfusion antibody, yet who had features of acute transfusion reactions and no evidence of haemolysis. Meticulous investigations of transfusion reactions may reveal more such cases in the future.
- There is variability in the investigation and management of acute transfusion reactions.
- Eighty-one of the reactions developed more than 15 minutes into the transfusion (68%), and 39 (34%) occurred more than 30 minutes after the start. The 2005 National Comparative Audit[7] of bedside transfusion practice suggests that the majority of patients do not have observations recorded after 15 minutes. This highlights the need for transfusions to be administered at times, and in locations, permitting careful observations of the patient, and strengthens the advice that out-of-hours transfusions should be avoided if at all possible.
- Twenty of the case reports were associated with infusion of FFP, in all cases the standard product provided by UK blood services. There were 6 reports associated with inappropriate use of FFP. In all 6 of these cases, FFP was given for warfarin reversal.

RECOMMENDATIONS

New recommendations from this report

- Hospitals should have a policy that ensures that serious adverse reactions to transfusions are recognised and reported. This is a legal requirement under the BSQR.

  Action: Trust CEOs, HTCs, HTTs

- Prothrombin complex concentrate (PCC), rather than FFP, is the product of choice for the reversal of oral anticoagulation (warfarin) in patients with major bleeding. In the absence of major bleeding, PCC (or FFP if PCC is not available) could be used for warfarin reversal for emergency surgery.

  Action: HTCs, HTTs, Consultant haematologists with responsibility for transfusion

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2006	Serious transfusion reactions can occur at any stage during the transfusion, emphasising the need to keep all patients visible and accessible to nursing staff. Out of hours transfusions should be avoided unless essential and where there is adequate monitoring	**HTTs**	The national comparative audit of overnight transfusion has added to the evidence that overnight transfusions need to be monitored as closely as those carried out during the daytime
2005	All serious transfusion reactions must be fully investigated. Bacterial cultures must be taken in a transfusion reaction, when the rise in temperature exceeds 1.5ºC or the reaction is otherwise sufficiently severe to merit discontinuing transfusion	**Consultant haematologists with responsibility for transfusion**	BCSH guidelines on the investigation and management of transfusion reactions are being developed

8. Haemolytic Transfusion Reaction (HTR)

Definition

Haemolytic transfusion reactions are split into two categories: acute and delayed. Acute reactions are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; and confirmed by a fall in Hb, rise in lactate dehydrogenase enzyme (LDH), positive DAT and positive crossmatch. Delayed reactions are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; and confirmed by 1 or more of: a fall in Hb or failure of increment, rise in bilirubin, positive DAT and positive crossmatch not detectable pre-transfusion. Simple serological reactions (development of antibody without positive DAT or evidence of haemolysis) are excluded.

DATA SUMMARY

Total number of cases	**23**	*Implicated components*		*Mortality / morbidity*	
		Red cells	**21**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths in which reaction was contributory	**2**
		Platelets	**2**	Major morbidity	**5**
		Other	**0**		

Gender		*Age*		*Emergency vs. routine Core hours vs. out of core hours*		*Where transfusion took place*	
Male	**8**	<16 years	**1**	Emergency	**7**	A & E	
Female	**15**	<1 year	**0**	Routine	**15**	Theatre	
		<4 weeks	**0**	Not known	**1**	ITU/HDU/recovery	
						Wards	
				In core hours		Community	
				Out of core hours		Other	
				Not known/applicable	**23**	Not known	**23**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)		
In how many cases was failure or absence of IT a factor?	**0**	
In how many cases was a transfusion possibly unnecessary or inappropriate?	Not known	

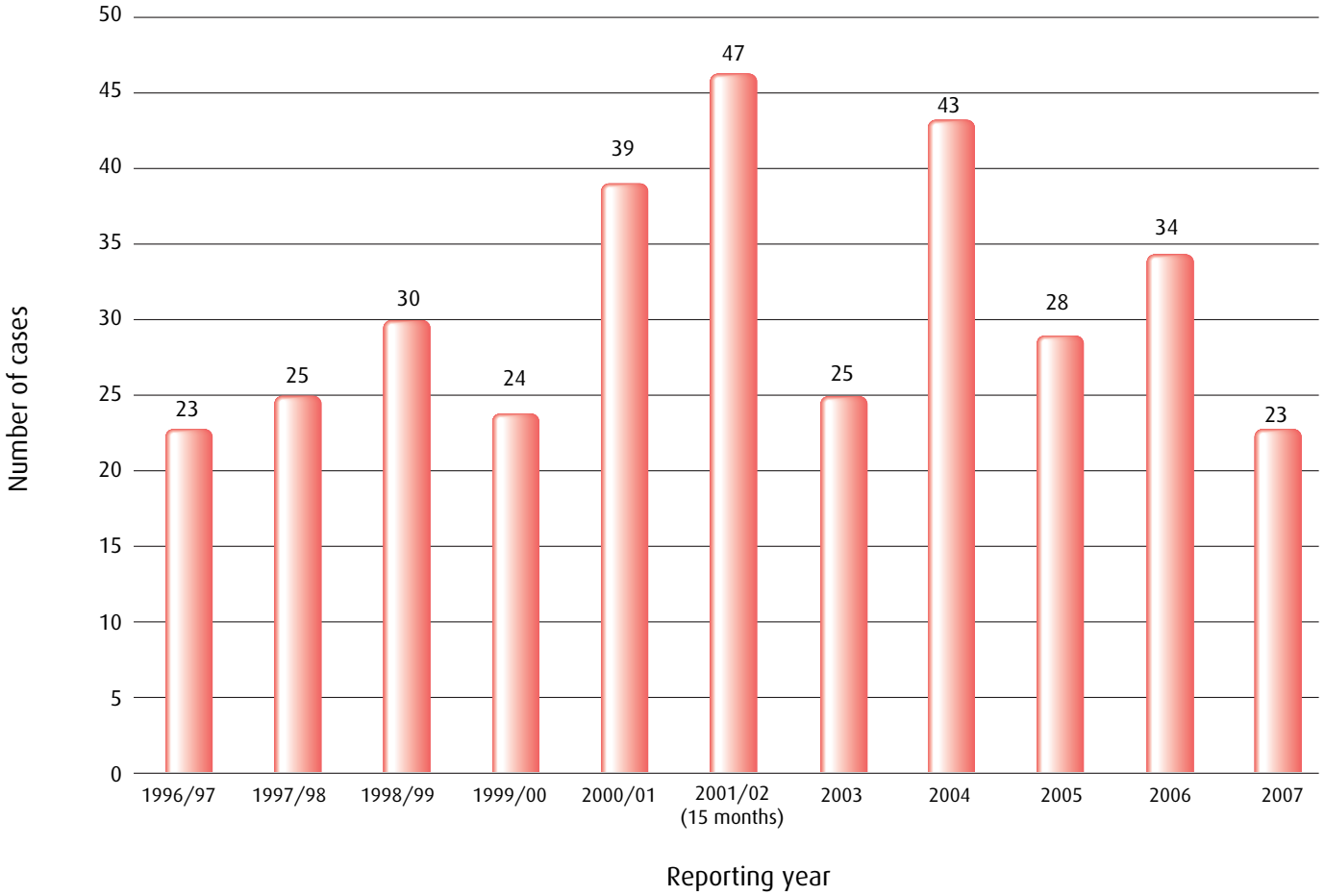
Twenty-seven questionnaires were received; 3 were transferred to the ATR section, and 1 to the IBCT section. This section describes the main findings from 23 completed questionnaires: 3 acute and 20 delayed reactions.

Patients

8 males and 15 females.
Ages ranged from 10 to 89 years.

One report relates to a patient <16 years: a 10-year-old girl suffered an AHTR following an ABO-incompatible platelet transfusion (Case A2).

Figure 7
Number of cases of HTR analysed since 1996
[Cases in this section were referred to as delayed transfusion reactions until 2006]



Mortality, morbidity, and imputability

Acute (n = 3)

There was one clear case of major morbidity relating to intravascular haemolysis following ABO-incompatible platelet transfusion (Case A1 – imputability 3): the patient made a full recovery. A second case was less clear-cut – this appeared to be intravascular haemolysis due to anti-A, but was not proven (Case A2 – imputability 1). The third suffered only minor morbidity (imputability 3).

Delayed (n = 20)

There were four deaths in this group – two were reported as definitely unrelated to the DHTR, whereas the other two were reported as possibly contributory – see Cases D15 and D20. The reactions were reported as probably related (imputability 2) in 3 cases and as possibly related (imputability 1) in 1 case.

Three patients suffered major morbidity: 1 had deteriorating renal function requiring dialysis and admission to ITU. However, diagnosis was complicated by the acute clinical picture (imputability 2 – see Case D2). The second (imputability 3 – see Case D7) dramatically dropped her Hb from 8.5 g/dL to the pre-transfusion level of 3.6 g/dL, 5–6 days post transfusion of 6 units of red cells. The third (imputability 2 – see Case D15), dropped her Hb way below the pre-transfusion level of 7.0 g/dL to 2.7g/dL – this might have been a case of hyperhaemolysis, but could also have been a developing AIHA; this patient subsequently died and has been included in the previous paragraph.

The remaining 14 patients suffered minor or no morbidity. In 7 cases the reaction was reported as probably related (imputability 2) to the transfusion, and in 6 cases definitely related (imputability 3). One case was less clear (imputability 1) – the patient was readmitted 58 days after transfusion, with several new red cell antibodies and a 4g drop in Hb, thought to be excessive for the amount of blood loss. However, the DAT was negative and transfused red cells remained in the circulation.

At least 1 patient required a further transfusion as a result of the DHTR.

Laboratory signs of haemolysis

Many patients showed laboratory signs of haemolysis without any clinical signs being noted. The laboratory signs are often complicated by the underlying disease, and are defined as follows:

- Group 1 (3 patients) Positive DAT only
- Group 2 (7 patients) Falling haemoglobin(↓Hb)/positive DAT/spherocytes (2 of these parameters)
- Group 3 (9 patients) ↓Hb + jaundice ± positive DAT ± spherocytes
- Group 4 (1 patient) As group 3 + renal impairment

Timing of reaction in relation to transfusion

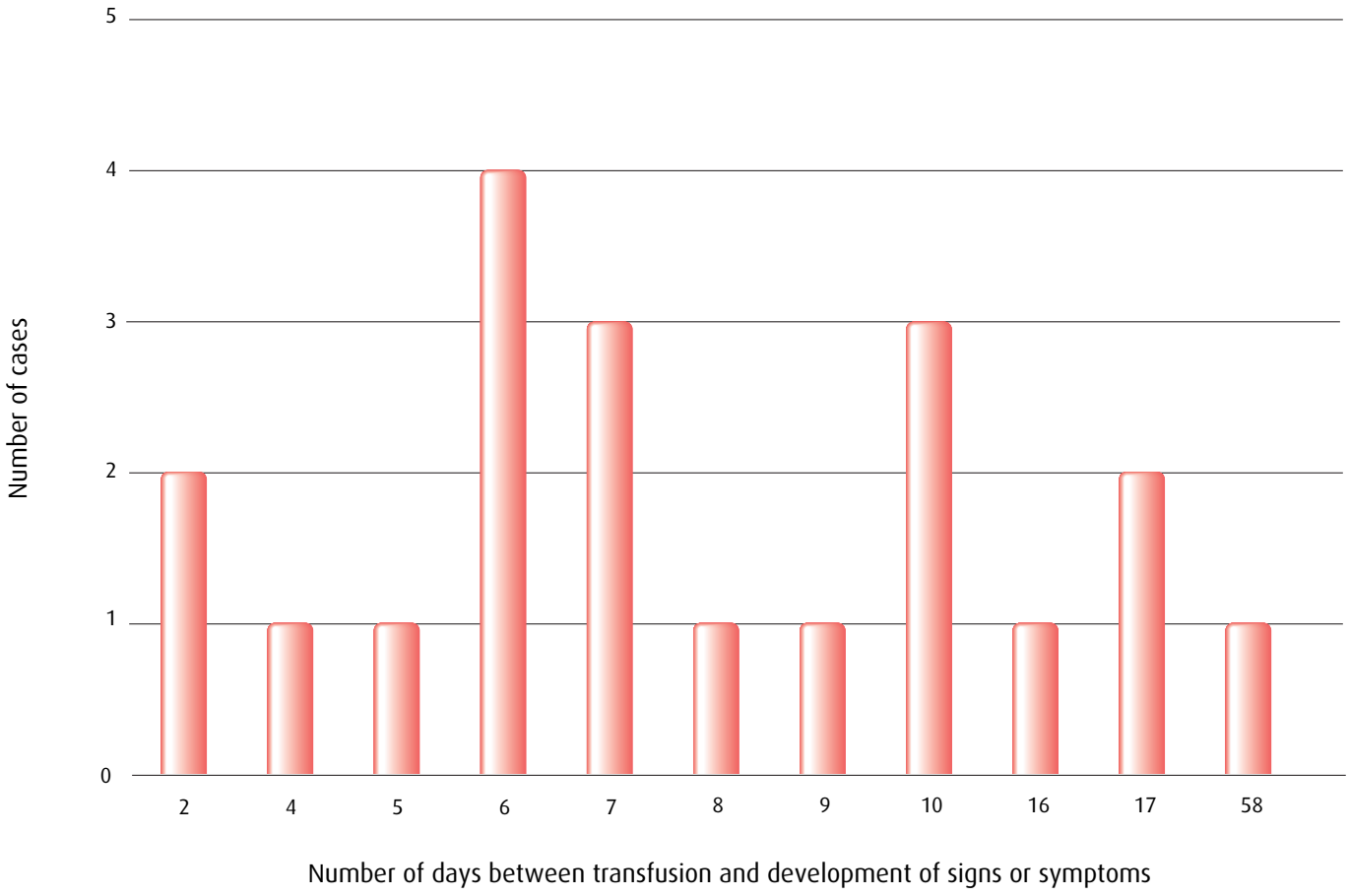
Acute

2 reactions occurred during the transfusion, and 1 immediately post transfusion.

Delayed

Figure 8 shows the reported interval in days between the implicated transfusion and signs or symptoms of a DHTR.

Figure 8
Time interval between HTR and transfusion



Median = 7 days
Range = 2 to 58 days

The intervals given are necessarily those when the signs or symptoms were first noted. In asymptomatic cases this relates to the number of days that elapsed before a repeat sample was received for group and screen, or crossmatching. There were 2 cases where symptoms were noted within 48 hours of transfusion: 1 of these patients also received a previous transfusion 7 days before the onset of laboratory signs, which was more likely to have been implicated in the DHTR than the reported transfusion (see Case D6); the other was a case of possible hyperhaemolysis (see Case D15).

Serological findings

Acute reactions

Two reactions were due to anti-A from mismatched platelets, 1 apheresis platelet donation and 1 derived from pooled buffy coats. Both were tested and found negative for high-titre anti-A and anti-B prior to issue; however the buffy coat unit was retrospectively found to be positive for high-titre anti-A. The third case involved weak anti-Fy^a retrospectively identified in the pre-transfusion sample; in this latter case there was insufficient laboratory testing to confirm haemolysis. Table 24 shows details.

Table 24
Acute reactions – serology and symptoms and laboratory signs

Case number	Antibody(ies) in plasma	Clinical symptoms	Laboratory evidence	Comments
A1	Anti-A	Fever, rigors, nausea, vomiting	Hb↓; bilirubin↑; DAT pos (C3 coating only; eluate non-reactive)	Group O buffy coat platelets – high-titre anti-A identified
A2	Anti-A	Generally unwell	Hb↓; bilirubin↑; DAT pos (C3 coating only; eluate not performed)	Group O apheresis platelets
A3	Anti-Fy^a	Fever, head and chest pain, hypotension, tachycardia, cyanosis	Hb; weak anti-Fy^a identified; DAT negative	Known anti-Ce + -e

Case A1

A 17-year-old group A D negative male with ALL and a platelet count of 3 x 10^9/L, was given 1 unit of buffy coat derived O D negative platelets – the reason for the supply of group O rather than group A platelets by the blood service is not clear. During the transfusion the patient suffered from dramatic and prolonged rigors, nausea and vomiting, and the transfusion was discontinued. Laboratory tests indicated a sharp rise in bilirubin from 40 µmol/L to 109 µmol/L, and a fall in Hb from 7.1 to 4.9 g/dL. The patient fully recovered from the reaction. All 4 constituent donations had tested negative for high-titre anti-A and anti-B by routine automated testing prior to issue. Retrospective testing showed that 1 of the donations had a high-titre IgM anti-A of 1 in 1,024 and the same donor had previously tested positive for high-titre anti-A in 3 of 8 donations.

Case A2

A 10-year-old female with ALL was transfused with 1 unit of group O apheresis platelets, because no group A platelets were available. During the transfusion the patient became unwell, but no specific details are known. Laboratory tests indicated a sharp rise in bilirubin from 40µmol/L to 102 µmol/L, and a fall in Hb from 10.2 to 8.2 g/dL. The donation was tested and found negative for high-titre anti-A. The patient fully recovered from the reaction. Subsequent donations from the same donor have all tested negative for high-titre anti-A.

These platelet transfusions occurred towards the end of 2006, and since then the National Blood Service (NBS) testing strategy has been revised to identify a higher percentage of donations as high-titre positive. New control reagents have also been produced in the interim and are now in routine use by the UK Blood Services.

Case A3

A 56-year-old female with ovarian cancer and known anti-Ce + e, required a 2 unit transfusion for anaemia. At the end of the second unit the patient developed a fever, head and chest pain, tachycardia and hypotension. Weak anti-Fy^a was identified retrospectively in the pre-transfusion sample by a reference laboratory. The Hb fell from 9.4 g/dL immediately post transfusion to 8.2 g/dL the next day, but the DAT was negative and no other tests were undertaken to confirm that this was a haemolytic reaction. A similar reaction was noted during a transfusion a year before. The patient clearly had a reaction to the red cell transfusion but the only evidence that this was haemolytic was a drop in Hb (imputability 1).

Learning points

- Group O platelets can cause acute haemolytic reactions even when tested and labelled negative for high-titre haemolysins. They should only be used for non-group O patients (particularly paediatric patients) as a last resort, and should not be kept by hospitals as stock.
- Acute reactions are often difficult to classify, particularly when laboratory tests are not undertaken, and when the patient is seriously ill.

Delayed reactions

Kidd antibodies were the most commonly implicated, in 11/20 (55%) of cases, either singly or in conjunction with other specificities. Table 25 shows the specificity of new antibodies detected post transfusion, by blood group system.

Table 25
Delayed reactions – serology and time after transfusion

Case no.	New antibody (ies) in plasma	Antibodies in eluate	Comments	No. days post tx
D1	Anti- Jk^b + enz anti-C	Anti-Jk^b	Bilirubin ↑; Hb ↓ Death unrelated	8
D2	Anti-Jk^a	Anti-Jk^a	Bilirubin↑; LDH ↑; Hb↓ creatinine↑ Reqd dialysis and ITU admission	7
D3	Anti-Jk^a	Anti-Jk^a	Pre-existing anti-E; Bilirubin↑; Hb ↓	16
D4	Anti-Jk^a + e	No eluate performed	Jaundice	6
D5	Anti-C (+Fy^a)	Anti-Fy^a + C	3 units incompatible blood tx in emergency; bilirubin↑	10
D6	Anti-Fy^a + HTLA + ? anti-f	Anti-Fy^a	No Hb increment; sample too old Death unrelated	2 - 10
D7	Anti-Jk^b + Lu^b	No eluate performed	Pre-existing anti-K+C; Bilirubin ↑; Hb↓	6
D8	Anti-C+S	Eluate negative	Jaundice and ↑bilirubin but varices; no Hb increment, but bleeding	10
D9	Anti-Jk^b	No eluate performed	Hb↓	10
D10	Anti-C+K+Kp^a+Lu^a	No eluate performed (DAT negative)	Hb fell 4g over 58 days	58
D11	Anti-Jk^b + S + M + unidentified antibodies	No eluate performed (DAT negative)	Pre-existing anti-Le^{a+b} SCD; Hb↓; haemoglobinuria	17
D12	Anti-Jk^a	Eluate negative	Pre-existing anti-Fy^a + enz anti-C^w bilirubin↑; haemoglobinuria	5
D13	Anti-Jk^b + D	No eluate performed (DAT negative)	Hb↓	4
D14	Anti-D	No eluate performed	Bilirubin↑; Hb↓; spherocytes; further transfusion required	7
D15	None ? Hyperhaemolysis	No eluate performed	Pre-existing anti-E+K; bilirubin↑; Hb↓ Death probably unrelated	2
D16	Anti-Fy^a	Anti-Fy^a	Jaundice; bilirubin↑; Hb↓- but liver trauma	9
D17	Anti-E (enzyme only)	Anti-E	No signs or symptoms	17
D18	Weak reaction – specificity not identified	Anti-Fy^a	No signs or symptoms	7
D19	Anti-Jk^a	Anti-Jk^a	No signs or symptoms	6 – 8
D20	Anti-Jk^a	Anti-Jk^a	Bilirubin↑; no Hb increment; Death probably unrelated	6

Table 26
DHTRs – new specificities by blood group system

Antibody specificity by blood group system	Number of cases	Sole *new* antibody
Kidd		
Jk^a	6	5
Jk^b	5	1
Rh		
D	2	
C	4 (1 enzyme only)	1
E	1 (enzyme only)	
e	1	1
?f	1	
Kell		
K	1	
Kp^a	1	
Duffy		
Fy^a	4	2
MNSs		
S	2	
M	1	
Other		
Lu^a	1	
Lu^b	1	
HTLA	1	

Serology – DHTRs only

Table 27 shows the technology used for antibody screening by IAT.

Table 27
IAT technology used for antibody screening

IAT screening technology	Number of cases	By automation
DiaMed	7	6
BioVue	9	6
Solid phase	3	3
Liquid phase microplate	1	0

For pre-transfusion testing, plasma was used in 16 of the 20 cases, serum was used in 2, and 2 were not stated.

An IAT crossmatch was undertaken in 10 cases (7 had antibodies present pre-transfusion, and 1 was retrospective), immediate spin was undertaken in 2 cases, and electronic issue (EI) in 8. This is likely to be representative of techniques being used routinely, although available data are incomplete. In 2005, 26% of UK laboratories were routinely using electronic issue, and data provided by a proportion of UK laboratories for the National Transfusion Laboratory Collaborative telephone survey suggest that this is now much higher. The data also suggest that an even higher proportion of transfusions are given based on EI, as it is the higher throughput laboratories that are more likely to be using full automation and EI.

Use of eluates

In 12/20 cases (60%) an eluate made from the patient's post-transfusion red cells was tested for antibody – this has increased from 35% last year; 8/12 were performed in reference labs and 4 in-house. In 10 cases specific antibody(ies) was identified.

Retrospective testing findings

Retrospective testing of the pre-transfusion sample was undertaken in house in 10 (50%) cases; 2 were referred directly to the reference centre, and another 5 were confirmed by a reference centre.

Clinical management and review

Twenty-one (91%) of cases were referred to the HTC, and 13 (57%) to the Transfusion Centre Reference Laboratory.

Delayed haemolytic transfusion reactions (DHTR)

Case D2

A 36-year-old male with antiphospholipid syndrome and peripheral vascular disease required massive transfusion (> 30 units of red cells) following rupture of the iliac artery during a stenting procedure. Ten days later the patient showed clinical and laboratory signs of a severe DHTR, though the clinical picture was complicated by the acute clinical condition. The patient suffered from dyspnoea, jaundice, falling Hb and deteriorating renal function, requiring dialysis. The DAT was positive and anti-Jk^a was identified in the post-transfusion plasma, and in an eluate made from the patient's red cells.

Case D5

A 56-year-old male admitted with a ruptured aortic aneurysm received an emergency transfusion of 2 units O D negative and 6 units of ABO/D matched red cells. Retrospective serology revealed anti-Fy^a, and 3 of the transfused units were found to be incompatible. A further 14 units of Fy(a-) red cells were transfused over a 4 day period. Ten days after admission the patient was febrile and jaundiced, and the bilirubin rose to 150 µmol/mL. The NBS reference laboratory identified anti-C in addition to anti-Fy^a (anti-E could not be excluded); the DAT was positive (both IgG and C3 coating) and an eluate made from the patient's red cells contained both anti-Fy^a and anti-C. The patient made a full recovery.

This case above is interesting as, although incompatible blood was transfused and anti-Fy^a was eluted from the transfused red cells, no signs of a transfusion reaction were noted until day 10.

Case D6

A 70-year-old female with an ischaemic transverse colon and sepsis, received 3 units of red cells during a hemicolectomy. Five days later a new sample was received for further crossmatching as the postoperative Hb was 6.8 g/dL. One unit of red cells was transfused, on each of 3 successive days, starting on the day after the sample was taken. Two days later the patient became jaundiced and the Hb had dropped back to 6.1 g/dL. The patient was on ITU with multi-organ failure, making a diagnosis of DHTR complicated. The DAT was positive and the post-transfusion plasma contained anti-Fy^a, which was also eluted from the red cells. The NBS reference laboratory also identified a possible anti-f and an HTLA antibody. It is not known which of the units were Fy(a+). The patient died on ITU but this was unrelated to the DHTR.

A procedural review identified that a new sample should have been requested after the first of the 3 units transfused postoperatively, because the patient had been transfused 6 days earlier.

Case D7

A 62-year-old female was admitted with an Hb of 3.5 g/dL and referred to a haematologist. She produced an old BTS card stating that she had anti-K + anti-C, and was transfused with 5 units of phenotyped red cells. Six days later her Hb fell dramatically from the post-transfusion level of 8.5 g/dL back down to 3.6 g/dL, with no evidence of bleeding. The bilirubin increased from 22 to 83 µmol/mL. Anti-Jk^b and anti-Lu^b were identified in both the plasma and an eluate. The patient made a full recovery.

Case D15

A 63-year-old female was admitted through ED, with dehydration, confusion and renal impairment. She had been transfused 6 days previously and had known anti-E+K and a positive DAT (IgG and C3 coating). E-K- units were all found to be incompatible using a BioVue technique, but the reference laboratory reported no antibodies using different techniques. She was transfused with a further 3 units of E-K- red cells for symptomatic anaemia. Over the next 2-3 days her Hb dropped from 7.0 g/dL pre-transfusion to 2.7 g/dL, her bilirubin rose from 14 µmol/L to 69 µmol/L, and the plasma showed haemolysis. No further antibodies were identified by the reference laboratory and the DAT was equally positive pre- and post-transfusion. A further 8 units of red cells were transfused over the next 4 days, and the patient was started on IVIg, but died before a full diagnosis could be made. It is unclear whether the haemolysis was due to a developing AIHA or hyperhaemolysis as a result of the transfusion.

Case D20

An 89-year-old male with myeloproliferative disease required 2 units of red cells for top-up transfusion. He had received a transfusion 6 days previously. A new sample was taken 2 days before the implicated transfusion. The antibody screen was positive, anti-K identified, and 2 units of K- blood were given. During transfusion of 1 of the units the patient became febrile, had an increase in heart rate and difficulty breathing, and the transfusion was stopped; however, the reaction was not reported to the transfusion team until 2 days later. The bilirubin rose from 15 to 50 µmol/L and the Hb dropped from 7.1 g/dL pre-transfusion to 6.1 g/dL over the 5 days following transfusion. However, the reporter feels that these factors could have been due to developing disease. A sample taken 2 days after transfusion was DAT positive and anti-K again identified. Weak anti-Jk^{a}, reacting only by a sensitive enzyme antiglobulin test, was identified by the reference laboratory in both the pre- and post-transfusion plasma samples and eluates. The patient died, but this was thought to be unlikely to be related to the transfusion (imputability 1).

Although a reaction occurred during transfusion, it was thought likely that the patient was suffering from a delayed reaction to the earlier transfusion.

Learning points

- If a patient has been transfused within the last 3-14 days, a fresh sample should be taken within 24 hours of the next transfusion, in line with BCSH guidelines[16].
- Kidd antibodies are often difficult to detect, and more sensitive techniques may be required to confirm the identification.
- Transfusion reactions should be reported the transfusion team immediately, so that appropriate investigations can be undertaken.

COMMENTARY

- Group O apheresis and on this occasion pooled platelets, which tested negative for high-titre haemolysins, have once again caused haemolytic reactions, although in 1 case retrospective testing confirmed that 1 of the donors was high-titre positive. There have been 11 previous reports to SHOT of group O platelets causing ATRs in group A or B recipients – 4/7 (57%) have occurred in paediatric patients (in 4 cases the age was not recorded), and in 8/11 cases apheresis platelets were implicated.

- In all cases but 2 (where an answer was given), plasma rather than serum was used for both pre- and post-transfusion investigations. It is known that weak complement binding antibodies, e.g. some examples of anti-Kidd, may be missed when using plasma, unless more sensitive techniques are used, e.g. enzyme IAT.

- This year 60% of investigations included testing an eluate made from the patient's red cells, compared with only 35% last year. Where a mixture of antibodies is present, an eluate may help to distinguish which specificity(ies) is more likely to be implicated in a haemolytic reaction. Furthermore, the implicated antibody may be present only in an eluate. Identification of all specificities present is essential if further haemolytic reactions are to be prevented.

RECOMMENDATIONS

There are no new recommendations this year; however, previous recommendations remain relevant and the first 5 are pertinent to this year's cases.

Year first made	Recommendation	Target	Progress
2005	All cases of suspected AHTR and DHTR should be appropriately investigated, and ideally referred to a reference laboratory. Referring hospitals should make it clear to reference laboratories that they are investigating an HTR to ensure that timely, appropriate tests are undertaken. Clinical details should be completed on the request forms and the donation numbers of the units transfused should be included, so that their phenotype can be determined	**Hospital blood transfusion laboratories, Blood Service reference laboratories and the NBTC Transfusion Laboratory Managers' Working Group**	BCSH guidelines for investigation and management of transfusion reactions are in progress
2005	Reference laboratories should ensure that investigation of DHTRs includes testing an eluate made from the patient's red cells when the DAT is positive	**Blood Service reference laboratories**	Eluates were undertaken in 60% of cases this year compared with 35% in 2006 and 50% in 2005; however, numbers are too small to draw any conclusions
2005	Pre-transfusion testing on patients who have been recently transfused and require further transfusion should be carried out in accordance with BCSH Guidelines[16] relating to the timing of the samples	**Hospital blood transfusion laboratories and the NBTC Transfusion Laboratory Managers Working Group**	This recommendation was made in Guidelines for Compatibility Procedures in Transusion Laboratories, BCSH (2004)[16]
2003	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	**BBTS and BCSH**	During 2008 this issue will be addressed by the writing group for the revised BCSH guidelines for compatibility procedures in blood transfusion laboratories
2001/02	Investigation of a suspected HTR should include retesting of the pre-transfusion sample (where still available) by different or more sensitive techniques. Consideration should also be given to requesting clotted samples for investigation of suspected HTRs and using polyspecific AHG. These actions may involve referral to a reference centre	**Hospital blood transfusion laboratories and the NBTC Transfusion Laboratory Managers Working Group**	BCSH guidelines for investigation and management of transfusion reactions are in progress
2001/02	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	**The CMO's NBTC and its counterparts in Scotland, Wales, and Northern Ireland**	This recommendation was made in the BCSH Guidelines (BCSH, 2004)[16]
2000/01	Group identical platelets should be selected whenever possible, with group O being the last choice for non-group O recipients. Blood Services should stock higher levels of non-group O platelets	**Hospital blood transfusion laboratories, Blood Service Issue departments and the NBTC Transfusion Laboratory Managers Working Group**	'Amendments and Corrections' to the BCSH guidelines 'Transfusion Guidelines for neonates and older children' clarifies these recommendations (2004)

9. Transfusion-Related Acute Lung Injury (TRALI)

Definition

Transfusion-related acute lung injury (TRALI) is defined as acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6 hours of transfusion, not due to circulatory overload or other likely cause.

DATA SUMMARY

Total number of cases	**24**	*Implicated Components*		*Mortality / morbidity*	
		Red cells	**5**	Deaths due to transfusion	**1**
		FFP	**0**	Deaths in which reaction was contributory	**0**
		Platelets	**5**	Major morbidity	**15**
		Other (therapeutic granulocytes, buffy coat)	**1**		
		Undetermined	**13**		

Gender		*Age*		*Emergency vs. routine Core hours vs. out of core hours*		*Where transfusion took place*	
Male	**9**	<16 years	**0**	Emergency		A & E	
Female	**15**	<1 year	**0**	Routine		Theatre	
		<4 weeks	**0**	Not known	**24**	ITU/HDU/Recovery	
						Wards	
				In core hours		Community	
				Out of core hours		Other	
				Not known/applicable	**24**	Not known	**24**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)	
In how many cases was failure or absence of IT a factor?	Not applicable
In how many cases was a transfusion possibly unnecessary or inappropriate?	1 inappropriate, 23 not known

In this reporting year 36 initial reports of suspected TRALI were received, but 12 were subsequently withdrawn – 4 by the reporters because the events were attributed to other causes, and 8 cases did not fulfil the above definition. Six of them had clear alternative reasons for symptoms: 2 bronchopneumonia, 1 fat embolism, 3 congestive cardiac failure. Four cases occurred more than 6 hours after transfusion and in 3 cases the chest X-ray (CXR) did not show bilateral infiltrates. More than one reason for exclusion was present in 5 of these cases.

Twenty-four cases were analysed and the assessed probability of TRALI is shown in Figure 9. One patient died in a case assessed as probable TRALI; this death was assessed as probably related to TRALI. Three patients died of their underlying condition and all others made a full recovery. Thirteen of the 24 analysed cases concerned late reporting of incidents which had occurred before December, 2006. This may explain the drop in case reports seen in the 2006 SHOT Annual Report, followed by a rise this year.

Website tables

Summarised information is presented in this chapter. Data extracted from individual TRALI questionnaires and laboratory results for each case have been tabulated and are available on the SHOT website www.shotuk.org.

TRALI Table 1 Patient and component details and patient characteristics
TRALI Table 2 Clinical characteristics and radiological features of cases reported as TRALI
TRALI Table 3 Treatment, investigation results and likelihood of case being TRALI

Figure 9
Summary of cases

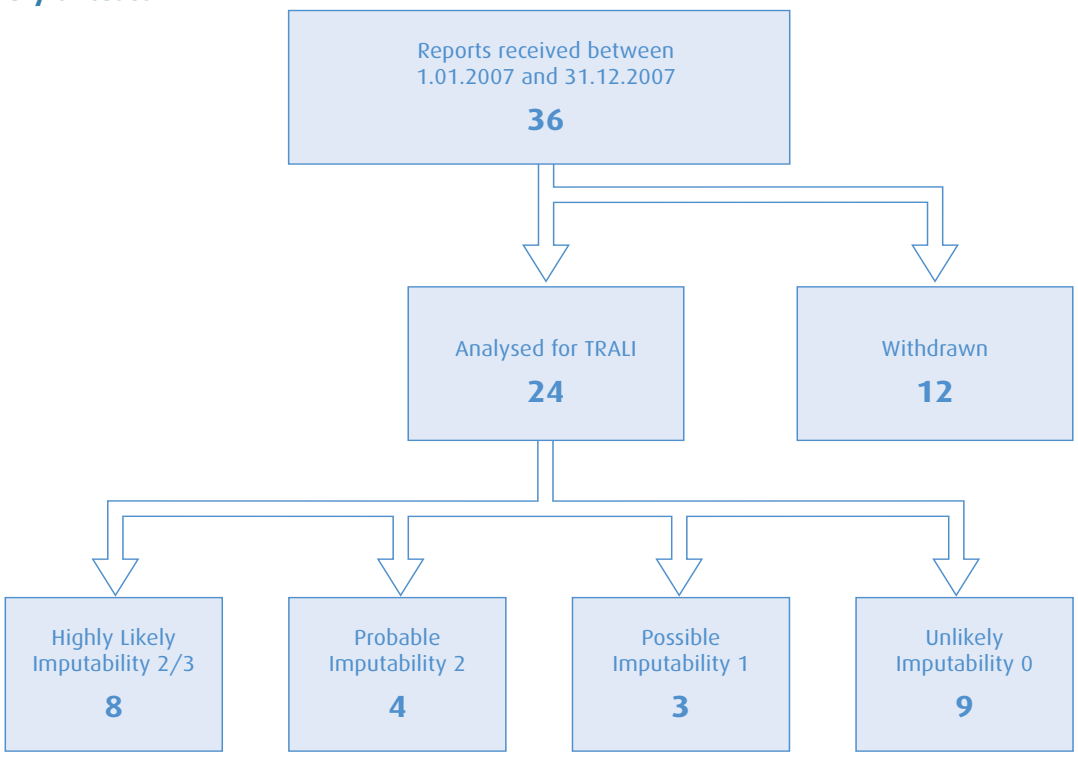
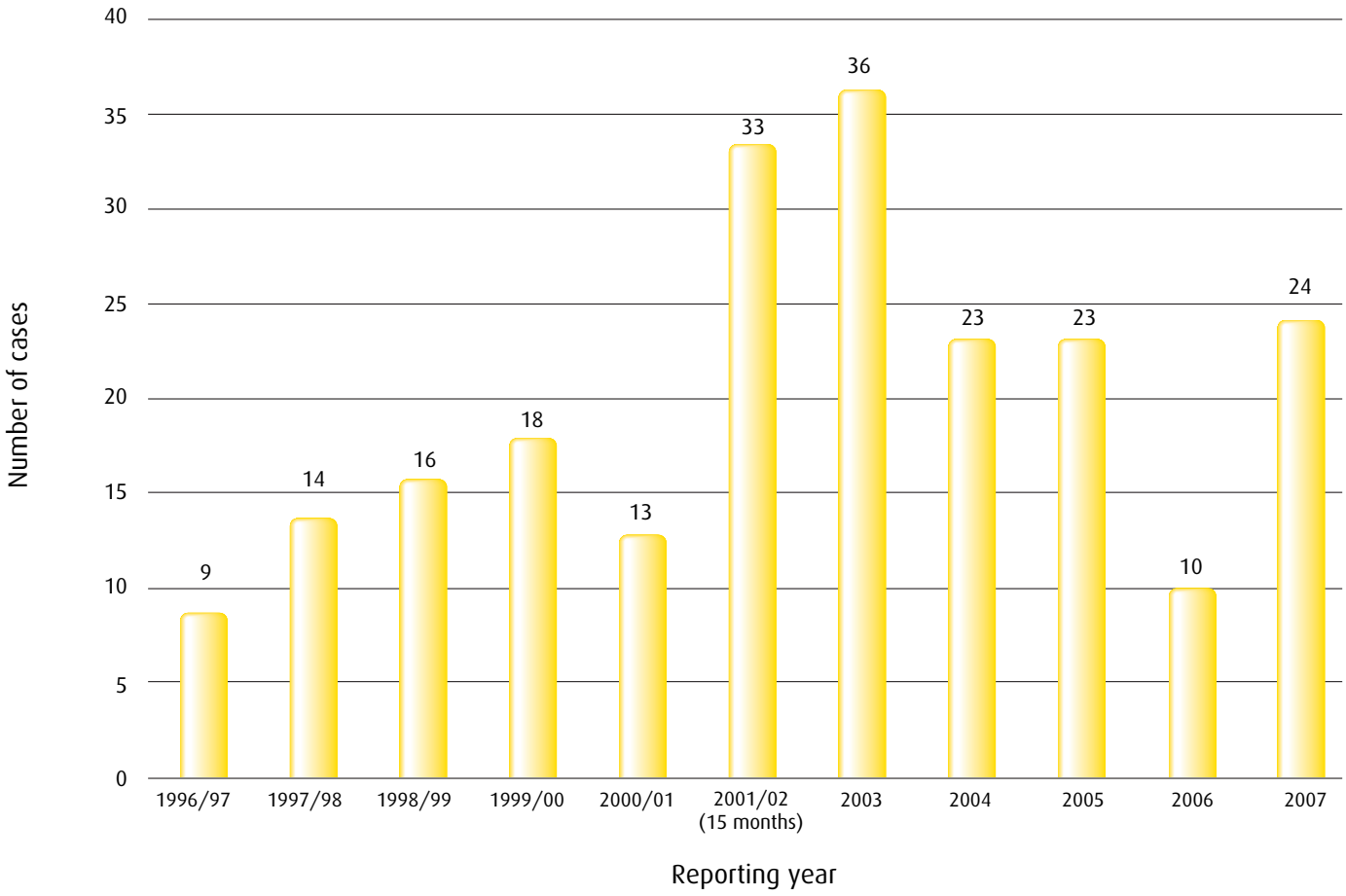


Figure 10
Cumulative cases of TRALI 1996–2007



Assessment of TRALI reports

TRALI is difficult to diagnose because there is no specific test for this condition and it is easily confused with other causes of acute lung injury, cardiogenic pulmonary oedema and circulatory overload. The diagnosis is straightforward if acute lung injury (ALI) occurs in a previously fit transfused patient and relevant leucocyte antibodies are found. Often however, it occurs in patients who have other risk factors for the development of ALI or Acute Respiratory Distress Syndrome (ARDS). When TRALI is suspected, a detailed assessment of the clinical event is required together with investigation of the patient and donors. Early discussion with the blood service is required and blood samples (EDTA and clotted) from the patient should be sent promptly to a blood service reference laboratory.

Clinical factors which have been taken into consideration in the assessment of reported cases include: time between transfusion and respiratory deterioration; radiological features; possibility of infection; other risk factors for ALI/ARDS; evidence of circulatory overload and/or impairment of cardiac function; pre-existing cardiac, pulmonary, renal or other disease; fluid balance in the previous 24-48 hours; and response to diuretics were assessed when possible.

Results of TRALI laboratory investigations may not be definitive. Because of the frequency of leucocyte antibodies in the donor population, donor antibodies would also be found in many uneventful transfusions if they were similarly investigated. In an NBS study of 1166 female donors, HLA antibodies were found in 14.5% (personal communication, Dr S. MacLennan). It is important to establish whether concordance exists.

The likelihood of TRALI has been assessed in each case. Two intensive care specialists and a transfusion medicine expert (TRALI Expert Panel) have initially assessed all cases reported to the NBS in 2007 (22 of 24) before laboratory investigation. A transfusion medicine specialist, who has also reviewed cases for the past 4 years, has subsequently assessed all cases with the results of TRALI investigations. Reports were finally graded on the basis of both clinical features and laboratory results. Complete results of investigations were not available in 6 cases. Four of these cases were not investigated following advice from the expert panel.

As in previous years, cases were divided into 4 groups: 'Highly likely', where there was a convincing clinical picture and positive serology; 'Probable', where there was either a less convincing history and positive serology or a good history and less convincing or absent serology; 'Possible', where either the clinical picture or serology was compatible with TRALI, but other causes could not be excluded; and 'Unlikely', where the picture and serology were not supportive of the diagnosis (Figure 9).

American–European Consensus definition compared with SHOT definition

Cases have also been separately assessed by the same SHOT analyst for probability of TRALI according to the American-European consensus definition for comparative purposes. This definition was based on panel assessment of evidence presented by experts (evidence level 3 / 4, grade D)[17,18]. This resulted in 9 cases being classified as TRALI and 12 cases as possible TRALI; 3 would have been excluded because there was some evidence of heart failure.

Age

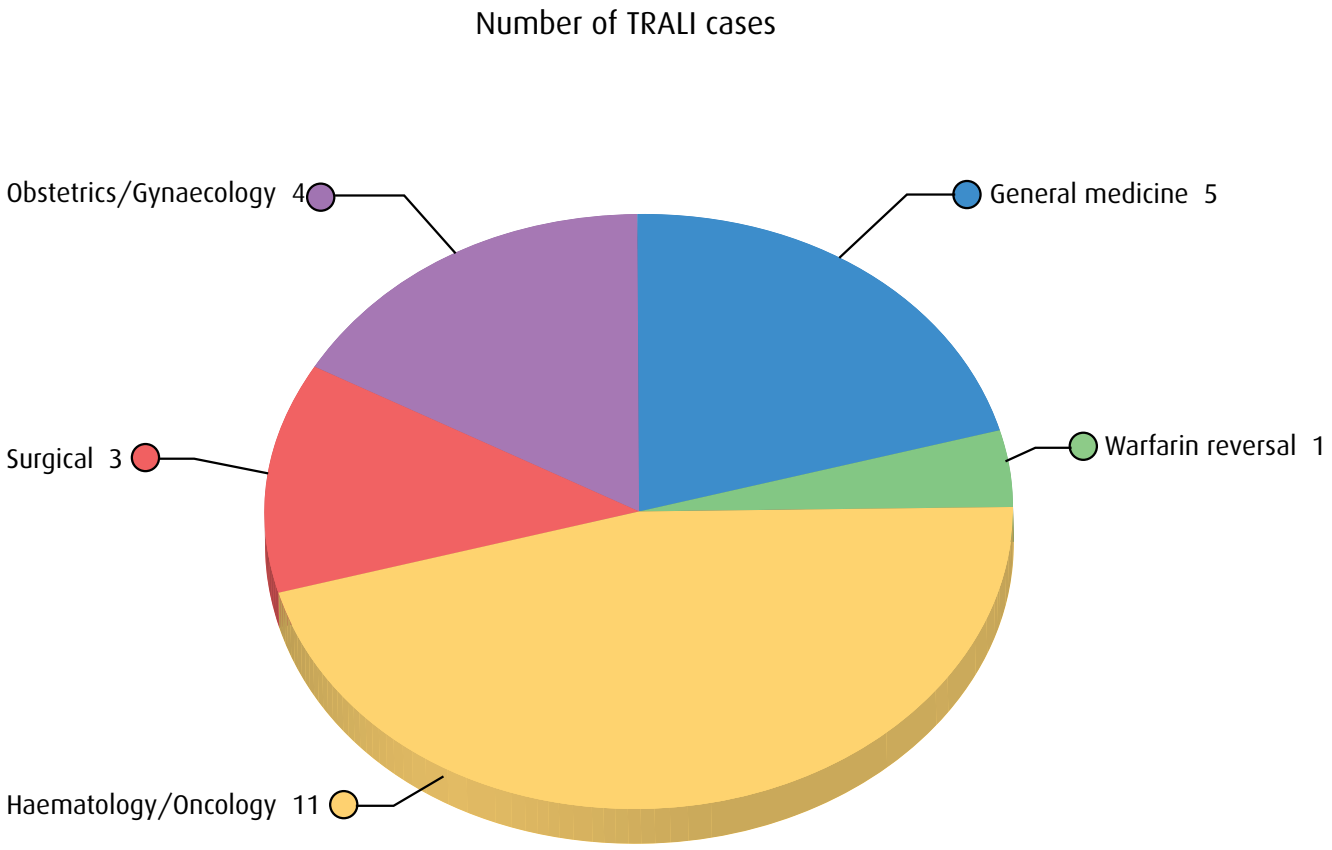
Patient ages ranged from 16 to 88 years with a median age of 50. Two patients were under 18 years of age.

Clinical Speciality/diagnosis

Reports have been analysed according to clinical speciality (Figure 11). The most frequent speciality was haematology/oncology (11 case reports, 46%) followed by general medicine (5), obstetrics and gynaecology (4), and surgery (3). There was 1 report following warfarin reversal with FFP together with red cells and platelets in a patient with a ruptured ectopic pregnancy. This case was assessed as unlikely to be TRALI. All 4 units of FFP were from untransfused males; and all other donors were either untransfused males or females who tested negative for concordant antibodies.

Analysis of cumulative figures since 1996 from 219 analysed reports of suspected TRALI has shown that haematology/oncology combined provided the highest number of reports of suspected TRALI (81, 37%) and surgery provided the second highest (73, 33%).

Figure 11
Clinical speciality/diagnosis



Clinical features

Clinical presentation

Details of all reported cases are tabulated in TRALI Table 2 on the SHOT website www.shotuk.org.
All cases, by definition, had been dyspnoeic or tachypnoeic and hypoxic with CXR features of acute lung injury. Fifteen patients (63%) were treated in intensive care units, of these 2 were already on ITU before the event. Ten patients (42%) required mechanical ventilation of whom 2 were already on ventilators at the time of the reaction. Fever/rigors were reported in 10 patients, absent in 12 and not recorded in 2. Hypotension was reported as part of the reaction in 7 cases, absent in 16 and not reported in 1. Three of the cases with hypotension had laboratory support for the diagnosis.

Patient outcomes

Details of all reported cases are tabulated in TRALI Table 3 on the SHOT website.
One patient died probably due to TRALI. Three other outcomes were reported as death unrelated to transfusion. Twenty patients were reported to have made a full recovery from the episode.

Laboratory results

Details of all reported cases are tabulated in Table 2 on the SHOT website.
All cases were referred to a blood centre for investigation, and 20 of 24 cases were subsequently investigated at reference laboratories. Complete TRALI investigations were achieved in 18 of these cases. Laboratory investigations were not undertaken in 4 of the 24 analysed cases following advice from the TRALI Expert Panel; 2 of these had involved patients with severe sepsis, 1 with cardiac impairment and 1 with hepato-renal impairment.

Donor antibodies

All donors in whom concordant leucocyte antibodies were identified were female. Transfused males (transfused pre-1980) were investigated but none was identified with relevant antibodies. Untransfused males were only investigated if all other donors had been investigated and excluded and no other likely cause for ALI had been identified. All individuals who have been transfused since 1980 have been excluded from donation in the UK since 2004.

Concordant donor leucocyte antibodies (i.e. donor HLA or granulocyte antibody corresponding with patient antigen) were found in 11 of 18 (61%) complete case investigations this year. Seven cases were associated with concordant HLA antibodies only (4 with HLA class I and class II antibodies and 3 HLA class II only) and 3 cases had concordant donor HNA antibodies only. Another case had donors with concordant HNA and HLA class I antibodies. The antibody specificities are listed in Table 28.

Table 28
Concordant donor antibodies – specificities and implicated components

Antibody	Specificity/ies	Component *
HLA class I and HNA	HLA-A2 and HNA-1a	Therapeutic granulocytes (buffy coats)
HLA class I and class II	HLA-A2 and DR4	Whole blood (Case 3)
HLA class I and class II	HLA-A2 and DR4	Platelet pool (buffy coat only)
HLA class I and class II	HLA-B39, DR8, DR13, DQ4	RBC OA
HLA class I and class II	HLA-B27, DR51, DQ6	RBC OA
HLA class II	HLA-DR 17	Platelet pool (buffy coat only)
HLA class II	HLA-DR13, DR17 and DR52	Apheresis platelets (Case 2)
HLA class II	HLA-DQ6	Platelet pool (buffy coat only)
HNA	HNA-1a	Platelet pool (buffy coat only)
HNA	HNA-1a	RBC OA
HNA	HNA-3a	RBC OA

* Platelet pools are produced by pooling components from 4 donors. One donor (preferentially male) contributes a whole unit of plasma (nominally 300 mL) and a buffy coat (platelets suspended in approximately 30 mL of plasma), and 3 other donors (either gender) each contribute a buffy coat. A dose of therapeutic granulocytes usually comprises buffy coats from 10 donors (not pooled).

Patient antibodies

Leucocyte antibodies were identified in 7 patients and in 4 of these the antibodies matched at least 1 donor. Leucocyte antibodies were negative in 11 patients and not known in 6. In all cases except 1 (therapeutic granulocytes) leucocyte depleted components had been transfused and the patient antibody is, therefore, not thought to have caused these clinical events. In the case which followed buffy coat transfusions to provide therapeutic granulocytes, the patient had anti-HLA-B45. Nine of the 10 buffy coat donors were negative for this HLA type but a repeat sample could not be obtained from the tenth donor so it was not possible to exclude concordance with this transfused component. Two of the buffy coat donors were found to have concordant antibodies with this patient; 1 had anti-HLA-A2 and 1 had anti-HNA-1a.

Components

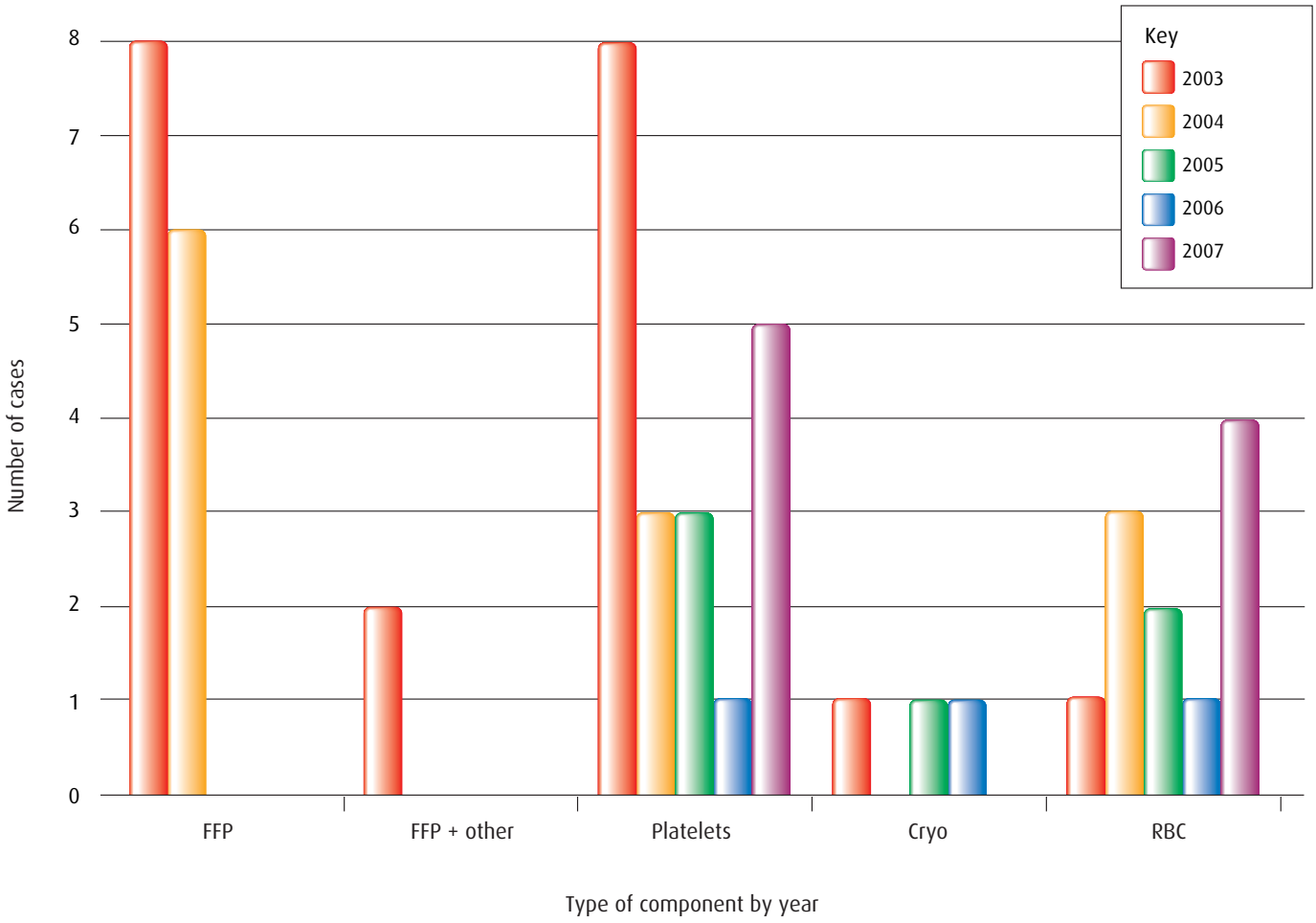
Details of all implicated components are tabulated in TRALI Table 1 on the SHOT website and are also included in Table 28 above.

All implicated components with concordant donor leucocyte antibodies were donated by females. Platelets were implicated in 5 cases, RBC Optimal Additive (OA) in 4 cases, whole blood in 1 and buffy coat granulocytes in 1. Of the 5 platelet related cases, 1 received apheresis platelets and 4 received pools. The implicated donors for the pools contributed only a buffy coat to the pool in each case. No case was found involving FFP or the plasma contribution to a platelet pool containing a proven concordant antibody, but in 1 case (Case 1) investigation could not be completed.

Comparative data on implicated components since 2003

TRALI cases proven to involve donors with concordant leucocyte antibodies have been analysed by implicated component from 2003 to 2007. Results are shown in Figure 12. Cases involving FFP with concordant antibody have dropped from 10 in 2003 to none in the last three years. Cases involving platelets and red cells with concordant antibodies have increased this year.

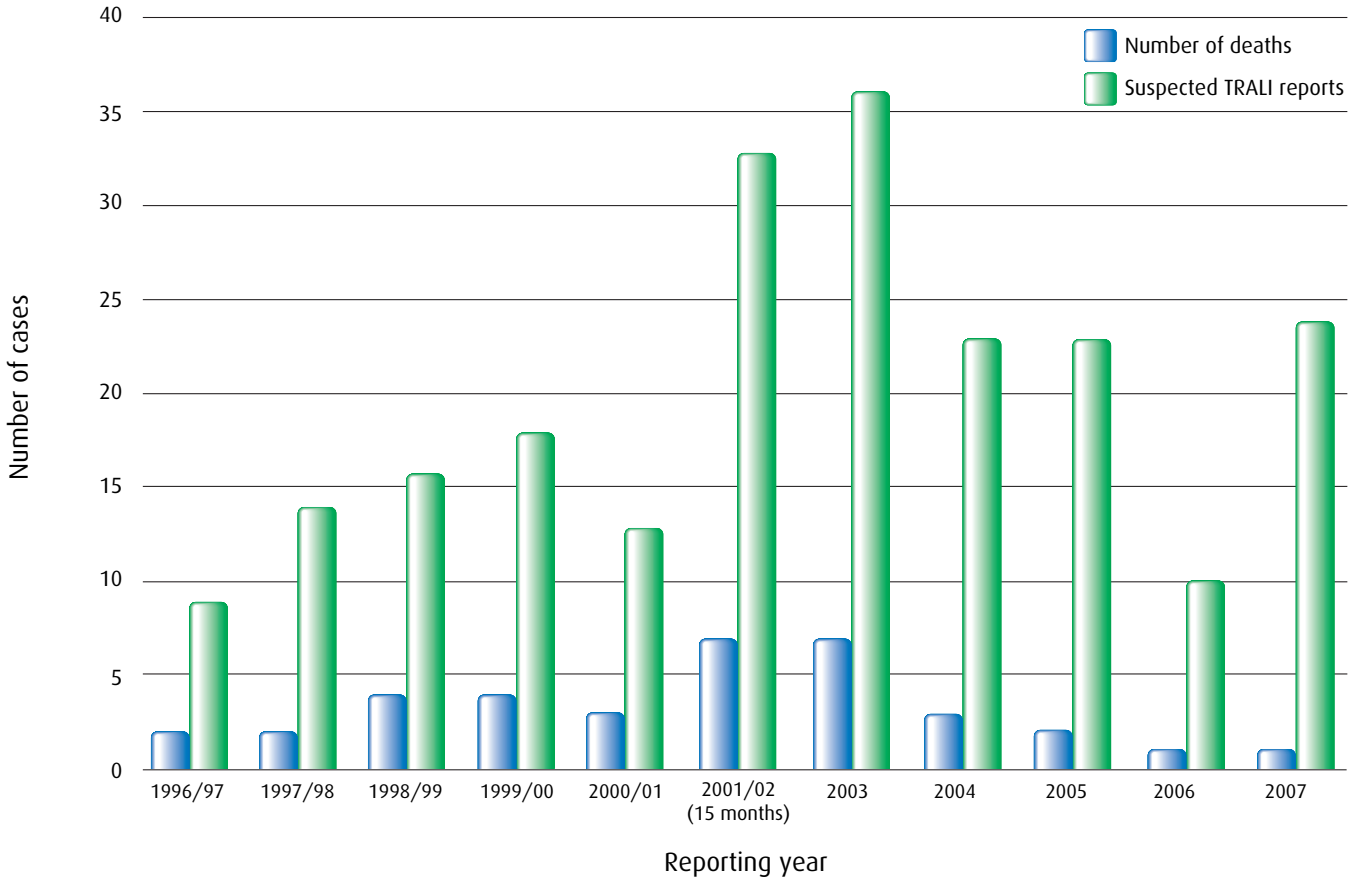
Figure 12
Cases of TRALI with concordant donor antibody analysed by implicated component and by year 2003–2007



Annual reports and deaths 1996–2007

The annual number of reports of suspected TRALI and deaths at least possibly due to TRALI each year from 1996 are shown in Figure 13. Annual reports of TRALI and deaths due to TRALI continue to show a reduction compared with 2003; preferential male plasma policies were introduced in late 2003. The reduction in cases in 2006 compared with 2004 and 2005 may have been due to unfamiliarity with the new web-based reporting system. More than half of the 24 analysed 2007 reports were late reports relating to cases transfused in earlier years. Three occurred in 2005, 10 in 2006 and 11 in 2007.

Figure 13
Deaths at least possibly due to TRALI and number of suspected TRALI reports by year



Case histories

The case numbers used here correspond with those used on the web-based tables.

Case 1

A 64-year-old patient with myelodysplasia was admitted with melaena. Her haemoglobin was 10.7 g/dL and her platelet count was 16 x 10^9/L. She was transfused with 2 platelet pools. She had been able to walk around the ward before transfusion and had no history of cardiac problems. She collapsed with dyspnoea 10 minutes after transfusion of the second pool was completed. The clinical detail was scanty but indicated that she required ITU admission and ventilation for two weeks before she died and that her CXR showed an ARDS picture. The reporter indicated that she had no history of cardiac problems, she was not overloaded with fluid and her ECG and troponin measurements showed no evidence of a cardiac event.

Donor investigations found that the platelet pool transfused closest in timing to the event included both 300 mL plasma and buffy coat platelets (approximately 30 mL plasma) from a female donor with HLA-DR11 antibodies; and buffy coat platelets only from a female donor with non-concordant HLA class I antibodies and HLA class II antibodies specific for HLA-DR11,12,13,14,17,18 and weak antibodies to HLA-DR1 and HLA-DR8. The samples from the patient were only sufficient for HLA class I typing and the significance of the multiple HLA class II antibodies could not, therefore, be determined. On balance, this case was assessed as probable TRALI. The patient's death was assessed as probably related to TRALI.

Case 2

A 30-year-old patient who was 35 weeks pregnant had refractory ITP and a breech presentation. She was known to be asthmatic. A caesarean section (CS) was planned and she was given two units of apheresis platelets before this was performed under general anaesthesia. During this procedure the baby was safely delivered but the patient bled approximately 1.5L blood quickly and was given syntocinon and ergometrine together with 1L normal saline and 500 mL Hexastarch. At the end of the procedure, the anaesthetist reversed paralysis and was waiting to extubate but the patient developed bronchospasm and tachycardia and then copious secretions from endotracheal (ET) tube described as red-tinged, white froth. She was treated with frusemide and nebulisers and was transferred to ITU. A 600 mL diuresis followed over the next 2 hours but she could not be extubated. Her secretions settled over 2½ hours but she required continuing ventilation for the next 3 days. Her CXR showed bilateral fluffy opacities. She made a complete recovery.

Donor investigations found that the first platelet unit had been donated by a female donor who had multiple HLA class II antibodies including antibodies specific for HLA-DR13, DR17 and DR52. The patient typed positive for all 3. This case was assessed as highly likely to have been TRALI.

Case 3

A 27-year-old female was admitted after a 3–5 day history of abdominal pain with hypotension and tachycardia: a ruptured ectopic pregnancy was diagnosed with 2 litres of blood in the abdomen. She was taken to theatre for a laparotomy and was transfused with 2 units of whole blood in theatre. She remained tachycardic overnight with oxygen saturation of 96% on 2 litres of oxygen via nasal specs. On the following day, her haemoglobin was 65 g/L and she was transfused with 1 further unit of whole blood. Two hours after this unit was commenced she collapsed with acute respiratory distress, oxygen saturation 70% on 2 litres of oxygen and a temperature of 39^{0}C. Portable AP chest X-ray showed bilateral non-specific increased density of lower zones with small areas of volume loss in the right lung. She was supported with CPAP on ITU and made a rapid recovery. She was discharged home 4 days after her surgery.

The unit of whole blood was donated by a 43-year-old female who had multiple HLA class I and class II antibodies, including antibodies to HLA-A2 and HLA-DR4, both of which were present in the patient.

COMMENTARY

- TRALI remains a serious complication of transfusion with 12 probable or highly likely cases this year.
- One death was probably related to TRALI; this is the same mortality as in 2006 which was the lowest reported since 1996.
- Eight of 36 initial case reports did not fulfil the SHOT TRALI case definition and were excluded from analysis. Four analysed cases were not investigated following advice from the TRALI National Expert Panel.
- An overall increase was observed in the number of reports received in 2007 which met the definition compared with 2006. In 2007, 13 of 24 cases concerned late reporting of suspected TRALI that had occurred before December, 2006. This will have contributed to the observed decrease in reports in 2006 and relative increase in 2007.
- TRALI cases assessed as highly likely/probable (imputability 2/3) have increased this year to 12 in contrast to previous decreases from 22 in 2003 to 13 in 2004, 6 in 2005 and 3 in 2006. This may be partly explained by delayed reporting of 2006 cases.
- Increases were also seen this year in the number of cases with concordant donor leucocyte antibodies following red cell (5) and platelet (5) transfusion. Eight of these 10 cases involved transfusion of only a relatively small quantity of donor plasma (RBC OA (4) or only the buffy coat contribution to a platelet pool (4)). Also, 1 case followed transfusion of 10 buffy coat granulocytes – each buffy coat contains approximately 30 mL of plasma. In this case 2 donors had concordant antibodies. The increased reporting of cases concerning relatively small quantities of plasma may reflect increased awareness of TRALI and haemovigilance reporting requirements.

- There is clear evidence that TRALI can follow transfusion of components containing relatively little plasma. With regard to platelet pools, replacement of the plasma contribution to the pool by male plasma or platelet additive solution (PAS) is likely to reduce but not eliminate the risk of antibody-mediated TRALI.

- Female donors were implicated in all cases in which concordant leucocyte antibody was found (11 cases). Eight cases involved HLA antibodies and 4 cases HNA antibodies (one of the cases had both). The implicated components were RBC OA (4 cases), whole blood (1), platelet pool (4), apheresis platelets (1) and buffy coat granulocytes (1).

- Whole blood was implicated in Case 3. This was used to correct postoperative anaemia. Whole blood is never indicated for use in these circumstances.

- No case of TRALI due to transfusion of FFP from a donor with a concordant leucocyte antibody has occurred during the last 3 years.

- One highly likely case of TRALI followed transfusion of platelets from a female apheresis donor who had multiple concordant HLA class II antibodies. Screening of all female donors for leucocyte antibodies has not yet been introduced throughout the UK, although the Welsh Blood Service already routinely screens female apheresis donors for HLA antibodies.

- The Department of Health recommends increasing the proportion of platelet doses provided by apheresis to 80% (to reduce the number of donors to whom each recipient is exposed). This makes it more important to consider introducing the screening of female donors for leucocyte antibodies by all UK Blood Services. PAS replacement of plasma in apheresis donations instead would not be sufficient because 100 mL of donor plasma would still be left on the platelets.

- The NBS introduced preferential recruitment of male apheresis platelet donors in 2006, but existing female platelet donors continue to donate (approximately 25% donations). NBS will shortly introduce screening of all new female apheresis donors for leucocyte antibodies, and replacement of 70% plasma in platelets with platelet-additive solution is under consideration. The Welsh Blood Service already routinely screen all female apheresis donors for HLA antibodies.

- FFP from the Welsh Blood Service (WBS), Northern Ireland Blood Transfusion Service (NIBTS) and Scottish National Blood Transfusion Service (SNBTS) is 100% male, and plasma for platelet pooling from WBS and SNBTS is also 100% male. NBS in 2007/08 produced 93.7% of FFP and 86.6% of plasma for platelet pooling from male donors. Increase to 100% from male donors for both of these components should be possible when NBS move to the overnight hold of whole blood prior to processing, which will be phased in in 2008/9.

RECOMMENDATIONS

There are no new recommendations for this year.

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2006	UK Blood Services should continue to investigate and apply methods to reduce the continuing risk of TRALI associated with apheresis donations, reducing the number of female donors on the panel, and testing those remaining for HLA antibodies. This year only 1 case involved an apheresis donor with a concordant antibody but this recommendation remains relevant	**UK Blood Services**	The UK Blood Services have increased the proportion of male only plasma for platelet suspension since last year, with WBS and SNBTS now up to 100%. Screening of female apheresis platelet donors is already underway in WBS and is soon to commence in NBS
2005	Hospital staff should continue to be aware of TRALI and report possible cases to the local blood centre to facilitate investigation. Detailed clinical information is needed to allow accurate clinical assessment of these cases. Blood samples (clotted and EDTA) from affected patients should be sent promptly for laboratory investigation. Continued education of all relevant staff about this condition is encouraged	**HTTs**	BSQR and NPSA requirements have increased awareness of the need for training and education in transfusion medicine beyond competencies. A Royal Colleges and Specialist Societies subgroup of NBTC is addressing this in Engdand; doctors' transfusion education (e-learning) is mandatory in Scotland and Northern Ireland
2005	Cases should be evaluated early by the consultant(s) involved and prompt discussion with the blood service is helpful. A team approach including the haematologist and chest physician and/or ITU consultant is recommended	**Clinical users of blood and consultant haematologists with responsibility for transfusion**	
2005	Case 3 from the 2005 report emphasizes the importance of avoiding transfusing whole blood	**Blood Services, clinical users of blood and consultant haematologists with responsibility for transfusion**	Whole blood is no longer supplied by any of the four UK Blood Services. It is still used in the Channel Islands

10. Post-Transfusion Purpura (PTP)

Definition

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

DATA SUMMARY

Total number of cases	**2**	*Implicated components*		*Mortality / morbidity*	
		Red cells	**2**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths in which reaction was contributory	**0**
		Platelets	**0**	Major Morbidity	**0**
		Anti-D	**0**		

Gender		*Age*		*Emergency vs. routine Core hours vs. out of core hours*		*Where transfusion took place*	
Male	**0**	<16 years	**0**	Emergency		A & E	**0**
Female	**2**	<1 year	**0**	Routine		Theatre	**0**
		<4 weeks	**0**	Not known	**2**	ITU/HDU/recovery	**0**
						Wards (clinics)	**0**
				In core hours	**0**	Community	**0**
				Out of core hours	**0**	Other	**0**
				Not known	**2**	Not known	**2**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)

In how many cases was failure or absence of IT a factor?	**N/A**	
In how many cases was a transfusion possibly unnecessary or inappropriate?	**N/K**	

Two cases of PTP were reported this year, 1 associated with HPA-1a antibody and 1 with HPA-1b antibody.

Case 1

A 74-year-old female was admitted for elective abdominal aortic aneurysm repair. Her preoperative platelet count was 242 x 10^9/L. She had an estimated blood loss of 5536 mL and was transfused uneventfully with 11 units of red cells and 2 units of fresh frozen plasma perioperatively. Eleven days later it was found, incidentally, that her platelet count had decreased markedly to 15 x 10^9/L. She had no related signs or symptoms.

Investigations identified that she had an HPA-1a alloantibody. She was treated with high dose, intravenous immunoglobulin (2g/kg over 5 days). She remained asymptomatic and her platelet count recovered to more than 50 x 10^9/L in 2 days and to more than 150 x 10^9/L in 4 days. She suffered no related morbidity. She was multiparous and her last pregnancy had been more than 20 years previously. She had no previous history of transfusion before this admission. She had received enoxaparin postoperatively but results of HIT investigation were not reported.

Case 2

A 48-year-old female had a laparotomy on 13th July, 2007. Her platelet count on the previous day had been 562 x 10^9/L; 7 days later she was transfused uneventfully with 2 units of red cells to treat anaemia associated with sepsis. On the day before transfusion her platelet count was 484 x 10^9/L but 8 days later, her platelet count had decreased to 137 x 10^9/L, dropping to a nadir of 7 x 10^9/L within the next 2 days. She developed purpura associated with the thrombocytopenia but no overt bleeding.

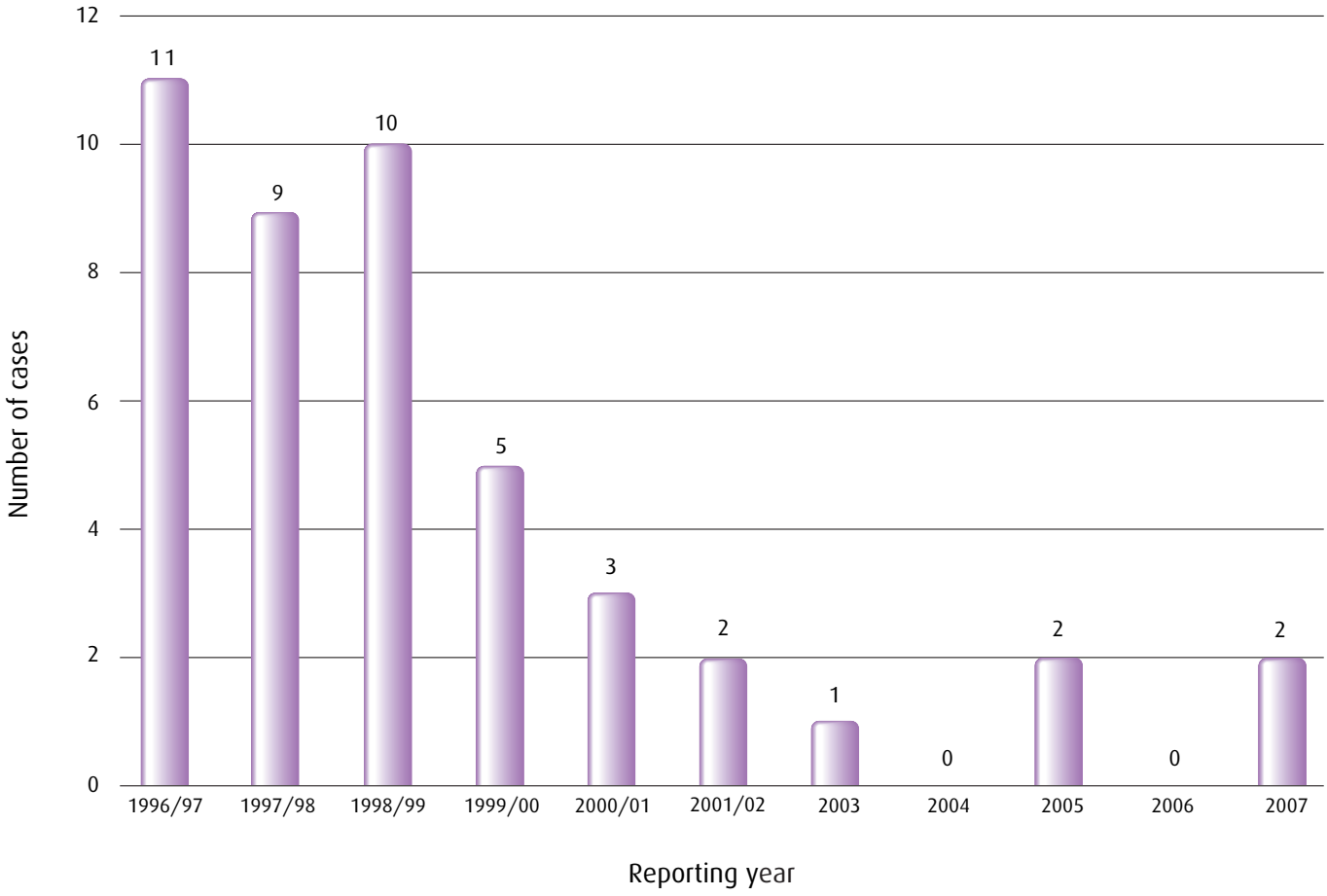
Investigations identified that she was homozygous for HPA-1a and had an HPA-1b alloantibody. She was treated with intravenous immunoglobulin and HPA-1b negative platelets. The platelet transfusions were followed by transient count increments of between 8 and 11 x 10^9/L. Her platelet count recovered to > 50 x 10^9/L within 6 days and to 146 x 10^9/L within 9 days. She suffered no related morbidity and made a full recovery from PTP. Information was not provided about the patient's past history of transfusion or pregnancy.

Cumulative data

The chart (Figure 14) shows the number of cases of confirmed PTP reported to SHOT annually since 1996. A sustained decrease in the number of cases of PTP has been observed since the introduction of universal leucodepletion in 1999.

Since 1996, platelet antibodies with specificity for HPA-1a, either alone or in combination with other platelet antibodies, have been the most frequently identified antibodies in SHOT reports of confirmed PTP. Thirty-five patients (78%) had HPA-1a antibodies and 12 had antibodies to other HPA. HPA-1b antibodies were found in 5 cases (11%), 4 of which occurred before leucodepletion and 1 this year. HPA-5b antibodies have only been reported in 1 case (2%). All except 1 of the cases with non-HPA-1a antibodies were reported before the introduction of universal leucodepletion in 1999.

Figure 14
Number of cases of confirmed PTP reported to SHOT each year



RECOMMENDATIONS

- Clinicians need to maintain awareness of this rare but treatable complication of transfusion.
- When PTP is suspected there should be referral to a platelet reference laboratory for relevant investigations.

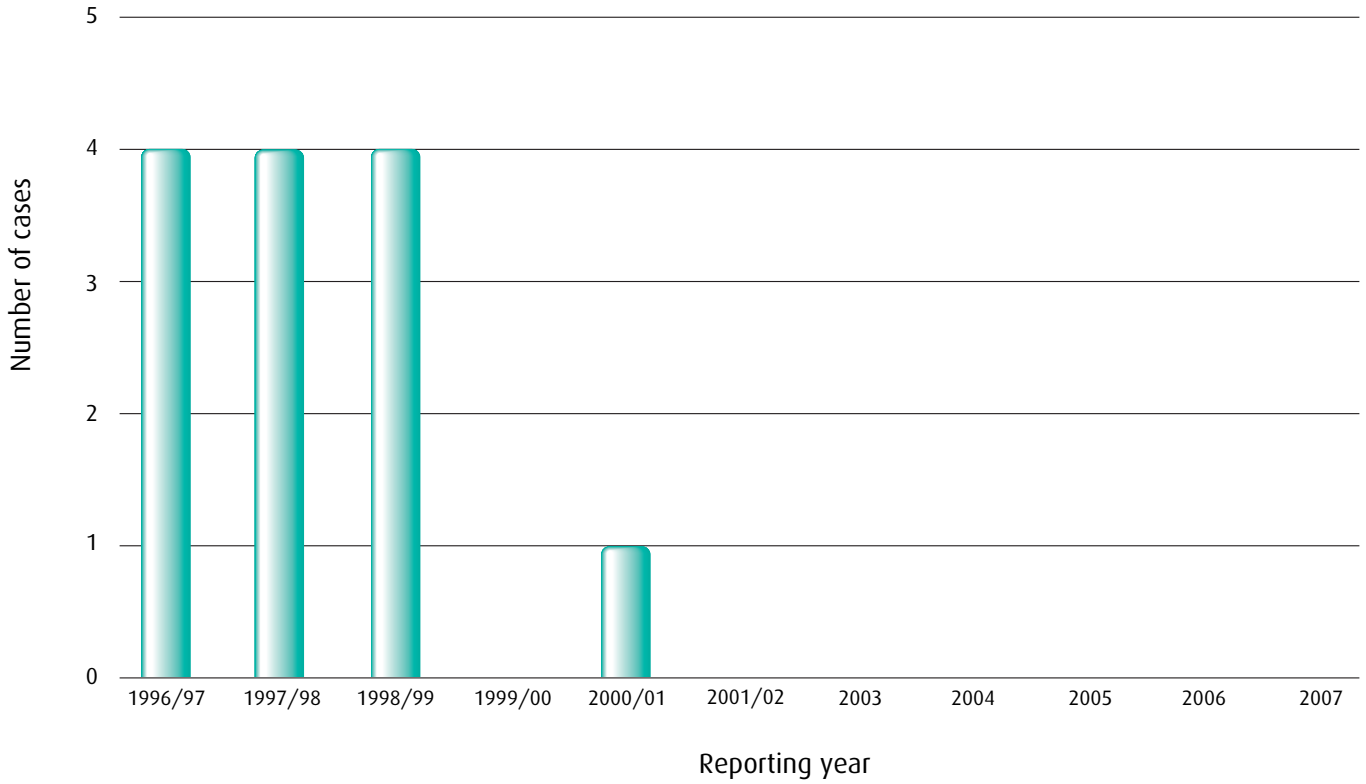
11. Transfusion-Associated Graft-Versus-Host Disease (TA-GVHD)

Definition

Transfusion-associated graft-versus-host disease is a generally fatal immunological complication of transfusion practice, involving the engraftment and clonal expansion of viable donor lymphocytes, contained in blood components in a susceptible host. TA-GVHD is characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days following transfusion. The diagnosis is usually supported by skin / bone marrow biopsy appearance and/or the identification of donor–derived cells, chromosomes or deoxyribonucleic acid (DNA) in the patient's blood and/or affected tissues.

There were no new cases of TA-GVHD during the 2007 reporting period.

Figure 15
Number of cases of TA-GVHD reported to SHOT each year



COMMENTARY

- Since the inception of SHOT, 13 cases of TA-GVHD have been reported, all of which were fatal. The following graph shows the number of cases of TA-GVHD reported to SHOT each year since the scheme began in 1996. All cases involved red cell transfusion, and in 3 cases platelets were also transfused.

- Leucodepletion of all blood components was introduced by the UK Blood Services in 1999 and this is the most likely reason for the marked reduction in the number of reports of TA-GVHD. However, a recent review of TA-GVHD in the UK published by SHOT includes 2 cases where leucocyte-depleted products were given[19]. The point was made that although leucodepletion processes are highly consistent, the possibility of an individual unit failing the LD process cannot be excluded.

- TA-GVHD has a very high mortality; death was reported in all 13 cases reported to SHOT since 1996.

- The 2007 IBCT chapters indicate that there were 62 patients who had a requirement to receive irradiated blood (in accordance with BCSH guidelines[20]) but who received non-irradiated products. There were 39 clinical, and 23 laboratory errors. These errors include 12 relating to IT problems or incorrect use of IT. This is an unacceptably high number of errors which should be completely avoidable. Laboratory errors which result in special requirements (such as irradiated blood products) not being met must be reported to SABRE as well as SHOT[2].

- A recent survey of the use of irradiated blood products shows that there is wide variation in practice in terms of deciding which patients should receive irradiated components and how requirements should be documented and communicated. Not all hospitals informed patients about their requirements.

RECOMMENDATIONS

New recommendations from this report

- The importance of irradiation, and the rationale behind it should be focused on during teaching of junior haematology and oncology doctors. This education is part of the curriculum for Specialist Trainees, but foundation year doctors in these specialities may remain ignorant despite being frequently called upon to order components.

  Action: Hospital Trusts, Medical Schools, NBTC, Royal Colleges, Specialty Training Committees, GMC, PMETB

- Systems should be put in place for pharmacy to inform the hospital transfusion laboratory of prescriptions for purine analogues. Such systems work well in some Trusts and best practice can be shared.

  Action: Hospital Trusts, Hospital Liaison networks, BBT network, SHOT Transfusion Practitioner network

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2006	Awareness of groups at risk of this condition and knowledge of the risk factors, symptoms and signs must be maintained by all involved in the transfusion process	**Hospital Trusts, Medical Schools, NBTC, Royal Colleges, Specialty Training Committees, GMC, BCSH**	This is a continuing subject for discussion at all levels
2003	Gamma or x-ray irradiation to 25 Gy of blood components for those at risk of TA-GVHD remains essential. BCSH Blood Transfusion Task Force Guidelines (1996) define groups requiring this prophylaxis	**Hospital Trusts, Medical Schools, NBTC, Royal Colleges, Specialty Training Committees, GMC, BCSH**	An update of the BCSH guidelines is in progress. A more recent table of indications can be found in *Transfusion Handbook,* 4th edn
2003	Good communication is required in all cases but particularly when patient care is shared between different hospitals. Hospitals must have clear protocols to ensure accurate information relating to this risk is communicated in a timely manner. Utilisation of a patient card and leaflet are recommended: an example is the BCSH/NBS leaflet available from NBS Hospital Liaison or via the NBS hospitals website	**Hospital Trusts, Hospital Liaison networks, BBT network, SHOT Transfusion Practitioner network**	This is a continuing subject for discussion at all levels

12. Transfusion-Transmitted Infection (TTI)

Definition

A report is 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 1 component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection,

or,

- at least 1 component received by the infected recipient was shown to contain the agent of infection.

DATA SUMMARY

Total number of cases	3

Implicated Components	
Red cells	**2**
FFP	**0**
Platelets	**1**
Other	**0**

Mortality / morbidity	
Deaths due to transfusion	**0**
Deaths in which reaction was contributory	**0**
Major morbidity	**3**

Gender	
Male	**1**
Female	**2**

Age	
<16 years	**0**
<1 year	**0**
<4 weeks	**0**

Emergency vs. routine Core hours vs. out of core hours	
Emergency	**0**
Routine	**3**
Not known	**0**
In core hours	**2**
Out of core hours	**1**
Not known/applicable	**0**

Where transfusion took place	
Emergency	**0**
Theatre	**0**
ITU/HDU/Recovery	**0**
Wards	**3**
Community	**0**
Other	**0**
Not known	**0**

Information technology and appropriateness of transfusion (in the opinion of the SHOT reviewer)	
In how many cases was failure or absence of IT a factor?	**0**
In how many cases was a transfusion possibly unnecessary or inappropriate?	**0**

Reports of suspected transfusion-transmitted infections

During 2007, 25 reports of suspected transfusion-transmitted infections were made from blood centres throughout the UK to NBS/HPA Centre for Infection Surveillance. All UK blood centres contributed to the scheme.

Three reports (bacteria), described below, were determined to be TTIs according to the above definition. Twenty-one cases were concluded as not transfusion-transmitted infections (4 hepatitis B [HBV], 3 hepatitis C [HCV], 7 HIV, 2 HTLV, 1 malaria, 1 Parvo B19 and 3 bacteria). One case (CMV) is pending complete investigation.

Case report of transfusion-transmitted *Enterobacter cloacae*

A recipient (62-year-old female) was prescribed red cell treatment for anaemia. This patient was diabetic and in renal failure. Soon after the start of the first unit (21 days old) she became tachycardic with rigors, hypertension and pain at the IV site. The transfusion was stopped, blood cultures taken and antibiotics started. The patient made a full recovery. *Enterobacter cloacae* was isolated from the blood cultures taken from the patient at the time of the reaction and from the red cell pack. Pulsed field gel electrophoresis (PFGE) shows that the strain isolated from the patient's blood culture

and the strain isolated from the remains of the red cell pack were identical. The donor was recalled and skin swabs were taken from the venepuncture site. No enterobacter or coliforms were isolated. *Enterobacter cloacae* is not part of usual skin flora, so the absence of this bacteria on the skin is not surprising. It is also unlikely that the donor was bacteraemic at the time of donation. An associated platelet unit had already been transfused, with no adverse reaction reported. This investigation was concluded to be a proven case of bacterial contamination of a red cell unit with *Enterobacter cloacae*; the source of the contamination was not identified.

Case report of transfusion-transmitted *Pseudomonas putida*

An 89-year-old female patient was prescribed red cell treatment for postoperative anaemia. One and a half hours after the start of the first unit (17 days old) she became tachycardic and short of breath. The transfusion, which started during the evening, was terminated, blood samples were taken and the patient was started on antibiotics. The patient made a full and rapid recovery. *Pseudomonas putida* was isolated from the patient blood sample and from the red cell pack. These isolates were confirmed by PFGE to be the same strain. There were no associated units.

Pseudomonas putida is an environmental organism, and transient bacteraemia in a healthy donor is unlikely. It is able to survive at 4°C and this strain was able to grow actively at that temperature, although only at a high inoculum. Fridges and cold rooms at the blood centre and at the hospital transfusion laboratory were examined for contamination but all were negative. The surface of the pack was also negative. This investigation was concluded to be a proven case of bacterial contamination of a red cell unit with *Pseudomonas putida*; the source of the contamination was likely to be environmental, but the exact source was not identified, despite investigation of likely sources.

Case report of transfusion-transmitted *Bacillus cereus*

A 47-year-old female was transfused with 1 unit of pooled platelets (4 days old) during the morning because of a low platelet count (owing to leukaemia). Before the end of the transfusion, the patient became pyrexial and hypotensive. The transfusion was stopped and the patient was started on antibiotics. Although very unwell for the first 12 hours following transfusion, she made a full recovery within 4 days. *Bacillus cereus* was isolated from the pooled platelet pack. Associated red cells and plasma from the donations contributing to the buffy coat were all negative. This investigation was concluded to be a proven case of bacterial contamination of a pooled platelet unit with *Bacillus cereus*; the source of the contamination was not identified.

Other incidents

Near Miss

A 4-day-old apheresis platelet unit (pack 1 of 2) was returned to the blood service by a hospital following an observation of a large white clump in the pack; *Staphylococcus aureus* was isolated (not methicillin resistant). The platelets were so heavily contaminated that Gram positive cocci could be seen in an uncentrifuged smear of the pack contents. The second pack (4 days old) had been transfused into a paediatric oncology patient with no adverse effect. Had this pack also been contaminated with *S. aureus,* it is not unreasonable to assume that the patient would have experienced a reaction. Both packs had been subject to bacterial screening prior to issue, with negative results. The contamination of one of the two packs remains unexplained.

Staphylococcus aureus in apheresis platelet unit

vCJD

There have now been 4 cases of transmission of vCJD infection (see Table 29 for years of transfusion) associated with blood transfusion; three of the recipients developed clinical vCJD. These cases were among a small group of recipients of blood who were under active surveillance as they had received blood components from donors who later developed vCJD. Although there are no reports of transfusion-transmitted vCJD or prion disease in this report, 1 case reported in the 2006 Annual Report was in fact identified in early 2007. All 4 cases had received transfusions of non-leucodepleted red blood cells between 1996 and 1999; none relate to plasma products. Since 1997 the UK blood services have introduced a number of precautionary measures, including leucodepletion of all blood components (1999), use of methylene-blue virally inactivated FFP obtained outside the UK for children under 16 (2002), importation of plasma for fractionation (1998), imported solvent detergent (SD) treated FFP for adult patients with thrombotic thrombocytopenic purpura (TTP) (2006), and the exclusion of donors who have received a blood transfusion in the UK since 1980 (2004).

Cases reported as pending in previous years

The case reported as pending in 2004 (HHV-8) is now completed. No donor was found to have evidence of HHV-8 infection; it was concluded that there was no evidence of transfusion transmission. The pending HBV case from the 2006 report was confirmed as not transfusion transmitted.

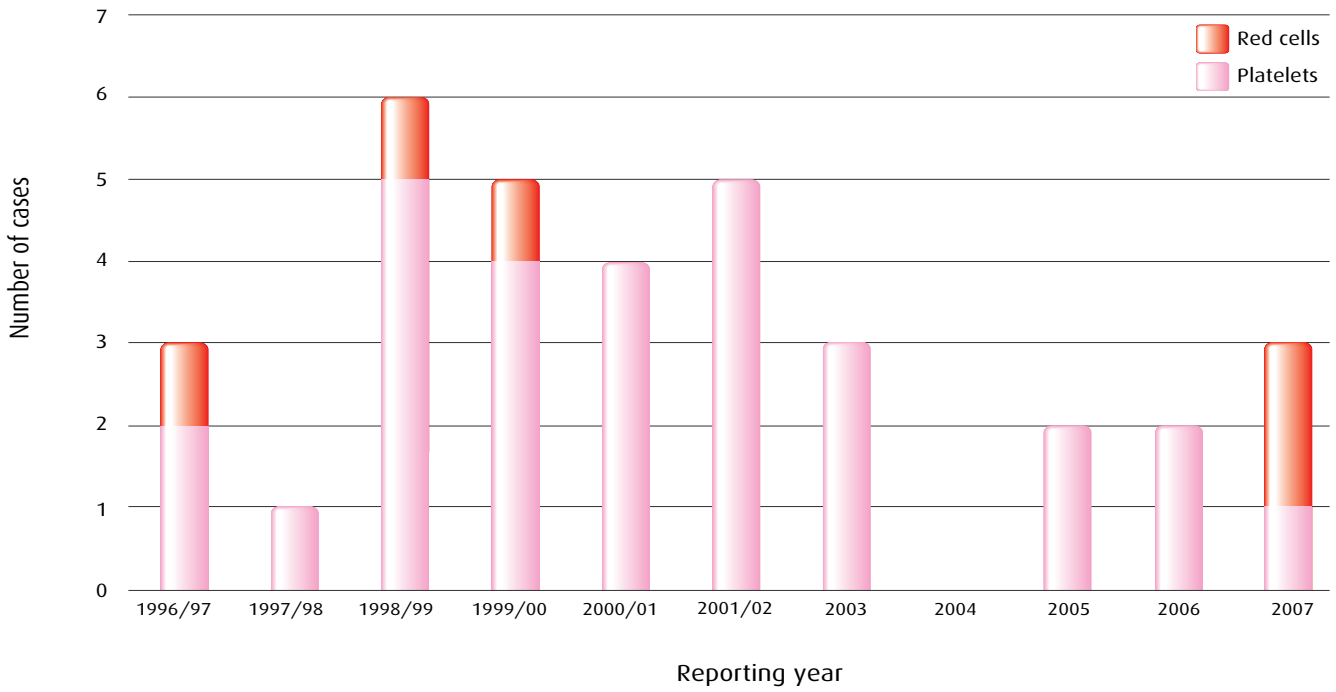
Cumulative data

Reports of suspected viral and bacterial TTIs have traditionally been received and investigated by the UK blood services, and then reported to a national TTI surveillance scheme outside of, but closely aligned with, SHOT. From here, data were included in the annual SHOT reports. Cases reported in one year to the blood services were included in the same SHOT reporting year, even if the investigation had not been completed. Investigation of some suspected viral TTIs may take many months, which is why the decision was taken to report all known cases within the same reporting year, for completeness, rather than waiting until the investigation had finished. For example, the suspected HHV-8 transmission first reported in the SHOT 2004 report was completed in late 2007. Hence, each year, some cases were reported as pending and the conclusion was reported in the subsequent report. This procedure differs from that adopted by SHOT, where cases were included in the year that the investigation was completed. Previous SHOT reports have included data on total mortality and morbidity; these were generated by counting the cases reported in the main paragraph in each chapter. Unfortunately this missed TTI cases initially reported as pending, which were later confirmed to be TTIs. These counts also excluded the vCJD and prion cases reported in recent years. Consequently some differences in numbers presented in the last report have been identified. The cumulative data presented below, in addition to the mortality and morbidity data in the data summary on page 102, are accurate and should replace all previous data.

Bacterial data

Since 1996, 34 cases of transfusion-transmitted bacterial infection have been reported (Figure 16), of which 8 recipients died due to the transfusion. The majority of these cases (n = 28) relate to platelet units (10 apheresis and 18 pooled).

Figure 16
Confirmed bacterial transfusion-transmitted infections, by year of report and type of unit transfused (Scotland included from 10/1998)*

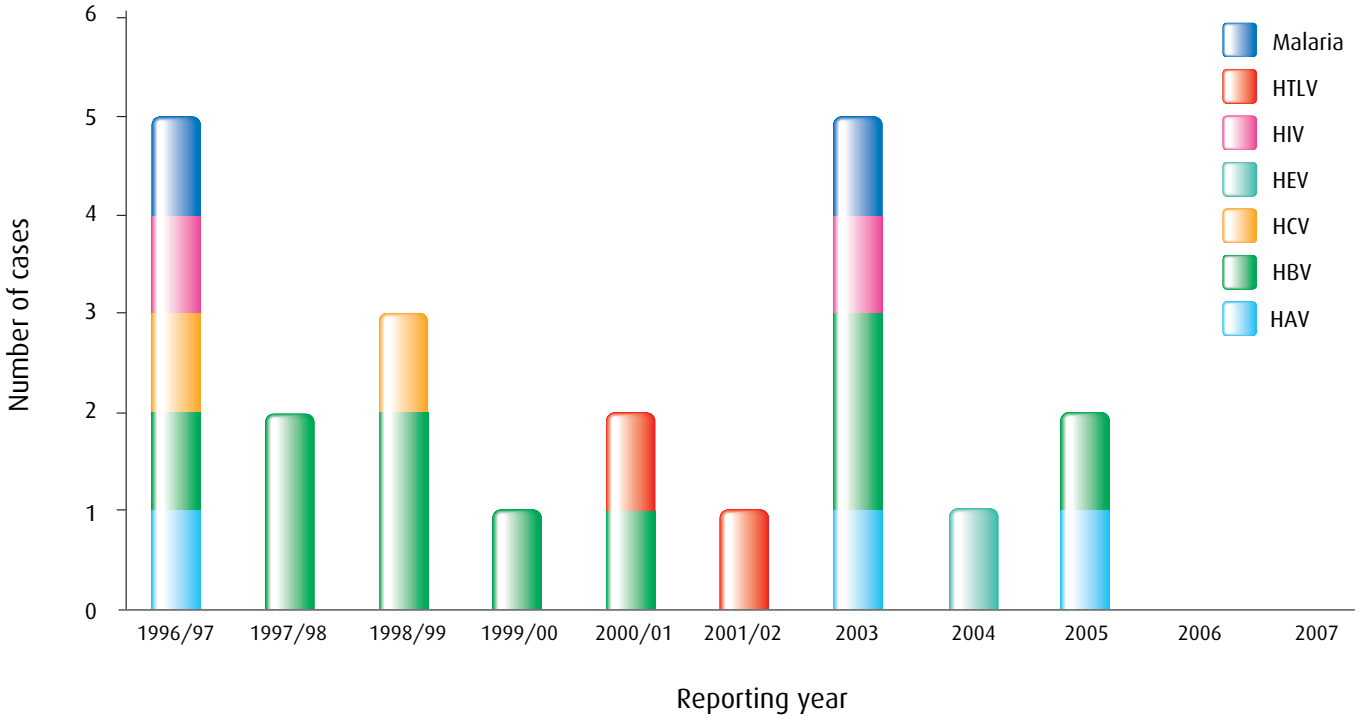


* In 2004 there was a further incident involving contamination of a pooled platelet pack with *Staphylococcus epidermidis*, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely (not included in Figure 16).

Cumulative viral data

Since 1996, 22 cases of transfusion-transmitted viral infections have been reported (Figure 17): 10 HBV, 3 HAV, 1 HEV, 2 HCV, 2 HIV, 2 HTLV and 2 malaria. There have been no cases of transfusion-transmitted viral infections for 2 years running (2006 and 2007).

Figure 17
Confirmed transfusion-transmitted viral infections, by year of report and infection (Scotland included from 10/1998)



* The year of transfusion can be many years prior to the year the case is investigated and reported in SHOT, due to the chronic nature of some of these infections leading to delay in identification of the infection.

Table 29
Cumulative TTI data shown by SHOT report year (Scotland included from 1998-99 report)

	1996-1997	1997-1998	1998-1999	1999-2000	2000-2001	2001-2002	2003	2004	2005	2006	2007	Total	Death (due to infection)	Major morbidity	Minor morbidity
Bacteria	3	1	6	5	4	5	3	0	2	2	3	34	8	23	3
HAV	1	0	0	0	0	0	1	0	1	0	0	3	0	2	1
HBV	1	2	2	1	1	0	2	0	1	0	0	10	0	10	0
HCV	1	0	1	0	0	0	0	0	0	0	0	2	0	2	0
HEV	0	0	0	0	0	0	0	1	0	0	0	1	0	0	1
HIV	1	0	0	0	0	0	1	0	0	0	0	2	0	2	0
HTLV	0	0	0	0	1	1	0	0	0	0	0	2	0	2	0
Malaria	1	0	0	0	0	0	1	0	0	0	0	2	1	1	0
Prion	0	0	0	0	0	0	0	1	0	0	0	1	0	1	0
vCJD	0	0	0	0	0	0	1	0	1	1	0	3	3	0	0
Total	**8**	**3**	**9**	**6**	**6**	**6**	**9**	**2**	**5**	**3**	**3**	**60**	**12**	**43**	**5**

Further cumulative data are available at http://www.hpa.org.uk/infections/topics_az/BIBD/menu.htm.

COMMENTARY

- After the introduction of diversion of the first 20 mL of a donation (2002) and improved donor arm disinfection, bacterial contamination of platelets and red cells continues to occur, albeit at a lower level, and causes major morbidity in transfusion recipients. Despite full investigations by the blood services, the source of contamination was not identified in any of the 3 cases this year. Visual inspection of 1 platelet unit prevented the probable transmission of *S. aureus*; it is important that staff starting the transfusion visually check all components prior to transfusion. However, bacterial contamination is possible even in the absence of visible features.

- This is the first instance since 1999 of any report of bacterial contamination and transmission from a red cell unit. These 2 cases were not linked in any way. The occurrence of 2 cases in a year was most likely a chance finding due to the small number of events.

- For the second year running there were no confirmed viral transmissions consistent with the current very low estimated risk of HIV (0.25 per million), HCV (0.02 per million), HBV (1.62 per million) and HTLV (0.10 per million) infectious donations entering the UK blood supply. For more information see http://www.hpa.org.uk. *[Follow the headings: infectious diseases, topics A-Z, blood borne infections in blood donors, epidemiological data.]*

- The risk of acquiring vCJD from blood transfusion is unknown. The incidence of vCJD has been declining since 2000 and the number of people harbouring infection is uncertain. Prevalence of infection in the general population, and in the donor population, is unknown. Susceptibility and the incubation period of the disease are affected by genetic factors. The risk of transfusion transmission will be related to the prevalence of infection and to the length of any asymptomatic 'carrier state' with blood infectivity. The precautionary measures introduced by UK blood services, described above, should reduce the risk of acquiring vCJD through blood transfusion.

- Of the 3 confirmed TTIs, 2 transfusions took place during core hours and 1 outside of core hours. All were appropriate transfusions.

- Surveillance of TTIs tends to be biased towards ascertainment of acute cases that are clinically apparent. The onset of symptoms related to a transfusion-transmitted viral infection may occur from several weeks to years after the date of the transfusion. Just under half of the investigations into suspected viral transmissions reported here were transfused in 2003 or earlier. The reporting of incidents involving acute infections that tend to be clinically apparent and diagnosed within days after receipt of the infectious transfusion, such as bacteraemia, may be relatively complete, but incidents involving chronic viral infections may not.

RECOMMENDATIONS

New recommendation from this report

- Staff involved in transfusion should remain vigilant for visual signs of bacterial contamination of red cell and platelet units. However, bacterial contamination is possible even in the absence of visible features, so staff should remain vigilant for any adverse reactions post transfusion.

  Action: HTTs/ nurses/ BMS's

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2005	Hospitals should consult the blood services 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 and packs returned to blood services for testing	**HTTs**	Guidance for English hospitals can be found on the NBS hospitals website: http://www.blood.co.uk/hospitals/library/request_forms/aer/; for other services please discuss with your supply blood centre
2003	Efforts to prevent bacterial contamination of blood components should continue. These include: ■ 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) with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion The UK blood services should continue to investigate methods to reduce bacterial contamination	**UK blood services hospital transfusion laboratories, staff undertaking pre-transfusion bedside checking**	UK blood services have introduced enhanced donor arm cleansing and continue to monitor and evaluate the success of all interventions
2003	Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately	**HTTs**	Serious Adverse Reactions are required to be reported by hospitals under the terms of the BSQR

13. Transfusion-Associated Circulatory Overload (TACO)

Definition

TACO includes any 4 of the following that occur within 6 hours of transfusion:

- Acute respiratory distress
- Tachycardia
- Increased blood pressure
- Acute or worsening pulmonary oedema
- Evidence of positive fluid balance

The 3 cases reproduced below are in the inappropriate transfusion section of the IBCT chapter. The level of detail in the cases reported does not always allow a definitive diagnosis of TACO, though it is highly likely from the information given. Data for 2008 are to be collected on a specifically designed questionnaire, which will ensure that the correct information is documented.

In all 3 of these cases TACO was probably avoidable if the doctors involved in each patient's care had made more appropriate decisions regarding prescription of components. However, TACO may not invariably be related to inappropriate or unnecessary transfusion, as some patients may have undiagnosed cardiac problems or suffer unexpected circulatory compromise following transfusion. Nevertheless, full clinical assessment and informed prescribing would reduce the number of cases.

TACO n = 3

Case 1

Transfusion of 7 units of FFP to reverse warfarin

A 61-year-old male patient with an INR of 6.0 required warfarin reversal prior to elective surgery. He was given Vitamin K 5 mg and 4 units of FFP over 160 minutes. Without any further INR being performed he then received another 3 units over 45 minutes, at which point he became unwell with rigors, chills, wheeze and a temperature of 38.3°C. His oxygen saturation on air was 80%. He was managed with diuretics and oxygen. The planned surgery was performed the following day.

Case 2

Involvement of too many personnel in decision to transfuse

A 20-month-old girl on regular dialysis for end stage renal failure attended for routine haemodialysis and her father reported that she had been unwell. A consultant commenced dialysis urgently and, as the Hb was 5.0 g/dL, requested 2 units of blood to be given during dialysis. The dialysis was completed before the blood was ready so a decision was made by a second consultant to give 250 mL of blood slowly over 6 hours. This message was conveyed between the dialysis unit nurse and the ward nurse by the patient's father. The notes were later collected and a third and fourth nurse set up the transfusion. Observations were done by the fourth nurse. No pre-transfusion observations were done. At 5.20 and 35 minutes into the transfusion the patient was hypertensive, tachypnoeic and irritable; her oxygen saturations were unrecordable. The nurse thought this was normal for the patient. The transfusion was completed in 1 hour (not 6) and a fifth nurse then realised that the patient's extremities were blue. A sixth nurse administered oxygen while an anaesthetist was called who performed emergency intubation. The patient was transferred to paediatric ITU where she underwent sedation, high-frequency oscillatory ventilation and haemofiltration. The patient made a full recovery.

Case 3

Misunderstanding and lack of knowledge leads to excessive preoperative platelet transfusion

An 81-year-old man was preoperatively transfused with 4 units of platelets within a 4 hour period. The patient developed cardiac failure, the operation was cancelled, and medical intervention was necessary. In fact the orthopaedic specialist trainee doctor had written in the notes 'Arrange 4 units of platelets'. The junior non-specialist doctor assumed this meant to order and transfuse 4 units of platelets prior to surgery. When ordering, the junior non-specialist doctor was advised by a BMS to seek a haematology opinion as the order appeared inappropriate. This advice was not sought.

COMMENTARY

Inevitably there will be potential for overlap between cases categorised as TACO or as 'inappropriate or unnecessary'. In future years TACO cases will be systematically collected and grouped together in a discrete chapter. Assessments of appropriateness of the clinical decisions will be discussed.

14. Autologous Transfusion

Definition

Autologous transfusion comprises any adverse events or reactions associated with autologous transfusion methods, including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution or PAD (preoperative autologous donation).

This chapter appears for the first time this year, to coincide with the intraoperative and postoperative cell salvage adverse events reporting pilot which is being run by the UK Cell Salvage Action Group. The Action Group is working in conjunction with SHOT to begin to collect reports of these events systematically. Until now there have been occasional unsolicited reports to SHOT. It is anticipated that in future there may be more reports now that this joint project is actively collecting data.

Of the 3 events below, the first is included in the IBCT chapter and the remaining 2 appear in the ATR chapter.

Autologous transfusion n = 3

There was 1 case involving postoperative autologous cell salvage in which a patient was over-transfused with a large volume of autologous blood. Although the volume transfused was inappropriate, and not within either the manufacturer's or the hospital's policy. There was no untoward reaction in the patient.

Case 1

High volume of salvaged blood reinfused

A 58-year-old female patient was underwent bilateral knee replacement and blood was salvaged bilaterally from drains postoperatively on HDU. The policy from the manufacturer of the device and the hospital policy stated that a maximum of 1000 mL could be reinfused. The HDU nurses reinfused 2280 mL as they were unfamiliar with the process. There was no adverse reaction.

The second case highlights the importance of users of cell salvage equipment being fully familiar with its use and able to troubleshoot if there are problems. Following the manufacturer's protocol and locally developed hospital policies is essential.

Case 2

Hypotensive reaction may have been caused by incorrect washing

An 82-year-old male patient had intraoperative cell salvage performed using a Haemonetics cellsaver 5 machine whilst undergoing vascular surgery. He received the first unit of salvaged blood (484 mL), with no adverse reaction. The second collection was slightly under the recommended volume, at 473 mL. After a few mL of this unit had been reinfused, the patient became hypotensive, and the transfusion was stopped, and vasoconstrictors were given. The reaction was not immediately attributed to the blood transfused. The unit was then restarted, with the same effects. Microbiological examination revealed growth of coagulase negative staph which was not considered to be a contributing factor. The cell salvage team concluded that under-collection may have led to incorrect washing, and have amended polices and retrained accordingly.

The third case describes a minor reaction to reinfusion on blood salvaged postoperatively. It will be of interest to collect data on the relative frequency of reactions to washed and unwashed cells.

Case 3

Febrile reaction to reinfusion of postoperatively salvaged blood

A 64-year-old male patient, who had previously been transfused on two occasions, had 600 mL of blood collected via a Bellovac drain after knee replacement. The report states that the blood was reinfused over 4 hours and 30 minutes. The patient then developed an isolated febrile reaction. No investigations were performed.

COMMENTARY

SHOT continues to collect data on adverse events arising from autologous transfusion and is now working in collaboration with the UK Cell Salvage Action Group. It is hoped that reporters will liaise with the relevant operational teams in their Trusts to ensure that adverse reactions are documented, investigated and reported. At the current time there is very little data available on this topic to inform modifications in techniques and practice.

15. Paediatric Cases

Definition

Paediatric cases comprise all those occurring in patients under 16 years of age.

This chapter summarises the data on numbers of paediatric cases from the other chapters in this Annual Report. All cases are included in the data in their respective chapters.

Table 30
Paediatric cases 2007

Category of case	Number between 1 and 16 years	Number between 4 weeks and 1 year	Number under 4 weeks	Total cases
IBCT	**22**	**11**	**12**	**45**
Wrong blood administered	*0*	*1*	*0*	*1*
WBIT	*0*	*0*	*0*	*0*
Inappropriate or unnecessary	*4*	*1*	*3*	*8*
Handling and storage	*4*	*3*	*0*	*7*
Irrad/CMV not met	*9*	*1*	*6*	*16*
Other special requirements not met	*3*	*0*	*0*	*3*
Wrong group for stem cell transplant	*2*	*1*	*0*	*3*
Wrong blood from lab	*0*	*1*	*0*	*1*
Pre Tx testing error	*0*	*3*	*0*	*3*
Procedural error	*0*	*0*	*3*	*3*
Anti-D related	**2**	**0**	**0**	**2**
ATR	**5**	**2**	**0**	**7**
HTR	**1**	**0**	**0**	**1**
TRALI	**0**	**0**	**0**	**0**
PTP	**0**	**0**	**0**	**0**
TA-GVHD	**0**	**0**	**0**	**0**
TTI	**0**	**0**	**0**	**0**
TOTAL	**30**	**13**	**12**	**55**

These cases can be divided into 2 groups – those in which the risk of the adverse incident was increased because of the age group of the patient, and those in which the event occurred by chance in a young patient.

IBCT cases related to the age group of the patient n = 27

- Three cases of inappropriate transfusion in children between 1 and 16 resulted in significant over-transfusion because their small size was not taken into account when prescribing red cells. All of these transfusions resulted in a Hb above the normal range. One resulted in life threatening TACO (see page 108).
- Two cases related to excessive time taken to transfuse red cells, one because of a small cannula in a 3-year-old, the other because the red cells were erroneously written up over 8 hours per unit for a 15-year-old child.
- Failure to meet special requirements for irradiation and CMV negative components was common in the paediatric age groups. In 10 cases in children over 4 weeks old suffering from malignancies (all but 1 were haematological) the clinicians did not inform the laboratory of the need for irradiated components (9 cases) or CMV negative components (1 case) (see page 46).
- Six neonates under 4 weeks old had special requirements for irradiation which were not met – 2 with DiGeorge syndrome, 3 following IUT and 1 for neonatal cardiac surgery.

- In 3 cases children post SCT received blood of the incorrect group – 2 cases owing to a lab oversight, and 1 case in which the clinicians did not communicate the history to the lab.
- In 3 cases the laboratory failed to issue appropriate MB treated FFP for a child under 16.

Cases not related to age of patient n = 28

- Anti-D errors in 2 girls of 14 years old, post-partum/post-TOP.
- Seven allergic/anaphylactic cases in the ATR chapter (see page 71).
- Haemolysis in a 10-year-old child who was given group O D positive platelets when her own group was group A D positive (Case A2, page 82). There have been previous reports of significant haemolysis following administration of group O platelets to A and B recipients, with more than half the reports having occurred in children.
- A further 18 IBCT errors (see Table 30).

COMMENTARY

A total of 55 cases (of 561) reported in 2007 related to children under 16 years of age. In a significant number of these adverse incidents the risk of occurrence was higher because of the age of the patient, as previously highlighted by SHOT[21]. Prescribing for paediatric patients should only be carried out by those with appropriate knowledge and expertise in calculating dosage and administration rates in this group. Special requirements are more common in paediatric patients, because of the range of congenital and malignant conditions for which they may be hospitalised, and special care is needed to ensure that documentation, handover and communication is effective and comprehensive. Laboratory BMSs must be aware of special component requirements in patients under 16, and routine checking for additional flags should be carried out based on date of birth.

RECOMMENDATIONS

New recommendations from this year

- Prescribing for paediatric patients should be carried out only by those with appropriate knowledge and expertise in calculating dosage and administration rates for this group.

  Action: HTT and clinical users of blood

- Special requirements are more common in paediatric patients, because of the range of congenital and malignant conditions for which they may be hospitalised, and particular care is needed to ensure that documentation, handover and communication is effective and comprehensive.

  Action: HTT and clinical users of blood

- Laboratory BMSs must be aware of special component requirements in patients under 16, and routine checking for additional flags should be carried out based on the date of birth.

  Action: HTT, hospital transfusion laboratories and consultant haematologists with responsibility for transfusion

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2003	BCSH guidelines on transfusion of neonates and children should be implemented	**RCPCH, RCN, staff in paediatric units and transfusion laboratories**	SHOT 'Lessons for paediatric staff' produced 2006; SHOT in Obstetrics (2007); NBS paediatric conference February, 2007

16. Near Miss Reporting

Definition

A Near Miss event refers to any error which, if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before transfusion took place.

The above shortened definition of SHOT Near Miss was suggested at the Near Miss Workshop in November, 2006.

Although human error is commonly an initiating event, a faulty process or system invariably permits or compounds the harm, and should be the focus of improvement, with barriers put in place at each stage of the process to prevent or at least reduce the likelihood of errors occurring. Where human error is a factor it is important to ask why a person acted in a certain way at the time, or made the decision they did, based on information available at the time. Environmental and workplace factors can play a significant contributory role.

The 'risk' of a Near Miss event is the product of its potential severity and its likely occurrence. Unfortunately, the potential severity of many transfusion errors is patient fatality or severe morbidity.

The transfusion process can be conveniently divided up into stages, and there are already some barriers in place to prevent errors at each stage, but it is important to realise that some errors may only be detected in retrospect.

1. The **Pre-testing** phase, where the request is rejected, cancelled or amended due to:

- sample errors, such as missing or incomplete ID, use of addressograph labels, under filled samples, inappropriate sample, no sample
- request errors, where vital information (name, signature of requestor, product requested) is missing from the request
- the inappropriateness of the request in the clinical situation
- the request being made on the basis of an erroneous Hb or coagulation result

Barriers in place to prevent error:

- application of national standards for sample labelling and completion of requests
- national indication codes for appropriate transfusion
- local laboratory procedures for acceptance of requests
- local protocols developed to guide appropriate transfusion
- local training and competency assessment
- maintenance of clean/complete transfusion database
- flags and alerts correctly in place on the database
- quality systems in place in haematology laboratories

2. The **Testing** phase, where:

- despite apparent correct labelling, the blood in the sample has come from a different patient – 'Wrong Blood in Tube'; this is a pre-testing error which only comes to light at the point of testing (if it is noticed that there are previous results available for the patient)
- equipment failure or error leads to an incorrect group recorded for a patient or an incorrect / incomplete compatibility result
- manual result interpretation or transcription leads to an incorrect group recorded for a patient
- an incorrect / inappropriate product / component has been selected by the laboratory for the patient
- the product / component has been mislabelled by the laboratory prior to issue for the patient
- the product / component has been stored inappropriately in the laboratory

Barriers in place to prevent errors:

- national guidance for the selection of components for patient with special requirements
- national guidance for grouping and compatibility testing for patients
- national guidance and legislation for the correct storage of blood products / components
- maintenance of clean/complete transfusion database
- local SOPs for the operation of equipment and action in the event of equipment malfunction
- local SOPs for compatibility testing procedures
- local SOPs for labelling and issuing products / components
- local training and competency assessment

3. The **Collection and Administration** phase, where:

- the wrong product / component is collected from the blood bank
- the product / component is transported to the wrong clinical area
- the product / component is incorrectly / inappropriately transported to the clinical area or receiving hospital
- the product / component is incorrectly / inappropriately stored in the clinical area
- there is a partial failure in the checking / administration / monitoring process at the patient bedside

Barriers in place to prevent errors:

- national/professional guidance on the administration of blood products / components and the monitoring of the transfused patient
- local Trust policy for the checking / administration of products / components for transfusion
- local training and competency assessment

Existing data have already shown where the majority of Near Miss events take place, with around 50% relating to sample labelling, and there seems to be little or no advantage in continuing to collect data which simply adds to the numbers of events reported, as discussed in the report of the SHOT Near Miss survey from 2006.

Many hospitals already collect data routinely on numbers of samples rejected and report regularly via clinical governance mechanisms within their Trusts, with the aim of influencing practice by feedback about performance.

Of greater value may be the origin / root cause of these errors, and this information could be analysed against the background of the introduction of formal competency assessment for clinical staff undertaking venepuncture and the collection and administration of blood products / components. It may be that many are not errors at all in the true sense, but cases of non-compliance with procedure or guidelines.

The value of any usable feedback from a Near Miss scheme is directly related to the amount of information provided for each individual event and the amount of effort each Trust will have to put in to the reporting process.

The first phase of the Near Miss pilot has been run from 1st April, 2008, for a period of 1 month, to obtain some up-to-date denominator data against which to measure the occurrence of WBIT errors, for example.

The second phase of the pilot, looking at the much smaller numbers of errors detected within the laboratory quality system, will run for a longer period, possibly six months, and details of what and how to report will be made available soon.

17. Learning From Our Mistakes – Taking Corrective Action

When reporting to SHOT, and also more recently to MHRA, reporters are asked to identify whether a root cause analysis (RCA) was carried out, whether the event was reviewed locally and what the outcomes of the review were. SHOT has recognised the value of these data. A full root cause analysis may not always be necessary or appropriate; the local Clinical Risk team is usually an excellent resource and will provide advice and support on the best approach to adopt. As a minimum, a tool such as the 'Five Whys' can assist the team to identify the primary cause of the problem and why it occurred. Further information on available tools to support RCA is available on the SHOT website http://www.shotuk.org. Any corrective actions described by reporters can be used to recommend quality improvements, inform practice and prevent common problems reoccurring in the future. When considering corrective actions the investigator should also consider if recall of any component(s) is required.

Root Cause Analysis is a retrospective review of a patient safety incident undertaken in order to identify what, how, and why it happened. The analysis is then used to identify areas for change, recommendations and sustainable solutions, to help minimise the reoccurrence of the incident type in the future.

http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/patient-safety-tools-and-guidance/rootcauseanalysis/

Examining the *Administration of Wrong Blood* cases reported in the IBCT category this year, 10 out of the 11 ABO-incompatible transfusions reports stated that they had undertaken a root cause analysis. The majority of incidents involved failures in the collection process. Corrective actions described included:

- reviewing inadequate staffing levels in the clinical area
- prioritising the implementation of blood tracking systems
- re-evaluating storage facilities
- developing a transfusion care pathway
- modifying transfusion/laboratory policies to eliminate the possibility of the error recurring

Corrective Action is action taken to eliminate the cause of the existing nonconformity [incident] to prevent its recurrence.

One reporter also identified that a re-audit of practice would be undertaken following implementation of the corrective action to ensure the new process had the capability to prevent further incidents. Despite advice from NPSA in 2007 (http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/notices/blood-transfusions/) to discontinue the use of compatibility forms during the final patient identity check where they were still being used as part of the checking process, very few RCAs recommended removing them as one of their corrective actions.

A number of reporters stated that the staff involved had received retraining and competency assessment and/or the local policy had been restated. For frequently reported system failures such as handling and storage errors this may be entirely appropriate. However, for wrong blood events where the patient receives entirely the wrong unit or suboptimal treatment due to their transfusion requirements not being met, or inappropriate or unnecessary transfusion being prescribed, reporters should address the root cause of the problem. It may become evident that the cause of the event relates mainly to an individual's behaviour or poor practice, and this should be dealt with via an appropriate local route.

Despite highlighting major deficiencies in all parts of the transfusion process, training and/or competency assessment and restating policy were the main corrective actions described in a number of cases. This was particularly evident in the inappropriate / unnecessary section of the IBCT chapter: the majority of reporters suggested that they had not undertaken an RCA or local review by the hospital transfusion committee, despite failures in reporting laboratory results that meant that patients received an unnecessary transfusion. However, in 1 case the reporters stated that following an investigation the associated risk assessment suggested that changing the process could increase the potential for errors and recommended retraining of the individual involved in the incident.

Preventative action is action taken to eliminate the cause of potential nonconformity [incidents].

http://www.isixsigma.com/dictionary

There are a range of tools available on the SHOT http://www.shotuk.org and NPSA www.npsa.nhs.uk websites, to assist practitioners in undertaking root cause analyses, developing risk assessment processes, including matrices, and implementing corrective actions. The root cause analyses shared with SHOT can assist readers in focusing on the SHOT recommendations and help them to identify appropriate preventative actions.

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19. Glossary

AHG	Antihuman globulin
AHTR	Acute haemolytic transfusion reaction
AIHA	Autoimmune haemolytic anaemia
ALI	Acute lung injury
ALL	Acute lymphoblastic leukaemia
AML	Acute myelocytic leukaemia
ARDS	Acute respiratory distress syndrome
ATR	Acute transfusion reaction
BBT	Better blood transfusion
BBTS	British Blood Transfusion Society
BCSH	British Committee for Standards in Haematology
BMS	Biomedical scientist
BMT	Bone marrow transplant
BP	Blood pressure
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventative actions
CAT	Column agglutination technology
CCST	Certificate of completion of specialist training
CEO	Chief executive officer
CfH	Connecting for Health
CLL	Chronic lymphocytic leukaemia
CMO	Chief medical officer
CMV	Cytomegalovirus
CPAP	Continuous positive airway pressure
Cryo	Cryoprecipitate
CS	Caesarean section
CTS	Controlled temperature storage
CXR	Chest X-ray
DAT	Direct antiglobulin test
DH	Department of Health
DHTR	Delayed haemolytic transfusion reaction
DNA	Deoxyribonucleic acid
DTR	Delayed transfusion reaction
ECG	Electrocardiogram
E. Coli	Escherichia coli
ED	Emergency department
EDTA	Ethylenediaminetetraacetic acid
EI	Electronic issue
EPR	Electronic patient record
ET	Endotracheal
FBC	Full blood count
FFP	Fresh frozen plasma
FY	Foundation year
G and S	Group and screen / group and save
GI	Gastrointestinal
HAV	Hepatitis A virus
Hb	Haemoglobin
HBc	Hepatitis core
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDU	High dependency unit
HEV	Hepatitis E virus
HHV-8	Human herpes virus
HIT	Heparin induced thrombocytopenia
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen or Health Protection Agency
HTC	Hospital transfusion committee
HTLA	High-titre low avidity
HTLV	Human T-cell leukaemia virus
HTR	Haemolytic transfusion reaction
HTT	Hospital transfusion team
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
IBGRL	International Blood Group Reference Laboratory
IBMS	Institute of Biomedical Science
ID	Identification
Ig	Immunoglobulin
INR	International normalised ratio
ISBT	International Society of Blood Transfusion
ITU	Intensive therapy unit
IUT	Intrauterine transfusion
IV (i.v.)	Intravenous
JRCPTB	Joint Royal Colleges Postgraduate Training Board
LDH	Lactate dehydrogenase enzyme
LIMS	Laboratory information management system
MB-FFP	Methylene Blue Fresh Frozen Plasma
MCT	Mast cell tryptase
MDS	Myelodysplastic syndrome
MF	Mixed field
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	Medical laboratory assistant
MSBTO	Microbiological Safety of Blood Tissues and Organs
NBS	National Blood Service
NBTC	National Blood Transfusion Committee (England)
NEQAS	National external quality assurance scheme
NHSBT	National Health Service Blood and Transplant
NHSLA	National Health Service Litigation Authority
NIBTS	Northern Ireland Blood Transfusion Service
NICE	National Institute for Clinical Excellence
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency
NTLC	National Transfusion Laboratory Collaborative
OA	Optimal additive
ODA	Operating department assistant
PAS	Platelet additive solution or Patient administration system
PBSC	Peripheral blood stem cells
PCC	Prothrombin complex concentrate
PFGE	Pulsed-field gel electrophoresis
PMETB	Postgraduate Medical Education and Training Board
POCT	Point of care testing
PTP	Post-transfusion purpura
RAADP	Routine antenatal anti-D prophylaxis
RBRP	Right blood to right patient
RCA	Root cause analysis
RCN	Royal College of Nursing
SABRE	Serious adverse blood reactions and events
SaBTO	Safety of Blood Tissues and Organs
SAE	Serious adverse event
SAR	Serious adverse reaction
SCT	Stem cell transplant
SLA	Service level agreement
SNBTS	Scottish National Blood Transfusion Service
SOP	Standard operating procedure
SPN	Safer practice notice
TACO	Transfusion-associated circulatory overload
TA-GVHD	Transfusion-associated graft-versus-host disease
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenic purpura
vCJD	Variant Creutzfeldt Jakob disease
WBIT	Wrong blood in tube
WBS	Welsh Blood Service
WCC	White cell count

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