SERIOUS HAZARDS OF TRANSFUSION

SHOT

Annual Report 2008

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 Physicians

Royal College of Surgeons, the four UK Blood Services

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1. Foreword

This is the 12th SHOT Annual Report and, as last year, it is being published at the end of June to coincide with the submission of haemovigilance data to the EU Commission by the Medicines and Healthcare products Regulatory Agency (MHRA).

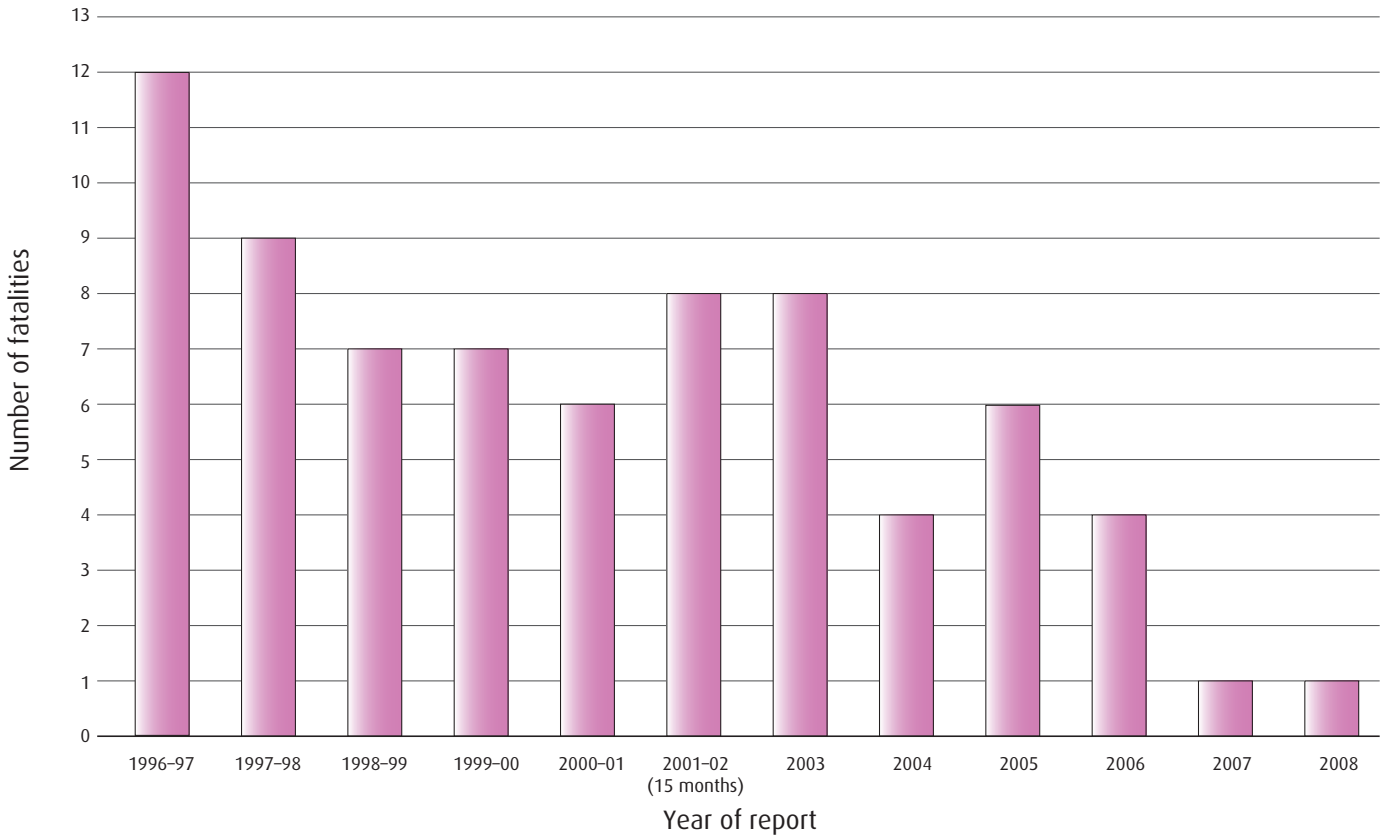
This year has seen a large (85%) increase in the number of cases reported (1040 reports in 2008 compared with 561 in 2007), which is likely to be the result of greater familiarity with and acceptance of the statutory adverse incident reporting requirements under the Blood Safety and Quality Regulations (BSQR) 2005[1], as well as the now strengthened recommendations to report to SHOT. A list of organisations and bodies explicitly requiring participation in SHOT follows in the Introduction on page 3.

Over the 12 years of reporting, the trends observed by SHOT have borne the hallmarks of an effective vigilance system. The number of events reported overall has risen, while the frequency of the most serious events has fallen. As the reporting culture has developed and become widespread, there has been a lessening of fear of consequences, together with greater understanding of how a vigilance system exerts its effect – i.e. not by individual punitive measures to reporters of serious events, but by observations of longer term trends and patterns, followed by changes of practice to reduce the risks of recurrence. In this report the fall in the number of ABO-incompatible transfusions over the last 12 years is shown in Figure 6 on page 34, and the decrease in the number of cases of transfusion-related acute lung injury (TRALI) cases, and mortality from TRALI is shown in Figure 16 on page 118.

Below is a graph showing a continuing fall in the number of cases of mortality definitely related to transfusion since SHOT reporting began in 1996.

Figure 1
Decline in mortality definitely related to transfusion 1996–2008

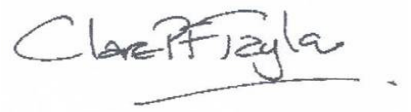
NB The 'year' 2001–2002 was a 15 month period



These data together demonstrate the utility of an effective haemovigilance system in increasing patient safety through a learning and improvement culture, with the focus on safety and quality, monitoring and audit.

It is clear from our participation data (Chapter 4) that SHOT is still only receiving a fraction of possible reports, so although the trends in reporting are likely to be representative of the whole, reporting remains incomplete. SHOT urges all hospital and trust Chief Executive Officers to encourage and support the development of effective systems for capturing adverse events data in blood transfusion so that this excellent record in haemovigilance may continue to develop, for the benefit of patients.

Dr Hannah Cohen MD FRCP FRCPath
Chair, SHOT Steering Group



Dr Clare Taylor PhD FRCP FRCPath
SHOT Medical Director

2. Introduction

ORGANISATIONS THAT REQUIRE EVIDENCE OF REPORTING TO SHOT

In the past, reporting to SHOT has been voluntary. In recent years a number of quality, inspection and accreditation organisations and government bodies within the United Kingdom have made reporting to SHOT a requirement; SHOT has identified all these organisations and their specific requirements and these are listed below.

1. Clinical Pathology Accreditation Ltd, United Kingdom (CPA UK)

Standard H2 Assessment of user satisfaction

H2.1 Laboratory management shall:

d) Participate in the evaluation of clinical effectiveness, audit and risk management activities of the parent organisation or external bodies.

CPA clarifies this in the document 'Assessment of Haematology':

It is not always possible to include an experienced transfusion specialist BMS assessor to routine hospital blood banks. CPA assessors are required to conduct an audit of transfusion medicine incident reporting during the assessment visit to this type of laboratory. This audit shall include Serious Hazards of Transfusion (SHOT).

We are requesting that the assessors focus on SHOT reporting under the standard H2.1d. The emphasis in the audit should be in establishing whether there is a framework and a culture in the laboratory within which errors are:

- *Reported to senior staff*
- *Fully investigated to root cause if appropriate*
- *Corrective action put in place*
- *Lessons learned*
- *A report submitted to SHOT.*

The emphasis should not be on the errors themselves. Areas of laboratory practice in which errors reported to SHOT have occurred include the following:

- *ABO grouping errors using manual techniques*
- *Failure to consult historical records leading to failure to provide antigen negative red cells for patients with previously documented alloantibodies or failure to provide for special transfusion requirements, e.g. for irradiated blood*
- *Selection and issue of unsuitable components, e.g. for neonates, due to lack of awareness of guidelines and lack of 'flagging' system*
- *Numerous instances of failure to follow SOPs*
- *Poor stock management leading to issue of expired units, particularly from satellite blood refrigerators.*

2. The Care Quality Commission (England), Core Standards for Self Assessment 2008–2009

First domain: Safety

Domain outcome: Patient safety is enhanced by the use of healthcare processes, working practices and systemic activities that prevent or reduce the risk of harm to patients.

Standard C01a

Healthcare organisations protect patients through systems that identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents.

Proposed 2008/09 elements

Element one – All provider sectors

Incidents are reported locally and nationally via the appropriate reporting route(s) to the National Patient Safety Agency (NPSA), Health and Safety Executive, Medicines and Healthcare products Regulatory Agency (MHRA), Health Protection Agency, Healthcare Commission, the Counter Fraud and Security Management Service and *all other national organisations* to which the healthcare organisation is required to report incidents.

3. National Patient Safety Agency (NPSA, England and Wales)

Safer Practice Notice 14

Reporting incidents

Staff should be encouraged to report patient safety incidents relating to blood transfusions, including Near Misses, to their local risk management systems and to the hospital transfusion team (consultant haematologist with responsibility for blood transfusion, transfusion practitioner and transfusion laboratory manager), which are responsible for reporting to SHOT. It is essential that all such events are reported to SHOT, using the SABRE electronic reporting system, so that lessons are learned and shared, and the effect of interventions monitored.

4. Department of Health (DH, England)

Health Service Circular 2007/001: Better blood transfusion – safe and appropriate use of blood

All NHS Trusts that undertake blood transfusion:

Should participate in the Serious Hazards of Transfusion (SHOT) scheme on the reporting of serious and Near Miss events (www.shotuk.org), and fulfil the MHRA's requirements for reporting adverse reactions and events (SABRE).

5. Department of Health and Social Service and Public Safety Northern Ireland

Safety, Quality & Standards Directorate (SQSD)

Health Service Circular (SQSD) 30/2007

NPSA Safer Practice Notice 14

'The Department endorses the principles outlined in this Notice which was designed to improve the safety of blood transfusions and to promote strict checking procedures at each stage of the blood transfusion process. Progress towards implementation will be coordinated through the Northern Ireland Regional Transfusion Committee. Organisations need to be aware of this Safer Practice Notice, in order to assist in complying with criteria 5.3.1(f)(9), 5.3.2 and 5.3.3(f) of the Quality Standards for Health and Social Care (safe practice in the use of blood and blood products, learning from adverse incidents and implementation of evidence based practice through guidance, for example, NPSA). These Quality Standards underpin clinical and social care governance reviews in health and social care organisations. Independent sector organisations, where blood transfusions are administered, will also wish to provide evidence to the Regulation and Quality Improvement Authority that implementation is complete.'

6. NHS Quality Improvement Scotland

Clinical Standards for Blood Transfusion, Standard 4b.3

Reports of serious adverse events or reactions and Near Miss incidents to Serious Adverse Reactions and Events (SABRE) and the Serious Hazards of Transfusion initiative to be made by the relevant staff.

7. Welsh Assembly Government

Healthcare Standards for Wales, Standard 16

Healthcare organisations have systems in place:

a) to identify and learn from all patient safety incidents and other reportable incidents;

b) to report incidents to the National Patient Safety Agency's (NPSA) National Reporting and Learning System and other bodies in line with existing guidance;

c) to demonstrate improvements in practice based on shared local and national experience and information derived from the analysis of incidents; and

d) to ensure that patient safety notices, alerts and other communications concerning safety are acted upon within required timescales.

Technical guidance on Standard 16

Having sustainable systems outlining accountability and arrangements, including:

- Policies and procedures on specific reporting requirements, e.g. serious incidents, RIDDOR, Ionising radiation, blood transfusion (SHOT and SABRE).

NEW IN THIS 2008 REPORT

Changes to IBCT chapter sections

The number of incorrect blood component transfused (IBCT) cases along with the total number of SHOT reports has increased year by year with an especially marked increase in 2008. The breakdown of cases of IBCT has also changed over the years. In 1996–97, IBCT consisted only of phlebotomy errors, wrong blood in tube (WBIT), administration (ward-based patient ID errors) and laboratory errors resulting in wrong transfusion. Additional categories emerged in around the year 2000, and these have increased significantly, not just in absolute numbers, but as a proportion of the IBCT category. While *special requirements not met* is a genuine category of incorrect blood component transfused, *handling and storage errors* and *inappropriate and unnecessary transfusion* are not. In these two latter categories the correct blood is transfused to the patient. Inclusion of these two categories as a part of IBCT results in skewing of the data, so that the much quoted SHOT pie-chart suggests more 'wrong blood' episodes than have truly taken place.

This year, therefore, *inappropriate and unnecessary transfusion* and *handling and storage errors* have been removed from IBCT into separate stand-alone categories and chapters. The graph in Figure 6 (page 34) shows the number of IBCT cases going back to 2003, with *handling and storage* and *inappropriate and unnecessary transfusion* separated from the total. SHOT feels that this is now more representative of the number of incorrect blood component episodes.

Reports made on the IBCT questionnaires during 2008 were categorised under 6 major headings as in the 2007 SHOT report:
administration of wrong blood
special requirements not met
wrong blood in tube (WBIT)
laboratory errors
handling and storage errors
inappropriate and unnecessary transfusion.

There is no overlap in the numbers of each category, so the total number of cases in these 6 categories is the total number of reports on IBCT questionnaires.

As handling and storage errors and inappropriate and unnecessary transfusion are not true instances of the incorrect blood component being transfused, and for the sake of clarity and also for international comparison are no longer in the IBCT chapter but reported in separate chapters, the IBCT chapter therefore now contains the following 4 categories:

Administration of wrong blood – where there was a collection error and, or, failure of the bedside check.
Special requirements not met – where the patient's special requirements have not been met irrespective of the location of the error, i.e. both laboratory and clinical will be included in the total.
Wrong blood in tube – WBIT are those events which resulted in a transfusion irrespective of outcome.
Laboratory errors – where the primary error has occurred in the laboratory.

There is one further subsection that includes reports from all of these categories:

IT errors – where the reporter has identified a specific problem that matched the categories from the 2007 SHOT report. These are all duplicates, so appear in their primary category, but will be discussed in this separate section as well.

As mentioned above, in the 2008 SHOT Report handling and storage errors and inappropriate and unnecessary transfusion will be presented in separate chapters, as they are not true IBCT.

Handling and storage errors are related to the administration of expired components, excessive time to transfuse, and cold chain errors. Cases arise in clinical and laboratory settings, and in the transport of blood components.

Inappropriate and unnecessary transfusion comprise events in which a transfusion was given because of an incorrect result or poor knowledge or prescribing. Incorrect results may arise from verbal or written communication errors, or an error in the transfusion, haematology, or coagulation laboratory, or during point-of-care testing.

Newly established SHOT reporting categories

Cases of transfusion-associated circulatory overload (TACO) have been specifically requested in 2008, and the number of reports has increased. These have been reported in detail in a new chapter. One reported case was designated by SHOT as transfusion-associated dyspnoea (TAD) and has been reported separately. This type of pulmonary transfusion complication is recognised by the ISBT and included in their definitions.[4] A substantive section is included in this report of adverse events related to autologous transfusion. This year the chapter focuses on the results of a cell salvage adverse events data collection pilot.

Cell Salvage Pilot

This year, the separate chapter on autologous transfusion related adverse incidents contains the reports of the cell salvage adverse events pilot. This was a joint initiative between the UK Cell Salvage Action Group (UK CCAG) and SHOT, which ran for 6 months from April to September 2008. SHOT will be incorporating the data set from the pilot (with some augmentation and improvement) on the new web-based data capture system and it is hoped that all adverse events relating to cell salvage will continue to be reported as well as any other autologous transfusion-related events.

Participation

There is a new chapter this year on participation in SHOT reporting, which shows the number of SHOT reports sent in by the 4 UK countries and by the 10 English regions. There is also some analysis of the category of reports most often sent. UK and regional variations have been observed, with Wales being the most enthusiastic reporter and Scotland sending the fewest reports in relation to the number of components issued by the relevant Blood Service. In the future more detailed analysis will be possible, including on a trust by trust basis, allowing benchmarking between hospitals, trusts and regions, which will provide the basis for sharing good practice and for learning opportunities. There is of course considerable overlap with the data held by MHRA, as explained in the participation chapter. MHRA have expressed concerns about non-reporters to SABRE, especially those institutions that are larger blood users.

SHOT hopes that the publication of these data and of more detailed data in future will allow reporting organisations to improve their awareness of SHOT (and MHRA) reportable incidents and enhance their local methods of vigilance and data capture. As well as the statutory requirement to report adverse events to the regulator, MHRA, reporting is an important part of professional good practice for all professional groups involved in transfusion. It is only by continuous monitoring, or audit, of transfusion practice and outcomes that patient care can undergo continuing improvement in quality and safety, with further risk reduction, as already demonstrated by the last decade of SHOT reporting.

Paediatrics

SHOT has now a formal link with the NHSBT Paediatric Transfusion Group, and as a result a more detailed analysis of paediatric SHOT reports has taken place this year. Previously, short paediatric chapters appeared in 2003 and 2007. It is now SHOT's intention to analyse paediatric cases systematically every year in detail, as it is clear that there are specific areas of risk affecting children. These relate in part to the small size and blood volume of paediatric patients, to the range of medical and surgical conditions affecting this age group (and the special transfusion requirements that ensue) and to difficulties of venous access, identification and other practical issues. SHOT feels that these need to be highlighted and addressed separately from the main body of SHOT data, which is slanted towards adult transfusion practice.

Undertransfusion

There has been increasing interest in the literature in recent years in possible patient harm arising from undertransfusion or delayed transfusion. SHOT has not previously requested that such cases be reported, but this year, in the inappropriate and unnecessary transfusion section, there is one such case. Just as with other 'new' categories, it is often reporter concern that results in a new type of report being collected. SHOT is very willing to receive more reports of this nature.

Appropriateness of transfusion

This year the analysis of SHOT reports has not included any formal assessment of the appropriateness of the transfusions implicated in the cases. The questionnaires did not request sufficient detail on this, and many reporters are not in a position to pass comment as they are not directly clinically involved with the majority of cases they report. Inappropriate and unnecessary transfusion is therefore discussed in a separate chapter on this specific category, the cases included being those in which inappropriate transfusion was the primary error. There are also some comments in the text regarding inappropriate use of FFP for warfarin reversal.

UPDATE ON 2007 RECOMMENDATIONS

Last year the following recommendations were made:

- transfusion medicine to be a module in the core curriculum for doctors in training
- accredited staff to be responsible for safety in the laboratory and clinical areas
- increased familiarity with guidelines for anti-D administration and their rationale
- improved participation in haemovigilance.

The Royal Colleges and Specialist Societies Committee, a subgroup of the National Blood Transfusion Committee (NBTC), has taken on the crucial task of gaining agreement to a core curriculum for transfusion medicine with all the Royal Colleges in hospital specialities and it aims to make further progress with this in the near future. A separate initiative is underway to utilise the Scottish e-learning 'Learn blood transfusion' package as a compulsory milestone for FY1 and FY2 doctors in England, as it is in Scotland, Wales and Northern Ireland. For this the support of the GMC / PMETB or the new Medical Education England (MEE) will be essential. The NBTC has a potentially powerful infrastructure to drive safe and effective hospital transfusion practice. Education of junior doctors is an essential prerequisite for this, and SHOT looks to the national transfusion committees to lead and drive initiatives in junior doctor education.

The UK Transfusion Laboratory Collaborative has produced evidence-based standards and recommendations for staffing levels and skills, working patterns, automation in transfusion laboratories and competencies especially for out-of-hour's staff. A paper is in press with *Transfusion Medicine* at the time of writing and will be accompanied by an editorial. The publication will be disseminated to a large number of stakeholders and interested parties as soon as it is available.

The Transfusion Laboratory Anti-D Education Group has been set up as part of a UK anti-D educational collaborative under the umbrella of the NHS Blood and Transplant (NHSBT) Appropriate Use Group and the UK Better Blood Transfusion Network. The group has to date produced a list of learning outcomes, and has already facilitated an education day about anti-D that was well attended and received. There are plans to develop flowcharts for laboratory and clinical areas and to contribute to a new e-learning module in collaboration with SNBTS.

Participation in haemovigilance has undoubtedly improved in 2008 with an 85% increase in the number of reports submitted (from 561 in 2007 to 1040 in 2008), representing a more rapid rate of increase than in any previous two consecutive years. The number of non-reporting hospitals and trusts has dropped, according to MHRA, and the proportion of reporting organisations sending only one report in a reporting year to SHOT has also dropped. It is hoped that this trend will continue as more and more reporters reap the benefits of the learning points and shared good practice that arise from haemovigilance nationally as well as the accepting of a culture of 'friendly surveillance' in the hospital, which should be the cornerstone of any form of teamwork.

SaBTO

The Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) is assessing options for further reducing the potential risk of variant CJD transmission via blood components and will be advising on strategies to reduce the bacterial contamination of platelets.

SaBTO and the NBTC (and equivalents in Wales, Northern Ireland and Scotland) continue to develop their complementary roles in giving expert independent advice to the UK Health Departments, the Blood Transfusion Services and the NHS on initiatives to improve both the safety of blood components and of transfusion medicine practice.

SHOT INITIATIVES IN 2008

Dendrite Clinical Systems to develop new SHOT database

It is anticipated that this will be the last year that the SHOT Report is produced from the 'questionnaire' system of collecting data. This method was instigated at the outset in 1996 and over the years the data set used in the paper questionnaires has evolved, being refined and augmented over 12 years. Trends and patterns have emerged, and new types of event and reaction have been reported, creating new categories. Current SHOT reporting categories for transfusion reactions are very similar to those recently developed by the International Society of Blood Transfusion (ISBT) Haemovigilance Working Party, as a step towards standardisation of reports for international comparison. SHOT will make final small amendments to reporting categories in order to fit the ISBT categories fully, once they are formally published. Definitions and categories of transfusion errors and Near Miss events are due to be developed shortly by a working group of the ISBT and International Haemovigilance Network (IHN). The paper questionnaires were uploaded onto the SHOT side of the SABRE website, and since November 2005 the questionnaires have been completed online following the notification of each case by a reporter through SABRE.

SHOT has contracted Dendrite Clinical Systems – a company with a proven track record in developing, maintaining and producing reports for both national and international databases across many clinical specialties – to develop a web-based database for the collection of SHOT data across the UK, with links to the existing SABRE system. The dataset being used is based on the existing questionnaires, but the format for data collection will involve mainly tick-boxes and drop-down selection lists. The details initially recorded on each case will lead the reporter to the correct pages to complete, so that only the relevant pages need be completed. Demographic data will be collected in detail from each reporting organisation and for each report. Following the initial request for demographic data, the cases will be divided into those involving transfusion of a component to a patient (SHOT reports) and those in which transfusion did not take place (Near Miss). There will also be an early option to report a cell salvage related adverse event. The main SHOT cases will be divided into error-based reports (incorrect blood component transfused (IBCT), inappropriate and unnecessary transfusion, and handling and storage errors) and physiological transfusion reactions. A free text box in which to write 'the story' very briefly will always be available so that the much valued narrative aspect of the SHOT report is preserved. Each page will need to be completed fully and will automatically be saved before the reporter can move to the next page. The process should be much faster and more intuitive than the current system, in which many reporters find they have to scroll through long sections of the questionnaires to find the relevant questions to answer. All reports sent to SHOT during 2009 will be entered onto the new database manually by SHOT office staff, who may need to contact reporters for additional information, or to help with this process.

SHOT is purchasing a data analysis system as well as the database, which will allow for more detailed, customised analysis including a variety of visual representations of data. It is therefore likely that the next Annual SHOT Report may have a somewhat different style of content from the preceding ones, and future developments, especially regarding information extraction from the data, will be greatly facilitated by the new system.

UK Transfusion Laboratory Collaborative

The UK Transfusion Laboratory Collaborative was established in 2006 in response to SHOT reports, year-on-year, that 30–40% of 'wrong blood' event errors originate in the hospital blood transfusion laboratory, with a disproportionate number occurring outside 'core hours'. The collaborative was formed originally between SHOT and the IBMS, and extended to include key professional groups involved in laboratory transfusion medicine: the RCPath, the CMO's NBTC and its counterparts in Scotland and Wales, the BBTS and UK NEQAS. The collaborative has produced recommendations on minimum standards for hospital transfusion laboratories, which address staffing, technology, and training and competence.[2] There was an extensive consultation process. The recommendations are based on two national surveys of UK laboratories.[3] They are intended to encourage effective and appropriate use of technology and staff in hospital transfusion laboratories within the framework of current legislative requirements. They will help hospitals and trusts to achieve the minimum standards of proficiency and practice set by the Health Professions Council (HPC) and as required by the UK Blood Safety and Quality Regulations (BSQR 2005).[1] The aim is to reduce blood transfusion laboratory errors by 50% within 3 years. The Collaborative's recommendations will be sent to all transfusion laboratory and service managers, and for the attention of chief executive officers of hospitals and trusts. Implementation will be monitored through current MHRA inspections (where applicable to BSQR 2005). The impact on transfusion laboratory errors will be monitored by SHOT reporting. It is recognised that not all existing hospital transfusion laboratory structures currently

meet all the recommendations. However, hospitals and trusts will be expected to work towards these recommendations if transfusion services are reconfigured, as new posts are established or new staff members are appointed.

FUTURE DEVELOPMENTS IN SHOT

Benchmarking of participation and other SHOT data

The new web-based data capture system will allow all demographic data regarding reporting organisations and their issue data, as well as the reporting pattern, to be analysed very easily. Benchmarking between UK countries, English regions and individual reporting organisations will become very straightforward. SHOT is already receiving increasing numbers of requests for de-anonymised data so that direct comparisons can be made within countries or regions, and between similar hospitals and trusts. This is certainly part of the current trend for non-anonymised data to be circulated and compared; this has already been implemented with data from UK NEQAS and the Blood Stocks Management Scheme. Naturally, the anonymity of individual patients and of individual medical and other staff is preserved.

Previously uncategorised complications of transfusion

The patterns and trends of new (especially uncommon) and emerging adverse reactions to blood can only be appreciated if data is collected and analysed centrally. SHOT will therefore continue to collect all adverse events or reactions related to blood component transfusion, and where reporters feel these incidents do not fit existing categories they can be reported on the new web-based data capture system as 'previously uncategorised complications of transfusion' (PUCT) in line with the ISBT definitions.[4] One example is related to the possible commencement of the pilot of prion filtration, for which SHOT has agreed to collect any adverse event reports that relate to the use of these filters.

Follow up of potential sensitisation to D antigen

This year there has been a 120% increase in the number of adverse incidents reported relating to the anti-D category, with 42% (58 cases) relating to omission or late administration of anti-D. The patient is thus exposed to possible sensitisation to the D antigen, with a significant risk of haemolytic diseases of the newborn (HDN) in subsequent infants. This is therefore classified by SHOT as having potential for major morbidity. However, currently SHOT has no data on the follow-up of these patients 3-6 months later for re-testing, to establish whether or not they have developed immune anti-D. The new web-based data collection system will generate an automated email for cases of omission or late administration of anti-D; the reporter will be informed when the follow-up tests are due and reminded that the results should be entered into the SHOT database.

3. Summary of Main Findings and Cumulative Results

Data analysed for this report were collected between 1st January 2008 and 31st December 2008.

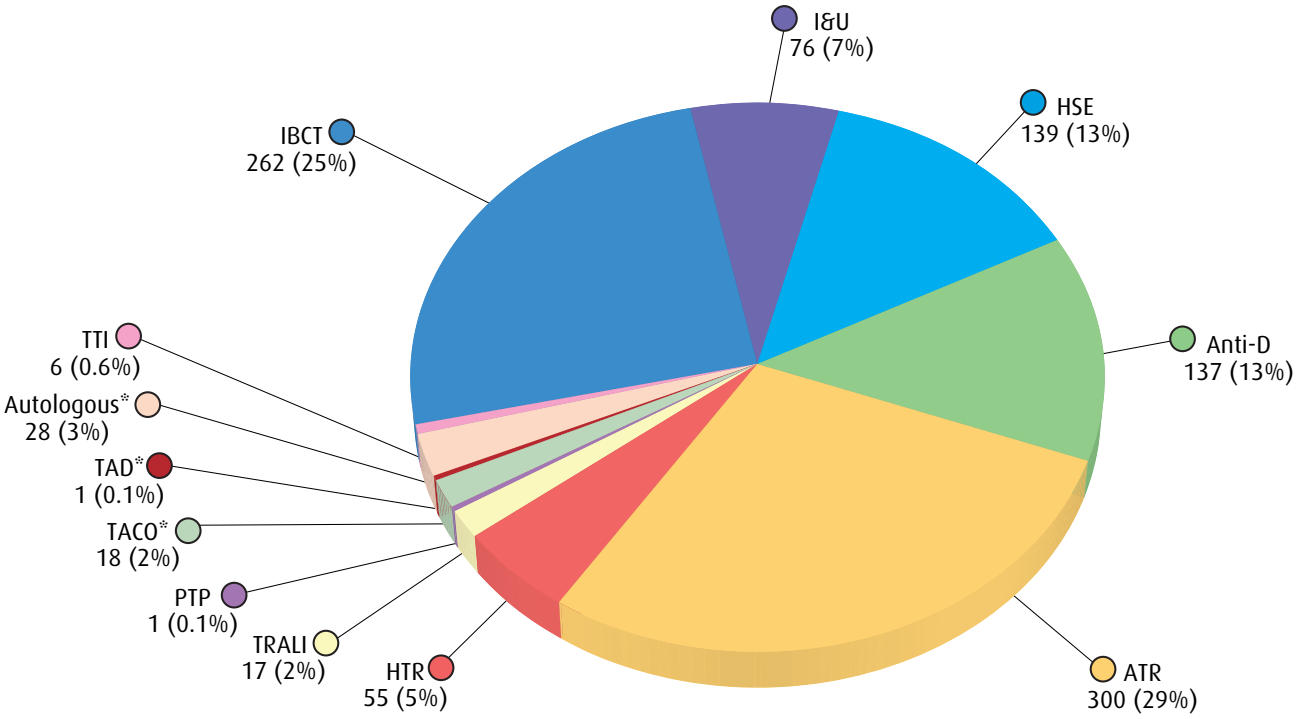
Numbers of questionnaires completed

The total number of questionnaires reviewed this year is 1040, representing an increase of 85% since 2007, when 561 were reviewed. This year some new categories have been formed, and the structure of reporting of the data received on IBCT questionnaires has altered (see page 5). The overall figures are summarised in Table 1 and Figure 2 below.

Table 1
Summary of reports reviewed

IBCT	I&U	HSE	ANTI-D	ATR	HTR	TRALI	PTP	TA-GvHD	TTI	TACO	TAD	AUTO-LOGOUS	Totals
262	76	139	137	300	55	17	1	0	6	18	1	28	**1040**

Figure 2
Cases reviewed n = 1040



*New Categories for this year

Clinical versus laboratory errors

In total, laboratory errors account for 200 (19%) of the total 1040 cases included in this annual report. These consist of 132 IBCT events, 47 anti-D related events and 21 handling and storage errors.

Numbers of components issued

The total number of components issued by the four transfusion services of the UK has decreased once again during the financial year 2007–2008, representing a further decrease of 2.4% since 2006–2007. Individually red cell, platelet, FFP and cryoprecipitate usage have each continued the trend followed in the preceding 8 years, with red cell usage dropping a further 2.7% and FFP usage dropping 3.7%, while platelet use has increased by 1.2% and cryoprecipitate usage has risen by 0.9%.

Table 2
Yearly summary of issues by the 4 UK Blood Services 1999–2008

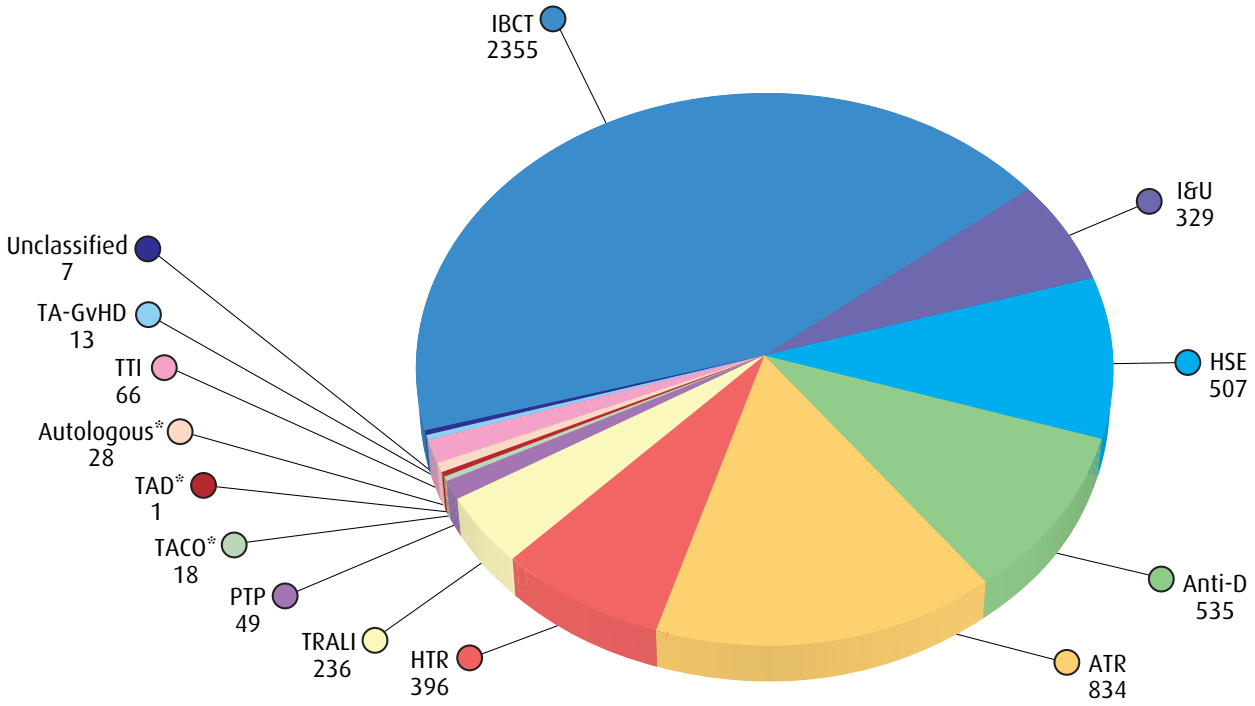
Year	Red Blood Cells	Platelets	FFP	Cryoprecipitate	Totals
1999–2000	2,737,572	249,622	365,547	94,114	**3,446,855**
2000–2001	2,706,307	250,259	374,760	95,456	**3,426,782**
2001–2002	2,679,925	251,451	385,236	88,253	**3,404,865**
2002–2003	2,678,098	251,741	377,381	92,768	**3,399,988**
2003–2004	2,607,410	264,539	372,855	95,417	**3,340,221**
2004–2005	2,428,934	258,528	313,019	102,719	**3,103,200**
2005–2006	2,316,152	259,654	320,852	106,139	**3,002,797**
2006–2007	2,235,638	255,474	306,444	116,672	**2,914,228**
2007–2008	2,174,256	258,419	295,085	117,699	**2,845,459**

Although overall blood component usage in the UK until April 2008 has continued to decrease, there have been signs recently that this trend may not continue, and blood component usage may plateau or even increase again in future.

Table 3
Total issues of blood components from the Transfusion Services of the UK in the financial year 2007–2008

	Red blood cells	Platelets	FFP	Cryoprecipitate	Total
National Blood Service	1,816,872	218,459	250,644	99,928	2,385,903
Welsh Blood Service	95,207	8,526	12,121	2,418	118,272
Scottish National Blood Transfusion Service	208,909	24,065	25,554	14,703	273,231
Northern Ireland Blood Transfusion Service	53,268	7,369	6,766	650	68,053
TOTAL	**2,174,256**	**258,419**	**295,085**	**117,699**	**2,845,459**

Figure 3
Cumulative numbers of cases reviewed 1996–2008 *n* = 5374



*New Categories for this year

Figure 4
Comparison of report types 1996–2008

NB 2001–02 was a 15 month period

* New categories for this year

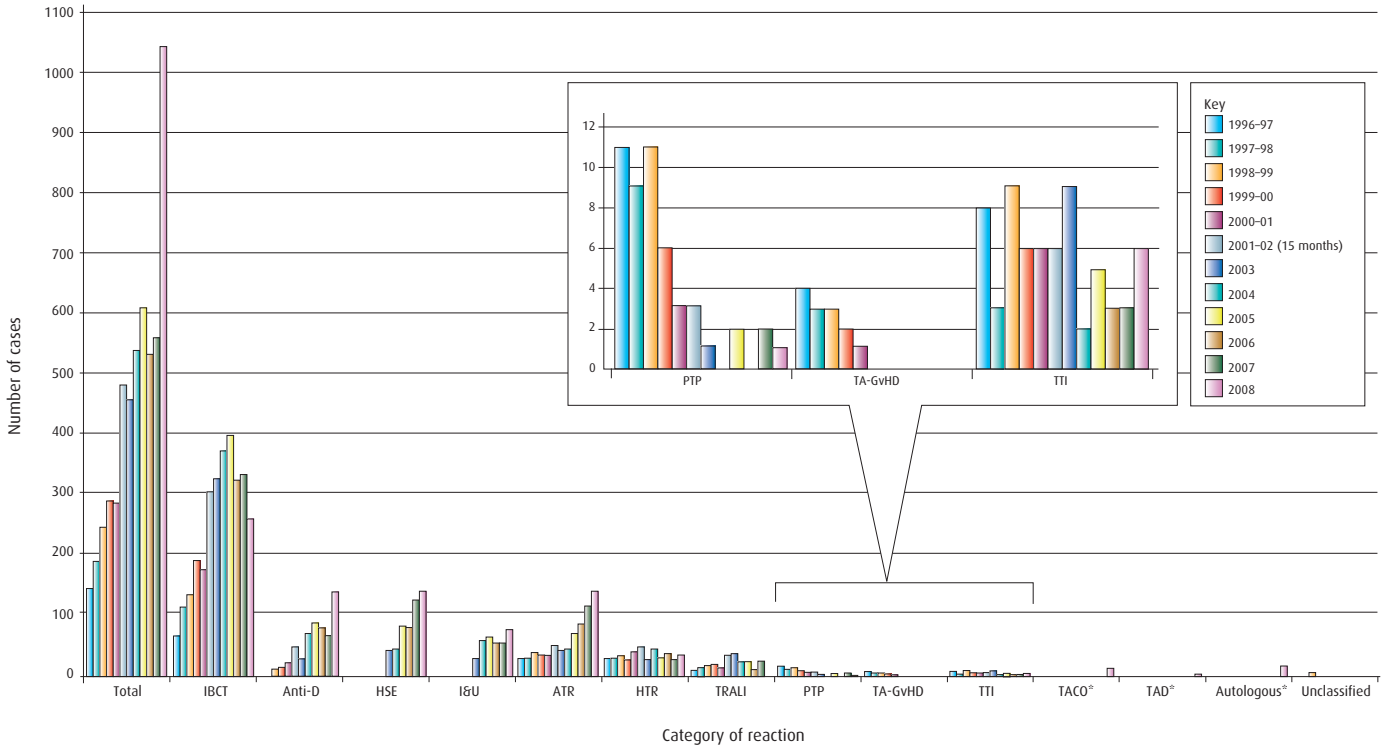


Table 4
Cumulative mortality/morbidity data 1996–2008

	Total	IBCT	I&U*	HSE*	Anti-D	ATR	HTR*	TRALI	PTP	TA-GvHD	TTI	TACO**	TAD**	AUTOLO-GOUS**
Death in which transfusion reaction was causal or contributory	**125**	24	2	0	0	18	11	40	2	13	14	1	0	0
Major morbidity probably or definitely attributed to transfusion reaction imputability 2/3)	**421**	112	1	0	24	31	40	147	13	0	46	6	1	0
Minor or no morbidity as a result of transfusion reaction	**4806**	3164	73	139	176	782	344	49	34	0	6	11	0	28
Outcome unknown	**15**	11	0	0	0	3	1	0	0	0	0	0	0	0
TOTAL ***	**5367**	**3311**	**76**	**139**	**200**	**834**	**396**	**236**	**49**	**13**	**66**	**18**	**1**	**28**

* I&U and HSE counted in IBCT totals before this year
** TACO, TAD and AUTOLOGOUS new categories this year
*** Excludes 7 cases from 1998–99 that were not classified.

OVERVIEW OF 2008 RESULTS

Transfusion-related mortality

There was 1 death reported in 2008 that was a direct consequence of the blood component being transfused. This was a case of transfusion-transmitted bacterial infection, in which a pancytopenic patient with AML received a routine prophylactic platelet transfusion and died from *Klebsiella pneumoniae* infection proven to have been transmitted from the donor via the platelets.

There were a further 9 deaths in which a patient who was already very unwell died following a transfusion reaction, and the reaction was considered to have contributed to the death at that time. This included 2 cases of inappropriate and unnecessary transfusion, 4 acute transfusion reactions, 1 haemolytic transfusion reaction, 1 transfusion-associated circulatory overload and a second transfusion-transmitted bacterial infection, which was in fact from the same apheresis platelet donor, via the second half of the same donation.

Patients developed major morbidity from most types of reactions and events and these are summarised in the paragraphs below, and discussed in detail in each chapter.

Incorrect blood component transfused

A total of 477 cases were reported on IBCT questionnaires in 2008. This represents an increased reporting rate, now 16.8 per 100,000 components issued, compared with 11.4 in 2007. Handling and storage errors (139 cases) and inappropriate and unnecessary transfusion (76 cases) have been described in separate chapters as the incorrect blood component is not transfused in these events. This leaves 262 true IBCT events in this section.

There were 47 reports of ward-based blood administration errors, and in 29 of these the incorrect unit had been collected from the controlled temperature storage (CTS) site. All these incorrect transfusions could have been prevented by a diligent bedside check of the patient's identity against the component. Although there were 4 ABO-incompatible red cell transfusions resulting from these errors, there were no fatal cases. There were 2 cases of major morbidity from haemolysis due to ABO incompatibility.

There were 5 phlebotomy errors resulting in transfusions based on 'wrong blood in tube'. These caused 3 episodes of ABO-incompatible red cell transfusion with no fatalities but major morbidity in 2 cases.

A total of 91 primary laboratory errors resulted in incorrect blood components being transfused (excluding special requirements not met) and these resulted in 3 ABO-incompatible red cell transfusions.

There were a total of 117 cases reported in which special requirements were not met, of which 100 related to a requirement for CMV negative or irradiated components. Of the 117 cases, 41 (35%) occurred because of laboratory errors or omissions.

Overall, laboratory errors accounted for 132 (50%) of the 262 cases of incorrect blood component transfused.

The increased reporting has been especially marked among the laboratory error category, possibly due to increased awareness as a result of the emphasis placed on the laboratory by the Blood Safety and Quality Regulations 2005.[1]

Inappropriate and unnecessary transfusion

There were 76 cases reported in the category of inappropriate and unnecessary transfusion. The largest category, 38 cases, involved patients transfused on the basis of erroneous haemoglobin, platelet or coagulation results owing to poor sampling, transcription errors, use of another patient's results or other miscommunications. A further large category was that in which the errors were due to poor knowledge of basic transfusion medicine, including incorrect prescribing. There were 2 fatalities in this group in which the inappropriate transfusion was thought to have contributed to the death, 1 due to undertransfusion and 1 to overtransfusion, both in bleeding patients. There was 1 case of major morbidity in a 1-year-old child who was massively over-transfused for anaemia and required venesection.

Attainment of appropriate knowledge and experience in transfusion medicine for clinical staff remains a major issue for medical educators.

Handling and storage errors

A total of 139 cases were included in this category, none of which caused mortality or major morbidity. The most common subcategory was cold chain errors (61 cases) followed by transfusion of expired red cells. The majority of cases in these categories occurred outside the responsibility of the hospital transfusion laboratory. Another large group comprised cases of excessive time taken to transfuse (24 cases), which were all primary clinical errors.

Overall in this category 118 events (85%) resulted from primary errors outside the laboratory, and 21 events (15%) were the result of laboratory errors.

It is essential that clinical and portering staff involved in the transfusion process have sufficient knowledge to appreciate the critical points in the tasks and work to clear protocols.

Anti-D related events

A total of 137 anti-D related adverse events were recorded by SHOT in 2008 of which 58 were omission or late administration of anti-D. The resulting potential for sensitisation to the D antigen in a woman of childbearing age constitutes a potential for major morbidity. In addition 63 cases related to the inappropriate administration of anti-D to patients who did not require it. Overall, in 90 cases the error or omission was clinical while in 47 cases the laboratory was responsible.

Robust education, training and protocols are required to ensure that anti-D is issued appropriately and on a named patient basis.

Acute transfusion reactions

In 2008 there were 300 reports of acute transfusion reactions (ATR). No deaths were the direct result of any reaction, but there were 4 deaths in which the reaction was implicated. These occurred in patients who were already frail with severe underlying illnesses. There were 9 cases of major morbidity in which patients suffered cardio-respiratory arrest or required admission to ITU. The largest group overall was of isolated febrile reactions with 123 cases, followed by minor allergic reactions with 58 cases.

Reporting of ATR and their management is very variable across the UK and between different hospitals and trusts. All acute transfusion reactions that are of sufficient severity to warrant stopping the transfusion should be investigated appropriately and reported.

Haemolytic transfusion reactions

Fifty-five haemolytic transfusion reactions were reported. There were no deaths among the 9 acute haemolytic transfusion reactions (AHTR), but there were 2 cases of major morbidity requiring ITU admission. Delayed haemolytic transfusion reactions (DHTR) were reported in 46 patients, including 1 very sick recipient who died, in which the reaction may have contributed to the death. There were 4 cases of major morbidity related to DHTR.

Group O platelets, even when labelled as negative for high-titre haemolysins, are still implicated in AHTR. Great care must be taken to weigh up all risks when selecting platelets, especially for children.

The quality of investigations carried out for HTR continues to improve, but reactions in which Kidd (Jk) antibodies are implicated remain frequent and challenging.

Transfusion-related acute lung injury

In 2008 there were 17 cases of transfusion-related acute lung injury (TRALI), a reduction from the 24 cases reported the previous year. Although 4 patients died, these were cases considered 'unlikely' to be TRALI (imputability 0), and the deaths were due to other causes. There were therefore no deaths from TRALI this year, the lowest since SHOT reporting began. There were 12 patients who required mechanical ventilation, i.e. who suffered major morbidity.

Antibodies concordant with HLA antigens in recipients were found in 7 female donors. These consisted of 3 donors contributing to separate platelet pools all transfused to the same patient, 1 apheresis platelet donor and 3 FFP donors. It is notable that these 3 cases of proven TRALI from FFP occurred due to FFP from female donors in the English NBS.

Post-transfusion purpura

There was 1 case of post-transfusion purpura (PTP) in 2008; the patient responded to treatment and had no serious sequelae. The decrease in the frequency of this complication has again been sustained since universal leucodepletion commenced in 1999.

Transfusion-associated graft-versus-host disease

There were no cases of transfusion-associated graft-versus-host disease (TA-GvHD) reported in 2008. Once again there has been a negligible incidence of this complication since universal leucodepletion was introduced in 1999.

Transfusion-transmitted infection

In 2008 there were 33 suspected cases of transfusion-transmitted infection (TTI) reported by blood centres and hospitals in which the suspect packs, and the donors, were investigated. Four incidents of contaminated units of platelets were proven to have transmitted bacterial infection to 6 recipients. Two of the packs were apheresis collections of platelets which were split between 2 recipients. Of these 1 recipient died of the infection resulting from the platelet transfusion, and there was 1 death to which bacterial transmission from the platelets contributed. Two patients suffered major morbidity and 2 minor morbidity.

There were no proven cases of viral or protozoal transmission in 2008. There have been no further reports of vCJD transmission by blood component transfusion.

Serious complications from bacterial contamination of blood components remains a challenge for the UK Blood Services.

Transfusion-associated circulatory overload

In 2008 there were 18 reports of transfusion-associated circulatory overload (TACO) based on the definition from the International Society of Blood Transfusion (ISBT). There was 1 death in which the transfusion was implicated and 6 cases with major morbidity (requiring ITU admission and CPAP or ventilation). There was serious morbidity thought to be life-threatening by the reporter (although not fulfilling the criteria for major morbidity) in a further 4 cases.

TACO is a serious complication of transfusion and is commonly reported to haemovigilance systems in Europe and Canada. However, as TACO is a new reporting category for SHOT, it is anticipated that the number of reports will increase.

Transfusion-associated dyspnoea

There was 1 case in the new category of transfusion-associated dyspnoea (TAD) in 2008. The patient received granulocytes and buffy coats and suffered major morbidity requiring ventilation for a week.

Autologous transfusion

All 28 cases in the autologous transfusion section in 2008 arose through the cell salvage adverse events pilot, a joint initiative involving the UK Cell Salvage Action Group and SHOT. Of these cases 25 arose from intraoperative cell salvage (ICS) and 3 from postoperative cell salvage (PCS). There were 5 hypotensive reactions reported from ICS, but no mortality or major morbidity.

Monitoring of patients receiving autologous transfusion is as important as it is for those receiving allogeneic transfusion. SHOT will continue data collection for adverse events related to cell salvage and all other forms of autologous transfusion.

Paediatric cases

In 2008, 92 (8.8%) of the total 1040 events reported occurred in children under 18 years of age, with 20 of these cases (1.9% of total cases) occurring in children less than 4 weeks old. These cases are included in the relevant sections throughout this Annual Report, and are discussed in detail in the paediatric chapter, with emphasis on those events that occurred specifically because of the age, size or disease spectrum of the paediatric patient.

Paediatric transfusion is a specialised area with many specific considerations from both laboratory and clinical perspectives, which require input from practitioners experienced and knowledgeable in paediatric transfusion medicine.

Near Miss events

The Near Miss chapter this year gives the results of the recent 2-part pilot carried out by SHOT. Phase 1 received details of all group-and-save and crossmatch samples rejected by the laboratory at the point of entry during 1 calendar month. A total of 224,829 samples were received in 121 transfusion laboratories in the UK in the time period, of which 8535 (3.8%) were rejected. Phase 2 ran for 6 months and looked at errors in samples that were detected after passing through the initial barrier of the 'booking in' stage. True WBIT events accounted for 90/214 (42%) errors in phase 2, of which 74 were detected by comparison with historical data.

The proportion of all sample errors attributable to medical staff appears disproportionately high.

The new database will facilitate the continued reporting of the whole range of Near Miss events to SHOT.

4. Participation in Haemovigilance

Data analysed for this chapter

All reports made to SHOT in the years 2006, 2007 and 2008 including all Near Miss reports and reports that were later excluded or withdrawn.

Introduction

This is a new chapter for the annual SHOT report. Although in the past SHOT has presented the number of cases sent by reporting organisations in relation to the number of blood components issued, it has never undertaken an in-depth analysis of participation data. This year SHOT presents participation data for the years 2006, 2007 and 2008. These data represent information accumulated since the implementation of the Blood Safety and Quality Regulations 2005[1] and reporting via SABRE, as well as the introduction of quality improvement standards in transfusion in all of the four UK countries. The data presented should be viewed as providing a baseline against which to measure the success of these standards.

In another departure for SHOT, these data will be presented by country (UK, England, Northern Ireland, Scotland and Wales) and, for data within England, by Regional Transfusion Committee (RTC). The data presented are for all reports to SHOT via SABRE, and include reports that are withdrawn subsequent to the initial report as well as Near Miss reports, both categories currently being defined as not being SHOT reportable.

The term 'reporting organisation' is used throughout this chapter. A reporting organisation may be a single hospital, a trust or a health board. While a reporting organisation may be registered on SABRE and report all of their incidents under a single login, there are a number of organisations that have several reporters registered for reporting to SABRE. For the purposes of clarity SHOT has grouped all of the SHOT data downloaded from SABRE by reporting organisation, even where there are separate registered reporters from that site.

Differences between reporting to SHOT and to the MHRA

Reporting to the MHRA is defined as statutory reporting. Statutory reporting is that which is required under any statutory instrument such as an Act of Parliament or Regulation, in this case the Blood Safety and Quality Regulations 2005.[1]

Reporting to SHOT is required in order to meet national professional standards or guidelines and the requirements of external quality bodies and external accreditation bodies (see 'Organisations that require evidence of reporting to SHOT', Chapter 2, page 3).

When organisations report Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE) via SABRE, they can:

- make a report to the MHRA only
- make a report to the MHRA and make the report available to SHOT
- make a SHOT only report.

The differences between what is reportable to each organisation are given in the table below (Table 5).

Table 5

MHRA	SHOT
All serious adverse reactions	All serious adverse reactions
Serious adverse events that occur in blood establishments and in, or within the broad responsibility of, hospital transfusion laboratories. Includes events where components were transfused as well as Near Miss events	Serious adverse events that occur within the process of blood component transfusion including all clinical areas. Only includes events where components were transfused. Near Miss events are recorded separately.

Table 6
Total number of reports made to SHOT

The data below include Near Miss events and reports subsequently excluded or withdrawn.

	2006	2007	2008
England	1050 (82.1%)	1113 (82.9%)	1816 (83.4%)
Northern Ireland	41 (3.2%)	45 (3.4%)	68 (3.1%)
Scotland	98 (7.7%)	84 (6.3%)	148 (6.8%)
Wales	90 (7.0%)	99 (7.4%)	145 (6.7%)
United Kingdom	**1279 (100%)**	**1341 (100%)**	**2177 (100%)**

There has been an increase in the total annual number of reports to SHOT since its inception in 1996 and there has been a particularly steep increase in the number of reports made in 2008 compared to the gradual increase over the previous 2 years.

Table 7
Total number of reports to SHOT per 10,000 components issued

	2006	2007	2008
England	4.3	4.6	7.7
Northern Ireland	5.3	6.6	10
Scotland	3.6	3.1	5.4
Wales	7.5	8.4	12.3
United Kingdom	4.4	4.8	7.8

The total number of reports per 10,000 components issued also demonstrates the steep increase in the number of reports in 2008 (Table 7). There is a quite marked variation in the reporting rate between the 4 UK countries, with the highest rate of reporting from Wales and the lowest from Scotland.

Number of reports per reporting organisation for the UK and the 4 countries

Table 8

UK	2006	2007	2008
Mean	5.7	5.9	9.2
Median	4	4	6
Mode	1	1	1
Range	51	44	67
Minimum	1	1	1
Maximum	52	45	68
Total no. of reports	1279	1341	2177
No. of organisations	223	226	237

Table 9

England	2006	2007	2008
Mean	5.7	6.1	9.6
Median	4	4	6
Mode	1	1	1
Range	51	44	67
Minimum	1	1	1
Maximum	52	45	68
Total no. of reports	1050	1113	1816
No. of organisations	183	185	189

Table 10

Northern Ireland	2006	2007	2008
Mean	4.6	4.5	6.8
Median	3	3	4
Mode	1	6	6
Range	10	11	30
Minimum	1	1	1
Maximum	11	12	31
Total no. of reports	41	45	68
No. of organisations	9	10	10

Table 11

Scotland	2006	2007	2008
Mean	4.9	4.67	5.7
Median	4	3	3
Mode	1	1	1
Range	14	15	26
Minimum	1	1	1
Maximum	15	16	27
Total no. of reports	98	84	148
No. of organisations	20	18	26

Table 12

Wales	2006	2007	2008
Mean	8.18	7.62	12.1
Median	5	7	8
Mode	5	3	10
Range	25	20	46
Minimum	1	1	3
Maximum	26	21	49
Total no. of reports	90	99	145
No. of organisations	11	13	12

Reporting activity by organisation

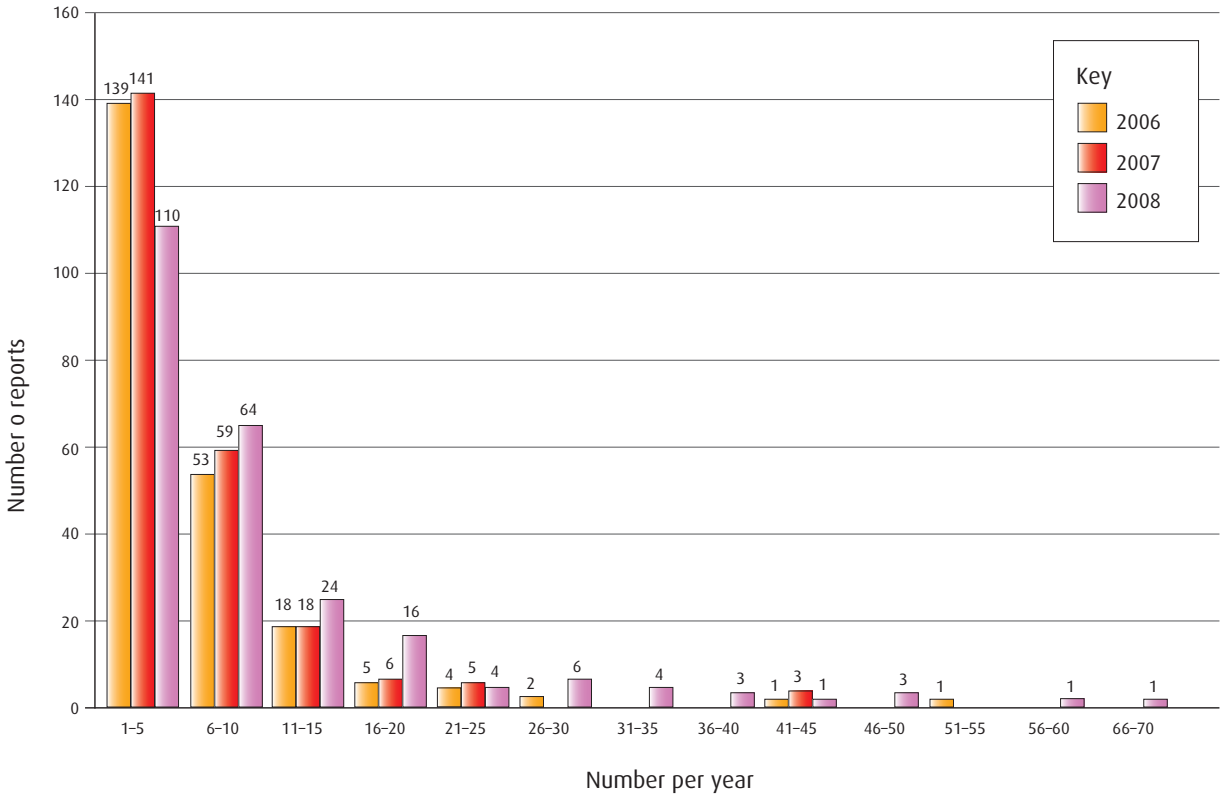
While the mean and the median give an indication of overall reporting activity, the worrying statistic is the mode, i.e. the most frequently occurring value, which for the United Kingdom overall (Table 8) remains 1 report per organisation per year. There is, however, some variation between the constituent countries with Wales (Table 12) and Northern Ireland (Table 10) having a mode of 10 and 6 respectively in 2008. The minimum number of reports is consistently 1 report per organisation per year with the exception of Wales (Table 12) in 2008. It is difficult to understand how blood banks can have only 1 incident per year, either a physiological reaction, or an error or a Near Miss, to report to SHOT. SHOT does not currently have issue data for individual blood banks and is therefore unable, at this stage, to provide data on the number of reports by components issued for each reporting organisation. Looking at the number of reports submitted using issues as the denominator may go some way to explaining the variation in the number of reports submitted to SHOT but it is obvious that some reporters are not reporting incidents that are SHOT reportable. In 2006 there were 51 organisations reporting a single incident and the equivalent figure was 48 in 2007. However, in 2008, only 29 organisations made one report, a reduction of approximately 40%. This implies that some reporting organisations that were not fully participating previously have begun to do so.

Non-reporters

It must be noted that no data are presented on the number of reporting organisations that made no reports to SHOT, so these figures relate only to those actively participating in SHOT reporting.

Data from MHRA at the end of the 2008 reporting year revealed that of their 303 registered reporters, 45 (15%) had submitted no reports to MHRA during 2008. This is an improvement on 2007 when nearly 25% of registered reporters sent no reports. Although the majority of these reporters were from small hospitals issuing fewer than 500 units of red cells per year, a significant minority are bigger users. Some of these non-reporters to MHRA may, of course, have submitted some 'SHOT only' reports (clinical errors), which are not part of the MHRA's remit to collect.

Figure 5
Number of reports per reporting organisation, UK



Types of reports made to SHOT

As well as looking at the number of reports that organisations make to SHOT, the types of reports that organisations make was also analysed (Table 13). Worryingly, the largest group are reporters who only report errors and Near Miss incidents but no physiological reactions. For the organisations that only report errors and Near Miss incidents, it must be assumed either that there is no mechanism for reporting physiological reactions or that there is a lack of awareness among clinical and laboratory staff regarding the importance of reporting transfusion reactions to the laboratory. There may also be a lack of awareness among junior laboratory staff and on-call staff who do not work regularly in transfusion.

In addition there is also a small group of reporters who report nothing but physiological reactions. Even more puzzling is the small number of organisations who have only reported incidents relating to the administration of anti-D and those that have withdrawn all their initial reports.

Table 13
Analysis of types of incidents reported to SHOT by UK reporting organisations

Category	2006	2007	2008
Organisations that reported Anti-D incidents only	6	3	2
Organisations that reported Anti-D incidents and also had reports withdrawn	0	1	0
Organisations that reported physiological reactions only	12	11	8
Organisations that reported errors and Near Miss events only	117	116	103
Organisations that reported errors, Near Miss events and physiological reactions	80	88	121
Organisations that had all reports withdrawn	8	7	3
TOTALS	223	226	237

Number of reports by reporting organisation for the Regional Transfusion Committees in England, 2006–2008

Table 14

2006	East Midlands	East of England	London	North East	North West	South Central	South East	South West	West Midlands	Yorkshire & Humberside
Mean	4.6	6.3	6.5	4.4	4.7	7.4	6.1	5.0	5.6	8.3
Median	4	4	4	3	4	7	3	4	3	7
Mode	1	3	1	1	4	7	1	2	3	1
Range	10	21	51	14	15	16	22	11	41	27
Minimum	1	1	1	1	1	2	1	1	1	1
Maximum	11	22	52	15	16	18	23	12	42	28
Total no. of reports	55	114	216	48	127	74	97	95	95	125
No. of organisations	12	18	33	11	27	10	16	19	17	15

Table 15

2007	East Midlands	East of England	London	North East	North West	South Central	South East	South West	West Midlands	Yorkshire & Humberside
Mean	5.9	6.5	6.8	5.1	4.3	8.8	6.4	6.1	5.4	6.4
Median	4	5	3	4	3	5	5	5	2	3
Mode	1	5	3	1	1	1	3	1	1	1
Range	19	23	44	11	12	44	12	20	40	24
Minimum	1	1	1	1	1	1	2	1	1	1
Maximum	20	24	45	12	13	45	14	21	41	25
Total no. of reports	71	110	238	51	113	114	89	122	107	96
No. of organisations	12	17	35	10	26	13	14	20	20	15

Table 16

2008	East Midlands	East of England	London	North East	North West	South Central	South East	South West	West Midlands	Yorkshire & Humberside
Mean	6.7	7.4	9.8	10.0	8.6	11.6	8.7	8.2	15.2	9.8
Median	5	7	6	5	7	6.5	7	8	6	5.5
Mode	1	9	2	1	7	8	7	3	2	4
Range	19	22	46	38	49	67	26	17	58	27
Minimum	1	1	1	1	1	1	1	1	1	1
Maximum	20	23	47	39	50	68	27	18	59	28
Total no. of reports	80	141	381	90	259	185	130	131	228	157
No. of organisations	12	19	39	9	30	16	15	16	15	16

The 3 tables above show the reporting activity by organisation in the English Regional Transfusion Committees. As with the national data there is a marked increase in reporting in 2008 compared to the gradual increase in the preceding 2 years. As expected there is variation between the regions but the minimum number of reports per organisation remains 1, with one exception in 2006 and one in 2007.

COMMENTARY

This the first time that SHOT has carried out this exercise, and therefore the data presented will provide the benchmark against which future participation data can be judged. As already mentioned, all four UK countries have introduced healthcare and quality standards (see page 3), which explicitly require reporting to SHOT. SHOT is now able to provide data that can assist in the evaluation of these initiatives.

It is obvious from the data that there are still a lot of serious adverse events and physiological reactions that are not being reported to SHOT. It is of concern that they might also not be reported locally and subsequently that no actions are initiated to reduce patient risk. The National Patient Safety Agency (NPSA) has produced a briefing document called 'Act on Reporting: Five actions to improve patient safety reporting'.[5] SHOT recommends that all reporters undertake the following action plan to improve their reporting both locally and to SHOT.

RECOMMENDATIONS

- **Establish current level of reporting**
  What is your rate of reporting – how does it compare with that of similar organisations? How has it changed over time?

- **Give feedback to staff**
  Does your organisation provide feedback to individual reporters and staff? How can this be improved? Have you combined incident data with other sources such as investigations, litigation and complaints to 'tell the story' of key risks and challenges?

- **Focus on learning**
  What changes in patient care have been made as a result of reporting? Could your staff give examples of changes following reporting, such as new equipment or practice?

- **Engage frontline staff**
  What formal training do you provide on incident reporting for new and existing staff? Do you have safety champions at directorate or ward level?

- **Make it easy to report**
  How easy is it for staff to report incidents? Do all clinical specialties and staff groups report?

- **Make reporting matter**
  Do staff believe that your reporting systems are focused on improving safety rather than blaming individuals? What do recent staff survey results tell you? How are you assured that incident reporting is being used to 'close the loop' and act on the risks identified?

5. Key Message and Main Recommendations

This year's SHOT Report has highlighted the differences between different hospitals, trusts, regions and countries, in the way certain parts of the transfusion process are carried out. In particular the differences relate to the use of local or regional protocols and SOPs, and the standards used and expected within them. Notable examples arising from analysis of the cases in this report include:

- variation in local systems for identifying and reporting transfusion-related adverse incidents within clinical and laboratory areas, and differing thresholds for reporting
- hospital transfusion laboratories using a variety of bespoke or customised IT systems that differ in the degree to which they assist a laboratory staff member to identify patients with special requirements, paediatric patients, those with a complex transfusion history or those with discrepant or erroneous results
- the competency assessments carried out in hospitals for staff involved in the transfusion process (including clinical, laboratory and other staff) vary in terms of the actual content of the assessment and the method of assessment, causing lack of comparability and transferability between hospitals and trusts.

This national inconsistency of standards is a cause for great concern as the least well performing hospitals and trusts in each area may not be achieving optimal patient safety.

SHOT's three major recommendations this year therefore relate to standardisation of practice across the UK in haemovigilance participation, laboratory IT systems and competency assessment. These recommendations have been drafted after consultation with stakeholders to ensure full support for their implementation.

1. Awareness of criteria for reporting adverse events and reactions

Reporting organisations should ensure that all members of the hospital transfusion team and the broader staff involved in the transfusion process are fully aware of the criteria for reporting adverse events and reactions to SHOT (and MHRA) including the reporting of cell salvage and Near Miss events. Details of what to report and how to report it are readily available on the SHOT and MHRA/SABRE websites as well as in the Annual SHOT Report and Summary. This process would be aided by a position statement on the requirements for haemovigilance in the UK.

Action: HTTs

2. A national specification for transfusion laboratory IT systems

A national specification for transfusion laboratory IT systems should be developed with minimum standards, which should be met by all hospital transfusion laboratories participating in any way in pre-transfusion testing or issuing of blood components for transfusion. The national transfusion committees should lead this initiative in collaboration with the UK Transfusion Laboratory Collaborative, BCSH and BBTS. Liaison with software developers is essential to enable safety initiatives to be effectively incorporated into existing systems.

Action: NBTC and equivalents in Scotland, Wales and Northern Ireland
Developers of software for laboratory IT systems

3. Competency assessment and standardised, transferable competency certification of all staff involved in transfusion

Hospitals and Trusts are in the process of rolling out competency assessments for all staff involved in the transfusion process as a result of the NPSA recommendation (SPN 14) and the MHRA requirements for laboratory competencies. Comprehensive competency frameworks have been developed by NPSA which are used within trusts as a basis for local training and competency assessments. However a standard, nationally transferable, checklist of minimum requirements for certification of competency for staff involved in transfusion needs to be developed, agreed and disseminated. The NPSA should initiate this project in collaboration with relevant stakeholders.

Action: NPSA

The second three recommendations this year relate to the process of the administration of blood to patients. There are two specific areas highlighted in various sections of this report, and not for the first time. The first is the inappropriate use of the compatibility form for the bedside checking of blood component and patient identification, which involved 18 cases of wrong blood administration in 2008. The second is the timing of routine monitoring observations of patients undergoing transfusion; throughout this report it is clear that many transfusion reactions occur later than 15 minutes after the start of a blood component transfusion, and sometimes many hours later. A third recommendation is more generic, and relates to the need for a more supportive culture of teamwork in the clinical practice of medicine, including transfusion medicine. The NPSA initiative 'Seven steps to patient safety' is a helpful guide for trusts in their development of a supportive culture of safe working aimed at NHS staff in all healthcare settings (www.npsa.nhs.uk/sevensteps).

4. Discontinue use of the compatibility form for checking patient identification

The compatibility form issued from the transfusion laboratory computer system (at the time of printing the blood component labels) should be discontinued except in hospitals where it is an integral part of the traceability record for the component in question.

Action: HTTs

5. Ensure adequate observation of patients receiving transfusion

Guidelines for blood administration must include a requirement that observations are done at baseline, throughout the transfusion of blood components and regularly during the subsequent 24-hour period in order that serious transfusion reactions are identified immediately and not missed. Patients having day case transfusions should be advised to contact the clinical team if late reactions occur, and they should be given a 'contact card' with access to 24-hour clinical advice.

Action: BCSH

6. Develop a supportive culture for hospital staff involved in transfusion

Doctors, nurses, midwives, biomedical scientists and other staff should be encouraged to ask for help and clarification when they recognise that their own knowledge and skills are inadequate for the situation in which they find themselves. Failure to do so could be deemed negligent if an incident occurred. A culture of supportive, friendly surveillance and teamwork needs to be encouraged and nurtured in all clinical and laboratory areas, and any lessons learned must be shared with the relevant Governance and Risk Management groups and users.

Action: Trust directors of clinical governance and risk management

PAST RECOMMENDATIONS STILL RELEVANT

Year first made	Recommendation	Target	Progress
2007	See update in the Introduction, page 7.		
2006	Inclusion of transfusion medicine in core curriculum for junior doctors.	**NBTC, JRCPTB, Royal Colleges Academy, Postgraduate Education Committee**	Royal Colleges and Specialist Societies group of NBTC instigated review of current curricula.
2006	Specialty accredited laboratory and clinical staff in all hospitals.	**Hospital CEOs, UK TLC, BBT network, RCN, BBTS**	UK 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.
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 that 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 has been established in 2007. SNBTS training package www.learnbloodtransfusion.org.uk endorsed in Scotland, Wales and NI.
2002	SHOT recommendations must be on the clinical governance agenda.	**Trust CEOs, Trust Risk Management Committees and HTCs**	No mechanisms for monitoring.
2001	An ongoing programme of education and training for all staff involved in transfusion.	**NBTCs and network, Trust CEOs, NPSA/NBTC/SHOT initiative**	Mandated by NPSA SPN 'Right Patient, Right Blood'. Also a requirement of NHSLA standards. Educational tool 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 Miss events in 2005.
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 inaugural meeting 2008.

REPORTING CATEGORIES

Table 17 shows the active reporting categories for 2008–2009 together with details of what should be reported to SHOT in each one.

Table 17
Active reporting categories for 2008

Term	Definition	What to report
IBCT (Inappropriate Blood Component Transfused)	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.	This category currently includes: 'Wrong blood' events where a patient received a blood component intended for a different patient or of an incorrect group, including components of incorrect group given to BMT/SCT or solid organ transplant patients. Transfusion of blood of incorrect specification or that did not meet the patient's special requirements.
Inappropriate and unnecessary transfusion	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, in which, during the transfusion process, the handling and storage may have rendered the component less safe.	'Unsafe' transfusion where there were handling or storage errors such as component out of temperature control, or delay in completion of transfusion.

Near Miss events	Any event that, if undetected, could result in the determination of a wrong blood group, or issue, collection or administration of an incorrect, inappropriate and unsuitable component, but that was recognised before transfusion took place.	Phases I and II of the 2008 pilot have now been completed and are described in this annual report. Reporting of all Near Miss events will continue through the new web-based online reporting system.
Acute Transfusion Reaction	Reactions occurring at any time up to 24 hours following a transfusion of blood or blood components, **excluding** cases of acute reactions due to 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 >1ºC +/- minor rigors and chills **Minor allergic** skin +/- rash **Anaphylactic** hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hrs of transfusion **Severe allergic** 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 one 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 >1º C, with no features of an allergic reaction, but with one 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 one 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	Included 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. ***And either*** at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection; ***or*** at least one component received by the infected recipient was shown to contain the agent of infection.	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 neg infant • Anti-D given to wrong patient • Incorrect dose given • Anti-D given that 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 was developed for 2008 and will be utilised in paper form until the new web-based reporting system goes live.
TAD (Transfusion-Associated Dyspnoea)	Respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO or allergic reaction.	Respiratory complications of transfusion of unknown cause.
Autologous Transfusion	Transfusion of a patient's own blood or blood component back to themselves, which may be either after pre-storage (+/- manipulation of component), during periods of acute blood loss, or during the specialist management of haematological disorders.	Adverse events or reactions related to: • intraoperative or postoperative cell savage • preoperative autologous deposit • acute normovolaemic haemodilution • other autologous components.

DEFINITIONS

Imputability

In addition to the definitions of the reporting categories in the SHOT report as shown in the previous table (Table 17) 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 comorbidities 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

- Deaths 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 death, i.e. the likelihood that a death was 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 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
- Jaundice including 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 unless there is immediate medical intervention

Core hours

SHOT asks reporters to select the time the event or reaction took place from three time periods. Of these 08.00 to 20.00 generally constitutes core working hours, while the two bands 20.00 to 00.00 and 00.00 to 08.00 are both out of hours. No differentiation has been made regarding the day of the week. The reporter is also asked to define whether this time period was regarded as within normal working hours, on a shift system or on an on-call system, at the time the incident took place. These data are frequently not given, so the analysis of the frequency of occurrence of events and reactions in hours or out of hours is incomplete.

6. 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 intended for another patient that was incorrect in terms of its specification.

DATA SUMMARY

Total number of cases	**262**

Implicated Components	
Red cells	**201**
FFP	**11**
Platelets	**27**
Other *(specify)*	**12**
Unknown	**11**

Mortality / morbidity	
Deaths due to transfusion	**0**
Deaths in which reaction was contributory	**0**
Major morbidity	**5**

Gender	
Male	**119**
Female	**141**
Unknown	**2**

Age	
16 years+ to 18 years	**4**
1 year+ to 16 years	**14**
28 days+ to 1 year	**6**
Birth to 28 days	**15**
unknown	**0**
Total	**39**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**64**
Routine	**171**
Not known	**27**
In core hours	**82**
Out of core hours	**38**
Not known/applicable	**142**

Where transfusion took place	
ED	**2**
Theatre	**13**
ITU/NNU/HDU/Recovery	**10**
Wards	**71**
Community	**0**
Outpatient / day unit	**17**
Not known	**149**

Changes to IBCT chapter

Over the years since SHOT began reporting in 1996, the IBCT chapter has evolved and new subcategories have emerged that have been included in IBCT. These categories were not present in the original reports in 1996–97 when the errors fell into just three categories, which were:

- requesting blood and/or sampling the patient
- laboratory errors including grouping, crossmatching and labelling
- collection of blood from the storage sites (usually blood bank) and administration errors.

Categories emerging since the 2000–2001 SHOT Report are: special requirements not met, inappropriate and unnecessary transfusion, and handling and storage errors (originally called unsafe transfusion).

Special requirements not met include cases where CMV negative or irradiated components were required but not given for a variety of reasons. This still constitutes a substantive IBCT and these are included in this chapter along with failures to meet other special requirements such as phenotyped blood or methylene blue treated fresh frozen plasma (MB-FFP). However, cases of inappropriate and unnecessary transfusion are now regarded as a separate category as there is no actual evidence of an incorrect blood component being transfused. These are cases where the correct component specification has been given to the patient but where the transfusion was inappropriate and unnecessary. Likewise, handling and storage errors have now been removed from the IBCT chapter since once again these are cases where the correct blood component is transfused but where the handling or storage of the component has been incorrect prior to transfusion.

Therefore there are two new chapters in this 2008 SHOT report: *inappropriate and unnecessary transfusion* and *handling and storage errors.*

This IBCT chapter includes:

- incorrect component being given due to administration errors (wrong patient, wrong component)
- incorrect component transfused because of laboratory errors
- special requirements not met (clinical and laboratory)
- wrong blood in tube (WBIT) resulting in incorrect blood component (or patient) transfused.

The anti-D related events were reported separately as a discrete chapter (outside of IBCT) in the 2007 report and this will continue this year. Errors and adverse reactions relating to autologous transfusion and cell salvage are also reported in a separate chapter, with no overlap in the figures within this chapter.

After the four main parts of this chapter there is a section about IT errors in IBCT, which discusses the same cases that are reported in the four parts leading up to it. These are not new cases, but are discussed in the light of the IT failures that they involve or with reference to the potential for IT to be used to prevent such errors.

Reports of IBCT *n* = 477

A total of 492 cases were received on IBCT questionnaires. Some were withdrawn during the course of analysis because they did not meet the criteria of the categories in IBCT and others were classified as '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 chapter (page 66) and are not included in the total.

Therefore a total of 477 cases were included that were reported on IBCT questionnaires, which is a large (36%) increase from 2007 when 352 IBCT questionnaires were included. This represents another increase in the reporting rate with 16.8 cases reported per 100,000 components issued by the four UK Blood Services, an all-time high for SHOT reporting.

Table 18
Comparison of numbers of cases reported on IBCT questionnaires

Year	Number of cases reported on IBCT questionnaires	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
2008	477	16.8

Of these 477 IBCT questionnaires, 139 are reported in a separate chapter on handling and storage errors and 76 have been reported in a separate chapter on inappropriate and unnecessary transfusion.

This leaves 262 cases to be discussed in the IBCT category.

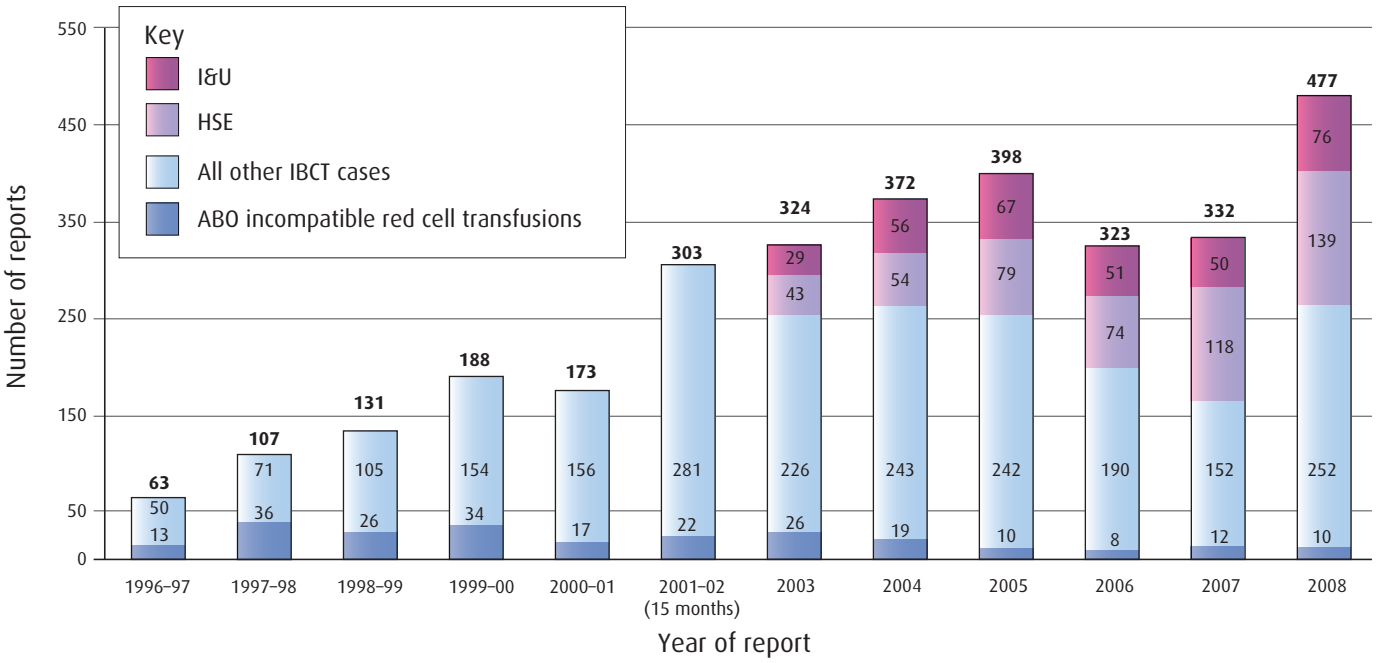
Time of day of transfusion episodes for cases reported on IBCT questionnaires

This part of the questionnaire has been poorly answered this year, as in previous years, with the section left blank in 315 questionnaires out of 477 (66%). Of the remainder, 117 took place between 08.00 and 20.00, 30 between 20.00 and midnight and 19 between midnight and 08.00.

Routine versus emergency transfusion for cases reported on IBCT questionnaires

The section regarding whether transfusions included in this chapter were routine or emergency was completed in 429 questionnaires (90%) and showed that 134 were in emergency situations and 295 were in routine or elective situations. A further 22 reported the information as not known, and in 26 the section was left blank.

Figure 6
IBCT and ABO-incompatible red cell cases 1996–2008



The histogram above shows the total number of reports in the IBCT category year by year since SHOT reporting began, as well as the number of cases of ABO-incompatible transfusion as a subgroup of IBCT cases. For this reporting year (2008) and the preceding 5 years, the numbers of inappropriate and unnecessary transfusions as well as the numbers of handling and storage errors are each shown in a different colour in the bars that represent the total reports on the IBCT questionnaires. This year, for the first time, these two categories have been separated from the true IBCT cases and are written about in a separate chapter.

Table 19
Summary of cases reported on IBCT questionnaires

Type of event	Number of cases 2007		Number of cases 2008	
Administration of wrong blood component		**24**		**47**
• ABO-incompatible red cells	9		4	
• D-incompatible red cells	2		3	
• Compatible wrong blood components	10		32	
• Incorrect component type	3		3	
• Other *(component given when not prescribed)*	0		5	
Wrong blood in tube (WBIT)		**7**		**5**
• ABO incompatible	1		4	
• D incompatible	1		0	
• Incorrect Hb	4		1	
• Compatible	1		0	
Special requirements not met – CMV/irrad		**76**		**100**
• Clinical errors and omissions	49		70	
• Laboratory errors and omissions	25		30	
• Blood Service errors and omissions	1		0	
• Unclassifiable	1		0	

Special requirements not met – other • Laboratory related cases • Clinical related cases	 15 2	**17**	 11 6	**17**
Laboratory errors *(excluding special requirements not met)* • Wrong blood issued • Wrong ABO/D type for SCT patient • Pre Tx errors – testing • Pre Tx errors – procedural	 15 5 5 15	**40**	 39 4 8 40	**91**
Miscellaneous IBCT		**0**		**2**
(Sections below formerly IBCT, now in separate chapters)				
Inappropriate and unnecessary transfusion • Based on wrong Hb (platelet or coagulation) result • Based on POCT INR/platelet count • Haem/coag laboratory errors • Poor knowledge and prescribing	 28 2 3 17	**50**	 38 3 10 25	**76**
Handling and storage errors • Technical and administration errors • Transfusion of expired red cells • Excessive time to transfuse • Cold chain errors (including 20 laboratory-related)	 15 12 57 34	**118**	 9 45 24 61	**139**
TOTAL		**332**		**477**

Summary of key data for true IBCT cases *n* = 262

Mortality entirely related to IBCT event *n* = 0

There were no fatal cases resulting directly from ABO-incompatible transfusion or other IBCT this year.

Mortality in which IBCT event contributed *n* = 0

There were no IBCT cases this year in which the transfusion contributed to the death of a patient.

Major morbidity *n* = 5

There were 5 cases of major morbidity arising from ABO-incompatible red cell transfusion. This consisted of 2 acute HTRs from erroneous bedside administration of ABO-incompatible red cells, 2 acute HTRs from ABO-incompatible red cells given following a phlebotomy error resulting in 'wrong blood in tube' (WBIT), and 1 case of acute HTR resulting from a laboratory error.

ABO-incompatible transfusions *n* = 11

A total of 11 ABO-incompatible transfusions were given in 2008, which included 10 ABO-incompatible red cell transfusions. Four of these cases arose from bedside administration errors, 3 from WBIT phlebotomy errors and 3 from laboratory errors. This figure remains very low despite the great increase (from 164 to 262) in the number of true IBCT reports in 2008.

There were no cases of incompatible platelet or FFP transfusion resulting from clinical errors, but 1 transfusion of ABO-incompatible FFP resulting from a laboratory error.

D-incompatible transfusion *n* = 17

There were 17 D-incompatible red cell transfusions in 2008. Three arose from administration errors and 14 from laboratory errors. These consisted of 10 D typing errors, 3 component selection errors and 1 incorrect group issued following a mismatched stem cell transplant. There were none from WBIT errors.

Administration of wrong blood *n* = 47

Overview

In this subcategory 42 questionnaires were received; none were transferred out of the section and 5 were transferred in from the inappropriate and unnecessary transfusion section. In these 5 cases a blood component was administered that had not actually been prescribed, because of a failure of bedside checking.

This section therefore describes the main findings from 47 completed questionnaires.

Of these 47 cases, 18 occurred in male patients and 28 in female patients with gender not given in 1 case.

A total of 8 reports involved patients under 18 years old. Of these, 5 patients were aged under 28 days, 2 were between 1 year and 16 years, and 1 was between 16 and 18 years. Two paediatric patients received the incorrect component type, and the remaining 6 paediatric patients received the wrong red cells, which happened to be compatible.

Table 20
Number of wrong blood episode in emergency and routine situations

Emergency	13
Routine	27
Unknown	7

Table 21
Number of wrong blood episodes occurring in core hours and out of hours

In core hours 08.00–20.00	26
Out of hours 20.00–00.00	10
Out of hours 00.00–08.00	11

Mortality and major morbidity

There were no fatalities directly due to administration of wrong blood, and there were 2 cases of major morbidity (see cases 3 and 4).

Blood component collection

A total of 29 of the 47 cases involved the initial collection of the incorrect unit from the blood bank issue refrigerator, followed by failures of all subsequent barriers to administration of wrong blood components, in particular the bedside component against patient ID check.

Table 22
Staff responsible for the collection of the incorrect unit from the blood issue site

Registered nurse or midwife	15
Porter	8
Unqualified nurse	1
Health care assistant	1
Operating department assistant	1
Housekeeper	1
Anaesthetist (doctor)	1
Unknown	1

Without denominator data it is hard to draw inferences but, as errors commonly occur at this stage in the process, it must be seen as a 'weak link'. Strategies need to be put in place to ensure that personnel who collect units of blood from the blood issue site are fully trained, competent, aware of the critical nature of the tasks involved, and able to take personal and professional responsibility. Only 16 of these 28 staff were reported to have received training.

Errors included:

- using documentation from the wrong patient
- using incomplete or inadequate documentation
- taking documentation of 2 patients at once, causing confusion
- not checking details of all patient identifiers against unit being collected

An electronically locked issue refrigerator would prevent some of these errors, although such systems can be bypassed or overridden.

Bedside checking

All cases in this section could have been prevented by a properly carried out bedside check of the patient ID wristband against the unit. The check was either absent altogether, or had supposedly been completed using various items of paperwork plus the unit of blood, but excluding the patient themselves (either verbally, or by the wristband attached to the patient). Frequently the 'bedside' check had been carried out remotely from the patient, in another room, or at the nurses' station. A worrying recurrence in the wording of reports to SHOT is 'the check was completed in the treatment room, but unfortunately the nurse then connected the unit to the wrong patient'. It is of course not possible to complete the checks in the treatment room, unless the patient is in there, but some reporters seem unclear about this.

Additionally, failure to read the prescription chart has resulted administering the incorrect component in 4 cases, and a component where none had been prescribed in 5 cases.

In 9 cases the unit was correctly checked against the patient ID wristband – but errors still occurred from misreading the band, from the patient having two ID bands on different limbs bearing different details, or from the band not being attached to the patient at the time (and belonging to another patient). In some cases where a correct ID check was carried out, the patient received the wrong component type, or one which had not been prescribed.

Table 23
Bedside checking errors

Unit checked against compatibility form	18
Unit checked against patient's notes	2
Unit checked against prescription chart	2
Patient asleep so did not give antibody card	1
No bedside ID check performed	16
No details given	1
Unit correctly checked against patient ID band	7
TOTAL	**47**

Table 24
Number of staff involved in final check

Single-person check	13
Two-person check	33
No detail	1
TOTAL	**47**

Anecdotally, 2 person checks are used more frequently throughout the UK, despite the recommendations given in the BCSH blood administration guidelines, 1999.[6] There were 34 trusts where 2-person checks are carried out according to local protocols, while 13 trusts conducted single-person checks as standard. In 1 case the administration of a wrong component has led a trust to consider changing from 2-person to single-person check.

Table 25
Grade of staff involved in bedside checks

Grade of staff	First checker	Second checker
Registered nurse / midwife	42	27
Operating department practitioner	1	0
Junior doctor	1	2
Consultant	2	3
Locum / agency staff	1	1
Unqualified nurse	0	1
TOTAL	**47**	**34**

Registered nurses and midwives conduct the majority of pre-transfusion checks prior to blood component administration, but in emergency or theatre situations others become involved in this process.

Erroneous administration of ABO-incompatible red cells *n* = 4

This is the lowest number of ABO-incompatible red cell transfusions reported in a year since reporting to SHOT began in 1996. This is notable since the overall number of IBCT reports in 2008 is at an all-time high, having risen by 36% since 2007.

In all 4 cases the error started with the collection of the incorrect unit from the blood bank issue refrigerator. Interestingly the personnel involved were 2 porters, 1 'housekeeper' and 1 registered nurse. The error during the collection process was further compounded by errors and omissions during the checks prior to administration.

Three of these 4 patients subsequently died, but the mismatched transfusion was not considered to cause the death or to contribute to it in any of the cases.

In Case 1 there was development of respiratory problems (but no haemolysis), which was thought to be unrelated to the transfusion, and in Case 2 there was no clinically discernable reaction. Both of these patients died of unrelated causes.

There was major morbidity in Case 3 and Case 4, with evidence of an acute haemolytic transfusion reaction. One patient subsequently died of unrelated causes, and the other recovered with no long term sequelae.

Case 1
Lack of understanding of what a patient ID check involves, and why

A 67-year-old female haematology patient in a side room was prescribed a transfusion. A trained 'housekeeper' took the correct patient documentation to the blood refrigerator but collected a unit for another patient with the same first and last name. The details on the pack were checked against the accompanying compatibility form and the signing out ledger, but not with the documentation brought down for the ID check. A similar error took place on the ward, in which the red cell unit was 'checked' by 2 registered nurses against the compatibility form outside the patient's room. A nurse entered the room and administered the transfusion without a bedside patient ID check. The transfusion record sheet for the patient was signed by the 2 members of staff stating that all checks had been completed satisfactorily. The error came to light when the blood for the intended recipient was found to be unavailable. The patient developed respiratory problems several hours later but was already severely ill and died later the same day. The patient was group O D positive and received a whole unit of group A D positive red cells. There was no record of haemolysis, and imputability was placed at between 0 and 1.

Case 2

No patient ID check even when administering non-group O units believed to be group specific

A 77-year-old man with a ruptured abdominal aortic aneurysm was admitted via the ED straight to theatre for emergency surgery. An anaesthetist collected what he thought was emergency group O D negative blood from the theatre satellite refrigerator, which was in fact group B D positive blood issued for a specific patient. This anaesthetist then handed the unit to a second anaesthetist who administered it believing it was group specific, but no appropriate ID check was carried out. Group specific units were soon issued from blood bank for the patient, who was group A D positive. The error was then detected by a consultant anaesthetist who spotted the different blood group of the new units labelled for this patient. There was no evidence of a transfusion reaction or haemolysis, and the patient died as a result of his ruptured aneurysm.

Case 3

Acute haemolytic reaction in frail 91-year-old man administered ABO-incompatible red cells

A 91-year-old male patient who had sustained a head injury and intracranial bleed was prescribed a transfusion that was administered after midnight. The incorrect unit of red cells was collected by an untrained, registered nurse. Pre-transfusion checks were conducted by 2 registered nurses against the compatibility document, which was signed, timed and dated. The patient was wearing a wristband ID but this was not used in the checking process. The patient was group O D positive and he received group B D positive red cells intended for another patient. After 100 mL had been transfused he became agitated and pyrexial and the transfusion was discontinued. He deteriorated with hypotension (BP 70/40), haematuria and abdominal pain together with cardiac problems and died 9 days later. The coroner concluded that death was due to causes other than the transfusion.

Case 4

Lack of positive ID check at collection and administration

A 92-year-old male patient with a GI haemorrhage was prescribed a blood transfusion in the ED. Correct documentation was taken to collect the unit, but was not used to identify the unit at the issue refrigerator. The incorrect unit was collected and was checked by 2 staff nurses against accompanying paperwork, but not checked against any other patient ID, as the patient did not have wristband ID attached and was unable to participate in the checks himself. The patient was group B D positive and the unit commenced was group A D positive. After 50 mL the patient developed an acute reaction and the transfusion was stopped. He developed haemolysis and but recovered fully

As discussed above, in all 4 of these cases the first procedural error, of collection, was followed by a second error of bedside checking, thus allowing the transfusion of ABO-incompatible red cells to go ahead. The repeated use of the compatibility form (or other paperwork) as the identifier for the patient is very worrying, as it betrays a lack of understanding of the purpose of the bedside patient ID check.

Erroneous administration of D-incompatible red cells *n* = 3

D positive red cells were given erroneously to 3 patients who were D negative. In 2 cases no patient ID checks were performed; in 1 the paperwork was signed at the nurses' station by nurses in a hurry, and in the other – an emergency – blood delivered in a transport box to the ED was assumed to be for the haemorrhaging patient only. In a third case the bedside ID check against the wristband was performed correctly, but the unconscious patient had 2 wristbands bearing 2 different patients' details.

Case 5

Lack of ID checks at patient's side

A haematology patient required a second unit of red cells, so the registered nurse looking after the patient co-opted a second registered nurse to do the patient ID check. All the documentation was competed and signed by both nurses at the nurses' station. The first nurse then took the unit into the 6 bedded bay alone, and administered the blood to the patient opposite the one for whom it was intended, without a bedside ID check. A group A D negative patient was thus transfused with a unit of group O D positive red cells. No transfusion observations were conducted. Both nurses had received transfusion training within the previous 12 months.

Case 6

One patient – 2 wristbands – one of which contained details for another patient

A 69-year-old male patient was in ITU unconscious following major surgery. The patient had a wristband on each wrist, one of which contained details for another patient. The correct checking procedure was completed at the bedside, but the patient's identification was taken from the wrong identification label on his wrist. The patient, who was group A D negative, received a unit of group O D positive red cells intended for another patient.

Case 7

No patient ID check made in emergency situation when box of blood for 2 patients delivered to ED

Blood for 2 patients was sent in the same box from blood bank to the ED. A 37-year-old male trauma patient required urgent transfusion and blood for a different patient was taken from the box and administered by an anaesthetist without checking the details of the patient in any way. Each member of staff thought the other had performed ID checks. The patient, who was group O D negative, received a group O D positive unit. He died due to his major trauma.

Wrong blood components transfused that happened to be compatible *n* = 32

There were 32 cases in which errors similar to those described above took place, but serendipitously the incorrect components transfused were ABO and D compatible with the patient transfused. All but 2 of these cases involved red cells, 1 involved platelets and 1 involved FFP.

There was 1 case in which the recipient required CMV negative, irradiated red cells; the wrong unit transfused was ABO and D compatible, but did not meet the patient's special requirements.

Incorrect use of documentation when collecting blood components from the issue refrigerator, and absence of bedside patient ID checks (replaced with remote signing of paperwork) are recurrent problems in this group of cases. In addition there are some cases in which another patient's crossmatched units have been mistaken for emergency (or flying squad) group O D negative units, and transfused without any further checks.

Six of the 8 paediatric blood administration cases are in this section, including 4 under 4 weeks of age with 3 involving transfusion to twins. One of these involved transfusion of platelets intended for a 10-year-old child to another child in the same ward: both patients were group A D positive.

The number of wrong blood transfusions that were compatible may point to an emphasis on checking of the patient group and little else. Certainly one would expect approximately 1 in 3 units, if given randomly, to be ABO incompatible.

Case 8

Incorrect documentation used to collect red cells from issue refrigerator

An anaesthetist asked an ODP to collect 2 units of blood crossmatched for the patient in theatre. The ODP filled out a 'Blood Collection Form' with details from a wristband left in the anaesthetic room, assuming that this wristband was from the patient in theatre. In fact, the wristband had been removed from a patient on the previous list. The ODP gave the form to a theatre support worker who correctly collected the units of blood named on the form. The anaesthetist checked the label on the unit of blood against the accompanying compatibility report only and did not check the patient ID on the blood unit against the patient's wristband. The patient was group O D positive and the unit administered was group O D negative.

Case 9

Bedside check omitted in favour of a treatment room check

Forms and documentation for a transfusion were completed and signed by 2 registered nurses in the treatment room. One of the nurses then took the unit and connected it to a different patient, also awaiting transfusion, without a bedside patient ID check. A little later blood was being prepared for transfusion to this patient, who was found to already have a transfusion running, so the error was discovered. Both patients were group B D positive.

A sentence that appears in several reports of blood administration errors states: 'They checked unit in the treatment room and completed the documentation appropriately', which, as discussed above, implies that there are still widespread misconceptions, in spite of training and competency assessment, about what the pre-transfusion checking and signing process is actually there to achieve.

Case 10

Incorrect units collected in place of emergency group O D negative blood

A patient was rushed to maternity theatres for a Caesarean section as she was starting to haemorrhage. The anaesthetist requested emergency group O D negative blood. A midwife, who had received transfusion training, went to the maternity theatre's satellite blood refrigerator and collected 2 units of blood from the top drawer without any checks, assuming it was the emergency blood. The 2 units of red cells were given rapidly. The anaesthetist commented that the blood was group O D positive, but as the patient was group A D positive, the anaesthetist was happy it was compatible. It was only when they took it down that they realised the blood was allocated to a patient, and was not the emergency blood.

Case 11

Lack of recognition of paediatric emergency units, and adult crossmatched units used instead

A neonate required emergency transfusion and 20 mL was administered from a unit of group O D negative red cells removed from blood bank by a registered midwife who had not received training. The unit was not labelled for emergency use, but was labelled for an adult patient on the maternity unit. The bedside check was not done and the blood was not signed out of the blood bank. The blood bank was stocked with 2 emergency group O D negative Octapacks suitable for neonates, which were not used. The baby died the same day, unrelated to the transfusion.

Incorrect component type given to the correct patient *n* = 3

In these cases the wrong components were administered against a prescription that clearly stated the required component, highlighting a lack of knowledge of component types and their appearance among staff involved in the collection and transfusion of blood components.

In 1 case, red cells were administered in place of platelets, and in 1 case FFP was given instead of platelets. A child 11 days old received FFP instead of platelets.

Case 12

Red cells administered instead of platelets

A unit of platelets was prescribed for administration overnight, with a further unit of red cells to be given in the morning. Although the staff nurse believed she had given a unit of platelets, she had collected and transfused a unit of red cells, administering the component over 50 minutes as per the platelet prescription. The prescription form was completed with confirmation of bedside checks. When questioned, the nurse stated she did not know the difference between a bag of red cells and a bag of platelets.

Case 13

FFP administered instead platelets

Red cells, platelets and FFP were ordered although there was no clinical indication for FFP written in the notes. The patient was prescribed platelets but FFP was collected in error from the blood bank by a porter and administered to the patient instead. The error was not realised during the 2 person bedside check. It only came to light when blood bank contacted the ward to ask why the platelets had not been used.

Case 14

FFP administered instead of platelets

FFP, red cells and platelets were requested for a patient 11 days old with sepsis. Platelets were prescribed by the doctor, but a registered nurse mistakenly collected FFP from the laboratory blood refrigerator. The nurse was reported as looking for a non-cellular component and seeing the FFP in the refrigerator, thought this was platelets. The nurse signed in the register for platelets, even though the donation number was different. The unit of FFP was transfused on the ward following checks by 2 registered nurses, thinking that this component was platelets. The error was noticed the next day by the BMS when platelets for the patient were found in the platelet agitator.

As well as demonstrating a lack of knowledge about component types among the personnel collecting and administering blood components, it is clear that these errors would still have been prevented if complete and thorough checks of unit type and number had taken place at the time of collection or at the bedside prior to administration of the units.

Transfusion of component to correct patient but without a prescription *n* = 5

In these cases components were transfused without having been prescribed, or authorised, by the clinicians in charge of the patient's care. The issue here is not the recognition of different components, but the omission to check the component had been prescribed before administering the blood component. The components were all for the correct patient.

Three cases involved transfusion of red cells, and 2 transfusion of platelets. In 1 case of red cells and 1 of platelets, a unit in excess of the number prescribed was administered. In 2 cases no clinical decision to transfuse had been taken, and no prescription or authorisation made, but nursing staff transfused red cells that were available from blood bank. In the final case, red cells had been prescribed and given and a decision about platelet transfusion deferred to the next day. However, they were erroneously collected and transfused.

Case 15

Platelets for planned administration the next day administered without prescription a day early

Platelets had been ordered for an 11-year-old child for administration the following day, pending a final decision (and prescription) on the ward round. Two units of red cells had already been transfused, but the porter collected the platelets too. The platelets were given by a registered nurse without a prescription.

Volume of incorrect blood component transfused

As shown in Table 26 below, the error was recognised soon after the component was connected in 15 cases in which < 50 mL was transfused. In several cases the reporter commented that due to saline being present in the giving set, it was considered that the patient was not actually exposed to the wrong component. In 1 case this meant that practitioners felt able to change the giving set and transfuse the unit to the correct patient. There were 2 such cases in the 2007 SHOT report. Even if exposure is uncertain these cases should still be reported.

Table 26
Volume of wrong component administered (mL or units)

Volume given	Number of cases
< 50	15
50–99	3
> 100	5
Whole unit	21
> 1 unit	3
TOTAL	**47**

There are 21 cases in which the whole unit was transfused and a further 3 in which more than 1 wrong unit was administered. It is a concern that over 50% of administration errors are not recognised until the transfusion of the unit or units is complete.

COMMENTARY on component administration errors

There has been an increase in the number of reports of administration errors this year, as well as a decrease in the number of ABO-incompatible red cell transfusions, and the number of serious outcomes (death due to transfusion and major morbidity).

The types of error reported have not changed, except that this year there are 5 cases reported in which components were given without any prescription – this category has not emerged so explicitly previously.

Lack of underpinning knowledge of the rationale behind the required steps of the blood administration protocol still accounts for many of the errors reported, and in many cases the reporter pointed out that the staff involved had successfully completed training and competency assessment within the previous year. The content of training and assessments is crucial to their success. Performing of the correct tasks will only occur reliably when practitioners understand what they are aiming to achieve and why, whereas adherence to a complex, but apparently meaningless, series of tasks will break down very rapidly under pressure.

A transfusion checklist may be a useful adjunct to the blood collection and administration procedure. This report describes errors in every possible step of the process from blood leaving the issuing laboratory, to its administration to the patient, including:

- BMS handing incorrect unit to person collecting component
- wrong patient documentation brought to laboratory to collect component
- correct documentation brought but not used
- misreading of documentation
- transportation of several patients' components together
- failure to recognise correct component type
- inappropriate checking of documents against unit
- signing documentation remotely from patient
- absence of any bedside patient ID check
- failure to consult prescription
- incorrect ID attached to patient
- unlabelled patient asleep or unconscious

However, it remains the case that a properly conducted final bedside check of the patient's ID against the unit to be transfused would prevent every case, with the possible exception of the case in which a patient was wearing 2 different ID wristbands.

While professional responsibility must be taken at every stage by the personnel involved, the final barrier to wrong blood administration is at the bedside, and this cannot be over-emphasised. Patient identification is at the root of a large number of errors in hospitals – not only in transfusion practice, but in drug administration, investigations, operative procedures and so on. It is essential that formal bedside patient identification becomes second nature to all healthcare personnel whenever they are involved with delivery of individualised patient care.

Learning points

- Patient ID should be confirmed with the patient or carer on admission, ensuring that names, date of birth and hospital number are correct, and that a search for previous records is carried out.
- Wristbands must be issued and worn, and should contain standard patient ID details in accordance with NPSA SPN 24 (standardising wristbands improves patient safety).[7]
- A bedside check between the patient's ID wristband and the label on the blood component is essential to prevent component administration errors. Any other checking or signing of documentation is secondary and does not constitute the patient ID check. If there is no wristband the transfusion should not commence.
- Documentation of the prescription must be available, the component prescribed, the dose and rate of transfusion given, and any special requirements, and this must be checked and signed by the staff administering the blood component transfusion However, this does NOT constitute the bedside patient ID check (above).
- Pre-transfusion baseline observations must be documented, and the patient must have observations at 15 minutes and regularly throughout the transfusion. It must be possible to observe the patient easily in the ward.

Wrong blood in tube errors (WBIT) *n* = 5

These cases occur when the sample tube is labelled correctly for a patient, but in fact contains a blood sample from a different patient. This may affect samples either for a group and crossmatch, or for haemoglobin (FBC) or both. This year there are 3 cases involving the transfusion of large volumes of ABO- incompatible red cells. Two of these involved phlebotomy of the wrong patient preoperatively, 1 by a doctor and 1 by a phlebotomist. One of these cases caused an acute haemolytic reaction, which was not recognised as such at the time. In the third case the ABO-incompatible transfusion had taken place 11 years earlier, and came to light on the current admission. Again, an acute reaction had occurred but was not recognised as transfusion related at the time. In a fourth case a junior doctor had bled the wrong patient, and ABO-incompatible red cells were crossmatched, but luckily not given. Platelets and FFP were given – including group A platelets to this group O patient, with potential poor increment, but no reaction. A fifth case involved the incorrect patient being bled (unclear by whom), resulting in an incorrect low haemoglobin level and an incorrect group assignment, fortunately group O. The patient was transfused unnecessarily as he was not anaemic, but the units given were compatible with his actual group, which was group AB D positive.

There were no cases of D-incompatible transfusions reported in this group this year.

In 2 cases the samples were taken from the wrong patient by a junior hospital doctor; in 1 case a phlebotomist bled the wrong patient, while in 2 cases it is not recorded who took the samples.

Case 1

Doctor's phlebotomy error results in 2 unit ABO-incompatible transfusion

An elderly patient was bled and grouped as group B D positive and transfused with 2 units of B D positive cells because of anaemia (cause not given). This patient had been bled by a doctor during normal working hours. A subsequent sample that grouped as A D positive was rechecked and proved to be the correct group. The wrong patient had been bled when the original sample was required. Fortunately the patient did not suffer any ill effects from 2 units of ABO-incompatible blood.

Case 2

Phlebotomist's patient ID error results in 3 unit ABO-incompatible transfusion

An elderly gentleman required an amputation for gangrene and was grouped as B D positive, and 3 units of this group were given to him in the perioperative period. A postoperative sample taken a few days later prior to a laparotomy grouped as O D positive. The patient had in fact suffered some respiratory problems, further anaemia and hyperbilirubinaemia following his original transfusion, but these had been attributed to his multiple comorbidities and possible fluid overload. The patient died of complications unrelated to his ABO-incompatible transfusion. The incorrect sample taken from the wrong patient had been taken by a phlebotomist.

Case 3

Acute HTR from ABO-incompatible transfusion comes to light 11 years later

The patient, an elderly male, grouped as O D negative, which was discrepant with his original blood group recorded in the computer system 11 years earlier as A D negative. Further investigation revealed that 11 years earlier he had received 2 units of group A D negative blood resulting in a haemolytic episode with renal failure requiring dialysis. A full recovery was made and it is not clear from the records whether at the time the transfusion was implicated in this reaction. It is now established that the patient is group O D negative.

Case 4

Doctor's phlebotomy error in emergency situation

A middle-aged man with hepatic failure and perforated ulcer grouped as A D positive and 6 units of red cells were crossmatched and 10 units of FFP and 2 units of platelets were issued, all group A D positive. The FFP and platelets were given but fortunately the red cells were not. Subsequent samples revealed that the patient was in fact group O D positive and the doctor had bled the wrong patient. The patient suffered no reaction.

Case 5

Incorrect Hb level and group following patient ID error

A middle-aged gentleman with brain metastases and seizures had samples taken for a repeat haemoglobin and a group & save, which revealed that his haemoglobin had dropped from 13.7 to 8.9 g/dL. The patient was therefore crossmatched on this sample and 2 units of blood were given. This resulted in a post-transfusion haemoglobin of 15.3 g/dL. The reporter comments that a historical group of AB D positive was subsequently discovered on this patient, but it was not clear if this was from long in the past or from another hospital. It was clear that the wrong patient had been bled as both the haemoglobin and the blood group were incorrect. Fortunately the wrong patient's blood group was O D positive and there was no reaction.

COMMENTARY

Once again these cases highlight the inherent dangers in inadequate patient identification and the possibility of bleeding a wrong patient for both FBC and transfusion samples. Two of these 5 cases involved phlebotomy definitely carried out by a junior doctor, 1 involved a phlebotomist, in 1 the staff group was not given, and in 1 it was too long ago to know. In 2 cases it was pure serendipity that prevented the patient from receiving ABO-incompatible red cell transfusion.

Learning points

- It is essential to have positive patient identification using the patient's wristband to label the sample tube at the bedside, however familiar the patient. Doctors are responsible for a disproportionate number of sample errors (see Near Miss chapter page 160) and must be educated in the critical importance of patient ID for every medical intervention.

Special requirements not met (SRNM) *n* = 117

The total number of cases in this section is 117 compared with last year's total of 93.

The table below (Table 27) shows the breakdown of the different special requirements omitted, and the number of cases of a clinical or laboratory origin. There were no cases in 2008 arising from a blood establishment error or omission.

Table 27
Types of special requirements not met, and proportion of primary clinical and laboratory errors

Type of special requirement	Clinical Cause of Omission	Laboratory Cause of Omission	Total
Irradiation	56	20	76
CMV negative	7	7	14
CMV & irradiation	7	3	10
HLA matched component	1	1	2
Hb S negative required	1	0	1
Paediatric methylene blue treated component	0	5	5
Paediatric apheresis platelets	0	1	1
Phenotyped component	3	4	7
Antigen negative component	1	0	1
TOTAL	**76**	**41**	**117**

This year 45 female and 72 male patients did not have their special requirements met.

Of these a total of 18 were patients under 18 years of age. There were 3 aged 0–28 days, 4 aged 28 days to 1 year, 10 aged 1–16 years, and 1 aged 16–18 years.

Clinical based cases of SRNM *n* = 76

The majority of cases where special requirements were not met related to requests for patients who required irradiated components, but this requirement was not made clear to the laboratory by the clinical staff at the time of requesting the component. A smaller number of cases related to non-communication of a requirement for CMV negative components, or components requiring both specifications. Generally, it appears from the information supplied to SHOT that the doctor ordering the components did not know of the criteria for irradiated or CMV negative products, or was not familiar enough with the patient to realise that this was necessary.

Of the 56 clinical omissions to request irradiated blood, the indications for irradiation were as follows:

- 31 prescription of fludarabine or other purine analogues
- 11 bone marrow transplant or stem cell transplant
- 9 Hodgkin's disease
- 5 indication not given

Of the 7 clinical omissions to give a product both CMV negative and irradiated, the indications were as follows:

- 2 bone marrow transplant or stem cell transplant
- 3 prescription of fludarabine or other purine analogues
- 1 pure red cell aplasia
- 1 indication not given

Other clinical omissions to make a request for special requirements probably also related to lack of transfusion medicine knowledge in non-specialised staff admitting patients through the emergency department.

Case 1

Requestor does not inform blood bank that patient is pregnant

A patient who was 22 weeks pregnant was admitted via the ED with status epilepticus and transferred to ITU. The Hb was 6.7g/dL and 2 units of red cells were requested. No diagnosis was given on the request form despite boxes being available to tick (i.e. pregnant yes/no/unsure). The following day it was discovered by blood bank staff that the patient was pregnant and the units were investigated. One had been, by chance, CMV negative, the other had not.

Case 2

'Sickle cell disease' not stated on request for red cells

A patient was admitted with anaemia and assigned a new hospital number as a new PAS system had recently been installed. No previous transfusion was sought, although this patient had a previous record on another number. The request form stated only 'anaemia' as the indication for transfusion: although the patient suffered from sickle cell disease the diagnosis was not given and therefore laboratory staff were not prompted to check for any previous transfusion history on an old hospital number. The patient was transfused non-phenotyped blood.

In 13 of the 76 cases linked with clinical omission to provide special requirements, the root cause of the problem related to the fact that the patient was undergoing shared care between 2 hospital sites, sometimes within the same trust and sometimes in separate trusts. Information not communicated included:

- irradiated products required due to treatment with purine analogues
- a diagnosis of Hodgkin's disease
- recent mismatched BMT or SCT
- bowel transplant and requirement for irradiated CMV negative components
- requirement for HLA matched platelets

Case 3

SCT centre did not inform referring hospital of ABO mismatched transplant

A patient was referred to another trust for a BMT. Post transplant no details of the donor group were sent to the referring trust, so consequently the blood transfusion department there were unaware that the patient had received a major mismatch marrow (the patient was group O D positive and received a group A D positive transplant) and now required a different group FFP and platelets. The transplant team at the other trust was contacted and they faxed through a copy of the transplant protocol. At the bottom is a distribution list of all those who had received a copy, but this did not include the referring hospital.

COMMENTARY on clinical cases

Doctors not usually working in haematology or oncology may be required to request blood components for these patients despite unfamiliarity with special requirements – a problem that arises from shift working and extensive cross-covering.

Doctors working in non-haematology specialties must be educated sufficiently in transfusion medicine to know that certain patient groups, such as pregnant women and sickle cell patients, have important special requirements for safe transfusion.

Medical staff in the ED and critical care should be reminded of the importance of identifying whether a patient is pregnant. The request form is there to facilitate this, and requires a diagnosis or reason for transfusion, and specifically asks about pregnancy. It should be an absolute requirement, enforced through the Risk Committee and Clinical Governance framework, that transfusion request forms are fully completed. Blood bank staff should be required to ask for these details if they are not given.

Shared care inevitably results in a situation where communication of essential information is required, and there is a risk of communication breakdown. This appears to be the result of a lack of knowledge, especially among clinicians, of the critical transfusion requirements which may arise from the diagnosis and treatment of the shared patient. Detailed

information changes hands, but transfusion details may be omitted, or the transfusion staff may be left out of the communication loop.

Laboratory-based cases of SRNM *n* = 41

The laboratory failed to provide components of the correct specification on 41 occasions. In 5 further instances, although the primary error was clinical, the laboratory could have picked up on the need for the special requirement if staff had been more vigilant. In 2 cases, where phenotyped blood was not issued appropriately, alloantibodies were produced.

The errors in this section mirror those of previous years. In some cases there were no computer flags to prompt laboratory staff but a number of errors occurred when flags were present, and missed, by laboratory staff. It is of note that in a number of cases where errors occurred there was more than one special requirement:

Case 9

Laboratory misses fact that there are 2 special requirements

A patient required CMV negative and irradiated blood components. The request for 2 units of red cells was made. CMV negative but not irradiated units were issued and administered.

Case 10

BMS omits to issue CMV negative components for pregnant woman with sickle cell disease

A patient was pregnant on the high dependency ward and had sickle cell disease. Her Hb was 5g/dL. A request was made for 4 units of red cells urgently. Phenotyped units were requested due to sickle disease but the BMS forgot to order CMV negative units. The patient received all 4 units overnight, the error being discovered when more units were requested the following day to cover the C-section.

COMMENTARY on laboratory cases

Failure to provide irradiated components when required was the biggest group (20/47 cases) in this category. In some cases it is clear that hospitals are relying on a ticked box on the component request form to highlight the need for irradiation. This is easily missed in the laboratory. A more robust mechanism should be in place for informing the laboratory, prior to a request for transfusion, that irradiated components are required for a particular patient. This may or may not involve pharmacy.

There were 5 cases where MB-treated FFP should have been issued to patients under 16 years of age but was not, and 1 case where a child did not receive apheresis platelets. There were no computer warning flags in any of these cases and, although warning flags can be missed, consideration should be given to setting up warning flags based on the date of birth of the patient.

Failure of laboratory staff to select appropriate components when warning flags are present is hard to understand, particularly when the majority of errors are in normal working hours, for routine blood provision and when issued by transfusion specialist BMS staff.

Learning points

- A robust process must be in place for ensuring that the laboratory is aware of the need for irradiation, before transfusion is required.
- Medical staff must have sufficient transfusion knowledge to understand the implications for special requirements of some medical therapies and interventions. This directly affects doctors working in haematology, oncology, paediatrics and obstetrics but must include doctors on call and cross covering.

The following learning point from last year remains pertinent:

- Competency assessment of staff working in the transfusion department must include competencies in the provision of blood components for specific groups of patients and in understanding the importance and use of 'special requirement' flags.

Miscellaneous cases of IBCT *n* = 2

A neonate with hydrops fetalis was massively transfused thereby producing a misleading blood group. Because the child had been registered on 2 separate occasions the 2 records were not matched with each other and therefore the post-transfusion apparent change in group was not recognised.

Case 1

Dual registration results in mis-grouping of massively transfused neonate

A very sick 2-day-old neonate with hydrops fetalis grouped as B D positive and was given large volumes of group O D negative blood in the neonatal period. Subsequently a second sample was taken and details were entered into the neonatal computer system, which interfaced with the hospital computer system. However, the previous medical record number was not retrieved by the computer and a new hospital number was created by the neonatal system. Thus 2 medical record numbers were in use. This second sample grouped as O D positive and the neonate subsequently received group O FFP and platelets. The erroneous group was detected because the patient had been heavily transfused with group O D negative blood prior to the second grouping sample being taken. Because of the 2 hospital numbers, there was no previous record of this in the laboratory. The reporter did not feel that there was a laboratory error involved. The patient was extremely sick and no haemolytic reaction was detected in response to the plasma and platelet transfusions. The patient subsequently died of other complications of hydrops fetalis.

In the second case a hydropic baby was given units incompatible with a maternal antibody, which may or may not have contributed to the baby's condition. The antibody would have been detected antenatally if the hospital had complied with guidelines regarding antenatal screening.

Case 2

A hydropic baby is transfused S positive units, though mother has anti-S, not checked antenatally

A baby girl was born at 37 weeks gestation following emergency CS for reduced foetal movement. The child was pale and floppy and hydropic with petechiae and the Hb was 2g/dL. The baby was group AB D positive, the mother group B D positive and the father group A D positive. Emergency group O negative blood (140 mL) was given. Laboratory tests showed the baby was DAT positive. The mother's plasma contained anti-S titre 1/8 at delivery, and baby and father were both S positive. The anti-S had been undetectable at booking, and the mother was not re-tested at 28 weeks as this was not policy in D positive mothers. There was a poor/absent increment in Hb following transfusion, and the emergency blood was found to be S-positive. An exchange transfusion of S-negative units was prepared and transfused. Samples were sent to NBS, where it was suspected that the immune hydrops was probably caused by an antibody to private antigen from the father, as yet unknown. The mother's anti-S titre was not thought to be high enough to be the primary cause, although it cannot be ruled out.

The laboratory now complies with BCSH guidelines and has persuaded the PCT to fund testing at 28 weeks for all pregnancies, regardless of Rh status.

IBCT events originating in the hospital transfusion laboratory *n* = 132

There are a total of 132 IBCT cases in which the primary error arose in the laboratory, which represents 50% of the total 262 IBCT cases. They have been summarised in Table 19 on page 34 and are discussed in more detail here. Laboratory cases resulting in special requirements not met (41 cases) are discussed above.

In total, laboratory errors account for 200 of the total 1040 cases included in the SHOT report this year. This consists of 132 IBCT events (see Table 28 below), 47 anti-D related events (see page 82) and 21 handling and storage errors (see page 76).

In 2007 there were 121 cases involving laboratory errors consisting of 40 primary laboratory errors, 36 cases of special requirements not met, 20 laboratory-based handling and storage errors, 24 anti-D related laboratory errors and 1 HTR.

The has been a 65% increased in laboratory-related errors. However, the increase in overall reporting to SHOT this year stands at 85%, so the increase in laboratory errors is less than the overall increase. As a percentage of reports included in this 2008 annual report, laboratory errors – at 200 of 1040 cases – represent 19% of the total.

The vast majority of errors are procedural. Mistakes in testing account for only 31 errors (15.5%). Many years of improvements in testing, through participation in the UK NEQAS BTLP scheme, probably account for this. Laboratories now need to concentrate on procedural deficiencies.

Table 28
Summary of laboratory-related errors *n* = 200

Type of error	Number of cases from this chapter
Wrong blood	**39**
Wrong sample selected	4
ABO grouping error	5
D grouping error	11
Incorrect component selected	14
Incorrect labelling	4
Others	1
Wrong group selected for SCT patient	**4**
Wrong ABO group	4
Wrong D group	0
Other pre-transfusion testing errors	**48**
Testing errors	8
Procedural errors	40
Special requirements not met	**41**
Irradiated component	20
CMV negative component	7
CMV negative and irradiated	3
Phenotyped component	4
MB treated FFP	5
IgA deficient cells	0
HLA matched platelets	1
Apheresis platelets not given to a paediatric patient	1
TOTAL	**132**
Anti-D related laboratory errors	**47**
Handling and storage related laboratory errors	**21**
GRAND TOTAL LABORATORY ERRORS	**200**

Wrong blood incidents *n* = 39

This year 'wrong blood' incidents resulted from laboratory errors in 39 cases. This compares to only 15 cases last year.

Three cases involved babies < 4 months old, 1 case involved a 9-month-old baby, 1 case a 2-year-old and in 1 case the age was not given. All other cases were in adults over 18 years of age.

Incidents occurred in an emergency setting in 20/39 cases, while 14 were routine and 5 unknown. Seven of the errors occurred during normal working hours while 29 occurred out of hours, and the time was not given in 3 cases. The staff involved out of hours included 18 BMSs who normally work in transfusion and 11 who do not routinely work in transfusion.

The 39 errors were:

- In 4 cases the wrong sample was tested: 3 for grouping tests and 1 for a crossmatch. The first case resulted in a group A D positive patient being grouped as O D positive and receiving 2 units of group O D positive red cells. In the second case the samples that were transposed were both group A D positive. In the third case 2 samples were transposed resulting in a group O D positive patient being grouped as AB D positive and receiving 2 units of group AB D positive blood and a group AB D positive patient being grouped as O D positive and receiving 3 units of group O D positive blood. Neither patient had adverse reactions and the error was only discovered a year later when 1 of the patients returned to the hospital and had their blood group tested. The error in crossmatching caused no adverse reaction.

- Five ABO grouping errors. One of these errors was an urgent, manual, tile group that was misread. This resulted in a group AB patient receiving 3 units of group A FFP. The second case is difficult to interpret and may not have been an error: a sample from a patient on chemotherapy was grouped as O D positive but the patient insisted they had been grouped as B D positive at another hospital. The laboratory repeated their tests, which showed a group O forward group; however, the reverse group only reacted with group A cells. The patient required blood, and refused to give another sample, so group O D positive units were transfused. A year later the same patient returned and again grouped as O D positive, to be transfused with group O D positive blood. Samples were sent to the local NHSBT reference laboratory, which neither detected B antigen nor showed reaction with group A cells in the reverse group. It is not possible to say whether a weak mixed field reaction was missed or whether the disease state had caused the B antigen to disappear. The other 3 cases were groups performed using automated systems, which then required manual intervention/interpretation. These 3 cases are given below as case studies.

- Eleven errors in D typing. There were 4 female patients > 60 years old and 7 male patients. In 10 cases this resulted in D positive blood being given to D negative individuals and 1 case of O D negative blood being transfused to an O D positive patient. Three of the patients formed anti-D. Ten of the errors were made using manual techniques. Three cases definitely involved transcription errors, with results being correctly recorded on worksheets and then erroneously entered onto the LIMS, while in the other cases the results appear to have been misread. In 1 case the presence of cold agglutinins may have contributed to the error. The final case involves an incorrect interpretation of a weak D result on a sample tested on the Ortho Innova. This is a recognised problem, as highlighted in a number of UK NEQAS exercises and known to the laboratory involved, yet the BMS failed to repeat the D type with further anti-D reagents as per the local SOP (see Case 5 below).

- Fourteen cases of incorrect component selection. Six cases involved red cells. In 1 case this resulted in a neonate having an exchange transfusion with blood outside the specification of blood for neonatal exchange. A second case also involved inappropriate selection of blood for a neonate: the group A premature baby of a group O mother with anti-Fya was transfused group A blood that had not been tested for Fya and was issued using electronic issue. Other cases involved Group O blood being given to an AB patient, O D positive blood to an A D negative patient, O D positive to an O D negative patient, and an O D positive Octapack to an AB D negative baby. Four cases involved cryoprecipitate. In 3 cases cryoprecipitate was issued when FFP

was requested and in 1 case 10 pools of cryo were issued and transfused when 10 single units or 2 pools had been required. In 2 cases platelets for specific patients were transposed. Two cases involved FFP; in 1 case group O FFP was given to a group A patient and in 1 case cryodepleted FFP was issued when FFP was required.

- Four cases occurred in which units were labelled incorrectly by the laboratory, 1 case involving red cells and 3 cases involving platelets. The bedside check failed to identify the previous error.

- In 1 case a phone call was received to crossmatch blood for patient X and send it to an off site location. The full details of the patient were not noted and unfortunately a patient with a similar name (different hospital number and date of birth) was being tested at the same time. Blood was sent over labelled for patient Y but transfused to patient X. The error was noted when the second unit was checked at the bedside pre transfusion. Fortuitously, the 2 patients had the same blood group and a negative antibody screen.

Case 1

Historical error elucidated from full electronic laboratory records and automation

On authorising a blood group on patient X, the pathology computer flagged a mismatch with historical data, which gave the blood group as AB D positive. The blood group from the sample was interpreted as O D positive. The sample labelling was correct and the blood group was re-analysed and found to be O D positive. The doctor agreed to take a further blood sample, which was also found to be O D positive. The historical search identified that 2 units of AB D Positive red cells were transfused a year earlier with no adverse effects. Having identified when the sample was tested, the archive record on the automation was interrogated and it was found that the sample had been analysed with 1 other sample, which grouped as O D positive; the patient had been crossmatched and 3 units of red cells transfused. The patient had received antenatal care from another hospital and was grouped as AB D positive at booking and at 28 weeks' gestation. The conclusion of this investigation was that the 2 blood samples had been transposed and an O D positive patient had received 2 units of AB D positive red cells in 2007 with no adverse effects. The second patient, whose correct blood group was AB D positive, received 3 units of O D positive red cells in 2007 with no reaction.

Case 2

When IT fails electronic issue cannot be used

A 19-year-old female was admitted as an emergency with head trauma. The sample was tested using routine automation but the interface stalled and the result was entered manually onto the LIMS. Results from the wrong patient were entered. The blood was then issued using electronic issue. Four units of A D positive blood were transfused to this O D positive patient. The error was identified when the patient developed symptoms of a HTR with red urine and falling haemoglobin. Fortunately the patient made a full recovery from her ABO-incompatible transfusion.

Case 3

Competency assessment on blood group anomalies must form part of training

A grouping discrepancy was highlighted on the automated group of a 74-year-old patient requiring transfusion for anaemia. The forward group was A, but there was no reaction with the B cells on the reverse group. The BMS rechecked the group and thought that there was a weak reaction with the anti-B and interpreted the group as AB. However, as there was uncertainty, the BMS selected group A red cells for transfusion. Further testing of the sample by laboratory staff, the following day, confirmed that the group was A. It was felt that inexperience led to the mistake.

Case 4

The difficulties encountered with cases of AIHA

A 93-year-old female with AIHA was transfused 4 units of group A D positive blood, rather than group O D positive blood, because of a laboratory error in result interpretation. The patient sample was tested routinely overnight but the group results were not transmitted because they required interpretation. The antibody screen results were 3+ and the DAT 4+. Next morning the card was manually interpreted, incorrectly, as group A D positive and the result entered onto the LIMS. Further samples were sent to NBS RCI for investigation but a crossmatch was not requested. RCI phoned to say that the patient had autoantibodies and anti-E and suggested selecting E negative, K negative blood for crossmatching. Later the need for blood became urgent and a 4-unit crossmatch was set up, selecting A D positive, E negative, K negative blood. The crossmatch was incompatible as was the auto. The blood was issued with a warning that the blood was incompatible and that the patient should be closely monitored. The error was noticed when the

RCI report arrived in the post. The patient transfusion administration chart stated 'nil adverse event'. Over the next few days her Hb gradually fell but she had no effects that could not be attributed to her underlying condition. It was concluded that the drug regime used to suppress the AIHA had afforded protection against the incompatible units.

Case 5

D types must not be assigned on one weak reaction

A patient initially gave a weak reaction with anti-D and was reported as D positive without further investigation. Two units of D positive red cells were transfused and all subsequent samples grouped strongly as O D positive with no mixed field. Fourteen group O D positive red cells and 6 group O D positive platelets were transfused over a 3 week period. Several months later the patient presented as group O D negative with anti-D. Genotyping at IBGRL confirmed the patient as D negative.

Case 6

Take due care when selecting blood for special patient groups

Two units of blood were ordered from NHSBT, 1 unit for a neonatal exchange transfusion and the other a genotyped unit for a child with thalassaemia major. The duty BMS issued the irradiated unit, specified for exchange transfusion, to the thalassaemia major patient and the non-irradiated, genotyped unit for the exchange transfusion. The error was detected when the paediatrician realised they did not have sufficient blood to complete the exchange transfusion. The child with thalassaemia major did not receive any blood as the mistake had been identified prior to commencement of her transfusion.

Case 7

Take due care when selecting platelets for special cases

NHSBT delivered 2 units of platelets for 2 different patients. The BMS transposed the units and issued the pack of HLA matched platelets, specifically ordered for a haematology patient, to the other patient, who was bleeding. The platelets were ABO compatible.

Case 8

Is causing less distress to a paediatric patient a valid reason for using less safe practice?

While a 9-month-old male patient was in the anaesthetic room under anaesthesia, blood was taken for a group & save test. This is the usual procedure for children to avoid distressing younger children prior to (elective) surgery. To check the blood group type, a manual group & save was performed. The BMS authorised the blood group and antibody screen as group O D positive, antibody screen negative, and 2 units of O D positive units were issued and transfused. This was a misreading by the BMS. The patient was actually group O D negative when a repeat sample was tested later using automation. No anti-D had been formed at the time of the report.

COMMENTARY on wrong blood incidents

The number of laboratory errors contributing to 'wrong blood' events has increased this year from 15 to 39. This is a significant increase and mirrors the increase in reporting in all categories. The increased errors are largely in D typing and component selection.

The number of ABO errors have remained relatively constant for the last 3 years (see Table 29 below). This year the errors have resulted in 4 ABO-incompatible transfusions: 2 units of AB blood being transfused to a group O patient, 2 cases of 4 units of group A blood being transfused to group O patients and 1 case of group A FFP being transfused to a group AB patient.

Fourteen cases of D-incompatible transfusion due to laboratory errors are reported this year, with anti-D known to have been produced in 3 cases at the time of writing. Fortunately all 3 of these patients were women over 60 years of age.

Table 29
Trends in laboratory based ABO grouping errors, with causes

Year	Total No. of Cases of ABO Errors	Wrong Sample Tested	Interpretation /Transcription Errors	Other	ABO-incompatible Transfusions (all components)	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	0	No morbidity
2007	7	3	4		2	No morbidity
2008	8	3	5		4	1 AHTR

As reported in previous years the majority of errors occur out of hours. However, this year, the number is huge, 29/39 cases or 74%. Another data gathering exercise is required to determine current workload data to see whether this increased error rate is a reflection of an increase in workload outside routine hours or an increase in the error rate, or both. This year the majority of errors made out of hours were made by BMS staff who work regularly in transfusion (18/29 cases or 62%). Half of the errors made were in blood component provision for emergency cases.

All but one of the ABO and D typing errors occurred because of mistakes in manual procedures. The fact that errors occur most often during manual procedures has been documented in consecutive SHOT reports. Despite this evidence that manual procedures are inherently less safe than automated ones, patients for elective surgery are still being tested, at the last minute, by manual methods and this requires review.

The increase in component selection errors is interesting, particularly in regard to the number of errors in the selection of cryoprecipitate, as it parallels the introduction of the new component, pooled cryoprecipitate, by the NHSBT in October 2006. It should be possible to set up warnings in the LIMS to highlight when the component issued for a patient does not match that of the component ordered. This facility does not appear to be widely used/available. There were a number of component selection errors that resulted from carelessness at the point of issue, often when specific components had been ordered from NHSBT, arriving ad hoc; see Case 4 and Case 5 above, and further examples in the 'Other pre-transfusion testing errors' section.

In 9 cases it was believed that the final bedside check could have picked up these laboratory errors and prevented mis-transfusion.

Learning points

- Electronic issue must only be used on the first presentation of a patient if the results of that sample have been tested using full automation with an interface to the LIMS and there have been NO manual interventions.
- Before staff are deemed competent to work alone they must be aware of, and competency assessed to deal with, blood grouping anomalies.
- Blood grouping can be problematic in the presence of cold agglutinins. Laboratories need to review procedures and staff training to ensure presence of clear instructions and competence in dealing with this problem, including when to send samples away to a reference laboratory.
- When new components are introduced, training must be given to all staff to allow thorough familiarisation with the component appearance, label and specification.
- BMSs must take care when issuing components to patients with specific requirements.
- NHSBT should review the packaging of components that look similar, to assess whether they could be more easily identified, particularly when those components are often used in emergency situations.
- The IT system should be configured to flag a component discrepancy between that ordered and that issued, and this should be fully validated. If this is not possible locally these development requirements must be raised with LIMS suppliers.
- Telephone requests for blood components must follow the strict rules that are in place for written requests, i.e. the patient's full name, hospital number and date of birth must be obtained.

The following learning points from previous reports remain pertinent:

- 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.
- 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 components issued for SCT/BMT recipients *n* = 4

All cases were in adults. Three were routine transfusions and 1 was an emergency. Two cases occurred during normal working hours, 1 during a shift and the timing was not known in the fourth case.

In the first case group A blood was given to a group A recipient of a group O transplant, 1 month post transplant. The transplant information was not passed on to the laboratory but the request form contained the clinical detail 'post allo BMT' and the reporter thought the laboratory should have made further enquiries. There was no adverse reaction from the transfusion.

In the second case the BMS failed to add pertinent transplant blood group information to the LIMS. The historical group was A D positive but group O D positive units were required post transplant. Ten units of group A D positive blood were transfused over a 5-month period. No adverse reactions occurred.

In the third case the donor of a peripheral blood stem cell transplant was group A D positive and the recipient group O D positive. The patient should have been given group A D positive platelets but received group O D positive platelets on 4 occasions. No adverse reactions occurred.

In the final case the donor of a bone marrow transplant was group O D negative and the recipient group A D positive. A granulocyte transfusion was required and 3 units of group A D positive granulocytes were issued when group O D negative should have been selected. Although donor and recipient blood group details were on the LIMS, unfamiliarity with the use of granulocytes meant that the significance of the blood group was not realised.

Learning points

- Simple yet robust procedures must be in place for recording transplant details.
- Selection of blood and blood components post transplant must be included in competency assessments.

Pre-transfusion testing errors *n* = 48

The number of errors in this category has more than doubled from 20 cases last year. Two of the cases involved babies under 4 months of age' there were 2 cases in children under 16 years, and 2 further cases in patients under 18. In 1 case the age was not stated and the rest occurred in adults.

Twenty-one cases occurred during normal working hours, 24 cases out of hours, and the time was not stated in 3 cases. Of the 24 errors made out of hours, 14 were made by BMSs who normally work in transfusion, 9 by BMSs who do not and in 1 case the status of the BMS was not known.

The 48 errors can arbitrarily be 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, e.g. incorrect test selection, failure to follow procedure

Testing errors n = 8

Seven of the errors resulted in weak antibodies being missed, with no adverse events following these errors. The eighth error involved the use of the wrong sample for a crossmatch on a patient with AIHA and multiple antibodies. This patient suffered an acute transfusion reaction that resolved with no complications.

Two interpretation errors occurred: in 1 case an initial interpretation of non-specific antibody was later interpreted as an anti-Fyb by more experienced staff (an NBS reference centre error) and in the second case an anti-Jka was excluded on the basis of a positive Jka type when in fact the sample typed was a post-transfusion sample.

It is debatable whether 3 of the cases in this section were errors or just very weak antibodies, at the limit of detection, that reacted more strongly with one technique than another.

Procedural errors n = 40

In 34 of these cases the patient suffered no reaction. Of the remaining cases:

- 1 outcome was not stated
- 1 died from underlying condition
- 1 involved a possible transfusion reaction but was not thought to be related to the error
- 1 involved a mild reaction
- 1 patient with AIHA produced anti-E (and it is difficult to say whether there was a reaction because of the AIHA)
- 1 case involved the production of anti-K in a 17-year-old female

There were many different types of procedural error:

Testing unsuitable samples n = 9

There were 8 cases where the sample used was too old (ranging from a few hours out of usable time to 27 days out of date) and 1 case where the sample was tested despite a discrepant date of birth between sample and request.

Case 9

IT warning flags are only helpful prompts. Staff must understand the reasons behind protocols.

The patient had been transfused on 28/01. The sample was therefore unsuitable to use from 30/01 according to local policy. Despite this the sample was used to serologically crossmatch blood on 03/02, the computer indicating that electronic issue was unavailable. The 2 members of staff involved in the incident were senior members of the haematology department working in blood transfusion 'out of hours'. It was clear that they did not understand the reason for the computer indicating that electronic issue was unavailable. The blood was transfused uneventfully.

Failure to find historic records n = 4

In 1 case the use of an ED number meant that a record under the hospital number, with anti-E, was not found. There was 1 case where a name search was performed incorrectly and a record with anti-E was not found. In a third case the staff forgot to search the old database, missing a record with anti-e+K. In a final case there were 2 hospital numbers on file, merging of records did not take place, and so the record with anti-Fy^a on file was missed.

Failure to provide correctly phenotyped units n = 12

- 2 cases where clerical error, when ordering specific phenotyped units from NHSBT, meant that blood of an inappropriate phenotype was received and then crossmatched: units that were Jkb negative rather than Fyb negative and units that were not S typed when they should have been. The crossmatches were compatible as the antibodies were historic and not detected in the current sample.
- 2 cases where antibody information, given over the phone from reference laboratories, was misheard: anti-S misheard as anti-f, and anti-C misheard as anti-E.
- Not issuing phenotyped units to a patient with AIHA resulted in an Ro patient being given E positive blood, which produced anti-E.
- Crossmatching E-c- for a patient with sickle cell disease who required e-C- phenotype due to historic antibodies.
- Failure to provide K negative units for a patient with historic anti-K.
- Failure to provide K negative units to a pre-menopausal female who produced anti-K.
- Failure to select Fy^a/C^w negative units for a patient with historic anti-Fy^a and anti-C^w.
- Failure to receive appropriately phenotyped units due to a clerical error, regarding a historic antibody specificity, on the request form to a referral laboratory.
- The BMS did not realise that antigen negative blood had to be obtained for historic antibodies (anti-f plus anti-Jk^a). As the current antibody screen was negative, crossmatch compatible blood was issued.
- Failure to understand the importance of historic maternal antibodies when selecting blood for a neonate. The mother had anti-c+E (though this was not detected on the current sample), but group O D negative blood was issued to the baby without a crossmatch.

Case 10

The importance of antibody history

Patient arrived in the ED with a GI bleed. Two units of flying squad group O D negative blood were used. A group antibody screen and retrospective crossmatch on the group O D negative units was performed. The antibody screen was negative but the BMS on call noticed that the patient had previously had anti-Jka and anti-f. About 12 hours later the ward phoned asking for more blood to be crossmatched. The current antibody screen was negative and the BMS did not realise that antigen negative blood should have been selected. All units were crossmatch compatible. The patient received 3 units of group A D positive blood. The following day the incident was discovered by routine day staff and all units were Jka typed. All were Jka positive (including the flying squad blood) and 2 of the group A D positive units were also positive for f. The patient died from the underlying condition.

Cases in which blood was issued despite incomplete pre-transfusion testing n = 12

- 2 cases where the group & screen was not complete.
- 4 cases where antibody identification was not complete.
- 1 case where antibody identification was not performed.
- 1 case where the crossmatch was incomplete but the blood was labelled.
- 1 case where blood arrived from NHSBT and the BMS thought it had been crossmatched and issued it without crossmatching.
- Failure to update critical notes following antibody identification that had an impact on the subsequent presentation of the patient.
- BMS went straight to a warm NISS antibody screen and crossmatch because of a historic cold agglutinin. The antibody screen was negative and the crossmatch was compatible and 4 units of blood were issued. The patient suffered a mild transfusion reaction of pyrexia, nausea and rigor, so a transfusion reaction investigation took place. Routine screening and crossmatch methods were employed. The cold agglutinin was no longer detectable but a weak alloantibody was detected.
- Blood issued via electronic issue (EI) before DAT complete.

Case 11

The need for complete documentation

Six units of blood were issued using emergency procedures for a patient admitted with a GI bleed. Full compatibility testing was completed retrospectively. An antibody was detected in the screen and 1 unit out of the 6 issued was incompatible. The BMS immediately contacted the clinical area to recall the units; however, 4 units, including the incompatible unit, had already been transfused. On investigation, laboratory testing of the patient's previous sample had detected and identified anti-C+D+E. However, the patient's critical notes had not been updated. This resulted in the BMS being unaware of the requirement to provide antigen negative blood during the emergency. There was no adverse reaction reported.

Errors during crossmatching n = 3

- 1 case where an immediate spin crossmatch was used when an IAT crossmatch should have been used.
- 1 case where the BMS continued to issue blood by EI following a transfusion reaction, with no investigation into the reaction.
- 1 case where a neonatal sample was used for the crossmatch when the maternal sample should have been used.

Cases that are reported in other sections of this chapter, because that is where the primary error occurred, had secondary errors of inappropriate use of electronic issue (EI).

- Two cases from 'Wrong blood' incidents:
  - EI on a baby when the mother had anti-Fya and possible maternal IgG anti-A.
  - EI of blood on first presentation of patient, following a manual intervention on recording the grouping result.
- The cases reported above, under incomplete pre-transfusion testing:
  - EI performed when the antibody screen was positive, but the identification was outstanding.
  - EI performed when DAT outstanding.

COMMENTARY on pre-transfusion testing

The increase in the number of errors from 20 last year to 48 this year is at least in part accounted for by the overall increase in reporting in 2008 in all categories, which reflects increased awareness of what to report and greater participation in the SHOT scheme. In addition, as laboratories improve their quality systems in line with the Blood Safety and Quality Regulations 2005[1] and the new CPA Standards (www.cpa-uk.co.uk) there may be better recognition of procedural failures.

The percentage of errors occurring out of hours still appears to be higher than within core hours but this is not as marked as in the cases of 'Wrong Blood' errors.

Learning points

- Errors are still being made in using inappropriate samples. Computer warning flags are a useful tool but must be backed up with strong theoretical knowledge.
- In both the 'wrong blood incidents' section and this section, careless errors seem to have been made in issuing specially selected components sent from NHSBT. Care must be taken when issuing specialist components.
- Competency assessment must comprehensively cover the areas of phenotype selection, antibody history and appropriate use of EI.

Brought forward from last year:

- Laboratories must ensure that robust systems are in place for highlighting 'outstanding' work on a patient.
- Transfusion laboratories must have thorough search strategies when looking for patient histories in order to find and reconcile multiple entries for a patient.

RECOMMENDATIONS for IBCT chapter

New recommendations for 2008

- Competency assessment of staff involved in the transfusion process must be relevant to the person's core role and knowledge requirements. This must be carried out in accordance with NPSA SPN 14.

  Action: Clinical risk managers, HTTs

- All staff must be trained (and competency assessed) in recognising the different blood components and their labels.

  Action: Clinical risk managers, HTTs

- The potential risks of access to emergency O D neg units within satellite fridges should be recognised and strategies put in place to minimise lack of correct identification. Clear guidance should be formulated regarding their use and potential risks associated with their removal from fridges. The emergency units should be separated and clearly labelled.

  Action: Clinical risk managers, HTTs

- Shared care discharge notification, giving tick-box options for special requirements, with reasons, should be completed by the referring clinicians and forwarded to the receiving hospital through the laboratory network.

  Action: NBTC, RTCs

- Laboratory procedures should be validated in line with the BSQR and should be revisited following an error as part of Corrective and Preventive Actions.

  Action: Transfusion laboratory managers

- Competency assessment in laboratories must be linked to process. BMS staff must be competent in performing the test but must also have a thorough understanding of the context in which the test is being performed, i.e. the test in relation to a specific patient and the clinical information. Basing competency assessment on National Occupational Standards (NOSs) will enable this, as NOSs have both 'Performance' criteria and 'Knowledge and Understanding' criteria.

  Action: Transfusion laboratory managers

- The UK Transfusion Laboratory Collaborative has recommended minimum standards for hospital transfusion laboratories in terms of staffing, technology, training and competence. This document is in press in *Transfusion Medicine*[2] and should form the basis for future laboratory planning.

  Action: CEOs, Pathology managers

Recommendations from previous years

Year first made	Recommendation	Target	Progress
2007	Education of doctors and nurses involved in transfusion must continue beyond basic competency to a level where the rationale behind protocols and practices is understood. Transfusion medicine needs to be a core part of the curriculum.	**NBTC, Royal Colleges, GMC**	Royal Colleges and Specialist Societies Committee working with NBTC.
2007	Staff involved in blood component transfusion must be aware of their professional accountability and responsibility.	**GMC, NMC, IBMS, professional insurance schemes**	
2001	Existing procedures should be re-examined for flaws that could lead to systems errors.		BCSH Guidelines on Blood Administration, currently under review.
2002	Resources must be made available in Trusts to ensure that appropriate and effective remedial action is taken following transfusion errors.	**HAs, PCTs, Trust CEOs through HTCs and risk management structures**	No mechanisms for monitoring.

6.1 IBCT Errors Relating to IT Systems

Problems with IT systems, their incorrect use or deficiencies continue to cause IBCT incidents. In 2008 there were 44 reported incidents, compared with 25 in 2007 (see Table 30). All incidents originated in the transfusion laboratory. Twenty-nine cases involved red cells, 11 platelet components, 3 FFP and 1 pooled buffy coat. Four of the 44 cases occurred in children.

Table 30
Categorisation of cases in which IT systems caused or contributed to errors

NB Some reports involved more than 1 error (most commonly failure to issue irradiated and CMV negative components)

Error	Reports	Non-irradiated component transfused	Antigen positive unit transfused	Non-CMV neg unit transfused	Wrong group after SCT	Other	
Failure to consult historical record	8	6		3		1	Issued non-HLA matched platelets
Historical record not identified	1		1				
Ignored/missed warning flag	7	3	3			1	Issued inappropriate group FFP
Failure to update warning flags	10	5	1	3	2	0	
Computer system 'down'	3					3	ABO incompatibility due to error in manual transcription Wrong component selected and issued Wrong group issued manually (wrong sample selected)
Data not transferred from old system	2	1	1			0	
Electronic blood tracking system errors/misuse	1					1	Expired platelets issued despite alert
Failure to merge or reconcile records	1		1			0	
Error/deficiency in computer system	11						See Table 31
TOTAL	**44**	**15**	**7**	**6**	**2**	**6**	

Table 31
Incidents caused by errors or deficiencies in the Laboratory Information Management System (LIMS)

Error/Deficiency	No.	Notes
Allowed issue of red cells before completion of crossmatch	3	
Allowed issue of wrong component	1	Cryoprecipitate issued instead of FFP
Allowed issue of buffy coat without compatibility screen	1	Special requirements of this component not entered in LIMS
Allowed issue of Kell positive red cells to pre-menopausal female	1	No alert algorithm on LIMS
Allowed crossmatch on outdated specimen	2	
Allowed component to be issued with wrong label or tag	3	• 1 unit of red cells and 1 pack of platelets issued with wrong traceability tag (2 separate incidents) • compatibility labels transposed on 2 packs of platelets issued simultaneously

Case histories

Case 1

The danger of manual transcription of results when the computer is 'down'

Following an urgent request for blood for a patient with cranial trauma going to surgery, the on-call BMS manually transcribed incorrect blood grouping results when the laboratory computer interface 'stalled'. Two units of group A red cells were transfused to a group O patient who subsequently developed red urine and falling Hb, but otherwise made a complete recovery.

Case 2

Multiple errors lead to transfusion of red cells of the wrong ABO group post BMT

A group A patient received a bone marrow transplant from a group O donor (both were D positive). Despite appropriate prior notification by the clinical team, the LIMS was not updated to warn of the new requirement. Six units of group A red cells were issued during routine working hours over the next 2 months. Following receipt of a further notification, the appropriate note was then made on the LIMS. However, because of failure to check the historical record, a further 4 units of group A red cells were issued over the next 3 months before the error was noted. The patient experienced no adverse effects.

Case 3

Cryoprecipitate issued in mistake for FFP

An urgent request for 2 units of FFP for a bleeding patient was received at a time when the LIMS was 'down'. The single-handed on-call BMS erroneously selected and issued 2 packs of pooled cryoprecipitate. The LIMS normally reconciles the component selected with the request at point of issue, and the laboratory SOP states that 2 members of staff should check an issue in this situation whereas only 1 person was available. The reporter noted that the cryoprecipitate was probably incorrectly stored on the 'FFP shelf' of the issue refrigerator and that the 5 unit pools of cryoprecipitate are now similar in volume and appearance to units of FFP.

Case 4

Computer rule leads to transfusion of non-irradiated and CMV-screened platelets

A group A D negative male patient with non-Hodgkin's lymphoma required irradiated and CMV negative components. This was recorded on the LIMS. Appropriate platelets were ordered from the blood centre. Because of limited availability of group A CMV negative donations, the blood centre issued a group B D positive adult therapeutic dose (second choice

according to national guidelines). However, the hospital LIMS had a rule that prevented issue of this combination of ABO groups. The on-call BMS dealing with the issue was 'distracted' by this occurrence and selected an alternative pack of non-irradiated, non-CMV screened platelets of group A, which were transfused to the patient. The issuing BMS also did not check the special requirements flag.

COMMENTARY

As in previous years, failures to update warning flags on the LIMS, failure to notice (or heed) warning flags and failure to consult the historical record remain common causes of IBCT. This is a significant contributory factor in failure to issue appropriate irradiated, CMV negative or antigen negative components. In 2 cases, failure to update warning flags led to the issue of components of an inappropriate ABO group after allogeneic stem cell transplantation. A number of reports commented that navigating through the laboratory information management system (LIMS) to identify all warning flags is often complex, tedious and involves accessing multiple screens. As recommended last year, the redesign of systems to exhibit all clinically essential warning flags on the opening screen is a priority.

Twenty-five per cent (11) of these IT-related IBCT occurred outside 'core' laboratory working hours, 20% (9) occurred in emergency situations but 84% (37) involved staff working regularly in the laboratory. Of the 6 incidents involving BMSs who do not work routinely in the transfusion laboratory, 5 took place 'on-call'. One case of failure to notice a warning flag was attributed to a clerical worker in the laboratory reception. No case this year was attributed to a locum BMS.

There were18 individual cases involving errors in issuing irradiated or CMV negative components. Although the 'root cause' was in the laboratory, clinical errors in indicating special requirements on request forms (9 cases) or transfusion prescriptions (8 cases) compounded the problem. Non-irradiated components were issued in 2 paediatric surgical cases of patients with Di George syndrome and 1 case of a baby with possible severe combined immunodeficiency (SCID). On each occasion, the administering clinical team did not notice or prevent the error.

Analysis of the reported data indicates that at least 14 of the 44 IBCT (32%) could have been, but were not, prevented at the point of the final bedside check. In 11 of these cases 2 people were checking, and in the other 3 incidents 1 person performed the check.

Component selection and manual transcription errors remain a risk when the LIMS is off-line and IBCT errors continue to occur because historical data on special requirements are not transferred when new laboratory information systems are installed. Again this year, a patient received red cells positive for a blood group to which they were known to have developed alloantibodies in the past, because of failure to reconcile multiple computer records on the same patient.

It remains a priority to improve the capability of laboratory IT systems to incorporate algorithms based on patient demographics and/or data incorporated in the component label by the issuing blood centre (see 2007 Annual SHOT Report), e.g. using the date of birth and gender of the patient to ensure the selection of non-UK virus-inactivated FFP for patients under 16 years old, or the use of Kell negative red cells for premenopausal women. Data on the component label, such as irradiation or CMV status, could be used to generate an additional warning flag at the point at which the component is reserved for a patient with known special requirements. The final electronic check should also prevent components being issued with the wrong compatibility label or traceability tag.

DISCUSSION OF LABORATORY IT STANDARDS

- SHOT, as a member of the UK Transfusion Laboratory Collaborative, fully endorses the coming publication[2] of recommendations with regard to hospital transfusion laboratory staffing, technology, training and competence. SHOT strongly supports the need to determine and maintain appropriate staffing levels and skill mix to ensure safe and effective routine and emergency service provision. Incidents analysed in this and many previous SHOT reports add weight to the Collaborative's recommendations for ongoing training programmes and annual competency assessment for all staff who work at any time in the transfusion laboratory. The document places special emphasis on maintaining the competency, including familiarity with local protocols and systems, of staff working intermittently in the transfusion laboratory. There are particular issues around locum and temporary staff. SHOT data also endorse the recommendations on the

routine use of 'walk away' automation, used 24/7, to eliminate manual errors. Finally, the routine use of 'electronic issue' of red cells, where the LIMS fully meets national guideline standards to support this, and full 'vein to vein' electronic blood tracking where remote issue of blood components is introduced, will make a significant contribution to transfusion safety. Adequate resources need to be made available to allow these improvements to occur.

- Work should continue with suppliers of laboratory information management systems to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label.

- Frequent reconciliation or linking 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 laboratory process performed by appropriately trained and competency-assessed senior 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.[7] However, this requires careful change control as 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. Manual transcription of results should be held to an essential minimum.

- 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. At the same time, alert systems should not prevent the issue of clinically appropriate components of a group different to that of the patient.

- Staff must be trained to perform search strategies to ensure that all relevant records are accessed. Work is required to develop appropriate and effective search strategies, perhaps coordinated 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

- Most failures to consult the historical record or identify warning flags 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.

- 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 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, previously detected elsewhere, 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 SOPs are consistent with national guidelines and followed fully by all laboratory staff. [8] 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

Recommendations from this year's report

- Chief executive officers of hospitals and trusts, and their hospital transfusion teams, must use the UK Transfusion Laboratory Collaborative report as a basis for achieving the minimum standards recommended for staffing, skill mix, automation, training and competency in their hospital transfusion laboratories.[2]

  Action: Trust CEOs, HTTs

- Standardisation of IT systems is required across the UK, and a national minimum specification for hospital transfusion laboratory IT systems should be developed. This would then be used when working with individual suppliers of LIMS systems.

  Action: NBTC and equivalents in devolved administrations

Recommendations 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**	Coordination now achieved between NBTC, NPSA, CfH. National standard specification under development. Implementation is dependent on central funding through CfH or by individual Trusts.

6.2 Right Blood Right Patient (RBRP)

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 instructive nevertheless. They are not included in the overall numbers of IBCT cases. One case was transferred to the Near Miss category (a satellite refrigerator failure resulting in components being wasted), a further case was transferred to the anti-D section and 1 misidentified antibody was transferred to the IBCT category. There are 101 cases in this 2008 report, compared to 65 in the 2007 report, representing a 55% increase in the number of reports in the Right Blood to Right Patient category in 2008.

Table 32
Right blood to right patient episodes *n* = 101

Elements that were wrong on blood packs, documentation, identity bands, etc:	Number of incidents
Name alone or with other elements	24
DOB alone or with other elements	32
Transposed labels on 2 units for same patient	20
Hospital or NHS number	10
Donation number	8
Miscellaneous	
Failure to use address as defined in hospital transfusion policy	1
'Issue' documentation / prescription missing during final bedside checking procedure	3
Wrong expiry date on label (IT error)	1
Incorrect assigned unit supplied, e.g., paedipak	2

If the correct checking procedures had taken place during the patient's admission, in the laboratory and at the bedside, all these errors could have been prevented.

Table 33 shows where the error(s) should have been detected but were not or were ignored.

Table 33
The checking procedure(s) that did not detect the error(s)

Checking Procedure	Number of incidents
Admission + bedside check	6
Laboratory + bedside check	44
Sampling + bedside check	20
Sampling + laboratory + bedside check	13
Laboratory + collection + bedside check	8
Collection + bedside check	5
Documentation + laboratory +/- bedside check	5

There are many opportunities for staff to identify an error during the transfusion process. However, it is imperative that on admission the patient minimum data set is recorded correctly, verified by the patient (or carer) and transcribed accurately onto the medical case notes, identification wristband and subsequent tests and documentation. In 6 cases the primary error occurred at admission, resulting in:

- duplicate case notes and 2 or more hospital numbers
- transposition of the patient's first name and surname
- incorrect spelling of names
- incorrect date of birth

These errors often occurred during a previous admission. In a case of transposed names the error had remained unidentified for 2 years.

The majority of reports involved some type of clerical error, with the patient's name or date of birth wrong in 50% of cases. Worryingly, in a number of cases the error was identified and either ignored, or staff were advised by the laboratory to continue with the transfusion.

In 5 cases the transfusion took place despite the patient not having a wristband (or alternative patient ID) in place, and in a further 5 cases the transfusion was commenced with no relevant documentation available, e.g. the prescription sheet or traceability label.

Case 1

Wrongly labelled unit transfused despite error having been detected and corrected

When the patient was admitted, his date of birth had been entered incorrectly on Patient Information Management System (PiMS). He was prescribed a unit of FFP and during the pre-transfusion check he mentioned that his date of birth was wrong. The FFP was returned to the laboratory. He was then correctly admitted on PiMS and the FFP was re-ordered. Unfortunately the porter collected the incorrectly labelled (wrong date of birth) FFP as it was still on the bench in the laboratory. The nurses administering the transfusion assumed that it was now correct and did not repeat the pre-transfusion check. The unit was transfused. The patient did not have an ID wristband in situ, as the incorrect one had been removed and a corrected one had been generated but had not been replaced before the transfusion took place.

Case 2

A pointless 'check' between two incorrect documents generated by the same computer system

A clerical error occurred in the laboratory while inputting the unit number for the (laboratory generated) prescription sheet and compatibility label. The details on the request form were correct. The nurses administering the component failed to carry out a patient identification procedure; they checked the prescription form against the compatibility label, both of which had the incorrect unit number. They did not check the documentation with patient ID wristband as this was not present.

Learning points

- It is imperative that staff are vigilant at all times when participating in the patient identification process, i.e. when the patient is admitted, in the laboratory and in clinical areas.
- NO wristband (or alternative patient ID) – NO transfusion.
- The compatibility form or prescription sheet should never be used as part of the final patient identification check.
- Documents generated by the same system, e.g. the laboratory IT system on to the PiMS system can never be usefully checked against each other.

7. Inappropriate and Unnecessary Transfusion (I & U)

Definition

- Transfusions given on the basis of erroneous, spurious, or incorrectly documented laboratory testing results for haemoglobin, platelets and coagulation tests.
- Transfusions given as a result of poor understanding and knowledge of transfusion medicine, such that the decision to transfuse puts the patient at significant risk, or was actually harmful.
- Undertransfusion or delayed transfusion resulting in poorer patient outcome.

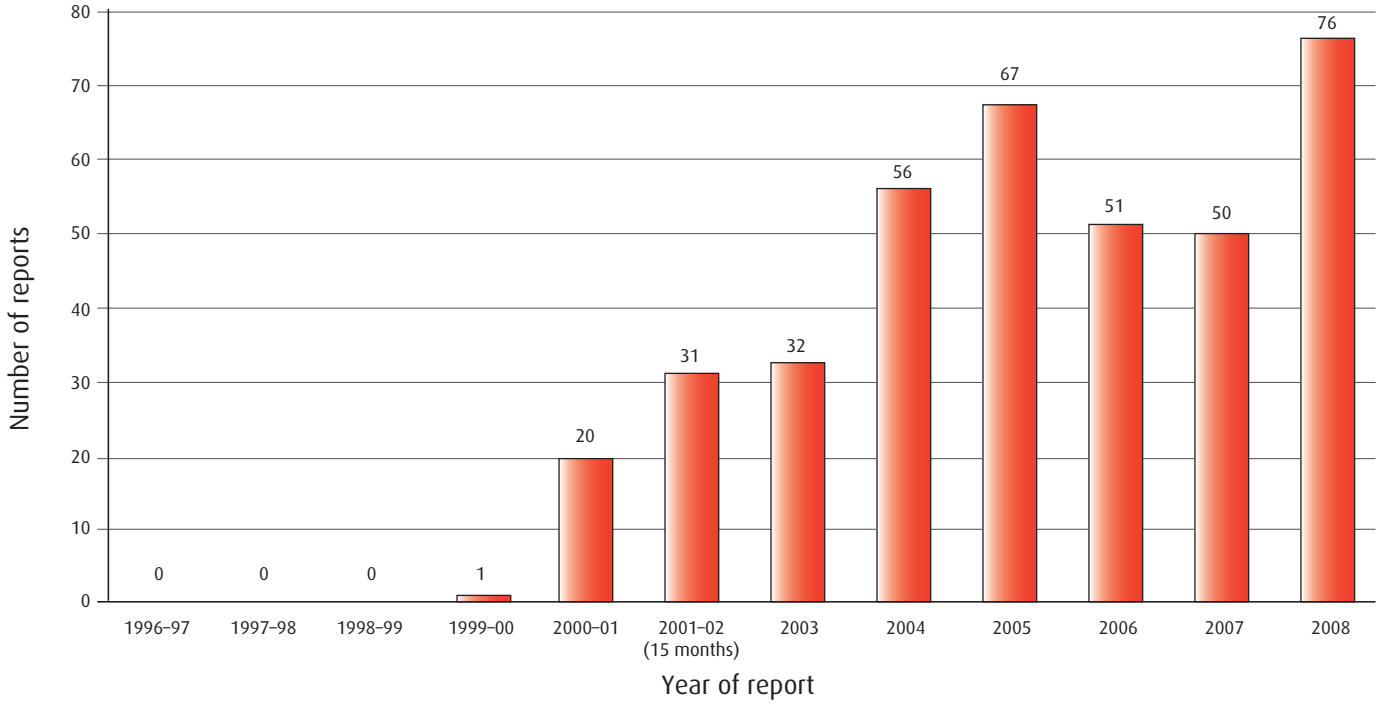
DATA SUMMARY

Total number of cases	**76**	*Implicated Components*		*Mortality / morbidity*	
		Red cells	**60**	Deaths due to transfusion	**0**
		FFP	**5**	Deaths in which reaction was contributory	**2**
		Platelets	**6**	Major morbidity	**1**
		Other *(specify)*	**2**		
		Unknown	**3**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**27**	16 years+ to 18 years	**2**	Emergency	**26**	ED	**1**
Female	**49**	1 year+ to 16 years	**2**	Routine	**44**	Theatre	**1**
Unknown		28 days+ to 1 year	**3**	Not known	**6**	ITU/NNU/HDU/Recovery	**1**
		Birth to 28 days	**0**			Wards	**9**
				In core hours	**7**	Community	**0**
		Total	**7**	Out of core hours	**8**	Other	**2**
				Not known/applicable	**61**	Not known	**62**

There were 76 cases of inappropriate and unnecessary transfusion in 2008 compared with 50 in the 2007 report (Figure 7). This follows the trend since 2000 for an increased number of reports in this category each year. Of these, 48 were reported to SHOT only through the SABRE website, while 26 were reported to MHRA as serious adverse events (SAE) and 2 were reported as serious adverse reactions (SARs). In fact none of the SAEs were reportable to MHRA as even the laboratory-related errors were related to the haematology laboratory rather than the transfusion laboratory.

Figure 7
Cases of inappropriate and unnecessary transfusion 1996–2008



As previously, the final responsibility in the vast majority of these cases lies with medical staff, who assess the patient both clinically and in the light of laboratory results, make the decision to transfuse, and decide upon the component, dose and rate of transfusion. In effective teams a form of friendly surveillance of others' decisions and actions means that there should be supportive input from nursing and biomedical staff, which may highlight problems and prevent errors – but ultimately the knowledge and experience of the doctor is the most important factor, and with that rests the final responsibility for the decision.

Emergency vs. routine: In 26 cases the event took place in an emergency setting and in 44 cases in a routine or elective setting; in 6 cases this information was unknown or unavailable.

Age of patients: There were 2 children between 16 and 18 years of age, 2 between 1 and 16, and 3 between 4 weeks and 1 year.

Gender: There were 49 female and 27 male patients.

In core hours versus out of hours
and
Where the transfusion took place

Both of these last two sections of the questionnaire were very poorly answered with over 80% of respondents leaving the section blank. Therefore no inferences can be made. The new web-based data gathering system for SHOT, to be implemented later this year, will undoubtedly rectify this problem.

Mortality
There were no deaths caused directly by the component transfusion. There were 2 deaths in which the transfusion, or lack of transfusion, probably contributed to the death of the patient. Both patients suffered from gastrointestinal bleeding, in differing circumstances (see cases 6 and 7 below).

Major morbidity
There was 1 case in which the polycythaemia resulting from inappropriate overtransfusion necessitated venesection (see Case 10 below).

Transfusions based on wrong Hb, platelet or coagulation result *n* = 38

Transfusion based on wrong haemoglobin result *n* = 36

There were 36 cases in which a patient was transfused with red cells on the basis of an erroneous or spurious result, as shown in Table 34 below.

Table 34
Erroneous Hb results

Cause of falsely low Hb value	Cases
Falsely low Hb due to phlebotomy from drip arm	10
Transfusion based on an old Hb result although a much more recent result was available	5
Results switched with those from another patient	5
Results incorrectly transcribed in notes	4
Stasis in a syringe during difficult phlebotomy	4
Verbal miscommunication of results	2
Unknown cause of incorrect result	6
TOTAL	**36**

Case 1

Transfusion and multiple investigations based on a drip arm haemoglobin

A patient was admitted with dizziness and collapse and a history of CVA. The patient's haemoglobin was 11.4 g/dL on admission but had dropped to 6.9 g/dL the next day. The FBC was not repeated and the patient was transfused 2 units of red cells even though there was no evidence of any blood loss. In addition various investigations were requested post transfusion, including abdominal ultrasound and haemolysis screen. An inpatient referral was made to a consultant haematologist who assessed the patient and questioned the validity of the Hb result; the FBC that the consultant then requested showed a haemoglobin of 13.1g/dL, and he also found the sample had been taken from the same arm as the drip.

Case 2

Transfusion based on a year-old haemoglobin

Two units of blood were requested for an orthopaedic trauma case because of low Hb prior to theatre. The blood was provided and administered on the 20th/21st of the month. A phone call to the laboratory on the 21st to confirm the preoperative Hb alerted the staff to the fact that the samples sent on the 19th for full blood count and coagulation screen had clotted and could not be analysed. A previous result from exactly the same date a year earlier had an Hb of 9.7g/dL and this was the result that was acted upon. The postoperative Hb was 13.9 g/dL.

In these cases the clinical picture and the results were discrepant, but this was not discerned by the doctors looking after the patients, who prescribed blood components on the basis of the results alone, without reference to the history, signs and symptoms.

Case 3

Lack of communication between shifts in SCBU results in baby being transfused twice

A 2-month-old premature baby had a haemoglobin on the 8th of 9.9 g/dL requiring top-up, and the team on duty that day in SCBU prescribed and gave 60 mL of red cells. On the 11th another team in SCBU noted the low Hb from the 8th, made a decision to transfuse, and prescribed and gave 70 mL of red cells. No tick had been placed on the treatment chart, the prescription sheet had not been filed in the correct place, and the notes were not checked for recent transfusions. Thus the patient was accidentally transfused twice.

This case highlights the problems that can result from the shorter working hours and lack of overlap between medical and nursing teams on specialist units. A detailed handover had not taken place, a box on a treatment chart had not been ticked, and a prescription sheet had not been filed. This baby therefore received the elective top-up transfusion twice, 3 days apart, on the basis of the Hb from a single day. Worryingly, the decision to transfuse was also made twice, despite the fact that one would expect a different clinical picture on the 2 occasions.

Platelet transfusion based on spurious pancytopenia *n* = 1

Case 4

Spurious pancytopenia results in unnecessary hospital admission and prophylactic platelet transfusion

A patient was bled for an FBC by a GP practice nurse after presenting with arthralgia and a rash. The results showed a pancytopenia, with Hb 9.2 g/dL, WCC 0.4 x 10^9/L and platelets 7 x 10^9/L. The sample was examined and no clot was present, and it was re-tested producing the same result. The patient, who appeared well, was admitted to a medical admissions ward out of hours, where an admitting junior doctor telephoned an on-call haematologist who advised isolation because of neutropenia, and a platelet transfusion. The patient was reviewed by the haematologist in the morning and found to be well, apyrexial, with no purpura or petechiae, and a repeat FBC showed an Hb of 13.4 g/dL, WCC 8.2 x 10^9/L and platelets 351 x 10^9/L.

Learning points

- Junior doctors need to use their clinical acumen and knowledge when prescribing therapies, and need to be prepared to question results that do not fit the clinical picture.
- Handover and documentation of interventions are paramount in areas where teams are working in shifts without continuity of daytime staff.

Transfusion based on misheard coagulation result *n* = 1

A doctor telephoned for the results of a clotting screen and misheard the results, leading him to prescribe FFP for coagulopathy, when in fact the results were normal.

Inappropriate and unnecessary transfusion based on a haematology or coagulation laboratory error *n* = 10

There were 10 cases in which errors either in the routine haematology laboratory or the coagulation laboratory were the basic cause of the administration of inappropriate transfusion. In 4 of these cases platelet clumping was present in the patient sample but this was not reported on from the laboratory because the film was not examined in time prior to the decision to transfuse. In 1 of these cases platelet clumping was reported to the clinicians, but owing to a failure of verbal communication the cardiologists (who had been in discussion with a haematology trainee) still went ahead and ordered platelet cover for an angiogram procedure.

In 2 cases there was an error because there was a clot present in the full blood count sample resulting in a spuriously low haemoglobin. In 3 cases the sample was of small size owing to difficult phlebotomy. This was not detected in the laboratory as a possible cause of erroneous results and the low MCHC that was also present was not noted. In 1 case a BMS erroneously entered a fibrinogen result manually into the computer moving the decimal point so that the fibrinogen concentration looked lower by a factor of 10. The patient was subsequently transfused with cryoprecipitate unnecessarily.

Table 35
Haematology or coagulation laboratory errors

Category of haematology or coagulation laboratory error	Cases
Platelet clumping on FBC (EDTA) sample	4
Clot in FBC sample	2
Small or short sample	3
Transcription error of fibrinogen result	1
TOTAL	**10**

Case 5
Short sample gives spurious result leading to 3 unit transfusion
A woman requesting a termination of pregnancy had samples for blood count and group & save taken by a phlebotomist. A small sample was taken into a paediatric bottle because of poor venous access. The Hb was reported as 6.3g/dL. The woman was admitted that night for transfusion of 3 units of red cells prior to operation the following day. No repeat FBC was taken before transfusion, and no tests were requested to investigate cause of anaemia. Two days later FBC was reported as 15.6g/dL, suggesting that the previous FBC had been erroneous and that transfusion had been unnecessary.

In Case 5 the following errors and causes may be identified:

- collection of an inadequate sample for FBC
- failure of haematology laboratory to indicate that this sample was inadequate and to request a repeat
- lack of medical assessment of patient, and unquestioning acceptance of results
- clinical decision to transfuse in a non-urgent situation, without a clinical assessment or consideration of the cause of anaemia.

These cases highlight the responsibility of the laboratory to ensure that the material they are offered for testing fulfils their requirements. In addition those taking samples should be aware of the effects of short samples and platelet clumping, and must be vigilant and circumspect about results.

Inappropriate and unnecessary transfusion based on erroneous POCT result *n* = 3

Two of these cases involve near patient testing equipment for full blood count that was performed in satellite laboratories by medical staff. In both cases transfusion was based on the erroneous full blood count from the point of care testing (POCT) equipment before confirmatory haemoglobin was available. There was a third case in which a patient was over-transfused because a junior doctor relied on the haemoglobin results from a blood gas machine. This should not have been used and was not designed to be used as a source of accurate haemoglobin estimation.

Transfusions based on poor basic knowledge and prescribing *n* = 25

Of the 25 cases in which there was evidence of poor knowledge and understanding of transfusion medicine and of correct prescribing of blood components, 4 were related to nurses and 21 to junior doctors reflecting the fact that it is a medical role to make the decision to transfuse and to prescribe blood components. The breakdown of subcategories is shown below in Table 36.

Table 36
Poor knowledge and prescribing

Categories of poor knowledge and prescribing	Cases
Overestimation of rate and volume of blood loss	7 (one fatality)
Wrong basic component given for indication, e.g. FFP instead of platelets	4
Transfused despite documented decision to the contrary (includes one JW)	3
Small patient prescribed inappropriately large volume	2
Inappropriate use of flying squad blood	2
Slow response to serious blood loss, undertransfusion	1 (one fatality)
Confusion over correct dose/number of units of cryoprecipitate	1
Lack of understanding of transfusion triggers in sickle cell disease	1
Inappropriate use of FFP to correct mildly abnormal INR that was in fact normal	1
Inappropriately rapid transfusion through two cannulae in elective case	1
Mistaken diagnosis of anaemia due to acute GI bleed when in reality the condition was one of chronic anaemia and menorrhagia not requiring urgent transfusion	1
TOTAL	**24**

There were 2 fatalities related to transfusion in this group. The first involved undertransfusion of an elderly patient with a low haemoglobin and a high INR who was suffering from atrial fibrillation.

Case 6
Inadequate management of acute bleeding associated with high INR on warfarin

An elderly lady on warfarin for AF was admitted with bleeding PR. She was found to have Hb 6.8g/dL and an INR of 7.2. She was given vitamin K 2mg IV and 3 units of FFP were requested. All 3 units were taken from the refrigerator at the same time and were transfused over 3 hours. This report was initiated as it was believed that storage requirements for FFP had not been met. Soon after completion of the third unit the patient developed an itchy, erythematous rash and was given IV chlorpheniramine and hydrocortisone. Six hours later the patient was found collapsed and resuscitation was unsuccessful. Postmortem examination showed fresh blood in the bowel and cause of death was given as haemorrhage from large bowel. In spite of blood results on admission and persistent hypotension, this patient received no intravenous therapy apart from the FFP and no blood transfusion was given, although 4 units were crossmatched on admission.

This patient was inadequately managed and collapsed and died from the gastrointestinal haemorrhage with which she had been admitted during this episode. This is the first case reported to SHOT where undertransfusion was main thrust of the report, although inappropriate transfusion FFP and a mild allergic transfusion reaction were also part of the story. This patient was not adequately assessed or monitored clinically, and did not undergo appropriate management of her high INR or her acute blood loss.

The second fatality related to massive overtransfusion of a patient who presented with coffee ground vomiting and possible melaena. The patient was transfused on the basis of the story given rather than the clinical features and the FBC sample was delayed due to difficult venous access. Subsequent samples were tested revealing Hb sequentially of 16.6g/dL, 18.3g/dL and 20.8g/dL over a period of 24 hours. The elderly patient subsequently died.

Case 7
Over-estimation of blood loss from GI bleeding leads to massive overtransfusion

An elderly inpatient had a coffee ground vomit at 02.00 and some melaena. Intravenous fluids were given and blood samples taken showing a Hb of 14.3g/dL at 04.30. Her Hb the day previously had been 14.7 g/dL. Observations were initially stable, but at 05.50 the BP was unrecordable and 2 units of red cells given. At 06.10 after another haematemesis a further 2 units were transfused. A BMS asked for repeat samples, which were not sent due to difficult venous access. After a further 2 hours BP was stable, and 2 further units of red cells were given. Hb results were not reviewed until 17.00 when the Hb was Hb16.6g/dL. At 22.30 Hb was 18.3g/L, the next day at 15.00 Hb was 20.8g/L. and the following day at 18.30 the patient died.

This case highlights the difficulties that junior doctors may have in assessing the actual degree of bleeding/haemorrhage in a patient, which may be at variance with the history given by the patient or other staff. Clinical assessment of severity of bleeding is notoriously difficult and requires experience of similar situations and a calm approach. A degree of unfamiliarity with the situation, and possible anxiety over the signs may mean that a careful clinical examination and scrutiny of the laboratory results does not take place in a timely fashion.

There were an additional 5 cases in which an actively bleeding patient was given unnecessary quantities of red cells due to the erroneous assessment by the junior doctors that there was life threatening bleeding. In all cases the haemoglobin had been normal at the time the clinical judgement was made, and once the results came back from the laboratory this was apparent. In all cases the post-transfusion haemoglobin was above the upper limit of the normal range. In 1 case a diagnosis of anaemia due to acute GI bleeding was made by junior doctor in a lady who was actually suffering from chronic anaemia due to menorrhagia.

Case 8

Overestimation of blood loss from acute GI bleed

A patient was admitted to the ED with GI bleed. The Hb was 12.1g/dL on admission. Two units of emergency blood were given, followed by a further 6 units of crossmatched blood over the next 12 hours. The Hb was not checked until all 8 units had been transfused, by which time the Hb was 18.5g/dL.

Case 9

Unnecessary transfusion based on obviously erroneous result

A patient was admitted to the ED and samples were sent for FBC and crossmatch. A Hb result of 2.7 g/dL was telephoned and the BMS advised to repeat the FBC as the result was suspect. However, this was not done and the patient was transfused 2 units of red cells. On admission to the ward a further FBC was checked, showing Hb 13.7 g/dL. However, 4 further units had already been prescribed and given, resulting in a post-transfusion Hb of 18.8 g/dL.

Case 10

Overtransfusion and subsequent venesection of a 1-year-old under shared care

A small 1-year-old undergoing shared care attended her DGH for a top-up transfusion of 2 paediatric units of red cells as recommended by the tertiary referral centre. This was written on the prescription sheet as 2 units and did not state the volume to be given. As she had not previously been transfused at the DGH, and being over 1 year old, the laboratory supplied adult red cell packs. Four days post transfusion her Hb was high and the error was discovered. The Hb continued to rise so the patient was venesected.

Case 11

Confusion over correct adult dose of cryoprecipitate

A patient was given 10 packs of pooled cryoprecipitate rather than the recommended 2 packs. This was due to the order being placed in 'old units'.

COMMENTARY

As in previous years, the majority of these cases involve insufficient knowledge and experience of junior doctors, and inadequate engagement with other staff to obtain help.

The scenarios described above include examples of:

- Insufficient care with basic tasks such as phlebotomy technique and communication, verbally or in writing, of results.
- Lack of clinical acumen when weighing up the clinical picture with the (apparent) laboratory results.
- Lack of a supportive team structure in which input from medical, nursing and biomedical staff is mutually supportive and identifies errors.
- Inadequate knowledge of blood components and their appropriate use in clinical situations, especially the interpretation of the clinical and laboratory signs of coagulopathy.
- Inexperience in assessing blood loss in a bleeding patient, compounded by unwillingness to seek the opinion of more senior or experienced colleagues.

RECOMMENDATIONS

- Trainee doctors in all hospital specialities must receive sufficient transfusion medicine education to be comfortable and safe in the clinical and laboratory assessment of anaemic and bleeding patients, and to be able to use blood components optimally to manage them.

  Action: NBTC

- A culture shift in the clinical arena is required so that when a doctor feels unable to handle a clinical scenario, requesting and obtaining appropriate help is easy, and negative judgement is avoided.

  Action: Trust CEOs

8. Handling and Storage Errors (HSE)

Definition

All reported episodes in which a patient was transfused with a blood component or plasma product intended for the patient, but which, during the transfusion process, the handling and storage may have rendered the component less safe.

DATA SUMMARY

Total number of cases	**139**	*Implicated Components*		*Mortality / morbidity*	
		Red cells	**121**	Deaths due to transfusion	**0**
		FFP	**10**	Deaths in which reaction was contributory	**0**
		Platelets	**8**	Major morbidity	**0**
		Other *(specify)*	**0**		
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**59**	16 years+ to 18 years	**1**	Emergency	**41**	ED	**2**
Female	**78**	1 year+ to 16 years	**5**	Routine	**74**	Theatre	**6**
Unknown	**2**	28 days+ to 1 year		Not known	**24**	ITU/NNU/HDU/Recovery	**7**
		Birth to 28 days				Wards	**69**
		unknown		In core hours	**58**	Community	**1**
		Total	**6**	Out of core hours	**39**	Other	**5**
				Not known/applicable	**42**	Not known	**49**

A total of 140 questionnaires were received; on review 5 were withdrawn, 1 was transferred out to the IBCT section, and 5 were transferred in from the IBCT section. This section describes the main findings from 139 completed questionnaires: the main categories are shown below in Table 37.

Table 37
Categories of handling and storage errors

Type of case	2007	2008
Technical administration errors	15	9
Transfusion of expired red cells	12	45
Excessive time to transfuse	57	24
Cold chain error	34	61
TOTALS	**118**	**139**

Technical administration errors *n* = 9

There were 9 cases in which there were technical administration errors. While this demonstrates a 40% reduction from the number of cases reported in 2007, it is of concern that practitioners continue to add drugs directly to the blood bag or fail to discontinue units when an obvious puncture to the bag has been identified during the transfusion episode.

Table 38
Technical administration error types

Type of Error	Number of cases
Leaking component bag identified and transfusion continued	2
Blood given through solution giving set	1
Furosemide added directly to blood in bag	1
Blood transfused without using a blood warmer despite being indicated	1
Unit transfused >48 hours after crossmatch and/or transfusion of 1st unit	2
Blood transfused with no accompanying documentation	1
IV pantoprazole given at the same time as a unit of red cells via 3-way tap	1

Case 1

Transfusion continued despite leak from port exposing contents to contamination

A patient was transfused with 2 units of red cells and the nurse giving the units noticed that blood was leaking from the port into which the giving set was connected. She continued the transfusion rather than stopping it and informed the blood bank after the event. The bags were sent back to the local Blood Establishment laboratory for investigation but no defect was found. The patient suffered no ill effects.

Transfusion of expired red cells *n* = 45

There were 45 cases in which expired blood was given to patients. In 9 cases the BMS failed to check the expiry date prior to issue of the component. In 4 cases there was no formal check performed when the unit was collected (in 3 cases by the portering staff and 1 by an unqualified nurse). The unit was checked by 2 nurses in 32 cases. In 5 reports the error involved the Blood Service, the Laboratory and the clinical area. In all 5 cases there were at least 4 opportunities for the expired unit to be detected. In 2 cases the warnings from the electronic blood tracking system were overridden and in 1 case the electronic system was 'down' and the expiry date was not checked at issue.

The error occurred after 20.00 in 16 cases. In 7 cases the units were issued within hours of the expiry date; 4 of these cases were identified as 'urgent' requests.

Two reporters suggested that the rollout of an electronic tracking system would be accelerated in an effort to prevent this type of error reoccurring. A number of reporters also suggested that, following the root cause analysis process, they would review their blood issue SOPs and processes.

Case 2

Lack of knowledge leads to inappropriate concerns and non-compliance with basic protocols

A unit of blood was removed from the blood bank by an auxiliary nurse, who did not see that it had expired at midnight the previous day. The 2 registered nurses who undertook the pre-administration check were worried that the donor and recipient blood groups differed (even though the accompanying documentation clearly stated the blood groups were different but compatible). The nurse rang the laboratory for advice and then continued the checking procedure. The nurses thought that they had completed the checks when they were distracted by the blood group, but in fact they had not completed the pre-administration check. The transfusion was commenced and transfused with no adverse effect upon the patient. The error was identified when the second bag of blood was commenced and checked by the same nurses.

Case 3

In absence of security normally provided by the electronic system, basic checks are omitted

The electronic blood track system was 'down' when the nurse was sent to collect 1 unit of red cells from the blood bank. The BMS on duty used the manual override code to unlock refrigerator, and handed the unit to the nurse. The expiry date was not checked by the BMS or the nurse during the manual removal process. The pre-transfusion check was conducted at the patient's bedside. The nurse stated that expiry date was checked but the fact that the unit had expired the previous night was not recognised. The unit was transfused to the patient with no ill effects. The error became apparent during a refrigerator stock audit later that morning.

Excessive time to complete administration of blood component *n* = 24

There were 24 cases in this category, all but 3 of which relate to nursing and midwifery staff. This demonstrates a 58% reduction in the number of cases reported in 2007. Of the 24 cases, 29% were out of core hours – 18% fewer than in 2007. In 23 cases the component transfused was red blood cells.

Table 39
Breakdown of times of transfusions that took excessive time to run

Time Period	Number of cases
08.00 to 20.00	17
20.00 to 00.00	3
00.00 to 08.00	4

In 6 cases the unit was in progress for more than 6 hours. In 2 further cases 2 cases transfusion took over 9 hours, and in both of these the transfusion was commenced after 20.00.

Case 4

Slow transfusion due to poor venous access not attended to appropriately in overnight transfusion

A patient was prescribed 4 units of red cells for anaemia. A porter collected the 3rd unit at 01.00 and the component was commenced at 01.15. The blood ran slowly so the cannula was re-sited and transfusion ecommenced at 05.50. The midwife on the day shift tried to flush the cannula to complete transfusion, which was documented as stopped at 10.00 incomplete. The prolonged transfusion time was only noticed when the TP Practitioner was auditing the documentation process. In total the blood component had been administered over a 9 hour period.

Case 5

Overnight transfusion prescribed for 4 hours not monitored and runs for 10 hours

A unit of red cells was collected from controlled blood refrigerator at 21.10. According to documentation, transfusion was commenced at 21.30 by a trained trust bank nurse and an agency nurse, with the prescription for transfusion over 4 hours. The transfusion was not documented on a fluid balance chart. The bank nurse went home at 23.00 and the agency nurse took responsibility for the patient. Day staff took over at 08.00 and the unit was still running. The transfusion was eventually stopped at 08.30. The transfusion had been running for more than 10 hours.

These cases highlight some of the well documented problems associated with overnight transfusion. Staffing levels are lower, and the ward environment at night is less conducive to full monitoring and checking of patients for observations, reactions and transfusion rate. Overnight transfusions should not take place except in emergency situations.

Cold chain errors *n* = 61

Table 40

Type of Error	Number of cases
Alarm Related	4
Equipment Failure, e.g. platelet agitator, suspected power failure	4
Delivery or transfer of components	10
Inappropriate storage of components	42
Returned to stock when should have been discarded	*23*
Returned to satellite refrigerator when should have discarded	*7*
Stored inappropriately in clinical area, e.g., out of order refrigerator, transport box, non-validated transport / storage, unknown	*8*
Stored inappropriately in laboratory area, e.g. faulty platelet agitator	*4*
Origin of error not stated (possible transport error)	1
TOTAL	**61**

In 6 cases there was either a power failure or suspected refrigerator failure where the refrigerator failed to alarm. Red cell components stored at inappropriate temperatures were subsequently transfused to a number of patients. In 2 cases platelets were issued from faulty platelet agitators.

The majority of errors – 48/61 (79%) – involved the patient receiving 1 or more units of red cells that had been either inappropriately transported or had been out of controlled temperature storage (CTS) for more than 30 minutes and then returned to CTS.

The '30 minute rule' refers to the time limit accepted in the UK for a red cell unit to be out of CTS, and which, if not exceeded, still permits the unit to be replaced back into CTS for re-use.[9] This is because red cells that have been out of CTS for longer may have warmed and bacterial proliferation could commence prior to return to storage. The Handbook of Transfusion Medicine (4th edition) states that the transfusion of red cells should be completed 'within 4 hours after it is removed from controlled temperature storage' (CTS).[9] This applies regardless of how long the unit has been out of CTS prior to commencement of administration to the patient. The important factor here is that no red cell unit should be out of CTS for more than 4 hours before completion of transfusion because of the risk of bacterial proliferation once the blood has warmed to room temperature. In 26 of the cases reported as cold chain errors the blood had been returned to a satellite refrigerator or the Blood Bank but the excessive time out of CTS was either not recorded or ignored (in 5 cases an electronic tracking system warning was ignored). The component was subsequently re-issued and transfused to the original recipient; or crossmatched, issued and transfused to another patient.

Blood components stored inappropriately in transport boxes were implicated in at least a further 10 cases. In 1 case an error originating in the laboratory was compounded by further errors during the transport and administration procedures (see Case 6 below).

In 45% of reports the error occurred in theatre, accident and emergency, or intensive care / high dependency areas or community hospitals, often when the blood was transported between units.

No patient experienced a transfusion reaction.

Case 6

Undue responsibility placed with porter, and lack of liaison about critical patient transfer

A patient in ITU was bleeding with coagulopathy. Large volumes of plasma and red cells were required. Transfer to another hospital was arranged for specialist management, and 4 units of red cells were to be available for the transfer. The porter collected 4 units of red cells from blood bank but packed them in a bag containing dry ice (suitable for FFP and cryoprecipitate, NOT for blood) and delivered them to the ITU. The laboratory was unaware that the units were taken. The patient received 1 unit of red cells before transfer and a further 2 units during transit. On arrival, the remaining unit was found to be frozen. The patient suffered no ill effects.

Several errors and omissions contributed to this incident:

- A bag containing dry ice from a delivery of FFP was left beside the transport boxes used for red cells.
- The porter packed the red cell units in the cool bag despite this being a BMS responsibility.
- ITU staff did not inform the transfusion laboratory that red cells were required for transfer to another hospital.
- ITU staff did not recognise that the red cell units were inappropriately stored (in a bag containing dry ice).

Once again, staff with no medical training were involved in critical points in the transfusion process, in this case involving the transfer of a very sick patient between specialist units. Despite this there was no liaison between medical staff and the laboratory BMS, no instructions were given, and there appears to have been a lack of knowledge regarding basic storage requirements for red cells.

Case 7

Red cell unit returned to stock despite being out of CTS for over an hour

In this case 6 units of red cells were issued to theatre, and 3 were transfused. The remaining 3 units were placed in the theatre satellite blood refrigerator and later returned to the hospital transfusion laboratory unused. Subsequently 1 of these units was issued and transfused to another patient. A retrospective check revealed that the re-issued unit had been out of CTS for more than 1 hour. The recipient showed no ill effects. The hospital transfusion laboratory is now quarantining all returned blood components from satellite fridges to confirm that the cold chain has been maintained before reissue.

Case 8

Undue responsibility placed with a porter, compounded by ignoring the electronic tracking system

A unit of blood was collected from blood bank at 17.15. The patient was not cannulated and the doctor was unable to achieve this despite several attempts. The porter returned blood to the issue refrigerator at 20.20 but did not inform the BMS that the unit had been out of CTS for more than 3 hours. A warning from the electronic blood track system was ignored. Because of a stock refrigerator problem, there was no specific location available for returned red cell units. The same unit was reissued from the refrigerator at 23.00. The alert from the electronic blood track system was ignored again. The unit was then administered to the patient at 23.30.

Once again the reporter of this case implies that the porter should have been in a position to relay details about the red cell unit to the BMS, which is clearly beyond the role of a porter. The electronic blood tracking system was presumably used correctly by the porter, as the warning about the time out of CTS was ignored twice. Once again, to place the onus on the porter to respond appropriately to this situation is inappropriate. Finally, protocols should dictate that all returned units are placed in a specific section / tray in the blood refrigerator, allowing the BMS staff to re-check all units and the cold chain details prior to reissue. A problem with an alternative blood storage site is no reason for this to be abandoned.

COMMENTARY

There has been a significant reduction in the number of technical and excessive time to transfuse errors reported to SHOT in 2008. However, some staff continue to put patients at risk by failing to undertake basic monitoring procedures (allowing a transfusion of red cells to continue for more than 9 hours) or practising unsafely (continuing the transfusion of leaking components). Errors continue to occur after 20.00.

Conversely, there has been a significant increase in the number of cold chain and transfusion of an expired unit errors. This may be an example of improved reporting. However, it is disturbing that in 30 cases a blood component was transfused despite being stored inappropriately, and, in over 75% of cases, 2 nurses failed to detect an expired unit when undertaking the final check at the patient's bedside.

All staff should be reminded that they have a professional responsibility to practise safely, and to ensure that their knowledge and skills are kept up to date when participating in the transfusion process. Often there is an opportunity for the error to be identified early in the process but for various reasons that opportunity may be missed. This may be due to lack of knowledge or understanding of the process, or the rationale behind protocols and SOPs. Staff who do not have the appropriate knowledge, training and competencies should not be expected to participate in the transfusion process at any stage.

Learning points

- It is imperative that each member of the staff, laboratory, support and clinical staff is vigilant when undertaking their part of in the transfusion process.
- Unqualified or untrained staff must not be involved in any part of the transfusion process.
- Staff should never be expected to perform duties beyond their usual role or competency. This especially applies to portering staff.
- The use of electronic blood tracking systems does not prevent errors occurring, particularly when practitioners use the override facility or ignore warning signals.
- The expiry date must be checked by the laboratory staff before the component leaves the hospital blood bank and by the clinical staff as part of the pre-administration check before the transfusion is administered.
- Transfusion of a blood component should be completed within 4 hours of leaving controlled temperature storage (CTS).
- A unit of red blood cells removed from CTS but not started within 30 minutes can still be administered provided the transfusion can safely be completed within 4 hours of leaving CTS. In this scenario the case is not reportable either as a Serious Adverse Event (SAE) to MHRA or as a handling and storage error to SHOT.
- A unit that has not been transfused CANNOT be returned to CTS for storage or reissue if it has been out of CTS for more than 30 minutes. If a unit is replaced into CTS after 30 minutes, then this is reportable as an SAE to MHRA, and if it is subsequently transfused then it is also reportable to SHOT.
- Excessive transfusion time (greater than 4 hours) is reportable to SHOT as a handling and storage error.

RECOMMENDATIONS

- Hospitals should review who collects and transports blood. Only appropriately trained, competent staff should participate in the collection and transport of blood components. All staff must have sufficient knowledge to appreciate the critical points in the task.[1]

  Action: HTCs

9. Adverse Events Relating to Anti-D Immunoglobulin

Definition

An adverse event relating to anti-D Ig is defined as an event relating to the prescription, administration or omission of anti-D Ig that has the potential to cause harm to the mother or foetus immediately or in the future.

DATA SUMMARY

Total number of cases	**137**	*Implicated Components*		*Mortality / morbidity*	
		Red cells	**0**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths in which reaction was implicated	**0**
		Platelets	**0**	Potential for major morbidity	**58**
		Other (anti-D Ig)	**137**		
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**0**	< 18 years	**4**	Emergency		ED	
Female	**137**	< 16 years	**0**	Routine		Theatre	
Unknown	**0**	< 1 year	**0**	Not known	**137**	ITU/NNU/HDU/Recovery	
		< 4 weeks	**0**			Wards	**118**
		unknown		In core hours	**25**	Community	**19**
		Total	**4**	Out of core hours	**7**	Other	
				Not known/applicable	**105**	Not known	

This section describes the main findings from 137 completed questionnaires. The reports are broken down into the reporting categories shown in Table 41. Under current legislation,[1] adverse events related to anti-D immunoglobulin are reportable as 'SHOT only'.

Table 41
Reporting Categories

Category of adverse event	Number of cases
Omission or late administration of anti-D immunoglobulin	58
Inappropriate administration of anti-D immunoglobulin	63
to a D positive patient	*38*
to a patient with immune anti-D	*14*
to a mother of a D negative infant	*6*
given to the wrong patient	*5*
Wrong dose of anti-D immunoglobulin given according to local policy	10
Administration of expired or out of temperature control anti-D Ig	3
Additional laboratory errors	3
administration of a different product instead of anti-D Ig	*1*
clerical error recording batch of anti-D Ig issued	*2*
TOTAL	**137**

Mortality *n* = 0

There was no known foetal mortality following the omission or delay in administration of anti-D, but these data have not been systematically reported or collected.

Major morbidity *n* = 58

In 58 of the 137 cases anti-D was administered late or omitted altogether, resulting in the potential for sensitisation of the patient to the D antigen. This satisfies the current SHOT definition of major morbidity.

In 1 case, sensitisation to the D antigen occurred following failure to administer anti-D (see Case 1 below). A recommendation in the 2007 SHOT report regarded the follow up of potentially sensitised patients, stating that the outcome should be reported to SHOT. This is not yet taking place, and at the present time there is no mechanism for active follow up by the SHOT office of these cases. It is anticipated that this will become possible in future using SHOT's new web-based data collection system.

Clinical versus laboratory errors

For the reporting year 2008, 137 events relating to anti-D immunoglobulin administration are summarised in Table 42 below, with a breakdown of the proportion of clinical and laboratory errors that were primarily responsible.

Table 42
Adverse incidents involving anti-D Ig administration, with site of primary error

Type of event	Cases	Number of Primary Errors		
		Midwife	Laboratory	Doctor
Omission or late administration of anti-D Ig	**58**	50	8	-
Anti-D Ig given to D positive patient	**38**	19	18	1
Anti-D Ig given to patient with immune anti-D	**14**	7	7	-
Anti-D Ig given to mother of D negative infant	**6**	1	5	-
Anti-D given to wrong patient	**5**	5	-	-
Wrong dose of anti-D given	**10**	4	6	-
Anti-D Ig expired or out of temperature control	**3**	3	-	-
Other handling errors – 1 x wrong product given and 2 x clerical error recording batch number issued	**3**	-	3	-
TOTALS	**137**	**89**	**47**	**1**

Of most concern were 58 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. In 63 cases anti-D was inappropriately administered, resulting in unnecessary exposure to a human blood product.

Omission or late administration of anti-D *n* = 58

In 50/58 cases the primary error was made by a midwife. Five cases occurred in the community, and 53 in a hospital setting. A recurring theme in the review of these incidents is the need for more robust procedures and documentation of anti-D administration as recommended by the Health Service Circular 'Better Blood Transfusion',[10] together with clearer lines of communication and strict adherence to existing protocols.

In 8 cases the primary error was in the transfusion laboratory.

Overall, where anti-D was given late 3 cases occurred in the antenatal setting and 36 postnatally, while in reports where anti-D was omitted altogether 11 were antenatal cases and 8 postnatal.

Clinical error examples *n* = 50

In 1 case, anti-D was never issued because the relevant samples took 12 days to reach the laboratory and the clinical area did not follow up on the requirement for prophylaxis.

In 7 cases, anti-D was correctly issued by the laboratory and collected by the clinical area, but subsequently found in a ward refrigerator up to 10 days after the patient had been discharged.

Laboratory error examples *n* = 8

In 1 case, anti-D was correctly issued to the mother, but the cord results were telephoned to the ward from the laboratory as D negative, and the resulting confusion led to a significant delay in administering the immunoglobulin.

A lone worker BMS omitted issuing anti-D for a postnatal patient owing to pressure of work, and then forgot to tell other staff at shift handover. The outstanding work was picked up 48 hours later, and the anti-D was eventually given outside the 72 hour window.

Case 1

Manual transcription error in the laboratory results in omission of anti-D and D sensitisation

A pregnant patient had bloods taken at booking clinic. The BMS performing ABO and D grouping manually recorded the result as D positive instead of D negative. Consequently routine antenatal anti-D prophylaxis was not administered, nor would anti-D have been considered for any potentially sensitising event the patient may have suffered. This patient was found later in pregnancy to have developed an immune anti-D.

Case 2

Baby with weak D recorded as D negative, resulting in omission of anti-D for the mother

A BMS altered a baby's blood group on the LIMS from 'weak D' to D negative in order to facilitate a request for blood made by the clinical area for the baby. Because the baby's group was now ostensibly D negative, the mother never received anti-D Ig.

Inappropriate administration of anti-D *n* = 63

This group is further subdivided into four categories (see Table 41).

Anti-D Ig given to D positive patients *n* = 38

There were 28/38 cases in the antenatal setting, and 10/38 in postnatal patients.

Overall 20 errors were clinical, 19 made by midwives and 1 by a doctor, and 18 primary errors arose in the laboratory.

Clinical error examples n = 20

In 19/38 of these cases the primary error was made by a midwife, with 15 originating in the community and the other 4 in hospital.

It is striking that all these cases involved issue of anti-D from a remote stock held in the clinical area, or at a GP surgery. A number of the case reviews offered by reporters highlighted the intention to issue anti-D on a named patient basis only following the discovery of the errors, in line with recommendations made in HSC 'Better Blood Transfusion'.[10]

Case 3

Lack of knowledge of when it is appropriate to issue anti-D

Two midwives separately checked the hospital computer system, which clearly showed the patient as D positive, but still proceeded to issue anti-D Ig to the patient from a stock held in the clinical area.

In 2 further cases, anti-D was administered by midwives on the basis of a 'D negative' warning sticker incorrectly affixed to the front of a D positive patient's notes, and in 2 cases anti-D was administered on the basis of an incorrectly transcribed verbal grouping report.

Case 4

Junior doctor gives anti-D without knowledge of patient's blood group

Following a day case gynaecological procedure, a FY2 grade doctor prescribed and administered anti-D immunoglobulin from a clinical stock to a patient, without a blood grouping report being available in the clinical area, and without checking to see what the blood group was. The patient was subsequently reported to be D positive.

Laboratory error examples n = 18

- 3 cases where anti-D was issued incorrectly to a D positive patient by an MLA or a trainee BMS, and in 1 of these cases the incorrect issue was validated by a second BMS.
- 7 cases where the laboratory issued anti-D Ig even though the LIMS clearly showed the patient to be D positive, and in 1 case it was noted that the issue labels also clearly stated the patient was D positive.
- 1 case where anti-D was issued on the basis of an incorrect verbal grouping result from another hospital.
- 1 case where anti-D was issued on the basis of a D-negative result from another hospital, but the patient subsequently tested as weak D by a different methodology in the issuing laboratory.
- 1 case where a BMS incorrectly entered D-typing results onto the LIMS.
- 2 cases where anomalous results from automated testing systems were incorrectly interpreted and edited.
- 2 cases where anti-D was issued on the basis of previous, much older, D negative results, but where the patient tested as weak D using the current sample.
- 1 case where the laboratory made no check at all on grouping records before issuing anti-D by a manual process, assuming the clinical area must have checked the D-type before making the request.

Anti-D Ig given to patients with immune anti-D *n* = 14

Of these 14 reported cases, 7 resulted from a primary clinical error and 7 from a laboratory error; 6/14 cases occurred in the antenatal setting, with 8/14 being reported postnatally.

Clinical errors n = 7

In the 7 clinical cases the primary error was made by a midwife or nurse and in 5 of these cases anti-D was administered from stock held in the clinical area.

In 6/7 of these cases, there was a failure to take note of, or even read, laboratory reports that clearly indicated the patient either already had immune anti-D or required further investigation to resolve a positive antibody screen.

In the last case, the patient was admitted to the ED, where anti-D Ig was obtained from pharmacy and administered on the basis of a historical group on an old admission card, which did not have a record of her new antibody status.

Laboratory errors n = 7

5/7 of the laboratory errors involve IT to some degree.

- 1 case in which there was no hazard flag on the LIMS, even though the patient was known to have immune anti-D, and a locum BMS issued anti-D on request.
- 1 case where a hazard flag was ignored and anti-D issued by a manual method.
- 1 case where a hazard flag indicating immune anti-D was deliberately overridden by a BMS when issuing anti-D via the LIMS.
- 2 cases which involved not checking reports properly before issue. In both cases the laboratory reports clearly indicated that the patients had immune anti-D, but also contained comments from earlier (unsensitised) pregnancies advising issue of prophylactic anti-D in response to sensitising events. Midwives administered anti-D from stocks held in the clinical area.

Of the 2 further cases, 1 was due to failure of the laboratory to recognise a very strongly positive antibody screen in the maternal sample as immune anti-D rather than post-injection anti-D.

In the final case, anti-D was issued postnatally on the basis of the cord D type, but before the results of the maternal antibody screen were available. The patient had a strongly positive antibody screen, and appeared to have been sensitised against the D antigen even though RAADP had been administered correctly during the pregnancy.
It must of course be remembered that administration of unnecessary anti-D may be preferable, in terms of risk, to omission of necessary anti-D. The BCSH guidelines state that 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 can not be quickly resolved, then prophylactic anti-D should be administered rather than place the patient at risk by withholding it.[11]

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

Only 1 of these was a clinical error, where anti-D Ig was administered from a remote stock held in the maternity department despite there being a report that the infant was D negative.

The remaining 5 cases resulted from laboratory errors.

- 1 case in which case D-typing was made more difficult because the cord had a weakly positive DAT. The BMS proceeded to issue anti-D Ig on the basis of a supposed D positive cord result, despite both the laboratory SOP and a senior BMS clearly stating repeat testing by a second BMS was necessary. Repeat testing on the same sample, and also a fresh sample, showed the cord to be D negative.
- 1 case where cord samples were 'swapped' in the laboratory prior to testing, and the incorrect result was reported.
- 1 case in which an MLA recorded the cord D-typing result incorrectly.
- 2 cases in which anti-D was issued when the results clearly showed the cord to be D negative. In 1 of these cases, the anti-D was issued by a locum BMS.

Anti-D Ig given to the wrong patient *n* = 5

These are exclusively clinical errors involving failure of basic identification checks at the bedside prior to administration.

There were 2/5 cases reported antenatally, and 3/5 cases involving postnatal patients.

In 2 cases, midwives checked the identification details on the anti-D against the laboratory issue form before administering it to the wrong patient.

In 2 cases, there appears to have been no formal identity check procedure undertaken at all.

The final case is below:

Case 5

Use of patient notes in an ID check, in place of the patient's wristband or verbal confirmation

A midwife collected anti-D Ig, and then took it to the wrong patient along with the intended patient's notes. She then proceeded to check identification details against the notes rather than with the patient and administered the anti-D.

Wrong dose of anti-D given *n* = 10

2/10 cases were in the antenatal setting and 8/10 were postnatal.

Laboratory errors n = 6

2 cases involved incorrect dose calculations cased on estimations of foeto-maternal haemorrhage (FMH) by hospital laboratories using Kleihauer Tests;

- in 1 case too much anti-D was issued (3750 iu instead of 1250 iu as indicated by FMH estimation)
- in 1 case too little anti-D was issued (500 iu instead of the required 1000 iu)

In 1 case a BMS issued 1500 iu anti-D in response to a sensitising event, for which 500 iu should have been issued, because the patient was due to receive RAADP in 3 days' time.

In 1 case the laboratory issued a second, unnecessary dose of anti-D, apparently not realising that the first dose had already been issued.

In 1 case a 2500 iu dose of anti-D was issued by the laboratory to replace stock 250 iu doses in the clinical area. This dose was subsequently administered by a midwife to a patient who required a 250 iu dose.

In 1 case a BMS issued 250 iu anti-D instead of the 1250 iu dose indicated by the clinical situation.

Clinical errors n = 4

In all 4 cases an incorrect dose of anti-D was selected for administration by clinical staff from remote stocks.

Anti-D expired or out of temperature control *n* = 3

These 3 cases were exclusively clinical errors in the antenatal setting, where expired anti-D Ig was selected and administered from remote stocks.

Other laboratory errors *n* = 3

In 2 cases there was a clerical error recording the batch number of anti-D Ig when issued by the laboratory.

In 1 case (below) the laboratory issued inappropriate products to replace remote clinical stock.

Case 6

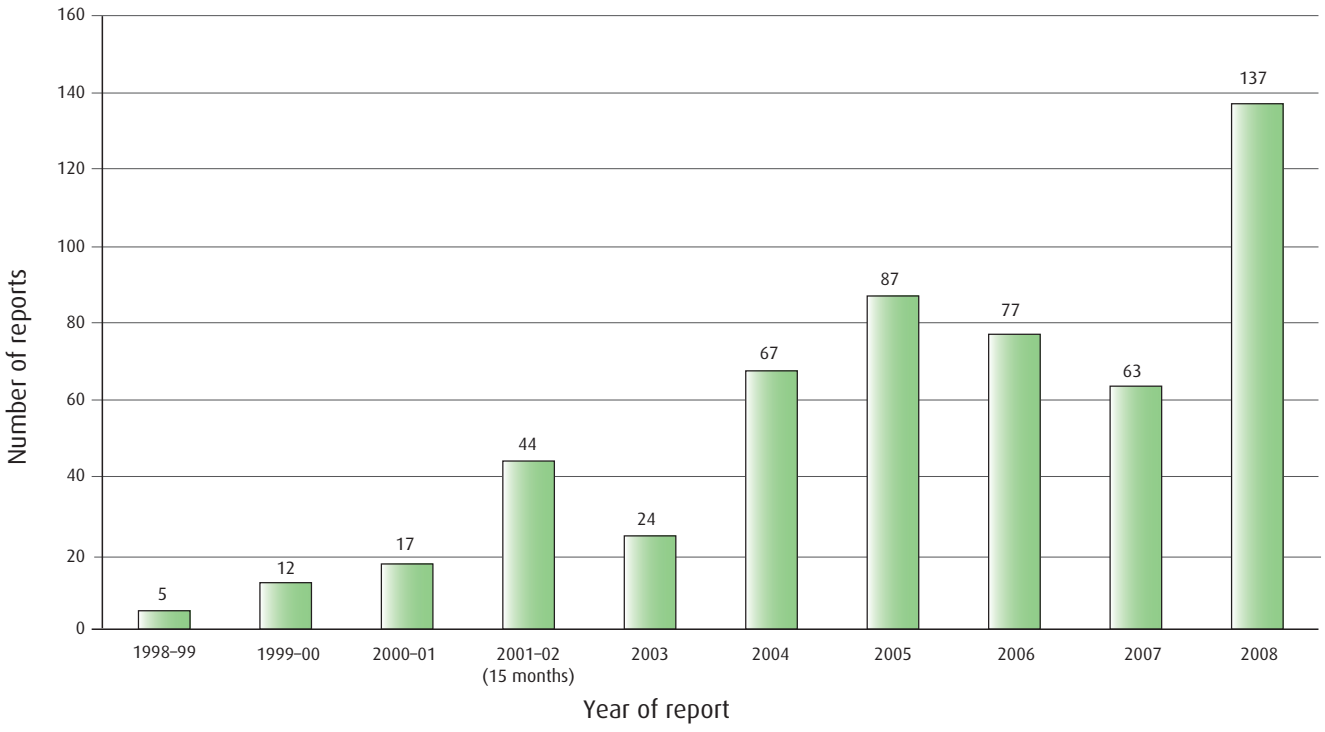
A totally different immunoglobulin given instead of anti-D

A vial of Herpes Varicella Zoster globulin was issued by the transfusion laboratory to the clinical area included in a supply of 250 iu anti-D bulk stock. The discrepancy was missed at the bedside checking stage, and a midwife administered the incorrect globulin in place of the indicated 250 iu anti-D Ig.

COMMENTARY

The number of cases reported to SHOT under the anti-D category has more than doubled in the reporting year 2008, presumably because of increased awareness of the need to report adverse events associated with the administration of this blood product. This represents the continuation of an upward trend in reporting since SHOT reporting commenced in 1996 (see Figure 8 below).

Figure 8
Anti-D cases 1998–2008



It is noted that many of the case reviews undertaken in the hospitals echo the recommendations in last year's SHOT report, of the need for robust protocols, for good communication, and for good record-keeping with regard to traceability of anti-D immunoglobulin.

It is perhaps surprising that the bulk of events (44/58), where anti-D Ig was given late or omitted altogether, occurred in the postnatal setting, where it has always been assumed that robust protocols already exist, rather than antenatally where there appears to be greater uncertainty regarding anti-D administration.

It is also instructive that many of the cases of inappropriate or incorrect administration involve the issue of anti-D from remote stocks held in the clinical area. In fact 21% of all anti-D cases reported in 2008 relate to anti-D issue from remote stocks or from pharmacy, and there appear to be insufficient checks in place to ensure the security of the process.

While it must be acknowledged that for reasons of geography and accessibility some maternity units will require their own stock of anti-D immunoglobulin, perhaps its release should be subject to laboratory control under the auspices of a robust agreed protocol. Trusts need to review and critically assess the need for anti-D Ig to be stored in and issued from clinical areas or pharmacy departments rather than from the transfusion laboratory.

It would appear that despite the (presumed) presence of a clinical protocol for administration of anti-D and a patient group directive, there is still inadequate knowledge and understanding of the physiology and rationale behind RAADP among those making the decision to administer anti-D.

Laboratory errors continue to contribute to around one third of the cases reported, and it is of concern that errors similar to those previously reported are being made, despite the errors being publicised in previous SHOT reports.

Anti-D issues are still being manually processed outside the relative security of a laboratory computer system and, even where hazard flags are in place, they are being ignored or even purposely overridden in order to facilitate the easy option of issuing anti-D without considering whether or not it may be appropriate.

It is not appropriate to allow trainee BMS staff, MLAs or locum staff unfamiliar with local practice to issue anti-D immunoglobulin, and the recommendation from last year's SHOT report that only experienced BMS staff should interpret results and oversee the issue of anti-D bears repeating this year.

Robust protocols, drawn up in partnership by clinical and laboratory staff, are essential. Too often the laboratory is seen as the ultimate decision maker in whether or not a patient needs anti-D, when the request should clearly come from the clinicians (SHOT recommendation, 2005) based on both the clinical situation and a good understanding of the significance of the results produced by the laboratory.

It must also be remembered that anti-D Ig is a 'prescription only medicine'[12] and therefore must only be administered after individual prescription by a medical officer or independent prescriber or under the auspices of a patient group directive.

Trusts must ensure that there is representation from midwives and obstetricians on hospital transfusion committees, with the aim of drawing up straightforward local protocols for the request, issue and use of anti-D Ig based on well established national guidance.[11,13]

RECOMMENDATIONS

New recommendations from this report

- Trusts should ensure that robust systems under overall control of the hospital transfusion laboratory are in place for anti-D Ig to be issued on a named patient basis, to ensure both appropriate use and to meet traceability requirements.

  Action: HTCs

Recommendations still active from previous years

Year first made	Recommendation (Previously Learning Points)	Target	Progress
2007	D-typing should be performed by the routine methodology available in the blood bank, not by emergency techniques, which may not be as robust.	**Consultant haematologists with responsibility for transfusion, HTCs, HTTs**	
2007	Trusts should comply with the requirement in HSC 2007/001 Better Blood Transfusion, to: 'Ensure the use of anti-D immunoglobulin follows the same rigorous patient identification, recording and traceability requirements as all other blood products and components.'	**Consultant haematologists with responsibility for transfusion, HTCs, HTTs**	
2007	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 enable all hospitals to develop local guidelines that reflect national consensus.	**NBTC, NHSBT Appropriate Use of Blood Group, IBMS, BBTS, BCSH, Royal Colleges of Midwives, O&G, GPs**	
2007	There should be clinical follow-up and retesting in six 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.	**Trust CEOs, consultant haematologists with responsibility for transfusion, HTCs, HTTs**	
2005	Laboratories undertaking antenatal serological testing should have clear protocols based on BCSH Guidelines (www.bcshguidelines.co.uk), including algorithms for repeat testing in cases where there is uncertainty whether anti-D is passive or immune.	**Trust CEOs**	
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. Current legislation does not permit issue of anti-D Ig from the laboratory without a clinical request.	**Royal Colleges of Midwives, O&G, GPs, consultant haematologists with responsibility for transfusion HTCs, HTTs**	Highlighted as an area for action in BBT3. 'SHOT in Obstetrics' document. Several educational symposia aimed at midwives and junior doctors have taken place.

10. Acute Transfusion Reactions (ATR)

Definition

Acute transfusion reactions are defined as those occurring at any time up to 24 hours following a transfusion of blood or blood components, excluding cases of acute reactions due to an incorrect component being transfused, haemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), or those due to bacterial contamination of the component.

DATA SUMMARY

Total number of cases	**300**	*Implicated Components*		*Mortality / morbidity*	
		Red cells	**180**	Deaths due to transfusion	**0**
		FFP	**33**	Deaths in which reaction was implicated	**4**
		Platelets	**69**	Major morbidity	**9**
		Cryoprecipitate	**0**		
		Other *(multiple components)*	**18**		
		Unknown			

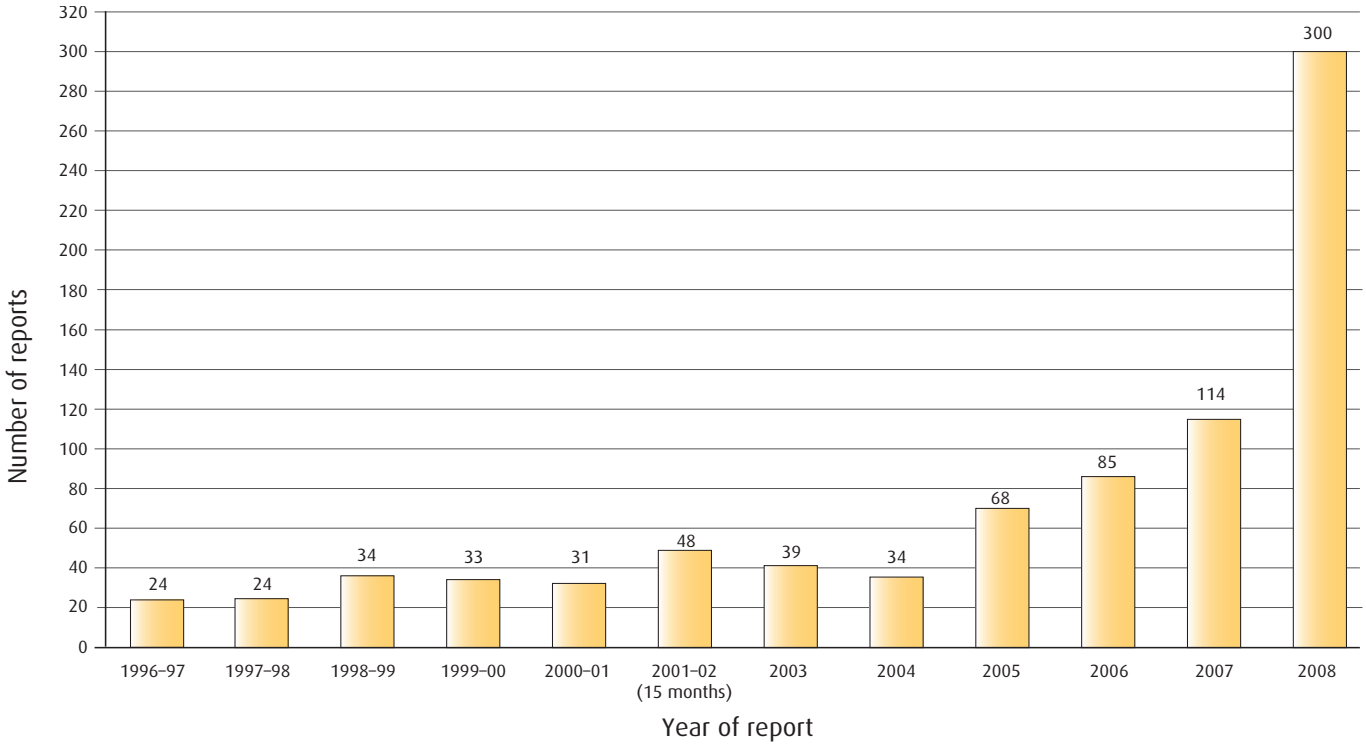
Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**160**	16 years+ to 18 years		Emergency	**58**	ED	
Female	**140**	1 year+ to 16 years	**23**	Routine	**221**	Theatre	
Unknown		28 days+ to 1 year	**3**	Not known	**21**	ITU/NNU/HDU/Recovery	
		Birth to 28 days	**1**			Wards	
				In core hours	**229**	Community	
		Total	**27**	Out of core hours	**69**	Other	
				Not known/applicable	**2**	Not known	**300**

A total of 310 questionnaires were received. On review, 8 were withdrawn, 2 were transferred to the TACO chapter, 1 was transferred to the haemolytic transfusion reaction (HTR) chapter, and 1 case that was originally reported as a HTR was transferred to this chapter.

The 300 completed questionnaires reported in this section represent a marked increased from the previous year, in keeping with the total increase in SHOT reports. ATR reports represent 28% of the total, compared with 20.4% of the 114 reports in 2007.

The age of patients ranged from 1 day to 93 years, with a mean age of 58 years. There were 160 male and 140 female patients. The data include 25 paediatric cases.

Figure 9
ATR cases 1996–2008



Reporting patterns and incidence

There are a total of 237 reporting organisations making haemovigilance reports to SHOT in 2008. Of these, 105 have sent all 300 reports in this category. Furthermore, 3 reporting organisations supplied 76 reports (25.3% of cases), and 1 submitted 35 case reports.

Reporting patterns this year and previous years strongly suggest that ATRs are still being significantly under-reported, with 103 reporting organisations having sent no physiological reaction reports in 2008. One possible reason for under-reporting may be that symptoms, signs and laboratory investigations cannot be used to prove that a reaction is or is not caused by the transfusion, except in rare cases of IgA deficiency in the recipient. But in spite of this, and although the threshold for submitting a SHOT/SABRE report may vary from one hospital to another, it is hard to understand how so many hospital transfusion teams thought they had nothing to notify, even if imputability proved low on further analysis. Details of reporting to SHOT are available on the SHOT and MHRA/SABRE websites, as well as in this Annual Report and Summary.

Types of acute transfusion reaction

The classification of acute transfusion reactions can be difficult, as inevitably they are often seen in patients with intercurrent illness who may have other causes for their symptoms. Classification does not necessarily have any bearing on the management of the acute reaction or of future transfusions. The International Society for Blood Transfusion (ISBT) has developed standard definitions for non-infectious adverse transfusion reactions in order to help national haemovigilance organisations worldwide to generate data that will be comparable internationally.

The current SHOT categories of acute transfusion reactions are as follows:

- **Isolated febrile** – rise in temperature >1ºC with or without minor rigors and chills.
- **Minor allergic** – skin irritation with or without rash.
- **Anaphylactic** – hypotension with one or more of: rash, dyspnoea, stridor, wheezing, angioedema, pruritus or urticaria, during or within 24 hours of transfusion.
- **Severe allergic** – a severe reaction with immediate risk to life occurring during or within 24 hours of transfusion, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress.
- **Hypotensive** – 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 and any underlying conditions that could explain hypotension have been excluded.

- **Febrile with other symptoms/signs** – rise in temperature >1°C, with no features of an allergic reaction, but with one or more of myalgia, nausea, change in blood pressure or hypoxia.

Table 43
Categories of ATR by component

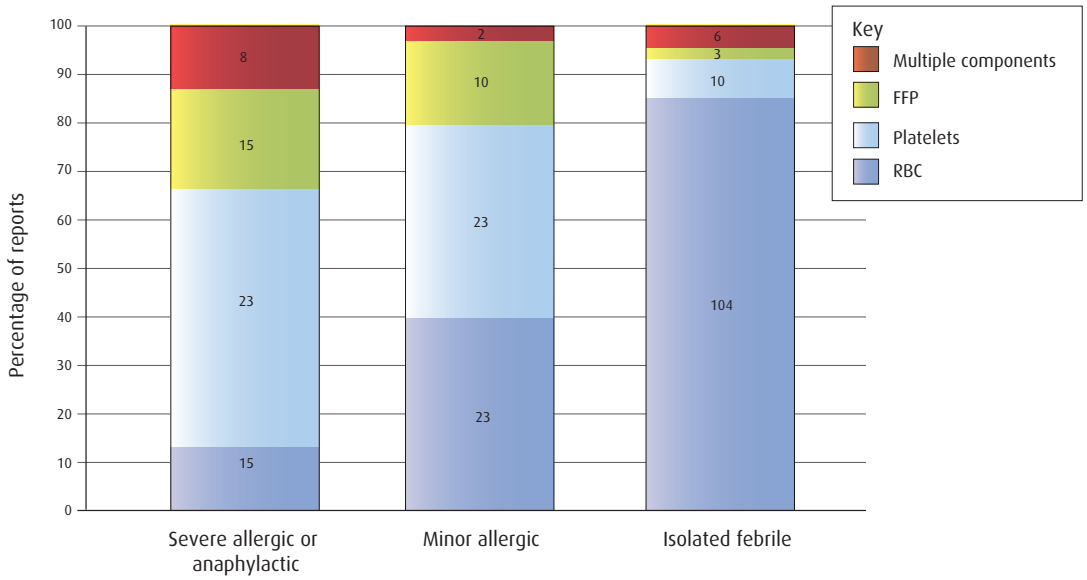
Reaction	Red cells	Apheresis platelets	Buffy coat platelets	Platelets unspecified type	Plasma	Multiple components	Total
Anaphylactic	7	8	4		8	5	**32**
Severe allergic	8	8	3		7	3	**29**
Hypotensive	5	1			2	1	**9**
Febrile with other symptoms or signs	23	2	4		2	1	**32**
Minor allergic	23	15	8		10	2	**58**
Isolated febrile	104	6	4		3	6	**123**
Unclassified	10	3	2	1	1		**17**
TOTAL	**180**	**43**	**25**	**1**	**33**	**18**	

The variation in reaction type between red cells and plasma-rich products is illustrated in Figure 10. Febrile reactions are encountered more frequently with red cell transfusion, and severe allergic and anaphylactic reactions are seen more frequently with platelet and plasma transfusions.

Reactions to platelets

This year there were 69 reported reactions to platelets. The percentage of reactions attributed to apheresis rather than pooled (buffy coat) platelets has risen from 47.5% in 2007 to 62% this year. This is likely to be explained by the percentage of apheresis platelets issued, which in England has risen over the same time period from 52.3% to 60.3%. However, a sustained increase in reactions to one component type would indicate a need to assess the effect of any changes in processing.

Figure 10
Commonest reactions by component type



'Unclassified' reactions

There were 17 reports recorded as 'unclassified' – mostly relating to elderly patients with intercurrent illness and atypical signs. Two unclassified reports are in children: a 3-year-old with AML and chest symptoms, and an 8-year-old on chemotherapy who developed a rasping cough. These cases are all included in this chapter as the hospital transfusion teams involved, using the information present at the time, thought that a diagnosis of ATR was most likely. Further attempts to classify these reactions were not made, as management of the patient and the exclusion of other potentially serious causes of the symptoms were the main priority of the clinical team, and these are not dependent on the classification of the reaction.

Deaths

There were 5 reports concerning patients who died shortly after transfusion. All the patients were either frail or had serious underlying illness. In 4 cases the transfusion reaction might have been a contributory factor in the patients' deterioration. These 4 cases include 2 hypotensive reactions, and 1 classified as a febrile reaction with other symptoms or signs. In Case 3 below, it is not possible to state whether the severe facial swelling was due to angioedema (a severe allergic reaction) or due to venous obstruction. Unfortunately it was not possible to trace the deceased patient's clinical notes.

Case 1 raises an important issue. This patient had been the subject of a SHOT report in 2007, with a hypotensive reaction. On that occasion, HLA antibodies were negative, mast cell tryptase (MCT) was normal, and IgA levels were low but no IgA antibodies were detected. Washed platelets were subsequently transfused without problems. This second episode may have been due to severe intercurrent illness, but it highlights the fact that the mechanism of hypotensive reactions, along with other reactions classified as acute transfusion reactions, is poorly understood.

Case 1

Hypotensive reaction to platelets may have contributed to death of septicaemic leukaemia patient

A 29-year-old man, seriously ill with relapsed leukaemia, was transferred to ITU with respiratory distress and septic shock. He was transfused a unit of platelets with chlorpheniramine and hydrocortisone cover because he had experienced an episode of hypotension following unwashed platelets in the past. Within 30 minutes he developed severe hypotension and back pain and was treated with intravenous colloid and metaraminol. His condition further deteriorated and he suffered a fatal cardiac arrest six hours later. Cultures of the unit and giving set were negative, but blood cultures revealed pseudomonas septicaemia, which was likely to have predated this transfusion. Although the patient was seriously ill, the hypotensive episode may have contributed to his death.

Case 2

Possible transfusion reaction may have contributed to death of patient with myeloma

An 80-year-old woman with myeloma was admitted for a single-unit red cell transfusion, which was completed without problems. Twenty minutes later she developed pyrexia, rigors, back pain and nausea. She was treated with antihistamine, hydrocortisone, adrenaline and salbutamol, but rapidly became very ill and was transferred to ITU, where her condition deteriorated further. She died 2 days later and at postmortem the cause of death was established as cardiac failure. Cultures of the patient's blood and the red cell unit were negative. Repeat red cell serology was not performed. It is not possible to state whether all these symptoms were related to the transfusion, but this episode may have contributed to her death.

Case 3

Transfusion of man later found to have possible SVC obstruction may have contributed to death

A 70-year-old man with pneumonia received 1 unit of red cells over 5 hours. Towards the end of the transfusion he became severely dyspnoeic with facial swelling and subsequently died. At postmortem, he was found to have a large chest malignancy. Further details of the malignancy, or whether there was any evidence of vascular obstruction, are not available. The possibility that the transfusion caused the facial swelling and subsequent deterioration cannot be excluded.

Case 4

Hypotensive reaction to red cell transfusion may have contributed to death from cardiac failure

An 88-year-old woman with a Hb of 6.3 g/dL post hip replacement received 2 units of red cells over 5 hours and then a third unit was commenced. Within 15 minutes, her blood pressure fell from 100/59 to 68/40. She was treated with intravenous hydrocortisone and piriton, but her condition deteriorated over the next 24 hours and she died. Blood cultures were negative. The cause of death was stated to be cardiac failure. It is possible that the hypotensive event contributed to the patient's death.

Case 5

Minor allergic reaction probably did not contribute to death of terminally ill patient

A 77-year-old woman receiving terminal care experienced a minor allergic reaction during a red cell transfusion. Her overall condition subsequently worsened and she died the following day. Although the allergic reaction was likely to have been related to the transfusion, it is unlikely that this resulted in the patient's death.

Reports of major morbidity

This year there were 9 cases of major morbidity either because patients suffered cardio-respiratory arrest, or because they needed admission to intensive care because of the new symptoms. There were 3 patients who had anaphylactic reactions, 3 had allergic reactions, 2 had febrile reactions with other symptoms or signs, and 1 had a hypotensive reaction. Of these, 7 cases – 3 of which are described below – had an imputability level of 3.

Case 6

Severe allergic reaction following multiple component transfusion

A 57-year-old man experienced major haemorrhage while on ITU following sigmoid colectomy. He required rapid transfusion with 11 units of red cells, 2 units of apheresis and 3 of buffy coat platelets, 8 units of FFP, and 2 pools of cryoprecipitate. During these transfusions he developed bronchospasm and ventilation became very difficult. The reporting team could not identify which of the components caused this reaction. He was treated with antihistamine and hydrocortisone and subsequently improved. Cultures of the patient and units were negative, and serum IgA was normal.

Case 7

Severe anaphylaxis with full recovery following FFP infusion

A 75-year-old female patient required FFP for postoperative bleeding and developed an anaphylactic reaction with rash, dyspnoea and profound hypotension. Her blood pressure fell from 110/70 to 55/35 and she required cardiopulmonary resuscitation. She received noradrenaline and dobutamine and her condition improved over the next 2½ hours. Investigations were normal.

Case 8

Inappropriate transfusion of FFP for warfarin reversal results in anaphylaxis

A 75-year-old woman was given 3 units of FFP to reverse warfarin prior to an amputation. She developed a severe anaphylactic reaction, with a rash, dyspnoea and angioedema. Her blood pressure dropped from 109/82 to 67/40. She was admitted to ITU and treated with hydrocortisone, antihistamine and adrenaline. Her condition improved over the next 2 hours.

Case 9

Hypotensive reaction in a child following MB-FFP infusion

A 1-year-old male infant with Fallot's tetralogy received a unit of paediatric MB-FFP. During the transfusion he became hypotensive. Initially this was thought to be due to hypovolaemia, and the rate of transfusion was increased. Ten minutes into the transfusion, after 50 mL had been transfused, his blood pressure fell further from 80/43 to 55/20. He suffered further deterioration and circulatory collapse requiring cardiopulmonary resuscitation. Serum IgA was normal, and cultures from the FFP unit and patient's blood were negative.

Anaphylactic reactions *n* = 32

There were 32 patients who experienced anaphylaxis. One case (Case 3 above) involved a patient who died soon after the transfusion. The death may have been related to a large chest neoplasm found at postmortem. Four suffered major morbidity, involving ITU admission or a callout of the cardiac arrest team.

The imputability was given as zero in 2 cases, including 1 death, described above (Case 3). In 1 case, the reporting team changed the imputability from 1 to zero as investigations had proved negative. However, it must be stressed that investigations rarely have a role in the confirmation or classification of acute transfusion reactions. Imputability was given as 1 in 13 cases, 2 in 16 cases and 3 in 1 case.

Case 10

Anaphylaxis following multiple components may be due to FFP

A 75-year-old man required transfusion with 6 units of red cells and 4 units of FFP in theatre. He developed an urticarial rash over his trunk, his systolic blood pressure dropped from 120 to 40 mm Hg, and his oxygen saturation from 96% to 89%. He was treated with intravenous hydrocortisone and adrenaline and his condition improved. Serum mast cell tryptase was raised at 17.7 units immediately after the event, falling to a normal level of 4.4 units several hours later. The transient rise in MCT is in keeping with an anaphylactic reaction, and the reporting team attributed this to the FFP.

Case 11

Unknown significance of HLA antibodies

A 34-year-old woman had had an emergency Caesarean section for HELLP syndrome. Two days postoperatively her platelet count was 45 x10^9/L. She was given a unit of apheresis platelets over 20 minutes. Immediately after the transfusion she developed a rash, angioedema, chest pain and dyspnoea. Her blood pressure fell from 128/83 to 90/48 and her oxygen saturation fell to 87%. She was treated with 2 doses of hydrocortisone 100mg and her blood pressure and oxygen saturation returned to normal within 25 minutes. Culture of the patient's blood and the apheresis unit were negative. Blood was sent for HLA, HPA and HNA antibodies and the patient was found to have anti-HLA B37. As the HLA status of the donor was not determined, it is difficult to determine the significance of this.

Severe allergic reactions *n* = 29

There were 29 cases of severe allergic reactions, including 3 with major morbidity. One is discussed in the section on major morbidity (Case 6). The other 2 cases are described below:

Case 12

Severe allergic reaction leading to cardiac arrest after platelet transfusion

A 56-year-old man with consumptive thrombocytopenia was given 1 unit of pooled platelets in theatre immediately before a knee arthroscopy. He developed a rash and hypotension (although not to the degree required by the definition of anaphylaxis) under anaesthetic, followed by cardiac arrest, from which he was successfully resuscitated. Treatment included intravenous adrenaline and nebulised salbutamol via the endotracheal tube. His vital signs returned to normal within 30 minutes. Serum IgA level was normal. It was decided to use washed blood components for future transfusion.

Case 13

Severe allergic reaction following transfusion of FFP

A 40-year-old man with alcoholic liver disease and hepatorenal syndrome was given 2 units of FFP to correct his INR prior to ascitic tap. Within 1 hour, he developed urticaria and bronchospasm, and was reported to have a respiratory arrest. He responded to intravenous chlorpheniramine. Investigations were negative except for a low haptoglobin, probably due to his severe liver disease.

There were 12 paediatric patients suffering severe allergic reactions, 7 of which were associated with apheresis platelets with 1 involving transfusion of multiple components, described below. Imputability of all cases was given as either 2 or 3.

Case 14

Severe allergic reaction in boy receiving multiple blood components

A 13-year-old boy had been stabbed and needed emergency angiography. He had received a rapid transfusion of 6 units of red cells, 4 units of MB-FFP and 2 pools of cryoprecipitate. It was not known which of the latter components may have caused the reaction. While in the radiology department he developed urticaria, angioedema and dyspnoea, but maintained good oxygen saturation. He was managed with hydrocortisone, antihistamine and adrenaline and made a good recovery. Investigations revealed a non-specific HLA antibody. The clinical team had considered whether intravenous contrast medium had been a cause of his reactions, but he went on to receive further contrast medium without any problems.

Management of transfusion reactions

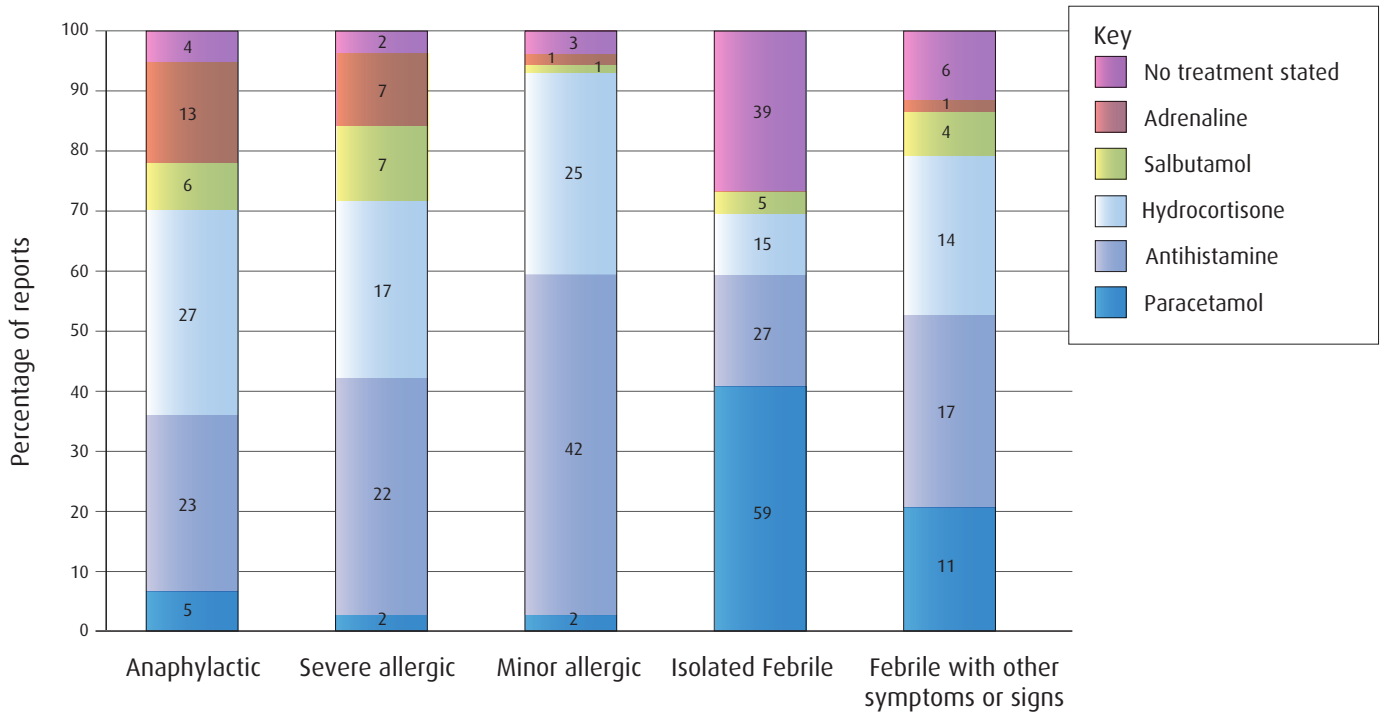
Management of the transfusion

In 180 (60%) of reported cases, the transfusion was stopped completely because of the reaction. In 6 cases (2%) the transfusion was stopped temporarily, and in 23 cases (7.7%) the transfusion was already complete. In only 10 cases (3.3%) was the transfusion continued. In 81 cases (27%), no information was given.

Drug Treatment

Figure 11 shows that treatment given for the more severe forms of transfusion reactions differs from that given for isolated febrile or minor allergic reactions. It is appropriate that treatment in the acute situation is aimed at relief of symptoms and signs. Paracetamol was the most widely used drug for febrile reactions, being given in 50% of simple febrile reactions and nearly 25% of febrile reactions with additional symptoms or signs. An antihistamine, usually chlorpheniramine, was prescribed to alleviate allergic types of ATR, being administered in nearly 60% of minor allergic, 40% of severe allergic and 30% of anaphylactic reactions. This is accepted practice, but its considerable use in isolated febrile reactions (27 patients) and in febrile reactions with additional signs of symptoms is not evidence based.[14] Salbutamol and adrenaline have a role in more severe reactions.

Figure 11
Drug treatment and type of reaction



Treatment of anaphylactic reactions

Management of anaphylactic transfusion reactions should be based on guidelines produced by the UK Resuscitation Council.[15] Treatment involves initial resuscitation, administration of high concentration oxygen, and consideration of a rapid IV infusion of saline or Hartmann's solution. Adrenaline is the first drug of choice, with antihistamines as a second line treatment. Steroids may help prevent or shorten protracted reactions. Consideration should be given to the use of bronchodilators, adrenaline or other cardiac drugs as set out in the Resuscitation Guidelines.

Management of subsequent transfusions

All but 5 cases were reviewed by the HTC or by the HTT. In 3 cases the decision was made to use washed components in the future, and in 3 cases it was decided to give prophylaxis with hydrocortisone and antihistamine. In 1 case, the clinical team was advised to request HLA matched components. The majority of the cases with a management plan for future transfusion involved patients with anaphylactic or severe allergic reactions, but there was 1 case each of isolated febrile or minor allergic reactions. In 1 case, it was ensured that all clinical departments were aware of the availability of prothrombin complex concentrates (PCCs) in preference to FFP for serious bleeding due to warfarin. In response to a case involving an anaphylactic reaction related to FFP, an HTT circulated a reminder that non-urgent transfusions should not be performed at night.

Investigations

The most commonly performed investigations are shown in Table 44.

Table 44
Commonly performed investigations

Investigation	Number of reports	Number of positive or abnormal results
Culture of patient's blood and/or component for bacterial growth	173	Patient blood cultures were positive in 13 cases, none of which were associated with positive blood component cultures. Of these, 9 were isolated febrile reactions reported with red cells, which suggests that the fever was related to sepsis rather than transfusion and highlights the difficulties in ascribing imputability. In 1 case, a hypotensive reaction to apheresis platelets, there was a fatality. This is described in the section on patient deaths. Cultures of the blood component were positive on 7 occasions, in all cases thought to be due to contaminants (4/7 components were red cells)
Red cell serology	45	Nil significant
Mast cell tryptase assay	25	In 6 cases MCT rose then returned to baseline
Serum IgA levels with or without antibodies	54	Nil
HLA antibody screen	29	Non-specific positive in 9 cases. In 1 case, anti-B37 demonstrated.

Value of investigations

Mast Cell Tryptase (MCT) assay

A transiently raised MCT, returning to baseline levels a few hours after the event, is suggestive of mast cell activation.[15] However, the test cannot determine the cause of the mast cell activation.

IgA levels

The prevalence of IgA deficiency is approximately 1 in 700, with about 30% of individuals with low IgA levels having IgA antibodies. Not all individuals with anti-IgA antibodies will experience transfusion reactions. The incidence of acute transfusion reactions due to anti-IgA is estimated to be between 1 in 20,000 and 1 in 47,000.[16] Transfusion recipients who have experienced anaphylactic or severe allergic reactions, especially if repeated, should be investigated for possible IgA deficiency.

Bacterial culture of the patient's blood and the implicated unit

The possibility of transfusion-transmitted bacterial infection should be considered when a patient with ATR is being assessed, especially if platelets are involved. The blood component should be inspected for signs of contamination, e.g. partial clotting, cloudiness or discolouration, or gas formation. The visual inspection of a component is a critical part of the pre-administration check. Patients with pyrexia and rigors severe enough to cause the transfusion to be stopped must have blood cultures and the implicated unit must be cultured.

Repeat red cell serology

The possibility of an ATR, including ABO incompatibility, should always be borne in mind especially in patients who are experiencing sudden onset of back pain, rigors, wheeze or hypotension. The patient's details and the compatibility label on the unit must be checked as part of the initial assessment of the patient.

HLA antibodies

HLA antibodies are commonly found in transfusion recipients and are rarely of clinical significance. There is no strong evidence base linking HLA antibodies to acute transfusion reactions. However, some patients who are refractory to platelet transfusions and who have HLA antibodies experience symptoms suggestive of an acute transfusion reaction. In patients who experience repeated severe allergic reactions to platelets, it may be helpful to check platelet increments within 24 hours of a platelet transfusion before proceeding to measure HLA antibodies. The HLA type of the implicated donor will also be required before any inference regarding causation can be made.

Timing of transfusions

The time of day at which the implicated transfusion was commenced was recorded in 298/300 cases.

- between 08.01 and 20.00 hours in 227 (76.2%) cases
- between 20.01 and 24.00 in 43 (14.4%) cases
- between 24.01 and 08.00 in 28 (9.4%) cases

The proportion of urgent transfusions was higher between 20.01 and 08.00 (42%) than during core hours of 08.01 to 20.00 hours (12.7%).

Timing of reaction after start of implicated unit

The time between commencement of the implicated transfusion and the start of the reaction was noted in 274 cases, with an average of 66 minutes, with a range of <1 minute to 440 minutes (7 hours and 20 minutes). Crucially 199 reactions (72.6%) occurred more than 15 minutes after commencing the transfusion, which highlights the need for proper regular monitoring of the patient and the requirement for transfusions to be carried out where there are sufficient trained staff to observe the patient.

Imputability

It can be difficult to ascribe imputability (i.e. the likelihood that a blood component has caused the reaction) as there are no diagnostic tests that will confirm or exclude a blood component as the cause of the reaction. In addition, most patients have intercurrent illness, or are receiving treatments that could have induced the reaction. Imputability, where given, has been assigned by the reporting teams as follows:

- 0 (unlikely) 37 cases
- 1 (possible) 152 cases
- 2 (likely or probable) 98 cases
- 3 (certain) 9 cases

In several cases the reporting team changed the imputability from a higher score to zero when investigations proved

negative. However, as discussed above, diagnosis of an acute transfusion reaction is based on a clinical diagnosis of symptoms and signs. Investigations are of use in excluding other potentially serious causes for the symptoms, but not often in proving the reaction to have been transfusion related.

Appropriateness

The appropriateness is hard to judge in many of the cases both for the reporter (usually the HTT) and for SHOT. However, there are 6 reports (the same number as in 2007) of transfusion reactions associated with the use of FFP for warfarin reversal, 1 of which was a severe allergic reaction. FFP is not indicated for this purpose, except when life, limb or sight-threatening haemorrhage occurs and prothrombin complex concentrates are not available.[17]

Acute transfusion reactions with development of antibodies

In 1 case initially reported as HTR, a patient with an isolated febrile reaction was found on repeat red cell serology to have developed anti-Co(b). There was no evidence of haemolysis, and the antibody formation was unlikely to have been incidental.

Paediatric cases

There are 25 cases of ATRs in patients under 18, representing 8% of the total ATR cases, compared to 6% (7/114) in the 2007 report. These cases are discussed in full in the paediatric chapter.

Serious Adverse Reaction reporting

There were 49 'Serious Adverse Reaction' (SAR) events reported to SHOT only, and not to the MHRA. Although many were too minor to be considered SAR events according to the MHRA definition, 4 patients had their hospital stay prolonged as a result of a reaction and these should have been reported to MHRA as well as to SHOT.[18]

RECOMMENDATIONS

New recommendations this year

- Initial management of a suspected transfusion reaction should be directed towards rapid assessment of the patient's condition, and treatment of their symptoms and signs.

- It cannot be assumed that all adverse reactions to blood components are due to an ATR in a category defined in this chapter. Unless the diagnosis is clear, patients whose reactions are severe enough to warrant stopping the transfusion should be fully investigated to identify other potentially serious causes of the symptoms such as TRALI, bacterial contamination, TACO or haemolysis. In addition, it should be borne in mind that symptoms may be due to, or augmented by, the patient's underlying condition or other intercurrent illness. Hospitals should have a policy for the investigation and management of ATRs based on current best practice. An update of BCSH guidelines is in progress.

- As the mechanism of ATR is still not clear, the role of unselected testing for HLA, HPA or HNA antibodies appears very limited. Patients who experience anaphylactic or severe allergic reactions after platelets should have an increment measured between 1 and 24 hours after transfusion. A severe reaction could indicate platelet refractoriness, in which case HLA matched components would be indicated. Otherwise, the next step should be a trial of PAS-suspended platelets, or washed components, before embarking on HLA testing.[19]

- ATRs that meet the MHRA criteria for SAR, i.e. those that are '... fatal, life-threatening, disabling or incapacitating, or that result in or prolong hospitalisation or morbidity', should be reported to MHRA as well as SHOT through SABRE.[18]

  Action: HTT and HTC

- The ISBT reporting categories for transfusion reactions[4] are being promoted by ISBT and IHN to be adopted internationally to facilitate comparison of data. SHOT analysis categories will need to be adapted to fit with this classification.

  Action: SHOT

Recommendations still active from previous years

Year first made	Recommendation (Previously Learning Points)	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.
2007	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 could be used for warfarin reversal for emergency surgery, and FFP used only if concentrate is not available.	**Consultant haematologists with responsibility for transfusion**	There are still some ATRs reported relating to inappropriate use of FFP, although the proportion of cases is lower relative to the increased overall reporting in 2008.
2007	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.	**HTCs, HTTs**	BCSH guidelines on the investigation and management of transfusion reactions are in development. All ATRs fulfilling the BSQR definition of SAR must be reported to MHRA.

11. Haemolytic Transfusion Reactions (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, confirmed by a fall in Hb, rise in LDH, positive DAT and positive crossmatch.
- Delayed reactions are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; confirmed by one 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	**55**

Implicated Components	
Red cells	**51**
FFP	**0**
Platelets	**4**
Other *(specify)*	**0**
Unknown	

Mortality / morbidity	
Deaths due to transfusion	**0**
Deaths in which reaction was implicated	**1**
Major morbidity	**6**

Gender	
Male	**24**
Female	**31**
Unknown	

Age	
16 years+ to 18 years	**1**
1 year+ to 16 years	**3**
28 days+ to 1 year	**0**
Birth to 28 days	**0**
Total	**4**

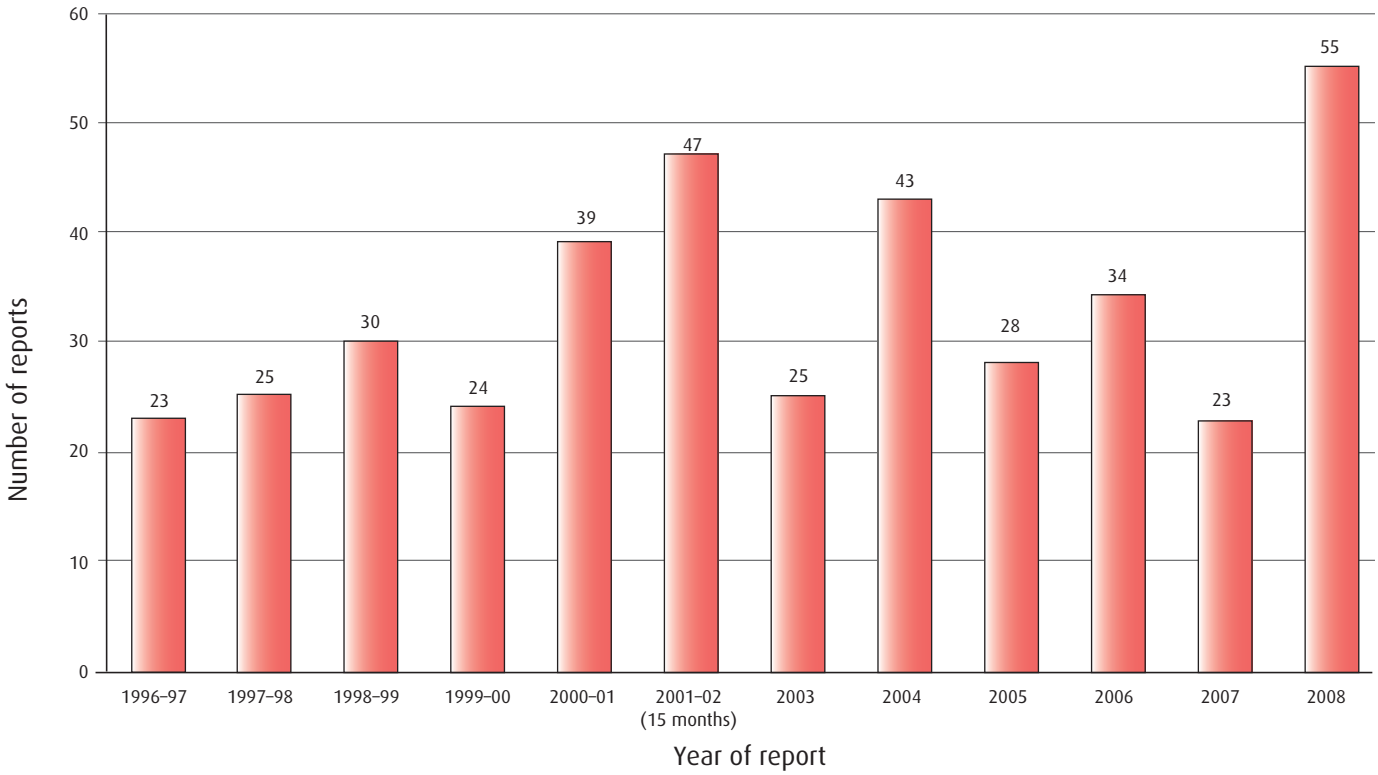
Emergency vs. routine and core hours vs. out of core hours	
Emergency	**10**
Routine	**41**
Not known	**4**
In core hours	
Out of core hours	
Not known/applicable	**55**

Where transfusion took place	
ED	
Theatre	
ITU/NNU/HDU/Recovery	
Wards	
Community	
Other	
Not known	**55**

In total, 63 questionnaires were received; on review 2 were found to be duplicate reports from 2 different hospitals, 3 were transferred out to the IBCT section, 2 were transferred out to the ATR section, 2 were withdrawn altogether, and 1 was transferred in from the ATR section.

This section describes the main findings from 55 completed questionnaires: 9 acute and 46 delayed reactions.

Figure 12
Number of cases of HTR reviewed since 1996



Patients

There were 24 male and 31 female patients, with an age range from 14 months to 94 years.

Of these, 4 patients were under 18 years of age: a 14-month-old and a 7-year-old suffered acute reactions to group O platelets, an 8-year-old patient with sickle cell disease suffered an episode of hyperhaemolysis, and a 16-year-old with sickle cell disease suffered a delayed reaction due to anti-S.

Mortality, morbidity, and imputability

Acute haemolytic transfusion reactions (AHTR) *n* = 9

There were no deaths caused, or contributed to, by these transfusion reactions. The patients in cases A8 and A9 suffered reactions with imputabilities of 2 and 3 respectively. Both patients died subsequently of their underlying disease.

There were 2 cases of major morbidity from AHTR. Case A2 (imputability 2) related to an incompatible red cell transfusion and Case A7 (imputability 1) to an ABO-incompatible platelet transfusion. Both patients required ITU admission but made a full recovery.

The remaining 5 cases of AHTR suffered minor or no morbidity. Two were reported as definitely related to the transfusion (imputability 3) and 3 probably related (imputability 2).

Delayed haemolytic transfusion reactions (DHTR) *n* = 46

There was one death in this group (Case D33) in which the reaction (imputability 2) possibly contributed to death. This patient suffered from CCF, hepatorenal failure and sepsis, was already extremely unwell when the reaction occurred, and died 2 weeks later. The reporter thought that the DHTR possibly contributed to the death.

There were 4 cases of major morbidity. The patient in Case D23 has required long-term dialysis since the DHTR; although no antibodies have been detected, this was reported as probably related to the transfusion (imputability 2). There were 2 other cases of major morbidity in which the patient showed signs of deteriorating renal function, but did not require dialysis (cases D9 and D45); 1 was reported as definitely related (imputability 3) and 1 probably related (imputability 2) to

the transfusion. In Case D16, the patient suffered a dramatic drop in Hb 5–6 days post transfusion, requiring emergency admission and a 4 unit transfusion.

Of the remaining 41 cases, 26 suffered minor morbidity and 15 had no clinical signs or symptoms, with the only laboratory signs being a positive DAT and development of antibody.

Timing of reaction in relation to transfusion

AHTR

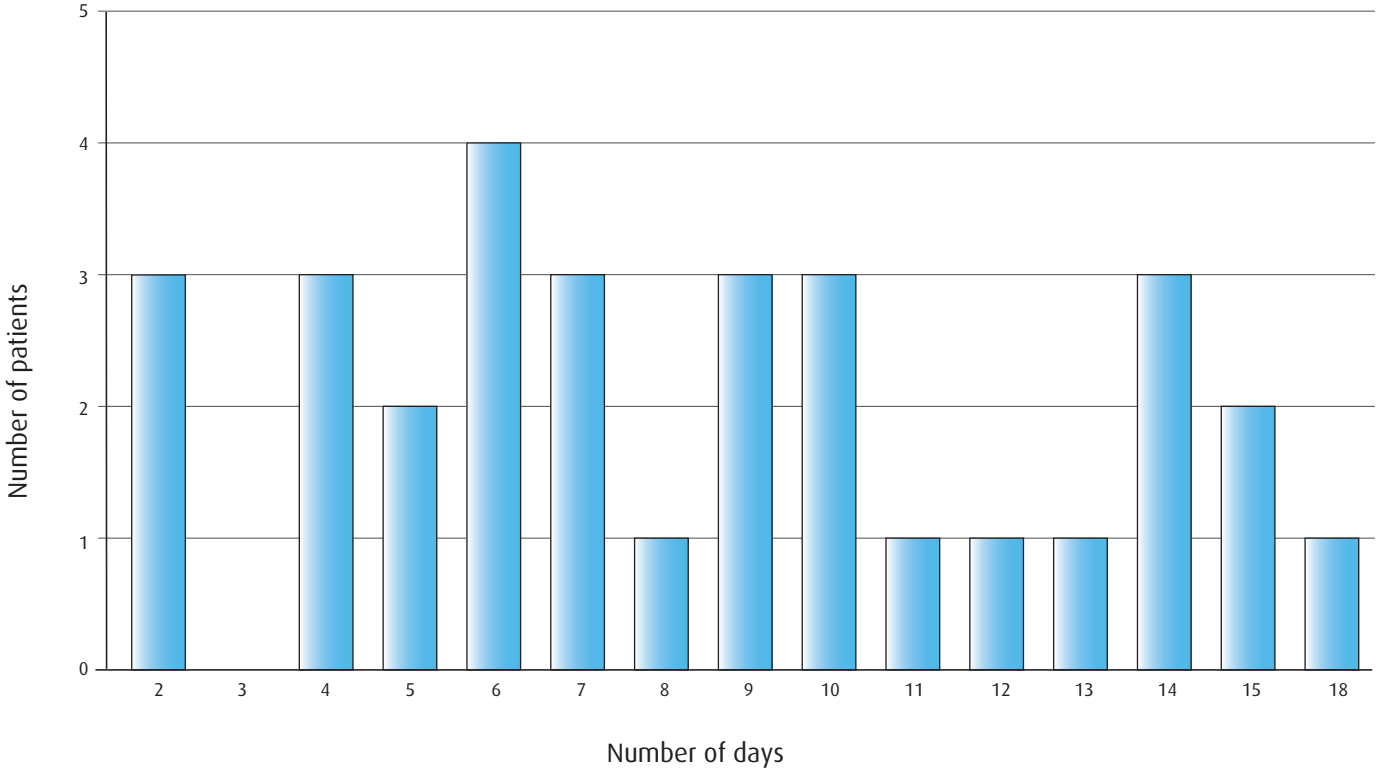
In all, 6 reactions occurred during the transfusion and 3 within 24 hours of transfusion (2 were reported as 'next day').

DHTR

Figure 13 shows the reported interval in days between the implicated transfusion and clinical signs or symptoms of a DHTR. The median is 8 days, and the range 2–18 days.

New antibodies were found between 5 and 38 days after transfusion in the 15 asymptomatic cases.

Figure 13
Number of days between transfusion and reaction



Serological findings

AHTR *n* = 9

There were 4 reactions due to anti-A from mismatched platelets. These were 3 apheresis donations, of which 2 were HLA matched, and 1 derived from pooled buffy coats. All platelets were labelled negative for high-titre anti-A and anti-B. However, the pooled buffy coat donation was retrospectively found positive for a high-titre IgG anti-A.

In 2 cases, patients were transfused with incompatible blood before antibody identification was complete: 1 had a serious reaction requiring ITU admission (Case 2) caused by anti-Jk^{a}+Fy^{b} and 1 had a milder reaction due to anti-Fy^{a}.

There was 1 reaction in a patient where anti-Jk^{a} was, retrospectively, weakly detectable in the pre-transfusion sample using a different IAT technique (A1).

In 2 cases (A3 and A4) there were laboratory signs of haemolysis although no antibody was identified until 2 and 6 days after the transfusion respectively. In the latter case the Jk(a+) unit was weakly incompatible on retrospective testing using a different IAT technique.

Table 45
AHTR cases

Case number	Antibody (ies) in plasma	Clinical symptoms	Laboratory evidence	Comments
1	Jk^a	Fever, tachycardia, abdominal pain	0.5 g/dL↓ in Hb; pos DAT; anti-Jk^a eluted	Antibody only detectable pre-transfusion by LISS tube, not DiaMed.
2	Jk^a + Fy^b	Fever, rigors	bilirubin↑; Hb↓; pos DAT	Blood given urgently before IBGRL confirmed Ab ID. Initially thought to be anti-JMH; ITU admission required.
3	Jk^a	Dyspnoea, chest and lumbar pain	Pos DAT; anti-Jk^a eluted 6 days later	Implicated unit Jk(a+), but antibody not identified until 6 days post Rx. Unit retrospectively weakly positive by DiaMed but negative by LISS tube.
4	c+E + non-specific	Fever, rigors	Bilirubin↑ neg DAT; no antibodies detected for 2 days	Implicated unit was c positive.
5	Fy^a	Fever; dyspnoea, jaundice	Bilirubin↑; Hb↓; pos DAT; no eluate performed	Antibody screen weakly positive but blood required urgently.
6	A	Fever, rigors, dyspnoea, hypotension, jaundice	Bilirubin↑; no Hb increment; LDH↑	Required ITU admission.
7	A	None reported	Bilirubin↑; Hb↓; pos DAT; anti-A eluted	High-titre IgG anti-A in buffy coat group O platelets; death unrelated.
8	A	None reported	Bilirubin↑; Hb↓; pos DAT; anti-A eluted	HLA matched apheresis plts were not IgG anti-A negative. 14-month-old died, death unrelated.
9	A	Rigors, pyrexia	pos DAT; anti-A eluted	Platelets negative for high-titre anti-A.

AHTR cases

Group A patients receiving Group O platelets

Case A6

A 71-year-old male with Hodgkin's disease received 2 units of group A red cells and 1 unit of group O apheresis platelets. On completion of the platelets he became dyspnoeic and wheezy, then hypotensive, pyrexial and jaundiced. The Hb remained at 8.2g/dL despite a 2 unit red cell transfusion, and the bilirubin increased from 28 to 237 µmol/L. The patient became increasingly unwell, and was admitted to ITU. In-house testing showed the DAT to be positive pre and post transfusion, but this was not confirmed by the reference centre and the eluate was non-reactive. The donor was confirmed as negative for high-titre anti-A. Although no anti-A was evident in the plasma or eluate, there is clear evidence of a haemolytic episode.

Case A7

A 7-year-old boy on PICU who was group A received a pool of group O buffy coat derived platelets in an emergency. The platelets were labelled as high-titre negative. There were no immediate signs of an acute transfusion reaction, but the following day the bilirubin rose from 23 to 88 µmol/L and the DAT was positive. Anti-A was present in the plasma and was eluted from the patient's red cells, necessitating the use of group O red cells for future transfusion. The patient died from his underlying disease.

Case A8

A 14-month-old baby with leukaemia, group A received 2 apheresis doses of group O HLA matched platelets. The next day the baby suffered a sharp and unexpected fall in Hb and his bilirubin showed a marked rise. The DAT was positive and anti-A was detected in both plasma and eluate. The donor was retrospectively shown to have a high-titre IgG anti-A1.

Case A9

A 76-year-old female patient with MDS who was group A received 1 donation of group O HLA matched platelets followed by 2 units of group A red cells. During the second unit of red cells the patient developed a fever and rigors and the transfusion was discontinued. The DAT became positive and anti-A was detected in the plasma and eluate. The platelets were negative for high-titre anti-A and anti-B.

Learning point

- Group O platelets can cause acute haemolytic reactions even when tested and labelled negative for high-titre haemolysins. They should not be kept by hospitals as stock, and should only be used for non-group O patients as a last resort. This applies especially to paediatric patients.

Severe acute reaction due to misidentified antibody

Case A2

A 62-year-old male patient with diabetes, renal impairment, dehydration and sepsis, required blood to cover a below knee amputation. All panel cells were positive by IAT and surgery was postponed while samples were referred to the red cell reference laboratory. The DAT was strongly positive (IgG coating), as were all cells tested, even after alloadsorption. A panel treated with 2-aminoethylisothiouronium bromide (AET) was negative, and a specificity of anti-JMH was tentatively reported, which is unlikely to be of clinical significance. Four units were issued by the reference laboratory, 2 of which were transfused. Eight days later a further 4 units were issued and samples were requested for referral to IBGRL and for molecular genotyping. During transfusion of the first unit, the patient developed rigors and pyrexia and the transfusion was stopped. The Hb fell from 7.3 to 4.3g/dL and there was a rise in bilirubin. The patient was admitted to ITU. Further investigation revealed anti-Jk^a and anti-Fy^b, in addition to autoantibody, all confirmed by IBGRL. The eluate was positive but gave non-specific reactions. The implicated unit was Jk(a+). An additional 8 units of Jk(a-) blood were transfused and the patient made a full recovery.

It is possible that the patient was suffering a DHTR from the first transfusion in addition to the AHTR, perhaps explaining the fall in Hb to below pretransfusion levels.

Learning point

- If there is any doubt about the specificity of an alloantibody in the presence of a positive DAT (or transfused cells), referral for genotyping will allow for the selection of antigen matched blood, while further serological testing is performed.

DHTR *n* = 46

Kidd (Jk) antibodies were the most common, implicated in 32/46 cases (70%) either singly or in combination with other specificities; 48% of all new antibodies had Kidd specificity; and 69% of all new sole antibodies were Kidd.

Table 46 shows details of the serology, laboratory signs and time interval by case, and Table 47 shows the specificity of new antibodies detected post transfusion, by blood group system.

Table 46
Serology, laboratory signs and timing of reaction

Case number	New antibody (ies) in plasma	Antibodies in eluate	Comments	Days post transfusion
1	c+E+Jk^{a}	E	Anti-K previously identified; No signs or symptoms	8-16
2	c+E+Jk^{a}	Jk^{a}	Anti-Jk^{a} not identified in plasma; Hb↓	14
3	Jk^{a}	Jk^{a}	Anti-E pre-transfusion; Hb↓ bilirubin↑	9
4	Jk^{a}	Jk^{a}	Hb↓ bilirubin↑	14
5	Jk^{b}	No eluate done	Hb↓ bilirubin↑	5
6	S	No eluate done	Hb↓↓ bilirubin↑↑	15
7	C+?K	One cell pos – specificity not determined	Hb↓ bilirubin↑	10
8	Jk^{b}+Lu^{a}	Jk^{b}	Hb↓ bilirubin↑, but liver disease and bleeding	10 days
9	Jk^{a}	Jk^{a}	Anti-D and anti-K previously identified; Hb↓ bilirubin↑ creatinine↑ haemoglobinuria	13
10	k	k	Hb↓ bilirubin↑	10
11	M	No eluate done	Hb↓ bilirubin↑	12
12	Fy^{a}	Fy^{a}	No signs or symptoms	14
13	None		Post-transfusion hyperhaemolysis in patient with sickle cell disease bilirubin↑ Hb↓ haemoglobinuria	7
14	E	No specificity	Hb↓	15
15	Jk^{a} + cold autoantibody	No eluate done	Anti-D+C pre-transfusion Hb↓ bilirubin↑	2
16	Jk^{a}+M+E	Jk^{a}, M, E	Hb↓↓ bilirubin↑↑	5
17	Jk^{a}	Jk^{a}	No signs or symptoms	13
18	Jk^{b}	No eluate done	No signs or symptoms	10
19	E+Jk^{b}	Negative	Antibodies only detected with polybrene; Hb↓ bilirubin↑	14
20	c+E	c	Hb↓	2-6
21	C+S	Eluate negative	Hb↓ bilirubin↑	9
22	E+Fy^{a}+Jk^{b}	Fy^{a}	No signs or symptoms	11
23	None	Eluate negative	DAT pos pre & post C3 only; Hb↓ bilirubin↑	6
24	Jk^{b}	Not stated	Hb↓ bilirubin↑	2
25	E	E + wk reactions ?anti-c	No signs or symptoms	38
26	Jk^{a}	No eluate done	Hb↓ bilirubin↑↑	4
27	Jk^{b}	Jk^{b}	Hb↓ bilirubin↑	4
28	K	No eluate done	No signs or symptoms	38
29	K+Jk^{a}	Jk^{a}	Hb↓ bilirubin↑↑	2
30	Jk^{a}	Jk^{a}	Hb↓ bilirubin↑	6
31	Jk^{a}	No eluate done	Hb↓ bilirubin↑	6

32	Jk^a	No eluate done	No signs or symptoms	8
33	Jk^b	No eluate done	Anti-c pre-transfusion Hb↓ bilirubin↑ creatinine↑	4
34	Jk^a	No eluate done	No signs or symptoms	5
35	$S+Fy^a+Fy^3+Jk^b$	Non-reactive	Antibodies known elsewhere but not detectable pre-transfusion Hb↓↓	14
36	Anti-N + autoantibody	Negative	Autoantibody likely responsible for haemolysis Hb↓ bilirubin↑	8
37	Jk^a	No eluate done	No signs or symptoms	7
38	$c+Jk^a+Fy^a$	c, Fy^a	Hb↓↓ bilirubin↑↑	11
39	Jk^a+f	Jk^a	Hb↓↓ bilirubin↑	9
40	Jk^a+C^w	No eluate done	No signs or symptoms. Antibodies known elsewhere but not detectable pre-transfusion	3
41	E	E	No signs or symptoms	14
42	Jk^a	No eluate done	No signs or symptoms	10
43	Jk^a	Jk^a	No signs or symptoms	Not stated
44	Jk^a	Jk^a	Hb↓	7
45	Jk^b+E	Eluate negative	Hb↓ bilirubin↑↑ creatinine↑	7
46	Jk^a	Jk^a	No signs or symptoms	Not stated

Table 47
DHTRs – new specificities by blood group system

Antibody specificity by blood group system	Number of cases	Sole *new* antibody
Kidd		
Jk^a	22	15
Jk^b	10	5
Rh		
C	2	0
E	10	3
c	4	0
f	1	0
C^w	1	0
Kell		
k	3	1
k	1	1
Duffy		
Fy^a	4	1
Fy^3	1	
MNSs		
S	3	1
M	2	1
N*	1	1
Other		
Lu^a	1	0

** Patient also had autoantibodies*

Serological Techniques Used – DHTRs only

Table 48
IAT technology used for antibody screening

IAT screening technology	Number of cases*	By automation
DiaMed	22	19
BioVue	10	10
CRRS	3	3

** 11 reports had no answer in this section; in 9 of the 11 cases, there were pre-existing antibodies*

- This spread of IAT technology matches that used overall by UK laboratories (data from UK NEQAS questionnaire September 2008).
- In 35 cases plasma was stated as being used for pre-transfusion testing, while 11 reports had no answer to the question.
- 24 undertook an IAT crossmatch (8 of these had a positive antibody screen), 2 an immediate spin, and 16 electronic issue; 4 reports had no answer to the question.

Use of eluates

In 29/46 (63%) of cases an eluate was made from the patient's post-transfusion red cells and tested for antibody. This has increased from 60% in 2007 and 35% in 2006. Of these 29 eluates, 23 were performed in reference laboratories and 6 in-house. In 21 cases a specific antibody(ies) was identified.

Retrospective testing findings

Retrospective testing of the pre-transfusion sample was undertaken in house in 18 cases (39%): the same results were obtained in all 18 cases. However, in only 8 of these cases was repeat testing confirmed by a reference centre or by a different technique

DHTR cases

DHTR possibly contributed to death

Case D33

73-year-old male patient with CCF, peripheral vascular disease and hepatorenal dysfunction was transfused 2 units of red cells for anaemia. Six days later anti-c was identified and 2 units of c negative blood were transfused. After 4 days the patient became jaundiced with laboratory signs of haemolysis: raised bilirubin, rising creatinine (already high), falling Hb and reduced haptoglobins. The DAT was positive, anti-Jk^{b} was identified in addition to anti-c, but no eluate was performed. The patient died 2 weeks later. Although already very sick, it was thought that the DHTR might have contributed to this man's death.

Long term morbidity but no detectable antibody

Case D23

A 41-year-old female patient with SLE and factor XI deficiency received a 3 unit transfusion for anaemia. She presented 6 days later in the ED with aches and pains, dark urine and jaundice. Bilirubin was raised, and Hb had dropped from 11.3 to 9.0 g/dL. The creatinine was significantly raised and the patient is now continuing dialysis awaiting a renal transplant. The DAT was positive pre and post transfusion (complement coating only), but the eluate was non-reactive. Despite testing by the hospital and the reference laboratory with a variety of techniques on plasma and serum (with the addition of fresh complement), including enzyme IAT and PEG IAT, no antibodies were detected. Although the serology was all negative, there was no other explanation for the haemolytic episode, which was thought probably to be due to the transfusion. The patient has been fully phenotyped and if further transfusion is required Jk(a-), S- K- blood will be provided.

Major morbidity with full recovery

Case D9

A 67-year-old female patient with known anti-D+K was transfused 3 units post THR and discharged with a Hb of 11.4 g/dL. She was readmitted 13 days later with chills, nausea, vomiting, jaundice and dark urine. Hb had fallen to 8.7g/dL, bilirubin and LDH were raised and the urea and creatinine were both elevated, indicating a serious haemolytic reaction. Anti-Jk^{a} was identified in the plasma and eluate.

Case D45

A 94-year-old male patient with acute coronary syndrome received 4 units of red cells for anaemia. Seven days later the patient was admitted with jaundice and haematuria. Bilirubin and creatinine were raised and the Hb dropped to its pre-transfusion level. Anti-Jk^{b} + E were identified, and although the DAT was positive (complement coating only) the eluate was non-reactive.

Case D16

A 21-year-old female patient received 8 units of red cells over a 2 day period for postoperative bleeding, and was discharged with a Hb of 14.3 g/dL. Five days later she required emergency admission with severe jaundice, dark urine and a Hb of 9.5g/dL. By the following day the Hb had fallen to 6.3g/dL, necessitating an urgent 4 unit transfusion. The DAT was positive and anti-Jk^{a}+M+E were detected in both the plasma and the eluate. On investigation there was documentation in the notes of anti-Jk^{a} from previous testing at a different hospital. It is not known whether the patient produced an antibody card.

Antibody only detectable using non-standard technique

Case D19

A 27-year-old male patient with NHL and an Hb of 7.5g/dL received 2 units of red cells and was discharged with a Hb of 9.5g/dL. He was readmitted 18 days later weak and lethargic with difficulty breathing. His Hb had dropped to 5.7g/dL and the bilirubin was raised. The DAT was positive (IgG coating) but the eluate was non-reactive. No antibodies were detected, so samples were referred to the NBS reference centre, where anti-Jk^{b}+E were identified by polybrene technique only.

There is clearly some evidence of haemolysis in this case; however, the Hb dropped to lower than the pre-transfusion Hb, and it is not clear how much of the picture is due to DHTR and how much to the underlying disease. There was no pre-transfusion sample available to confirm the presence or absence of these weak antibodies or a positive DAT prior to the transfusion.

Known antibodies cause severe delayed reaction

Case D35

A 35-year-old female patient with sickle cell disease received a 7 unit exchange transfusion of Rh and K matched blood in preparation for surgery. Two weeks later the patient presented to another hospital with an apparent sickle cell crisis, urinary tract infection and fever. The initial Hb was 7.9 g/dL but this dropped to 3.7g/dL over the next 4 days. The antibody screen was positive and this hospital had a record of previous multiple antibodies for the patient. Investigation by the reference laboratory revealed anti-S+Fy^{a}+Fy3+Jk^{b}, with a positive DAT (both IgG and complement) but a non-reactive eluate. Despite the massive drop in Hb the patient remained reasonably well and was treated with IVIg as no compatible blood was available. The HbS level was at 89% on readmission, indicating haemolysis of all the transfused red cells, but additional hyperhaemolysis cannot be excluded.

Learning points

- If used appropriately, antibody cards can prevent DHTRs. However, patients need to understand the importance of this information, and need to be encouraged to show them to hospital staff on admission, and certainly if a transfusion is required.
- Evidence in the notes of previous antibodies should be made available to the transfusion laboratory.
- 'New' patients with sickle cell disease are likely to have been tested and possibly transfused elsewhere. They are at higher than average risk of developing red cell antibodies and where possible hospitals should actively seek a transfusion and antibody history.

COMMENTARY

Group O platelets, both apheresis and pooled, that tested negative for high-titre haemolysins have once again caused haemolytic reactions. In 1 case retrospective testing showed that one of the donors was in fact high-titre positive for IgG anti-A. There have been 13 previous reports to SHOT (at least 8/13 in children under 18) of group O platelets causing ATRs in group A or B recipients, with a further 4 (2 in children) this year. The majority have therefore been in paediatric patients.

The BCSH guidelines[20] recommend the use of ABO identical platelets as the first choice, with provision of group O platelets to non-group O recipients only as the last choice for paediatric patients.[21] There is evidence that major ABO mismatched platelets (e.g. A to B) have a reduced transfusion efficacy,[22,23] which must be balanced against the risk of AHTR with a minor mismatch (e.g. O to A). When a decision needs to be made regarding the group of platelets to transfuse, liaison between the laboratory and the clinical team looking after the patient is essential, so that conflicting special requirements (e.g. CMV negative, HLA matched) can be carefully prioritised to minimise risk to the patient, and maximise transfusion benefit.

Finally, the risk of AHTR in these unavoidable situations might be reduced if the cut off for 'high-titre' anti-A along with anti-B for identifying high-risk group O donors was set at a lower limit than the current 1/128.

This year 63% of investigations included testing an eluate made from the patient's red cells, compared with 60% last year and only 35% the year before. Where a mixture of antibodies is present an eluate may help to distinguish which specificity(ies) is the more likely to be implicated in a haemolytic reaction. Furthermore, the implicated antibody may only be present in an eluate. Identification of all specificities present is essential if further haemolytic reactions are to be prevented.

Kidd (Jk) antibodies were implicated in 70% of DHTRs and also in 60% of non-ABO AHTRs. Acute reactions occurred in 2 patients where the Kidd antibody was retrospectively weakly detectable in the pre-transfusion sample by a different technique (one by DiaMed but not LISS tube, and the other vice versa). This demonstrates that no single technique will detect all weak antibodies and highlights the difficulties with detection of Kidd antibodies.

Two serious DHTRs occurred in patients known to have antibodies, but which were undetectable at the time and not known about in the transfusion laboratory providing the blood. In one case the evidence was in the patient's notes, and in the other case a patient with sickle cell disease was well known to another hospital usually treating the patient and to the blood service reference laboratory.

RECOMMENDATIONS

New recommendations this year:

- Blood services should review the critical titre of 1/128 for screening high-titre anti-A and anti-B, and consider whether donations should be screened for IgG in addition to IgM antibodies.

  Action: UK Blood Services

- Prior to transfusion, an antibody history and a transfusion history should be actively sought for previously unknown patients with sickle cell disease. This must include contacting the local blood service reference laboratory as well as any other hospitals the patient has attended.

  Action: Hospital; blood transfusion laboratories

- A national register of patients with antibodies, linked between the red cell reference laboratories, should be considered.

  Action: UK Blood Services

Previous recommendations still relevant

Previous recommendations remain relevant and the first 2 are particularly pertinent to this year's cases.

Year first made	Recommendation	Target	Progress
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.
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).
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 63% of cases this year and 60% last year compared with 35% in 2006 and 50% in 2005. This appears to be progress.
2001–02	Investigation of a suspected HTR should include re-testing 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**	This will be addressed in the revision of the BCSH Guidelines for Compatibility Testing, which are in progress.
2005	Pre-transfusion testing on patients who have been recently transfused and require further transfusion should be carried out in accordance with BCSH Guidelines relating to the timing of the samples	**Hospital blood transfusion laboratories and the NBTC Transfusion Laboratory Managers Working Group**	
2003	There is a need for a review, coordinated 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**	Revised BCSH guidelines for compatibility procedures in blood transfusion laboratories are in progress.

12. 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 causes.

DATA SUMMARY

Total number of cases	**17**	*Implicated Components*		*Mortality / morbidity*	
Highly likely / probably	**6**	Red cells	**0**	Deaths due to transfusion	**0**
Possible / unlikely	**11**	FFP	**3**	Deaths in which reaction was implicated	**0**
		Platelets	***2**	Major morbidity	**14**
		Other *(specify)*			
		Unknown	**12**		
		**1 of these cases received 3 implicated platelet pools*			

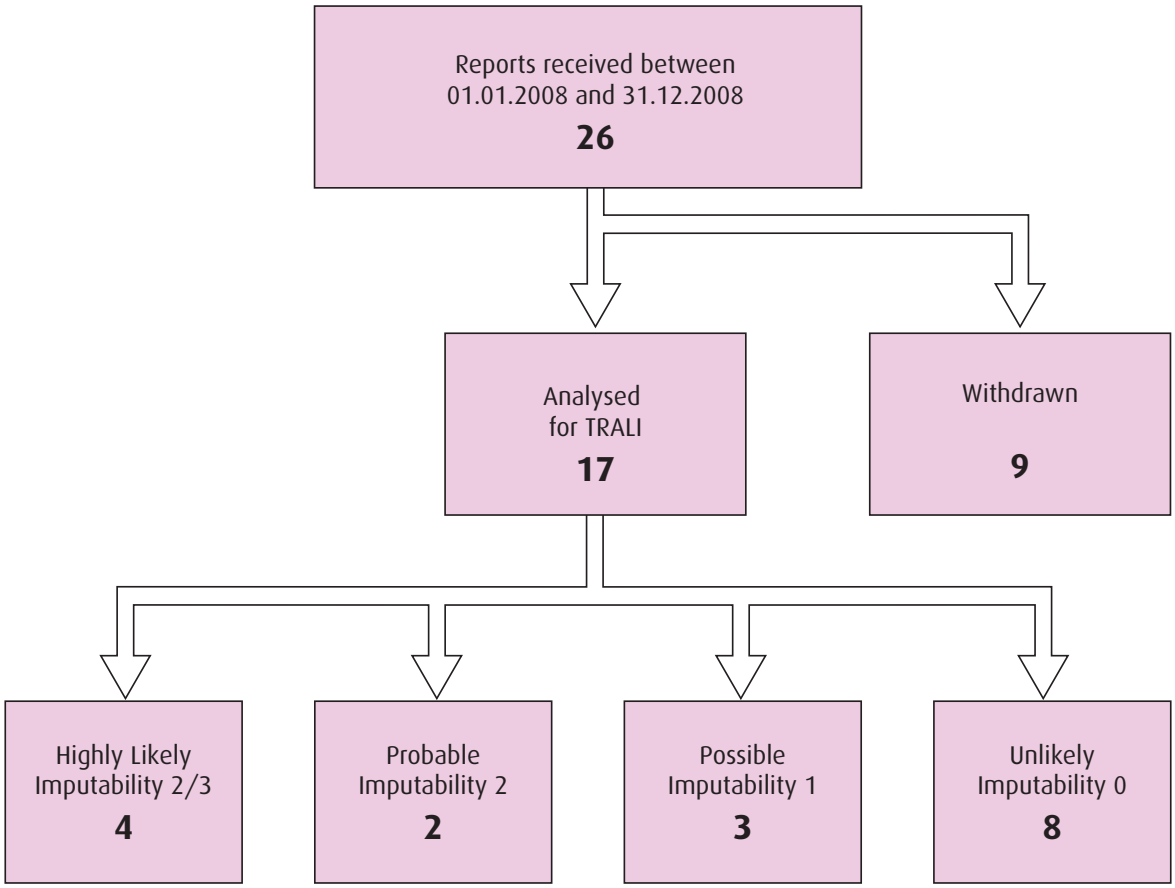
Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**10**	16 years+ to 18 years	**2**	Emergency		ED	
Female	**7**	1 year+ to 16 years		Routine		Theatre	
Unknown		28 days+ to 1 year		Not known	**17**	ITU/NNU/HDU/Recovery	
		Birth to 28 days				Wards	
				In core hours		Community	
		Total	**2**	Out of core hours		Other	
				Not known/applicable	**17**	Not known	**17**

In all, 26 questionnaires were received; on review 9 were withdrawn. This section describes the main findings from 17 completed questionnaires.

Of the 9 withdrawn cases, 2 were taken out by the reporters because alternative reasons for symptoms had been identified (one patient had cardiac failure and infection with no evidence of ALI and the other had pneumonia). The other 7 cases were withdrawn because they did not meet the SHOT definition for TRALI. In 5 of these patients the symptoms occurred more than 6 hours after transfusion and 4 of those with symptoms late after transfusion also had other factors accounting for their respiratory symptoms (chest infection, pre-existing cardiac disease, systemic vasculitis, very high white cell count and tretinoin treatment). In 3 cases there was no radiological support for the diagnosis.

The remaining 17 cases were analysed and the assessed probability of TRALI is shown in Figure 14. While 4 patients died, TRALI had been assessed as clinically unlikely in all of them and each had other significant pathology. The 13 others made a full recovery. Of the 17 analysed cases, 6 concerned late reporting of incidents that had occurred in 2007.

Figure 14
Summary of cases



Assessment of TRALI Cases

TRALI is difficult to diagnose because there is no specific test for this condition and it is easily confused with alternative causes of acute lung injury (ALI), cardiogenic pulmonary oedema or circulatory overload. The diagnosis is straightforward if ALI occurs in a previously fit transfused patient and relevant leucocyte antibodies are found. Often, however, respiratory deterioration occurs after transfusion in patients who have other reasons for this and/or additional risk factors for 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 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. All 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 female donors, HLA antibodies were found in 15%.[24] It is therefore 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 NHSBT in 2008 (14 of 17 cases) before laboratory investigation. A transfusion medicine specialist, who has also reviewed cases for the past 5 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 7 cases; 3 of these were not investigated because the TRALI expert panel considered that the clinical picture was caused by alternative reasons for respiratory deterioration.

As in previous years, cases were divided into 4 groups (as shown in Figure 14 above):

- '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.
- 'Unlikely', where the picture and serology were not supportive of the diagnosis

Classification of cases according to American-European Consensus criteria

All reports were also classified using the American-European Consensus criteria.[25,26] This gave the following results:

TRALI	6
Possible TRALI	11
Outside definition	9

These results match the overall figures for the same cases obtained using SHOT criteria for classification, although 2 individual cases fell into different categories using the 2 systems.

Website tables

Summarised information is presented in this chapter. Data extracted from individual TRALI questionnaires and laboratory results 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

Age

Patient ages ranged from 17 to 81 years with a median age of 38. There were 2 patients under 18.

Clinical specialty

Reports have been analysed according to clinical specialty. The most frequent specialty was general medicine (8 cases) followed by haematology/oncology (3) obstetrics and gynaecology (3) and surgery (3).

Analysis of cumulative figures since 1996 from 236 reports of suspected TRALI has shown that haematology/oncology combined has provided the highest number of reports of suspected TRALI (83, 35%) and surgery the second highest (76, 32%). General medicine was reported as the specialty in only 25 cases (11%). These figures are likely to reflect the differential pattern in blood component usage in the specialities, especially with regard to plasma-based components (FFP and platelets).

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. Fourteen patients were treated in ITU, of these 3 were already on ITU before the event. Twelve patients required mechanical ventilation from between 1 and 17 days (median 3.5 days). Fever and/or rigors were reported as present in 8 patients, absent in 8 and not recorded in 1. Hypotension was reported as part of the reaction in 8 cases, absent in 8 and not recorded in 1.

Patient outcomes

Details of all reported cases are tabulated in TRALI Table 3 on the SHOT website www.shotuk.org.
No patient died as a result of TRALI; 4 patients died of other causes and 13 made a full recovery from the episode.

Laboratory results

Details of all reported cases are tabulated in Table 2 on the SHOT website www.shotuk.org.
All cases were referred to a Blood Centre for investigation and 12 were subsequently investigated at Reference Laboratories. TRALI investigations were completed in 10 of these cases.

Donor antibodies

Concordant donor leucocyte antibodies (i.e. donor HLA or granulocyte antibody corresponding with patient antigen) were found in 5 of 10 completely investigated cases. Four cases were associated with concordant HLA antibodies only (3 with both HLA class I and class II antibodies and 1 with HLA class II only). One recipient received concordant donor HNA antibodies in 1 platelet pool and HLA class I and class II antibodies in 2 other platelet pools. The antibody specificities and implicated components are listed in Table 49.

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.

Table 49
Concordant donor antibodies – specificities and implicated components

ANTIBODY	SPECIFICITY(IES)	COMPONENT *
HNA	HNA-1a	*Platelet pool (donor of buffy coat only)
HLA class I and class II	HLA B-52, -B62, -DR14, -DR52	*Platelet pool (donor of buffy coat only)
HLA class I and class II	HLA-B52, -B62, Cw4, -DR14, -DR15, -DR52, -DQ6	*Platelet pool (donor of buffy coat only)
HLA class I and class II	HLA-B62, -DR11, -DR52	FFP
HLA class I and class II	HLA-A1, -Cw7, -DR11, -DR13	FFP
HLA class I and class II	HLA-A2, -DR11, -DR52	Apheresis platelets
HLA class II	HLA-DR4, -DR53, -DQ3	FFP

** These 3 platelet pools were all transfused to the same recipient. 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.*

Patient antibodies

The presence or absence of patient antibodies is no longer routinely tested because all components except granulocytes are leucodepleted in the UK. Patients are only tested for HLA and neutrophil antibodies if the transfused component was apheresis or buffy coat granulocytes.

Components

Details of all implicated components are tabulated in TRALI Table 1 on the SHOT website www.shotuk.org and are also included in Table 49 above.

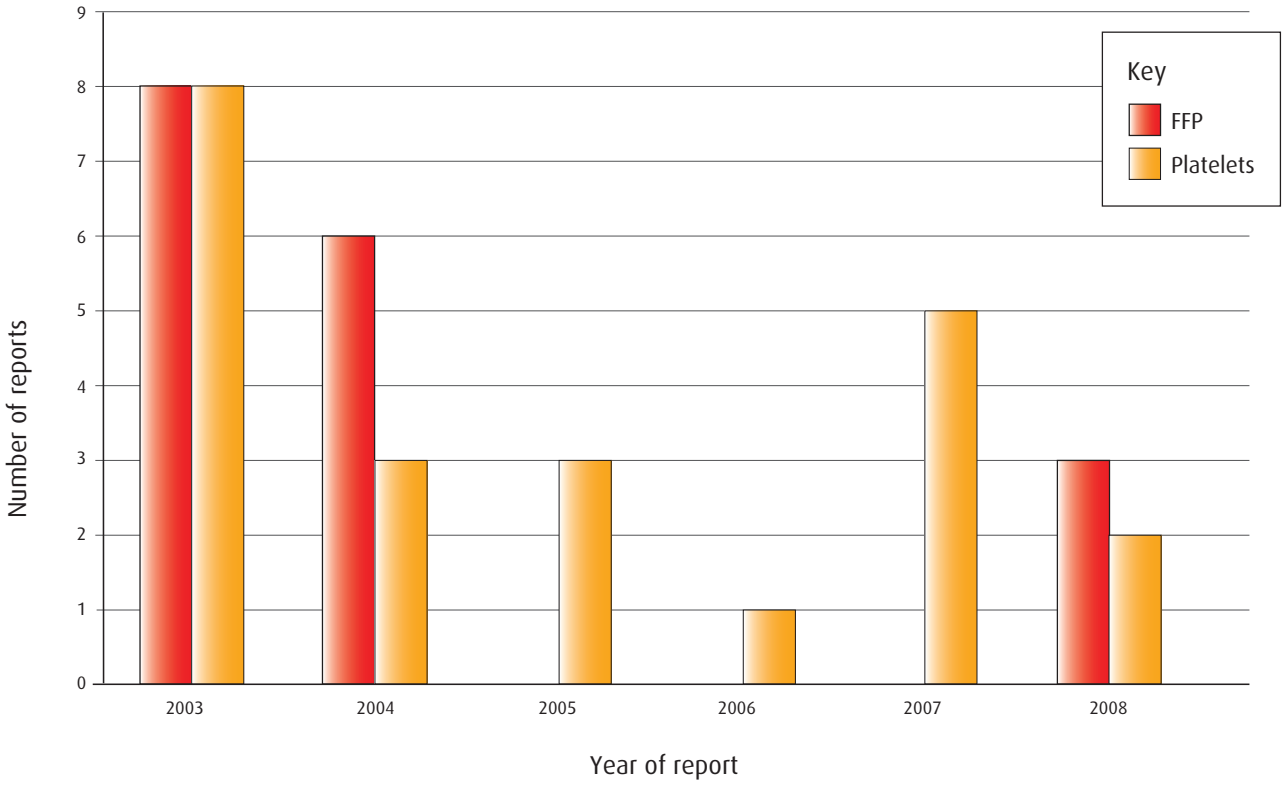
All implicated components with proven concordant donor leucocyte antibodies were donated by females. Platelets were implicated in 2 cases, of whom 1 received apheresis platelets and 1 received 3 different platelet pools in which 1 buffy coat per pool was from an implicated donor. The 3 implicated donors for the pools contributed only a buffy coat each. Three cases were found following female FFP. No case was found with a proven concordant antibody associated with RBC transfusion.

The reported risk of TRALI in 2008 following transfusion of components with concordant donor leucocyte antibodies was 1 in 98,362 units of all issued FFP and 1 in 129,210 issued units of platelets. No such case followed red cell transfusion. The risk following implicated female FFP was much higher at 1 in 9,283 of issued units.

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 2008. Results are shown in Figure 15. Disappointingly, 3 cases of TRALI have occurred following implicated female donor FFP in 2008. No case of TRALI due to FFP with concordant donor antibody was reported in 2005, 2006 or 2007, following the introduction of preferential use of male donors for FFP in late 2003.

Figure 15
Cases of TRALI with concordant donor antibody in FFP or platelet components 2003–2008

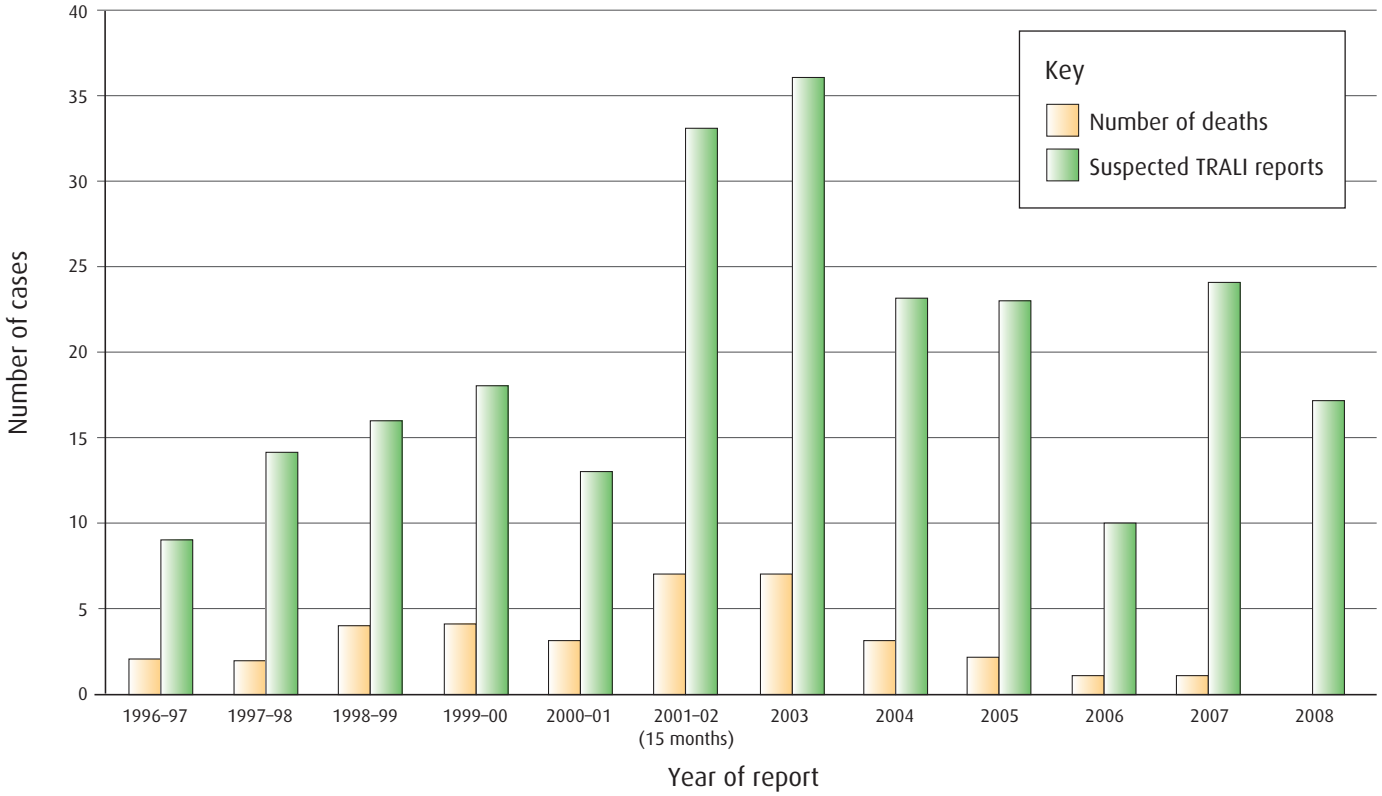


Annual reports and deaths 1996–2008

The annual number of reports of suspected TRALI and TRALI deaths at least possibly due to TRALI each year from 1996 are shown in Figure 16. 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.

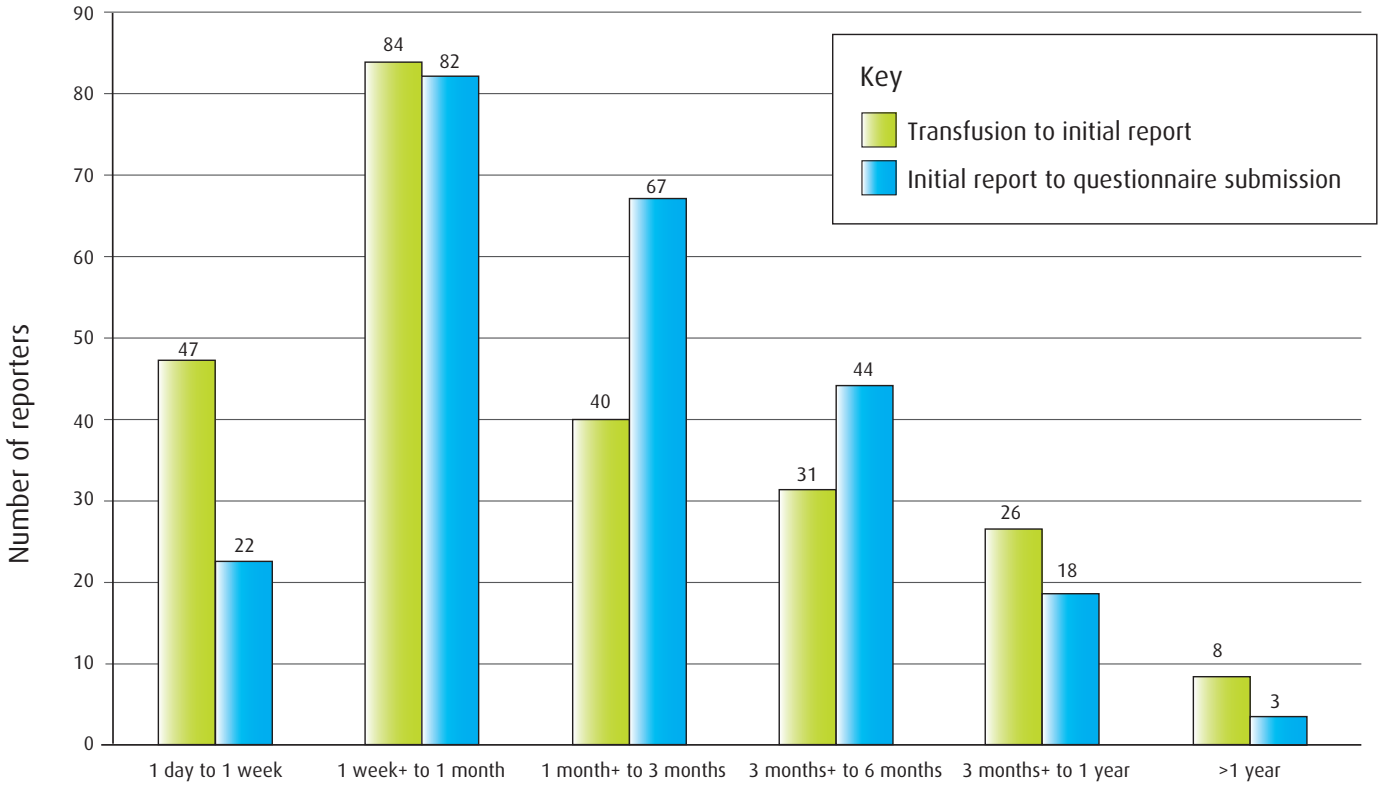
Figure 16 shows the frequency of TRALI, plus TRALI-related deaths, based on the date of receipt of the completed SHOT questionnaire at the SHOT office. This is the way the data has been presented in all previous SHOT reports.

Figure 16
Deaths at least possibly due to TRALI and number of suspected TRALI reports by year



The figure below demonstrates the problem of late reporting, showing that there are some cases of TRALI that are, for a variety of reasons, very slow to be reported fully.

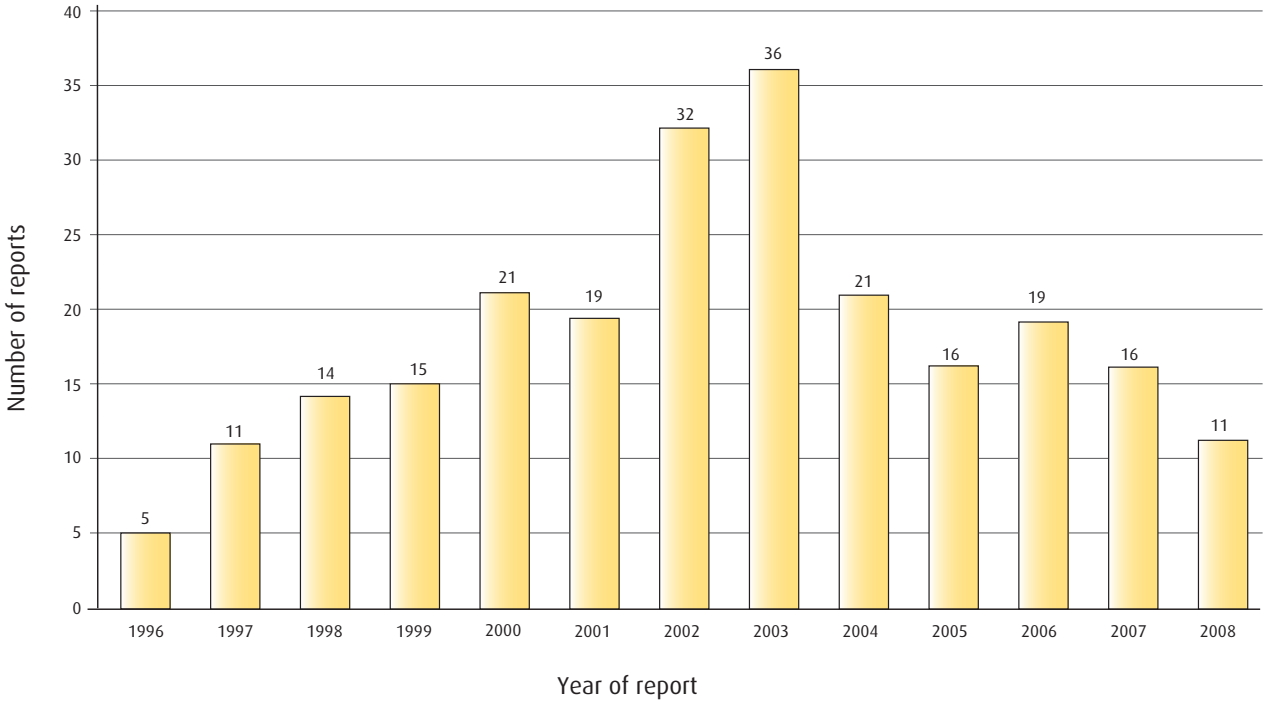
Figure 17



Perhaps a more meaningful graph is shown opposite in Figure 18, which demonstrates the number of TRALI reports assessed each year analysed by the date of each event instead of the date that each report/questionnaire was received.

This reduces the marked drop in reported TRALI cases in 2006 seen in Figure 16, which was accounted for by delayed reporting of a higher proportion of events in 2006 (the first full year of online reporting to MHRA and SHOT). However, the overall downward trend in the number of TRALI cases is more consistent, in keeping with the likely effect of the switch to preferential use of male plasma for FFP and platelets, which was rolled out gradually starting towards the end of 2003.

Figure 18
TRALI by year of transfusion *n* = 236



Case histories

TRALI highly likely

Case 1

Young man undergoing treatment for varices develops TRALI following platelet transfusion

A 17-year-old male with chronic liver disease was admitted for elective banding of oesophageal varices under general anaesthetic. He was transfused with 1 unit of platelets because he was thrombocytopenic and had a prolonged nosebleed. His chest X-ray showed 'no problems'. Next day he went to theatre where a further platelet unit was given during the procedure. The bands were applied uneventfully and his endotracheal tube was removed. He became severely hypoxic and hypotensive and his temperature increased to 40°C. He was reintubated and 'frank fountain-like pulmonary oedema' came through the tube. His chest X-ray showed bilateral pulmonary infiltrates. He was transferred to ITU and required mechanical ventilation for 6 days. His Hb level increased from 8g/dL pre-procedure to 17g/dL a few hours later. His recovery was complicated by infection, pleural effusion and renal impairment but he subsequently recovered fully.

Donor investigations showed that the apheresis platelets transfused in theatre were from a female donor with a history of two pregnancies 25 and 28 years previously but no transfusion. She had multiple HLA class I and class II antibodies, which included HLA-A2, -DR11, and -DR52 concordant with the patient. It was concluded that this was highly likely to have been TRALI due to HLA class I and class II donor antibodies.

Case 2

Young woman develops TRALI following transfusion of FFP to correct prolonged APTT

A 29-year-old woman was admitted with acute abdominal pain and an exploratory laparoscopy was planned. She was found preoperatively to have a prolonged APTT and was transfused with 3 units of FFP between 20.10 and 21.30. One hour later her oxygen saturation dropped to 74% on 100% oxygen. Her chest X-ray showed 'white lungs' and she required intubation and mechanical ventilation for 3 days. She subsequently made a full recovery.

Investigations showed that the first unit of fresh frozen plasma had been donated by a female donor who had multiple HLA class I and class II antibodies, including antibodies to HLA-B62, HLA-DR11 and HLA-DR52, all of which were concordant with the patient. The other 2 units of fresh frozen plasma were donated by untransfused males who were not tested. It was concluded that this case was highly likely to have been TRALI due to donor HLA class I and class II antibodies.

Case 3
Withdrawn case
A 37-year-old woman was admitted at 18.00 with a ruptured ectopic pregnancy and went to theatre almost immediately. Intubation was straightforward with no apparent gastric aspiration. She had 2.5L of blood in her abdominal cavity and was transfused with 2 units of RBC and 1.5L of gelafusin between 19.00 and 20.00. Her postoperative haemoglobin was 8.7g/dL and she received 400 mL gelafusin over the next 12 hours. At 08.50 the following morning (13 hours post transfusion) she complained of shortness of breath and cough. She had a respiratory rate of 18 and was put on 3L of oxygen by nasal specs with 0_2 saturation 98%. She deteriorated during the day and was admitted to ITU 2 days post transfusion. Her chest X-ray showed 'extensive bilateral pulmonary consolidation probably due to alveolar oedema' but there was no clinical evidence of fluid overload. Her ECG was normal. She was treated with antibiotics although she was afebrile and it was thought unlikely to be infection. Pulmonary embolism was considered and excluded. She received non-invasive respiratory support with CPAP and made a full recovery.

Investigations showed that one of the RBC donors was a female with HLA class I and HLA class II antibodies, including HLA-A2 and HLA-DR1, which were both concordant with the patient type.

Case conclusion: this case was withdrawn from analysis because it occurred well outside the 6 hour time limit required by both SHOT and the American–European consensus definitions. This was the only withdrawn case in which the clinical picture and the investigations were otherwise consistent with transfusion-related acute lung injury.

COMMENTARY

Observed rates of TRALI remain lower than in 2003–2004 when TRALI risk reduction strategies were first initiated.

No deaths occurred as a result of TRALI this year. This is the lowest rate since 1996.

Female donors were implicated in all cases where concordant donor antibody was found (5 cases, 7 components).

Disappointingly, 3 cases of TRALI have followed transfusion of female FFP containing concordant donor HLA antibodies. The observed risk of TRALI was 1 in 9,283 units of female FFP issued. This emphasises the need to achieve 100% use of male plasma for FFP across the UK.

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. NHSBT in 2008 produced 89% of FFP and 88% plasma for platelet pools from male donors: firm plans are in place to achieve 100% male FFP and plasma for platelet pooling by August 2009. Consideration should then be given to recall all female FFP previously issued to hospitals once stocks of male FFP are sufficient to replace it.

One case followed transfusion of a platelet pool. The 3 implicated donors donated only buffy coats to the pool. The main plasma contribution was from a man. No case has been reported this year associated with a female donor of the main plasma contribution to a platelet pool.

One case followed transfusion of an apheresis platelet unit from a female donor with multiple HLA class I and II antibodies. NHSBT has just initiated pre-testing of women who wish to become platelet apheresis donors for HLA antibodies. This is welcomed but would not have prevented this case. Testing of established female apheresis donors must be made an aim when sufficient new apheresis donors have been recruited to mitigate against donor loss.

One case with a clinical history and serology consistent with TRALI following red cell transfusion has been excluded from the data because the symptoms commenced 13 hours post transfusion (TRALI definition requires symptoms within 6 hours of transfusion). Further data on the possible time frame during which a 'true' TRALI may occur would be valuable.

RECOMMENDATIONS

New recommendations

- UK Blood Services that have not yet achieved 100% male FFP and plasma to platelet pools must make this a priority. Exchange of male FFP for previously issued female FFP should be undertaken whenever feasible.

  Action: NHSBT and NIBTS

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**	'Amendments and Corrections' to the BCSH guidelines 'Transfusion Guidelines for neonates and older children' clarifies these recommendations.
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**	This recommendation was made in the BCSH Guidelines (BCSH 2004).
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**	BCSH guidelines for investigation and management of transfusion reactions are in progress.
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**	

13. 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	1	*Implicated Components*		*Mortality / morbidity*	
		Red cells	1	Deaths due to transfusion	0
		FFP		Deaths in which reaction was implicated	0
		Platelets		Major morbidity	0
		Other *(specify)*			
		Unknown			

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male		16 years+ to 18 years		Emergency	1	ED	
Female	1	1 year+ to 16 years		Routine		Theatre	
Unknown		28 days+ to 1 year		Not known		ITU/NNU/HDU/Recovery	
		Birth to 28 days				Wards	
				In core hours		Community	
		Total	0	Out of core hours		Other	
				Not known/applicable	1	Not known	1

Three questionnaires were received. On review 2 were withdrawn because neither had antibodies directed against HPA. One had chemotherapy-induced thrombocytopenia and the other had pre-existing thrombocytopenia of undetermined cause. This section describes the main findings from 1 completed questionnaire.

Case

Thrombocytopenia 12 days after a red cell transfusion

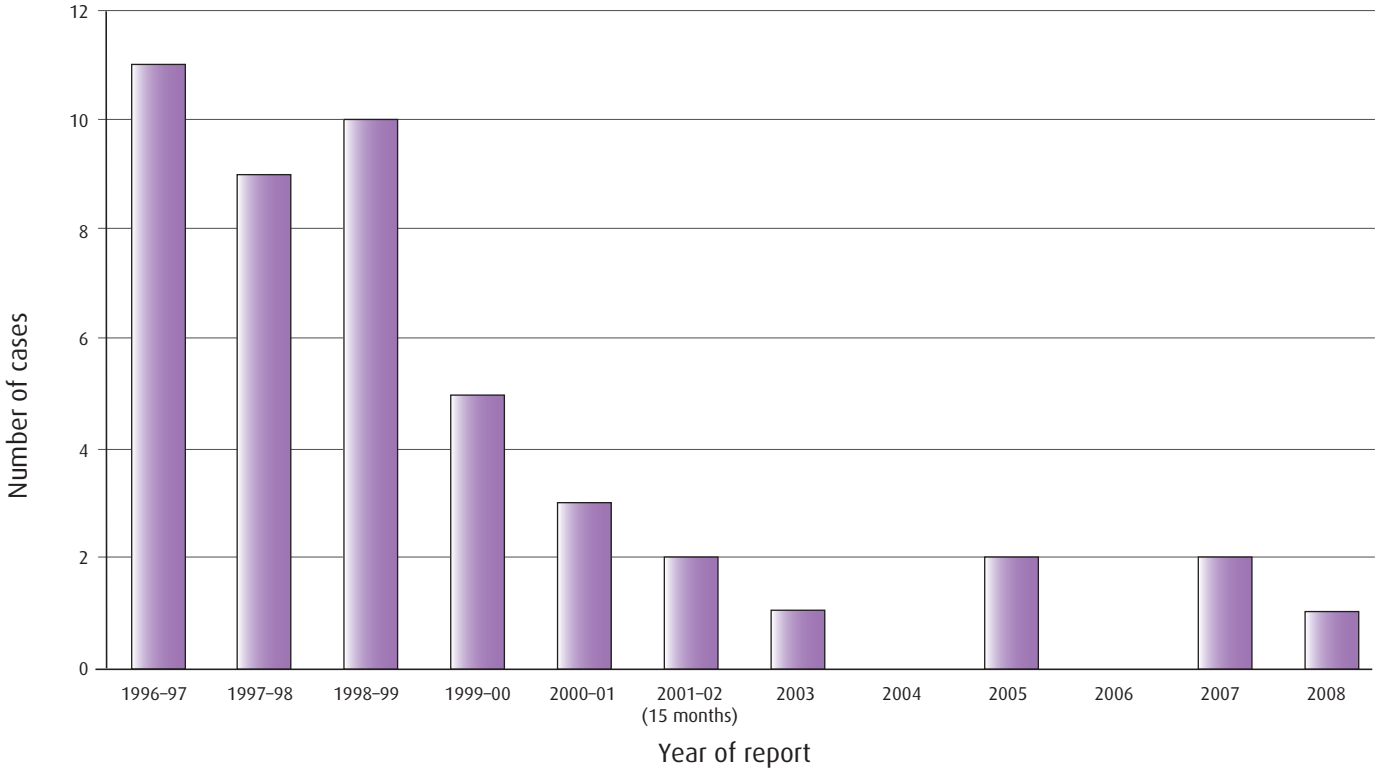
An 84-year-old female patient was admitted as an emergency with a fractured neck of femur. She had a normal preoperative platelet count (143 x 10^9/L) and was transfused with 3 units of red cells perioperatively. Twelve days later her platelet count was 6 x 10^9/L. She had purpura and bruising and platelet investigations were performed. Results indicated that her HPA genotype was HPA-1b1b and she had HPA-1a alloantibodies. She was treated with intravenous immunoglobulin (IVIg) and her platelet count recovered to above 50 x 10^9/L in 4 days and above 150 x 10^9/L in 5 days. She made a full clinical recovery. She had had 2 pregnancies many decades earlier but had never been transfused before.

Cumulative data

The chart in Figure 19 shows the number of antibody confirmed cases of PTP reported to SHOT annually since 1996; a total of 46 reports. A sustained decrease in the number of these cases has been observed since the introduction of universal leucodepletion in late 1999.

Since 1996, platelet antibodies with specificity for HPA-1a have been the most frequently identified. Thirty-six patients (78%) had HPA-1a antibodies either alone (31 cases) or in combination with other antibodies (5 cases). In 10 cases PTP was due to other HPA antibodies without HPA-1a. These included antibodies with specificity for HPA-1b, -2b, -3a, -3b, -5b and 15a, of which HPA-1b and HPA 3a antibodies were found most frequently (5 cases each). HPA-5b antibodies were found in only 1 case. All except 1 of the cases with non-HPA-1a antibodies were reported before the introduction of universal leucodepletion in 1999.

Figure 19
Number of cases of confirmed PTP reported to SHOT each year



RECOMMENDATIONS

There are no new recommendations this year.

Recommendations still active from previous years

- 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.

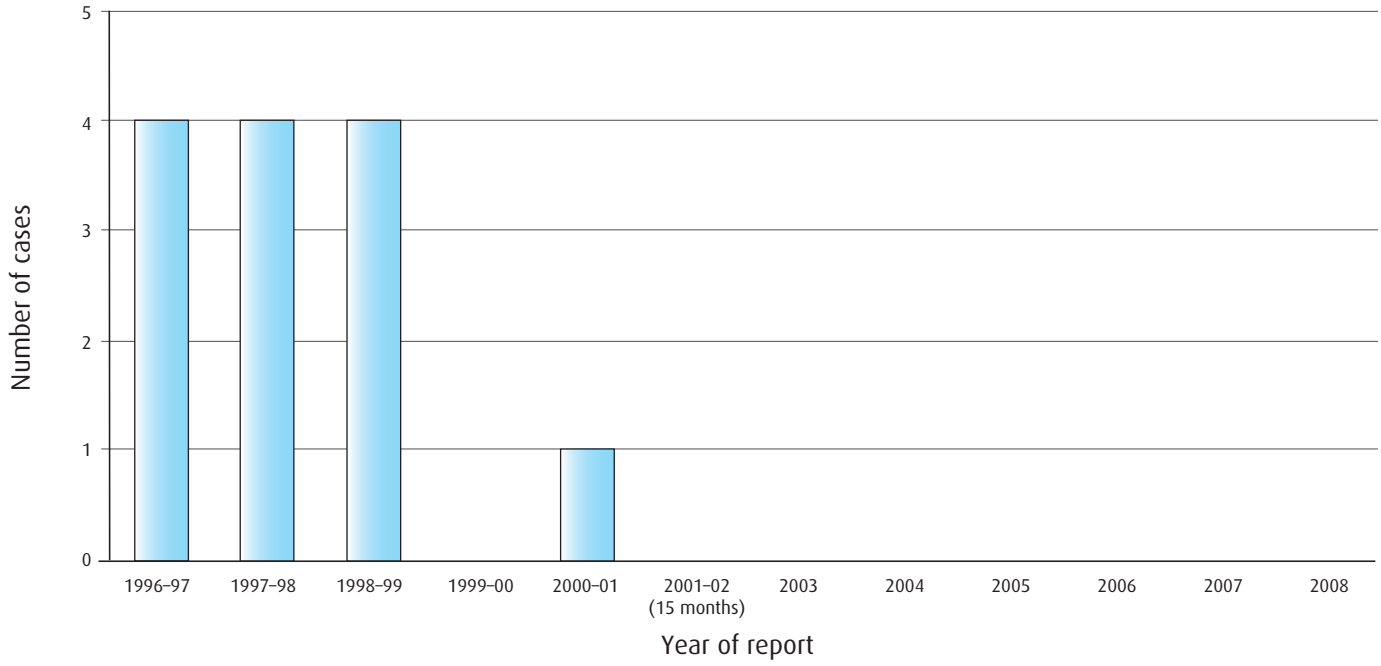
14. Transfusion-Associated Graft-versus-Host Disease (TA-GvHD)

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.

No new case of TA-GvHD was reported in 2008.

Figure 20
Number of cases of TA-GvHD reported to SHOT each year



COMMENTARY

- No report of TA-GvHD has been received during the last 7 years.
- A total of 13 cases of TA-GvHD have been reported to SHOT since 1996 all of which were fatal.
- Only 1 case has occurred since the introduction of leucodepletion of all components except granulocytes / buffy coats in late 1999; 2 cases have occurred following transfusion of leucodepleted components (1998–99 and 2000–01).
- This year 86 patients who had a requirement to receive irradiated blood in accordance with BCSH guidelines[27] received non-irradiated components but did not develop TA-GvHD. Sixty-three of these were attributed to clinical errors and 23 to laboratory errors. In the last 6 years there have been a total of 505 such cases, none of whom developed TA-GvHD.

RECOMMENDATIONS

No new recommendations from this report

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2003	Gamma or X-ray irradiation to 25 Gy of blood components for those at risk of GVHD remains essential. The BCSH Blood Transfusion Task Force Guidelines (1996) defines 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 the 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 that 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**	
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**	
2007	Teaching of junior haematology and oncology doctors should focus on the importance of irradiation and the rationale behind it. This education is part of the curriculum for specialist trainees, but foundation year doctors in these specialities may remain ignorant despite being frequently called on to order components.	**Hospital Trusts, Medical Schools, NBTC, Royal Colleges, Specialty Training Committees, GMC, PMETB**	
2007	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.	**Hospital Trusts, Hospital Liaison networks, BBT network, SHOT Transfusion Practitioner network**	

15. Transfusion-Transmitted Infections (TTI)

Definition

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

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

and, either:

- at least 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

Implicated Components		*Mortality / morbidity*	
Red cells	**0**	Deaths due to transfusion	**1**
FFP	**0**	Deaths in which reaction was implicated	**1**
Platelets	**6**	Major morbidity	**3**
Other *(specify)*	**0**		
Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**4**	< 18 years	**1**	Emergency	**1**	ED	**0**
Female	**2**	<16 years	**0**	Routine	**5**	Theatre	**0**
Unknown	**0**	<1 year	**0**	Not known	**0**	ITU/NNU/HDU/Recovery	**0**
		<4 weeks	**0**			Wards	**6**
				In core hours	**4**	Community	**0**
		Total	**1**	Out of core hours	**1**	Other	**0**
				Not known/applicable	**1**	Not known	**0**

Reports of suspected transfusion-transmitted infections

Most reports of suspected viral and bacterial transfusion-transmitted infections (TTIs) are received and investigated by the UK Blood Services and then reported to the NHSBT/HPA Infection Surveillance Unit. From here, data are included in the annual SHOT report. A number of reports are also received via the MHRA's online reporting system for Serious Adverse Blood Reactions and Events (SABRE).

Incidents reported in any one year to the blood services and/or MHRA are included in the same SHOT reporting year, even if the investigation is not yet complete, as the investigation into some suspected viral TTIs can take several months to complete.

During 2008, 33 suspected TTI incidents were reported by blood centres and hospitals throughout the UK.

Of these, 4 were confirmed (all bacterial, described below) according to the above definition; and among the remainder, in 1 case the bacterial report was concluded as undetermined (i.e. it was not possible to confirm or refute that the patient's infection was acquired via blood transfusion); in 2 incidents it was not possible to confirm or refute TTI because the blood unit was not available for investigation; in 23 investigations, the conclusion was not TTI (3 hepatitis B [HBV], 7 hepatitis C [HCV], 3 HIV, 1 Parvo B19, 1 toxoplasmosis, 1 chickenpox and 7 bacterial); and 3 incidents (1 HBV, 2 HCV) are pending complete investigation.

CONFIRMED INCIDENTS

Report of transfusion-transmitted *Staphylococcus epidermidis*

An elderly male patient was transfused with a unit of pooled platelets for thrombocytopenia. During the transfusion the patient developed chills, rigors, back pain and hypotension, and the transfusion was stopped. *Staphylococcus epidermidis* was isolated from patient blood cultures taken at the time of the reaction, and from the remains of the platelet pack. Four associated red cell units and 1 unit of fresh frozen plasma were recalled by the blood services but were found to be negative on culture.

All 4 donors contributing to the platelet unit were recalled. *S. epidermidis* was identified from venepuncture site samples from 2 of the donors, from pre-cleaning swabs only. Pulse field gel electrophoresis (PFGE) revealed that 1 of the strains was identical to that isolated from the remains of the platelet pack. The blood culture isolate from the patient was not available for further investigation and so it was not possible to determine whether all 3 isolates (from patient, donor and pack) were of identical strains. However, contamination of the platelet unit by skin flora from the donor venepuncture site was probably responsible for the patient's reaction. *S. epidermidis* is a common skin commensal and it is recognised that the donor arm cleansing procedure is not 100% effective.[28] Informal quality audits carried out by the blood services during 2008 suggested that the procedure could be improved, and an extensive staff re-training exercise was undertaken (see commentary).

Report of transfusion-transmitted Group G streptococcus (2 recipients)

A unit of apheresis platelets was split to produce 2 platelet doses. Pack 1 was transfused to a teenager with acute lymphoblastic leukaemia (ALL) who reacted with allergy-like symptoms. Pack 2 was transfused to a female patient in her 50s with acute myeloid leukaemia (AML) who developed chills, nausea and a feeling of impending doom. The remains of both units were returned to the blood services for investigation, with a delay in the return of pack 1 due to the initial diagnosis of an allergic reaction.

Blood cultures from both patients yielded Lancefield Group G streptococcus (GGS), as did cultures of both platelet units carried out at the blood services. GGS are known as both commensals and pathogens in animals and humans.[29] The apheresis donor denied any recent illness or change in bowel habit, but GGS was identified from their stool sample.

All 5 isolates (from both patients, both packs and the donor) were sent to a national reference laboratory for typing, and were found to be of the same strain. The likely but unproven chain of transmission was from donor gut to venepuncture site via the donor's fingers, and from there to the donated component. As with the previous case, it cannot be guaranteed that this chain of transmission would be prevented by donor arm cleansing (see commentary).

Report of transfusion-transmitted Group G streptococcus

A woman in her 50s with severe aplastic anaemia received 1 unit of pooled platelets. Within 5 minutes of starting the infusion the patient developed urticaria and pain along the access vein. She was given antihistamine and the transfusion was continued. One hour later she became pyrexial and hypotensive, requiring admission to the Intensive Therapy Unit (ITU). The transfusion was stopped and patient blood cultures were taken. These revealed Lancefield Group G streptococcus (GGS), as did cultures of the remains of the platelet pool. Four units of red cells and 1 unit of fresh frozen plasma associated with the implicated pack were recalled but cultures of these were all negative.

The donors contributing to the platelet pool were recalled; GGS was identified in stool samples provided by 3 of the 4 donors. Typing confirmed that 1 of these isolates represented the same strain as that isolated from both the patient blood cultures and the platelet unit. The donor denied any illness at or around the time of donation.

Report of transfusion-transmitted *Klebsiella pneumoniae* (two recipients)

A donation of apheresis platelets was split to produce 2 platelet doses. The first was transfused into a male neurosurgery patient (head injury) with pre-existing ischaemic bowel, liver disease and sepsis. The patient died 11 hours post transfusion and death was thought to be due the sepsis from the ischaemic bowel. As a transfusion reaction was not suspected, the transfused pack was not retained for further investigation. However, blood cultures had been taken from the patient prior to his death.

The second recipient was a male patient with AML with chemotherapy-related pancytopenia. Five minutes into the transfusion the patient became acutely unwell, requiring admission to ITU where he subsequently suffered a cardiac arrest and died. Blood cultures had also been taken from this patient prior to his death. The remains of the transfused pack were cultured at the hospital microbiology laboratory before being returned to the blood services.

Blood cultures from both patients yielded *Klebsiella pneumoniae*, as did cultures of the unit transfused to the patient with AML, and all 3 isolates were found to be of a single strain. The case was concluded as a proven incident of bacterial contamination of two platelet units with *K. pneumoniae*. This probably resulted in the death of the first patient and contributed to the death of the second. The source of the organism was most likely the donor gut, transferred to the venepuncture site and from there to the donated component. Both incidents were reported to the local Strategic Health Authority (SHA) as a Serious Untoward Incident.

OTHER INCIDENTS

Three suspected TTI investigations were undetermined in 2008. In 2 cases the blood packs transfused were not available for further investigation post transfusion to confirm or refute TTI. Similar cases appear in the Acute Transfusion Reaction (ATR) chapter in which it was not possible to confirm whether the patient's reaction was a result of bacterial contamination or due to some other cause.

Undetermined investigation: *Pantoea agglomerans*

An elderly, frail patient was transfused with 3 units of red cells for tumour related anaemia. After 200 mL of the third unit the patient developed chills, rigors, wheeze and shortness of breath, and died within an hour. The differential diagnosis included bacterial contamination, TRALI and fluid overload. The patient was not on antibiotics at the time of reaction and blood cultures were not taken.

The 2 empty packs and the remains of the third unit were returned to the blood service for investigation. The empty packs were washed out with sterile saline and cultures were set up. The exterior of the third pack was heavily contaminated with blood, and both ports had been used and blocked with spigots. Cultures were taken. This unit had been cultured at the hospital microbiology laboratory where Enterobacter species, Pantoea species and *Enterococcus faecalis* were grown. These organisms are all part of the normal intestinal flora.

Cultures of the first and second (empty) units yielded no growth and *Bacillus pumilus* respectively, while culture of the third unit yielded *Pantoea agglomerans*, consistent with the results from the cultures performed by the hospital. *Pantoea agglomerans* rarely causes infection in the normal host but is a common nosocomial isolate, arising from the endogenous intestinal flora of hospitalised patients. This recipient had metastatic carcinoma of the bowel and extensive oesophageal varices, so this organism could have originated from the patient. However, in the absence of blood cultures taken prior to the transfusion, confirmation is not possible. Similarly, it is not possible to confirm that the source of the coliform was a contaminated unit of blood, or that the coliform was the cause of, or contributed to, death.

Histopathology was inconclusive and investigation into possible TRALI is ongoing.

Undetermined investigation: blood unit not returned to blood service

An elderly patient with chronic myeloid leukaemia (CML) developed a pyrexial reaction during the second unit of a 2 unit red cell transfusion. The patient's blood cultures subsequently grew *Streptococcus sanguinis* and *Streptococcus salivarius*. The red cell unit was discarded and was not cultured. As a result, it is unknown whether this patient's infection was acquired via blood transfusion or not. The patient was treated with antibiotics and made a full recovery, and the hospital's policy on notifying the blood service of suspected TTI incidents was reviewed.

Undetermined investigation: blood unit not investigated by blood service

A male patient was transfused with 3 units of red cells for haematuria with urine retention. Five to 10 minutes into transfusion of the third unit the patient developed rigors and pyrexia. The transfusion was stopped and blood cultures were taken both after the initial reaction occurred and 12 hours later. Both cultures grew *Enterococcus faecalis*. No cultures had been taken from the patient prior to transfusion. The implicated unit was sent to the local blood centre but was not cultured for bacterial growth. Despite investigations into patient samples (culture of pre-transfusion urine and

catheter samples: both negative), an alternative source of infection was not found. It is unknown whether this patient's infection was acquired via blood transfusion or not.

Near Miss

In this category, 1 of 2 doses of apheresis platelets was returned to the blood service after blood bank staff noticed a large clump in the pack (Figure 21). The second dose was recalled and its appearance was normal. *Staphylococcus aureus* was isolated from the index pack. The donor was suspended from donation and skin, nasal and venepuncture site samples were taken. *S. aureus* was identified from the nasal sample. PFGE analysis confirmed that the isolates from the donor's nose and from the platelet unit were of the same strain. The donor did not appear to have a naturally high bacterial skin count; no *S. aureus* was detected from the skin and there was no history of skin disease. The donor was re-instated to an active donation status and requested to wash his hands and arms prior to making subsequent donations.

Figure 21
Staphylococcus aureus in apheresis platelet unit

Investigations reported as pending in previous years

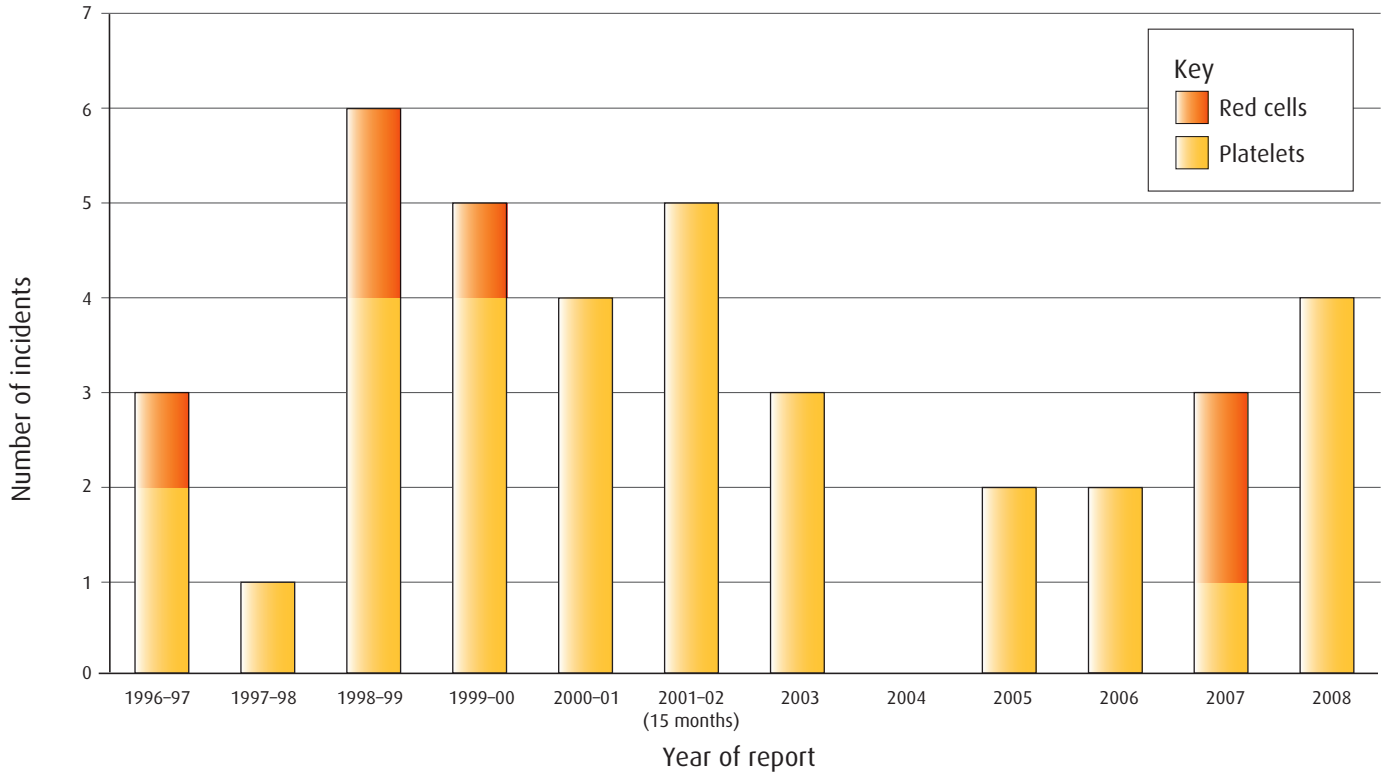
The CMV investigation pending in 2007 is now complete. No donor was found to have evidence of CMV infection, and it was concluded that there was no evidence of a transfusion-transmitted infection.

Cumulative data

Bacterial TTIs

Since 1996, a total of 38 bacterial TTI incidents have been confirmed (Figure 22), involving a total of 40 recipients (Tables 50 and 51). In total, 32 incidents have related to the transfusion of platelets and 6 have related to the transfusion of red cells. All of the confirmed cases in 2008 related to the transfusion of platelets.

Figure 22
Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from October 1998)*

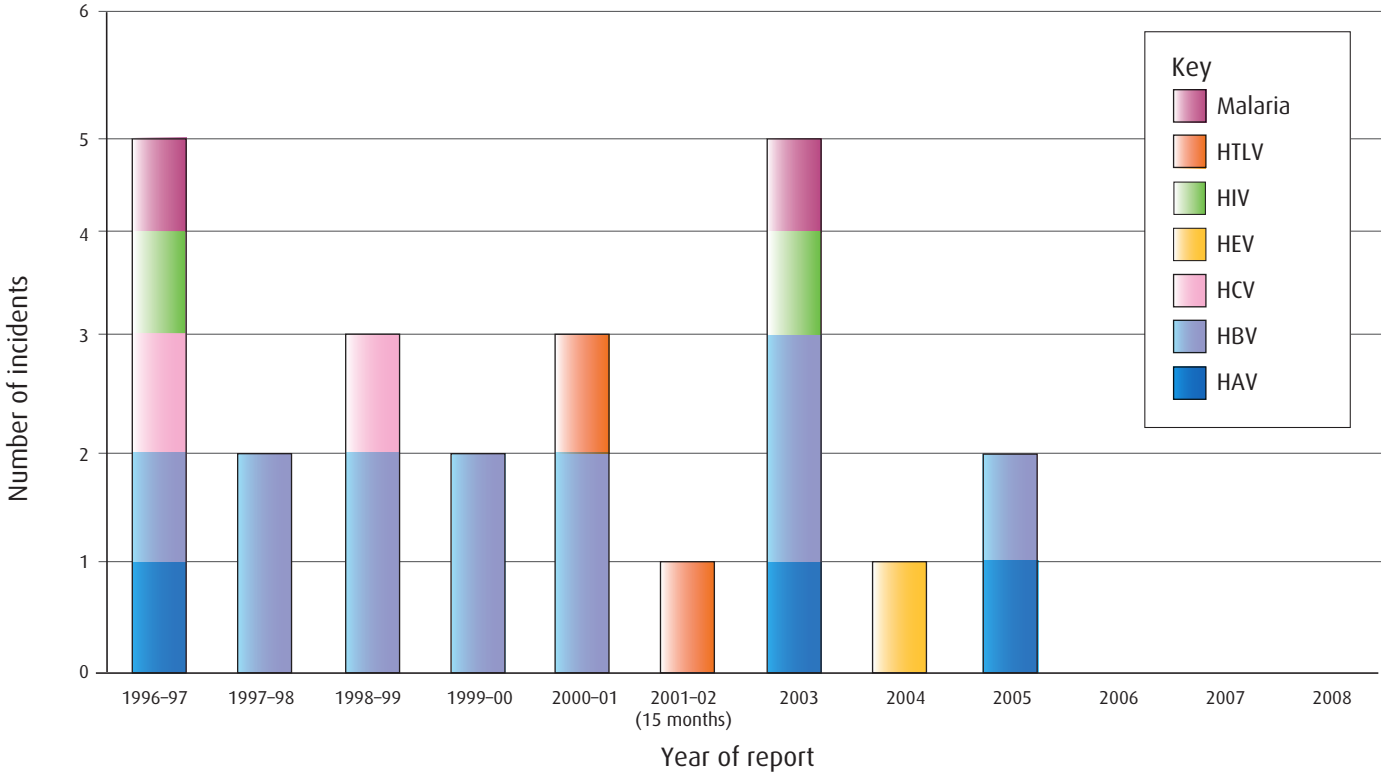


* *In 2004 there was a further incident (not included in Figure 22) involving contamination of a pooled platelet pack with S. epidermidis that did not meet the TTI definition because transmission to the recipient was not confirmed, although it was likely.*

Viral and parasitic TTIs

Since 1996, 22 confirmed incidents of transfusion-transmitted viral and parasitic infections have been reported (Figure 23), involving a total of 25 recipients. These include 10 HBV incidents (11 recipients), 3 HAV (3 recipients), 1 HEV (1 recipient), 2 HCV (2 recipients), 2 HIV (4 recipients), 2 HTLV (2 recipients) and 2 malaria (2 recipients) (Tables 50 and 51). There were no confirmed transfusion-transmitted viral or parasitic infections in 2006, 2007 or 2008.

Figure 23
Number of viral and parasitic TTI incidents, by year of report and infection type (Scotland included from October 1998)*†



* *The year of transfusion may 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.*

† *In 2003 an anti-HIV negative donation (donated in 2002) was reported HIV RNA positive on retrospective testing of a seroconverting donor. Red cells from the seronegative unit had been transfused into an elderly patient who died soon after surgery and her HIV status was not determined prior to death (not included in Figure 23).*

vCJD

To date, there have been 4 incidents involving the transmission of vCJD/prion infection via blood transfusion (no change from 2007 report, see Table 50 and Table 51 below). Reporting of suspected vCJD transmissions differs from that of other infections. The cases that have been reported were among a small group of recipients of blood who were under active surveillance because they had received blood components from donors who later developed vCJD. The 4 identified individuals had received non-leucodepleted red blood cells between 1996 and 1999.

Since 1997, the UK Blood Services have introduced a number of precautionary measures:

- 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)
- exclusion of donors who have received a blood transfusion in the UK since 1980 (2004).

Table 50
Number of confirmed TTI incidents in the UK between October 1996 and December 2008, by SHOT reporting year (Scotland included from October 1998)

	10/1996–09/2001	10/2001–12/2006	2007	2008	Total
Bacteria	19	12	3	4	**38**
HAV	1	2	0	0	**3**
HBV	7	3	0	0	**10**
HCV	2	0	0	0	**2**
HEV	0	1	0	0	**1**
HIV	1	1	0	0	**2**
HTLV	1	1	0	0	**2**
Malaria	1	1	0	0	**2**
vCJD/Prion	0	4	0	0	**4**
Total	**32**	**25**	**3**	**4**	**64**

Table 51
Number of infected recipients identified and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2008 (Scotland included from October 1998)

	Number infected recipients identified	Death (due to infection)	Major morbidity	Minor morbidity
Bacteria	40	10	26	4
HAV	3	0	2	1
HBV	11	0	11	0
HCV	2	0	2	0
HIV	4	0	4	0
HEV	1	0	0	1
HTLV	2	0	2	0
Malaria	2	1	1	0
vCJD/Prion	4	3	1	0
Total	**69**	**14**	**49**	**6**

COMMENTARY

In 2008, 4 confirmed bacterial TTI incidents were reported involving the transfusion of contaminated components to 6 recipients, 4 of whom recovered and 2 of whom died (1 death due to transfusion, 1 death in which transfusion was implicated). All 4 incidents related to the transfusion of platelet units. In 2 of the 4 cases, an apheresis donation was split in 2 and transfused into 2 recipients.

Of these, 4 transfusions took place within core hours, 1 took place outside of core hours and the time of 1 transfusion was unknown. There were 5 routine transfusions and 1 emergency transfusion (patient critically ill with head injury).

It is recognised that donor arm cleansing techniques are unlikely to be 100% effective in removing bacteria from the venepuncture site.[28] However, informal quality audits in 2008 suggested that the procedure could nevertheless be improved. An extensive staff re-training exercise has been undertaken and monitoring logs were implemented

to observe and record evidence of practice standards. A national audit programme is being developed to support effective pre-donation skin preparation. The UK blood transfusion services (UKBTS) have also asked the Standing Advisory Committee on Transfusion-Transmitted Infections (SACTTI) to produce standards on how donor arm cleansing should be monitored.

The 3 undetermined investigations in 2008 were all associated with the transfusion of red cells. The first case involved a unit in which the exterior was heavily contaminated with blood. The other 2 cases related to blood units that were not cultured for bacterial growth either because the bag had been discarded by the hospital or because the bag was delayed in transit to the blood service These incidents highlight the importance of care in the handling, transport and storage of units involved in post-transfusion reaction investigations. Packs must be appropriately sealed and packaged, and internal processes must ensure the timely return of units to the blood services and to the bacteriology laboratory. If hospitals choose to culture packs locally, the pack must still be returned to the blood services for further investigation.

Two TTI incidents in 2008 involved the transfusion of an implicated donation to more than 1 recipient. Suspected cases must be reported promptly so that associated units may be recalled. Difficulties arise when it is uncertain whether the reaction was due to a bacterial cause or not.

Visual inspection of 1 platelet unit prevented the probable transmission of *S. aureus* (Near Miss incident). It is important that staff starting a transfusion visually check all components prior to doing so. However, bacterial contamination can still occur in the absence of visible features.

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) is scheduled to discuss bacterial screening and pathogen inactivation of platelets in July 2009.

For the third consecutive year there were no confirmed viral transmissions, consistent with the very low estimated frequency of infectious donations entering the UK blood supply (2006-2007):

HIV 0.21 per million donations tested
HCV 0.02 per million donations tested
HBV 1.17 per million donations tested
HTLV 0.09 per million donations tested

For more information see www.hpa.org.uk. *(Follow the headings: infectious diseases, topics A-Z, blood borne infections in blood donors, epidemiological data.)*

Surveillance of TTIs tends to be biased towards acute cases that are immediately clinically apparent, but a high index of suspicion is required to ensure that the correct investigations are carried out. The onset of symptoms related to a transfusion-transmitted viral infection may occur from several weeks to years after the date of the transfusion. As a result incidents involving transfusion-related chronic infection may not be suspected and reporting may be incomplete.

RECOMMENDATIONS

New recommendations from this report

- Staff must maintain a high index of suspicion of bacterial causes when managing acute transfusion reactions. Symptoms may appear to be more allergic in nature, but cultures must still be performed whenever bacterial contamination is a possibility.

  Action: Hospital Transfusion Teams

- Staff involved in transfusion should report suspected cases of bacterial contamination to the blood services as soon as possible, in order to facilitate the return of implicated packs and the recall of any associated units, even though in some cases it may be difficult to determine whether the patient's reaction was due to a bacterial cause.

  Action: Hospital Transfusion Teams/UK Blood Services

- Strategies to reduce bacterial contamination of blood components should continually be reviewed. SHOT welcomes the involvement of SaBTO in this process.

  Action: SaBTO, UK blood services

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.	**Hospital Transfusion Teams**	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) - Enhanced donor arm cleansing using chlorhexidene - 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, blood collection teams, 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 possible interventions, such as bacterial screening and/or pathogen inactivation.
2003	Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately.	**Hospital Transfusion Teams**	Serious Adverse Reactions are required to be reported by hospitals under the terms of the BSQR.

16. 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

DATA SUMMARY

Total number of cases	18

Implicated Components	
Red cells	15
FFP	6
Platelets	2
Cryoprecipitate	1
20% human albumin solution	2
Unknown	0

Mortality / morbidity	
Deaths due to transfusion	0
Deaths in which reaction was implicated	1
Major morbidity	6

Gender	
Male	8
Female	10
Unknown	

Age	
16 years+ to 18 years	0
1 year+ to 16 years	0
28 days+ to 1 year	0
Birth to 28 days	0
Total	0

Emergency vs. routine and core hours vs. out of core hours	
Emergency	5
Routine	10
Not known	3
In core hours	10
Out of core hours	7
Not known/applicable	1

Where transfusion took place	
ED	
Theatre	1
ITU/NNU/HDU/Recovery	4
Wards	11
Community	
Other (Haematology Day care)	1
Not known	1

Data for 2008 have been collected on a new specifically designed questionnaire. Seventeen questionnaires were received; 2 were transferred in from the ATR section, resulting in a total of 19 cases. One of the 19 cases was assessed as unlikely to be TACO. This patient did not appear to exhibit classical features of an allergic reaction nor meet criteria for TRALI, and the reaction was categorised as a probable case of 'transfusion-associated dyspnoea' (TAD). It has not been included in this chapter but transferred to the new TAD chapter.

TACO definition

Based on the above definition from the International Society of Blood Transfusion (ISBT),[4] cases were assessed by the reviewer for probability for a diagnosis of TACO. Overall 6/18 cases were assessed to be highly likely (imputability 3), 8/18 cases were assessed to be probable (imputability 2), and 4/18 possible (imputability 1). The classification according to diagnostic criteria is shown in Table 52 below.

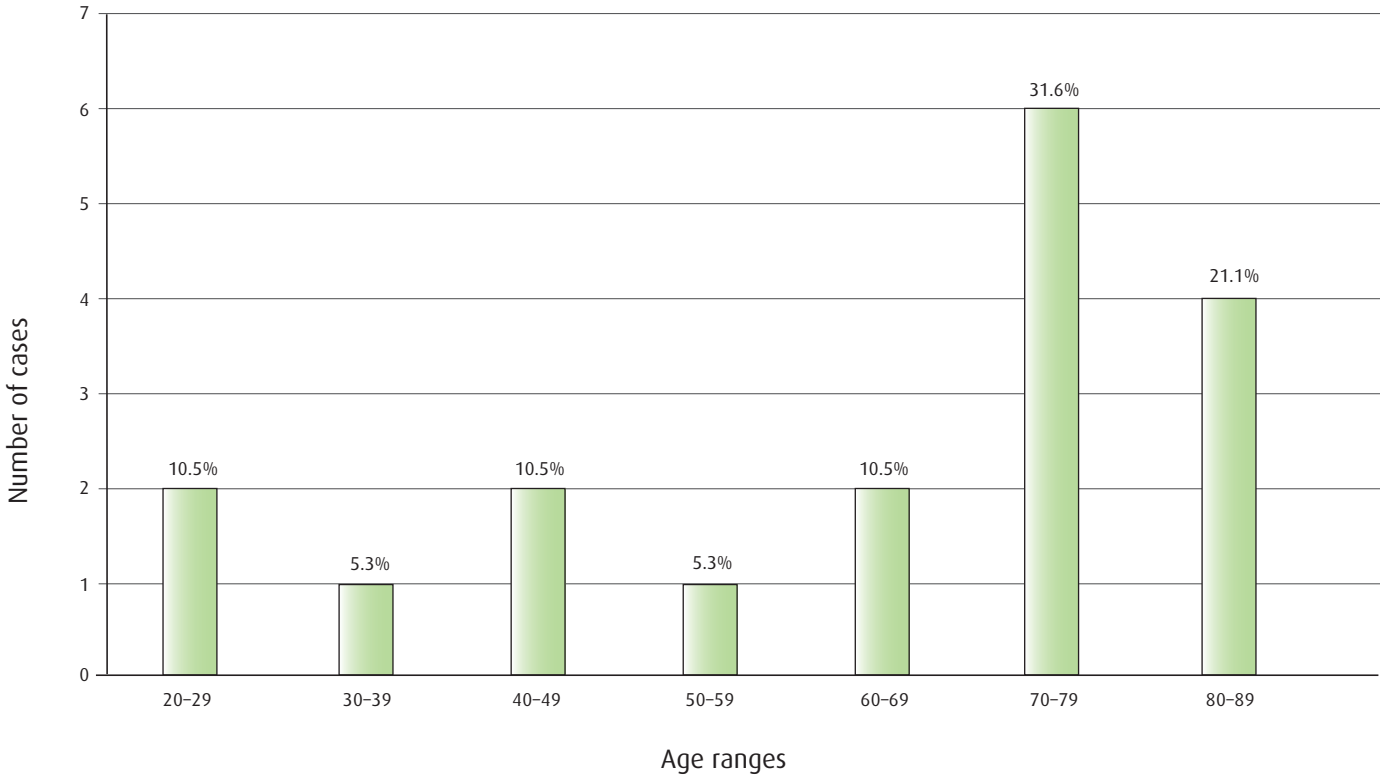
Table 52
Classification of cases according to diagnostic criteria, probability of TACO and imputability

Case number	Age & Sex	Acute respiratory distress	Tachycardia	Increased BP	Acute or worsening pulmonary oedema	Evidence of positive fluid balance	Probability of TACO	Imputability
1	M79	Yes	Yes	Yes	Yes	NR	Highly likely	3
2	M52	Yes	Yes	Yes	Yes	Yes	Highly likely	3
3	M77	Yes	No	Yes	Yes	Yes	Highly likely	3
4	F20	Yes	Yes	NS	Yes	Yes	Possible	1
5	F82	Yes	NS	NS	Yes	NR	Probable	2
6	M46	Yes	No	No	Yes	Yes	Possible	1
7	M60	Yes	Yes	No	Yes	Yes	Highly likely	3
8	M73	Yes	No	Yes	Yes	NR	Probable	2
9	M86	Yes	No	Yes	Yes	NR	Probable	2
10	F41	Yes	No	No	Yes	NR	Probable	2
11	M64	Yes	No	No	Yes	Yes	Probable	2
12	M74	Yes	Yes	Yes	Yes	Yes	Highly likely	3
13	F23	Yes	PEA arrest	No	Yes	No	Probable	2
14	M80	Yes	No	Yes	Yes	NR	Probable	2
15	F77	Yes	Yes	Yes	No	NS	Possible	1
16	F83	Yes	Yes	Yes	Yes	Yes	Highly likely	3
17	M36	NS	Yes	Yes	NS	NS	Possible	1
18	F73	Yes	Yes	No	NS	NS	Probable	2

Patients

There were 18 patients with TACO, 8 men and 10 women. The median age of these 18 patients was 72.5 (range 20–86) years, with 5 patients under 50 years. Over half the cases of TACO (10/18; 56%) occurred in patients >70 years. There were no patients under 18 years. The distribution of the patients' ages in those who had TACO is shown in Figure 24.

Figure 24
TACO: Distribution of patients' ages *n* = 18



Mortality *n* = 1

One patient with TACO died with the transfusion reaction implicated.

Case 13

A patient on ECMO receives massive red cell and platelet transfusion and suffers a fatal cardiac arrest

A 23-year-old woman was on extracorporeal membrane oxygenation (ECMO), which leads to consumption of RBC and platelets, and had liver failure. She was transfused 13 units of RBC, cryoprecipitate (1 adult dose) and platelets (3 pools), in ITU prior to a heart transplant. The rates of transfusion were not documented. The transfusion was followed by a severe hypotensive episode and a PEA (pulseless electrical activity) arrest. There was no evidence of bacterial contamination. The patient was multiply pre-transfused (as a childhood leukaemia survivor after a bone marrow allograft 20 years previously) and therefore screening for IgA deficiency was not performed. The referring team considered that the volume load probably triggered acute cardiac decompensation and the fatal cardiac arrest in this high risk patient (imputability 2).

Major Morbidity *n* = 6

Three of 18 patients with highly likely TACO (*n* = 1) were stated to have been transferred to the ITU as a result of the reaction (Case 1, Case 11 and Case 14), and 1 of these (Case 14) required continuous positive airway pressure therapy (CPAP). Imputability in these cases was assessed to be 3, 2 and 2 respectively.

A further 2 patients required ITU admission for other reasons, but the reporter stated that the reaction necessitated ventilation (Case 6 and Case 10, imputability 1 and 2 respectively). The reaction was stated to have necessitated CPAP in a sixth patient who was already in ITU (Case 7, imputability 3). Therefore, 5/18 patients with highly likely or probable TACO plus 1 possible case (i.e. 6/18; 33%) required ITU admission / ventilation / CPAP.

The details in these 6 cases are given below (asterisked).

Other serious morbidity *n* = 4

In a further 4/12 cases (22.2% of the total 18 patients with TACO), the reporter assessed that the reaction was life-threatening even though it did not fulfil the criteria for major morbidity. Therefore, TACO is a significant cause of serious morbidity.

Minor morbidity *n* = 8

All the remaining 8 patients with highly likely, probable or possible TACO experienced symptoms/signs.

Clinical details and transfused fluids in TACO cases

Table 53 summarises the clinical diagnosis or indication for transfusion in each case, the blood components and products transfused and the rate of transfusion, as well as details of other IV fluids given and fluid balance during the 24 hours prior to the reaction. Details on the rate of transfusion were recorded in 14/18 cases of TACO. The median time between the transfusion and the onset of symptoms was 0–2 hours in 10/18 cases (55.6%), 2–6 hours in 4 cases (22.2%) and 6–12 hours in 4 cases (22.2%). Details regarding IV fluids were given in 9 cases. Fluid balance was recorded in 7 of these 9 cases, and in a further 2 cases.

Table 53
Clinical diagnosis or indication for transfusion

Case no.	Sex & Age	Diagnosis/Indication for transfusion	RBC Units	FFP mL	Other	Rate of transfusion	IV fluids	Fluid balance mL
1*	M79	Chronic anaemia Hb 5.4g/dL	1+	0	0	NR	NR	NR
2	M52	Possible post-gastrointestinal bleed, varices, renal impairment, Hb 5.6g/dL, INR 1.9	3+	2000	20% HAS 400 mL	NR	0	+2200
3	M77	Sepsis / generally unwell, Hb 9.6g/dL	2+	0	0	4hrs/unit	2L crystalloid	+742
4	F20	Postpartum haemorrhage ~2L	4	0	0	4 RBC units/1 hr	2.5L colloid 1L crystalloid	+2800
5	F82	Myelodysplastic syndrome, thrombocytopenia platelets 3, Hb 9.6g/dL	2	0	Platelets 1 pool	RBC 2 hrs/unit Platelets 30 mins	NS	NR
6*	M46	Intraoperative haemorrhage: excision of tumour C4	9	300	0	Rapidly intra-op	2.2L colloid 3.5L crystalloid	+3700
7*	M60	Alcoholic cirrhosis, Acute renal failure	0	600	20% HAS 300 mL	30 mins/unit	1.9L colloid / crystalloid	+2465
8	F73	Coeliac disease, renal failure, history of MI Hb 7.6g/dL	2+	0	0	~3hrs/unit	NS	NR
9	F86	Atrial fibrillation, post-debridement of wound Hb 8.6g/dL	2	0	0	3hrs/unit	NS	NR
10*	F41	Postpartum haemorrhage ~3.5L	4	1000	0	rapidly	1L colloid 1L crystalloid	NR
11*	M64	Cholangiocarcinoma	0	2,750	0	1hr/unit	240 mL colloid 1L crystalloid	+1637
12	F74	Acute on chronic renal failure, recent MI Hb 6.9g/dL	1+	0	0	3hrs/unit	NS	+745
13	F23	Pre-heart transplant, on ECMO	13	0	Platelets 3 pools cryoprecipitate 1 adult dose	NR	NS	-640
14*	M80	Lymphoma Pre-op Hb 8.7g/dL	2+	0	0	~3.5hrs/unit	NR	NR
15	F77	Anaemia ?cause, recent MI, Hb 6.4g/dL	2	0	0	3hrs/unit	0	NS
16	F83	Myeloma, anaemia Hb 7.9g/dL	1+	0	0	4hrs/unit	1L crystalloid Oral fluid 800 mL	+1430
17	M36	Status epilepticus, liver impairment deranged clotting	0	1250	0	NS	NS	NS
18	F72	Chronic iron deficiency anaemia secondary to gastrointestinal loss, Hb 3.7g/dL, h/o IHD	2+	0	0	1-2hrs/unit	NS	NR

* *In these cases the patients required ITU admission / ventilation / CPAP*

Cases of acute haemorrhage in which more than one component type was transfused *n* = 4

There were 4 cases of TACO in which RBC plus other blood components/products and additional IV fluids were administered in situations of acute major haemorrhage. All the patients were relatively young, being 52, 20, 46 and 41 years of age respectively. In 3 of the 4 cases RBC and FFP were given, and in the fourth case RBC were given for PPH together with colloids and crystalloids only (Case 4).

Case 2

A man with acute major haemorrhage receives multiple components and develops TACO

A 52-year-old man was admitted with acute encephalitis, renal impairment and a suspected gastrointestinal (GI) bleed due to varices. The Hb was 5.6 g/dL and he received 3450 mL of blood components / products within 18 hours, despite a reduced urine output. These comprised: 3 units RBC (900 mL) starting at 00.30 on Day 1; 4 units (400 mL) 20% human albumin solution (HAS) starting at 16.30 on Day 1; 8 units (2000 mL) FFP starting at approximately 01.30 on Day 2 (no start or stop times and no observations were documented for any of these units); and a further 150 mL of RBC starting at 19.15 on Day 2. This further unit of RBC was stopped because the patient became unwell – with SOB, raised JVP, coarse crackles in both lungs and peripheral oedema. The urine output was 80 mL/hr. The O_2 saturation was low at 66%. The increasing SOB was attributed to the patient's general condition and fluid overload. He was given furosemide 40 mg. The O_2 saturation rose to 96%, with a urine output of 625 mL in 30 mins, a further diuresis of 1325 mL over the subsequent 4 hours, and symptomatic improvement. He was found to have gram negative bacilli in an ascitic fluid sample, so that sepsis was probably contributory to his anaemia. Coagulation studies showed a pre-FFP prothrombin time (PT) of 26 seconds with INR 1.9 and fibrinogen 1.9 (NR 1.5-4.0) g/dL and a post-FFP PT of 17 seconds, INR 1.4 and fibrinogen 2.1 g/dL.

Case 4

Young woman with PPH treated with RBC, colloid and crystalloid develops TACO

A 20-year-old woman had a PPH of 2L following emergency Caesarean section (CS) following failure to progress in labour. She was given 2.5L of colloid and 1L of crystalloid over 1 hr, and an RBC transfusion of 4 units (1200 mL) also over 1 hour. She became unwell, shivery and confused with tachycardia and dyspnoea. The O_2 saturations dropped to 50% with a pO_2 of 6 kPa. She was in positive fluid balance of 2800 mL (4700 mL in and 1900 mL out). She was given a diuretic resulting in a diuresis of 900 mL. After a further urine output of 1L her symptoms improved.

Case 6*

Major intraoperative haemorrhage results in massive transfusion causing TACO and ITU admission

A 46-year-old man underwent posterior removal of a vertebral tumour at C4 associated with a haemorrhage of 5L. He was transfused 9 units of RBC (2 L), 2 units of FFP (300 mL), 2200 mL colloid and 3500 mL crystalloid, all given rapidly intraoperatively. In recovery he had acute desaturation (82%) and bilateral crackles on auscultation of the chest. Furosemide was given, and he was transferred to ITU where he was ventilated and given a noradrenaline infusion plus furosemide, resulting in a diuresis of 4500 mL and immediate improvement, with the O_2 saturation rising to 92%. Charts revealed a positive fluid balance of 3700 mL (8700 mL in and 5000 mL out).

Case 10*

PPH treated with RBC, FFP, colloid and crystalloid results in ITU admission with TACO

A 41-year-old woman had a PPH of 3.5 L following elective CS for placenta praevia. She had been on enoxaparin and aspirin for recurrent deep venous thrombosis. She received 4 units of RBC and 4 units of FFP given rapidly in theatre plus 1L colloid and 1L of crystalloid. Postoperatively she developed pulmonary oedema and a 'white out' on the chest X-ray within 1–1.5 hours of the fluid given. The O_2 saturation fell to 80% with pO_2 5.24 kPa. She was hypotensive (BP 95/52) and bradycardic (P 45/min). She was given furosemide and passed 300 mL urine. She was transferred to ITU and ventilated for 2 days. The lung bases were clear on auscultation the morning after the episode. There was no fluid balance chart. A diagnosis of TRALI was considered, but was thought to be very unlikely on expert review by NHSBT.

Cases in which RBC transfusion was implicated *n* = 15

In 15/18 (83%) of cases red blood cells (RBC) had been given, with 13/15 RBC in additive solution and 2/15 plasma reduced red cells. RBC were transfused for anaemia in the absence of acute haemorrhage in 11/15 patients, and in the presence of acute haemorrhage in 4 cases (detailed above). In 10 of these 11 patients (i.e. excluding the patient on ECMO, Case 13 above), the onset of symptoms occurred during the second unit in 3 cases, after completion of transfusion of 2 units in 3 cases, and during the third unit in 4 cases. These 10 patients were all elderly, age range 72–86 years. Details are given above in Table 53 and in the cases below.

Cases in which FFP was transfused *n* = 6

There were 6 cases in which transfusion of FFP was implicated in TACO, of which 3 occurred in the presence of acute haemorrhage with RBC prescribed as well. These are described in the section above. Of the remaining 3 cases, Case 11 consisted of a very large volume transfusion of FFP, Case 17 was a case in which FFP was given for coagulopathy in the absence of bleeding (as occurred in Case 12 also), and in Case 7 FFP was given together with 20% HAS (see also Case 2 above).

Case 11*

Large volume FFP transfusion in a very sick patient causes pulmonary oedema

A 64-year-old man with cholangiocarcinoma was given 11 units of FFP (~2750 mL) as well as 250 mL of colloid and 1L of crystalloid. The indication for FFP transfusion was stated to be the patient's disease, although he was not bleeding. There was no record of vitamin K being given. The patient developed dyspnoea, wheeze and peripheral oedema, with O_2 saturation 98%. He was in positive fluid balance of 1637 mL (3397 mL in and 2655 mL out). The chest X-ray indicated pulmonary oedema. He was admitted to ITU where he was given a diuretic resulting in a diuresis of 1200 mL. The patient died from his disease, but the transfusion reaction was not implicated.

Case 17

Young patient develops TACO after transfusion of a large volume of FFP

A 36-year-old man with status epilepticus, unconscious and with deranged clotting due to liver impairment, was issued 5 units of FFP. While he was having the fifth unit, he was noted to have tachycardia and hypertension.

Case 7*

Transfusion of FFP and HAS results in severe episode of TACO in patient with renal failure

A 60-year-old man with alcoholic liver cirrhosis and acute renal failure was given approximately 600 mL of FFP over 30 minutes and 300 mL of 20% HAS. Halfway through the second unit of FFP he became very tachycardic, oliguric and wheezy, coughing up copious black frothy sputum. He was tachypnoeic, RR 40/min, with raised JVP and bilateral crackles in the chest. The pO_2 was 7.5 kPa. He was in positive fluid balance of 2465 mL (2817 in and 352 out). He was given a diuretic, but had no diuresis (urine output 33 mL) and his condition worsened. He was already in ITU, but the reaction necessitated CPAP.

TACO following RBC transfusion to elderly patients with concomitant conditions that increase the risk of TACO *n* = 7

Table 54 summarises the presence of concomitant medical conditions that increase the risk of TACO in the 18 cases reported. Of the 10 elderly patients who received RBC in the absence of acute blood loss (see above), 7 had concomitant medical conditions that could increase the risk of TACO: 4 had cardiac failure (1 with severe aortic stenosis and 1 with hypertension and right bundle branch block), 2 had renal impairment (1 with hypoalbuminaemia), and 1 had hypoalbuminaemia. In 3/7 of these cases, there was fluid overload, and in the remainder (4/7), fluid balance does not appear to have been recorded. TACO was assessed to be highly likely in 3 of the 7 cases detailed below, and probable in the other 4.

Table 54
Presence of concomitant medical conditions that increase the risk of TACO

Case number	Sex & Age	Cardiac failure	Renal impairment	Hypoalbuminaemia	Fluid overload
1	M79	No	No	No	NR
2	M52	No	No	No	Yes
3	M77	Yes	No	No	Yes
4	F20	No	No	No	Yes
5	F82	Yes	No	No	NR
6	M46	No	No	No	Yes
7	M60	No	Yes	Yes	Yes
8	F73	No	Yes	No	NR
9	F86	No	No	No	NR
10	F41	No	No	No	NR
11	M64	No	Yes	No	Yes
12	F74	No	Yes	Yes	Yes
13	F23	Yes	Yes	Yes	No
14	M80	Yes	No	No	NR
15	F77	No	No	No	NS
16	F83	No	No	Yes	Yes
17	M36	NS	NS	NS	NS
18	F73	Yes	No	No	NS

Case 14*

Preoperative top-up transfusion in elderly man results in myocardial damage and ITU admission

An 80-year-old man with lymphoma and Hb 8.7g/dL was given an RBC transfusion overnight, at the anaesthetist's request, prior to a lymph node biopsy. He had a history of hypertension, heart failure and right bundle branch block, and was experiencing shortness of breath (SOB). The transfusion proceeded although it was against hospital policy to issue blood products out of hours without verification from the on-call haematology consultant. Three units of RBC were provided and transfused commencing at 23.35, 03.30 and 08.00 respectively resulting in a Hb 12.5 g/dL. At 10.30 the patient became SOB, sweaty and confused, with pO_2 low at 7.3 kPa. He developed chest pain, pulmonary oedema and renal failure. The troponin was 0.32 µg/L (local reference range > 0.05 indicative of myocardial damage and, or, infarction). He required transfer to ITU for fluid management and CPAP and slowly recovered. Fluid balance details were not recorded.

Case 3

Frail elderly patient develops severe TACO during third unit of RBC

A 77-year-old male patient with peripheral vascular disease, severe aortic stenosis and cardiac failure underwent a right below-knee amputation. Four weeks later he had a chest infection and heart failure. The Hb was 9.6 g/dL. He was given a 2 unit RBC transfusion. He developed dyspnoea and reduced O_2 saturation during the first unit, which resolved after stopping the transfusion and restarting after 45 minutes. The following day a third RBC unit was started, and after 45 minutes the patient developed hypertension, reduced O_2 saturation (nadir 80%) and bradycardia. He complained of mild chills but remained afebrile. Following medical review, the transfusion was discontinued. A chest X-ray showed severe pulmonary oedema. In the 24 hours leading up to this reaction the patient had also had 2L of crystalloid. Analysis of fluid balance over this period showed: input 2407 mL, output 1625 mL and a positive balance of 782 mL. He was treated with a diuretic, following which he had a diuresis of 2L and his symptoms improved.

Case 5

Elderly woman with known cardiac failure develops TACO following routine top-up transfusion

An 82-year-old woman with myelodysplastic syndrome was transfused 2 units of RBC and 1 pool of platelets on the Haematology Day Care Unit. She had pre-existing cardiac failure. The pre-transfusion Hb was 9.6 g/dL with the platelet count 3 x 10^9/L. Two weeks later she was admitted as an emergency complaining of chest pain and SOB since the evening of transfusion. On examination she was in cardiac failure. She was given furosemide 40 mg and her symptoms improved.

Case 8

An elderly lady with cardiac impairment goes to ITU following a top-up transfusion

A 73-year-old woman with coeliac disease, renal failure and a history of myocardial infarction had a Hb of 7.6 g/dL and was given an RBC transfusion. The first unit was transfused over approximately 3 hours. While receiving the second RBC unit within 24 hours, she became breathless and hypertensive (BP 201/90), with pitting oedema of both lower limbs. Her cardiac failure necessitated ITU admission. There was no fluid balance chart in use. She was given a diuretic resulting in a diuresis of 830 mL with improvement in her symptoms.

Case 12

Elderly woman with anaemia due to renal failure develops TACO after a top-up transfusion

A 74-year-old woman with acute on chronic renal failure who had hypoalbuminaemia, a recent myocardial infarction and a Hb of 6.9 g/dL, was prescribed a 2 unit RBC transfusion. During the second unit she became wheezy, shaky, tachycardic (pulse (P) 113/min) and hypertensive (BP 159/127). The O_2 saturation was 96%. On examination she was in cardiac failure. She was in positive fluid balance of 745 mL. She was reviewed by the critical care outreach team and given oxygen, hydrocortisone and a diuretic (following which she passed 200 mL of urine) and nebulisers with good effect.

Case 16

Frail elderly woman develops cardiac failure during second unit of red cells

An 83-year-old woman with myeloma, intestinal obstruction, hypoalbuminaemia and a Hb of 7.9 g/dL was prescribed a 2 unit RBC transfusion. She also received 1000 mL of crystalloid and her oral fluid intake was 800 mL that day, resulting in a positive fluid balance of 1430 mL. Halfway through the second RBC unit she became breathless, tachycardic (P 105/min), hypertensive (BP 185/100) and pyrexial (T 39°C), with a raised JVP and acute pulmonary oedema (confirmed on a chest X-ray) and reduced O_2 saturation (89% on air). Following the reaction the patient was reviewed and a decision was made between medical staff and the family to place the patient on an end of life care pathway in view of her myeloma.

Case 18

Woman with gross iron deficiency anaemia transfused rapidly and develops TACO

A 72-year-old woman was admitted by ambulance to the ED at 1420 with jaundice, dramatic weight loss and mild SOB. She had chronic iron deficiency anaemia, Hb 3.7 g/dL, secondary to gastrointestinal loss. She had a probable diagnosis of chronic obstructive pulmonary disease (COPD), and ischaemic heart disease (IHD). The first unit of RBC was started at 01.00 the following day, the second unit at 02.00 and the third at 04.20. About 45 minutes into the third unit she complained of worsening SOB and headache, and was found to have tachycardia (P 120/min) with a respiratory rate (RR) of 22/min. The O_2 saturation was 95% on 40–60% O_2.The RBC transfusion was stopped, she was treated with diuretic and oxygen and her symptoms improved. Her post-transfusion Hb was 7.9 g/dL. The reaction was thought to have been caused by her underlying cardiac condition and the speed at which she was transfused.

TACO in the absence of concomitant medical conditions that increase the risk *n* = 3

Three cases (cases 1, 9 and 15) where TACO was considered to be highly likely (*n* = 1; Case 1 below), probable (*n* = 1) or possible (*n* = 1) occurred in elderly individuals in the absence of an obvious medical condition that increases the risk of TACO.

Case 1*

Elderly man with chronic anaemia but no risk factors develops TACO during second unit of blood

A 79-year-old male with chronic anaemia, Hb 5.4 g/dL, was admitted via the ED to the ward with a 3 day history of SOB, wheeziness and cyanosis. He was prescribed 2 units of RBC. The rate of transfusion was not documented. He became increasingly SOB part way through the second unit, with tachycardia (P 114/min), RR 24/min, a rise in BP (from 131/70 to 173/84), and a fall in O_2 saturation from 100% to 88% on 12 litres of O_2. He was mildly acidotic and agitated. The reaction resulted in admission to the ITU where he was given steroids and furosemide, following which he had a diuresis of 500 mL, and his symptoms settled within 2 hours. Details of fluid balance were not recorded.

Procedural Review

In 17/18 cases, the reaction was reported to the Hospital Transfusion Committee (HTC) and 1 was reported to the blood transfusion laboratory. One hospital did not have a HTC, but reported the case to the clinical governance department and the risk managers. Three hospitals reported the case to the clinical risk department or committee and 1 also on a local incident reporting scheme (Datix) as well as to the HTC. Five cases had been reviewed by the HTC and a further 11 were awaiting review by the HTC.

COMMENTARY

- TACO appears to be a significant cause of transfusion-related serious morbidity and mortality, which is potentially preventable in many cases. In this relatively small series (n = 18), there was 1 death where TACO was probably contributory (imputability 2) and 6/18 (approximately 33%) patients required ITU admission / ventilation / CPAP. In a further 4/18 cases (approximately 22% of the total), the reporter assessed that the reaction was life-threatening.

- The incidence of TACO reported to SHOT this year was 0.63/100,000 components compared with 3.7/100,000 components reported to TRIP (Transfusion Reactions in Patients, the Dutch Haemovigilance System) in 2005. The Quebec Haemovigilance System (QHS) reported that from 2000 to 2006, of 11,548 reports, 508 (4.4%) were categorised as TACO, with a case-fatality rate of 1.4%, and 21% of cases were considered life-threatening. The QHS also noted a steadily increasing incidence resulting in TACO becoming the most frequent serious transfusion hazard. This is the first year that SHOT has introduced TACO as a separate category, and it is anticipated that reporting will increase with increased awareness.

- The 2008 SHOT reports included cases of TACO associated with the transfusion of relatively modest volumes of RBCs (2 cases occurred during the second unit, 1 after two units and 4 during the third unit), particularly in elderly individuals (age range 72–86 years) who had concomitant medical conditions such as cardiac failure, renal impairment, hypoalbuminaemia or fluid overload, factors that increase the risk of TACO. Cases were also seen in elderly individuals in the absence of obvious comorbidity. In addition, TACO was observed in younger patients (<50 years), particularly in the context of severe haemorrhage when large volumes of IV fluids and blood components were transfused. There were no reports to SHOT of TACO in patients <18 years, whereas these accounted for 2.6% of TACO cases reported to the QHS. The incidence of TACO in the UK paediatric population is unknown.

- Symptoms of TACO may occur during the transfusion or after completion of the transfusion. This also applies to several other serious transfusion hazards.

- In 2 cases, large volumes of FFP were administered (Case 3: 2 L and Case 12: 2.75 L). While there are few proven indications for FFP, if FFP is indicated, BCSH guidelines state that the conventional dose is 10-15 mL/kg, with the dose dependent on the clinical situation and its monitoring.[30] A limiting factor to administration of an adequate volume of FFP is the patient's ability to tolerate the volume transfused. Prothrombin complex concentrate (PCC), in which the volume of a therapeutic dose is small, is the product of choice for reversal of warfarin anticoagulation associated with severe bleeding. Preliminary data suggest that PCC may also have a role in the reversal of coagulopathy in non-warfarinised patients with severe bleeding. However,

PCC are potentially thrombogenic and remain unlicensed for this indication. In acute traumatic massive haemorrhage, there is considerable interest in early formula replacement with FFP (e.g. 1:1 ratio of red cells to FFP). This approach is based on largely retrospective data in particular from the military. An observational study of transfusion practice in trauma patients is now in progress (personal communication, Dr Shubha Allard and Dr Simon Stanworth). National guidelines require updating to guide local practice.

- In 2 cases of TACO associated with FFP transfusion, the patients also received 20% HAS, which is hyperoncotic and may therefore lead to circulatory overload.

- The rate of transfusion was documented in 14/18 cases (78%) and fluid balance was recorded in only 10/18 cases (56%).

- Brain natriuretic peptide (BNP) was not measured in any of the cases reported. Preliminary data suggested that BNP and N-terminal pro-BNP were potentially useful in the diagnosis of TACO; however, a recent prospective study showed that these markers are of limited diagnostic value in the differentiation of TACO from TRALI in patients with acute pulmonary oedema after transfusion.[31]

RECOMMENDATIONS

- Increased recognition of TACO by clinicians and reporting to SHOT is needed, to raise awareness and increase focus on this important and in many cases potentially avoidable complication of blood transfusion.

  Action: HTT

- Education and training aimed at the recognition and avoidance of TACO is required for doctors across all specialties, and nurses at both national and local levels. Education and training of junior doctors, to ensure appropriate decision making as regards transfusion of blood components / products and appropriate prescription, remains a key priority.

  Action: NBTC

- Doctors should ensure careful clinical assessment of each patient to whom transfusion of components is being considered, to ensure that the proposed transfusion is appropriate. This is particularly important in the case of RBC transfusion to patients ≥70 years, regardless of the presence or not of concomitant medical conditions that may increase the risk of TACO. The minimum volume of blood components required should be prescribed to be transfused at an appropriate rate, in accordance with BCSH Guidelines on Blood Administration[32] (revised guidelines are in preparation).

- If it is necessary to transfuse RBCs to a patient with chronic anaemia, the risk of precipitating congestive cardiac failure may be minimised by administering a diuretic (e.g. oral furosemide 20 mg), and by reassessing the patient after the transfusion of each unit of red cells. The decision to give a diuretic must be based on clinical assessment of the patient.

  Action: HTT, BCSH

- Nursing staff should record the rate of transfusion and fluid balance in patients receiving blood components and act on signs suggestive of TACO. Transfusions should be administered at times, and in locations, permitting careful observation of patients throughout the transfusion and upon its completion. Out-of-hours transfusions should be avoided unless appropriate facilities are available. BCSH guidelines on blood administration in preparation should address these issues.[32]

  Action: HTT, BCSH

17. Transfusion-Associated Dyspnoea (TAD)

Definition

The category TAD has been introduced by the ISBT. TAD is characterized by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition or any other known cause. This will allow haemovigilance systems to classify all reported pulmonary reactions without the need for exceptions or inappropriate assignment.

DATA SUMMARY

Total number of cases	1	*Implicated Components*		*Mortality / morbidity*	
		Red cells		Deaths due to transfusion	0
		FFP		Deaths in which reaction was implicated	0
		Platelets		Major morbidity	1
		Granulocytes	1		
		Buffy coats			
		Unknown			

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	0	16 years+ to 18 years	0	Emergency	0	ED	0
Female	1	1 year+ to 16 years	0	Routine	1	Theatre	0
Unknown		28 days+ to 1 year	0	Not known	0	ITU/NNU/HDU/Recovery	1
		Birth to 28 days	0			Wards	0
				In core hours		Community	0
		Total	0	Out of core hours		Other	0
				Not known/applicable	1	Not known	0

This case was originally reported as transfusion-associated circulatory overload (TACO) but on review was thought to be more accurately described as TAD.

Once the new data collection system is installed (see Introduction, Chapter 2) reporters will easily be able to report cases of TAD. Until that time reporters are encouraged to report all cases of respiratory complications of transfusion via SABRE at which point SHOT office staff will contact you to offer help and advice.

Major Morbidity *n* = 1

The patient required ITU admission and CPAP because of the reaction (imputability 2).

Table 55
Diagnosis/Indication for transfusion, components/products transfused and fluid balance

Sex & Age	Diagnosis/Indication for transfusion	RBC Units	FFP	Other	Rate of transfusion	IV fluids	Fluid Balance
F57	Acute myeloid leukaemia, possible deteriorating fungal pneumonia	0	0	Granulocytes 250 mL Buffy coats 500 mL	~2hr	IV anti-fungal therapy	-240 mL

Case 1

Isolated respiratory distress without fluid overload following buffy coat and granulocyte transfusion

A 57-year-old woman with AML, neutropenia and suspected deterioration of a fungal pneumonia was prescribed a transfusion of buffy coats (volume 500 mL) and granulocytes (250 mL). These were delayed until after IV anti-fungal therapy, resulting in transfusion 750 mL over 2 hours. One hour later she became acutely SOB, tachycardic (P 114/min) with the O_2 saturation falling to 88%. She had cardiomyopathy and poor LV function on an echocardiograph, but there was no evidence of cardiac failure or of fluid overload, with a negative fluid balance of 240 mL. The reaction necessitated admission to ITU for CPAP. She remained in ITU for 1 week and was discharged from hospital 2 weeks later. This case did not meet criteria for TACO or TRALI, and did not have classical features of an allergic reaction, and was therefore was categorised as a probable case of TAD.

COMMENTARY

- Transfusion-associated dyspnoea (TAD), where the pulmonary complication cannot be assigned to the known pulmonary transfusion reactions TRALI, TACO or ATR, is a recognised entity.[4] TAD is reported to be usually mild; however, the reaction reported here necessitated ITU admission and CPAP. More information about this complication would be useful.

RECOMMENDATIONS

- All pulmonary reactions to transfusion should be reported to SHOT. Accurate information on the diverse spectrum of pulmonary complications of transfusion will inform a systematic approach to their appropriate investigation and management.

  Action: HTT

18. Autologous Transfusion

Definition

Any adverse event or reaction associated with autologous transfusion techniques, including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution or PAD (preoperative autologous donation).

DATA SUMMARY

Total number of cases	28

Implicated Components	
Autologous Red cells	**28**
FFP	
Platelets	
Other *(specify)*	
Unknown	

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

Gender	
Male	**16**
Female	**12**
Unknown	**0**

Age	
16 years+ to 18 years	**0**
1 year+ to 16 years	**2**
28 days+ to 1 year	**0**
Birth to 28 days	**0**
Total	**2**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**4**
Routine	**24**
Not known	**0**
In core hours	**14**
Out of core hours	**2**
Not known/applicable	**12**

Where transfusion took place	
ED	
Theatre/ITU/NNU/HDU/Recovery	**25**
Wards	**3**
Community	
Other	
Not known	

A total of 28 questionnaires were received and all have been analysed. There were no reports submitted during this reporting period that related to adverse events while undertaking acute normovolaemic haemodilution (ANH) or preoperative autologous donation (PAD). Both these methods are rarely undertaken and are not recommended as routine techniques.

Cell salvage adverse events pilot

The intraoperative and postoperative cell salvage (ICS and PCS respectively) adverse events pilot was a joint initiative between the UK Cell Salvage Action Group (UK CSAG) and SHOT. Cell salvage, both intraoperative and postoperative, is one of the techniques being more regularly employed by hospitals as part of their blood conservation programme. While these techniques are very safe when used by trained and competent staff, to date there has been no systematic collection of data relating to adverse incidents in these areas.

A survey commissioned by the UK CSAG in 2007 involved 212 hospitals, of which 113 said they use ICS (53.3%), 43 said they did not use ICS (20.2%) and 56 did not reply (26.4%).

The 6 month pilot commenced in June 2008 and all hospitals in the UK were invited to participate. Sixty-two hospitals agreed to participate.

The following were defined as adverse events:

- abandoned procedures due to operator error (incorrect assembly, use of non-intravenous (IV) solutions, incorrect anticoagulant, collection time exceeded)
- abandoned procedures due to machine failure (clotted lines/reservoirs)
- adverse clinical events or reactions (hypotension, air embolus, etc.)

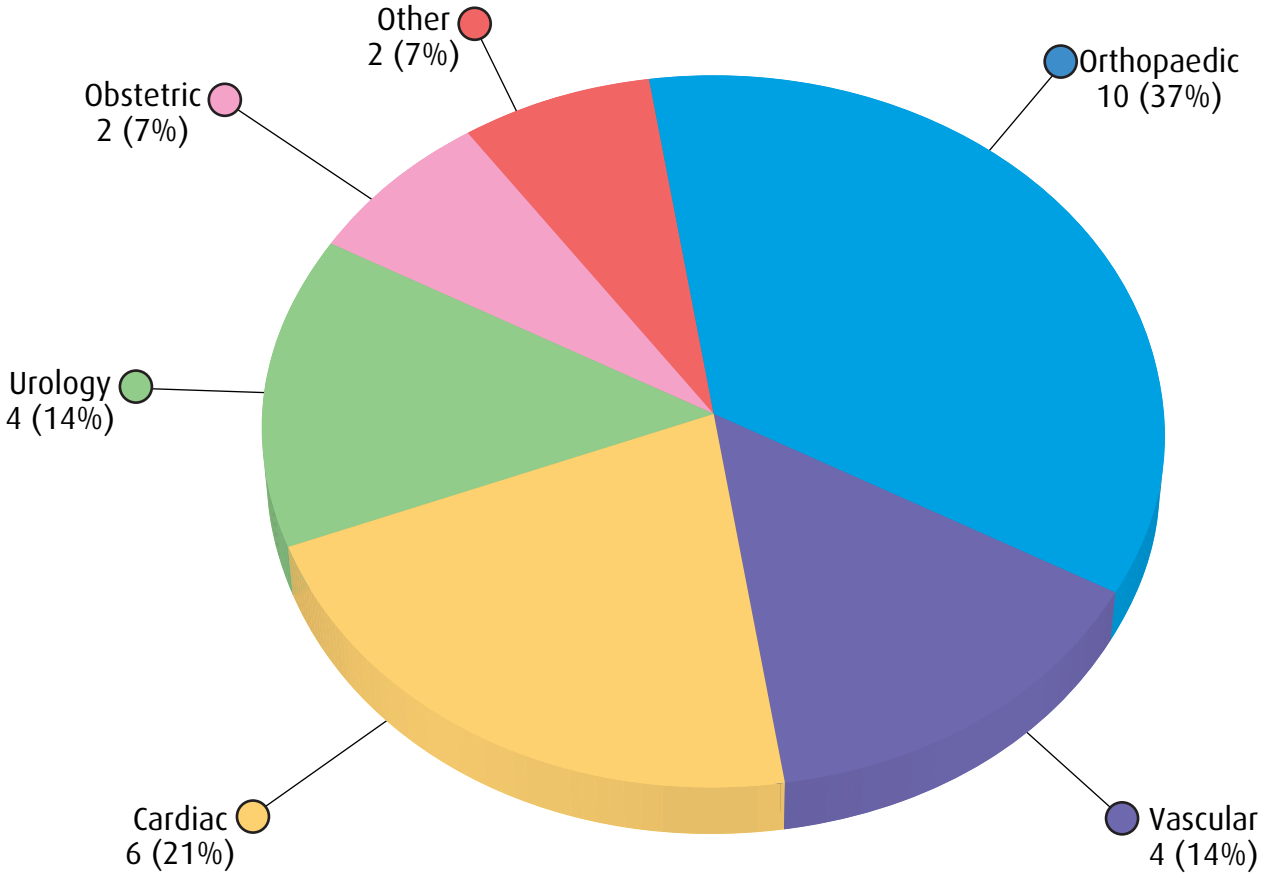
Overview of results

There were 28 reports from 15 participating hospitals. Of these, 3 incidents were reported to MHRA (2 machine failures and 1 reaction), 18 were not reported to MHRA (12 machine failures and 1 reaction), and 7 did not include a response. The operator errors could all be considered to relate to training issues. Of the incidents caused by machine errors, 5 incidents relating to clotting could equally be attributable to operator error if insufficient anticoagulation was incorporated/undertaken within the blood collection system.

Cell salvage type *n* = 28

- 25 intraoperative (washed) including 3 using a combined system (washed)
- 3 postoperative (unwashed)

Figure 25
Adverse events by specialty *n* = 28



Machine types and operators

Machine operators *n* = 32*

- 12 operating department practitioner (ODP)
- 3 perfusionist
- 2 consultant anaesthetist
- 11 nurse
- 4 manufacturer (commercial)

** In 4 procedures there were two operators:*

- *nurse plus manufacturer in 3 cases*
- *ODP plus perfusionist in 1 case*

Postoperative systems *n* = 3

- 2 Bellovac™ ABT, Astratech
- 1 Donor™, Van Straten Medical

ICS Machines *n* = 25

- 1 Fresenius C.A.T.S®
- 14 Haemonetics Cell Saver®
- 3 Haemonetics OrthoPAT®
- 7 Sorin Electa

Postoperative cell salvage incidents (PCS) *n* = 3

Operator error *n* = 3

- 2 bag fell off
- 1 collection bag not labelled

There were no machine or clinical adverse events or reactions from PCS in the pilot.

Intraoperative cell salvage incidents (ICS) *n* = 25

Operator errors *n* = 5

- 2 equipment not assembled correctly
- 2 non-IV saline used
- 1 surgeon dropped sucker

Machine errors *n* = 14

- 4 clotting of lines/centrifuge
- 1 clotting of filters
- 5 machine stopped working (3 OrthoPAT®)
- 2 failure not specified
- 2 other (harmony suction failure x 1, would not recognise bowl x 1)

Clinical adverse events and reactions *n* = 6

- 1 air embolus (minor morbidity)
- 5 hypotensive episodes (1 minor morbidity)

Case 1

Possible air embolus resulting from use of pressure bag during reinfusion

The patient was in ITU and extremely unwell with ischaemic bowel following emergency AAA repair. The BP and CO_2 dropped and the ITU team were called and noticed that the reinfusion bag was empty and still pressurised, suggesting that air had been forced into the central venous line. The reaction was attributed to air embolus. However, an echocardiogram failed to show the presence of air in the heart, and the hypotension and hypocarbia responded to increased inotropes, both of which would be unusual in symptomatic air embolus. Treatment was later withdrawn due to irreversible acidosis associated with ischaemic bowel. The possible air embolus has been classified as minor and not contributory to the death. Use of a pressurised system is against the manufacturer's instructions and Trust policy.

There were 5 reports of hypotension apparently caused by the reinfusion of cell-salvaged blood. This was the most common clinical incident reported. An attempt has been made to analyse the clinical scenarios and the common factors appear to be:

- use of acid citrate dextrose (ACD) as an anticoagulant
- use of a leucodepletion filter (LDF) during the reinfusion of autologous washed red cells

However, it appears that there are a number of other clinical issues:

1. Use of bedside LDF, which is known to cause hypotension when used with allogeneic blood occurring in 80 out of 20 million transfusions (0.0004%).[33]
2. These patients may have been hypovolaemic and therefore more susceptible to the vasoactive cytokines reinfused.
3. All patients experienced transient but significant hypotension corrected by the cessation of infusion plus or minus the administration of vasopressors
4. No long-term sequelae of this hypotension were noted.

These incidents will require further analysis. At this stage it is important that the possibility of an adverse event or reaction is recognised by the responsible clinician and treated by discontinuation of the infusion of the salvaged red cells and use of appropriate vasopressors and resuscitation fluid.

Denominator data

At the end of the pilot the participants were asked to provide denominator data for:

- total number of intraoperative cases undertaken during the period of the pilot
- total number of postoperative cases undertaken during the period of the pilot

Of the 62 hospitals taking part, 16 provided denominator data for the pilot period.

ICS procedures accounted for 2328 procedures with a range of 7–700 procedures per hospital, and this group accounted for denominator data for 13/25 reported incidents. The other 12/25 incidents did not supply denominator data.

PCS procedures accounted for 1412 procedures with a range of 4–450 procedures per hospital, and this group accounted for denominator data for all 3 reported incidents.

The paucity of data on the number of procedures undertaken, together with the very small number of procedures undertaken by some hospitals, may be a cause for concern. Further review of the data is required over a longer period to identify whether there is any correlation between the number of procedures undertaken and the frequency of adverse incidents. It is possible that organisations undertaking relatively few procedures have a disproportionate risk of adverse incidents due to infrequent use and lack of regular experience leading to operator error. This information gives strength to the work of the UK CSAG in:

- the need for education and competency assessments; these are already developed and available on the Better Blood Transfusion Toolkit at www.transfusionguidelines.org.uk
- a comprehensive UK reporting system for cell salvage.

RECOMMENDATIONS

- All cell salvage operators must undertake initial and regular update training and be assessed as competent. There should be documented evidence of competence in the form of a training record. Competency assessment workbooks are available for both ICS and PCS at www.transfusionguidelines.org.uk.

- All ICS and PCS related adverse events should be reported to SHOT.

- Monitoring of patients is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells.

- Cell salvage machines are classified as Medical Devices, so all adverse events attributable to machine errors and failures should be reported to the MHRA as well as SHOT.

Whereas the pilot has concluded, data collection has not concluded and reporting of these adverse events will now form part of routine SHOT reporting.

19. Paediatric Cases

Definition

Paediatric cases comprise all those occurring in patients under 18 years of age.

This chapter analyses the data on paediatric cases from the other chapters in this annual report. All the cases are also included in the data in their respective chapters. All children < 18 years of age are included and have subdivided by age bands within this: neonates ≤ 4 weeks old, infants > 4 weeks and < 1 year old, and children > 1 year and < 16 years old because each of these has specific recommendations regarding blood components. The chapter particularly highlights the cases related to the age of the patient.

Table 56

Category of case	No. ≤ 4 weeks	No. > 4 weeks to <1 year	No. 1 to < 16 years	No. 16 to < 18 years	Total paediatric cases
IBCT	**15**	**6**	**14**	**4**	**39**
Administration	5	0	2	1	8
Laboratory error	5	2	2	2	11
Special requirements not met (total)	3	4	10	1	18
Irrad/CMV negative	*2*	*4*	*4*	*1*	*11*
MB requirement	*1*	*0*	*4*	*0*	*5*
Others	*0*	*0*	*2*	*0*	*2*
Miscellaneous	2	0	0	0	2
Handling and Storage	**4**	**1**	**2**	**1**	**8**
Inappropriate/unnecessary	**0**	**3**	**2**	**2**	**7**
Anti-D related	**0**	**0**	**0**	**4**	**4**
ATR	**1**	**1**	**20**	**3**	**25**
HTR	**0**	**0**	**3**	**1**	**4**
TACO	**0**	**0**	**0**	**0**	**0**
TRALI	**0**	**0**	**0**	**2**	**2**
PTP	**0**	**0**	**0**	**0**	**0**
TA-GvHD	**0**	**0**	**0**	**0**	**0**
TTI	**0**	**0**	**0**	**1**	**1**
Autologous	**0**	**0**	**2**	**0**	**2**
Total	**20**	**11**	**43**	**18**	**92**

Introduction and overall trends

In 2008, 92 of the total 1040 reports (8.8%) involved patients < 18 years old. Furthermore, a total of 74/1040 (7.1%) were in children < 16 yr, 31/1040 (3.0%) reports were in infants < 1 yr, and 20/1040 (1.9%) in neonates ≤ 4 weeks. The overall number of reports has increased compared to previous years, particularly in the older age groups, but when compared with the summary data from the first 9 years of SHOT,[34] and the paediatric chapters in 2003 and 2007, the percentage of paediatric cases in 2008 is lower (Table 57). However, there are not sufficient data from consecutive years to make clear conclusions from these trends, and there is almost certainly under-reporting, particularly in the younger age groups.

There were a relatively high proportion of reports in the < 1 yr age group (31/92; 34%) of whom 20/31 (65%) were neonates ≤ 4 weeks old. This is consistent with the epidemiological survey of transfused patients in 2004, which showed that 4.2% red cell units were transfused to patients < 18 years, and 1.7% to infants less than 1 year,[34,35] i.e. infants received 40% of paediatric red cell units. However, these epidemiological data also suggest that there are still a disproportionately high number of paediatric reports compared to adults in both the < 18 yr and < 1 yr groups.

Table 57
Cumulative paediatric numbers and percentages

	1996–2005 [34] Number (%)	**2003** Number (%)	**2007** Number (%)	**2008** Number (%)
Total reports analysed	3239	449	561	1040
< 18 yr	321 (9.9)	59 (13.1)	-	92 (8.8)
< 16 yr	-	-	55 (9.8)	76 (7.3)
< 12 mths/1 yr	147 (4.5)	29 (6.5)	25 (4.5)	31 (3.0)
< 4 wks/1 mth	96 (3.0)	20 (4.5)	12 (2.1)	20 (1.9)

NB Age limits are < 12 mths/1 yr and < 4 wks/1 mth depending on the year of the report. In 2007, only reports of patients < 16 yr were included in the paediatric analysis.[34]

There was an age related pattern in the types of reports (Table 56). Error reports (incorrect blood component transfused, inappropriate and unnecessary transfusion and handling and storage errors) dominated in infants < 1yr, with 29/31 (94% of all infant reports), and were also disproportionately represented, overall comprising 54% of the 54 total paediatric error reports. Moreover, administration and laboratory error reports were most common in neonates ≤ 4 weeks old, accounting for 10/19 (53%) of the total paediatric administration and laboratory errors. In comparison, for ages 1yr to < 18yr only 25/61 (41%) reports were in error categories and ATR accounted for a further 23 (38%); the majority of paediatric ATR reports (92%) were in this age group. The 16 to < 18 yr group had reports in categories not found at earlier ages: anti-D, TRALI and TTI. Some of the age associated differences in error reports are related to the complexity of neonatal transfusion. The lack of transfusion reaction reports in infants may be due to their immunological immaturity. However, there may also be significant bias from under reporting of events such as ATR, TACO and TRALI in infants owing to lack of recognition of these in babies who are already very sick from other causes.

Overall, the majority of paediatric reports were error related, these comprising 54/92 (59%) of the total in 2008. This can be compared with the overall figure for adults of 45%, while overall in the whole report the percentage of error-related reports is 46%.

The largest error-related subgroup in paediatrics was SRNM with a total of 18 cases, followed by laboratory errors in 11 cases. Just over half (28) of the error reports were specifically related to the young age or small size of the patient, and special requirements arising from this (i.e. paediatric related). Unfortunately there has been little change in the total number of error reports in recent years despite efforts to increase awareness of paediatric transfusion issues. This is likely to reflect ongoing lack of knowledge and expertise regarding transfusion special requirements and administration for this complex group of patients. However, it is encouraging that these errors (59% of paediatric cases) compare favourably with the proportion of errors in the paediatric cases in previous years. In the 1996–2005 paediatric summary data errors accounted for 264/321 (82%) of paediatric cases, in 2003 errors accounted for 53/59 (90%) and in 2007 errors in under-16s accounted for 45/55 (82%) of the total paediatric cases. However, a possible factor appears to be the increase in the non-error reports (predominantly ATR) in the older age groups.

ATR cases made up the largest category of non-error reports in 2008 and accounted for 25/92 (27%) of all paediatric cases. This was a striking increase compared with previous years: 30/321 (9%) in the 1996-2005 summary data, 3/59 (5%) in 2003, and 7/55 (13%) in 2007 (see ATR section below).

Error-related reports *n* = 54

IBCT – Special requirements not met (SRNM) *n* = 18

The largest subgroup of paediatric reports involving errors was, as previously, SRNM with a total of 18 cases. These were mostly failure to give irradiated and/or CMV negative components or methylene blue FFP. Six of the 7 reports in infants < 1 yr were a failure to give irradiated components; 4 of these were for cardiac patients. The 10 reports from 1 to < 16 years combined failure to give MB-FFP and CMV negative components, with 1 each of failure to give apheresis platelets, sickle negative red cells for a patient with sickle cell disease, or an irradiated component. The underlying diagnosis in this age group was mostly solid tumour, haematological malignancy or bleeding.

The variation in the SRNM errors in the different age groups reflects the different underlying diagnoses, and also that it is less likely that non-MB-FFP will be selected for a small infant than for older children, as small-volume 'neonatal' FFP packs are all MB treated. In some cases, particularly in the older age groups, the SRNM was not specifically related to the patient being a child, for example needing irradiated components post fludarabine. Although errors at all stages of the transfusion process were contributory, the laboratory played a central role in 14/18 of the SRNM cases.

In the past SRNM accounted for 85/151 (56%) of error reports in 2003–2005,[34] 19/45 (42%) in 2007, and 19/54 (35%) in 2008. This is a possible downward trend but the numbers have shown no improvement over the last year and SRNM still represent a substantial proportion of all paediatric error reports.

IBCT – Laboratory error *n* = 11

The second largest subgroup of error reports were laboratory errors (11/54), of which 7 were in infants < 1 yr of age, all of whom were < 31 days old. Many of the cases could have occurred in any age group (see Chapter 6) and included 2 separate events where 'special' components were ordered from the NBS for 2 patients at the same time and the wrong component was issued by the laboratory. However, aspects of the errors were likely to have been paediatric related in 6/7 of the cases in infants < 1 yr. Three of these cases involved errors in providing red cells for infants < 1 month of age without crossmatching against the maternal sample, despite previous information that the mothers had antibodies. In one case a D positive paedipak was wrongly issued to a D negative infant.

Case 1

Infant given D-incompatible red cells due to assumption that paedipaks were all D negative

A 30-day-old group AB D negative infant required a red cell top-up transfusion. Only group O D negative paedipaks were routinely stocked in the hospital. However, on this occasion there were some D positive paedipaks stored within the same location as the D negative packs. The BMS issuing the blood out of hours selected units based on the expectation that only group O D negative units would be there. During the selection and issuing phases the fact that the blood was group O D positive was not realised, despite the hospital's computer software warning users when issuing across D group.

This is not the first time that an error of this type has occurred, and emphasises the need for particular care in hospitals that use group O D positive as well as group O D negative paedipaks.

In addition to reports in the laboratory error category, the laboratory also contributed significantly to errors in other categories: 14/18 SRNM and 4/8 HSE reports. This gives a total of 29/92 (32%) paediatric reports in which laboratory error was a major factor.

IBCT – Administration *n* = 8

Five of the 8 (63%) paediatric administration errors were in neonates ≤ 4 weeks old. In 3 of the neonatal cases, adult group O D negative blood was collected by nursing staff for perinatal resuscitation rather than blood stocked specifically for neonates. In another neonatal case, blood was given by mistake to the twin sister of the intended recipient, an error most likely to occur on neonatal units. The 3 non-neonatal cases were in patients between 10-17 years of age and did not involve paediatric-related scenarios. Two were instances of erroneous bedside checking.

IBCT – Miscellaneous *n* = 2

In the first case a neonate was grouped as B D positive on one occasion and subsequently group O D negative following large volume transfusion with group O D negative blood. Two different medical record numbers were used for these samples as a result of the way in which the hospital and neonatal computer systems interacted, so the laboratory had no indication that they were from the same baby. Group O FFP and platelets were issued and transfused but there was no evidence of haemolysis as a result. This case illustrates potential difficulties in patient identification as the result of having multiple separate computer systems.

The second case in this group related to an omission of antenatal testing at 28 weeks' gestation, resulting in transfusion of an inappropriate unit of S-positive red cells to a neonate whose mother had anti-S.

Both of these are discussed in the IBCT chapter on page 32.

Handling and storage errors (HSE)

There were 8 paediatric HSE reports, of which half were in neonates ≤ 4 weeks old. In 2 cases, there were problems with neonatal exchange units being used when more than 5 days old, due to a combination of older units being selected by the NBS and this not being detected by the hospital laboratories. In 5 of the 8 cases the problems were not specifically paediatric related.

Half the HSE cases could be attributed primarily to laboratory error, and the other half to ward error or a combination of the two.

Inappropriate and unnecessary transfusion

There were 7 reports of inappropriate and unnecessary transfusion in children, none of which were to neonates ≤ 4wks. Two of the 3 cases to infants < 1 yr were of transfusion on the basis of an incorrect Hb result; in 1 the result was from another baby and in the other the sample came from an arm with a drip running. In the third infant there was a failure to check that they had already been transfused (see I&U Chapter 7). There were 2 cases of excessive red cells transfusions to a 1-year-old and a 2-year-old. Both transfusions were to oncology patients but one of these occurred at the shared care centre, illustrating the need for good communication and training.

Case 2

Inappropriate prescription of red cells for a small child in 'units' instead of calculated volume

A 2-year-old child, small for her age and under shared care for treatment of a solid tumour, needed a transfusion. The central hospital requested that the shared care unit transfuse the child with 2 paedipak units of red cells. This was translated on the transfusion request form and prescription sheet as '2 units', without stating the volume required. Two adult units were issued and transfused without adverse reaction. However, the child was found to have a high Hb four days later and was subsequently venesected.

Case 3

Unfamiliarity with paediatric prescribing results in serious overtransfusion of a small child

A 1-year-old child required a transfusion as part of treatment for a malignancy. The blood was requested and prescribed by a doctor who was not familiar with the patient. A pre-filled request form was signed by the doctor without checking the notes for the volume required. The information on the request form was then used to complete the prescription with no consideration given for estimating the volume of blood according to the patient's weight. The patient had a post-transfusion Hb of 18.3 g/dL.

Both these cases illustrate a lack of understanding of the need to request and prescribe the correct weight-related volume to be transfused for children, instead of 'units' as prescribed for adults. These cases also highlight the absence of a requirement by laboratories to have a specific component volume requested for paediatric transfusions.

The final 2 cases in this category were 16–17-year-olds transfused on the basis of erroneous results (1 a blood gas Hb, and 1 an incorrect platelet count due to platelet clumping).

Non-error related reports *n* = 38

ATR

This is by far the largest category of the non-error paediatric reports, with 25 cases in 2008 (27% of all paediatric SHOT reports, the same proportion as in adults). Only 1 was from a neonate, with the majority of cases (23/25) occurring in children ≥ 1 year old. ATR accounted for 23/61 (38%) of all cases for the ≥ 1 year age group, a striking increase from previous reports both in the absolute number and proportion of ATR reports in this age group (2/30 in 2003 and 5/30 up to 16 years, in 2007).

The small numbers of ATR reports from the < 1yr age group may either reflect a lack of recognition of reactions or the immunological immaturity of infants.

In children the majority of reactions (18/25; 72%) followed platelets with 14 of these relating to apheresis platelets. Most paediatric reactions to platelets were to apheresis platelets rather than buffy-coat derived pools (14/18, 78%), consistent with the fact that most platelets given to children are from apheresis donors. However, this figure also demonstrates that some children are still receiving non-apheresis platelets.

Paediatric reports account for 26% of all ATR reports related to platelets. The EaSTR Study (Epidemiology and Survival of Transfusion Recipients) of transfusions in 29 representative hospitals over a 12 month period in 2001–02 showed that 4% RBC, 13% platelets, and 9% of FFP transfusion recipients were children < 16 years of age.[36] This suggests that the number of paediatric ATR reports due to platelets is disproportionately high in children.

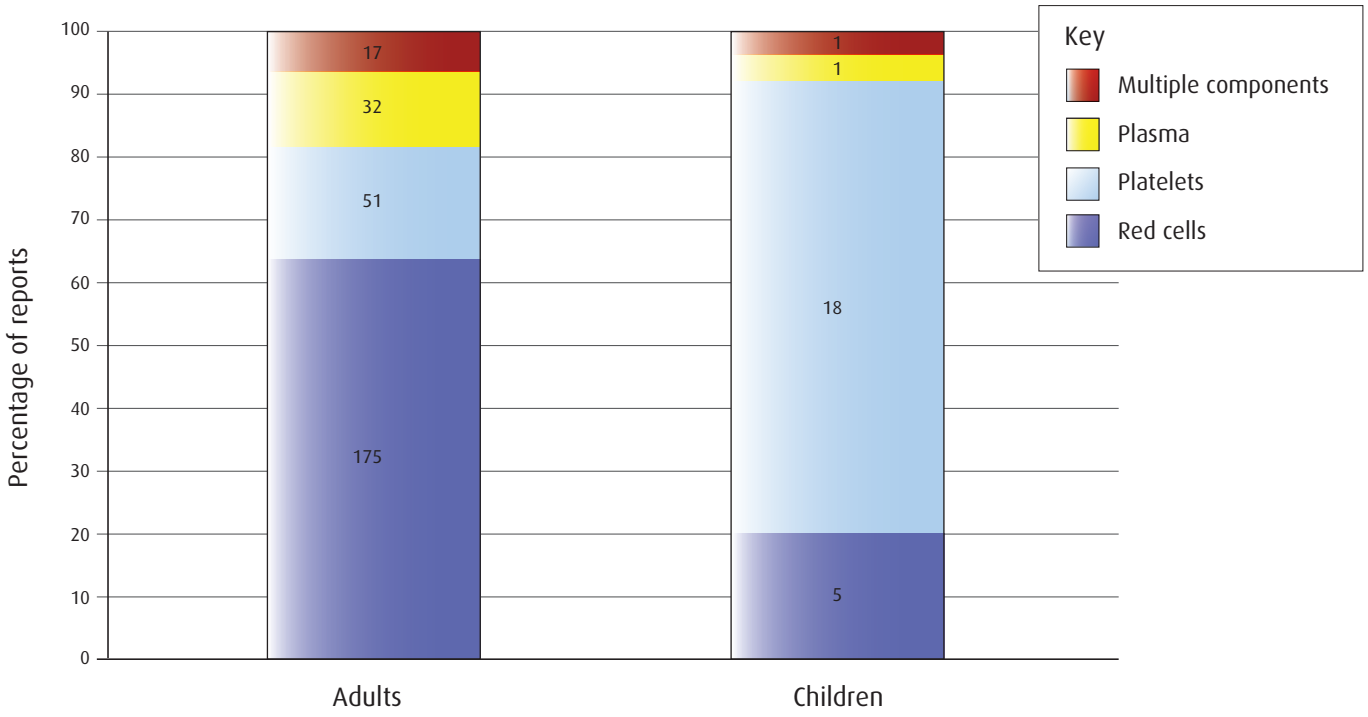
The high percentage of paediatric ATR reports due to platelets (72%) as compared to other components in 2008 contrasts with the paediatric summary data from 1996–2005, where the components implicated were RBC 14/30 (47%), platelets 12/30 (40%) and 4/30 FFP (13%).34 It also contrasts with the relative proportions of reports resulting from the different components in adults (Figure 26), although this difference is partly due to the large number of isolated febrile reactions reported in adults following red cell transfusions.

Table 58
Types of reactions for each component comparing paediatric with adult reports

NB See ATR, Chapter 10 page 90, for total numbers.

Reaction	Red cells		Total platelets		Fresh frozen plasma		Multiple components		Total	
	Adults	<18 yrs	Adults	<18 yrs	Adults	<18 yrs	Adults	<18 yrs	Adults	<18 yrs
Anaphylactic/ anaphylactoid	7		12		8		5		32	
Severe allergic	5	3	3	8	7		2	1	17	12
Hypotensive	5		1		1	1	1		8	1
Febrile with other symptoms or signs	23		4	2	2		1		30	2
Minor allergic	23		19	4	10		2		54	4
Isolated febrile	102	2	8	2	3		6		119	4
Unclassified	10		4	2	1		0		15	2
Total	**175**	**5**	**51**	**18**	**32**	**1**	**17**	**1**	**275**	**25**

Figure 26
Acute transfusion reactions by component type: a comparison between adult and paediatric reports



Types of reactions (as categorised as in the ATR chapter)

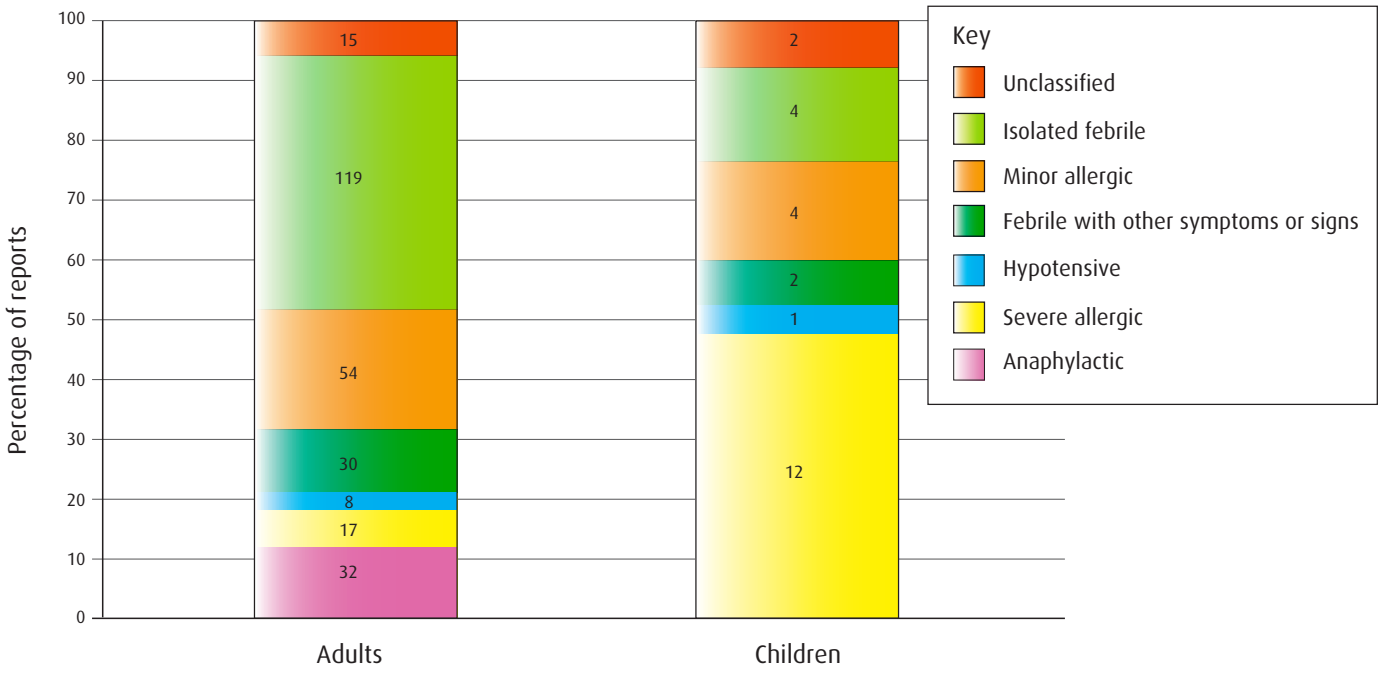
- **Generally** – the reactions reported in children tended to be more severe than those in adults (52% vs. 20% in the severe allergic/anaphylactic/hypotensive categories, see Figure 27). Few isolated febrile transfusion reactions were reported in children. These differences may be due to differences in reporting patterns.
- **RBC** – There were only 5 paediatric reactions reported, but 3 of these were severe allergic reactions, as compared to adults where the majority were isolated febrile or minor allergic reactions: 38% of reports of severe allergic reactions to red cells were in the paediatric age group.
- **Platelets** – 8/18 (44%) paediatric reactions were categorised as severe allergic. Of the total 'severe allergic/anaphylactic' reactions to platelets, 35% were in the paediatric age group.
- **FFP** – only 1 reaction to FFP alone was reported, although it was very severe.

Case 4

Severe hypotension and circulatory collapse in a young child given FFP

An 11-month-old infant with congenital heart disease was transfused FFP and after 10 minutes became hypotensive. The hypotension was initially thought to be due to hypovolaemia so the rate of FFP infusion was increased. However, this resulted in further deterioration and circulatory collapse requiring resuscitation, with opening of the chest and direct cardiac massage. As the patient's symptoms started while the transfusion was in progress and worsened when the rate of infusion was increased this was subsequently believed to have been a transfusion reaction.

Figure 27
Type of acute transfusion reactions – comparison between adult and paediatric reports



Underlying diagnoses

The 1 neonate reported had haemolytic disease of the newborn. Of the rest, 16 were patients with haematological malignancies or solid tumours, 3 had aplastic anaemia, 1 had had a bone marrow transplant, and there was 1 each with a cardiac, vascular, obstetric or trauma-related underlying diagnosis.

HTR

There were 4 paediatric reports of HTR, all of which were from children > 1 yr old (see HTR, Chapter 11). Two patients were group A and haemolysed following transfusion of group O platelets, and in 1 of the cases the platelets were HLA-matched. Both patients had sickle cell disease, and 1 of them developed hyperhaemolysis syndrome after an exchange transfusion pre-adenotonsillectomy. The other 2 patients were being treated for malignancies.

Paediatric reactions were only rarely reported in the HTR category in the past, but some reactions following transfusion of group O platelets to non-group O recipients have previously been included in other sections.

TRALI

There were 2 cases of TRALI, both in 17-year-olds (see TRALI, Chapter 12). There were only 3 paediatric TRALI cases in 2003, and none in 2007. There have been no SHOT reports to date of TRALI cases in infants < 1 yr, which may be either because they don't occur or because they are not recognised. There are very few reports in the literature of TRALI in neonates.[37,38]

Anti-D

There were 4 anti-D errors in patients aged 16–17 years old. One patient had had no antenatal care, perhaps because of circumstances related to her young age, and this may have contributed to delays in recognising that anti-D was needed post delivery.

TTI

There was 1 TTI in a teenager with acute leukaemia who was transfused with a unit of apheresis platelets with *Streptococcus dysgalactiae* and who recovered following antibiotic treatment (see TTI, Chapter 15, for details).

Autologous transfusion

There were 2 paediatric orthopaedic cases where there were difficulties with the cell salvage procedure, which was subsequently abandoned without adverse outcome (see Autologous Transfusions, Chapter 18).

TACO, PTP, TA-GvHD

There were no paediatric reports in any of these categories.

COMMENTARY AND LEARNING POINTS

- There were increased numbers of paediatric reports to SHOT in 2008, but a slight decrease in the overall proportion of reports from children. The majority of reports were still error related but there was a marked increase in the number of ATR reports in those ≥ 1 yr old.
- The transfusion laboratory played a major role in 29/92 paediatric reports (32%), suggesting the need for increased training and awareness of paediatric issues in the laboratory, including component special requirements and the need for crossmatching against the maternal sample where there are historical antibodies. There needs to be particular care in hospitals that use O D positive as well as O D negative paedipaks, and efforts should be made by the UK Blood Services not to alter the supply to hospitals whose policy is to only use O D negative.
- A number of the laboratory errors could have been detected at the bedside check, emphasising the ongoing need for training and awareness of paediatric component requirements among clinical as well as laboratory staff.
- As errors were disproportionately higher for the < 1yr age group all professionals need to pay particular attention when involved with transfusion for these patients. There continue to be reports of adult flying squad blood being given to neonates on obstetric units, and confusion between twins on neonatal units.
- Medical staff need to be aware of groups who need special attention, such as infants for cardiac surgery who may require irradiated components. Transfusion education must cover special requirements in paediatric conditions.
- Patients who are cared for between more than one hospital (e.g. oncology shared care or neonates/cardiac patients transferred to specialist units) are frequently involved in errors relating to special requirements due to lack of formalised communication mechanisms between hospitals. Such mechanisms must be in place involving both clinicians and the laboratory at both sites.
- Inappropriate prescriptions, especially in terms of rate and volume of component, are an ongoing problem that can lead to significant morbidity and mortality, and this needs to be further highlighted during junior doctor training.
- The striking increase in ATR reports in the ≥ 1 yr age group, particularly in platelet reactions, is likely to be due to changes in reporting patterns as there has been no alteration to apheresis platelet components during this period. The relative lack of reports in the infant age group is intriguing and may be a feature of their immature immune system. Further data and analysis of trends in this group will be of interest.
- The ongoing reports of haemolysis following transfusion of group O platelets to non-group O recipients are concerning and recommendations regarding their use for HLA matched recipients may need to be reviewed. These reports also highlight the need to ensure adequate availability of non-group O apheresis platelets (see recommendations in the main ATR chapter).
- The absence of TACO and TRALI reports in neonates and infants is noteworthy. This is part of the general lack of non-error reports including ATR in this age group and needs detailed future studies to identify the reasons. There may be significant lack of recognition or underreporting, but fundamental developmental differences may also contribute to this finding.
- Other adverse outcomes of transfusion such as morbidity associated with venous access are not being captured, and consideration should be given to defining other categories of adverse outcomes associated with transfusion for the neonatal and infant group.

RECOMMENDATIONS

New recommendations from this year

- The trend in increasing ATR cases, in particular in relation to platelets, needs careful monitoring.

  Action: SHOT

- Clinical staff should be encouraged to report all ward-based reactions and events including possible TACO, TRALI and neonatal ATR cases.

  Action: HTTs

Recommendations from previous years

Year first made	Recommendation	Target	Progress
2007	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.	**HTT, hospital transfusion laboratories and consultant haematologists with responsibility for transfusion**	This recommendation needs re-emphasis in 2008, and laboratories need sufficient manpower and IT to undertake this. Laboratories must also demand that they are given requests for paediatric transfusions in mL and not units.
2007	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.	**HTT and clinical users of blood**	The 2008 report demonstrates a need for continuing training in this area.
2007	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, communication and bedside checking are effective and comprehensive.	**HTT and clinical users of blood**	
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 Feb 2007.

20. Near Miss Reporting

Definition

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

SHOT has been running a Near Miss pilot exercise in 2008–09, looking at errors associated with transfusion samples, with the aim of obtaining up-to-date denominator data against which to benchmark other transfusion errors.

The transfusion process can be conveniently divided up into stages, and there are already some barriers in place to detect or prevent errors at each stage, such as national guidelines incorporated into local policies and SOPs, but it is important to realise that some errors may 'get through' the systems and only be detected in retrospect.

- the **pre-testing** phase is where the bulk of sample errors might be expected to be detected. The main barrier in place is the application of national standards for sample labelling and acceptance, which must be incorporated into local policies. Sample errors rejected at this stage should be investigated locally but do not constitute a Near Miss event reportable to SHOT.
- the **testing** phase, where, despite apparent correct labelling, the blood in the sample has come from a different patient – 'Wrong Blood In Tube'. Detection of this type of error within the laboratory quality management system relies on there being a historical grouping record for the patient with which to compare the current result.

Phase 1 pilot study

This was carried out over a period of one calendar month, from 1st April 2008, and involved an intensive data gathering exercise by which all samples rejected at 'booking in' were categorised by a 'tick box matrix', as shown below. The pilot was carried out by the hospital transfusion laboratory staff.

		1	2	3	4	5	6	7	8	9
What was the error?	Handwritten details missing									
	Handwritten details incorrect									
	Addressograph label on sample									
	Handwritten error over a pre-printed ID label									
	Sample underfilled / inappropriate									
	Sample and request don't match									
Was the sample relabelled, and then tested?	Yes									
	No									
Who took the sample?	Doctor									
	Nurse									
	Midwife									
	Support Assistant									
	Phlebotomist									
	Not Known									
When was the sample taken?	Core hours (defined locally)									
	Non-core hours									

Where was the sample taken?	Emergency Department									
	Medical Admissions Unit									
	ICU / HDU									
	Pre-op clinic									
	Obs & Gynae									
	Neonatal									
	Paediatrics									
	General ward									
	GP / Community									
	Not known									

A total of 131 hospitals or Trusts expressed an interest in participating in the pilot study, and data was eventually received from 121 of these.

Participation by country

England	**92**
Wales	**5**
N. Ireland	**6**
Scotland	**6**
Channel I.	**2**

For the sake of usefulness in terms of numbers and percentages, the data from the Channel Islands hospitals has been included (with their kind permission) with that from England.

All transfusion samples received by participating laboratories in one month

	UK	E & CI	W	NI	S
No. samples	224, 829	187,265	15,812	8968	12,784
No. samples per hospital	82–6155	82–6155	123–2283	600–3020	702–5966

Samples rejected at booking in

	UK	E & CI	W	NI	S
No. samples	8535	6868	858	376	433
% Samples received that were rejected	3.8	3.7	5.4	4.2	3.4
Range	0.4% – 13.2%	0.4% – 13.2%	0.5% – 12.6%	2.0% – 7.3%	2.1% – 6.5%

NB Samples were counted as 'rejected' even if they were amended and subsequently accepted for testing.

The rate of sample rejection is fairly constant across the UK, but the rate for individual hospitals within the mean figure ranges from only 0.4% of samples received in the transfusion laboratory to over 13% samples received.

Relabelling of samples

	UK		E & CI		W		NI		S	
Hospitals allowing relabelling	47	*39%*	33	*35%*	8	*53%*	0	*0%*	3	*50%*
% samples relabelled	27%		27%		17%		0%		42%	

Many hospitals have adopted the concept of 'zero tolerance' towards sample errors, and insist that an erroneous sample is retaken, but it is clear that nearly 40% of hospitals across the UK, and 50% in Wales and Scotland, still allow amendments to be made prior to testing.

Of particular concern are the 271 cases (3.2% of all rejected samples) where samples have been relabelled despite not knowing who had performed the original venepuncture and labelling. This means the signing of the tube to convey responsibility for correct patient ID is meaningless. This can in no way be considered to be good practice, and must inevitably increase the risk of mislabelling and potential serious consequences for the patient.

Reason for sample rejection (may be more than one)

	UK		E & CI		W		NI		S	
Details Missing	3280	*37%*	2489	*35%*	477	*55%*	159	*42%*	155	*32%*
Details incorrect	3273	*37%*	2762	*39%*	173	*20%*	150	*39%*	188	*39%*
Addressograph label	500	*6%*	412	*6%*	39	*4%*	28	*7%*	21	*4%*
Underfilled or Inappropriate Sample	1142	*13%*	876	*12%*	157	*18%*	31	*8%*	78	*16%*
Sample / Form different	583	*7%*	511	*7%*	23	*3%*	13	*3%*	36	*8%*

The bulk of the sample errors (74% across the UK) are related to missing or incorrect details on the sample bottles. The relatively high percentage of missing details in Wales may well be due to the extra requirement for the first line of the patient's address as an identifier, and also the resulting design of the sample labels, meaning it is easy to 'follow down' the boxes round the sample tube but miss those that are adjacent.

The use of 'addressograph' labels, or labels pre-printed away from the patient's side, continues to be a problem, despite recommendations in previous SHOT reports and BCSH guidelines. It must be emphasised that the misuse of pre-printed labels has implications for patient identification and subsequent care far beyond the boundaries of Blood Transfusion.

Who took the sample?

	UK		E & CI		W		NI		S	
Doctor	2711	*31%*	1959	*28%*	392	*46%*	196	*52%*	164	*38%*
Nurse	899	*10%*	790	*11%*	41	*5%*	24	*6%*	44	*10%*
Midwife	1261	*15%*	1046	*15%*	90	*10%*	63	*17%*	62	*14%*
HCA	60	*<1%*	52	*<1%*	7	*<1%*	0	*0%*	1	*<1%*
Phlebotomist	348	*4%*	327	*5%*	14	*2%*	2	*<1%*	5	*1%*
Not known	3254	*38%*	2694	*39%*	314	*37%*	91	*24%*	157	*36%*

It is of some concern that in the largest category of samples rejected by the laboratory, 38%, it is not known who performed the venepuncture and labelling of the sample. Where the person performing the venepuncture was recorded, the bulk of incorrect samples were taken by medical staff (31%), followed by midwives (15%) and nurses (10%).

Although at present there is a lack of denominator data regarding the overall breakdown of who bleeds patients for transfusion samples, it is felt that the proportion of medical staff involved in the errors is high.

Where were the samples from?

	UK		E & CI		W		NI		S	
Emergency Dept	1604	*19%*	1317	*19%*	204	*24%*	30	*8%*	53	*12%*
EMAU	349	*4%*	271	*4%*	59	*7%*	6	*2%*	13	*3%*
ITU / HDU	263	*3%*	187	*3%*	33	*4%*	17	*5%*	26	*6%*
Pre-op clinic	537	*6%*	469	*7%*	27	*3%*	19	*5%*	22	*5%*
Obs & Gynae	1589	*19%*	1254	*18%*	152	*18%*	98	*26%*	85	*20%*
Neonatal	72	*<1%*	58	*<1%*	5	*<1%*	6	*2%*	3	*<1%*
Paediatric	223	*3%*	164	*2%*	22	*3%*	25	*7%*	12	*3%*
Ward	2576	*30%*	2028	*30%*	246	*29%*	156	*41%*	146	*34%*
GP / Community	1127	*13%*	991	*14%*	66	*8%*	5	*1%*	65	*15%*
Not known	195	*2%*	129	*2%*	44	*5%*	14	*4%*	8	*2%*

While it may appear from these data that general wards (30%), emergency departments (19%) and obstetrics & gynaecology (19%) seem to generate more that their fair share of sample errors the numbers probably just reflect the high volume of group & save samples received from these clinical areas.

What time of day did the samples arrive?

	UK		E & CI		W		NI		S	
Core Hours	6210	*73%*	5061	*74%*	535	*62%*	272	*72%*	342	*79%*
Non-core Hours	2325	*27%*	1807	*26%*	323	*38%*	104	*28%*	91	*21%*

The definition of 'core hours' was left to the individual hospital to decide, as there is so much variation in exact hours worked across the country. SHOT has a working definition of 'core hours' as 08.00–20.00 Monday–Friday.

Across the UK, 27% of the rejected samples were recorded as arriving out of core hours, and this compares well with previous estimates of between 24–40% errors occurring out of hours as reported by SHOT from 1998–2004.

Phase 2 pilot study

This was carried out over a period of six months, from 1st September 2008 to 28th February 2009. Reporters were asked to submit cases where sample errors were detected after passing the initial barrier to rejection at the booking-in stage. Reports were made via SABRE as 'SHOT-only' notifications, and in response the SHOT Office sent a paper questionnaire to complete and return for analysis.

What was the error?	Details incorrect on the right sample			At what point was the error detected?	After booking in but prior to testing	
	Wrong Blood In Tube (WBIT)				During testing / selection of product / component	
Had the sample been relabelled?	Yes				At authorisation of results	
	No – zero-tolerance policy in place				On labelling the product / component	
Who took the sample?	Doctor	FY1			On collection of the product / component	
		FY2			At pre-administration checking	
		STR / Cons		Who detected the error?	MLA	
	Nurse	Student			Transfusion BMS	
		Staff Nurse			Other BMS	
		Sister/Charge Nurse			Nurse	
	Midwife				Porter	
	Health Care Assistant				Other (specify)	
	Phlebotomist			Is there a policy/SOP in place to prevent this type of error occurring?	No / Yes	
	Other				If yes, brief description of policy:	

What time was it taken?	08.01–16.00		How exactly was the error noticed?	
	16.01–20.00			
	20.01 - 08.00			
Where was the sample taken?	A/E Department		Was it detected by chance, or as a result of following protocols / QMS barriers to error?	
	Medical Admissions Unit			
	ICU / HDU			
	Women's & Children's			
	Paediatrics / Neonatal		Any further comments or information you may wish to supply:	
	GP practice			
	Ward (specify specialty)			
What was the request?	Group & Screen			
	Antenatal Group & Screen			
	Crossmatch / component issue			
Was it urgent?	Urgent			
	Routine			

On receipt of a notification report, 296 questionnaires were sent out. Of these, 220 completed questionnaires were returned either electronically or as paper reports, giving a return rate of 74.3%.

Subsequently, 6 questionnaires were withdrawn, leaving 214 for analysis.

What was the error?

Details incorrect on the right sample	**123**	*57.5%*
Wrong Blood In Tube (WBIT)	**90**	*42%*
Not known or no response	**1**	*0.5%*

Who took the sample?

Doctor	FY1	**38**	*18%*
	FY2	**47**	*22%*
	STR / Cons	**12**	*5%*
Nurse	Student	**0**	*0*
	Staff Nurse	**25**	*12%*
	Sister/Charge Nurse	**4**	*2%*
Midwife		**31**	*15%*
Health Care Assistant		**4**	*2%*
Phlebotomist		**22**	*10%*
Other		**25**	*11%*
Not known or no response		**6**	*3%*

What time was it taken?

08.01–16.00	**130**	61%
16.01–20.00	**32**	15%
20.01–08.00	**42**	20%
Not known or no response	**10**	4%

What was the request?

Group & Screen	**150**	70%
Antenatal Group & Screen	**19**	9%
Crossmatch / component issue	**45**	21%
Not known or no response	**0**	0

Was it urgent?

Urgent	**35**	16%
Routine	**173**	81%
Not known or no response	**6**	3%

At what point was the error detected?

After booking in but prior to testing	**44**	20.5%
During testing / selection of product / component	**66**	31%
At authorisation of results	**86**	40%
On labelling the product / component	**1**	0.5%
On collection of the product / component	**1**	0.5%
At pre-administration checking	**5**	2.5%
Not known or no response	**11**	5%

Who detected the error?

MLA	**10**	4%
Transfusion BMS	**159**	74.5%
Other BMS	**27**	13%
Nurse	**5**	2.5%
Porter	**0**	0
Other	**11**	5%
Not known or no response	**2**	1%

Was there a policy or SOP in place to prevent this type of error occurring?

All respondents indicated that there were organisational policies in place, based on national guidance, which covered sample taking and labelling. The sample taking process was covered mainly in the Trust transfusion policy, although many reporters had a separate venepuncture policy as well.

How was the error detected?

Of the 123 errors where the samples were from the correct patient, but where there were labelling errors that had been missed at booking in, 4 were detected at bedside administration of blood components, when it was realised that identification details were discrepant.

The other 119 errors were detected by the quality management system in the transfusion laboratory, where SOPs defined check procedures including:

- checking sample details against worksheets prior to testing on analysers
- checking sample details against worksheets prior to compatibility testing
- checking sample details against completed worksheets prior to authorisation of compatibility testing
- checking sample details against worksheets prior to authorisation of grouping results.

Of the 90 errors classified as 'Wrong Blood in Tube':

- 74 were detected because there was a discrepancy between blood group for the current sample and a historical group on the LIMS.
- 8 were detected because the person taking the sample realised that they had made an error and contacted the laboratory to inform them of this fact.
- 5 were detected because the clinical area were expecting either blood results or blood components for a particular patient, but were informed that results or components were available on a different patient (see Case 3 below).
- 2 were detected by alert BMSs who realised there was something unusual about the requests (see cases 1 and 2 below).
- 1 error was detected because a patient demanded to know why he had been bled twice in one day for a Group & Save request.

Case 1

Duplicate samples alert BMS to possible mix-up

The duty transfusion BMS working out of core hours noted that a second set of samples had been sent for the same patient in a very short space of time. On questioning the requesting doctor, it became apparent that the samples had been taken from a completely different patient, but labelled with the first patient's details. The samples were discarded prior to testing.

Case 2

Samples and requests on deceased patient alert BMS to error

A transfusion sample and request for blood components were received in the laboratory, where the duty BMS recognised the patient as having died in theatre some hours ago. On challenging the requesting doctor, it transpired that the sample had been taken from a different patient, but labelled using the deceased patient's notes.

Case 3

Unduly rapid G&S results alert clinicians to error

A group & save request was booked in routinely. The patient was new to the laboratory, and there were no discrepancies apparent on either the sample or the request form. The clinical team looking after the patient noted that a blood grouping result was available on the Trust electronic results reporting system and telephoned the laboratory to highlight that no grouping sample had yet been taken from this patient. The true identity of the sample was never established.

COMMENTARY

Near Miss events have long been recognised as a good indicator of strengths and weaknesses within the transfusion process. Near Misses often have the same root cause as actual transfusion accidents, but their relatively higher frequency allows systems to be analysed in more detail and deficiencies corrected before accidents occur.

The potential for an error to have a serious consequence depends on many factors, including the effectiveness of checks or barriers built into the process. Earlier SHOT annual reports have demonstrated that in many instances several errors may contribute to a 'wrong blood' event, and minor errors that evade the checks and barriers may play a significant part in a serious outcome for the patient.

Previous SHOT data have shown that around 50% of all Near Miss events, where an incorrect component was recognised before transfusion took place, occur at the sampling stage.

In phase 2 of the pilot study, 123/214 (57.5%) reports were of identification errors on correct samples that were missed at the sample receipt stage but detected on testing or checking within the laboratory. Actual WBIT errors accounted for a smaller number, 90/214 (42%), of errors. Of these, 76% of errors involve samples taken within core working hours, with 20% identified as arriving out of hours.

As in previous reports, the sample errors detected after acceptance for testing originate predominantly with medical staff (45%), but also with midwives (15%), nurses (14%) and phlebotomists (10%). The percentage of sample errors attributed to medical staff seems disproportionately high, and it would be interesting to obtain denominator data as to what proportion of all samples are taken by which group of staff. This would, however, be an intensive and difficult data gathering exercise, and until it is completed it may be enough to note that the figures obtained are comparable with previous SHOT annual reports. This emphasises the need for training as well as adherence to policies for venepuncture and sample labelling for all staff groups including doctors.

It is pleasing to see that check procedures put in place as part of the laboratory Quality Management System have been successful in screening out some of these errors, and there have been some examples of good laboratory practice in identifying 'out of the ordinary' requests that uncovered serious errors.

The importance of a clean, accurate transfusion database is highlighted by 74/90 WBIT errors being detected by comparison with historical data. If patients have never been grouped before, then there is a much higher likelihood that the errors will get through the system undetected, with the potential to cause death or major morbidity if components are issued on the basis of an incorrect blood group.

Local analysis of the origin/root cause of these Near Miss errors should be conducted against the background of competency assessment for clinical staff undertaking venepuncture, but what is apparent is a persistent failure to adhere to national and local policy regarding patient identification procedures.

The development of the new SHOT database later this year should facilitate the reporting and analysis of the whole range of Near Miss events, including WBIT errors, component selection and handling errors, collection and pre-administration errors.

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22. Glossary

AAA	Abdominal aortic aneurysm
ACD	Acid citrate dextrose
AF	Atrial fibrillation
AHG	Antihuman globulin
AHTR	Acute haemolytic transfusion reaction
ALI	Acute lung injury
ALL	Acute lymphoblastic leukaemia
AML	Acute myelocytic leukaemia
APTT	Activated partial thromboplastin time
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
BNP	Brain natriuretic peptide
BP	Blood pressure
BSMS	Blood stocks management scheme
BSQR	Blood Safety and Quality Regulations
BTLP	Blood Transfusion Laboratory Practice
CAPA	Corrective and preventative actions
CCF	Congestive cardiac failure
CCST	Certificate of completion of specialist training
CEO	Chief executive officer
CLL	Chronic lymphocytic leukaemia
CML	Chronic myeloid leukaemia
CMO	Chief medical officer
CMV	Cytomegalovirus
CPA	Clinical pathology accreditation
CPAP	Continuous positive airway pressure
Cryo	Cryoprecipitate
CS	Caesarean section
CTS	Controlled temperature storage
CVA	Cerebrovascular accident
CXR	Chest X-ray
DAT	Direct antiglobulin test
DGH	District general hospital
DHTR	Delayed haemolytic transfusion reaction
DNA	Deoxyribonucleic acid
DTR	Delayed transfusion reaction
ECMO	Extracorporeal membrane oxygenation

ED	Emergency department
EDTA	Ethylenediaminetetraacetic acid
EI	Electronic issue
EPR	Electronic patient record
ET	Endotracheal
FBC	Full blood count
FFP	Fresh frozen plasma
FMH	Foeto-maternal haemorrhage
FY	Foundation year
G and S	Group & Screen / Group & Save
GGS	Group G streptococcus
GI	Gastrointestinal
GMC	General Medical Council
GP	General practitioner
HAS	Human albumin solution
HAV	Hepatitis A virus
Hb	Haemoglobin
HBc	Hepatitis core
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDN	Haemolytic disease of the newborn
HDU	High dependency unit
HELLP	Haemolysis elevated liver enzymes low platelets
HEV	Hepatitis E virus
HHV-8	Human herpes virus
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen ***or*** Health Protection Agency
HPC	Healthcare Professionals Council
HSC	Health service circular
HTC	Hospital transfusion committee
HTLA	High-titre low avidity
HTLV	Human T-cell leukaemia virus
HTT	Hospital transfusion team
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
IBGRL	International Blood Group Reference Laboratory
IBMS	Institute of Biomedical Science
ICS	Intraoperative cell salvage
ID	Identification
Ig	Immunoglobulin
IHN	International Haemovigilance Network
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
JVP	Jugular venous pressure
JW	Jehovah's Witness
LDF	Leucocyte depletion filter
LDH	Lactate dehydrogenase enzyme
LIMS	Laboratory information management system
MB-FFP	Methylene Blue Fresh Frozen Plasma
MCHC	Mean corpuscular haemoglobin concentration
MCT	Mast cell tryptase
MDS	Myelodysplastic syndrome
MEE	Medical Education England
MF	Mixed field
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	Medical laboratory assistant
NBS	National Blood Service
NBTC	National Blood Transfusion Committee (England)
NEQAS	National external quality assurance scheme
NHSBT	NHS blood and transplant
NHSLA	NHS Litigation Authority
NIBTS	Northern Ireland Blood Transfusion Service
NICE	National Institute for Clinical Excellence
NISS	Normal ionic strength saline
NMC	Nursing and Midwifery Council
NOS	National occupational standards
NPSA	National Patient Safety Agency
NR	Normal range
OA	Optimal additive
ODP	Operating department practitioner
PAD	Preoperative autologous deposit
PAS	Platelet additive solution ***or*** Patient administration system
PBSC	Peripheral blood stem cells
PCC	Prothrombin complex concentrate
PCS	Postoperative cell salvage
PCT	Primary care trust
PEA	Pulseless electrical activity
PEG	Poly-ethylene glycol
PFGE	Pulsed-field gel electrophoresis
PiMS	Patient information management system
PMETB	Postgraduate Medical Education and Training Board
POCT	Point of care testing

PPH	Postpartum haemorrhage
PR	Per rectum
PT	Prothrombin time
PTP	Post-transfusion purpura
RAADP	Routine antenatal anti-D prophylaxis
RBC	Red blood cells
RBRP	Right blood to right patient
RCA	Root cause analysis
RCN	Royal College of Nursing
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
RR	Respiratory rate
RTC	Regional transfusion committee
SABRE	Serious adverse blood reactions and events
SaBTO	Advisory Committee on Safety of Blood Tissues and Organs
SAE	Serious adverse event
SAR	Serious adverse reaction
SCBU	Special care baby unit
SCT	Stem cell transplant
SD	Solvent detergent
SLE	Systemic lupus erythematosis
SNBTS	Scottish National Blood Transfusion Service
SOB	Shortness of breath
SOP	Standard operating procedure
SPN	Safer practice notice
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TA-GvHD	Transfusion-associated graft-versus-host disease
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenic purpura
UKCSAG	UK Cell Salvage Action Group
UKTLC	UK Transfusion Laboratory Collaborative
vCJD	Variant Creutzfeldt Jakob disease
WBIT	Wrong blood in tube
WBS	Welsh Blood Service
WCC	White cell count

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