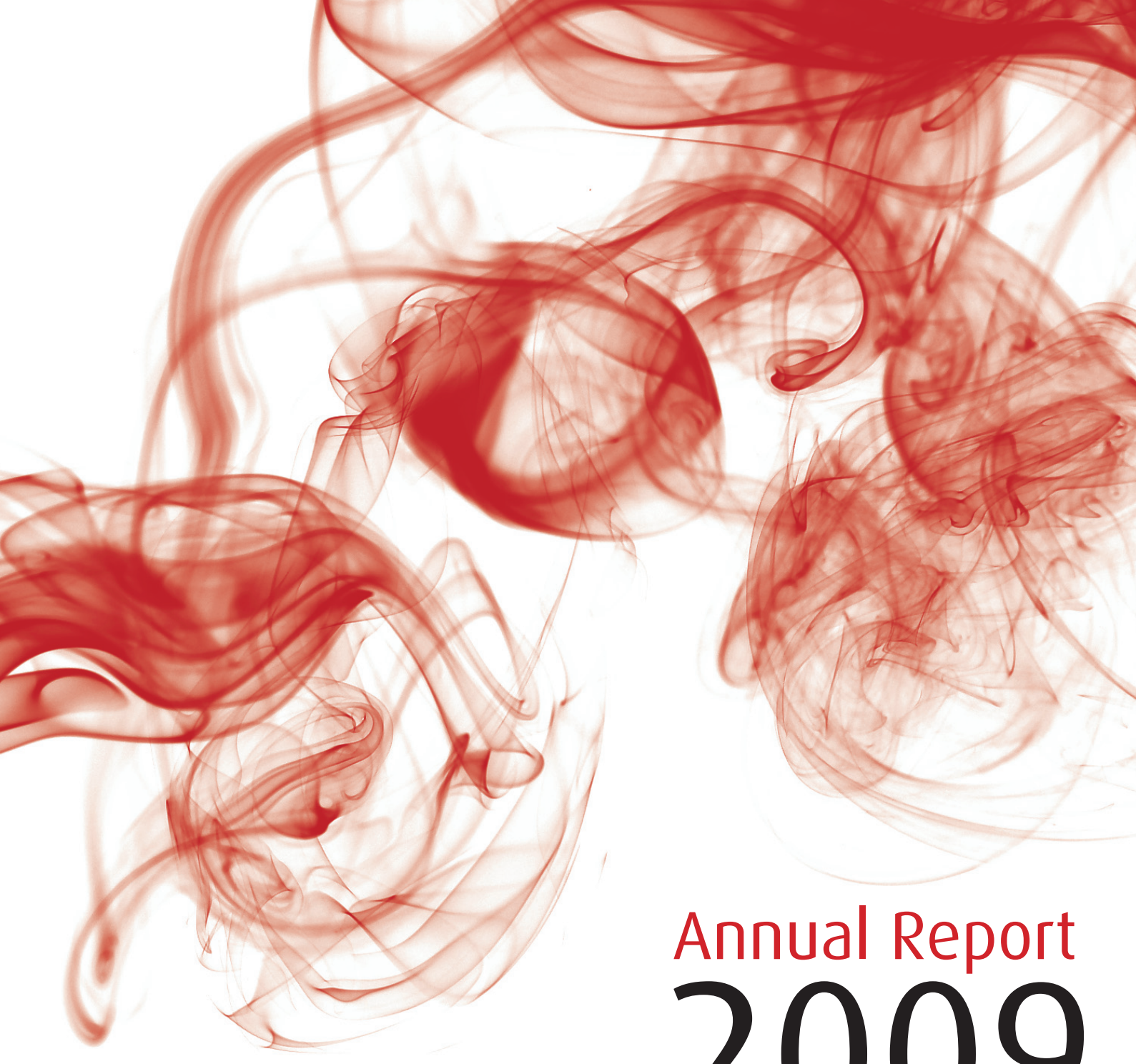

Annual Report 2009

Affiliated to the Royal College of Pathologists

The Steering Group comprises members representing the following professional bodies

British Blood Transfusion Society, British Society of Gastroenterology
British Society for Haematology, College of Emergency Medicine
Faculty of Public Health, Institute of Biomedical Science
NHS Confederation, Health Protection Agency Centre for Infections
Royal College of Anaesthetists, Royal College of Midwives
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

SERIOUS HAZARDS OF TRANSFUSION SHOT

Serious Hazards of Transfusion (SHOT)

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Operations Manager	Mr David Mold
Research Analyst	Mrs Hilary Jones
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Chair: Dr Clare Taylor

Dr Hannah Cohen, Mr David Mold, Mrs Hilary Jones, Mr Tony Davies, Mrs Hema Mistry, Mrs Julie Ball
Mrs Debbie Asher, Ms Caoimhe Cawley, Mr Bill Chaffe, Dr Catherine Chapman, Mrs Alexandra Gray, Ms Joan Jones
Ms Clare Milkins, Dr Helen New, Dr Derek Norfolk, Dr Fiona Regan, Mrs Elizabeth Still, Dr Hazel Tinegate

Steering Group (SG)

Chair: Dr Hannah Cohen

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Prof Mark Bellamy	The Intensive Care Society
Dr Su Brailsford	Health Protection Agency and NHS Blood and Transplant
Ms Lisa Brant	SHOT National Coordinator for Infectious Hazards
Ms Caoimhe Cawley	Health Protection Agency and NHS Blood and Transplant
Mr Bill Chaffe	Institute of Biomedical Science
Prof David Cox	NHS Confederation
Dr Roger Eglin	Transfusion Microbiology Specialist, NHSBT
Dr P Adrian Evans	College of Emergency Medicine
Mr John Getty	Royal College of Surgeons
Dr Brenda Gibson	Royal College of Paediatrics and Child Health
Dr Patricia Hewitt	Consultant Specialist in Transfusion Microbiology, NHSBT
Ms Joanne Hoyle	Royal College of Nursing
Ms Mervi Jokinen	Royal College of Midwives
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Sheila MacLennan	UK Forum
Mr John Marriott	Lay Member
Dr Brian McClelland	Founder Member
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Dr Tim Nokes	British Society for Haematology
Dr Derek Norfolk	British Committee for Standards in Haematology, National Blood Transfusion Committee
Dr Jonathan Potter	Royal College of Physicians
Dr Daghni Rajasingam	Royal College of Obstetricians and Gynaecologists
Ms Joan Russell	National Patient Safety Agency (co-opted)
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Dr Clare Taylor	Medical Director of SHOT
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NB All members of the WEG are members of the Steering Group in their own right

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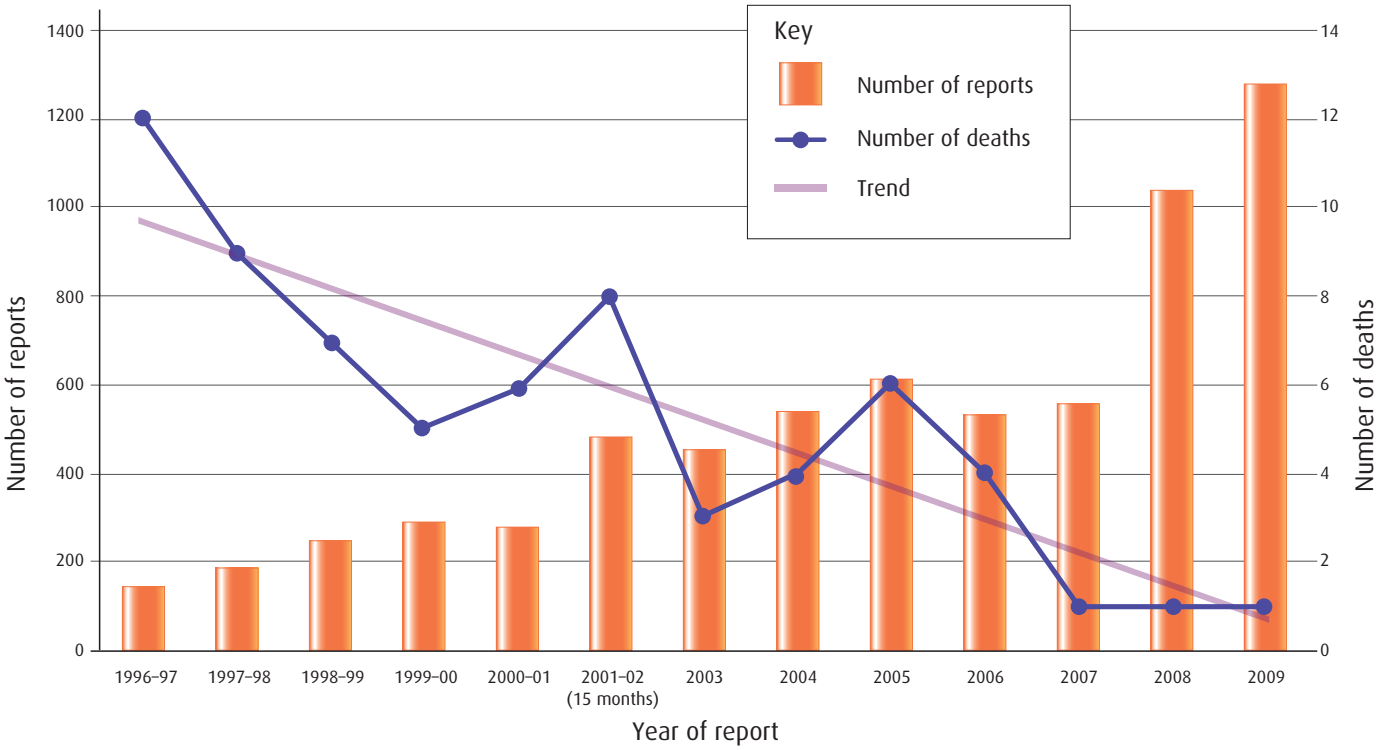
Contents

1. Foreword

The Serious Hazards of Transfusion (SHOT) Report 2009 is the 13th annual report of data and evidence-based recommendations produced by SHOT. In the first year of SHOT reporting 141 reports were submitted, of which 12 were fatalities definitely attributed to transfusion. For this 2009 report 1279 reports were analysed, with 1 death definitely related to transfusion, and 12 further deaths where the transfusion probably or possibly contributed to the death. The trends in total reports and definitely related fatalities are shown below in Figure 1.

Figure 1
Total reports and total deaths definitely due to transfusion between 1996 and 2009



These trends are the hallmark of an effective vigilance system, in that the participation in the scheme, and thus total reports, increases as users become engaged with the process while the number of serious incidents declines. In 1996/97 there were 36 cases in which patients suffered major morbidity from transfusion (excluding 3 cases of potential D sensitisation in young women/girls), plus 12 deaths, resulting in a serious outcome for 48/141 or 34%, of cases reported. In 2009 there were 73 cases of major morbidity (excluding anti-D related potential for major morbidity), plus one death definitely related to transfusion and 12 deaths in which the transfusion reaction may have contributed. The total of 86/1279, i.e. a fall to 6.7%, of patients with serious outcomes is further testament to the success of the scheme. Increased awareness of blood safety issues, through the haemovigilance scheme itself, and implementation of related initiatives based on the data collected combine to improve patient safety and outcomes.

Since 2007 SHOT has carried out detailed analyses of participation in haemovigilance reporting, publishing baseline data in the last (2008) report. These data show very important and positive trends in the patterns of reporting, with the number of organisations sending reports having increased substantially between 2006 and 2009 (see Figure 2, page 7). In 2006, 117 of 223 reporting organisations reported only errors and Near Miss events. In this report this number has reduced to 32 reporting organisations; however, the number of reporters sending reports of incidents in all three broad categories (errors, Near Miss and physiological reactions) has increased from 80 of 223 in 2006, to 206 of 255 in 2009. This reflects a big increase in awareness of blood safety issues and the direct benefits of participating in the scheme, and is a testament to the untiring work of members of the SHOT team in publicising SHOT and presenting SHOT data at numerous national and regional meetings, which has intensified since 2007.

Since participation in haemovigilance is a legal requirement for all organisations undertaking activity in any part of the transfusion chain, the UK Forum has requested that SHOT commences a process of partial de-anonymisation of SHOT data. In this report SHOT has therefore published a more detailed analysis of participation data than in 2008, with a breakdown by region, showing the rate of reports per 10,000 components issued, based on figures sent to the Medicines and Healthcare products Regulatory Agency (MHRA) by hospital transfusion laboratories. The figures for 2008 and 2009 are shown in Table 5 on page 8. Although it is still apparent that only a fraction of possible reports are sent in to SHOT, it is gratifying that there is such a definite and positive trend towards increased reporting.

Following this Foreword is a section which defines the role of SHOT as the UK's professionally led haemovigilance organisation and outlines the differences and similarities between SHOT and the MHRA in their approaches to haemovigilance. A similar document was sent by SHOT to the Department of Health in July 2009 (in response to a Parliamentary Question) and to the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in January 2010. It is hoped that this will help to clarify the current situation.

Dr Hannah Cohen MD FRCP FRCPath

Chair, SHOT Steering Group

Dr Clare Taylor PhD FRCP FRCPath

SHOT Medical Director

2. SHOT – The UK Haemovigilance Scheme

SHOT, established in 1996, is the UK's professionally led haemovigilance scheme for the reporting of transfusion-related adverse events and reactions.

SHOT's goal is to improve transfusion safety by haemovigilance. Through the involvement of the Royal Colleges and other professional bodies, the UK blood services and the four departments of health, the annual SHOT report provides authoritative data and evidence-based recommendations, for use by policy making bodies to:

a) improve patient safety through the improvement of standards of hospital transfusion practice;
b) aid in the production of clinical guidelines for the use of blood components;
c) educate users on transfusion hazards and their prevention;
d) identify new trends or patterns in adverse incidents which can be influenced by new safety interventions or further assessed by research and audit.

SHOT reports are entered by reporters onto a live database, designed in collaboration with Dendrite Clinical Systems™ and implemented on 4th January 2010. This is accessed via the front pages of the SABRE (Serious Adverse Blood Reactions and Events) online system, developed and shared with MHRA.

SHOT is regarded as the international 'gold standard' in haemovigilance and a model to other countries worldwide in the establishment of haemovigilance systems.

SHOT is integrated into the International Haemovigilance Network (IHN), which seeks to improve and standardise haemovigilance practice, allows for benchmarking between countries, shares good practice, and offers support and resource for nations developing haemovigilance for the first time.

SHOT annual reports, presentations at annual educational symposia and all other publications are available on its website: www.shotuk.org.

Legal requirement for haemovigilance data

The MHRA was appointed as the Competent Authority to implement the EU Blood Safety Directive[1] and the Blood Safety and Quality Regulations (BSQR) 2005,[2] the UK transposition of the EU Directive, on behalf of the Secretary of State. In its regulatory role, the MHRA emphasises the place of the quality management system (QMS) in blood establishments and hospital transfusion laboratories, and its legislative remit extends to the point where the transfusion laboratory responsibility ends.

The BSQR require that serious adverse events (SAEs) and serious adverse reactions (SARs) related to blood and blood components are reported to the Competent Authority for annual submission to the European Union (EU). A relatively small part of the overall remit of MHRA in relation to the BSQR is to collect headline figures for transfusion-related adverse events and reactions.

Thus, since 8th November 2005, all suspected SARs and SAEs relating to the quality and safety of blood and blood components must be reported to the MHRA. Reports are submitted to the MHRA through the statutory SABRE online reporting system. MHRA data are not available prior to 2005 as the BSQR and SABRE only came into being in 2005.

The SHOT report is published annually in June or July to coincide with the requirement under the BSQR 2005 for the annualised UK haemovigilance data to be sent to the EU Commission. MHRA is responsible for collating their SAR and SAE reports, and the Adverse Events subgroup of the MHRA's Blood Consultative Committee (chaired by the SHOT Medical Director) then conducts a reconciliation between SHOT and MHRA figures before the data for the EU are finally submitted.

Haemovigilance: statutory, mandatory or voluntary?

Reporting transfusion-related SARs and SAEs to MHRA is statutory. In the past, reporting to SHOT was voluntary, but in recent years a number of quality, inspection and accreditation organisations and government bodies within the UK have made it a requirement. These include: Clinical Pathology Accreditation Ltd (CPA UK) standard H2;[3] National Patient Safety Agency (NPSA), Safer Practice Notice 14 (SPN 14);[4] HSC (Health Service Circular) 2007/001 Better Blood Transfusion;[5] NHS Quality Improvement Scotland, Clinical Standards for Blood Transfusion, Standard 4b.3;[6] Welsh Assembly Government, Healthcare Standards for Wales, Standard 16.[7]

Differences between SHOT and MHRA

There are differences in the data collated by the SHOT scheme and by the MHRA; these are related to inherent differences in the reporting systems and the ways in which they work.

- Reporting transfusion-related adverse events and reactions to MHRA forms a small part of MHRA's remit in implementing BSQR 2005. UK-wide haemovigilance is SHOT's sole remit.

- SHOT is professionally led, with the SHOT Steering Group including representation from virtually all Royal Colleges and professional bodies involved in the transfusion process.

- MHRA uses confirmatory reports submitted by individual reporters to determine the outcome of cases including the imputability (i.e. the relationship of the transfusion to causation of the observed reaction). All cases reported to SHOT are subject to expert scrutiny by members of the Working Expert Group, to ensure that the data reported are accurate and comprehensive.

- The SHOT and MHRA figures can differ as a result of the inherent difference between the two reporting systems. An example is the number of reported cases of bacterial transfusion-transmitted infections (TTIs). This is because MHRA includes unproven cases based on the hospital reporter's assessment of the case, whereas the SHOT cases of bacterial transfusion-transmitted incidents are only those that have been formally investigated by the NHS Blood Transfusion Services (BTS) and the Health Protection Agency (HPA) and where the case is proven by microbiological investigation of the patient as well as the unit (with expert review of each case after full investigation by the blood services). Reporters may leave an imputability of 2 (likely), based on clinical suspicion, attached to a suspected bacterial TTI even though no tests were able to confirm the causal link. These data are therefore submitted to the EU by MHRA, but would be excluded from final SHOT figures.

- Evidence-based recommendations to improve patient safety backed up by complete, analysed data are published in the SHOT Annual Reports. Scientific papers, reviews, and lessons and learning points for specific target groups, as well as informative Newsletters, are published and distributed throughout the year. Feedback to reporters and stakeholders in order to learn lessons and thereby prevent the occurrence or recurrence of adverse reactions or events is a cornerstone of effective vigilance in any discipline. MHRA has not to date analysed its haemovigilance data or published its annual figures.

- SHOT collects a wider scope of data than does MHRA, extending into the professional and clinical areas of transfusion practice. SHOT collects data on adverse events and reactions related to the transfusion of blood and blood components (red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate, granulocytes). SHOT also (unlike MHRA) collects data on the following additional plasma products and components: solvent-detergent FFP, methylene-blue FFP and cryoprecipitate, anti-D immunoglobulin and autologous transfusion, including cell salvage. MHRA does not cover these as they are not required under the BSQR. SAEs which do not involve transfusion of a blood component to a patient are collected by SHOT under a subdivision of the Near Miss category.

3. Participation in Haemovigilance Reporting to SHOT

Data analysed for this chapter

Data analysed for this chapter include all reports made to SHOT in the years 2006–2009 including all Near Miss reports and reports that were later withdrawn.

Introduction

This is the second year that SHOT has presented participation data in this format. These data have been accumulated since the implementation of the BSQR 2005,[2] and, as with previous years, 2009 has seen an increase in the number of reports made though the increase has not been as steep as that seen in 2008. The total number of reports analysed here is made up from those evaluated by SHOT as reportable (1279), reports that were classified as Near Miss (799), and reports later withdrawn as not SHOT reportable (397).

The term 'reporting organisation' is used throughout this chapter. A reporting organisation may be a single hospital or may be a Trust or Health Board. While a reporting organisation may be registered on SABRE and report all of its incidents under a single login, there are a number of organisations that have several reporters registered for reporting to SABRE. For 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. In 2009 there were 295 SABRE registered reporters and there were 26 reporters who made no report to the MHRA via SABRE. Some of these may have made SHOT only reports.

Table 1
Total number of reports to SHOT by UK country 2006–2009

	2006		2007		2008		2009	
	Number	%	Number	%	Number	%	Number	%
England	1050	82.1	1113	83.0	1816	83.4	1983	80.2
Northern Ireland	41	3.2	45	3.3	68	3.1	70	2.8
Scotland	98	7.7	84	6.3	148	6.8	189	7.6
Wales	90	7.0	99	7.4	145	6.7	233	9.4
United Kingdom	**1279**	100	**1341**	100	**2177**	100	**2475**	100

Table 2
Total number of reports per 10,000 components by country 2006–2009

	2006	2007	2008	2009
England	4.3	4.6	7.7	8.1
Northern Ireland	5.3	6.6	10.0	10.5
Scotland	3.6	3.1	5.4	6.8
Wales	7.5	8.4	12.3	19.6
United Kingdom	**4.4**	**4.8**	**7.8**	**8.5**

The number of reports per 10,000 components issued has increased for the UK as a whole. However, there remains a marked variation between the four UK countries, with Wales increasing its reporting rate by 60% between 2008 and 2009.

Number of reports per reporting organisation by UK country

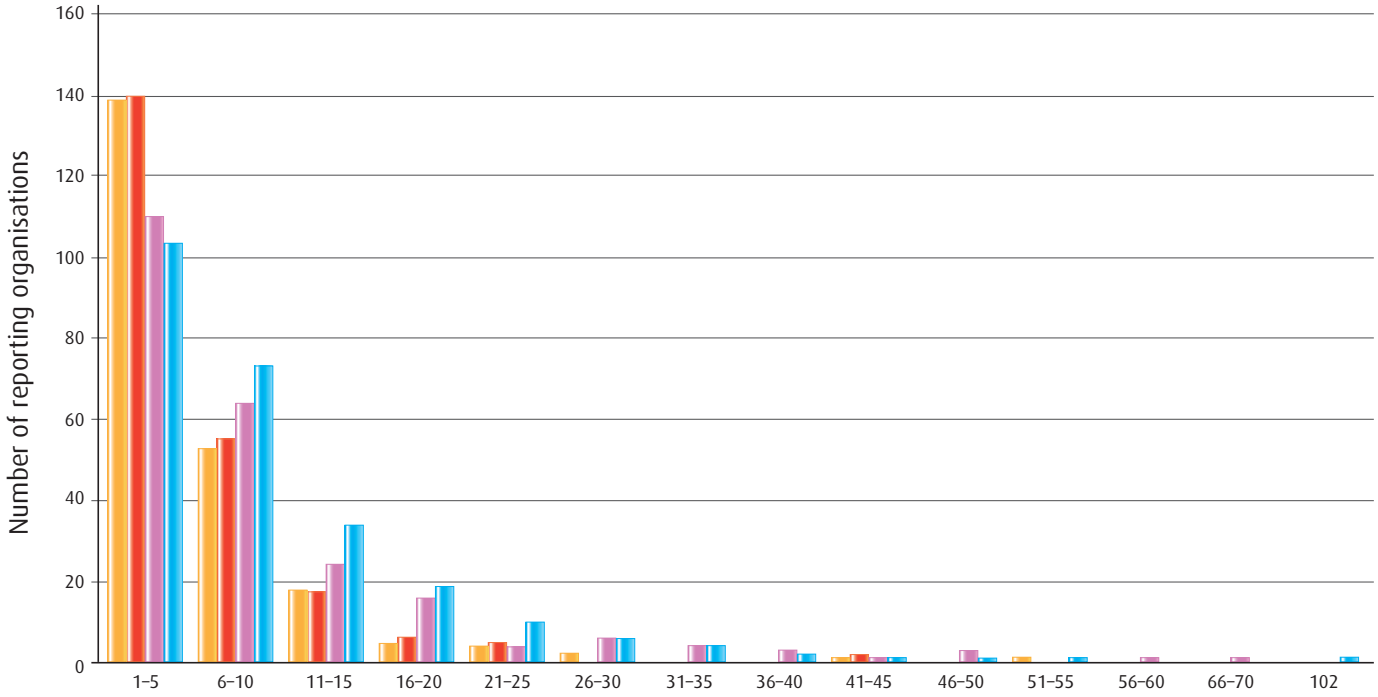
The next table (Table 3) gives a statistical analysis of the number of reports by each reporting organisation. Data are provided for the UK and its four constituent countries. The number of organisations making reports to SHOT has increased year by year with the largest increase seen in England. However, as discussed in last year's report, the most commonly reported number of incidents per organisation is 1 per year, although this statistic disguises differences between the UK countries. It is unlikely that hospital transfusion laboratories can have only 1 incident per year, whether a physiological reaction, an error or a Near Miss, to report to SHOT. With the advent of the new SHOT database, data on yearly issues by individual hospital transfusion laboratories will be collected, so that from 2010 SHOT will be able to provide data on the number of reports by components issued for each reporting organisation. Looking at the number of reports submitted with issues as denominator data will 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 all incidents that are SHOT reportable. In 2006 there were 51 organisations which reported a single incident and this figure was 48 in 2007. It dropped in 2008 to only 29 organisations, a reduction of approximately 40%. In 2009 there were still 29 organisations that made only 1 report, maintaining the considerable improvement over previous years.

Table 3
Average number of reports submitted per reporting organisation by UK country in 2008 and 2009

	UK		England		Northern Ireland		Scotland		Wales	
	2008	2009	2008	2009	2008	2009	2008	2009	2008	2009
Mean	9.2	9.7	9.6	9.8	6.8	7.8	5.7	6.5	12.1	16.6
Median	6	7	6	7	4	9	3	6	8	7
Mode	1	1	1	1	6	1	1	6	10	7
Range	67	101	67	48	30	20	26	16	46	100
Minimum	1	1	1	1	1	1	1	1	3	2
Maximum	66	102	68	49	31	21	27	17	49	102
Total no. of reports	2177	2475	1816	1983	68	70	148	189	145	233
No. of organisations	237	255	203	203	10	9	26	29	12	14

Figure 2 opposite shows a continuing decline in the number of organisations reporting only 1 to 5 reports a year from 2006 to 2009, with concomitant rises in the number of organisations in each of the higher reporting brackets between 6 and 30 reports a year, plus an increasing number of high reporters. This trend shows an increasing engagement with haemovigilance and it is hoped that this will continue.

Figure 2
Number of reports sent per reporting organisation, United Kingdom



	1–5	6–10	11–15	16–20	21–25	26–30	31–35	36–40	41–45	46–50	51–55	56–60	66–70	102
2006	139	53	18	5	4	2			1		1			
2007	140	55	17	6	5				2					
2008	110	64	24	16	4	6	4	3	1	3		1	1	
2009	103	73	34	19	10	6	4	2	1	1	1			1

Number of reports per reporting organisation

Types of reports made to SHOT

As with last year's data, SHOT has also analysed the types of reports that organisations make, shown in Table 4 below. The largest group in 2006 and 2007 were reporters who reported only errors and Near Miss incidents but not physiological reactions (*n* = 117 and 116 respectively). In 2009 there has been a very marked decline in this number and there has been a concomitant increase in the number of organisations reporting errors, Near Miss events and physiological reactions, i.e. across all reporting categories (from 80 in 2006 to 206 in 2009). HTTs are to be congratulated on this dramatic improvement. On the negative side, there is still a small group (9) of reporters who report only physiological reactions along with 32 organisations that are reporting only errors and Near Miss incidents. It can only be assumed either that there is no mechanism for reporting physiological reactions from patient care areas, or that there is a lack of awareness among clinical and laboratory staff regarding the importance of reporting transfusion reactions. There may also be a lack of awareness among junior laboratory staff and on-call staff who do not work regularly in transfusion. In 2008 SHOT noted a number of organisations that reported only incidents relating to the administration of anti-D and some that withdrew all their notification reports. Although fewer, there are still a very small number of organisations continuing these patterns.

Table 4
Analysis of types of incidents reported to SHOT

Category	2006	2007	2008	2009
Organisations which reported anti-D incidents only	6	3	2	2
Organisations which reported physiological reactions only	12	11	8	9
Organisations which reported errors and Near Misses only	117	116	103	32
Organisations which reported errors and Near Misses and physiological reactions	80	88	121	206
Organisations which had all reports withdrawn	8	7	3	6
Total	**223**	**225**	**237**	**255**

Number of reports by reporting organisation for RTCs in England

SHOT is continuing to analyse data by Regional Transfusion Committee (RTC) in England, and this year SHOT is also providing data on the number of reports per 10,000 components issued for 2008 and 2009. Rather than print a large number of tables representing previous data in the body of this report, only the 2009 and 2008 data are shown in Table 5 and summary data in Figure 3 (both below). The full data tables for each year are on the SHOT website (www.shotuk.org) and can be viewed or downloaded.

Table 5
Data in 2008 and 2009

	Mean		Median		Mode		Range		Min		Max		Total no. of reports		No. of organisations	
	2008	2009	2008	2009	2008	2009	2008	2009	2008	2009	2008	2009	2008	2009	2008	2009
East Midlands	6.7	11.0	5	7.5	1	20	19	22	1	1	20	23	80	132	12	12
East of England	7.4	9.4	7	8	9	5	22	29	1	1	23	30	141	169	19	18
London	9.8	10.1	6	7	2	1	46	48	1	1	47	49	381	395	39	39
North East	10	7.7	5	5	1	5	38	20	1	1	39	21	90	77	9	10
North West	8.6	9.7	7	9	7	5	49	48	1	1	50	49	259	281	30	29
South Central	11.6	10.6	6.5	8.5	8	2	67	43	1	1	68	44	185	170	16	16
South East	8.7	9	7	7	7	2	26	31	1	1	27	32	130	184	15	20
South West	8.2	8.2	8	7	3	1	17	26	1	1	18	27	131	181	16	22
West Midlands	15.2	10.1	6	4	2	4	58	39	1	1	59	40	228	192	15	19
Yorkshire & Humberside	9.8	11.7	5.5	8	4	6	27	33	1	1	28	34	157	199	16	17

Table 6 shows that there has been steady improvement in the reporting in most RTCs, with 7 out of the 10 increasing the number of reports made to SHOT over the previous year. The number of reporting organisations per RTC is mostly unchanged, but has increased in 3 RTCs (South East, South West and West Midlands).

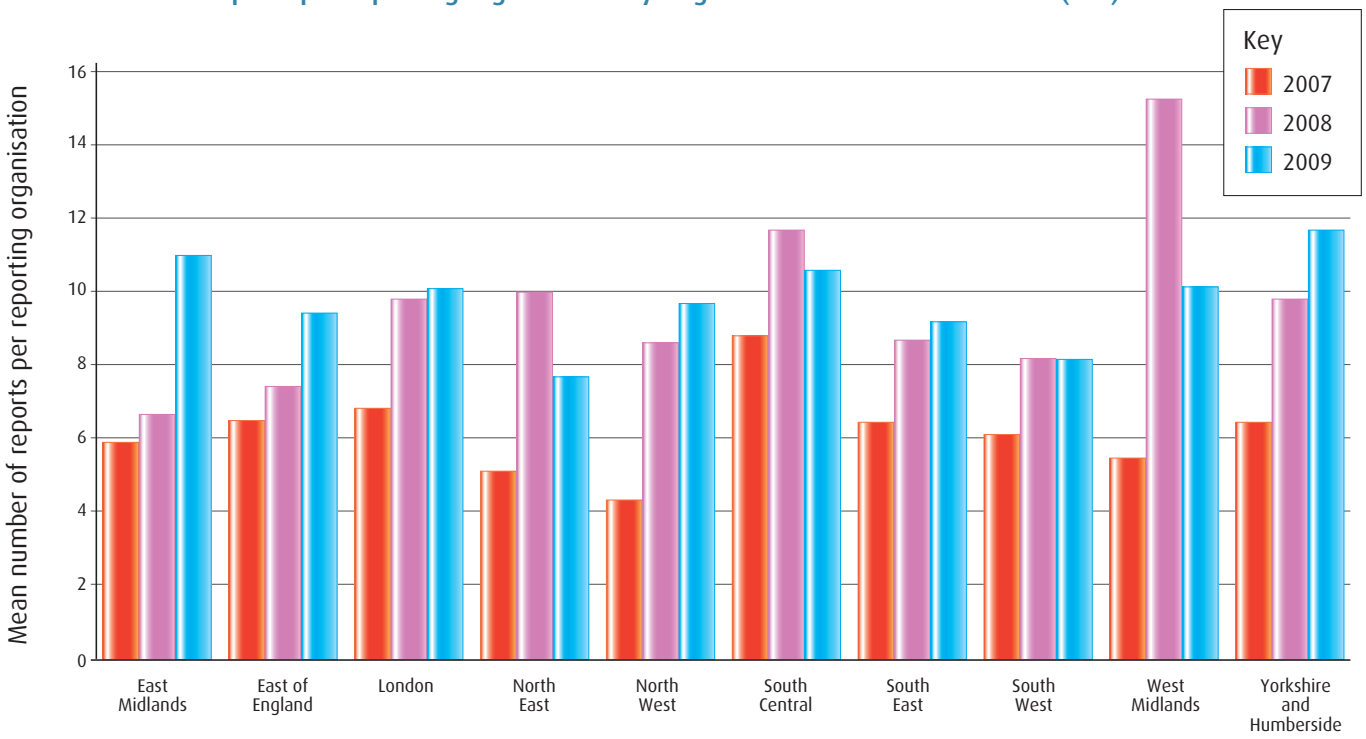
Table 6
Total number of reports per 10,000 components issued

NB The 2009 denominator data are incomplete and represent 91% of the total components issued within England

Regional Transfusion Committee	2008	2009
East Midlands	5.0	16.0
East of England	6.5	7.9
London	7.2	8.4
North East	7.5	8.7
North West	7.9	9.3
South Central	11.2	11.4
South East	7.9	9.4
South West	5.9	10.9
West Midlands	9.1	6.0
Yorkshire & Humberside	7.7	9.5

For the first time this year, SHOT is providing data on the number of reports per 10,000 components issued per RTC. These data must be viewed as providing a benchmark against which to judge future reporting trends. As with the data for the four UK countries, there is marked regional variation in England but most RTCs show an improvement over last year's reporting rate.

Figure 3
Mean number of reports per reporting organisation by Regional Transfusion Committee (RTC)



The chart above shows the mean number of reports per reporting organisation by RTC for the last three years and shows a very encouraging picture with improvements over the baseline year (2007) by all RTCs.

COMMENTARY

All the data presented in this section compare very favourably with the 2008 data. There are fewer non-reporting organisations, fewer organisations sending only one report, and fewer organisations sending only certain subcategories of reports. Overall reporting to SHOT has increased again in 2009 and it is anticipated that this trend will continue, as more Trusts and hospitals establish effective adverse incident reporting systems locally, and as the new online SHOT reporting website becomes familiar.

Reporters should remember that participating in haemovigilance remains a legal requirement. The MHRA's Blood Consultative Committee is aware that under-reporting or non-reporting may be an issue in some Trusts and hospitals, and decisions regarding inspections will increasingly be made taking haemovigilance systems into account.

RECOMMENDATIONS

Many reporters have clearly taken note of the 2008 main recommendation about increasing awareness among all staff involved in transfusion of reporting criteria for adverse events and reactions. Local reporting systems are improving and reporting to SHOT is increasing. Nevertheless, it is still clear that not all serious adverse events and physiological reactions are being reported to SHOT. It may be that in organisations with low SHOT reporting rates, incidents have also not been reported locally and corrective actions are not being taken to improve patient care. In the 2008 report

SHOT highlighted an NPSA/NHS Confederation briefing document, 'Act on Reporting: Five actions to improve patient safety reporting'.[8] All reporters should undertake the following action plan to improve their reporting both locally and to SHOT.

- **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?

  Action: CEOs of Trusts and hospitals in England, Northern Ireland and Wales, and of Health Boards in Scotland, HTTs

4. SHOT 2009–2010

UK Transfusion Laboratory Collaborative
Recommended minimum standards for hospital transfusion laboratories

The recommendations of the UK Transfusion Laboratory Collaborative, which SHOT initiated and in which SHOT is a main collaborator, have been sent to all laboratory and service managers as well as Trust/hospital chief executive officers in England, Wales and Northern Ireland and other stakeholders. They are also being considered by the Scottish Clinical Transfusion Advisory Committee (SCTAC) and have been circulated to stakeholders in Scotland.

The collaborative's work started in response to the year-on-year SHOT findings that 30%–40% of 'wrong blood' event errors are due to errors originating in the hospital laboratory with a disproportionate number occurring outside 'core hours'.

The collaborative, of course, recognises the constraints under which hospital laboratories are working and accordingly states in the recommendations: 'The collaborative recognises that not all existing hospital transfusion laboratory structures may currently meet all of 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.'

The collaborative's recommendations, supported by the Chief Medical Officers, provide minimum standards for hospital transfusion laboratories. They address staffing, technology, training and competence. 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 (2004)[9] and as required by the UK BSQR (as amended).[2]

The collaborative recommends that each Trust/hospital should develop an action plan to facilitate compliance with these recommendations. The collaborative's recommendations will help hospitals and Trusts to comply with the EWTD requirements, through the creation of the necessary critical mass of trained and competent staff in transfusion. SHOT will be evaluating the potential impact on laboratory incidents, and MHRA plan to monitor the recommendations where applicable to the BSQR.

The recommendations have been published in *The Biomedical Scientist*[10] and *Transfusion Medicine*.[11] The article is available for download as an Open Access article.[12] It is expected that there will be a web-based resource to support the implementation of and compliance with the recommendations of the laboratory collaborative. Until this is available, updates on and clarification about these recommendations will be made available to laboratory managers electronically and will be published in *The Biomedical Scientist*.

New SHOT website

The SHOT website has been redesigned and made simpler to use, with the aim of it becoming a comprehensive resource on haemovigilance for the UK. This went live on 30th March 2010 and has been well received. SHOT now has control of content management and is able to update and change the site without going through a third party. There is also a secure login page for the SHOT Steering Group and the Working Expert Group where agendas, minutes, papers for meetings and draft SHOT report chapters can be posted for download by SG and WEG members. New material and sections will be added regularly, and suggestions are always welcome.

SHOT and the International Haemovigilance Network (IHN)

The IHN (formerly the EHN, European Haemovigilance Network) is a professional network of haemovigilance organisations, now with worldwide membership. It holds an annual scientific meeting, hosted by one of the member countries, usually in February each year, and offers many opportunities for haemovigilance experts to work together to improve standards of blood safety. There has been close liaison with the IHN recently since SHOT's Medical Director (Clare Taylor) is also Secretary of the IHN.

Current IHN initiatives in which SHOT is collaborating include:

- A pilot of a new European database to collect data from all EU haemovigilance systems, allowing direct comparison and benchmarking.
- The commissioning of a haemovigilance textbook, the first of its kind, by Wiley-Blackwell, to be edited by members of the IHN Board and containing contributions from many IHN members. This is due to be published in 2011.

The IHN website is accessible to all, but additional material can be viewed by members. Membership is free to anyone working in haemovigilance in the UK, as SHOT itself is a member. Please email the Secretary, or go to the website www.ihn-org.net.

New web-based SHOT reporting system

The new SHOT web-based reporting system (developed with Dendrite, www.e-dendrite.com) went live on 4th January 2010. SHOT staff are very pleased that it has already received more reports than in the same period in any previous year, and reporters are completing the data entry soon after submitting the initial report. Some organisations are having problems completing reports due to local network speed via the NHS internet gateway. SHOT has approached NHS Connecting for Health (CfH), requesting that the traffic for the SHOT database is prioritised. A result on this is anticipated shortly. Dendrite are also exploring ways in which this issue can be resolved with CfH and BT.

From the point of view of reporters, the procedure for reporting has not changed greatly. Access is through SABRE as before, either via the MHRA or the SHOT website, and a notification form for the report is completed. In order that MHRA can pass the data to SHOT, the box to share it with SHOT must then be ticked (a legal requirement as SHOT reporting is not statutory), for every type of report: error related, reactions and Near Miss reports, which are now also being collected via this system. The 'SHOT only' box remains an option for all clinical reports, anti-D, etc. Within a couple of days of sending the initial report via SABRE an email is sent to the reporter from the new SHOT database containing a link to a record that will already have been created for completion of the report.

If any reporting organisation has not yet registered with the new database there is still an opportunity to do so after sending the first report. Registration can be done by calling the office. The new system is also collecting demographic data and some baseline issue data, which is the same as that collected annually by MHRA. Help documents including a user manual are available on the SHOT website or via the SHOT office. This document lists all the reporting categories and definitions to help reporters submit their data.

All events that are reportable to MHRA are now also collected by SHOT, so the 'Report to SHOT' box should always be ticked on the SABRE front page. Near Miss events (many of which are SAEs on SABRE) are quickly and easily reportable on the new SHOT system, as well as 'previously uncategorised reactions' and cell salvage related incidents.

Update on 2008 recommendations

Last year SHOT made recommendations sharing a theme of standardisation between practices at different hospitals, Trusts, regions and countries. This was because it was clear that there were variations in local systems for identifying and collecting adverse incident data, different specifications of IT systems often customised for use in individual laboratories, and differences in the educational material, training and subsequent assessment of personnel involved in the process of transfusion.

- **Awareness of criteria for reporting adverse events and reactions**
  SHOT has been active in producing and publicising reporting criteria via the website, newsletters, the Annual Report, and local, regional and national meetings. In 2009 there was again a marked increase in reporting to SHOT, and more importantly a reduction in the number of reporting organisations sending very few reports or reports in only a few categories. SHOT will continue its programme of activities in 2010, and in particular the SHOT Transfusion Liaison Practitioner will be working closely with HTTs through the hospital liaison network in the English regions. It is anticipated that the new Dendrite-based system will facilitate even greater participation in SHOT reporting now and in the future.

- **A national specification for transfusion laboratory IT systems**
  The IT subgroup of the National Blood Transfusion Committee has been reconvened in 2010 and will be developing a minimum IT specification for hospital laboratories, working with key stakeholders at NHSBT, NPSA and the Transfusion Managers Working Group. It will also prepare the way for working relationships with manufacturers of laboratory computer systems.

- **Competency-assessment and standardised, transferable certification for all staff involved in transfusion**
  The NPSA has produced further clarification and guidance about the implementation of SPN 14 (November 2006) sent in the form of a letter to Nursing Directors and Medical Directors.[13] In addition there have been further enhancements of the toolkit available on the website.[4]

5. Summary of Main Findings and Cumulative Results

Data analysed for this report were collected between 1st January 2009 and 31st December 2009.

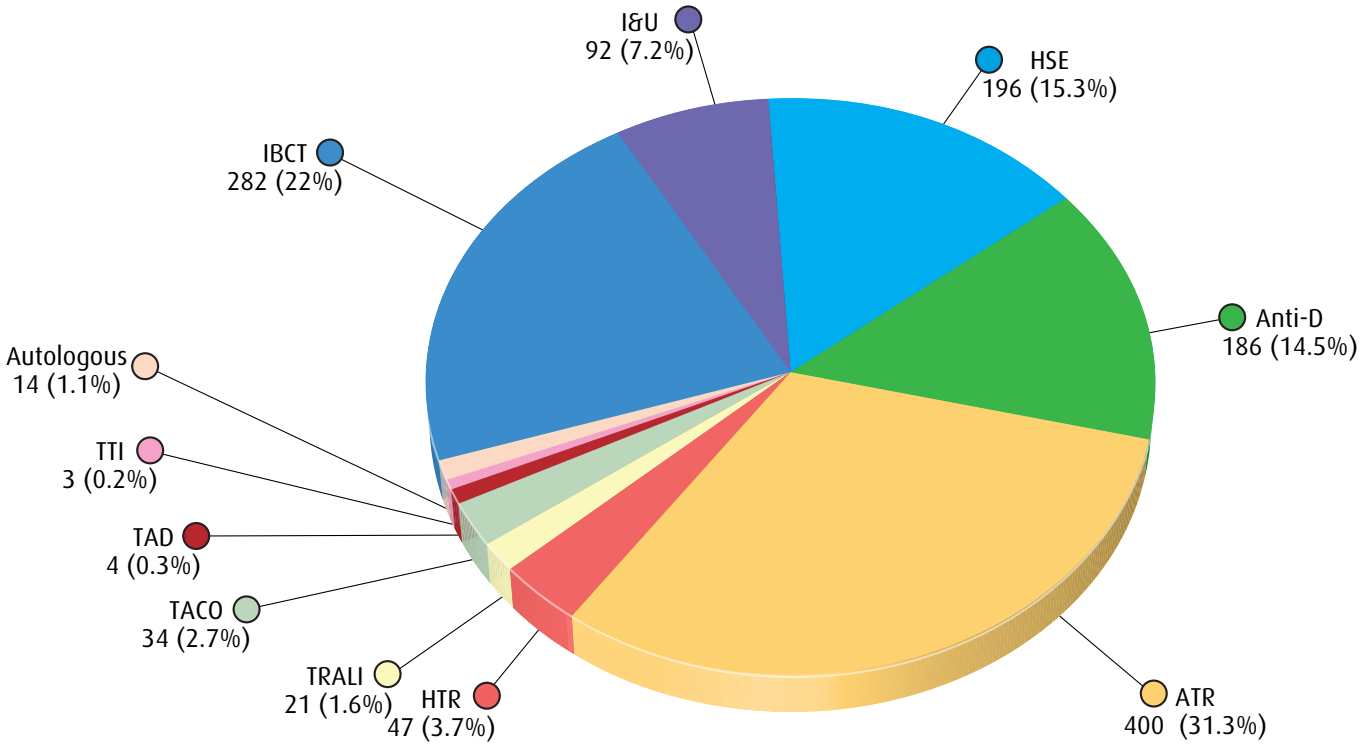
Numbers of questionnaires completed

The total number of questionnaires reviewed this year is 1279. This represents an increase of 23% since 2008, when 1040 were reviewed. The figures are summarised in Table 7 and Figure 4 below.

Table 7
Summary of reports reviewed 2009

IBCT	I&U	HSE	ANTI-D	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	AUTO-LOGOUS	Total
282	92	196	186	400	47	21	34	4	0	0	3	14	1279

Figure 4
Cases reviewed *n* = 1279



Clinical versus laboratory errors

Of the total 1279 errors, 230 originated primarily in the hospital transfusion laboratory (149 IBCT, 38 anti-D and 43 handling and storage errors) which is 18% of the total reports, the same proportion as in 2008. Laboratory errors also accounted for 149 of 282 cases of IBCT, i.e. 53% of IBCT reports, compared with 50% in 2008.

Numbers of components issued

In 2009 the number of components issued by the Blood Transfusion Services of the UK increased for the first time in over 10 years, by 2%. The increase has been similar across all 4 types of labile component (see Table 8, below).

Table 8
Yearly summary of issues by the 4 UK Blood Services 1999–2009

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**
2008–2009	2,209,153	266,312	306,740	121,555	**2,903,760**

Table 9
Total issues of blood components from the Transfusion Services of the UK in the financial year 2008–2009

Transfusion Service	Red Blood Cells	Platelets	FFP	Cryoprecipitate	Totals
National Blood Service	1,849,370	226,644	260,265	104,954	2,441,233
Welsh Blood Service	94,806	8,834	12,777	2,475	118,892
Scottish National Blood Transfusion Service	211,813	23,969	27,077	13,370	276,229
Northern Ireland Blood Transfusion Service	53,164	6,865	6,621	756	67,406
TOTAL	**2,209,153**	**266,312**	**306,740**	**121,555**	**2,903,760**

In addition to the components issued by the four UK Blood Transfusion Services, there is significant usage of Octaplas®, the solvent detergent treated FFP (SD-FFP), which is a batched pharmaceutical product available from Octapharma. In the financial year 2008–2009 there were 52,963 units of Octaplas® sold to hospitals and Trusts in the UK. This brings the total number of units issued to 2,956,723.

Figure 5
Cumulative numbers of cases reviewed 1996–2009 *n* = 6653

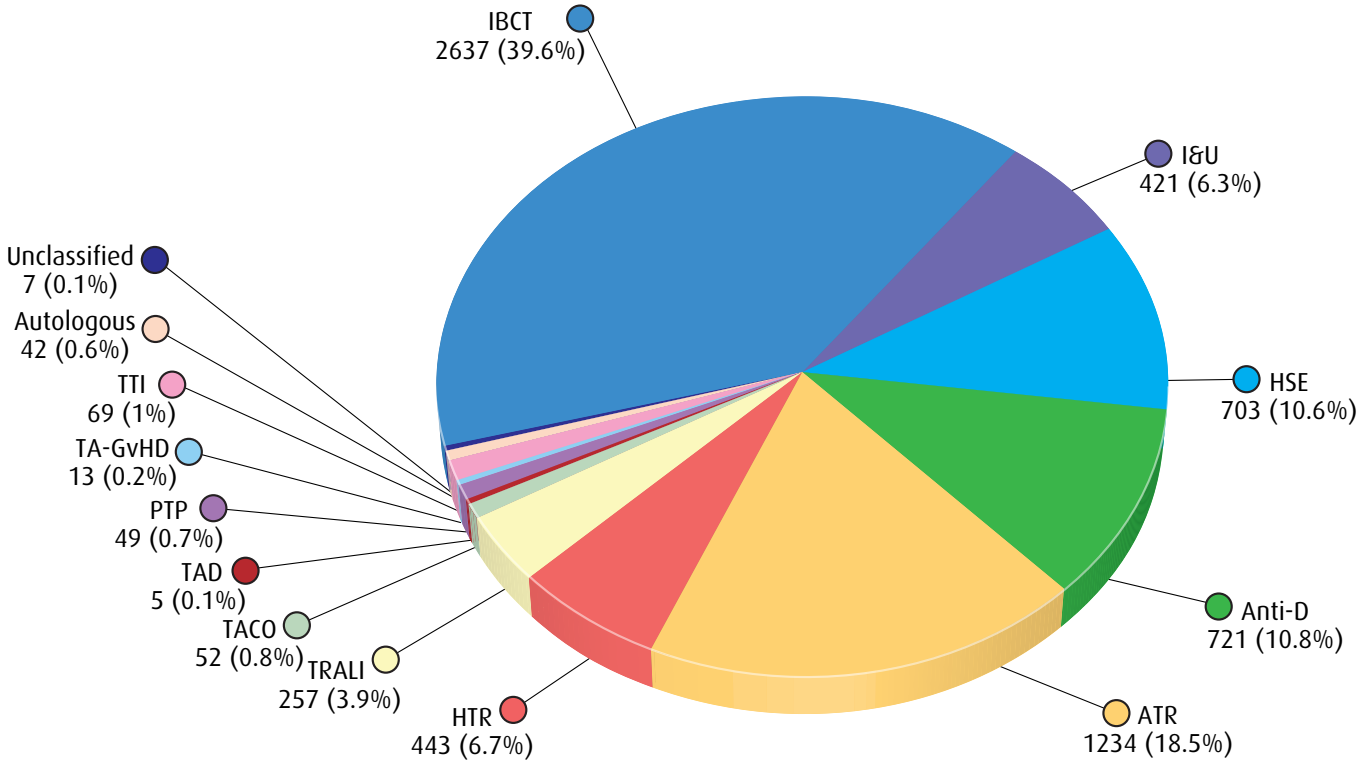


Figure 6
Comparison of report types 1996–2009

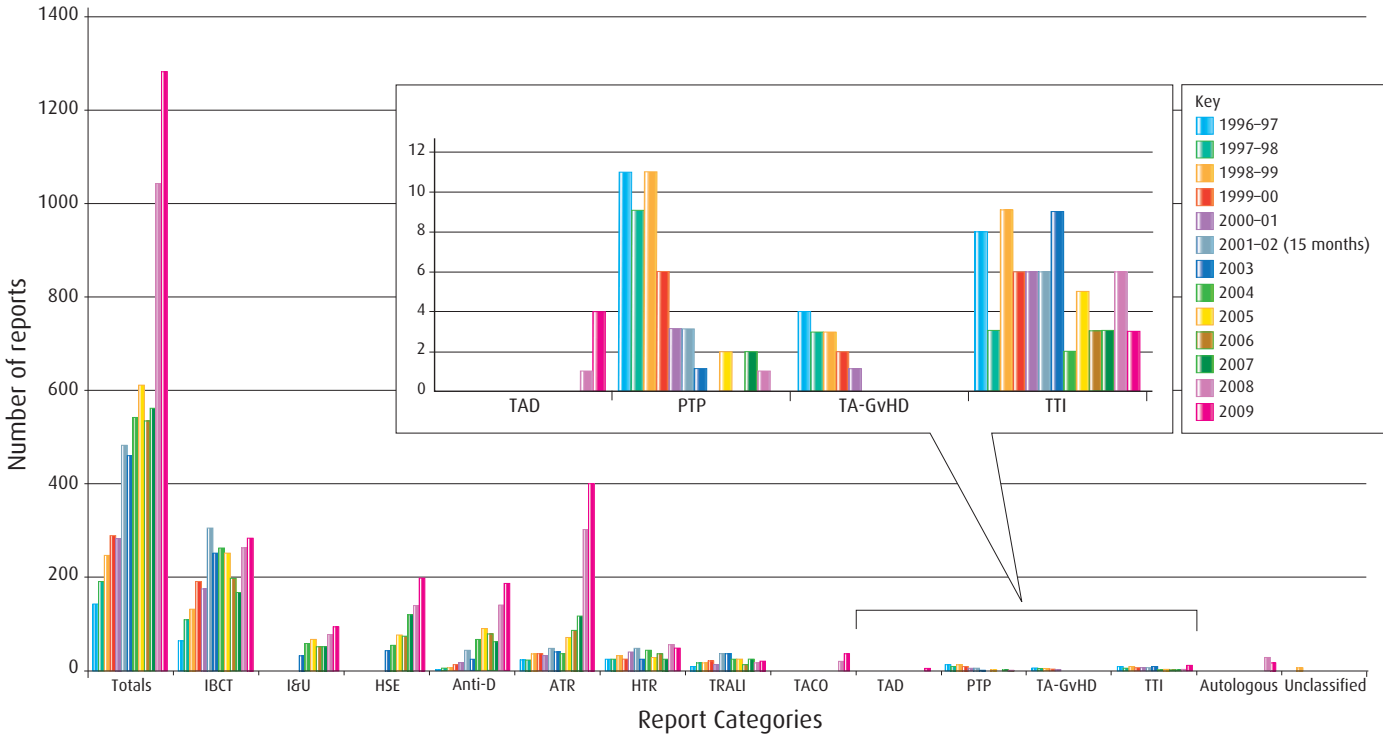


Table 10
Cumulative mortality/morbidity data 1996–2009
NB TACO, TAD and autologous are new since 2008, and HSE and I&U were separated from IBCT in 2008

	Total	IBCT	I&U	HSE	ANTI-D†	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	AUTOL-OGOUS
Death in which transfusion reaction was causal or contributory	138	27	4	0	0	19	11	42	5	0	2	13	15	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	495	116	3	0	25	58	48	165	18	1	13	0	48	0
Minor or no morbidity as a result of transfusion reaction	5998	3439	161	335	361	1154	383	50	29	4	34	0	6	42
Outcome unknown	15	11	0	0	0	3	1	0	0	0	0	0	0	0
TOTAL*	**6646**	**3593**	**168**	**335**	**386**	**1234**	**443**	**257**	**52**	**5**	**49**	**13**	**69**	**42**

**Total excludes 7 cases from 1998–1999 that were not classified*
†*Cases with potential for major morbidity included in the Anti-D data are excluded from this table*

OVERVIEW OF 2009 RESULTS

Transfusion-related mortality and major morbidity

There was 1 death reported in 2009 which was considered to be directly due to the transfusion: this is a proven case of transfusion-transmitted *Pseudomonas koreensis* infection in an elderly man undergoing palliative care for rectal carcinoma.

There were a further 12 deaths in which the transfusion contributed to a varying extent to the death of a patient who was already very unwell. These consisted of 3 Incorrect Blood Component Transfused (IBCT) events resulting in ABO-incompatible transfusion, 2 inappropriate and unnecessary (I&U) transfusion (over-transfusion), 1 acute transfusion reaction (ATR), 2 transfusion-related acute lung injury (TRALI) and 4 transfusion-associated circulatory overload (TACO).

Patients developed major morbidity from all of these categories of event, and the details are listed below and discussed in the relevant chapters. The total number of cases of major morbidity for 2009 is 73, plus 127 cases of potential major morbidity from late administration or omission of anti-D.

Incorrect blood component transfused (IBCT)

A total of 282 cases are included in this category, representing a further increase in reports of 7.6% since 2008. (Cases of I&U and *handling and storage errors* (HSE) have been analysed separately since 2008.)

There were no deaths caused directly by transfusion, but 3 patients died following reactions that were considered to have contributed to their deaths: all 3 related to ABO-incompatible transfusions. There were 3 cases of major morbidity from ABO incompatibility (of the total 14 ABO-incompatible transfusions). Two of these were also D incompatible. There were 5 further D-incompatible transfusions (1 administration error, 1 phlebotomy error and 3 laboratory errors).

A total of 149 (53%) of IBCT cases resulted primarily from a laboratory error and 133 (47%) from clinical and ward-based errors. In 2008 these figures were both 50%.

Special requirements not met (SRNM) accounted for 154 reports, of which 87 were clinical errors and omissions and 67 originated in the laboratory. The biggest subgroup was the 91 patients who should have received irradiated blood but who did not.

Properly carried out patient identification, and a complete bedside check, could have prevented the 40 blood administration errors, the 4 wrong blood in tube (WBIT) errors and at least 8 of the laboratory cases of 'wrong blood' (total 52 cases). This excludes cases in the SRNM category which may also be preventable at the bedside.

Inappropriate and unnecessary transfusion (I&U)

In 2009 a total of 92 cases were reported in this category, an increase of 21% since last year. Two patients in this group died following over-transfusion, and this may have contributed to their deaths. In total 15 cases were paediatric, double the number for 2008, and in particular related to the rate and volume of components given to small children. The 2 cases of severe morbidity were in paediatric patients, the first requiring venesection after over-transfusion, and the other a baby with long-term sequelae following delayed, inadequate treatment of severe neonatal anaemia. SHOT is keen to collect and analyse data on under- and over-transfusion (see also TACO, below).

As previously, the majority of cases relate to lack of knowledge and errors of judgement (often due to inexperience) in clinical staff. Education and senior support of staff dealing with transfusion-related problems remains a major objective for the Royal Colleges.

Handling and storage errors (HSE)

There were 196 cases in this category this year, an increase of 41% since 2008. There was no mortality and no major morbidity arising from these incidents. Once again the largest group was of cold chain errors, 84 cases, the majority (62 cases) relating to inappropriate storage of components. This year the second largest group concerned excessive time to transfuse, 69 cases, whereas in 2008 the next most frequent error was transfusion of expired components. Overall 43 (22%) of cases related to laboratory errors, while the majority (153, 78%) arose outside the laboratory and were the responsibility of clinical, portering and transport staff.

All staff involved in the transfusion process must understand the basic storage requirements of blood components. The cases in the SHOT report are those where the component was transfused, thereby posing a risk to a patient, but an additional concern is the many components wasted due to insufficient care being taken of cold chain requirements.

Anti-D related events

A total of 186 anti-D related events were reported to SHOT in 2009, an increase of 36% compared with 2008. There was no known fetal mortality from omission of anti-D, but there was 1 neonate who suffered HDN which had been missed due to an assumption that the anti-D detected was prophylactic, when it was immune. There were 127 cases of potential major morbidity where anti-D had been omitted or given more than 72 hours after the event. Clinical causes accounted for 80% of the errors, compared with 66% in 2008.

There must be full traceability for anti-D administered to patients. If it has been given late or omitted for a woman of childbearing potential, the recipient should be followed up actively to check for formation of immune anti-D.

Acute transfusion reaction (ATR)

There were 400 reports in this category in 2009, an increase of 33% on last year's 300 cases. No deaths occurred as a direct result of ATR, but there was 1 case in which a patient died and the transfusion reaction possibly contributed to the death. There were 27 cases of major morbidity, the majority (17) being anaphylactic reactions. Once again the minor reactions were the most frequent, with 193 febrile and 84 uncomplicated minor allergic reactions.

It is essential that moderate or severe reactions are properly investigated, and the possibility of bacterial contamination considered and acted on appropriately. Reactions which later prove not to be bacterial must be reported in the ATR category.

Haemolytic transfusion reaction (HTR)

There were 47 reports in this section, 8 AHTR and 39 DHTR, a slight reduction from 2008 when there were 55 cases. There were no deaths caused, nor contributed to, by these reactions. There were 3 cases of major morbidity from AHTR and 5 cases from DHTR; 2 required ITU admission, and 6 suffered deteriorating renal function including 1 who required dialysis.

Reactions are frequently reported in patients with sickle cell disease, who are vulnerable to haemolytic reactions because they have a high rate of sensitisation, are prone to episodes of hyperhaemolysis, have clinical symptoms which can mask HTRs and often move between different treatment centres. A national register of patients with antibodies would be very helpful in managing such patients.

Transfusion-related acute lung injury (TRALI)

There were 21 cases included this year: the graph showing TRALI cases by year of transfusion, rather than year of report (see page 112), shows a continuing downward trend in numbers. There were no deaths definitely due to TRALI, but 1 patient death was probably related, and 1 possibly related to TRALI. Eighteen patients were treated in ITU; 13 were admitted because of the episode, constituting major morbidity, and 5 were already on ITU before the event and are also included as major morbidity. Ten patients required mechanical ventilation. Antibodies concordant with HLA antigens in recipients were found in 8 donors, all female: the components implicated were FFP (2 cases), platelet pools (3 cases) red cells in optimal additive (OA) (3 cases, one of whom also received cryoprecipitate).

This reinforces the absolute requirement for provision of 100% male plasma for FFP and for suspension of platelet pools across all the UK blood services.

Transfusion-associated circulatory overload (TACO)

In 2009, 34 cases of TACO were reported, approximately twice as many as last year. There were no deaths definitely related to TACO, but 2 deaths probably related and 2 possibly related. There were 9 cases of major morbidity in which the patient was transferred to ITU. Three further patients were already in ITU at the time of the event so major morbidity was difficult to assess (but these are included as major morbidity in Table 10 on page 17). TACO therefore accounts for the highest number of cases of mortality and major morbidity in this annual report.

TACO is a relatively common complication of transfusion especially in the elderly and those with additional risk factors. Clinicians should be aware of the possibility of TACO, and its risk factors, and know how to minimise the chance of its occurrence bearing in mind also the appropriateness of the decision to transfuse (see I&U, above).

Transfusion-associated dyspnoea (TAD)

Four cases of TAD were reported in 2009, with no mortality or major morbidity. One patient required CPAP as a result of the reaction.

TAD is a heterogeneous entity and cases are likely to have varying physiological mechanisms. Reporting of all pulmonary complications of transfusion is essential if further understanding of these is to be achieved.

Post-transfusion purpura (PTP)

There were no cases of PTP reported in 2009.

Transfusion-associated graft-versus-host disease (TA-GvHD)

No cases of TA-GvHD have been reported in 2009, nor any since 2000–2001. However, 2 cases have occurred following transfusion of leucodepleted components (in 1998–99 and 2000–01). The absence of new cases must not be allowed to justify a relaxation of local practice in relation to provision of irradiated components. Irradiated components are administered to over 300,000 susceptible patients each year, and it is a highly effective method of preventing this universally fatal complication.

Transfusion-transmitted infection (TTI)

There were 3 reports this year, from 2 incidents. In the first incident, an expired apheresis platelet pack was contaminated with *Strep. pneumoniae*: associated units had been transfused to an adult with AML and 3 neonatal packs administered to a baby. Both patients suffered reactions, including a fever of 39.8°C in the adult patient and 40.5°C in the baby, but the reactions had not been identified as transfusion related. The second incident concerned an elderly patient with a malignancy who received red cells contaminated with *Pseudomonas koreensis*. He developed a pyrexia of 39.6°C and died later the same day of transfusion-transmitted sepsis.

Patients developing moderate or severe pyrexia following blood component transfusion must be suspected of having bacterial sepsis, and be investigated and treated appropriately.

Autologous transfusion

There were 14 cases reported in this section in 2009, 6 relating to intraoperative cell salvage and 8 to postoperative cell salvage. Five adverse reactions were reported relating to postoperative, unwashed autologous transfusion, including pyrexia, rigor and bradycardia. There were 3 cases of hypotensive reaction related to reinfusion of intraoperatively cell-salvaged blood.

SHOT is continuing to collect all cases related to autologous transfusion, including those collected in collaboration with the UK Cell Salvage Action Group.

Paediatric cases

Altogether 110 cases (9% of all SHOT reports in 2009) related to patients under 18 years of age, including 34 cases in infants under 1 year old. As before, the majority of paediatric reports were error related (IBCT, handling and storage, inappropriate and unnecessary transfusion), comprising 58% (64) of reports in children, compared to the 42% of adult reports which are error related.

Incidents termed 'paediatric-related', rather than occurring in children by chance, include a large number of errors relating to dose and rate of transfusion for small children, and the correct use of 'flying squad' red cells. Special requirements are frequently missed (25 cases), in particular indications for irradiation and MB-FFP for children under 16 years old.

Near Miss events

Near Miss data were not analysed in 2009.

The new online SHOT database is now collecting brief details of all Near Miss events (including all SAEs reported via SABRE) and an analysis of these will be included in the next report.

6. Key Messages and Main Recommendations

Laboratory and clinical IT systems

IT solutions to patient identification and for documentation of the audit trail for blood components have become more common in recent years. A variety of systems are on the market currently, with more in development. There is an enormous drive towards use of these systems from those who have implemented them successfully, from national advisory groups and from the manufacturers and retailers of the equipment.

Care must be taken to avoid the inherent problems of this approach, while maximising the benefit to patient safety. IT-based interventions cannot eradicate error, and indeed do not directly address the problem of human error.

More than 50% of cases reported to SHOT are ultimately caused by human error – including many of those in the IBCT sections (both laboratory based and clinical, including special requirements not met), in the handling and storage errors section, and the inappropriate and unnecessary transfusion section. In addition error-related cases account for most of the anti-D related events as well as many cases in the MHRA category of Serious Adverse Events (many of which are Near Miss according to SHOT criteria, as no blood component is transfused).

This year (2009) has seen the advent of a new subcategory of human error, specifically related to the use of IT systems both clinically and in the laboratory (see page 57). Undoubtedly the occurrence of certain errors can be reduced by appropriate implementation of IT-based checking systems, but new possibilities of error may also be introduced. Over-reliance on IT and believing that it circumvents human error can result in a decrease in understanding of and engagement with the transfusion process among the staff involved.

IT systems have a major contribution to make in adding electronic checking at vulnerable steps in the transfusion chain, and can provide accurate and complete data at the relevant stage in the process for consideration by the users – but they cannot prevent human error.

Adequate knowledge and skills are no less essential in the presence of a vein-to-vein electronic tracking system, and education and training must be comprehensive and appropriate to the staff groups involved at each stage. All staff must be familiar with the process, able to carry it out safely (with or without an electronic aid) and able to detect deviations from normal situations, and make safe, appropriate decisions as each circumstance arises. In addition, training specific to the use of electronic systems is required.

IT systems can:

- Match barcodes scanned from different source material
- Transfer data between parts of the system, parts of the same record or between records
- Recall data attached to specific patient ID accurately and completely
- Print, without transcription error, labels or results on a requested patient
- Be set to produce alarms and warning messages if non-matching data is scanned
- Display warning alarms and messages according to preset algorithms (e.g. date of birth)
- Allow specific data and high visibility warning flags to be added manually to patient records.

IT cannot:

- Ensure that the correct barcoded item is scanned
- Ensure that data is transferred between correct records (e.g. merging incorrect patients)
- Ensure that all of the patient-specific information recorded is accessed, read and understood
- Ensure that labels or results are requested on the correct patient
- Ensure that alarms, warning messages and flags are read and heeded
- Enhance patient safety unless it is used appropriately.

In this SHOT report the IT chapter highlights cases from throughout the report in which human errors occurred in relation to electronic systems; many are related to the list above of things that IT cannot do. Some of these errors occur in spite of the IT system that is there to help, and a few occur because of it.

Throughout this report cases have been discussed in which IT systems could be improved or enhanced to achieve greater safety for patients with less possibility of error.

Recommendation

Hospital transfusion laboratories need to liaise closely with manufacturers to develop and implement standard, detailed specifications for electronic systems in the laboratory, at the bedside and at the clinical-laboratory interface. An education package including minimum knowledge and skills, the appropriate use of these systems, and appreciation of their limitations should be a part of this joint project.

Action: CMOs' blood transfusion committees in England, Wales, Scotland and Northern Ireland working with stakeholders, blood transfusion services, clinical and laboratory transfusion specialists, manufacturers

Pulmonary complications of transfusion

There are a number of different physiological mechanisms through which patients may suffer pulmonary compromise following transfusion of blood components. The existing categories are transfusion-associated acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), allergic and anaphylactic reactions causing bronchospasm, and transfusion-associated dyspnoea (TAD). There are always additional cases reported to SHOT undoubtedly affecting the respiratory system, that are likely to be transfusion-related, but which are very hard to categorise within the definitions used by SHOT, based on ISBT definitions.[14] Cases that otherwise broadly fit the criteria for pulmonary complications of transfusion (TRALI, TACO and TAD) are not currently reported to the EU but cannot be included because they occur after the 6-hour cut-off post transfusion. However, SHOT is striving towards capture of the true rate of transfusion-related pulmonary complications, and the basic physiology and causal relationship to transfusion are the most important considerations when defining a transfusion complication. Pulmonary complications of transfusion, in particular TRALI and TACO, result in a high rate of major morbidity and mortality.

The new online SHOT database collects all pulmonary complications of transfusion. This will be refined in the future to allow reporting of cases that do not currently fit existing definitions. For haemovigilance systems to identify new patterns of complications, or new causes of reactions, it is important to include atypical data.

More studies are required to further define these grey areas. It would be helpful to perform serological investigations on all cases queried as 'possible TRALI' (e.g. including 'late' occurring cases), so as to provide a background against which clinical inclusion criteria can be evaluated.

Pending commencement of such a study, it may also be helpful if a database could be kept of the donors linked to the cases of possible or atypical TRALI that are not investigated. In the USA this approach has identified donors who are implicated again in subsequent cases, and investigations have then proved a serological basis for the reaction and a substantive diagnosis of TRALI.

Recommendation

All pulmonary complications of transfusion should be recorded and reported to haemovigilance systems even if they do not fully fit existing criteria. Research should be initiated to evaluate the current inclusion and exclusion criteria, especially for TRALI and TACO. A register of possibly implicated donors should be kept by the blood services.

Action: SHOT and its reporters, UK blood services and their R&D directorates

Patient identification

The patient identification check continues to be a critical point in the transfusion process where errors are made. These occur due to staff not following established protocols, resulting in no true check of the patient taking place. These errors are occurring despite the introduction of training and competency-assessments for all staff involved in the process,[4] and in one example a classic error occurred and was not detected *during* a competency-assessment (Case 1, page 64). While professional responsibility must be taken by all personnel involved at each stage in the process (SHOT recommendations 2007) it cannot be escaped that the final 'bedside' patient ID check is the last chance to detect certain errors that can occur earlier in the chain, as well as being a critical point for new errors.

Control of Infection teams have run a very successful campaign in hospitals in which patients have been empowered, and encouraged, to ask doctors and nurses whether they have washed their hands before they make physical contact with the patient. A decrease in nosocomial infections has been documented.[15]

SHOT recommends that a similar approach is now taken for patient ID – not just for blood transfusion, but across all disciplines and specialities.

Recommendation

A patient education campaign should empower recipients of blood transfusion, and all patients undergoing tests, procedures and surgery, or receiving drugs and therapies, to ask the staff, before they carry out the intervention: ***'Do you know who I am?'***

Action: NBTC, DH, Trust/hospital CEOs

Clinical handover

A considerable number of cases, in various sections of the SHOT report, have occurred out of hours, at times when staffing was reduced for various reasons, or when shift working meant that junior doctors were caring for large numbers of patients with whom they were not familiar.

The European Working Time Directive (EWTD,[16]) has been implemented by law across the UK but in a number of Trusts there have been few practical arrangements put in place to deal with the inevitable problems for patient care that this poses. Proactive new systems are required, and need to be implemented by high-level management within Trusts/hospitals to ensure effective handover between shifts and teams, and continuity of patient care. This will not only enhance patient safety and satisfaction but reduce unnecessary prolongation of stay due to communication failures.

The instigation of a method for formal handover of patients is essential if the EWTD and the associated shift working and cross-covering are not to result in detriment to patient care. This would also provide an invaluable education session for junior doctors, restoring a sense of being in touch with the clinical process. Despite the reduced hours, hospital doctors

are increasingly stressed by being spread thinly over many patients without proper information about the clinical progress and plans for those patients. Sick leave among junior doctors has increased hugely since implementation of the EWTD, and job satisfaction has reduced.[17]

Unfortunately, the detrimental effect of these changes will take time to show in outcome figures for Trusts or types of patients – and action must be taken without waiting for these data.

A new initiative by the Royal Colleges, spearheaded by the Royal College of Physicians, has developed a set of cross-disciplinary national standards and templates with e-learning modules in order to facilitate local implementation of a patient handover system. This tool allows a rolling electronic or paper update of current care, planned treatment and problems of patients, which is then used as the basis for a formal handover session at times of changing shift or on-call team.

Handover templates are freely available and can be found at: http://www.rcplondon.ac.uk/clinical-standards/hiu/medical-records/Pages/templates.aspx.

Recommendation

Trusts must implement the use of a documented handover tool, such as the one recently developed by the Royal Colleges, as part of a formal patient handover system.

Action: DH, Trust CEOs

Past recommendations still relevant

Year first made	Recommendation	Target	Progress
2008	See update on page 13.		
2007	Transfusion Medicine must be part of the core curriculum for doctors in training.	**NBTC, GMC, PMETB, Royal Colleges, Deaneries**	The Royal Colleges and the Specialist Societies sub-group of the NBTC is addressing this.
2007	Professional, accredited staff must take responsibility for transfusion safety in the laboratory and in clinical practice.	**NBTC, UKTLC, BBTS, IBMS, Trust/hospital CEOs**	The UKTLC has published minimum standards for hospital transfusion laboratories.[10,11]
2007	Obstetricians and midwives must be familiar with the anti-D prophylaxis programme and its rationale.	**NBTC, BCSH, RCM, RCOG, RCGP, HTTs and HTCs**	Educational days have taken place and been well attended. There appears to be a knowledge gap and educational programmes must continue to address this.
2007	Participation in haemovigilance must be improved as it is mandatory in the UK and the rest of Europe.	**DH, MHRA, SHOT, CEOs, HTCs, BTS**	Reporting to SHOT increased by 85% between 2007 and 2008, and a further 23% in 2008–2009.
2006	Speciality accredited laboratory and clinical staff in all hospitals.	**Hospital CEOs, NTLC, BBT network, RCN, BBTS**	The UKTLC has delivered recommendations to the DH.
2006	Comprehensive reporting to SHOT by all hospitals.	**Trust/hospital CEOs, SHOT, consultants with responsibility for transfusion, HTT, HTC**	SHOT reporting has definitely increased in 2008 and 2009, with increased reports, more participating organisations and more reports sent per organisation.

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. National Comparative Audit (NCA) platelet audit showed widespread inappropriate use of platelets and non-adherence to guidelines (www.nhsbtaudits.co.uk).
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 TP 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 set up working groups in 2006. Realignment of RTCs with SHA regions in 2007.
2002	HTTs must be established and supported.	**Trust CEOs**	Survey in 2004 (Murphy & Howell) showed 70% of Trusts had HTT but only 30% were supported. A further survey in 2006 (Murphy & Howell) stated that 97% of 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**	The Royal Colleges and the Specialist Societies subgroup of the NBTC was established in 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 14 '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, Trust CEOs**	Successive BBT initiatives promote this. The NHSBT Appropriate Use Group and Patients' Clinical Team are active. Red cell usage has fallen by > 15% since 2000.
2001	Transfusion practitioners should be appointed in all Trusts.	**Trust CEOs**	Requirement of BBT2. By 2005 appointed in 75% of hospitals (NCA organisational audit 2005).
2001	More transfusion medical consultant time is needed in hospital Trusts.		Requirement of BBT2, but there is a national shortage of consultant haematologists.
1999	All institutions where blood is transfused must actively participate in SHOT.	**Trust CEOs**	Requirement of BBT and NHSLA. Reporting has improved in 2008 and 2009 (see above).
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 commenced meetings in 2008.

Reporting categories

The reporting categories for 2009 are unchanged since those published in the 2008 report. These are available to view and download from the SHOT website www.shotuk.org.

Definitions

Imputability

The term 'imputability', as defined in the Blood Safety and Quality Regulations 2005, means 'the likelihood that a serious adverse reaction in a recipient can be attributed to the blood component transfused'.[2] A scale of zero to three is used as shown below:

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 should 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. In sick patients with complex conditions it is at times very hard to ascribe imputability.

Transfusion-related mortality

- Death directly and solely caused by the transfusion reaction
- Death in which the transfusion reaction probably contributed and which may not have occurred at that time had the reaction not taken place
- Death which occurred at the time of or soon after a transfusion reaction, in which the reaction might have contributed to the death, and it is not possible to exclude this.

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.

To avoid confusion, the term imputability is not used in the SHOT report in relation to whether death was related to the transfusion reaction.

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
- Life-threatening acute reaction requiring immediate medical intervention*
- 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.

** This category has been newly added by the SHOT Steering Group for 2009.*

7. 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 that was intended for another patient or which was incorrect in terms of its specification.

DATA SUMMARY

Total number of cases	**282**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**220**	Deaths due to transfusion	**0**
		FFP	**17**	Deaths in which reaction possibly contributed	**3**
		Platelets	**26**	Major morbidity	**4**
		Other *(specify)*			
		Unknown	**19**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**132**	18 years+	**242**	Emergency	**60**	ED	**4**
Female	**145**	16 years+ to 18 years	**3**	Routine	**189**	Theatre	**9**
Unknown	**5**	1 year+ to 16 years	**21**	Not known	**33**	ITU/NNU/HDU/Recovery	**14**
		28 days+ to 1 year	**9**				
		Birth to 28 days	**7**	In core hours	**82**	Wards	**76**
		unknown		Out of core hours	**45**	Community	**1**
		Total	**282**	Not known/applicable	**155**	Outpatient/day unit	**10**
						Not known	**168**

As in the 2008 report, this chapter comprises reports on 4 main types of errors which result in the transfusion of an incorrect blood component (plus 2 miscellaneous cases):

- Bedside blood administration errors
- Laboratory errors, testing and process errors
- Phlebotomy errors resulting in 'wrong blood in tube' (WBIT)
- Transfusion of components not meeting the patient's special requirements (SRNM).

The SRNM cases are divided according to whether they are clinical errors, largely of knowledge and/or communication (so that the transfusion laboratory did not know of the special requirement), and those which originated in the laboratory (in which the necessary information was available but not acted upon).

In 2009 a total of 282 IBCT reports were received, which is a 7.6% increase compared with 2008, when 262 cases were included. The rate of reports of IBCT for 2009 was 9.7 per 100,000 components issued by the UK blood transfusion services compared with 9.2 in 2008.

The data summary above shows that the data on cases in core hours and out of hours, and for the location of the patient when the error occurred, were poorly completed on the questionnaires. There were a total of 40 cases of IBCT occurring in patients under 18 years of age and these are discussed in more detail in the paediatrics chapter on page 140. The age range among adults was 18–97 years of age.

Table 11

Numbers of true IBCT cases and rate per 100,000 blood components issued 2003–2010

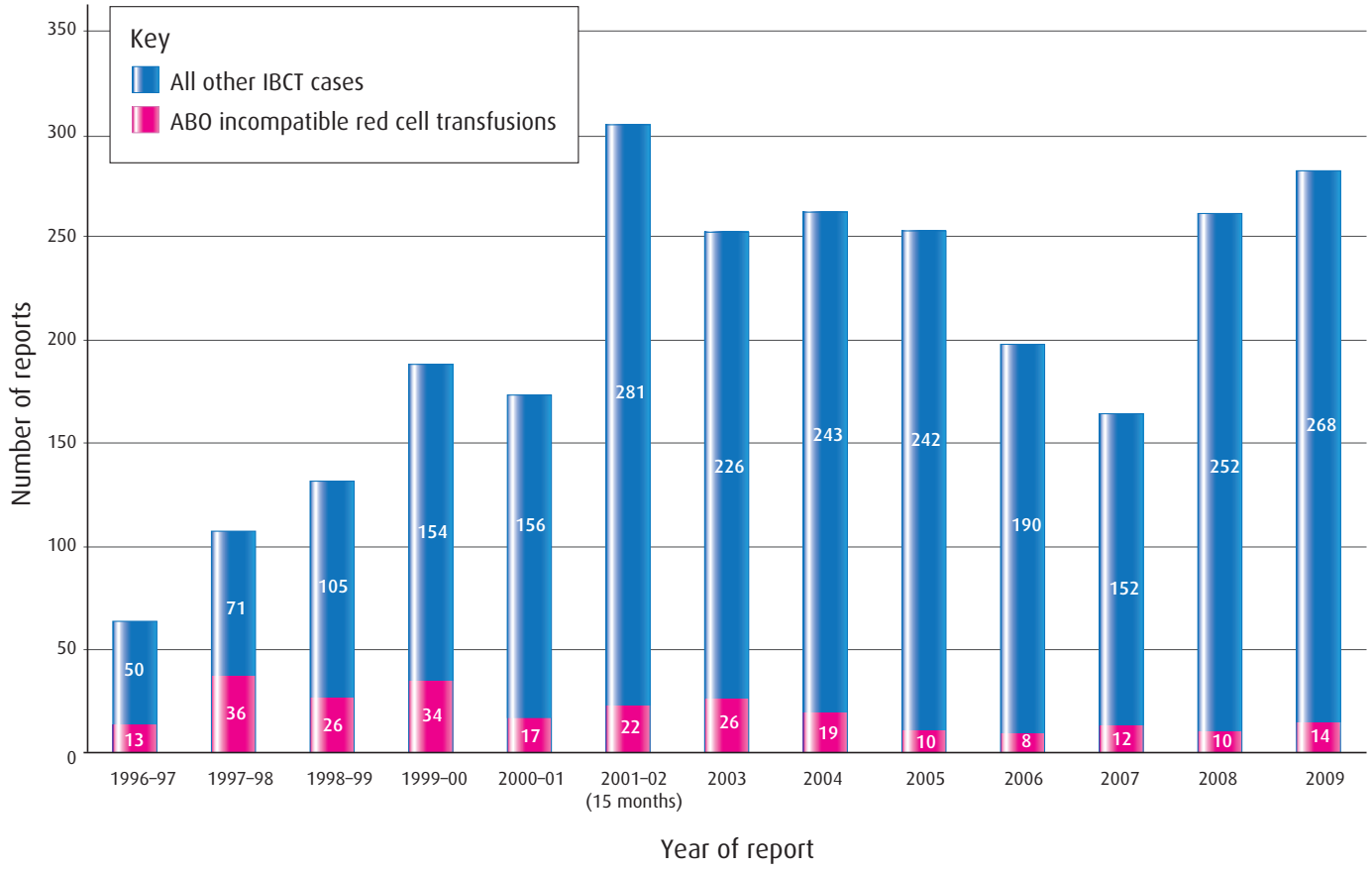
NB These figures exclude HSE and I&U; they are not categorised as IBCT and are reported in separate chapters.

Year	Number of cases reported on IBCT questionnaires	Reports per 100,000 components
2003	252	7.4
2004	262	7.8
2005	252	8.1
2006	198	6.6
2007	164	5.6
2008	262	9.2
2009	282	9.7

Figure 7

IBCT cases 1996–2009 showing ABO-incompatible transfusion

NB HSE and I&U cases are no longer included in the IBCT total (see 2008 Report) and are removed from the IBCT totals in this chart from 2003 onwards.



The histogram above shows the total number of reports in the IBCT category each year since SHOT reporting commenced in 1996. Until 2008, cases of *inappropriate and unnecessary transfusion* and *handling and storage errors* were included in this total. For the first time last year these were removed from IBCT and reported in separate chapters, as they do not involve transfusion of an incorrect component. This results in an apparent drop in IBCT cases. In reality the number of reports in all categories has continued to rise, as participation in haemovigilance has increased and reporters are becoming familiar with the reporting mechanisms and the benefits of contributing cases.

Table 12
Summary of IBCT cases

Type of event	No. of cases 2008		No. of cases 2009	
Administration of wrong blood component		**47**		**40**
■ ABO-incompatible red cells	4		10	
■ D-incompatible red cells	3		1	
■ Compatible wrong blood components	32		21	
■ Incorrect component type	3		1	
■ Other	5		7	
Wrong blood in tube		**5**		**4**
■ ABO-incompatible red cells	4		2	
■ D-incompatible red cells	0		1	
■ Incorrect Hb	1		0	
■ Compatible	0		1	
Special requirements not met – Clinical		**76**		**87**
■ Irradiation and CMV	70		79	
■ Other special requirements (including those arising from SCT)	6		8	
Special requirements not met – Laboratory		**41**		**67**
■ Irradiation and CMV	30		36	
■ Other special requirements	11		31	
■ Blood Service errors and omissions	0		0	
Laboratory errors (excluding SRNM)		**91**		**82**
■ Wrong blood issued	39		21	
■ Wrong ABO/D type for SCT patient	4		13	
■ Pre Tx errors – testing	8		9	
■ Pre Tx errors – procedural	40		39	
Miscellaneous IBCT		**2**		**2**
TOTAL		**262**		**282**

SUMMARY OF KEY DATA FOR ALL IBCT CASES *n* = 282

Mortality entirely related to IBCT event *n* = 0

There were no cases this year in which a patient died directly and solely as a result of an incorrect blood component transfused.

Mortality in which IBCT event contributed *n* = 3

There were 3 cases this year in which a patient died following a reaction to ABO-incompatible blood, where this may have contributed to the death. Two arose from administration errors (see Case 1 and Case 2, below) and 1 resulted from a phlebotomy error in the ED (Case 1, page 38). In these cases it is very difficult to define a causal link, but equally it is impossible to categorically state that an incompatible transfusion did not have an additional impact in an already critically ill patient.

Major morbidity *n* = 4

There were 2 cases of major morbidity resulting from administration errors, 1 from a phlebotomy error at the bedside involving misuse of an electronic aid to patient identification and 1 relating to a laboratory error. These are discussed in the relevant sections.

ABO-incompatible red cell transfusions *n* = 14

A total of 14 ABO-incompatible red cell transfusions were given, 10 resulting from bedside administration errors, 2 from wrong blood in tube phlebotomy errors and 2 due to laboratory errors in which the wrong sample was used for crossmatch. Two were also D incompatible. (Incorrect ABO groups given post SCT are not included here.)

D-incompatible red cell transfusion *n* = 5

There were 5 cases in which RhD-incompatible red cells were given (not including the 2 that were also ABO incompatible). One was the result of a bedside administration error, 1 a phlebotomy error and 3 were laboratory errors (2 RhD typing errors, 1 component selection error). (RhD-incompatible transfusions post stem-cell transplantation (SCT) are not included here.)

ADMINISTRATION OF WRONG BLOOD *n* = 40

Overview

In this subcategory 39 questionnaires were received and 1 case was transferred in from RBRP. Of these 40 cases, 13 occurred in male patients and 25 in female patients. Gender was not documented in 2 cases.

As in previous years a relatively high proportion of cases occurred either out of hours or in emergency situations, both of which have been shown to be associated with a greater rate of errors.

- 20 cases occurred during core hours and 16 out of hours: in 4 cases information on the time of transfusion was not available.
- 21 cases occurred in a routine setting and 13 were emergency transfusions: in 6 cases this information was not given.

A total of 5 reports involved patients under 18 years old. Of these, 4 were aged under 28 days and 1 patient was aged between 28 days to 1 year.

Mortality

There were no fatalities reported to be directly due to administration of wrong blood. However, there were 2 cases in which patients with severe underlying conditions died following an ABO-incompatible transfusion greater than 150 mL. The deaths were not unexpected given the clinical condition of the patients involved, so the final outcomes were inevitable and unchanged, but it is difficult to state with certainty that the transfusion reactions were totally unrelated to the timing of the death.

Case 1

ABO-incompatible transfusion during hip surgery of a patient with cardiac disease

An elderly patient with an underlying heart condition was transfused, during hip arthroplasty, with approx 200 mL of red cells intended for another patient. The transfusion was ABO incompatible: group B D positive blood was given to the group A D positive patient. The transfusion took place out of hours and no bedside checking took place. The patient was transferred to ITU and later died from cardiac problems. Postmortem investigations concluded that the cause of death was the underlying cardiac condition.

Case 2

Patient with severe anaemia, CCF and chest infection receives ABO-incompatible transfusion

An elderly patient was admitted as an emergency during the night with chest pain, ECG changes, chest infection and iron deficiency anaemia, and was deteriorating. A decision was taken to transfuse her but the incorrect unit was collected from the issue fridge of the blood transfusion laboratory. The patients shared a forename, had a similar surname and date of birth and were on the same ward. The recipient, who was group A D positive, had recently become unconscious at the time of transfusion and did not have a wristband. She received approximately 150 mL of group AB D positive red cells. She continued to deteriorate and died a few hours later. The report stated that it was not thought that the transfusion contributed to her death.

Major morbidity

There were 2 cases in which patients suffered severe reactions. One was stated to be 'an immediate reaction with risk to life' and the other, although categorised as 'mild immediate reaction without risk to life' resulted in the patient being transferred to HDU as a precautionary measure, so was perhaps borderline for major morbidity.

Case 3

ITU patient receives ABO-incompatible transfusion despite electronic bedside device

An agency nurse on ITU was caring for 2 patients. The Hb on the first patient showed as 6.6 g/dL from a blood gas machine reading. (A subsequent result on an FBC taken at the same time was 9.7 g/dL.) The nurse opened the electronic bedside documentation for a second patient while in the first patient's bed space. She asked another member of staff to print off a blood collection form for her, but the form printed out, and the unit subsequently collected, were for that second patient. With the unit, the nurse went to the first patient, but could not find a wristband (it was on the ankle) so checked the unit against the electronic details opened at the bedside, still for the second patient, and commenced transfusion. There was no written prescription for the blood. The recipient was group O D positive and the red cells were group AB D positive. The patient developed an acute severe reaction with respiratory distress, and became cold and clammy, and the transfusion was stopped after approximately 50 mL had been transfused.

This case also involved some additional errors. A calculated Hb value from a blood gas machine should not be used to inform a decision to transfuse, as they are inaccurate, with the Hb results not subject to external quality assessment and not intended for this purpose. Additionally, the presence of a handheld electronic device for patient ID did not prevent the error, and seemed to cause additional confusion. The agency nurse had not attended the hospital's transfusion training session.

Case 4

Incorrect unit collected and transfused despite training, competency-assessment and fridge locking system

A man who was group B D positive required a routine top-up post chemotherapy. An HCA who had been trained and competency-assessed collected the red cell unit from the locked issue fridge after hours without the formal checking of documentation. The patient was alert and conscious but was not involved in the checking procedure which was carried out at the nurses' station by 2 registered nurses against a compatibility form, not the patient's wristband. The patient received nearly 100 mL of ABO-incompatible red cells and developed pyrexia and rigors. He was transferred to HDU as a precautionary measure.

In this example all the staff involved were trained, and a lockable issue fridge had been installed to prevent unauthorised access, yet still the incorrect unit was collected and there was no bedside check. It is of concern that, more than 2 years after implementation of NPSA SPN 14[4] in which it was recommended that the compatibility form be phased out, there are still misunderstandings regarding what the bedside check is there to achieve, and 'checking' against the form, instead of the patient, is still taking place.

Erroneous administration of ABO-incompatible red cells *n* = 10 (of which 2 cases were also RhD incompatible)

In 7 of the cases the primary error was the collection of the incorrect unit from the controlled temperature storage (CTS) site. As 1 case occurred in ITU and 2 in theatres, the units involved may have been in satellite fridges in these cases. In the remaining 4 cases the incorrect unit was collected from the transfusion laboratory issue fridge.

Staff involved in collection errors are discussed below (page 36). A properly conducted bedside check would have prevented the IBCT in all cases. Two patients, 1 on a haematology/oncology day ward, did not have ID wristbands in situ, and 1 of these patients was unconscious (Case 2, above).

Case 5

Verbal ID carried out incorrectly on day ward patient with no wristband or photo ID

A patient required a top-up red cell transfusion following chemotherapy for carcinoma and attended the haematology/oncology day ward. The patient was not wearing a wristband and did not have photo ID. The registered nurse who administered the blood asked closed questions to which the patient responded 'yes' – the forename asked was the same, the surname had the same initial letter, but the date of birth was different. The blood, which was intended for a different (group A D negative) patient, was given to this group B D positive patient. Less than 50 mL were given and there was no adverse reaction.

Comments are made in some cases about poor levels of staffing in the clinical area, and staff being distracted by events occurring in relation to other patients. Bedside checking is discussed in more detail below.

Of the 10 cases, 4 were during core hours, and 6 were out of hours – clearly this is a high proportion. Three of the ABO-incompatible red cell transfusions were given in emergency situations, 2 of these out of hours. Although numbers are low, this tends to endorse previous findings that such errors are more likely both out of hours and in emergencies.

Two cases of ABO-incompatible red cell transfusion were also RhD incompatible. The case below is another example in which, despite training, checking procedures both at the time of blood collection, and again in theatres, were carried out wrongly.

Case 6

Man receives emergency transfusion which is both ABO and D incompatible with no ill effects

An elderly man with a lower GI haemorrhage was undergoing angiography and required emergency transfusion. A nurse took the correct documentation with her to collect the blood but did not check it formally and collected a unit for another patient with the same surname. This incorrect unit was handed to the nurse in theatre who checked the unit only against the accompanying compatibility form, not against the patient wristband. The patient, who was group B D negative, received 150 mL of group A D positive blood but did not suffer any adverse reaction. He proceeded to surgery the same day with no problems.

Two of the patients receiving ABO-incompatible red cell transfusions died following the episode, from underlying medical conditions; the transfusion was not considered to be contributory (see above).

Erroneous administration of RhD-incompatible red cells (which were ABO compatible) *n* = 1

RhD positive red cells were given erroneously to 1 further patient who was RhD negative, in addition to the 2 included with the ABO-incompatible group above. In all 3 cases no ID checks were performed; in 2 of the cases the incorrect blood had been collected from the transfusion laboratory fridge.

Case 7

Patient's son notices transfusion of incorrect D-incompatible unit of red cells

Blood was collected from the issue fridge for 2 patients on the same ward who required transfusion. One unit was taken to the bedside of one of the intended patients and two nurses completed the bedside check. None of the correct items, including the patient's wristband, was checked. After commencement of the transfusion the patient's son noticed that the details on the bag, stating the group as O D positive, were not those of his mother, who was group A D negative.

Of all cases of erroneous administration of red cells, 10 were ABO-incompatible and 19 compatible, which is the ratio (1:2) that would be expected by chance.

Wrong blood components transfused that happened to be compatible *n* = 21

There were 21 cases of blood being transfused which was not for the patient who received it, but where by chance the group administered was compatible with the ABO and D group of the patient. Of these cases 19 related to red cells and 2 to platelets.

The errors involved in these cases consisted of:

- Collection of a unit intended for a different patient from controlled temperature storage (CTS)
- Incorrect collection of adult instead of neonatal 'flying squad' blood, see below
- 'Checking' the unit remotely from the patient and then administering it to the incorrect patient
- Interchanging 2 units (after 'checking') intended for 2 different patients in the same clinical area (1 of these cases resulted in an ABO-incompatible transfusion, included above)
- Transfusion to a patient wearing a wristband with another person's details on it.

Case 8

Patient wearing the ID wristband intended for another patient

A woman with a haematoma had a low Hb and required transfusion, stated to be routine although it took place between midnight and 08.00. The wrong wristband had been put on the patient in the medical assessment unit. A group O D positive unit was transfused for which the patient details matched the ID wristband but which did not match the patient herself (who was group A D positive). Another nurse spotted the erroneous wristband on a later drug round.

The incorrect use of documentation when collecting components from the laboratory storage site, the absence of true bedside patient ID checks, and the checking of incorrect items or documents at the bedside or remote from the bedside are recurrent problems in this group of cases (see below).

The following case concerns collection of the incorrect unit, which occurred despite the presence of an electronically protected fridge. An alarm, which was flagging up that it was the incorrect unit for the documents being presented, was ignored or overridden.

Case 9

Wrong unit collected from electronic fridge despite alarm activation

An unqualified nurse collected a unit of blood from an electronically protected fridge. The unit she withdrew did not match the paperwork she presented (only the surname was the same) and the system alerted. However, the alarm was ignored or overridden. The red cells were handed to 2 registered nurses on the ward who conducted the bedside check. Although they were holding the unit of blood, one nurse read out the patient wristband details while the other checked these details against the patient's chart. The unit itself was not checked. The blood group matched the patient: both were group A D positive.

It is implied in the report that the staff involved had not been formally trained and competency-assessed, as achieving this was part of the corrective and preventive action.

Incorrect component type given to the patient *n* = 1

In this case the wrong component was administered against a prescription that clearly stated the correct component, highlighting a lack of knowledge of component types and their appearance among staff involved in the collection and transfusion of blood components.

Case 10

Lack of understanding and training leads to incorrect component selection

A newly qualified nurse was sent to collect platelets for a patient going to theatre. The nurse had been booked onto the Trust's competency-assessed blood transfusion training but had been withdrawn at the last minute because of staffing levels. The nurse did not know what platelets looked like and was not aware that they were not stored in

the fridge. After searching in the fridge, the nurse selected red blood cells for this patient. Red blood cells had not been prescribed but were available for use in theatre if required. The nurse returned to the clinical area, performed a compatibility check with a more senior nurse and commenced the transfusion. The error was not detected at this point because the ward was extremely busy and they were the only 2 qualified nurses on duty. The error was detected when the transfusion laboratory phoned the ward to remind them that the platelets were ready.

It is clear that the error could 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. Once again short staffing and a busy working environment are cited as contributing to this error.

Transfusion of component to correct patient but without a prescription *n* = 2

In these cases a component was transfused which had been neither prescribed nor authorised by the clinicians in charge of the patient's care. The issue here is not the recognition of different components but omitting to check that the component had been prescribed before administering it.

Case 11

Administration of unit without valid prescription

A junior doctor on call out of hours decided that a postoperative patient needed 2 units of RBC and a crossmatch sample was taken. Following discussion with a senior colleague it was agreed not to transfuse, but to re-check the Hb in the morning. This decision was documented in the patient's medical notes but not verbally communicated to the nursing staff. The 2 units of red cells were later requested for the patient by the nursing staff. A unit was commenced using an old prescription chart with 1 unit written up: this had been for possible transfusion in theatre the previous week but had not been necessary. The doctor identified the incident the next morning on the ward round when the patient told him he had received a unit of blood which the doctor knew he hadn't prescribed.

Unlabelled units delivered direct to clinical area *n* = 3

In all of these cases unlabelled components arrived from outside the treating hospital and had not been booked into, or issued by, the hospital transfusion laboratory, nor undergone any compatibility testing. Clinical staff cannot have completed any kind of bedside check as the units bore no patient identifiers.

Case 12

Unlabelled products transfused to wrong patient in error

Platelets for a patient in ITU were delivered to the ED by taxi from the BTS. The ED had also requested platelets for a patient. The ED took delivery of the platelets, which were for a different patient, and transfused them despite there being no documentation or label with any patient details.

Case 13

Emergency red cell delivery went straight to theatre and was immediately transfused

Blood and products delivered blue light from the BTS arrived in the ED but the multiple-trauma patient had gone to theatre. The NBS driver had been instructed to take the blood to the laboratory, and asked the way there. Because of the urgency, the nurse on duty in the ED directed him straight to theatre. The blood was not labelled for the patient but in the emergency the doctors decided to transfuse it. The blood was correct for the patient and there were no complications from the transfusion, although the patient died from trauma.

A third case involved a transfer from another hospital of a patient accompanied by some unlabelled red cell units, with no paperwork or transfer document. The units went with the patient to the clinical area, from where she was to go to theatre for an exploratory laparotomy. The blood was given in theatre despite the lack of a patient ID label or any documents.

Learning points

- All components arriving in a hospital with a transfusion laboratory should go to the laboratory first, to be booked into the inventory and issued using the hospital system to maintain traceability. This applies to emergency deliveries as well as transfers of units for individual patients.
- Hospitals should have SOPs for inter-hospital transfer of blood components.
- No clinical staff should transfuse components that are unlabelled or without a patient ID tag, unless specifically marked as 'flying squad' blood.

Paediatric cases *n* = 5

(discussed in more detail on page 140)

Four of the 5 administration errors reported were in newborn babies, and the fifth case involved a 3-month-old infant. Of the 4 neonates, 3 received adult 'flying squad' blood rather than blood suitable for neonates, and 1 – who was born to a mother known to have high levels of anti-c during the pregnancy – was given 'flying squad' rr red cells in error. In the fifth case, 'flying squad' blood was required for an infant who had arrested, but instead, blood crossmatched for another patient was collected and administered. There was no bedside check, but the infant was group A D positive whereas the blood given was group O D positive.

Lack of visual inspection of unit *n* = 2

In 2 cases the nursing staff administering red cells did not carry out a visual inspection of the unit before commencing the transfusion. In these 2 reports the red cell unit contained extensive blood clots and was unsuitable for transfusion. In neither case did any harm come to the patient. Visual inspection of blood components is an essential part of the pre-transfusion check, as haemolysis, clots or bacterial contamination of platelets may sometimes cause visible changes.

Details of administration errors

Volume of incorrect blood component transfused

As shown in Table 13 below, in 14 cases it appears that the error was noticed almost immediately after the transfusion started, as < 50 mL of blood was transfused.

Table 13
Volume of wrong component administered

Volume given	Number of cases
< 50 mL	**14**
50–99 mL	**3**
> 100 mL	**8**
Whole unit	**11**
> 1 unit	**0**
TOTAL	**36**

There were 11 cases in which the whole unit was transfused. This is not unexpected, since after the initial patient ID check pre-transfusion ID is unlikely to be reviewed. A number of reports include comments on short staffing and excessive workload.

Blood component collection

Of the 40 cases of wrong blood component administered (Table 12), 16 involved the collection of an incorrect unit from the hospital laboratory issues fridge, followed by the failure of all subsequent barriers to administration of wrong blood components – in particular the bedside check of component against patient ID.

Table 14
Staff responsible for the collection of the incorrect unit from the blood storage site

Registered nurse/midwife	**7**
Porter	**1**
Student Nurse	**2**
Health Care Assistant	**2**
Operating Department Assistant	**1**
Doctors	**2**
Unknown	**1**

Personnel who collect components from the blood issue site must be fully trained, competent, aware of the critical nature of the tasks involved, and able to take personal and professional responsibility. Only 10 staff involved in the collection process were documented as being trained, and 5 had received no training.

Errors included:

- Not checking details of all patient identifiers against unit being collected
- Staff using adult 'flying squad' blood that is not appropriate for neonatal use
- Selection of the incorrect component type
- Staff overriding/allowing other staff access to electronically locked issue fridges.

The improper use of IT solutions to reduce transfusion error is discussed in detail from page 57.

Bedside checking

Bedside patient ID checking could have prevented at least 28 of these 40 cases if properly carried out using the ID wristband against the component. The ID check was absent in 21 cases (i.e. either omitted completely or some erroneous form of check was carried out away from the patient). In 7 cases the check was completed at the bedside using various items of paperwork plus the unit of blood, but without any checks of the patient themselves (either verbally, or by the wristband attached to the patient). Of 40 cases, 3 patient ID wristbands were missing and 1 had incorrect details. All other cases in this group had correct ID wristbands although not always on their wrist.[18] In 3 cases no wristband details were recorded.

A cause for concern is the continued use of the compatibility form to 'check' the unit remotely from the patient. This contravenes the action points identified in the NPSA SPN 14.[4] This document clearly states that the reliance on using compatibility forms and checking these against the patient components has been a notable contributory factor to ABO-incompatible transfusions, advising that the compatibility form should be withdrawn. This was also a recommendation in the 2008 SHOT report and it is reiterated in the recently updated BCSH Guideline on the Administration of Blood Components 2009.[19]

The repeated theme of incorrect or no bedside check implies that there are still widespread misconceptions, in spite of training and competency-assessment, about what pre-transfusion checking, signing and documentation processes are actually there to achieve.

Table 15
Number of staff involved in final check

Single-person check	**12**
Two-person check	**21**
No detail	**7**
TOTAL	**40**

The data do not allow for any inference to be made regarding the relative effectiveness of a 1 or 2 person check. As previously reported, there were cases in which the reporter documented that the staff had been trained and competency-assessed but had still not followed the Trust protocols relating to blood transfusion.

COMMENTARY on component administration errors

There are fewer cases of bedside administration errors leading to IBCT than last year (40 versus 47) but more ABO-incompatible transfusions resulted (10 versus 4). However, the low number in 2008 was fewer than would be expected by chance if giving 47 wrong units to the incorrect recipient, and was purely serendipitous. Once again the protocols for positively establishing patient identity were not followed, in some cases despite training and competency-assessment. Patients are still being transfused with no wristband in place, and compatibility forms are still being used as a way of 'checking' ID. Explanations given included agency and locum staff, pressure of work and short staffing.

Learning points – patient identification

- No wristband – no transfusion.
- The compatibility form must not be used as part of a patient ID check.
- The patient must be physically present when the ID check is carried out. Any other check is not a patient ID check.
- Electronic devices are an aid to correctly reading and matching long barcodes, but staff using them must understand that the IT in itself cannot prevent errors.
- Patient ID is an absolutely fundamental part of the delivery of healthcare in any discipline, and should be second nature to all staff.
- It is crucial that the content and principles contained in any training and competency package are fully appreciated and understood if errors are to be avoided.

The following learning point remains relevant from last year:

- 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 SHOT report 2008) and must be educated in the critical importance of patient ID for every medical intervention.

WRONG BLOOD IN TUBE (WBIT) *n* = 4

These cases occur when the sample tube is labelled correctly for a particular patient, but contains a sample from a different patient. This may affect samples either for a group and crossmatch, or for haemoglobin (FBC) or both.

Of the 4 cases, 2 were ABO incompatible (but RhD compatible), 1 was RhD incompatible (but ABO compatible) and 1 was fully ABO and RhD compatible. Of the transfusions 3 were routine and 1 was an emergency. One took place in normal working hours (routine) and for the others time was not stated. All 4 patients were adult males.

The 2 cases of ABO-incompatible transfusion resulted in severe reactions, and in 1 case the patient died with the ABO-incompatible transfusion probably contributing to the death.

Case 1

Patient dies following acute HTR after phlebotomy error

An elderly man with chronic renal failure, anaemia and a history of falls attended the ED. He was crossmatched using a sample taken in the ED and on admission to ITU he was transfused as he was symptomatically anaemic with Hb 6.8 g/dL. After < 100 mL had been transfused he suffered fever, hypotension and bronchospasm and died a few hours later. The wrong patient, who was group A D negative, had been bled in the ED resulting in the wrong blood in a tube correctly hand-labelled for the intended patient, who was group O D negative. There had been no checking of the patient's ID at the bedside, either with the patient himself or with the wristband. The transfusion sample protocol had not been followed by a locum medical member of staff.

Case 2

Patient suffers respiratory arrest due to ABO-incompatible transfusion

A patient with anaemia due to malignancy was receiving a red cell transfusion as an outpatient. After < 50 mL had been transfused, he developed fever, rigors and bronchospasm followed by a respiratory arrest 20 minutes after commencement. The transfusion was stopped and he was admitted to the ward and stabilised successfully. Upon investigation it has been discovered that the original G&S sample had been mislabelled by a trained phlebotomist using a bedside computer-generated label, and it belonged to another patient who was group A D positive. The recipient was group O D positive. This was the patient's first transfusion so there was no previous transfusion history.

A further case involved a doctor who realised he had bled the wrong patient for the crossmatch when he saw a different patient receiving the transfusion. He had not followed the transfusion protocol and had labelled the sample away from the bedside with the details from the notes of the intended patient. He had bled a different patient, who fortunately had the same ABO and RhD group.

The fourth case detected a previous phlebotomy error 2 years previously resulting in a patient receiving 4 units of RhD positive blood when he was RhD negative. The error was discovered due to discrepant results on a subsequent admission requiring urgent transfusion for active haemorrhage.

COMMENTARY on wrong blood in tube

In all 4 cases the protocol for transfusion sample labelling was not followed correctly and this led to preventable errors being made.[19] In only 1 of the 3 cases was the member of staff involved documented as having been trained (the phlebotomist, see Case 2).

The errors and problems identified in these cases include:

- Not checking patient ID verbally or by wristband
- Labelling filled tube away from the bedside
- Using a computer-generated sticky ID label on a (pre-labelled) tube
- Deployment of locum staff not trained or familiar with standard procedures
- Reliance on bedside technology without full understanding.

All of the errors in this group were preventable if the person taking the sample had adhered to NPSA guidelines and local Trust policy for taking transfusion samples. The absence of this adherence led to 3 patients being given incompatible components, resulting in 1 fatality and 1 life-threatening reaction. Despite staff completing their blood transfusion competencies, work pressures can lead to staff 'cutting corners' and losing sight of the reasons for completing a comprehensive ID check.[19]

SPECIAL REQUIREMENTS NOT MET (SRNM) *n* = 154

The total number of cases in this section (clinical and laboratory) has increased this year to 154 compared with 117 last year. There are 87 cases with a primary clinical cause of the omission and 67 cases in which the responsibility lay within the hospital transfusion laboratory.

This year 81 male and 70 female patients did not have their special requirements met. In 3 reports the gender of the patient was not documented. A total of 25 patients were < 18 years old. There were 2 < 4 weeks old, 4 aged 4 weeks to 1 year, 17 aged between 1 and < 16 years, and 2 aged 16 to < 18 years. The remaining 129 patients were adults with an age range of 18 to 87 years.

Table 16
Special requirements not met, showing proportion of primary clinical and primary laboratory errors

Category of error (SRNM)	No. of clinical cases	No. of laboratory cases
Failure to consult patient notes (clinical or laboratory), or failure of communication from clinicians to laboratory, or poor knowledge of clinician	84	40
Irradiated component	69	22
CMV negative component	5	10
CMV negative and irradiated	5	4
HLA matched platelets		4
HLA matched and CMV negative	1	
BMT group change and irradiated	4	
Poor knowledge and/or failure to recognise the special needs of a specific patient group (clinical and laboratory)	3	27
Phenotyped component		17
MB treated FFP		7
Apheresis platelets not given to a patient < 16		3
Not using blood warmer	2	
Latex allergy missed	1	
TOTAL	**87**	**67**

SRNM following clinical errors or omissions *n* = 87

As in previous years 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 the non-communication of a requirement for CMV negative components or requiring both specifications. Generally, it appears from the information supplied to SHOT that the doctor ordering the components either 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 69 clinical-based omissions to request irradiated blood, the indications for irradiation were as follows:

- 26 fludarabine or other purine analogue
- 16 Hodgkin's disease
- 7 BMT or SCT
- 2 hairy cell leukaemia
- 2 AML
- 4 NHL
- 1 Waldenstrom's macroglobulinaemia
- 3 lymphoma (unspecified)
- 1 myeloma
- 3 CLL
- 2 IUT
- 1 Campath therapy
- 1 unknown.

Case 1

Non-irradiated red cells given to baby with previous IUT

A baby who had been the recipient of intrauterine red cell transfusions (IUTs) was given 4 non-irradiated paedipaks of red cells on 2 separate occasions. The request form did state that the mother had antibodies and that there had been 3 IUTs, but the special requirements were not specified. The prescription form did not specify irradiated blood.

Although a BMS might, on seeing the history of IUT, contact the clinicians for clarification, or decide to issue irradiated components, this is not core knowledge for laboratory staff. The requesting of special requirements for individual patients is a clinical responsibility.

Case 2

Consultant assumes that need for irradiation is already documented from several years earlier

An elderly patient had been on fludarabine for NHL since 2002 but no one had informed the laboratory that irradiated units would be indicated if any blood was required. The patient became anaemic and non-irradiated blood was issued and transfused. The consultant assumed that an alert was in the notes and on the pathology system and did not write the special requirement on the request form.

Of the 5 clinical omissions to give a product both CMV negative and irradiated, the indications were as follows:

- 1 post stem-cell transplant for B cell lymphoma
- 1 myeloma
- 1 NHL
- 1 post treatment cerebellar medulloblastoma
- 1 anaemia post treatment for malignancy (paediatric).

There were 5 cases in which CMV negative blood was indicated but not given. The indications were:

- 1 ECMO prior to heart-lung transplant
- 1 pregnancy (unrelated illness while pregnant)
- 1 pre-SCT
- 1 HIV with complications
- 1 unknown.

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. In a number of these cases the need for special requirements was clearly documented as part of the patient medical history.

In 15 of the 87 cases linked with the 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
- requirement for HLA matched platelets
- previous SCT.

Five of these 15 cases were documented as emergency admission via the ED.

Case 3

Patient transferred to another ITU, special requirement details for SCT omitted

A patient was transferred from his primary hospital, where he had undergone a stem-cell transplant, to another hospital within the same Trust in order to access an ITU bed. Each site has a blood transfusion laboratory. Platelets were requested by ITU and issued by the hospital transfusion laboratory. Irradiated components were not requested due to a lack of communication between the clinicians, and the laboratory records were separate from those at the originating hospital.

Case 4

Special requirements for ECMO patient not communicated between hospitals

A teenager requiring ECMO support prior to a heart-lung transplant was transferred from another Trust. The ECMO team did not notify the hospital transfusion laboratory of the requirement for CMV negative components. This request should also have been followed up by written confirmation on the form for special transfusion requirements.

Special requirements may be second nature to the clinicians dealing with particular patient groups day to day, but may be very unfamiliar to more general staff, e.g. on ITU or in a surgical unit.

Case 5

Error in transcription of patient details leads to special requirement not being met

A patient was admitted via the ED and a sample sent for group and crossmatch. Although the details on the sample and request matched, the patient was incorrectly identified, the name was transposed and misspelt, and the date of birth was wrong. A new hospital number was therefore created, so historical details of special requirements were not accessed. The patient received a non-irradiated unit of blood.

Case 6

Patient history not accessible due to change of address

A patient admitted through the ED required multiple units of blood and received 2 units initially. The following morning a nurse looking after the patient informed the laboratory that the patient had previously received an SCT and required irradiated blood components. The patient had moved house and this was their first admission since relocating. The remaining units were returned to the laboratory and replaced with suitable irradiated red cells.

There were a total of 4 cases in which clinicians did not inform the laboratory that an SCT had taken place in the past.

Case 7

Vital information regarding a recent BMT not communicated to the transfusion laboratory

A patient known to the Trust had FFP requested which was issued according to the historical blood group – O. However the patient had received a BMT (for CLL) at another hospital and the blood group had changed from group O to group B. None of the request forms indicated that the patient had had a recent BMT.

Two new special requirement categories were identified by reporters including 1 latex allergy case and 2 cases of patients who required blood warmers due to cold agglutinin disease.

In 56/87 cases the reporter stated that the BCSH guidelines relating to special requirements were not adhered to.[20]

COMMENTARY on clinical cases of SRNM

The number of cases in this subgroup SRNM has continued to rise and is still probably only a small proportion of the true number of these events. The majority of cases relate to patients for whom irradiated blood is indicated, who do not receive it. The prevention of TA-GvHD in susceptible patients is vital, and irradiation is effective in its prevention. The lack of clinical cases of TA-GvHD in recent years should be seen as the outcome of successful implementation of policies from the blood services and national professional guidance, not as an indication that the condition is obsolete.

Doctors not usually working in haematology and 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, especially since the EWTD.

Doctors working in non-haematology specialities, especially the ED and critical care, must also be educated sufficiently in transfusion medicine to know that certain patient groups, such as pregnant women and sickle cell patients, as well as past SCT recipients, have important special requirements for safe transfusion.

The request form is there to facilitate this, requiring a diagnosis or reason for transfusion, and it specifically asks about pregnancy. It should be an absolute requirement, enforced through the Risk Committee and Clinical Governance framework, that the transfusion request forms are fully completed. Transfusion laboratory staff should be required to ask for missing details.

Shared care inevitably results in a situation where the 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 critical transfusion requirements that may arise from the diagnosis and treatment of a shared patient. Detailed information changes hands, but transfusion details may be omitted, or the transfusion laboratory or practitioner may be left out of the communication loop.

SRNM following laboratory errors or omissions *n* = 67

These are discussed in the laboratory section beginning on page 51.

MISCELLANEOUS IBCT *n* = 2

Documentation of traceability of blood components, and of pre-transfusion storage conditions and duration of storage, along with a record of monitoring the patient during and after transfusion, are all essential – even if a home transfusion is being administered. Hospitals should have a protocol for transfusion at home.

Case 1

Home platelet transfusion administered without proper protocol or documentation

Two units of apheresis platelets were released from the hospital transfusion laboratory on the instruction of the haematology consultant for a colleague to administer to her mother at home. There was no hospital policy for this: no patient ID or compatibility paperwork was completed, nor were any observations documented.

Case 2

Incorrect selection of patient details at booking in to ED

A patient attended the ED, but when being booked in an incorrect patient with the same first and second names – though a different spelling of the first name – was selected from the computer system by the reception clerk. The DOB did not match what the patient stated, so the clerk altered the DOB on the computer system. The patient had an Hb of 6.8 g/dL and, with a different patient hospital number and first name and the altered DOB, was transfused. The error was retrospectively detected by the transfusion laboratory.

Patient identification procedures should be followed carefully at every stage of a patient's attendance at a hospital. Clerical and reception workers understand the possible consequences of patient ID errors and must know how to use the address as an additional identifier and be aware that there may be patients with similar names.

IBCT EVENTS ORIGINATING IN THE HOSPITAL TRANSFUSION LABORATORY *n* = 149

2009 has seen a total of 149 IBCT cases in which the primary error occurred in the laboratory, which represents 53% of the total 282 IBCT cases. All IBCT cases have been summarised in Table 12 (page 29) and are discussed in more detail below. Laboratory errors resulting in special requirements not met (SRNM, 67 cases) are discussed towards the end of this chapter.

Overall laboratory errors account for 230 of the total 1279 cases included in the 2009 SHOT Report (18% of all reports). This consists of 149 IBCT events, including 67 cases of special requirements not met (see Table 17, below), 38 anti-D related events (see page 81) and 43 handling and storage errors (see page 75).

In 2008 there were 200 cases involving laboratory errors consisting of 132 IBCT events, including 41 cases of special requirements not met, 47 anti-D related events and 21 handling and storage errors. This represented 19% of the total 1040 SHOT reports in 2008.

However, the increase in the overall reporting to SHOT this year (from 1040 to 1279 reports) stands at 23% while the absolute increase in laboratory-based reports, from 200 to 230, is 15%.

Table 17
Summary of Laboratory-related errors *n* = 230

Type of error	Number of cases from this chapter
Wrong blood	**21**
Wrong sample selected	2
ABO grouping error	5
D grouping error	4
Incorrect component selected	9
Incorrect labelling	1
Wrong group selected for SCT patient	**13**
Wrong ABO group selected	7
Wrong D Group selected	2
Procedural errors	4
Other pre-transfusion testing errors	**48**
Testing errors	9
Procedural errors	39
Special requirements not met	**67**
Due to poor serological knowledge/ failure to recognise the special needs of a specific patient group	27
Owing to failure to consult patient records thoroughly	40
SUBTOTAL	**149**
Anti-D related laboratory errors	**38**
Handling and storage related laboratory errors	**43**
TOTAL LABORATORY ERRORS	**230**

Mortality

There were no cases of mortality definitely related to laboratory IBCT events, nor any in which a lab IBCT event probably or possibly contributed to a patient's death.

Morbidity

One patient showed symptoms (severe pain in the back, abdomen, pelvis and legs, nausea, and tingling in the hands and feet) of an ATR during an ABO-incompatible transfusion of group A D negative blood to a group O D positive patient. There were 3 cases of minor morbidity which occurred as a consequence of errors; these are highlighted in the text. Three other minor acute transfusion reactions were reported but were not a consequence of the error that was made.

ABO and D incompatibility

Errors have resulted in 2 ABO-incompatible red cell transfusions: the case highlighted above which gave rise to an AHTR and a second case where group A D negative blood was transfused to a group B D positive patient. There were a further 5 cases where group A red cells were transfused to group A patients who were recipients of group O BMT/SCT and therefore should have received group O red cells. RhD positive red cells have been given to RhD negative individuals in 6 cases: once because RhD positive red cells were selected in error, twice due to D typing errors, and on three occasions D positive components were selected when the BMT/SCT transplant protocol demanded selection of RhD negative components. No adverse sequelae were reported as a result of these ABO and D typing errors other than the acute haemolytic transfusion reaction described.

Wrong Blood Incidents *n* = 21

This year 21 out of the 230 cases (9.1%) of laboratory errors accounted for 'wrong blood' incidents. This is in comparison with 39 out of 200 cases (19.5%) last year.

Four cases involved paediatric patients – a neonate, a 1-month-old baby, a 15-month-old baby and a 17-year-old. In 2 cases the age was not given. All other cases were in adults over 18 years old. Table 18 illustrates the time and circumstances under which these wrong blood incidents took place.

Table 18
Summary representing when incidents occurred

	Out of hours	In core hours	Unknown
Emergency	7	1	0
Routine	5	3	2
Unknown	0	1	2

As reported in previous years, more errors occurred out of hours. The staff involved out of hours included 8 BMSs who normally work in transfusion and 4 who do not.

The 21 errors were:

- Two cases in which blood was grouped and crossmatched for a patient using the wrong sample. In the first case this resulted in group A D negative blood being transfused to an O D positive individual; and in the second case group A D negative blood was transfused to a group B D positive patient. The transfusion was stopped after only 30 mL had been transfused and the patient experienced no adverse reaction.

Case 1

A malfunctioning analyser forced a manual group and crossmatch – and human error

A crossmatch sample was run on the grouping analyser, but the results failed to transmit to the LIMS due to non-identification of the results by the analyser. A manual group and crossmatch was started but the BMS was interrupted and on return to blood transfusion picked up the wrong sample and tested it.

- There were 5 ABO grouping errors, all of which occurred during emergencies. Three cases involved errors in manual, tube groups resulting in 1 group A D positive patient being grouped as O D positive and receiving

multiple group O components; 1 group B D positive patient being grouped as O D positive and receiving group O red cells and FFP; and 1 group O D positive patient being grouped as A D positive but fortuitously only requiring FFP. A further case involved a neonate being grouped manually as O D positive, and subsequently transfused group O D positive components. However, during a validation process the sample was selected at random and analysed using an automated system, and was grouped as AB D positive. This was later confirmed to be correct. The final case involved a 1-month-old baby that was transferred between 2 hospitals. This case is given below because it highlights the importance of good communication both in shared care situations and between 'shifts' in laboratories.

- There were 4 errors in D-typing that resulted in IBCT cases, all occurring during on-call emergency situations and using manual techniques. In no case was the reporter able fully to ascertain what had gone wrong. All the errors were detected during subsequent routine testing. There were 3 female patients (2 > 60 years old, 1 age unknown) and 1 male patient. The errors resulted in RhD negative blood being given to an RhD positive individual in 1 case and RhD positive blood being given to RhD negative patients in 2 cases. In the final case, despite being mistyped as RhD positive, RhD negative blood was selected and transfused to the patient. There were no cases of anti-D being formed at the time of reporting.

  A further 5 D typing errors resulted in anti-D being given unnecessarily; these are reported in the anti-D chapter, see page 81.

- In 9 cases the incorrect component was selected.
  - Two cases involved red cells. One of these cases occurred when 2 units of red cells, received from a reference laboratory for a named patient, were incorrectly issued to another patient of the same blood group. The error was detected by the BMS and the second unit was withdrawn. The patient experienced pyrexia and rigors 12 hours post transfusion but these symptoms were attributed to a septic episode. The other case involved a male patient whose blood group was O D negative being issued 1 unit of group O D Positive red cells in error. The patient had not produced anti-D at the time of reporting.

  - In 4 cases cryoprecipitate was issued when FFP was requested.

  - Three cases involved platelets. In 1 case RhD positive platelets were issued to an RhD negative patient with anti-D. In another case RhD positive platelets were issued to a female of childbearing potential necessitating the issue of anti-D immunoglobulin. In the final case a group A D positive unit was issued to a group O D positive patient; it appears that the wrong group was sent by the BTS and issued by the laboratory. The ward queried the different blood groups and the decision was made, not unreasonably, to transfuse the platelets.

- Only 1 case was reported as a result of incorrect labelling. A laboratory staff member was partway through the labelling procedure when they were called away: on returning they attached the label to the wrong pack. A patient was subsequently transfused platelets which were not HLA matched. Although the error originated in the laboratory, the discrepancy between the laboratory label and the donor number on the pack was not detected by the nurses collecting and transfusing the unit.

Case 2

Effective transfer of data is essential

A baby was transferred to another hospital and subsequently grouped as O D negative. The BMS contacted the first clinical team and was informed that the baby had recently been transfused. However, the second team were desperate for blood and 8 group O D negative paedipaks were issued. There was concern over the blood group so the case was handed over to the morning staff. The transfusion laboratory tried but failed to contact the referring hospital. The problem was not passed on the next day and group O D negative MB-FFP was issued. The patient was later found to be group A D positive, having been transfused with group O D negative blood at the first hospital.

COMMENTARY on wrong blood incidents

The number of laboratory errors contributing to 'wrong blood' events has decreased this year. This number is small, but ABO and D typing errors continue to be a problem when using manual techniques, generally in urgent situations. Consideration should be given to adding a second check if manual groups are to be performed.

Table 19
Trends in laboratory-based ABO grouping errors, with causes

Year	ABO errors	Wrong sample tested	Interpretation/ transcription errors	Other	ABO-incompatible transfusion (all components)	Sequelae
2009	6	2	5	0	4	1 AHTR
2008	8	3	5	0	4	1 AHTR
2007	7	3	4	0	2	No morbidity
2006	6	2	3	1	0	No morbidity
2005	22	9	12	1	9	1 AHTR
2004	18	5	12	1	6	1 death 1 major morbidity
2003	17	8	9	0	7	2 major morbidity

The trend shows a decrease in the number of reports over time, despite an overall increase in reporting to SHOT – this is a positive finding, and may be seen as a sign of improvement.

Table 20
Trends in laboratory-based D grouping errors, resulting in IBCT, with causes

Year	D errors	Wrong sample tested	Interpretation/ transcription errors	Tx of D+ to D- individual	Other	Sequelae
2009	5	1	4	2	0	No morbidity
2008	11	0	11	10	0	3 patients formed anti-D but none were of childbearing potential
2007	4	1	3	3 (I x 33-yr-old female)	0	No morbidity

Errors in component selection continue to occur, with 4 more cases of cryoprecipitate being issued when FFP was required. Laboratories should ensure clear separation of components which look similar and the LIMS should support prevention of this type of error.

In 8 cases it was believed that the final bedside check could have picked up these primary laboratory errors and prevented mistransfusion.

Learning points

- Where feasible all samples tested by manual methods should be tested using an automated system as soon as possible. Consideration should be given to:
    - adding a second check if manual groups are performed;
    - reassessing the use/availability of automation/IT to add security to manual methods, e.g. automated readers.
- A full RCA should be performed on all errors that led to a SHOT reportable incident and appropriate CAPA instigated.

The following learning points from previous SHOT reports remain pertinent:

- Training and competency-assessment in the laboratory must cover basic manual checking procedures to ensure that these are second nature at a time when automation and computerisation will have lessened experience and practice in these basic skills.
- When new components are introduced, training must be given to all staff to allow thorough familiarisation with the component appearance, label and specification.
- 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 then these development requirements must be raised with LIMS suppliers.

Wrong ABO or D type blood components issued for SCT/BMT recipients *n* = 13

All cases were routine transfusions: 1 case was in a 13-year-old patient and all the rest were in adults. Eleven of the cases occurred during normal working hours and 2 were outside normal working hours.

In previous years only errors in selection of ABO and RhD type have been seen for this group of patients. However, this year other errors have occurred necessitating a new subcategory, 'procedural errors'. Five procedural errors occurred this year: 2 cases in which BMSs failed to perform antibody screening prior to transfusion and 3 cases where information regarding the transplant had not been entered clearly or completely into the LIMS. The latter 3 errors resulted in 1 case in which a patient who had an ABO mismatched BMT had blood issued using electronic issue rather than a serological crossmatch, 1 case where red cells of the incorrect RhD group were selected and 1 case where blood of the wrong ABO group was selected.

In total, 7 out of the 13 cases resulted in the issue of components (5 red cells and 2 platelets) of the wrong ABO group. Six of these cases were a result of the BMS's failure to notice or heed warning flags or to read notes belonging to the patient.

In the final 2 cases RhD positive components were selected when the transplant protocol demanded selection of RhD negative components. Both patients were male and anti-D had not formed in either case at the time of reporting.

Learning points

The following learning points from previous reports remain pertinent:

- Simple yet robust procedures must be in place for recording transplant details. Use of a 'shared care' document is helpful but the information from this document must be clearly recorded in the LIMS.
- Selection of blood and blood components post transplant, including thorough consultation of the patient's history/warning flags/notepad entries, must be included in competency-assessments.
- New BCSH guidelines on compatibility procedures in blood transfusion laboratories are in progress. These guidelines will simplify blood group requirements post PBSCT/BMT in line with EMBT (European Group for Blood and Marrow Transplantation) guidelines.[21]

Other pre-transfusion errors *n* = 48

The number of cases in this category is the same as last year. Two of the cases involved babies under 4 months old. In 1 case the age was not stated and the remainder occurred in adults. Table 21 illustrates the time and circumstances under which these pre-transfusion errors took place.

Table 21
Summary representing when incidents occurred

	Out of hours	In core hours	Unknown
Emergency	10	5	0
Routine	12	16	1
Unknown	1	2	1

The staff involved out of hours included 10 BMSs who normally work in transfusion, 9 who do not routinely work in transfusion and 4 cases where the status of the BMS was not known.

The 48 errors have been divided into:

- Testing errors, i.e. the correct tests were performed but incorrect results obtained owing to poor performance of the test, transcription error, or incorrect interpretation.
- Procedural errors, e.g. incorrect test selection, failure to follow procedure.

Testing errors *n* = 9

Two transcription errors resulted in patients receiving antigen positive blood. In one case 2 days after a transfusion, bilirubin results were mildly elevated and the DAT weakly positive. The patient died but this was not related to the transfusion.

Case 3

Confusion during an emergency situation

A sample for a patient in critical care was placed on the transfusion analyser for processing. Two units of uncrossmatched blood were issued as soon as the blood group was known. A manual group and antibody screen was requested but not performed, and then the positive antibody screen results produced by the analyser were 'missed' and recorded as negative. A positive antibody screen was discovered 2 days later, and an anti-E identified. On look back it was ascertained that of 16 units transfused, 1 of the uncrossmatched units and 3 of the other units had been E positive.

Three interpretation errors occurred: in 1 case antibody identification was misinterpreted as anti-Kp^a. The procedure for a 2-person check on all samples where antibodies were detected failed. In a second case the presence of anti-Kp^a was overlooked in a patient with autoantibodies. In the final case a laboratory interpreted the antibody as 'non-specific' but when sent to NHSBT was found to be anti-Jk^a.

One case involved an error during a 6-unit crossmatch where the BMS typed the units for Lu^a at the same time as crossmatching, found 1 unit Lu^a positive, but issued that unit in error.

One case involved a patient with known cold agglutinins. Laboratory staff were aware of this and should have put a note on the paperwork to indicate that a blood warmer was required. They failed to do this. Nursing staff were not aware of the cold agglutinins so the patient was transfused with cold blood and had a minor reaction.

It is debatable whether to call the final 2 cases errors as both involved very weak antibodies (an anti-Fy^a and an anti-Jk^b) at the limit of detection, that gave negative results when tested manually but reacted weakly when tested the next day using automation. Neither patient suffered any adverse reaction.

Procedural errors *n* = 39

There were many different types of procedural errors:

Testing unsuitable samples n = 12

There were 12 cases where the sample was too old. Some errors were due to the BMS failing to check previous transfusion history whereas others were felt to be failures to follow protocol, knowing the transfusion history.

Failure to find historic records n = 10

Two of these cases involved neonates: in one case the mother had two records as her details had not been successfully merged. One record showed anti-D and the other no antibodies. Blood was issued by electronic issue due to the second record being accessed. In the other case a neonate grouped as A D negative and was issued with 2 group A D negative paediatric packs without consulting the maternal record which would have indicated transfusion of group O D negative units.

Of the remaining cases, historic records were not found by the laboratory owing to the following factors:

- an ED number used rather than a hospital number
- a surname change since the last record
- 6 cases where 2 separate databases were held in the laboratory – either current and legacy systems or 2 current systems (1 of these cases is also referred to in the testing section).

Case 4

The importance of accessing all available information when interpreting results

A BMS on duty was unable to identify an antibody specificity and issued crossmatch compatible blood. A senior BMS reviewed the antibody identification results prior to authorisation of the antibody report. The BMS thought that the results were indicative of anti-Fy^a and performed additional testing with Fy^a homozygous cells. Results indicated likelihood of anti-Fy^a. The BMS then looked back at historical data for the patient on a separate database. The patient had a previously detected anti-Fy^a but this data was not available on the current computer system.

Blood issued with incomplete pre-transfusion testing or without following the correct procedure n = 14

- One case in which the BMS failed to read the crossmatch before the results were entered on the IT system. The gel card was found in the centrifuge.
- One case where blood was issued, without investigation, despite the presence of a pan-reacting autoantibody.
- Two cases of failure to look up antibody screen results, therefore missing a positive antibody screen, and issuing blood by electronic issue.
- Blood crossmatched and issued without the antibody screen results being recorded.
- Blood issued despite an incomplete antibody screen and crossmatch.

- Failure to follow protocol resulted in the issue of incompatible blood, resulting in a mild reaction: rigors and pyrexia. This error could have been prevented if the clinician had passed on to the laboratory the vital antibody information given by the patient.
- One case involved an interruption during crossmatching, which contributed to blood being electronically issued rather than issued following an immediate spin technique.
- Two cases involved NHSBT. In 1 case the BMS assumed NHSBT had completed all pre-transfusion testing, and issued the units, when they had not. In a second case NHSBT sent phenotyped units rather than crossmatched units and the BMS assumed they had been crossmatched and issued them.
- One case where an MLA failed to obtain full patient identification when taking a telephone request.
- One case in which a unit of FFP was incorrectly put into the laboratory database as group O D negative when it was group O D positive. It was then transfused to a group O D positive patient. Although the sequelae in this case was of no clinical significance the use of 'copy' facilities on LIMS when inputting critical component information must be disabled.
- One case in which a BMS edited the results to negative, twice; when warning messages of 'wrong liquid level', which invalidates the test, were clearly displayed on an automated analyser.
- One case where a DTR was caused by a missed anti-Jk^b; laboratory protocol did not follow BCSH guidelines on pre-transfusion testing.[22] (See Case 5, below.)

Case 5

Different procedures might have prevented reaction

A pre-transfusion sample from a patient with known anti-K gave weak reactions with the K negative screening cells by an automated technique. The screen was repeated on the second analyser, which gave negative results, and testing against a panel of red cells was not undertaken. Four days later the patient showed signs of a severe DHTR including deteriorating renal function, and anti-Jk^b was detected in the post-transfusion sample. Retrospective testing on the pre-transfusion sample did not reveal anti-Jk^b; however, no different or additional techniques were used, and the sample was not referred for confirmation. The laboratory has since changed its policy, and a full antibody identification panel is undertaken on patients with known antibodies.

Errors during crossmatching n = 3

- 1 case where an incompatible unit was issued to a patient.
- 2 cases in which units were issued that expired before the day they were required.

There were a number of cases of inappropriate electronic issue this year: 1 due to the patient's historic record not being found, and 1 due to 'interruption' during crossmatch. There may have been others due to errors earlier in the pre-transfusion testing process, e.g. sample age, but these have been reported under the appropriate sections and whether they then led to inappropriate EI is unclear.

Case 6

Overriding warning signals

A request was received for 6 units of blood for a patient with anti-D+C. Antigen negative blood was selected and an IAT crossmatch set up. On reading the crossmatch 1 unit was weakly incompatible (+) by IAT. This result was correctly entered into the LIMS but the unit was not physically quarantined from the compatible units. The units were then issued to the patient: a warning message was displayed for the incompatible unit but this was overridden and the emergency issue option used. The unit was transfused before the error was identified.

COMMENTARY on pre-transfusion testing

Numbers of procedural errors remain constant with 40 in 2008 and 38 this year. Although not as marked as in the 'wrong blood incident' section, it appears that there are a disproportionately high number of errors occurring out of hours, even after taking workload into consideration. Local investigation into these errors must be carried out and a full RCA performed to ascertain why they occurred. SHOT endorses the recommendations of the UK Transfusion Laboratory Collaborative with regard to staffing levels, technology, training and competencies both in and outside core working hours.[10,11]

IT must be used to its full potential. It is difficult to understand why the following are not set up on LIMS:

- Preventing the issue of units that expire before the 'time required'.
- Reflex requesting of an antibody identification based on a positive result in the antibody screen so that there is clear, outstanding work still to perform before a crossmatch.

These points are also highlighted in the IT chapter.

Learning point

- Use of automation and IT can increase the security of testing but only if the messages/flags given are heeded and acted on appropriately. It is disappointing to report a number of examples this year that involve qualified staff overriding information, leading to the transfusion of what could be unsuitable units of blood. It is important that staff understand all warning messages and the necessary, appropriate actions to take following warnings.

The following learning points from previous reports remain pertinent:

- 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. New BCSH Guidelines on compatibility procedures in blood transfusion laboratories are in progress. These guidelines will simplify sample age requirements.
- Competency-assessment must comprehensively cover the areas of phenotype selection, antibody history and appropriate use of EI.
- Competency-assessment must comprehensively cover all warning messages from analysers and the LIMS and staff must be able to demonstrate appropriate actions.
- Transfusion laboratories must have thorough search strategies when looking for patient histories in order to find and reconcile multiple entries for a patient.[23]

Laboratory-based cases of SRNM *n = 67*

The 67 SRNM errors have been divided into SRNM based on the following:

- poor serological knowledge/failure to recognise the special needs of a specific patient group
- failure to consult patient records thoroughly.

This section mirrors that of previous years in which the majority of errors were associated with either failing to notice/heed warning flags or absence of warning flags, either because they have not been added or because they have been incorrectly deleted.

SRNM due to poor serological knowledge/failure to recognise the need for special requirements *n* = 27

Failure due to poor serological knowledge/carelessness in selection n = 11

- An incorrect order for blood was made for a neonate. Anti-D+Fy^{a}+Jk^{b} antibodies were identified in the mother, who initially refused to have a sample taken, so blood was crossmatched against the baby's sample in which only anti-D was detectable. The first BMS failed to order Jk^{b} negative units and the second BMS did not pick up on the error when crossmatching the blood.

- One case which resulted in failure to provide antigen negative units for a patient with anti-Jk^a plus anti-C^w.
- Failure to select a CDE negative unit for the 'flying squad' blood: 1 unit was C positive and was transfused to a patient with anti-C+D.
- A second case where the emergency group O D negative 'flying squad' blood that should have been CDE negative was found to be C positive, after an anti-C was found in a patient who had received the 'flying squad' blood.
- Four cases in which blood that was crossmatch compatible, but not Jk^a typed, was transfused to patients with known anti-Jk^a.
- Failure to issue appropriately phenotyped units to a patient with thalassaemia due to misinterpretation of nomenclature: i.e. the BMS had written 'R1R1 required', which was correct for the patient, followed by, 'i.e. e neg, K neg', which was wrong: the patient received R2R2 K neg blood instead of R1R1 K neg.
- e negative units were not selected for a patient with anti-C+e. The crossmatch was then performed incorrectly (Case 7).
- Failure to provide blood of the correct age, following a request to ensure that all units were < 7 days old. NHSBT only sent 4 units that met this requirement; the other 4 were older units and the laboratory did not notice the error.

Case 7

BMS staff must understand the clinical significance of warning flags on analysers

The patient was known to have an IAT reacting anti-C and enzyme only anti-e. As there was no R2R2 blood in stock the BMS selecting the blood decided that, as the anti-e was only reacting with enzyme treated cells, e positive blood could be selected. On the automated crossmatch 'too few cells' were indicated on the analyser. The BMS edited these results to compatible as she thought that this warning had occurred because the patient was anaemic. It was pointed out that the cells were from the donors, not the patient.

Failure to recognise the needs of specific patient groups n = 16

- Giving a female of childbearing age, who was phenotyped as c negative, c positive blood, against local protocol
- Five cases in which K positive units were issued to female patients under the age of 60
- Three cases of failure to provide apheresis platelets to children under 16 years of age
- Seven cases of failure to supply MB-FFP to children under 16 years of age.

SRNM due to failure to consult the patient records thoroughly *n* = 40

Table 22
SRNM due to failure to consult patient records thoroughly *n* = 40

Failure to	No. of cases
Failure to provide irradiated components	22
Failure to provide CMV negative components	10
Failure to provide CMV negative and irradiated components	4
Failure to provide HLA matched platelets	4

The next two cases have been selected to highlight that SHOT reportable incidents often occur because of a number of errors in the transfusion process.

Case 8

When the laboratory knows of a special requirement it should not have to be reiterated on request

A request was made for platelets. The BMS noted the requirement for HLA matched platelets and ordered them to arrive to cover overnight and for use the next day. The on-call BMS booked in and issued the HLA matched platelets. The platelets were not used overnight and the pack was returned to stock the following morning. A different BMS on specimen reception received a request for a unit of platelets for the patient. The need for HLA matched platelets was not mentioned. The BMS failed to notice the comment regarding the need for HLA matched platelets, entered on the laboratory system and on the laboratory whiteboard, and a pool of non-HLA matched platelets was issued and transfused. On discovering the error the ward was contacted and reminded that the patient needed HLA matched platelets and that this needed to be stated on the request. The HLA matched platelet was then reissued to the patient and transfused.

Case 9

Checking the need for a special requirement is the responsibility of all staff groups

A patient had received fludarabine and required irradiated components. While being transfused irradiated components, the patient stated that the blood he had received on a previous occasion had not been irradiated. An investigation ensued.

In the clinical area:

- *the patient's notes did not have an 'irradiated blood' alert sticker on them*
- *the prescription did not state irradiated blood – the relevant field on the prescription was blank.*

In the laboratory:

- *the patient's notes on LIMS contained a large amount of information including that irradiated blood components were required.*

Clearly a number of problems led to this error: omissions at ward level and an error on the part of the BMS. Was this simply a lapse by the BMS or could the notes on the LIMS have been clearer?

COMMENTARY on SRNM laboratory cases

This year has seen an increase in the number of paediatric cases: 7 cases where MB-treated FFP should have been issued to patients under 16 years of age and 3 cases where apheresis platelets should have been issued to the same patient group.[24] Two cases resulted from patients having more than 1 record in which data was not successfully merged or reconciled and as a result warning flags were deleted/missed during the transfer process.

Failure to provide irradiated components when required was the biggest group (22/67 cases). Some hospitals are relying on a ticked box on a request form to highlight the need for irradiation. This can be missed in the laboratory. As recommended in 2008, a more robust mechanism should be in place for informing the laboratory that irradiated components are required. The laboratory must then ensure that these requirements are consistently met without the need for further prompts.

Once again the failure of laboratory staff to select appropriate components when warnings flags are present is hard to understand, especially as the majority of the cases reported were during normal working hours. There does seem to be a particular problem when there are multiple special requirements. IT should be used to its full potential to prompt staff about special requirements either through algorithms based on date of birth and/or gender, or via warning flags. Warnings need to be clear and unambiguous and must be linked to the patient record, not one sample. Staff must then be competency-assessed to ensure that they fully understand all prompts/warnings/flags.

Case 8 above shows, again, that multiple errors, both clinical and laboratory, often contribute to cases of mistransfusion.

Learning points

- Simple yet robust procedures must be in place for recording special requirements. Use of a 'shared care' document is helpful but the information from this document must be clearly recorded in the LIMS.
- Once informed of the need for a special requirement the laboratory must ensure that the requirement is consistently met without the need for further prompts.
- Mistransfusion is often a result of multiple errors. It is important to investigate these incidents thoroughly by performing a full RCA so that all appropriate CAPA can be instigated.

The following learning points from previous reports remain pertinent:

- Assessment of staff working in the transfusion department must cover competency in the provision of blood components for specific groups of patients, and understanding the importance and use of 'special requirements' flags.
- Laboratories must give thought to the nomenclature used to describe phenotype requirements. It may be prudent to simply state the antigens that the red cells should lack, rather than use Weiner terminology, for example, which requires interpretation.

Errors involving NHSBT

These are discussed in the text but grouped here for clarity. There were 2 cases where the primary error was made by NHSBT and then not noticed by the hospital laboratory:

- platelets of the wrong ABO group were sent
- blood that was older than requested was sent.

There were 2 further errors where it is unclear whether there were mistakes or simply miscommunication between the hospital laboratories and NHSBT:

- In 1 case the BMS assumed NHSBT had completed all pre-transfusion testing, and issued the units, when they had not. In a second case NHSBT sent phenotyped units rather than crossmatched units. The BMS assumed they had been crossmatched and issued them.

RECOMMENDATIONS

RECOMMENDATIONS for clinical IBCT cases

- A transfusion checklist should be developed, ideally with an accompanying transfusion record section, in a similar style to the WHO surgical checklist (http://whqlibdoc.who.int/publications/2009/9789241598590_eng_checklist.pdf). This approach is a proven aid to patient safety and could prevent omission of critical steps in the process.

  Action: NBTC and counterparts in Scotland, Wales and Northern Ireland

- All point of care testing devices for Hb estimation must be fully validated and internal quality control and participation in external quality assurance schemes must be ensured. (See also recommendation on page 74.) Currently this is not the case for calculated Hb estimates from blood gas analysers. A study to evaluate the utility of these devices for Hb measurement should be undertaken and guidance and recommendations issued.

  Action: NBTCs, NEQAS, SHOT

- All staff must take full professional responsibility for their part in the transfusion process. Personnel involved at the point of component administration must understand that this is the final opportunity to check for errors earlier in the chain, and the sole remaining opportunity to be certain of the recipient's identity.

  Action: CEOs of Trusts/hospitals, HTCs and HTTs

- The existence, and the importance, of special transfusion requirements must be taught to junior doctors in all hospital specialities. Local mechanisms for ordering and prescribing components need to facilitate correct ordering, and remind clinical and laboratory personnel where possible.

  Action: CEOs of Trusts/hospitals, HTCs

- Hospitals must ensure that they have protocols and documentation systems for:
  - transportation of blood components accompanying patients transferring to other sites
  - administration to patients who may be permitted to receive blood components at home
  - ongoing information transfer between hospitals when patients have shared care at 2 or more sites.

  Action: HTCs, HTTs

RECOMMENDATIONS for laboratory IBCT cases

- Many hopes of error reduction have been pinned on extending automation and IT. An emerging theme from this year's report is that frequently it is still up to well trained staff, with underpinning knowledge, to interpret and heed warnings and flags and, unless appropriate actions are taken, errors will continue to occur.

  Action: Lead BMS for hospital transfusion laboratories, transfusion laboratory managers

- There is a requirement for manufacturers to provide affordable, secure automation for smaller laboratories that bridges the gap between manual methods and large 'walk away' analysers.

  Action: Manufacturers of blood grouping equipment, IT working group of the NBTC

- The number of errors in the SRNM category has remained high for a number of years. Laboratories must make a concerted effort to tackle this problem. This should be done at a local level as there will be different root causes in different Trusts.

  Action: HTTs

- Blood services 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.

  Action: UK Blood services

- 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 then these development requirements must be raised with LIMS suppliers.

  Action: HTTs, manufacturers of blood grouping equipment, IT working group of the NBTC

IBCT RECOMMENDATIONS FROM PREVIOUS YEARS (ALL SECTIONS)

Year first made	Recommendation	Target	Progress
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.	**Clinical risk managers, HTTs**	MHRA annual compliance reports ask whether competency-assessment is carried out. MHRA and CPA (UK) Ltd inspectors will look for evidence of competency-assessment.
2008	All staff must be trained (and competency-assessed) in recognising the different blood components and their labels.	**Clinical risk managers, HTTs**	NPSA has issued new guidance and deadlines for completion.
2008	Laboratory procedures should be validated in line with the BSQR and should be revisited following an error as part of Corrective and Preventative Actions.	**Transfusion laboratory managers**	
2008	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.	**Transfusion laboratory managers**	
2008	The UK Transfusion Laboratory Collaborative has recommended minimum standards for hospital transfusion laboratories in terms of staffing, technology, training and competence. This document has been widely disseminated and should form the basis for future laboratory planning.	**CEOs, Pathology managers**	Report published in *Transfusion Medicine* and *The Biomedical Scientist*, September 2009.[10,11] Report circulated to all CEOs in England, Wales and Northern Ireland. SCTAC considering.
2008	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.	**NBTC, RTCs**	
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**	

7.1 Errors Relating to IT Systems (IBCT IT)

In 2009, there were 61 reported incidents of IBCT errors relating to IT systems, compared with 44 in 2008 and 25 in 2007 (see Table 23). Forty-six incidents originated in the transfusion laboratory. Forty-seven cases involved red cells, 10 platelets and 2 plasma components. Six of the 61 cases occurred in children (1–8 years) and 3 in infants.

Table 23
IT Systems Errors
NB some reports involved more than 1 category of error

Error	Reports	Non-irradiated component transfused	Antigen positive unit transfused	Non-CMV neg unit transfused	Wrong group after SCT	Electronic issue error	Other
Failure to consult historical record	4	1	3				
Historical record not identified	1		1				
Ignored/missed warning flag	20	6	3		9		1 (red cells crossmatched on outdated sample) 1 (failure to issue platelets in PAS)
Failure to update warning flags	5	1	1		2		1 (failure to update product code led to issue of adult FFP for child)
Computer system 'down'	1						1 (manual component selection error – cryo instead of FFP)
Data not transferred from old system	3		3				
Electronic blood tracking system errors/misuse	9			1			7 (out of expiry date/ time components issued – see text) 1 IBCT
Failure to merge or reconcile records	5		4	1		2	1 (unable to issue red cell unit c/o discrepant ID numbers)
Error/deficiency in computer system or misuse	13	1	4	1		3	8 (miscellaneous – see text)
TOTAL	**61**	**9**	**19**	**3**	**11**	**5**	**21**

Cases

Case 1

Data not transferred from old system therefore 'antigen positive' unit transfused

A patient had a history of anti-C and anti-E on a previous computer system. This information was not checked prior to issuing blood on the new system. As a result the patient was transfused blood which was not negative for the C and E antigens.

Case 2

Not checking historical record leads to transfusion of 'antigen positive' red cell unit by EI

A sample was received from the ED from a patient with a GI bleed. The 'ED number' was used as a unique identifier on the sample. An on-call BMS, who works routinely in the transfusion laboratory, did not consult the historical record, which showed the presence of anti-E in the patient. Antibody screen was negative on this occasion and 2 units of red cells were issued electronically without selection for absence of E-antigen or serological crossmatch. There were no clinical sequelae.

Case 3

Not responding to warning flag leads to transfusion of inappropriate group after stem-cell transplant

An RhD positive patient received a bone marrow transplant from an RhD negative donor ('minor' RhD mismatch transplant). The protocol specifies the transfusion of RhD negative blood components post-transplant and a note to this effect was placed on LIMS. A BMS, working routinely in the transfusion lab during normal working hours, missed or ignored the warning flag and issued 2 units of RhD positive red cells.

Case 4

Manual editing of abnormal results leads to issue of potentially incompatible red cell units

A non-urgent request for 2 units of red cells was made for a patient with melaena. The BMS, on an overnight shift but working regularly in the transfusion laboratory, performed the group and screen on the autoanalyser. A 'wrong liquid level' (WLL) flag in one column of the antibody screen indicated a possibly invalid result that should be repeated. The result was manually edited to 'negative' and a crossmatch set up on the same autoanalyser. All crossmatch results were flagged as 'WLL'. These were, again, manually edited to 'negative' and 2 units issued and transfused. When the error in procedure was identified the following day, repeat testing confirmed the negative antibody screen and compatibility of the issued red cell units.

Case 5

Inappropriate access to electronically locked CTS leads to giving adult red cell unit to a neonate

A baby delivered by emergency Caesarean section had an Hb of 6.2 g/dL and required urgent transfusion. A staff grade doctor, who had not been trained or competency-assessed in using the electronic fridge control system, 'borrowed' the access card from a midwife and selected an emergency group O D negative red cell unit intended for adult patients (not CMV screened). This was noticed by the nurses performing the bedside administration check but their concerns were overridden.

Case 6

Expired unit removed from blood tracked fridge and not detected at bedside check

A unit of red cells was collected from a blood fridge with electronic tracking. The device produced an audible and visual alert that the unit had passed its expiry date. The porter ignored the alert and took the unit to the ward. Nursing staff failed to note that the unit was expired when the porter delivered it and again when performing the pre-transfusion check.

Case 7

Delayed communication between laboratories in the same hospital group, compounded by clinical error

A patient was attending haematology clinics at 2 hospitals in the same NHS Trust. His requirement for irradiated blood components was flagged on the LIMS system at hospital A, but not passed on to the transfusion laboratory at hospital B in a timely fashion, in breach of local protocol. The patient subsequently received 2 units of non-irradiated red cells at hospital B. The error was subsequently identified when transfusion laboratory A communicated the special requirement

to laboratory B. The clinical request and transfusion prescription at hospital B did not specify the requirement for irradiated components.

Case 8

Use of NHS number leads to failure to identify need for CMV negative components

The warning flag on the LIMS was only present in a patient record identified by the hospital ID number. On this occasion, the transfusion sample was labelled with the NHS number and the historical record was not identified. This incident was compounded by clinical failure to indicate special transfusion requirements on the request form or prescription sheet.

Case 9

Bedside computer access leads to misidentification and ABO-incompatible transfusion

An agency nurse was looking after patients 1 (group O D positive) and 2 (group AB D positive) in ITU. For convenience she accessed the details of patient 2 on the computer at patient 1's bedside and left the screen open at this page. When patient 1 needed transfusion, she asked another member of staff to print a blood collection form for her. The blood collection form was printed according to the current screen and red cells were collected for patient 2. When the red cells arrived the agency nurse went to patient 1's bed and was not able to locate a name band on the wrist (the patient was wearing a legible name band on the ankle) so she checked the red cells against the computer, which was opened at the bedside (still patient 2's information) and set up the transfusion. Patient 1 developed respiratory difficulties, and was cold, clammy, sweaty and distressed. The transfusion was stopped and symptoms resolved after 30 minutes. It was then that the agency nurse noticed that the red cells taken down from patient 1 were crossmatched and labelled for patient 2.

COMMENTARY

As in previous SHOT reporting years, common causes of IBCT are: failure to update warning flags on the LIMS or transfer patient data from legacy computer systems, failure to notice (or heed) warning flags, and failure to consult the historical record. Component selection and manual transcription errors remain a risk when the LIMS is off-line. Failure to merge or reconcile LIMS records in patients with multiple hospital ID numbers and case records led to transfusion errors in 5 patients. There were several cases where laboratory scientists deliberately overrode warning flags or results from automated analysers in non-emergency situations, seemingly without understanding the significance of their action and the potential for harm. This is especially dangerous where electronic issue of red cells is performed. It is essential that all staff are fully trained and competency-assessed *before* using laboratory IT systems and automated analysers.

There were 9 cases where IT errors contributed to failure to transfuse irradiated blood and 3 cases involving transfusion of a CMV unscreened blood component. The 2 most common adverse outcomes reported were transfusion of antigen positive (or unscreened) red cells in patients with known alloantibodies (19 cases) and administration of components of the wrong group after SCT (11 cases, compared with 2 in 2008). Selection of the correct blood group for component transfusion after SCT can be complex and the reports reveal deficiencies in the knowledge of both BMSs and clinicians, often compounded by poor communication. It is good practice to produce, in advance, a clear post-transplant transfusion plan for each patient, place appropriate notes on the LIMS and the case record, and ensure that transfusion request forms indicate that the patient has undergone SCT. This report repeats the recommendation to exhibit all clinically essential warning flags on the opening screen.

Forty-six of the IT-error cases reported to SHOT this year originated in the laboratory (75%). Twelve (20%) of IT-related IBCT occurred outside 'core' laboratory working hours. Eight (13%) occurred in emergency situations but 40 (66%) involved staff working regularly in the laboratory. This distribution is almost identical to 2008. For comparison, a large survey of transfusion practice in two UK regions also showed that 25% of transfusion requests are processed 'out of hours'.[25] The survey showed that 20% of requests in normal working hours and 37% of out-of-hours requests were 'urgent' (required within 1 hour). Although most errors are made by regular transfusion laboratory staff during 'normal working hours', 5 of the 12 incidents (42%) occurring outside core laboratory hours involved scientists who do not work routinely in the transfusion laboratory (a locum in one instance) and most of these cases involved failure to notice or heed warning flags.

As electronic 'blood tracking' systems enter more general use, SHOT is receiving reports of their misuse leading to IBCT. The case of a clinician, not trained or competency-assessed in the process, who accessed the electronically controlled blood fridge and transfused an inappropriate blood component is included to highlight how the 'human element' can compromise transfusion IT systems. There were 7 other cases where clinical staff or porters ignored warning notices when removing red cells from a blood fridge with electronic tracking. In 3 cases, red cells were transfused after their expiry date (not identified on the bedside check). The recent BCSH Guideline on Administration of Blood and Blood Components[19] emphasises the importance of reporting errors relating to blood tracking and bedside IT systems to haemovigilance schemes.

Problems with temperature monitoring systems leading to IBCT

Eleven cases (not included in Table 23) were reported in which problems with electronic temperature monitoring systems, or failure to respond correctly to alarms, led to the transfusion of blood components that had been stored out of controlled temperature range. Ten cases involved red cells stored in blood refrigerators and 1 case involved platelets. Although these cases do not fit into our usual definition of 'IT errors leading to IBCT' they exhibit common features worthy of comment.

In 5 cases the door of a blood fridge had been left ajar but had not been open far enough to trigger a door alarm (where fitted). In most of these the fridge was fitted with an air temperature alarm designed to trigger at 8°C, which was not exceeded, but no core temperature alarm was fitted. Subsequent temperature chart analysis showed that the core temperature had exceeded 6°C. Discovery of the rise in core temperature was delayed by failure to follow local SOPs in some cases. In 2 cases an alarm was activated but only rang in the local area where staff did not take appropriate action or alert the transfusion laboratory. This led to the wastage of large quantities of blood and the transfusion of 9 units of red cells that had been out of temperature control for short periods of time (none resulted in a clinical adverse reaction). In a report involving platelets, air-conditioning in the transfusion laboratory failed on a hot night and corrective action was delayed. A pack of platelets on the laboratory agitator overnight was erroneously issued, contrary to local SOP. The laboratory has since purchased a platelet agitator with a temperature-controlled incubator.

In response to clarification by MHRA, blood fridges are now being fitted with core temperature monitors designed to alarm immediately at 2°C and 6°C. Wherever possible, fridge alarms should be designed to alarm in a permanently manned location, preferably the transfusion laboratory. All relevant staff must be aware of the significance of fridge alarms and take immediate action according to local protocols. Alarms should be tested regularly. As well as a check on audibility and visibility, appropriate response to the alarm should be tested. Components that have been exposed to temperatures outside the designated range should be removed from accessible storage locations immediately to prevent inappropriate transfusion. 'Mock recalls' of units should take place regularly to ensure a functional process is in place.

Improving Laboratory Standards (based on data from 2009 and previous reporting years)

- SHOT endorses the recommendations of the UK Transfusion Laboratory Collaborative with regard to hospital transfusion laboratory staffing, technology, training and competencies.[10,11] Incidents analysed in this and previous SHOT reports add weight to the Collaborative's recommendations for training programmes and annual competency-assessment for all staff who work at any time in the transfusion laboratory. There is emphasis on maintaining competency, including familiarity with local protocols and systems, of staff working intermittently in transfusion. SHOT fully supports the routine use of 'walk away' automation, used 24/7, to eliminate manual errors and the use of 'electronic issue' of red cells, where the LIMS fully meets national guideline standards. 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 will need to be made available for 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 routine laboratory process that can be 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 NPSA Safer Practice Notice 24.[18]

- 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.

- 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 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. Alert systems should not prevent the issue of clinically appropriate components of a different group to the patient (such as after stem-cell transplantation).

- Transfusion laboratories should have access to the hospital Patient Administration System (PAS) and the ability to review haematology results on-line (ideally on the same screen).

- 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.[23] 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 must understand the working of these systems and be trained and competency-assessed to react appropriately to alarms and warnings and 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 for this year's report

- Failure of laboratory staff to identify or heed the historical record on LIMS remains an important cause of IBCT. There are a worrying number of cases reported to SHOT where laboratory staff are able to override a warning flag or a result on an automated analyser without clearly understanding the significance of their action or the potential for harm – a particular problem when blood is released by electronic issue. Lead BMSs for the transfusion laboratory, with appropriate support from senior management in the organisation, must ensure that all users of laboratory information management systems are trained and competency-assessed before using laboratory IT systems or automated analysers.

  Action: Lead BMS for hospital transfusion laboratories, transfusion laboratory managers

- Selection of blood components of appropriate blood group after allogeneic stem-cell transplantation can be complex. The recommendation is that transplant teams, in collaboration with the transfusion laboratory and/or transfusion centre, produce a post-transplant transfusion plan for each patient, ensure appropriate notes on the LIMS and the case record, and ensure that transfusion request forms indicate that the patient has had a transplant.

  Action: Transplant teams, hospital transfusion laboratories, HTTs

Recommendations from previous years

Year first made	Recommendation	Target	Progress
2008	Standardisation of IT systems is required across the UK. 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.	**NBTC and equivalents in devolved administrations**	The recommendation is now re-targeted to the newly formed IT subgroup of the NBTC.
2008	Chief Executive Officers of hospitals and Trusts must use the National 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.	**Trust CEOs, HTTs**	NTLC Report circulated to all CEOs in England, Wales and Northern Ireland in 2009, and under consideration by SCTAC. Report published in *Transfusion Medicine*, September 2009.
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.

7.2 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 an error or errors that should have led to the unit being rejected. These errors do not fit the definition of IBCT but are instructive nevertheless. They are not included in the overall numbers of IBCT cases. There are 143 cases in this 2009 report, representing a 32% increase in the number of reports in the RBRP category from 2008. On review 3 were transferred out to the IBCT section and 1 to the I&U section. This section describes the findings from 143 completed questionnaires.

Table 24
Right blood to right patient episodes *n* = 143

Elements that were wrong on blood packs, documentation, identity bands, etc.	**2008 Incidents**	**2009 Incidents**
Name alone or with other elements	24	43
Date of birth alone or with other elements	32	33
Transposed labels on 2 or more units for the same patient	20	31
Hospital or NHS Number	10	17
Donation/Pack Number	8	3
Miscellaneous		
Failure to use address as defined in hospital policy	1	2
Wristband missing or wrong wristband in place at final patient checking procedure	0	4
Incomplete or no Identification Tag issued with component	3	4
Incomplete issue procedures undertaken	0	3
Incomplete Request Form	0	2
Incorrect 'T' Number	0	1
Wrong expiry date on label (IT error)	1	0
Incorrect assigned unit supplied, e.g. paedipak	2	0
Total	**101**	**143**

As highlighted in previous years, had the correct checking procedures been undertaken during the patient's admission procedure, both in the laboratory and during the final patient identity check, all these errors could have been prevented. Staff have a personal and professional responsibility to ensure they adhere to the correct patient identification procedures at all times.

This report highlights a number of cases from the clinical and laboratory areas that demonstrate how errors went undetected despite staff having a number of opportunities to identify them and take corrective actions.

Case 1

Incorrect DOB on documentation not detected during competency-assessment

A doctor took a transfusion sample from a patient without a wristband and did not positively identify the patient, asking only the name. A labelled sample and a request form had the incorrect DOB, copied from admission documentation. The DOB error was not noted during pre-transfusion checks and the first unit was transfused. The nurses performing the bedside check were being assessed for competency during this procedure; they were passed as competent. The incorrect DOB was noted during checks of the second unit.

This case highlights the risk of failing to undertake a formal patient ID check prior to taking the blood sample, and how even when staff are being observed errors can still occur.

Case 2

Incorrect hospital number – detected but ignored

An FY1 doctor entered another patient's hospital number on a blood sample for a patient requiring a blood transfusion. As a result 4 units of blood were issued to this patient. When the nurses questioned the different number on the patient's wristband with the FY1, she requested them to ignore this because the patient urgently needed the blood. The patient's Hb was 6.2 g/dL. The nurses proceeded to give all 4 units of blood based on another patient's hospital number.

This case highlights the importance of checking patient details when completing the request form and sample tube and the importance of taking corrective action when risks or errors are identified.

Case 3

Transposition of barcoded labels on units for the same patient

Because the transfusion laboratory printer failed, a BMS handwrote issue reports and traceability labels, by mistake transposing the ISBT numbers on the peel-off sections of 2 units and writing 1 incorrect digit in the hospital number. The transposition of the barcode and the incorrect hospital number were noticed by ward staff before transfusion. The label was returned to the laboratory to be amended. The BMS had been under pressure to issue the blood: the porter was waiting, and had informed the BMS that the patient had collapsed.

This case emphasises the need for staff to be extra vigilant when errors occur in IT/electronic systems, even in emergency situations.

Case 4

Longstanding use of variations in patient's first name

The transfusion laboratory was contacted because the paperwork for the blood transfusion of a patient had an incorrect forename. The error was noticed on the ward while checking the second unit of blood. The sample and request form were correct, but the duty BMS did not notice the discrepancy with laboratory records. The sample was processed and blood issued (electronic issue): again the discrepant name was not picked up on issuing or labelling the blood. On investigation, there were multiple pathology requests for this patient with this discrepancy. On 1 request, the incorrect name had been used on the request form, so the name was changed. On other subsequent requests, the correct name was on the request, but the computer system was not updated. On one of these, a comment was put on that the forename on the sample was inaccurate.

This case stresses the importance of checking the patient details when inputting patient data on electronic systems and taking remedial action when a discrepancy is identified.

COMMENTARY

Each year SHOT emphasises the importance of checking the patient's identification details at every step of the patient episode. Errors at admission; incorrect spelling of the patient's first name or surname, or an incorrect date of birth, can remain in the patient's records for the duration of that episode or in some case for years. Often no remedial action is taken even when a discrepancy is identified by staff, the patient or their carers.

It is crucial that all staff involved in the transfusion process are trained and competent in patient identification procedures and that a culture of identifying errors and taking remedial action is encouraged. Adopting a proactive approach to learning from our mistakes can prevent common problems from recurring.

Learning points

- It is imperative that staff are vigilant at all times when participating in the patient identification process, especially 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.
- Staff should be extra vigilant in emergency or high risk situations, e.g. when IT systems are down.

8. Inappropriate and Unnecessary Transfusion (I&U)

Definition

- Inappropriate and unnecessary transfusions are those given on the basis of erroneous, spurious or incorrectly documented laboratory 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 is actually harmful.
- Under-transfusion or delayed transfusion resulting in poorer patient outcome.

DATA SUMMARY

Total number of cases	**92**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**68**	Deaths due to transfusion	**0**
		FFP	**7**	Deaths in which reaction was implicated	**1**
		Platelets	**11**	Deaths in which reaction possibly contributed	**1**
		Cryoprecipitate	**4**	Major morbidity	**2**
		Red cells and platelets	**2**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**35**	18 years+	**77**	Emergency	**28**	ED	**1**
Female	**55**	16 years+ to 18 years	**2**	Routine	**54**	Theatre	**1**
Unknown	**2**	1 year+ to 16 years	**7**	Not known	**10**	ITU/NNU/HDU/Recovery	**6**
		28 days+ to 1 year	**2**				
		Birth to 28 days	**4**	In core hours	**13**	Wards	**9**
				Out of core hours	**8**	Outpatient/day unit	**1**
		Total	**92**	Not known/applicable	**71**	Not known	**74**

There were 92 reports of inappropriate and unnecessary transfusion concerning 94 patients. One report concerned an identical prescription error affecting 3 neonates.

Emergency vs. routine

In 28 cases the event took place in an emergency setting and in 54 cases in a routine or elective setting; in 10 cases this information was not available.

Age of the patients

There were 77 patients over 18 years old and 15 paediatric cases (one involving 3 neonates, see above): 2 between 16 and 18 years of age, 7 between 1 and 16 years, 2 between 28 days and 1 year, and 4 between birth and 28 days.

Gender

There were 35 male and 55 female patients. In 2 cases the gender of the patient was not documented.

Core hours vs. out of hours
and
Where the transfusion took place

These two sections were very poorly answered again this year: 76% did not specify the time of transfusion and 85% did not specify where the transfusion took place. The new Dendrite web-based SHOT reporting system should rectify this problem.

Mortality

There were 2 deaths in this group where the transfusion of red cells possibly or probably contributed to the death. As the patients died very soon after receiving the red cells, full investigations were not performed.

Case 1

Unnecessary transfusion based on Hb result for a different patient

A patient with disseminated carcinoma was admitted and a sample for FBC was taken by a member of nursing staff. The hospital policy for positive ID of the patient was not followed and the sample tube was labelled with a different patient's details. (The report does not state whether a transfusion sample was mislabelled at the same time, only that both patients were group O D positive.) The patient's true Hb was 10.9 g/dL and there was no indication of bleeding or haemolysis. The incorrect patient's Hb was 6.0 g/dL and based on this a 3-unit transfusion was prescribed without querying the surprisingly low result. The patient suffered acute pulmonary complications during the first unit with a drop in pO_2, and the transfusion was stopped. A CXR post transfusion may have indicated TACO or TRALI. The patient deteriorated rapidly and died. The report stated that the death was considered to be possibly related to transfusion.

This patient did not require transfusion. Although he was suffering from carcinoma, the exact cause of death of the patient when it occurred is unclear. It seems likely that the administration of the red cells played a part by contributing to respiratory compromise.

Case 2

Request from BMS for repeat sample not heeded

Following abdominal surgery a patient fell in the ward and fractured her femur. Her most recent previous Hb was 15.9 g/dL. On testing a new FBC sample the BMS called the ward, gave an Hb of 6.1 g/dL, and requested another sample as he thought the result was incorrect. However, the result was passed to the medical team on the ward round by a nurse who did not mention the need to repeat the test. On the basis of the erroneous result, even though clinically there was not extensive bleeding, a 4-unit red cell transfusion was ordered by the consultant, and all 4 units were given without further review. The patient's Hb was 20.2 g/dL before surgery on the following day, and the anaesthetist was aware of this. The patient developed cardiac failure and died. This was thought to be probably related to the excessive transfusion.

This case reveals a number of omissions and errors of judgement. The crucial message to repeat the test was not passed on, but at the same time the doctors on the ward round did not, from a clinical perspective, assess the results to be inaccurate. No clinical assessment seems to have been made, nor basic observations. In any patient it is very rarely appropriate to transfuse 4 units of red cells back to back without review and repeat sampling – perhaps only in cases of massive active haemorrhage. It is possible the outcome might have been different had venesection been carried out once the very high Hb was discovered.

There are 5 cases this year in which requests for repeat samples, made by the haematology laboratory BMS, were ignored. In addition there is a case in which non-validated haematology results were viewed on the computer system and acted upon, while the lab was in the process of checking it for a clot. There seems little point in informing a clinical team of an erroneous result, verbally or electronically, when there is a risk of communication failure. The laboratory should call to request the repeat, stating that there is a clot or other problem with the sample, but without giving the meaningless result.

Major Morbidity

There was one patient that required venesection post transfusion.

Case 3

Entire adult unit of red cells given to infant

A request was made for top-up transfusion for a sick 1-year-old child with an Hb of 9.0 g/dL. A dose of 110 mL was calculated and prescribed. An adult unit of blood was issued but nursing staff did not see the volume prescribed and transfused the entire unit of blood (230 mL). This transfusion took place between midnight and 08.00. The error was detected by laboratory staff when the patient's post-transfusion Hb was 19 g/dL. The child required venesection.

The reporting hospital stated that the prescription chart could be improved to allow clearer prescription for paediatric blood transfusion volumes. However, it is essential that all staff working in paediatrics are aware of the principles of paediatric prescribing, based on body weight or surface area, whether administering blood components or pharmaceutical agents.

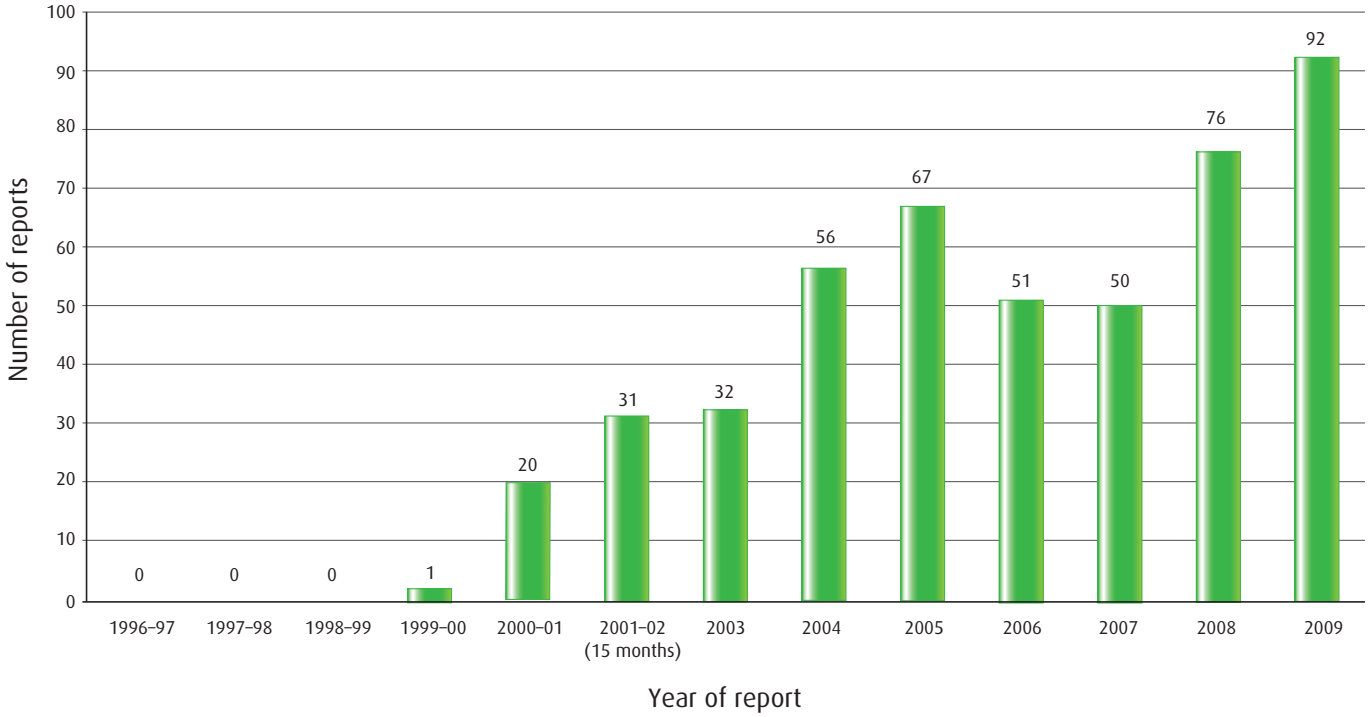
Case 4 below describes the delayed and/or under-transfusion of a very anaemic neonate. It was thought that the prolonged anaemia may have contributed to long-term morbidity in this infant.

Case 4

Delay in transfusing very anaemic neonate has long term consequences

A baby was delivered by CS and appeared unwell. There had been a massive transplacental haemorrhage and the infant's Hb was 4 g/dL. The clinicians did not know this result until 2 hours post delivery. There was then a further delay of 4 hours before the baby was transfused, owing to misunderstandings and communication failures between clinicians, portering staff and the transfusion laboratory. The team did not seem to know that neonatal 'flying squad' blood was available, nor did they ask for emergency blood even though the child was deteriorating. Blood was not prescribed. A sample was eventually sent but there were portering delays both in taking the sample and collecting the units. The total delay before transfusion commenced was over 4 hours. The baby became very sick and was transferred to a tertiary centre. There was long-term morbidity with developmental delay which may have been in part due to the prolonged period of extreme anaemia.

Figure 8
Cases of inappropriate and unnecessary transfusion 1996–2009



Broad breakdown of where primary errors occurred *n* = 92

As in previous years, most cases of inappropriate and unnecessary transfusion were the result of errors of judgement, lack of knowledge or lack of procedural awareness among medical staff (56 cases across all categories). These errors were made predominantly by junior doctors, but include those made by locums, staff-grade doctors and some consultants. In 7 of these cases the doctor had been informed that a result was unreliable (due to short sample, clots in sample or platelet clumping) and a repeat sample had been requested. This includes unverified results being accessible via the computer system. In 1 case standard FFP was requested instead of SD-FFP (Octaplas®) for a plasma exchange in a patient with TTP.

A further 18 cases were of 'clinical' origin, although exactly who was responsible is unclear from the case report (doctor, nurse, possibly phlebotomist). Ten of these are phlebotomy-related problems (diluted or drip arm samples) but it is not known who took the samples. There is 1 case of confusion about which component type was to be transfused, and 1 of confusion as to whether or not a prophylactic platelet transfusion was to be given (it should not have been, as the count was 89 x 10^9/L). In 5 cases there were communication failures between the laboratory and the clinical teams regarding the need to repeat inadequate (short, clotted, clumped) samples, as above. There were 2 cases of under-transfusion owing to multifactorial clinical errors, including communication and knowledge.

In 10 cases there was clear responsibility for the error in a member of the nursing staff, 4 of these involving transfusing blood to an infant or small child at a volume and/or rate which was much greater than that prescribed (Case 3, above). There was 1 case of an excessive rate of transfusion of red cells to an adult. The fatal case (Case 2, above) was multifactorial but the mislabelled Hb sample had been taken by a member of nursing staff. Four further cases involved incorrect verbal relay of Hb results, and misinterpretation of instructions in notes.

Hospital haematology laboratories were responsible for 8 cases of inappropriate or unnecessary transfusion by issuing incorrect results to clinicians before checking for clots, platelet clumping or short sample errors. There were 3 analyser errors; 1 involved 'flushback' in the machine and 2 were unexplained.

Transfusions based on wrong Hb, platelet or coagulation result *n* = 53

Transfusion based on wrong haemoglobin result *n* = 45

There were 45 cases in which a patient was transfused with red cells on the basis of erroneous or spurious results as shown below. One of these (Case 2, above) probably contributed to the death of the patient.

Table 25
Transfusion based on wrong haemoglobin result

Clinical causes of falsely low Hb value	Cases
Falsely low Hb due to phlebotomy from drip arm, or 'diluted sample'	8
Transfusion based on an old Hb result although a more recent result was available	5
Faulty sample (clotted, short, etc.) – lab requested repeat but request ignored and wrong result used	6
Hb result belonged to another patient (including WBIT for Hb sample)	7
Blood gas machine Hb used	4
Erroneous result from POCT Hb estimation device	3
Unauthorised results viewed from ward and acted upon	1
Substitution of WCC for Hb (transcription error)	1
Verbal miscommunication of results	1
Haematology laboratory causes of falsely low Hb value	
Hb lab analyser error ('flushback' in 1 case, underestimating Hb in 2 cases)	3
Short sample but lab issued result	2
Clotted sample not spotted by lab and results issued	1
Other	
Unknown cause of erroneous count	3
TOTAL	**45**

There are 4 cases of a doctor inappropriately using the Hb estimation from a blood gas machine as a basis for a decision to transfuse. In the case below an adequate clinical assessment of a stable patient did not take place, and the junior doctor used 'flying squad' blood on the Hb result from a blood gas machine alone.

Case 5

Blood gas analyser Hb used as trigger for emergency transfusion

An Hb of 5.0 g/dL obtained from an ED blood gas machine on a middle-aged female patient who was asymptomatic and not actively bleeding. One unit of O D negative red cells was already transfused when the laboratory result became available which was 8.9 g/dL. A further unit of O D negative blood was wasted due to inappropriate storage.

The reporter goes on to suggest review of the blood gas machine calibration, which, although essential, would still not mean that the Hb results obtained would be accurate enough to use as POCT for Hb levels. These instruments produce a calculated Hb result, which for many reasons may be inaccurate. They should not be used as a reliable measure of Hb.

There are, as ever, a number of cases of transfusion based on 'drip arm' or otherwise diluted specimens. In general a proper attempt to evaluate the clinical picture in relation to the Hb result, and comparison with previous results in the light of clinical events, should have alerted the prescribing clinician to the possibility of an erroneous result. Likewise in the 5 cases of genuine laboratory error an alert clinician might have queried the result.

Case 6

Dilute (possible drip arm) sample not queried, resulting in unnecessary transfusion

An elderly female patient arrived in the ED by ambulance suffering from shortness of breath and tachycardia. Intravenous fluid was administered and samples taken for laboratory tests. The Hb was 6.9 g/dL on that sample. The patient was admitted and the ward transfused 2 units of red cells overnight. At noon the next day the Hb was found to be 16.8 g/dL.

Case 7

Preoperative Hb from 'drip arm' results in unnecessary transfusion

A pre-surgery sample in a patient for total hip replacement following a fractured neck of femur was 6.2 g/dL and the junior doctor prescribed 2 units of red cells. A repeat Hb check immediately before surgery showed an Hb of 13.9 g/dL. It transpired that the earlier sample had been taken from above the IV infusion.

Transfusion based on spurious thrombocytopenia *n* = 8

In 4 of these cases of spurious low platelet count due to clumping the laboratory BMS had told the clinicians that there was platelet clumping, but nevertheless the 'count' had been given. In one of these the count was available on the computer system as a non-validated result, annotated with the message 'platelet clumping'. The inference from these accounts is that clinicians do not necessarily know what 'platelet clumping' means, nor the implication for interpretation of the platelet count, nor the action to take to validate the count – by film examination or citrate sample. Once again, it would be preferable if the spurious count was removed from the computer system, and not given at all, or else if the message 'platelet count normal' could be added.

Table 26
Causes of falsely low platelet count

Causes of falsely low platelet count	Cases
Transfusion of platelets based on falsely low count due to platelet clumping	5
Platelets transfused on basis of low platelet count due to clot in sample (lab errors)	2
Platelets transfused to patient on basis of a different patient's platelet count	1
TOTAL	**8**

Case 8

Erroneously low platelet count due to clumping in EDTA missed by lab

A middle-aged patient on the medical admissions ward with a viral illness had a platelet count of 67 x 10^9/L reported by the haematology laboratory. The patient had no bleeding, bruising or purpura. Advice was sought from a haematology consultant and platelets were advised and transfused. A repeat platelet count was 43 x 10^9/L. Blood films of both samples showed platelet clumping. The actual count was normal, with no indication for the platelets.

In this case the haematology laboratory staff should have checked the count and a blood film as the results were unexpectedly so low, and perhaps requested a citrate sample. All labs should have protocols in place for validation of out-of-range results.

Inappropriate and unnecessary transfusion based on poor basic knowledge, incorrect decision making or poor prescribing *n* = 37

The inappropriate and unnecessary transfusions reported in this category comprise cases where the excessive volumes transfused posed a potential or actual risk to the patient, rather than inappropriate on the basis of compliance with national guidelines or protocols.

Over-transfusion of small infants and children has been discussed in previous SHOT reports, and continues as an issue in 2009. One case required venesection (Case 3, above). Staff looking after and treating children must be appropriately trained in paediatrics and be fully cognisant of paediatric prescribing practices.

Table 27
Categories of poor knowledge or prescribing

Categories of poor knowledge or prescribing (excluding use of erroneous Hb)	Cases
Excessive volume/rate of red cells transfused to infant or child	8
Excessive red cell transfusion resulting in Hb above normal range	7
Transfusion of red cells for chronic iron deficiency anaemia	5
Inappropriate and excessive transfusion of patient with pernicious anaemia	1
Excessive cryo given due to lack of knowledge of pooled cryo packs	4
Incorrect component requested and/or given	4
FFP transfused to patient with normal coagulation screen	2
Transfusion of prophylactic platelets when count far in excess of trigger (FBC not checked)	1
Use of FFP to correct FXII deficiency coagulopathy	1
Use of 'least incompatible' units when no longer in emergency setting	1
Excessive quantities of platelets given (4 pools) to elevate count	1
Excessive rate of red cell transfusion in adult	1
Inappropriate night-time transfusion in a stable patient	1
TOTAL	**37**

Junior doctors require knowledge of the appropriate dose of red cells to correct Hb to safe levels in adults, taking account of the size of the patient, whether there is active ongoing blood loss, and comorbidities. Poor clinical assessment of the patient and the degree of blood loss continues to be a cause of over-transfusion.

Case 9

Over-transfusion of stable patient with upper GI bleed

An elderly patient had coffee-ground haematemesis and melaena, and a crossmatch request for 4 units of red cells was made. The Hb dropped but was at no time lower than 10.7 g/dL and the patient remained cardiovascularly stable throughout. All 4 units of red cells were transfused resulting in a post-transfusion Hb of 16.2 g/dL.

The junior doctor who prescribed the blood was perhaps inexperienced in assessing bleeding patients and worried by the visible blood loss. Trusts should utilise the guidance available from the Scottish Intercollegiate Guidelines Network,[26] and local protocols and training should reflect this.

Case 10

Over-transfusion following liver biopsy

A patient was admitted for a liver biopsy and became hypotensive 2 hours after the procedure. The Hb was 7.7 g/dL (pre-procedure Hb not given) and the patient was transfused 2 units on 3 separate occasions over the next 3 days. In total 6 units of red cells were administered. No monitoring of the patient's laboratory parameters took place. A subsequent Hb was 17.1 g/dL. The patient died and no further clinical details or test results are available.

Insufficient details are available to comment, though the death of the patient was due to underlying causes and not related to the over-transfusion.

There have been 5 reports this year of inappropriate transfusion of young female patients with chronic iron deficiency, 4 from the same reporting organisation, all female, aged 24, 25, 29 and 37. The final case involved an elective preoperative patient of over 70. This highlights a major clinical concern regarding appropriate management of such patients, who should not be exposed to the small but real risks of transfusion unless symptoms are severe or there is acute-on-chronic bleeding. It is an educational issue as important in primary care as in the hospital setting.

Case 11

GP demands that iron-deficient woman is transfused despite advice to contrary

A young woman with iron deficiency anaemia, Hb 5.5 g/dL, due to longstanding menorrhagia was sent to the ED by her GP. She was reluctant to have a blood transfusion and went home with a supply of iron tablets. The GP was not satisfied and sent her back. The transfusion practitioner discussed the patient's concerns with her and then requested the GP to reconsider the alternative options. The patient was sent back again, this time with a letter instructing that transfusion was needed. The request was not discussed at any point with a haematology consultant, and the patient was eventually, reluctantly, transfused.

Case 12

GP sends iron-deficient woman to the ED where junior doctors decide to transfuse

A GP detected an Hb of 6.6 g/dL in a young woman with chronic menorrhagia and referred the patient to the ED. The junior doctor there asked advice of the locum SpR who said to go ahead and transfuse, but the case was not discussed with a haematologist.

The 2 cases above were referred for transfusion by GPs, and no senior physician or haematologist was involved in the decision. It seems wholly inappropriate for referrals to the ED to be made demanding transfusion in any circumstances, but especially so in these cases of chronic iron deficiency anaemia.[27]

Under-transfusion *n* = 2

There were 2 cases reported which broadly fitted this category. One relating to delay in transfusing a neonate with extreme anaemia has been included in the major morbidity section at the start of this chapter (Case 4). The second, below, relates to an inappropriately low Hb in a patient following red cell exchange.

Case 13

Patient left with too low Hb following red cell exchange for sickle cell disease

A patient with HbSS required red cell exchange prior to routine surgery. The procedure was completed and the patient discharged. She went to the canteen where she collapsed and was admitted to the ED. Laboratory tests did not reveal any other possible cause except for the Hb of 8.6 g/dL, which, if it was mostly Hb A, was low for a patient previously with mostly Hb S. The patient was given 3 more units and made a full recovery.

COMMENTARY

In total there were 12 cases in which spurious results were acted upon and the patient given blood components inappropriately despite the haematology laboratory having either verbally, or via a message on an unverified result on the computer system, informed the team that a repeat sample was required. It is worrying in these cases that the result is given at all, when it is known to be incorrect; and that clinicians still think it may be valid. There appears to be a lack of understanding among doctors of the implications when they are informed that there was a clot, or that platelet clumping is present – perhaps they believe that the resulting inaccuracy is only marginal.

In common with last year, most cases of inappropriate and unnecessary transfusion are due to lack of knowledge of the staff involved (often junior doctors), or inability to apply knowledge meaningfully to a real clinical situation. Clinical assessment of patients is limited, and the clinical picture, including results, is not viewed as a whole. It may be that junior doctors lack sufficient experience to make reliable clinical judgements, and this in turn may relate to the reduced hours they work under the European Working Time Directive.[16] They are reaching middle-grade level, where such decisions are required of them having seen very few comparable clinical scenarios.

RECOMMENDATIONS

- Staff working with paediatric patients must be trained and familiar with paediatric prescribing regimens and dose calculation for children. A specially designed prescription chart for paediatrics may assist this.

  Action: Risk management boards, HTCs, HTTs

- Junior doctors must not be expected to clinically evaluate potentially bleeding patients if they are insufficiently experienced. Senior colleagues need to be involved in the decision to transfuse and the evaluation of patients with unexpected results. Doctors need to differentiate chronic anaemia from acute blood loss. BMS requests for repeat samples must be heeded.

  Action: Royal Colleges

- Blood gas machines must not be used for Hb estimation unless they are designed and calibrated to produce accurate, reproducible results with external quality assessment in place. (See also recommendation on page 54.)

  Action: POCT teams, manufacturers

- Haematology laboratories need protocols for dealing with out-of-range results, including trending and delta checks, films, and asking the haematologist. Potentially erroneous results should not be communicated to clinicians either verbally or as unverified results on the computer system. New samples should be requested, with an explanation, but the incorrect result should not be given.

  Action: HTCs

9. Handling and Storage Errors (HSE)

Definition

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

DATA SUMMARY

Total number of cases	**196**

Implicated components	
Red cells	**146**
FFP	**4**
Platelets	**13**
Other	**6**
Unknown	**27**

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

Gender	
Male	**92**
Female	**88**
Unknown	**16**

Age	
18 years+	**156**
16 years+ to 18 years	**1**
1 year+ to 16 years	**4**
28 days+ to 1 year	**3**
Birth to 28 days	**1**
Unknown	**31**
Total	**196**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**38**
Routine	**126**
Not known	**32**
In core hours	**19**
Out of core hours	**38**
Not known/applicable	**139**

Where transfusion took place	
ED	**4**
Theatre	**7**
ITU/NNU/HDU/Recovery	**11**
Wards	**98**
Community	**0**
Outpatient/day unit	**7**
Not known	**69**

Figure 9 illustrates the steady increase in HSE incidents reported to SHOT since 2003. A total of 196 cases were reported in this category, none of which resulted in mortality or major morbidity. As the culture of reporting has developed, 2009 has shown a 41% increase in HSE reports compared with 2008.

Figure 9
Number of HSE cases 1996–2009

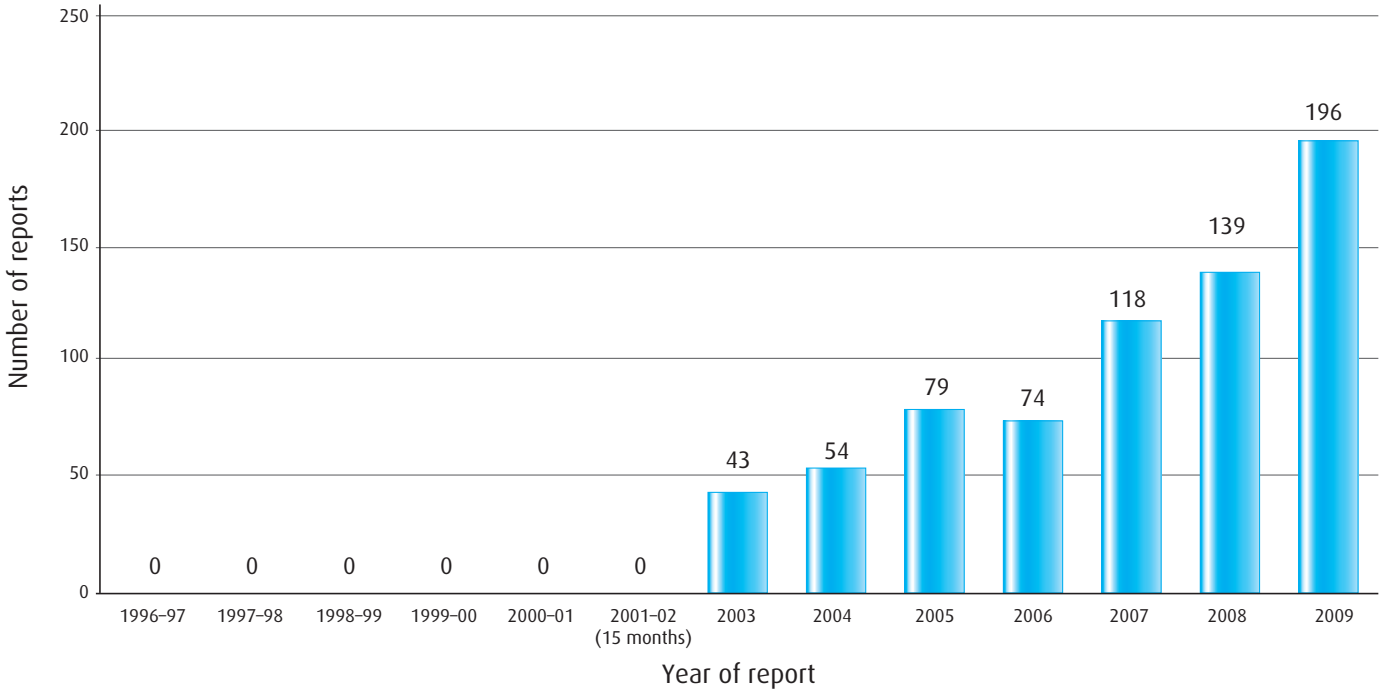


Table 28
Categories of handling and storage errors

Type of case	2008	2009
Technical administration error	9	12
Transfusion of expired red cells	45	31
Excessive time to transfuse	24	69
Cold chain error	61	84
TOTAL	**139**	**196**

Technical administration errors *n* = 12

There were 12 cases in which there were technical administration errors. Again this year there are 2 cases where a transfusion was continued despite the blood bag being pierced when inserting the administration set spike into the component port.

Table 29
Technical administration error types

Type of case	No.
Leaking component but transfusion continued	1
Blood given through incorrect solution giving set (includes 1 case of excessive time to transfuse + 1 case continued transfusion despite piercing the blood bag when changing the giving set)	11

Case 1
While changing an incorrect giving set the blood bag was inadvertently pierced
Red cell transfusion was commenced in theatre using the wrong giving set. The recovery room nurse noticed the error and while changing the giving set pierced the blood bag at the inlet end. With the agreement of the anaesthetist the blood bag was patched with a gauze swab and tape. The ward staff discarded the blood when the patient returned to the ward.

Transfusion of expired red cells *n* = 31

There were 31 cases in which expired blood was transfused to a patient. This demonstrates a 31% reduction in the number of cases reported in 2008. One aliquot from a paedipak was irradiated, issued and transfused despite being more than 14 days old. In 12 cases the blood had been issued (or was still available at issue) within 8 hours of the expiry date/time (2 units were issued within 30 minutes of the expiry date/time). Despite the staff being aware of the short expiry time, delays due to the patient's condition or technical problems led to a further delay in commencing the transfusion. Seven cases involved the transfusion of platelets or thawed FFP or cryoprecipitate after the recommended expiry date/time.

Excessive time to complete administration of blood components *n* = 69

There were 69 cases reported in this category: this is the largest increase in reporting in the Handling and Storage chapter (> 150%) from 2008. In 22 cases the transfusion overran by less than 60 minutes (≤ 15 minutes in 4 cases). In a further 22 cases, the transfusion overran by between 60 and 120 minutes. In 13 cases the transfusion overran by more than 2 hours; in 5 cases the transfusion took up to 10 hours to complete (6 hours in 3 cases, 7 hours in 1 case and in a routine transfusion episode for anaemia 9 hours 40 minutes). In 7 cases the duration of overrun was not given. The majority of transfusions took place during core hours (79%) and were in routine transfusion episodes (67%). One event reported the results of an audit of 'duration of transfusion' which identified 12 units which were transfused to different patients over longer than the 4 hour recommended time period.

Table 30
Breakdown of times of transfusion that took excessive time to run *n* = 47
NB not given in 22 cases

Time period	No.
08.00 to 20.00	34
20.00 to 00.00	8
00.00 to 08.00	5

Case 2
Expiry date checks are important especially prior to starting a transfusion
A unit of blood was collected from the hospital transfusion laboratory at 17.55. The unit expired at midnight that night. The staff had problems with the infusion device occluding during the transfusion. The transfusion commenced at 18.00 and concluded at 03.40, a total transfusion time of 9 hours 40 minutes, resulting in transfusion of blood past the expiry date. The patient suffered no ill effects.

COMMENTARY

- It is imperative that staff have the appropriate knowledge and understanding of technical issues when administering blood components, including the appropriate equipment requirements and the maximum time over which components can be administered after leaving controlled temperature storage (CTS).
- All staff should be aware that checking the expiry time is a critical part of the checking process at both issue and administration.
- The practice of issuing blood components, especially red blood cells, within 4 hours of their expiry time to reduce wastage levels should be discouraged.

Cold chain errors *n* = 84

Table 31
Summary of cold chain related errors

Type of error	No. of cases
Alarm related	5
Equipment failure	7
Delivery or transfer of components	10
Inappropriate storage of components	62
Returned to stock - *a) When they should have been discarded* *b) Without/no/incomplete cold chain documentation/traceability*	 *31* *8*
Returned to the satellite fridge when they should have been discarded	*3*
Stored inappropriately in clinical area, e.g. out of order refrigerator, transport box, non-validated transport box/storage, unknown	*20*
TOTAL	**84**

This year there were 84 HSE incidents which resulted from cold chain errors. This compares to 61 similar cases last year.

Three cases involved paediatric patients – a 9-month-old baby and children aged 12 and 17. In 15 cases the age was not given. All other cases were in adults over 18 years of age. As reported in previous years, 58% of the incidents occurred in a routine setting, 20% were emergencies and 22% were unknown. Of the 84 cases, only 1 patient experienced a mild reaction, and this is discussed in more detail below.

This year 12 equipment-related incidents were reported. In 5 of the cases staff failed to carry out the correct procedure following an alarm being set off on a refrigerator. The remaining 7 cases resulted either from a power failure or a suspected refrigerator alarm failure. Red cell components stored at inappropriate temperatures were subsequently transfused to a number of patients.

In all, 81% (68/84) of the errors involved patients receiving 1 or more units of RBC, platelets (7 cases) and FFP (1 case) that had been either inappropriately transported or had been out of CTS for more than 30 minutes and then returned to CTS. One patient experienced a mild reaction after being transfused a unit of RBC which been out of CTS for 70 minutes. The unit was returned to stock and reissued to the same patient, when it should have been discarded. The patient fully recovered.

The 2008 SHOT report provided updated advice on the '30 minute rule': 'A unit of RBC 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' (SHOT, 2009/MHRA). This applies regardless of how long the unit has been out of CTS prior to commencement of administration to the patient, providing the component has been stored appropriately during that time, i.e. NOT in the ward drug fridge. As a result of this advice SHOT no longer requires reporters to submit incidents highlighting an 'Excessive time to *start* transfusion' unless the overall transfusion was not completed within the recommended 4 hours (see learning points).

Completion of transfusion within 4 hours can be difficult in neonates due to vascular access and fluid load (see Paediatric Cases, page 140). Recent BCSH guidelines have adjusted for this, stating, that 'there should be no more than 30 minutes

between removing the component from the CTS and starting the transfusion; nevertheless the transfusion itself should take no more than 4 hours'.[19]

In 8 of the cases the time units had been out of CTS was unknown, owing to incomplete cold chain documentation. Some of these case studies are presented below.

Case 1

Units of blood returned to stock despite alert warning staff of incorrect procedure

Blood was removed from the central blood fridge using the Blood Track system for a patient requiring transfusion. The transfusion was postponed until the following morning and the unit of blood was returned to the fridge 37 minutes later. An alert came up on the screen stating the unit had been out of CTS for over 30 minutes so was unsuitable to be returned to store, but this was ignored by the HCA and the blood was placed back in the fridge. The shift BMS received an alert on the system in the laboratory; he was unable to leave the laboratory to fetch the unit, so he marked it on the system as unusable. The following morning the blood was removed for transfusion. The alert came up again but was ignored by the HCA and subsequently the unit of blood was transfused. The patient experienced no adverse reaction.

Numerous incidents this year describe staff overriding or ignoring warning signals. These are described in more detail in the IT chapter (page 57). The use of the electronic blood tracking systems does not prevent errors occurring, particularly when practitioners use the override facility or ignore warning signals.

Case 2

Incomplete documentation on how long units of blood were kept out of CTS

Four units of blood were removed from issue on 28th of the month at 20.45 for an emergency. Two of the units were transfused and 2 units were returned to stock on 29th at 09.52. The correct paperwork tracking how long the units were kept out of CTS was not signed, so it was difficult to identify who was involved. With no evidence of a valid Chain of Controlled Storage, these units were then reissued and used for another patient. This patient suffered no ill effects.

It is imperative that each member of laboratory, clinical and support staff is vigilant when undertaking their part in the transfusion process. It is important to ensure efficient bedside checks are performed and the necessary documentation is completed to verify the storage, transportation and administration of the blood through recorded identification. This forms part of an effective traceability matrix and aims to prevent inaccurate information being distributed.

COMMENTARY on cold chain errors

There has been a 38% increase in the number of cold chain errors reported in 2009; again this may be an example of improved reporting. This year has seen numerous incidents in which cold chain documentation has been incomplete resulting in components that may have been stored at inappropriate temperatures subsequently being transfused to patients.

This year SHOT has received a number of reports in which multiple patients are included as one event. These reports make reference to multiple patients being transfused with components that should have been discarded because of incomplete cold chain documentation. They also refer to failures to follow SOPs when a refrigerator alarm was activated. This type of batched reporting results in underestimation of the number of actual errors affecting patients. Nevertheless, reporters are advised to take on board the learning points to aid practice.

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 on in the process; however, this year some alarms and warnings have been ignored – perhaps owing to the lack of training or lack of understanding of the rationale behind the protocols and SOPs in use.

Learning points

- Blood components should be removed from CTS only when the transfusion is ready to commence, i.e. the patient is available, venous access has been checked and the component has been prescribed.
- Fridges should be cleaned at regular intervals by trained and competency-assessed individuals and should be well documented in the local SOP. It is the responsibility of the laboratories to monitor that this is being done as per the SOP and take effective CAPA if it is not being carried out effectively.[28]
- Red blood cell components should not be issued when there are 4 hours or less before their expiry time.
- The expiry date must be checked by the laboratory staff before the component leaves the hospital transfusion laboratory and by the clinical staff as part of the pre-administration check before the component is transfused. SHOT recommends that staff should be advised to cease the transfusion at midnight as the manufacturers' product liability ceases at midnight on the day of expiry.[28]

The following learning points from previous reports remain pertinent:

- Only staff who have been competency-assessed must be involved in any part of the transfusion process.
- Use of electronic blood tracking systems does not prevent errors occurring, particularly when staff use the override facility or ignore warning signals and alarms.
- The expiry date must be checked by the laboratory staff before the component leaves the hospital transfusion laboratory and by the clinical staff as part of the pre-administration check before transfusion.
- Transfusion of a blood component should be completed within 4 hours of leaving controlled temperature storage (CTS).
- A unit of RBC 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 subsequently transfused then it is also reportable to SHOT.

RECOMMENDATIONS

- Maintaining cold temperature storage conditions and guaranteeing the capture of valid and accurate monitoring data are the responsibility of all staff involved in the storage, transportation and administration of blood components. Clear guidance should be provided regarding the removal (and return should it not be required) of every blood component from validated storage areas.

  Action: HTCs, HTTs

- As part of the competency-assessment process the importance of checking the expiry date during the collection/final patient identity checks must be emphasised to all practitioners.

  Action: HTTs

10. Adverse Events Relating to Anti-D Immunoglobulin (Anti-D)

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 which has the potential to cause harm to the mother or fetus immediately or in the future.

DATA SUMMARY

Total number of cases	**186**	*Implicated components*		*Mortality/morbidity*	
		Red cells		Deaths due to transfusion	**0**
		FFP		Deaths in which reaction was implicated	**0**
		Platelets		Major morbidity	**1**
		Anti-D Ig	**186**	Potential for major morbidity	**127**
		Unknown			

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**0**	18 years+	**183**	Emergency		ED	
Female	**186**	16 years+ to 18 years	**3**	Routine		Theatre	
Unknown	**0**	1 year+ to 16 years	**0**	Not known	**186**	ITU/NNU/HDU/Recovery	
		28 days+ to 1 year	**0**			Wards	
		Birth to 28 days	**0**	In core hours		Community	**154**
		Unknown	**0**	Out of core hours		Outpatient/day unit	**32**
		Total	**186**	Not known/applicable	**186**	Not known	

This section describes the main findings from 186 completed questionnaires. However, 1 of the submitted questionnaires refers to a hospital audit involving 11 different patients, so the number of individual cases considered in this chapter is actually 196. The reports are broken down into the reporting categories shown in Table 32. Under current haemovigilance legislation,[2] adverse events related to anti-D immunoglobulin are reportable as 'SHOT-only'. Adverse reactions are reportable under the yellow card system for batched pharmaceutical products.

Table 32
Reporting categories

Category of adverse event	Number of cases
Omission or late administration of anti-D immunoglobulin	127
Inappropriate administration of anti-D immunoglobulin	62
to a RhD positive patient *to a patient with immune anti-D* *to a mother of a RhD negative infant* *to the wrong patient*	*27* *20* *6* *9*
Wrong dose of anti-D immunoglobulin given according to local policy	6
Administration of expired or out of temperature control anti-D Ig	1
TOTAL	**196**

Mortality *n* = 0

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

Major morbidity *n* = 128

In 127 of the 196 cases anti-D was administered more than 72 hours following a potentially sensitising event, 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. There was 1 case in which a baby was reported as suffering from haemolytic disease of the newborn (HDN) following an incorrect assumption by the laboratory that a positive antibody screen was due to prophylactic anti-D (see Case 6, below).

Clinical versus laboratory errors

For 2009, 196 events relating to anti-D immunoglobulin administration are summarised in Table 33 below, with a breakdown of the proportion of clinical and laboratory errors that were primarily responsible.

In past years the distribution of cases reflected the overall SHOT finding that around two-thirds of reports involve errors by clinical staff and one-third by laboratory staff, but this year the proportion of clinical anti-D related errors increased to 80% of the total reports.

Table 33
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	**127**	118	6	3
Anti-D Ig given to RhD positive patient	**27**	7	18	2
Anti-D Ig given to patient with immune anti-D	**20**	13	7	0
Anti-D Ig given to mother of RhD negative infant	**6**	3	3	0
Anti-D given to wrong patient	**9**	9	0	0
Wrong dose of anti-D given	**6**	2	4	0
Anti-D Ig expired or out of temperature control	**1**	1	0	0
Totals	**196**	153	38	5

There were 3 cases in which a positive antibody screen was incorrectly assumed by the laboratory to be due to prophylactic anti-D, so denying the patients appropriate follow-up for monitoring and treatment of HDN.

In addition there were 127 cases in which administration of anti-D Ig following potentially sensitising events was delayed or omitted, placing the patient at risk of developing immune anti-D.

In 62 cases anti-D was inappropriately administered, resulting in unnecessary exposure to a human blood product.

Omission or late administration of anti-D *n* = 127

In 118/127 cases the primary error was made by a midwife. Twenty-five cases occurred in the community, and 102 in a hospital setting.

As in last year's report, there are multiple cases where anti-D has been issued by the laboratory, only to be found days or weeks later in maternity fridges, indicating a failure of the discharge checklist.

Case 1

Failure to prescribe anti-D resulting in omission of prophylaxis

Anti-D was requested and issued from the transfusion laboratory on a named patient basis for a patient who was going to theatre for removal of an ectopic pregnancy. The anti-D was not written up on a prescription chart so was not given to the patient, and was found in a ward fridge some 4 months later.

Case 2

Poor advice from the laboratory results in omission of prophylaxis

A group B RhD negative patient who was 9 weeks pregnant had a miscarriage with surgical evacuation, and according to policy should have received 250 iu anti-D injection. It was noted on the ward 4 days later that the patient had not received anti-D; it was subsequently reported that the hospital transfusion laboratory advised that no anti-D was required, > 72 hours having elapsed since the event.

Learning point

- Anti-D Ig may still be at least partially effective if given up to 10 days following the potentially sensitising event and should not be withheld even if 72 hours have already elapsed.

Inappropriate administration of anti-D *n* = 62

This group is further subdivided into four categories.

Anti-D Ig given to D positive patients *n* = 27

Overall 9 primary errors were clinical, 7 made by midwives and 2 by a doctor; 18 primary errors arose in the laboratory. Twenty-four of 27 errors were made in a hospital setting, and 3 in the community.

Seven of 18 cases reported as originating in the laboratory involved patients who had been previously reported as RhD negative, and who subsequently tested as 'weak D' positive either in different laboratories or using different test systems in the same laboratory.

Six of 18 cases involved the issue of anti-D by the laboratory despite there being a record on the laboratory system that the patient was either RhD positive or weak D positive.

Five of 18 cases involved testing errors in some form: either the test was not performed correctly; or results were misinterpreted; or there were transcription errors when recording the results.

Case 3

Anti-D issued to a patient on the basis of an old result

Anti-D was issued by clinical staff from remotely held stock on the basis of a result from 15 years earlier which stated the patient was RhD negative. A current sample showed that the patient was weak D positive.

Case 4

Failure to check group results in inappropriate administration of anti-D Ig

A patient had been sent to the RAADP clinic where midwives requested anti-D without checking grouping results. Laboratory staff issued anti-D on request, also without checking the grouping result. The anti-D was then administered by the midwives, again without any check being made as to the blood group of the patient, who was RhD positive.

Case 5

RhD testing by rapid manual technique results in inappropriate administration of anti-D

A BMS, during a routine working day but under 'intense pressure' from clinical staff, performed RhD testing by a rapid manual technique and issued anti-D on the basis of a RhD negative result. Later testing by the routine laboratory methodology showed the patient to be RhD positive.

Anti-D Ig given to patients with immune anti-D *n* = 20

Of these 20 reported cases 13 resulted from a primary clinical error and 7 from a laboratory error.

Three of the 7 laboratory errors involved failure to consider that a strongly positive antibody screen could have been caused by immune anti-D rather than prophylactic anti-D.

Case 6

Assumption that positive antibody screen is prophylactic anti-D results in further administration and failure to monitor the mother

An antenatal sample at 28 weeks gestation showed the presence of anti-D and a BMS reported 'anti-D of probable prophylactic origin'. However, there was no record that the patient had been given any prophylactic anti-D. As a result of the report, further anti-D was administered, the mother was not closely monitored during the remainder of the pregnancy and the baby was born suffering from HDN.

Case 7

Failure of communication results in inappropriate administration of anti-D

A patient was transferred to another hospital, where a positive antibody screen was noted. A message from the referring hospital indicated that the patient had been given anti-D, so further anti-D was administered. The patient had, however, developed their own immune anti-D. The outcome for the infant was not recorded.

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

Three of these errors originated in the clinical area, and 3 in the laboratory. All 6 occurred in the hospital setting.

Case 8

Poor communication and involvement of multiple staff fail to prevent basic error

Mother and cord samples were received and grouped by a BMS on night duty, but no written results were recorded and the case was not handed over to day staff. A Kleihauer test was performed by the day shift and found to be positive. Results were validated by a senior BMS and anti-D was issued by the laboratory, and administered by the midwives. At no point in the process was the infant's blood group checked.

Case 9

Anti-D issued without waiting for results

A baby was born to an RhD negative mother. Anti-D was administered by midwifery staff 90 minutes later from stock held in the clinical area without knowledge of the baby's blood group, even though samples had been sent to the laboratory. The baby was RhD negative.

Anti-D Ig given to the wrong patient *n* = 9

These were exclusively clinical errors, involving failure to identify the correct patient.

Eight of 9 cases occurred in the hospital setting, and 1 in the community.

Case 10

Anti-D administered on the basis of a different patient's grouping report

An RhD positive patient was given anti-D in error, as a result of the wrong patient's blood group report being filed in her notes. The incorrect group was subsequently transcribed onto other paperwork, and the patient was administered anti-D following an amniocentesis.

Case 11

Failure of bedside check results in administration to a different patient

The transfusion laboratory issued anti-D to maternity for a postnatal RhD negative woman, labelled with correct patient details and accompanied by a correctly completed issue form. The midwife on the maternity ward failed to check any patient details at the bedside, and administered the anti-D to the wrong patient (who was RhD positive).

Wrong dose of anti-D given *n* = 6

Two of the 6 errors were by midwives, and 4 errors occurred in the laboratory. Five of 6 cases occurred in hospital and 1 in the community.

Case 12

Incomplete information and incorrect assumptions result in inadequate dose of anti-D

A 1250 iu dose of anti-D was issued by the laboratory on a verbal request for a post-delivery patient. The request form was sent retrospectively but contained no clinical details nor the dose required. The BMS did not associate this request with the previous issue, but assumed it was a sensitising event and sent 250 iu to the ward. The midwife then returned the 1250 iu dose already issued and administered the 250 iu dose instead, resulting in the patient receiving inadequate prophylaxis.

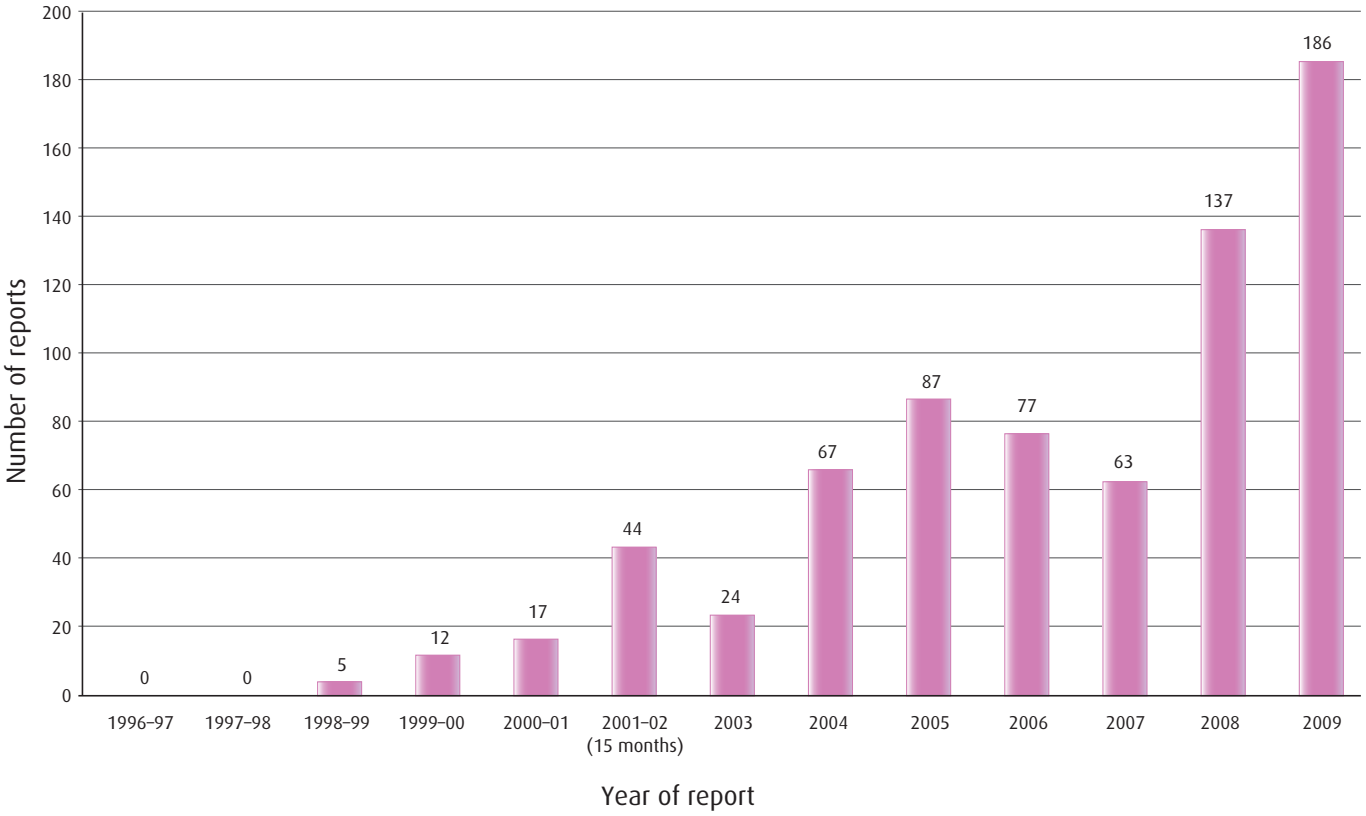
Anti-D expired or out of temperature control *n* = 1

This case was a clinical error in the antenatal setting, where expired anti-D Ig was selected and administered from a remotely held stock.

COMMENTARY

The number of cases reported to SHOT under the anti-D category has dramatically increased again in 2009, 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 10, on the following page).

Figure 10
Cumulative data



While it is encouraging to note the increase in willingness to report cases, it is unfortunate that many of the reports contain insufficient detail to allow a good analysis of exactly where and when things are going wrong.

What is apparent, however, is that exactly the same mistakes are being made by all staff groups this year as in previous years. They centre around failure to follow basic protocols, failure to take into account laboratory computer records, poor communication and poor decision making, underpinned by poor understanding.

It is disconcerting to note that a number of reports imply that clinicians are waiting for the results of assessment of transplacental haemorrhage before deciding whether or not to request anti-D to cover potentially sensitising events, rather than giving an initial dose of anti-D and then requesting more if indicated. This is symptomatic of the distinct lack of 'seamless' protocols developed between laboratory and clinical areas, where clear guidance can be included and areas of responsibility can be clarified.

A recommendation in the 2007 SHOT report related to the follow up of potentially sensitised patients, stating that the outcome should be reported to SHOT. It is anticipated that active follow-up of these cases by SHOT will become possible in future as the new web-based data collection system evolves.

There were 3 case reports, not included in the total figures, in which women had become sensitised and developed immune anti-D even though testing and relevant prophylaxis had been carried out correctly. SHOT will continue to take this type of report, even though no 'error' has occurred.

RECOMMENDATIONS

New recommendations from this report

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

Action: HTCs

Cases of late administration, omission, or inappropriate administration of anti-D immunoglobulin must be the subject of internal follow-up within Trusts/hospitals via established governance mechanisms.

Action: HTCs, Trust/hospital CEOs

Recommendations still active from previous years

Year first made	Recommendation (Previously Learning Points)	Target	Progress
2008	Trusts should ensure that robust systems under overall control of the hospital transfusion laboratory are in place, to ensure that anti-D Ig is issued on a named patient basis, to ensure appropriate use and to meet traceability requirements.	**HTCs**	The NHSBT Appropriate Use of Blood Anti-D Working Group has developed anti-D modules for both clinical and laboratory staff as part of the Learn Blood Transfusion e-learning programme.
2007	D-typing should be performed by the routine methodology available in the hospital transfusion laboratory, not by emergency techniques which may not be as robust.	**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 ensure that all hospitals are able 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**	The new SHOT online reporting system will be collecting this data from 2010.

11. Acute Transfusion Reactions (ATR)

Definition

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

DATA SUMMARY

Total number of cases	**400**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**264**	Deaths due to transfusion	**0**
		FFP (including 1 MB and 2 SD)	**44**	Deaths in which reaction was implicated	**1**
		Platelets (57 apheresis, including 3 HLA matched components, 23 pooled, 7 unknown type, including 1 platelet component in PAS)	**86**	Deaths in which reaction was not implicated	**1**
		Multiple components transfused	**6**	Major morbidity	**27**

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**184**	18 years+	**363**	Emergency		A & E	
Female	**215**	16 years+ to 18 years	**4**	Routine		Theatre	
Unknown	**1**	1 year+ to 16 years	**28**	Not known		ITU/HDU/Recovery	**2**
		28 days+ to 1 year	**3**	In core hours		Wards	
		Birth to 28 days	**2**	Out of core hours		Community	
				Not known/applicable		Other	
		Total	**400**			Not known	

In total 440 questionnaires were received; 28 were withdrawn, 6 were transferred to the autologous chapter, 10 to the TACO chapter, and 2 to the TAD chapter. A further 6 cases were transferred in from other sections: 1 each from HSE, TRALI and TTI, and 3 from HTR. A total of 400 cases have been reviewed for this chapter.

There were 193 febrile and 114 allergic reactions, and 30 whose features were indicative of anaphylaxis. There were also 28 reactions with mixed febrile and allergic features, 6 hypotensive reactions, and 29 which could not be classified further.

Mortality

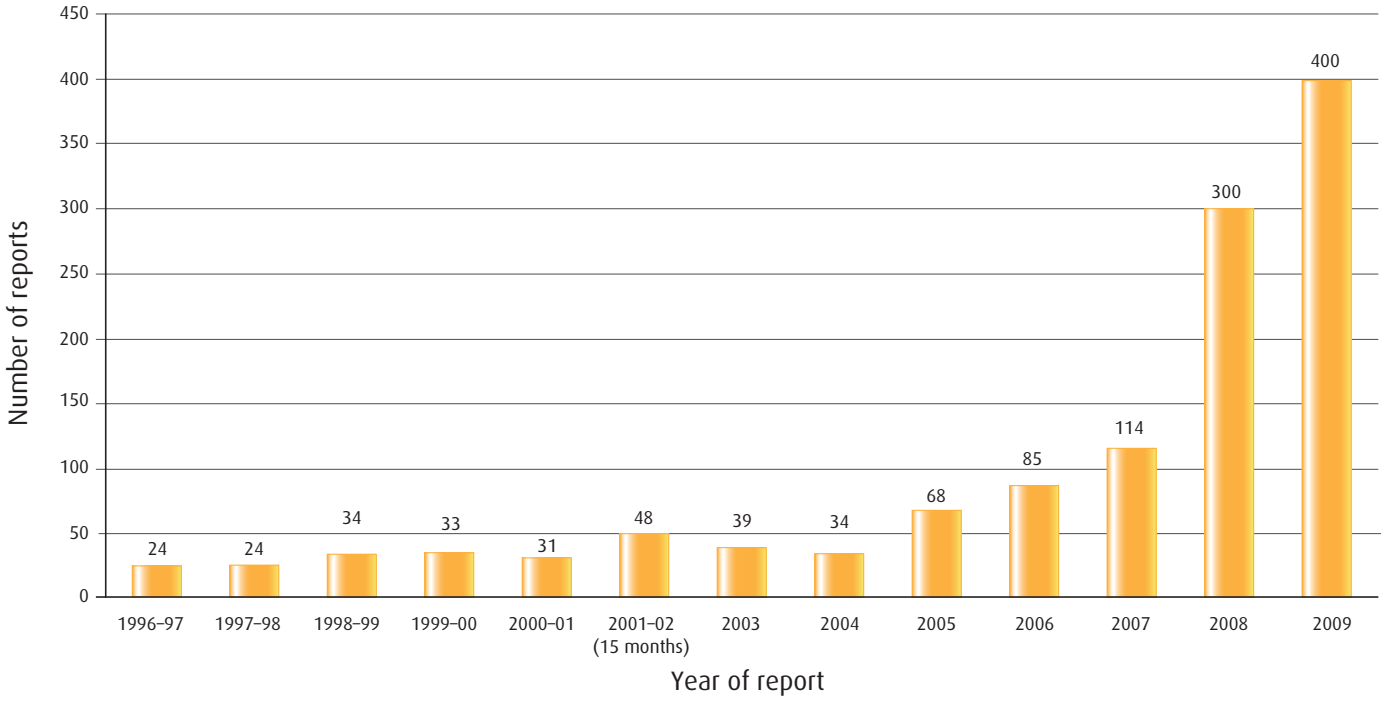
In 1 case, the patient's symptoms may have been attributable to a transfusion reaction and the possibility that the reaction could have contributed to the patient's death could not be completely excluded.

Case 1

Possible fatal reaction

A male patient with alcoholic liver disease was transfused with standard FFP. He became dyspnoeic and died during transfusion of the second unit. NHSBT was contacted and associated units from the donation were withdrawn. TRALI was ruled out as both plasma donors were male. Microbiological tests of the unit were negative. IgA investigations of the recipient were requested but not performed. The postmortem investigation demonstrated pneumonia and cirrhosis. It is not possible to state whether the dyspnoea was caused by a transfusion reaction of some type, and, if so, whether this contributed to the patient's death, as case notes are no longer accessible.

Figure 11
ATR cases 1996–2009



Classification of non-fatal acute transfusion reactions

The classification of acute transfusion reactions can be difficult, as reactions are frequently 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.

Major morbidity

Applying the SHOT criterion of 'Life-threatening acute reaction requiring immediate medical intervention', there were 27 cases of major morbidity from ATR where the immediate symptoms or signs were sufficiently severe for a delay in treatment to be life-threatening, even though recovery was usually rapid.

There were 17 anaphylactic reactions, 1 of which complicated a severe postpartum haemorrhage and resulted in the patient temporarily requiring intubation (Case 3, below), and 5 of which led to the crash team being called; in all these cases the patient recovered without cardio-respiratory support. There were 7 severe febrile reactions: the case below; 2 patients described as having reversible shut-down of their peripheral circulation; and 4 patients requiring acute management of hypotension (2 with adrenaline and 2 with volume replacement). Life-threatening reactions were also experienced by 2 patients with severe mixed febrile and allergic reactions, and 1 with a severe allergic reaction. One patient suffered a severe febrile reaction to a red cell transfusion and experienced worsening of pre-existing renal failure (Case 2, below).

Case 2

Did the transfusion reaction contribute to renal failure?

A female patient with acute renal failure and peripheral ischaemia was given a red cell transfusion. After 20 minutes, she developed a severe febrile reaction, with chest pain and dyspnoea. Her low urine output dropped further. She was given paracetamol. No investigations were performed. The reporting team stated that they could not exclude acute transfusion reaction as a cause for the deterioration in renal function.

In addition to the SHOT classification of acute transfusion reactions by death or major morbidity, the International Society for Blood Transfusion (ISBT) has developed standard definitions for non-infectious adverse transfusion reactions. These will help haemovigilance organisations generate data that will be comparable at an international level. Meanwhile, the following definitions have been put forward by the writing group of the forthcoming BCSH guideline on the investigation and management of acute transfusion reactions. Therefore, ATRs according to this classification are also shown.

Table 34
BCSH classification of Acute Transfusion Reactions

Category	1 = Mild	2 = Moderate	3 = Severe
Febrile type reaction	A rise in temperature up to 2°C with no other symptoms/signs	A rise in temperature of 2°C or more, and/or rigors, chills, other inflammatory symptoms/signs which precipitate stopping the transfusion	A rise in temperature of 2°C or more and/or rigors, chills or other inflammatory symptoms/signs which necessitate stopping the transfusion, medical review and/or hospital admission or prolongation of stay
Allergic type reaction	Transient flushing, urticaria or rash	Wheeze or angioedema with or without flushing/urticaria/ rash but without respiratory compromise or hypotension	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention and/or, directly result in or prolong hospital stay, or anaphylaxis (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes)[29]
Reaction with both allergic and febrile features	Features of mild febrile *and* mild allergic reactions	Features of both allergic and febrile reactions, at least one of which is in the moderate category	Features of both allergic and febrile reactions, at least one of which is in the severe category
Hypotensive reaction		Isolate fall in systolic or diastolic pressure of 30 mm or more in the absence of allergic or anaphylactic symptoms; no/ minor intervention required[30]	Hypotension leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms; urgent medical intervention required

Severity of reactions

Of the reactions that could be classified, 45 were severe, 197 moderate, and 132 were mild. (Cases of moderate and mild reactions are included on the website.)

Severe reactions

Although acute transfusion reactions are rarely associated with death or morbidity, they may present with severe symptoms in the acute situation. Of the 45 severe reactions (which includes the 27 life-threatening reactions in the section on major morbidity), 19 were anaphylactic, 5 were consistent with severe allergy, 14 were febrile, 6 showed mixed febrile and allergic features, and 1 was hypotensive. Reactions can present in any patient irrespective of whether they have experienced reactions previously. This highlights the need for transfusion to take place where there are

adequate resources both for monitoring the patient and for managing acute reactions, particularly anaphylaxis. This also applies to transfusions carried out in community hospitals or at home. (Additional cases of severe reactions are available on the SHOT website.)

Case 3

Anaphylactic reaction complicating massive transfusion

A young woman suffered a large (3 litre) PPH and was given 6 red cell units, 4 units of FFP and 2 pools of platelets. At the time of giving either the platelets or the plasma, she developed urticaria, angioedema, dyspnoea and tachycardia. Her O_2 saturation dropped from 98% to 80%, and her BP, having previously been normal, was unrecordable. She was intubated as an emergency and the cardiac arrest team were called. She was managed with intramuscular adrenaline, hydrocortisone and antihistamine, and settled within 48 hours. Investigations showed that HLA antibodies were present. Blood cultures of the patient were negative. MCT levels remained normal throughout.

Learning point

- Anaphylaxis should be managed according to the guidelines set out by the UK resuscitation council.[29] Patients should be transfused only where there is a member of staff present who is trained in the management of anaphylaxis and has access to appropriate treatment, particularly intramuscular adrenaline.

Other reactions reported as severe

Many incidents reported as acute transfusion reactions have some features which led them to be categorised as severe febrile or hypotensive reactions. However, the symptoms may have been due to other causes.

Case 4

Possible anaphylactic reaction

An elderly woman who was being transfused in a community setting developed itching a few minutes into a transfusion of apheresis platelets. Intravenous chlorphenamine 10 mg was administered. The patient rapidly became hypotensive (lowest BP 76/60) and unresponsive, but slowly recovered after administration of hydrocortisone 200 mg, adrenaline 0.5 mg, and O_2. She was admitted to hospital and discharged 3 days later. This may have been anaphylaxis, but hypotension is a recognised side effect of chlorphenamine.

Reactions which were not possible to classify further

There are 29 cases included in this chapter in which the hospital transfusion teams, using the information present at the time, decided that a diagnosis of acute transfusion reaction was most likely. Further attempts to classify these reactions were not pursued, as management of the patient, and exclusion of other potentially serious causes of the symptoms, should be the main priority of the clinical team, and are not dependent on classification of the reaction type. The following case illustrates some of the diagnostic difficulties that can be encountered.

Case 5

Possible febrile transfusion reaction

An elderly woman who had suffered a fractured neck of femur, dehydration and pressure sores was transfused with 3 red cell units over several days. During the transfusion her temperature rose by 1.9°C, and her blood pressure fell to 64/40. Blood cultures were positive for several species including Pseudomonas, but the unit of blood had been discarded. The transfusion team decided that, despite the patient's complex history, an ATR could not be excluded. The blood service was contacted and a recall of other related components was carried out.

Timing of reaction after start of implicated unit

Where recorded, and excluding 34 cases in which the reaction was reported after the transfusion was completed, the median time of onset of symptoms was 45 minutes. The time of onset differs for different types of reactions as seen in Table 35. It is worth noting that, for all types of reactions except anaphylaxis, which tends to have a more rapid onset, the mean time of onset is greater than 15 minutes, at which time observations are usually first recorded.[19] This emphasises the need for close observation of patients throughout the duration of the transfusion.

Table 35
Median time of onset of reaction by reaction type

Type of reaction	Number of cases where time given	Median time of onset, mins (range)
Febrile	177	60 (1–540)
Allergic	107	40 (1–420)
Anaphylactic	28	15 (1–110)
Mixed febrile and allergic	25	35 (1–195)
Hypotensive	6	20 (15–60)
Unclassifiable	23	60 (5–660)
Total	**366**	**45 (1–660)**

Learning point

- Acute transfusion reactions can occur at any time during the transfusion. Patients require careful observation throughout the transfusion process.

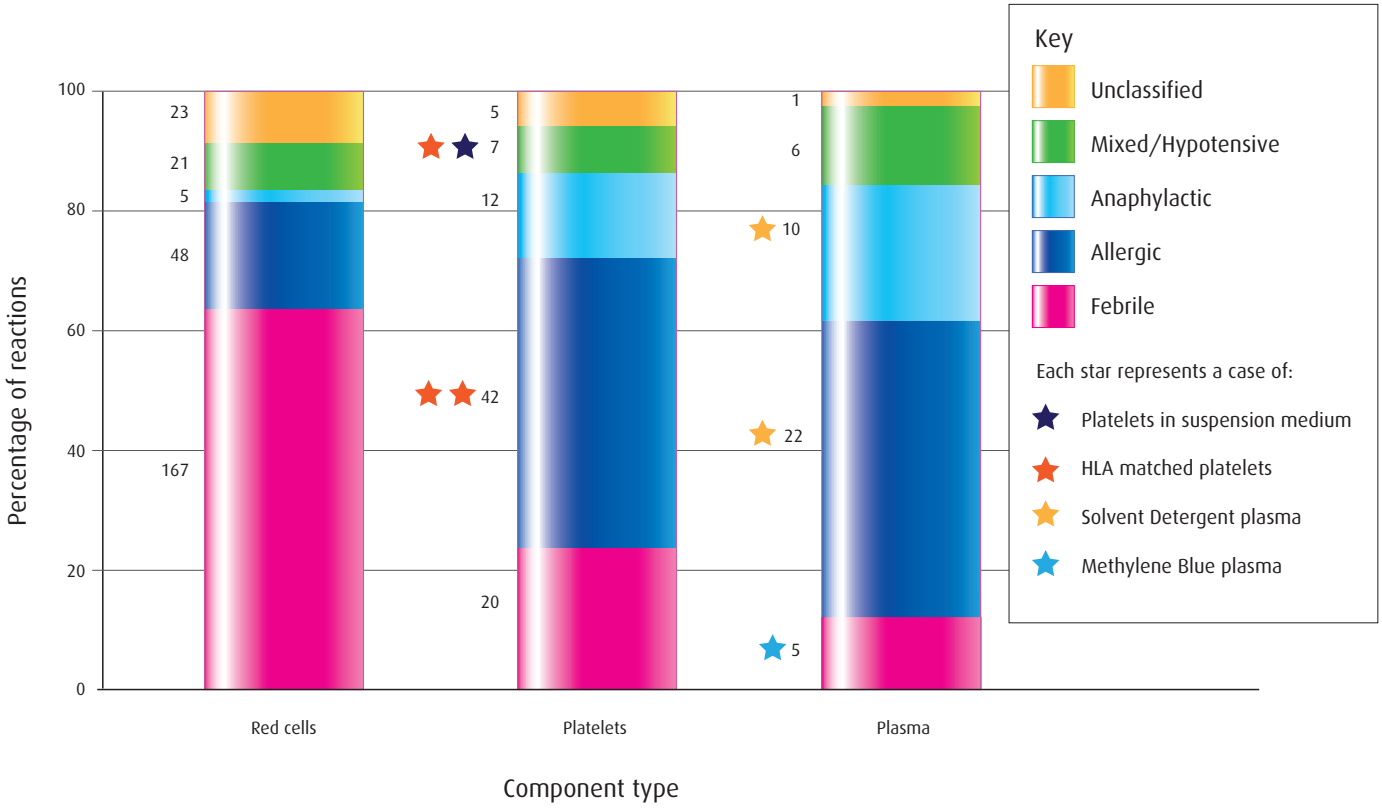
Reactions by component type

The incidence of febrile and allergic/anaphylactic type reactions by component is summarised in Table 36 below. The data in Figure 12 (also below) suggest that febrile reactions are less common with plasma than with red cell or platelet transfusions; allergic or anaphylactic reactions are much more frequent with plasma-rich components, especially platelets.

Table 36
Incidence of reactions by component type

Component	Febrile reactions, incidence per 100,000 units	Allergic or anaphylactic reactions, incidence per 100,000 units
Red cells	7.6	2.4
Platelets	7.5	20.3
Plasma	1.6	10.4

Figure 12
Reaction by component type (excluding 6 reactions which could not be attributed to a particular component)



Management of transfusion reactions

Stopping or slowing the transfusion

Drug treatment of transfusion reactions was covered in the 2008 SHOT Annual Report (page 96). Analysis of 2009 data shows no change in pattern. A breakdown of management of the transfusion (where information was available) is indicated in the table below.

Table 37
Management of the transfusion during ATRs

Action	Number of reports
Continue	6
Stop transfusion	264
Stop temporarily *(not known if restarted)*	21
Transfuse more slowly	7
Transfusion slowed, then stopped	3
Already completed	64
No information	35
Total	**400**

Management of subsequent transfusions

The following comments were received regarding subsequent transfusion management of individual patients:

- Washed components in future 9 reports
- Prophylaxis with antihistamine and/or hydrocortisone 8
- HLA matched components 7
- Blood to be given through warmer 1
- Diuretics to be used 1

Investigations

The value of investigations in ATR was discussed in the 2008 SHOT report. The most commonly performed investigations in 2009 are shown in Table 38 below.

In 101 patients, no investigations were performed: in the majority of these cases the reactions were mild, but 44 moderate and 6 severe reactions were not investigated. In all but the mildest cases, the possibility of other severe causes of adverse reactions such as TRALI, TACO, red cell incompatibility, or transfusion-transmitted infection, should be kept in mind. Core investigations, as set down in the recommendations, should be performed.

Table 38
Commonly performed investigations

Investigation	Number of reports	Number of positive or abnormal results
Bacterial culture of patient and /or unit	96	Patient blood cultures were positive in 13 cases, none of which were associated with positive blood component cultures. Nine of these were isolated febrile reactions reported with red cells. The fever was related to sepsis rather than transfusion, and highlights the difficulties in ascribing imputability. 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	35	Nil significant.
Mast cell tryptase assay	24	In 6 cases MCT rose then returned to baseline. A typical abnormal result is seen in Case 6 below.
Serum IgA levels with or without antibodies	96	Nil.
HLA antibody screen	46	Class I antibodies found in 2 cases.

Case 6

Role of mast cell tryptase (MCT)

An adult male patient who required a chest drain and had platelets of 60 x 10^9/L was given a pool of buffy coat platelets. Twenty minutes after the start of transfusion, he developed a rash, hypotension and dyspnoea. His O_2 sats fell to 50%. The transfusion was stopped, and he was treated with nebulised salbutamol. He improved within 4 hours. MCT was measured – initially 86.2 µg/L, 128 at 4 hours, and 12.1 after 24 hours (normal level < 13 µg/L). Serum IgA was normal and blood and platelet cultures were normal. The pattern of rise and fall of the MCT level is consistent with anaphylaxis,[31] and the history would suggest that this was related to the transfusion.

Bacterial culture of patient and unit

The possibility of transfusion-transmitted bacterial infection should be considered when assessing a patient who is reacting adversely to transfusion, especially when platelets are being transfused. The blood component should be inspected for signs of contamination. If bacterial contamination is considered to be a possibility, the implicated unit should also be cultured and the relevant blood centre informed, so that components from the same donor(s) can be withdrawn as necessary. A revised protocol for hospital sampling is being developed by NHSBT, with advice on the circumstances in which components should be sent to the reference transfusion microbiology laboratory.

Pyrexia and rigors may indicate moderate or severe transfusion reactions, or, more rarely, bacterial transfusion-transmitted infection. This year a number of cases that were referred from hospitals in England and North Wales to the National Bacteriology Laboratory did not meet the criteria for TTI as there was no evidence of the same transmissible infection in patient and donor. The majority of these were not reported to SHOT by the referring hospital. It is recommended that such adverse reactions should be reported because, if a patient has fever or rigors, it is appropriate to record this as an ATR.

A reaction in which the donor was implicated

In this case there was no evidence base to guide investigations on the donor. However, there may be occasions when a transfusion reaction is sufficiently severe, or is accompanied by unusual features such as new cytopenia, when investigation of the donor may be appropriate. Guidance on donor investigations is being prepared by NHSBT.

Case 7

Reactions in multiple recipients

One incident involved 3 infants in the same hospital who received paedipaks from 1 red cell donor, and who all developed rashes which resolved quickly. No investigations of the recipients were performed. The donor was contacted by a blood service consultant, who reported that there was no history of illness or allergy.

Learning points on investigations

- The recommendation that patient HLA, HNA and HPA studies should only be performed in selected cases, after discussion with a blood service consultant, still stands (see below).[32]
- It is striking that, despite concern among clinicians over the risks of transfusing patients who are IgA deficient, there have been no ATR reports related to this in 2009, and only 1 case in the last 5 years. Many aspects of IgA deficiency are in need of further study.[33] In order to determine the true significance of deficiency, and hence produce appropriate guidelines, it is recommended that IgA is measured in all cases of severe allergy or anaphylaxis.
- MCT is the recommended laboratory test to aid in the diagnosis of anaphylaxis, although it does not contribute to management in the acute phase. Patients who have been diagnosed with anaphylaxis should be considered for referral to an allergy clinic for advice on managing future reactions.[29]

Appropriateness of transfusions

From the data available, it can be difficult to assess the appropriateness of the transfusion. However, there were 3 cases of inappropriate transfusion with FFP for warfarin reversal in patients with no, or minor, bleeding. In 4 cases red cell transfusion, in relatively young patients with iron deficiency without evidence of bleeding, appeared inappropriate.

Reporting of ATRs

Forty-nine cases were reported to SHOT only, and not to the MHRA. In 4 cases patients appeared to have experienced minor morbidity as their hospital stay had been prolonged, and these reactions should have been reported to MHRA.[34]

The majority of cases (292) were discussed at the HTC, and this resulted in new local recommendations in 17 instances. Recommendations included: improvement to adverse incident reporting, management plans for a particular patient, and plans to improve training, monitoring, patient assessment or investigation. In 1 case, reinforcement of the hospital's warfarin reversal policy was advised.

COMMENTARY

- The number of acute transfusion reactions reported has increased further this year. This is mainly accounted for by increased numbers of febrile or allergic reactions, as anaphylactic and hypotensive reactions have not increased, and this is likely to be due to better reporting practice.

- Haemovigilance plays an important role in collating information on acute transfusion reactions for which the causes are not well understood, e.g. isolated hypotension. Continued reporting of such cases is valuable so that patterns and causations may be identified.

RECOMMENDATIONS

New recommendations

- All moderate and severe transfusion reactions should have investigations performed. Core investigations should include full blood count, U&E, LFT, repeat group and screen, and urinalysis. Additional investigations should be performed as dictated by the patient's symptoms. Bacterial culture of the patient and unit should be performed if TTI is thought to be a possibility. In such cases, a blood service consultant should be contacted for consideration of recall of associated components from the implicated donation.

  Action: HTCs, HTTs

- IgA should be measured in all patients who experience severe allergic or anaphylactic reactions. Measurement of IgA will help assess the relevance of IgA deficiency, and has clinical relevance for the patient, as it may indicate part of the spectrum of common variable immunodeficiency.[33]

  Action: HTCs, HTTs

Previous recommendations that are still current

Year first made	Recommendation	Target	Progress
2008	It cannot be assumed that all adverse reactions to blood or products are due to an ATR as currently defined in this chapter. Unless the diagnosis is clear, patients whose reactions are moderate or severe* should be fully investigated, with a view to identifying 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 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. * *Previously this recommendation read: '... reactions severe enough to warrant stopping'. However, a review of reports indicates that in nearly all such cases transfusions are discontinued.*	**HTCs, HTTs**	BCSH guidelines in preparation will stress the importance of recognising and managing symptoms.
2008	As the mechanism of ATR is still not clear, the role of unselected testing for HLA, HPA or HNA antibodies appears very limited.[32] 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 testing is indicated. Otherwise, for severe allergic reactions without refractoriness, the next step should be a trial of PAS-suspended platelets, or washed components, before embarking on HLA testing.	**HTCs, HTTs**	This will be stressed in the forthcoming BCSH guideline.
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.	**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.

12. 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 one or more of: 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 which was *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	**47**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**46**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths in which reaction was implicated	**0**
		Platelets	**1**	Major morbidity	**8**
		Other (specify)			
		Unknown			

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**21**	18 years+	**45**	Emergency	**6**	ED	
Female	**26**	16 years+ to 18 years	**0**	Routine	**37**	Theatre	
Unknown	**0**	1 year+ to 16 years	**2**	Not known	**4**	ITU/NNU/HDU/Recovery	
		28 days+ to 1 year	**0**			Wards	
		Birth to 28 days	**0**	In core hours		Community	
		Unknown	**0**	Out of core hours		Outpatient/day unit	
		Total	**47**	Not known/applicable	**47**	Not known	**47**

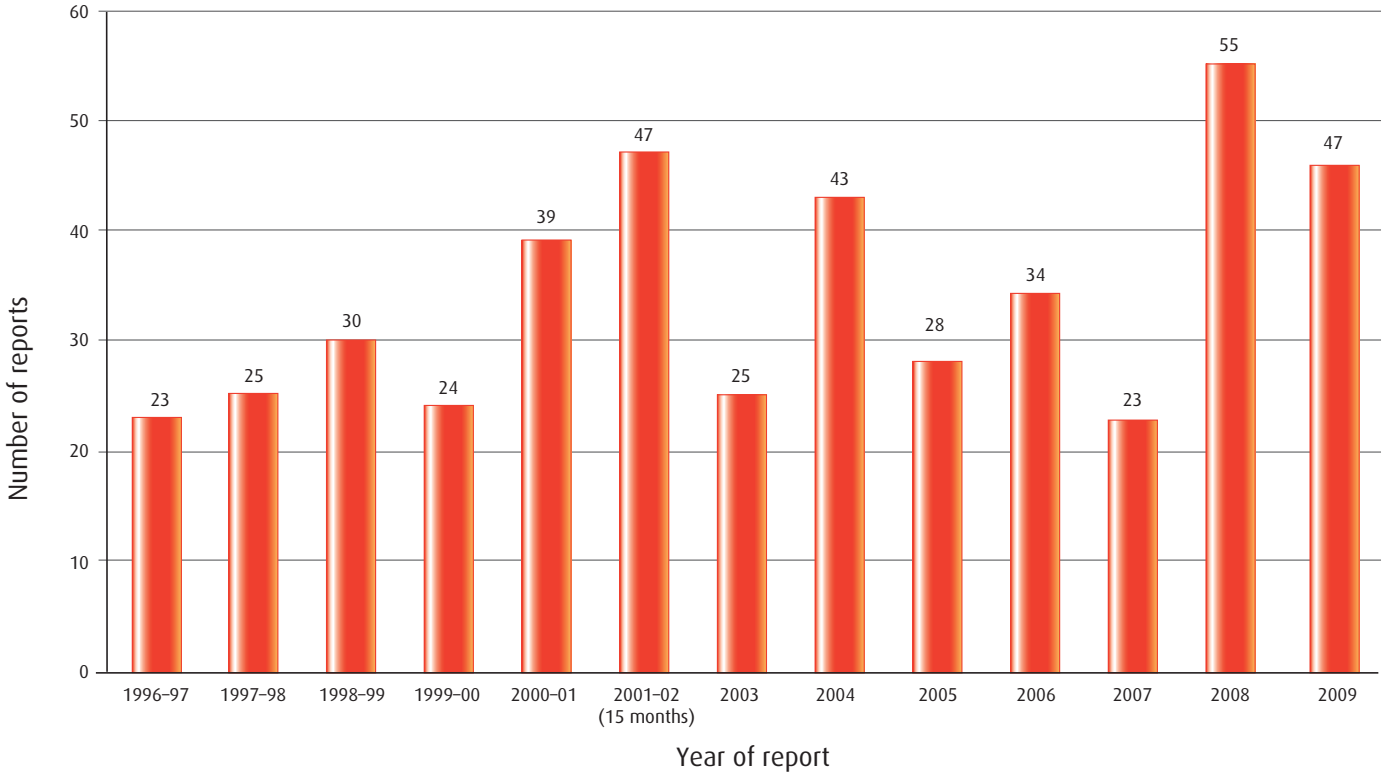
Sixty questionnaires were received; 9 were transferred out, 6 to the IBCT and 3 to ATR; 4 were withdrawn. This section describes the findings from 47 cases: 8 acute and 39 delayed reactions.

Patients

There were 21 male and 26 female patients, with an age range from 4 to 94 years old.

Two patients were under 18 years of age: 2 patients with sickle cell disease (SCD), aged 4 and 7, each of whom suffered a DHTR with anti-Jk^b and anti-S implicated respectively. The latter may have been preventable with better communication between hospitals, but probably also included an element of hyperhaemolysis.

Figure 13
Number of cases of HTR reviewed since 1996



Mortality, Morbidity, and Imputability

Acute haemolytic transfusion reactions (AHTR) *n* = 8

There were no deaths caused, or contributed to, by these transfusion reactions. There were 3 cases of major morbidity; one patient (A4) required ITU admission, while the other 2 (A7, A8) showed signs of deteriorating renal function.

Four reactions were reported as definitely related to the transfusion (imputability 3), 3 probably related (imputability 2), and 1 possibly related (imputability 1).

Delayed haemolytic transfusion reactions (DHTR) *n* = 39

There were 2 patients in this group who died from underlying disease, not related to the transfusion reaction. There were 5 cases of major morbidity. One patient (D10) required dialysis, but made a full recovery. One patient with SCD (D34) required ITU admission following a severe episode of hyperhaemolysis. The other 3 cases showed signs of deteriorating renal function, but did not require dialysis.

Of the remaining 32 cases, 23 patients suffered minor morbidity and 9 had no clinical signs or symptoms. One patient did not even develop a positive DAT, but the case is included in this chapter because of its unusual nature (D39). From 2010, the Dendrite database will accept reports of simple antibody formation without a positive DAT or any other signs or symptoms.

Case D39

Development of multiple red cell antibodies following platelet transfusion

An elderly patient with MDS received a total of 25 adult doses of platelets but no red cells, over a period of approximately a year, and developed anti-c, -E and -A_1, followed by anti-K, -S, -Fy^b, and -Jk^b. There were no clinical or laboratory signs of a haemolytic reaction. The patient finally developed platelet antibodies (anti-HPA-2a) in addition to his red cell antibodies.

Learning point

- Components containing any residual red cells can elicit an immune response.

Timing of reaction in relation to transfusion

AHTR

All the reactions occurred either during the transfusion or soon afterwards, with between 35 mL and the whole unit being transfused.

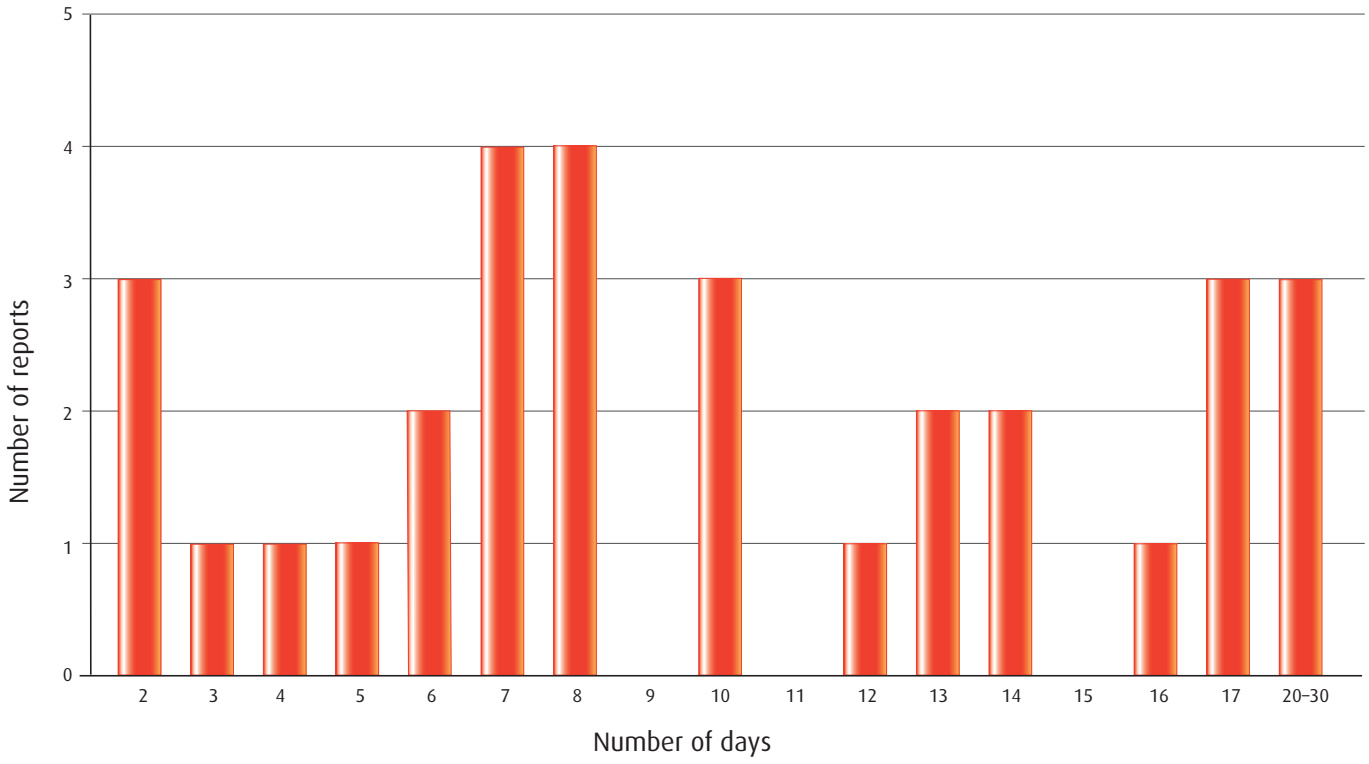
DHTR

Figure 14 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 to 26 days. New antibodies were found between 7 days and 10 weeks after transfusion in the 8 asymptomatic cases.

Serological findings – AHTR *n* = 8

All these cases have good laboratory evidence to support a haemolytic episode. However, these are complex cases and many of the antibody specificities identified are not usually associated with haemolytic transfusion reactions, e.g. Knops, Bg, and weak C^w. In other cases an antibody developed some time after the reaction and it is difficult to draw firm conclusions. Identification of an antibody does not necessarily mean that it is the cause of the reaction, and other causes such as bacterial contamination should also be considered, as should other unidentified or undetectable antibodies.

Figure 14
Interval between administration of implicated transfusion and signs or symptoms of DHTR



Antibody only detectable in eluate

Case A1

A patient with SCD with known anti-D received 2 units of red cells. Ten days later she received a further 4 red cell units over 4 days. At the end of the last unit, she became pyrexial and tachycardic, and haematuria was noted, all thought to be due to sickle cell crisis and medications. Two days later her Hb dropped from 7.4 to 5.0 g/dL. The only antibody detected in the plasma was anti-D, but anti-S was detected in an eluate. The 2 earlier units and 3 of the 4 later units were confirmed to be S positive, including the unit to which the patient reacted. With hindsight, the patient probably suffered a mixture of acute and delayed HTRs due to anti-S.

Delayed detection of antibody

Case A2

An elderly patient required 2 units of red cells postoperatively. She had a 1.6°C rise in temperature during the second unit and the transfusion was stopped. Her Hb fell from 11 to 8.5 g/dL over 6 days, at which point anti-Jk^a was identified. Bilirubin levels began rising and Hb falling within 24 hours of the transfusion, suggesting that this was an AHTR rather than an isolated febrile reaction followed by DHTR.

Case A6

A patient requiring blood for postoperative anaemia had a history of weak, non-specific reactivity by IAT. On this occasion the antibody screen was negative and red cells were compatible by IAT. Approximately three-quarters of the way through the first unit, the patient suffered fever, chills, rigors and dark urine, and the transfusion was stopped. Weak anti-Kn^a/McC^a was confirmed by IBGRL. However, 6 months later anti-Jk^a was identified in addition to the Knops antibody, with no evidence of intervening transfusion. Knops antibodies are not considered to be of clinical significance, but it is not clear whether the AHTR was caused by undetectable anti-Jk^a or something else.

Uncertain cause of reaction

Case A3

A patient with SCD and a history of multiple antibodies (anti-E, -Fy3, -Jk^b, -McC^a and anti-HI), was issued with red cells suitable for transfusion. After 60 mL had been transfused, she suffered fever, headache, loin pain, jaundice and dark urine. No further red cell alloantibodies were identified.

Case A4

A patient with anti-K, -C, enzyme-only auto-anti-e and a positive DAT was transfused with crossmatch compatible red cells. Towards the end of the unit, the patient developed a fever, dyspnoea and laboratory signs of haemolysis, and was admitted to ITU. No further antibodies were identified and it was thought that the transfusion exacerbated auto-immune haemolysis. A DHTR due to anti-C from transfusions 11–15 days earlier cannot be excluded.

Case A7

A patient with chronic anaemia became pyrexial after the third unit of red cells; this was followed by haemoglobinuria and deteriorating renal function. Anti-E and a pan-reactive autoantibody were identified in the post-transfusion sample only, by enzyme techniques only. The anti-E gradually became detectable by IAT and the DAT became weakly positive; however, an eluate was negative. All 3 units transfused were E negative. Transfusion of E negative blood a few days later caused a similar reaction. The patient's Hb increased following treatment with high dose steroids. It is not clear whether this reaction was due to an undetectable alloantibody, autoantibody, or something else.

Case A8

A patient with known anti-E and a non-specific cold antibody received 3 units of red cells compatible by NISS IAT. At the end of the third unit the patient developed fever, dark urine and jaundice. There was a rise in bilirubin, and a 2.0 g/dL fall in Hb. Anti-E and weak anti-C^w were identified in the post-transfusion sample, and retrospectively in the pre-transfusion sample using DiaMed and PEG IAT. An eluate revealed weak anti-C^w and the first unit was confirmed as C^w positive. However, the patient had a positive DAT before transfusion (IgG coating), was on high dose antibiotics, and had hypersplenism. The haemolysis continued for some time after the transfusion, and the patient required no further transfusion post splenectomy. The reporter concluded that the haemolysis was unlikely to have been due to the anti-C^w.

HLA antibodies apparent cause of AHTR

Case A5

Having been transfused 100 mL for symptomatic anaemia, a patient suffered nausea, vomiting, rigors, fever, abdominal and knee pain, tachycardia and hypotension. Her O_2 saturation fell to 90%. She required resuscitation with O_2 and fluids. Immediate symptoms were followed by signs of haemolysis. Pre- and post-transfusion antibody screens were negative and blood was issued electronically. Although the DAT was positive (IgG coating) on both the pre- and post-transfusion samples, an eluate was non-reactive. Anti-C and a pan-reactive autoantibody were detected using a 2 stage enzyme; a retrospective IAT crossmatch was initially incompatible, but the antibody was not identified. Three weeks later a further incompatible unit was found. Further testing showed the patient's plasma to be positive against HLA A28, B7 and B17 (Bg^c, Bg^a, Bg^b, respectively). The implicated donor was typed as HLA-B57 (a subgroup of B17); the serological incompatibility was not confirmed by IBGRL, but a CDC crossmatch was positive. Although the serological picture is not clear, this appears to be an acute haemolytic transfusion reaction due to Bg antibodies.

Learning points

- The patient's clinical condition can obscure the diagnosis of an acute haemolytic reaction.
- Testing an eluate is an important part of investigating an HTR.
- Presence of an alloantibody does not prove cause and effect.

Serological findings – DHTR *n* = 39

Kidd (Jk) and Rh alloantibodies were the most common, present in 18/39 and 19/39 (46 and 49%) cases respectively, either singly or in combination with other specificities.

Table 39 shows details of the serology, laboratory signs and time interval by case, and Table 40 shows the specificity of new antibodies detected post transfusion, by blood group system.

Table 39
Serology, laboratory signs and timing of reaction

Case no.	New antibody(ies) in plasma	Antibodies in eluate	Comments	Days post transfusion
1	K	Not performed	Hb↓ bilirubin↑; dark urine	7
2	C	None	Hb↓ bilirubin↑ creatinine↑	8
3	Jk^a	Not performed	bilirubin↑	17
4	K, c	Not performed	Hb↓ bilirubin↑ dyspnoea, hypotension	13
5	Jk^a	Jk^a	No signs or symptoms	14
6	Jk^a, K, warm auto	Jk^a	Hb↓	3
7	Jk^b	No specificity	Hb↓ bilirubin↑; fever during transfusion; known anti-K	10
8	K	Not performed	No signs or symptoms; died unrelated	7
9	C, E, auto-D	E	Hb↓ bilirubin↑. Normal D gene confirmed – presumably auto anti-D	13
10	Jk^a, E	Not performed	Hb↓ bilirubin↑↑; dyspnoea, hypotension, fever	10
11	E	E	No signs or symptoms; prob. primary response	10 weeks
12	Jk^a	None	bilirubin↑, poor Hb increment	16–18
13	D	Not performed	bilirubin↑	5–8
14	Jk^a	Not performed	Hb↓ bilirubin↑	17
15	c	Not performed	Hb↓	14
16	C	Not performed	no Hb increment. Known anti-Jk^a	?26
17	c	c	Hb↓ Hburia (?UTI)	4
18	Lu^a	Jk^a	No signs or symptoms	54
19	Jk^b	None	Hb↓ bilirubin↑ creatinine↑; known anti-c	7
20	Jk^a	Jk^a	Hb↓	22
21	Fy^a	Not performed	Hb↓ bilirubin↑	6
22	Jk^a	Jk^a	Hb↓	10
23	C, E	None	No Hb increment	??
24	Jk^a	Not performed	No signs or symptoms	10
25	Jk^b	Jk^b	Hb↓ bilirubin↑	23
26	Jk^a, C^w, auto	Jk^a + panagg	Hb↓ bilirubin↑	6
27	c	Not performed	Hb↓ bilirubin↑ LDH↑; known anti-E	17
28	E+K	K	No signs or symptoms	16
29	Jk^a	Jk^a	Hb↓	8
30	None	None	Hb↓ Hburia, methaem	7
31	E	E	bilirubin↑ creatinine↑	2–3
32	S (detected previously elsewhere)	Not performed	Hb↓↓ bilirubin↑; known anti-M (+S); also ?hyperhaemolysis	1–2
33	K	K	No signs or symptoms	74
34	Fy^a, Fy3, S	Not performed	Hb↓↓ dark urine, LDH↓, ?hyperhaemolysis	7
35	S, Jk^b	S+Jk^b	No signs or symptoms. Known anti-E	12–14
36	Fy3	Inconclusive	Hb↓↓ bilirubin↑↑ dark urine. Known anti-Fy^a+Jk^b+M. SCD	2
37	Jk^b	Jk^b M	Hb↓↓ bilirubin↑↑ Hburia	8
38	D	D	No signs or symptoms	28
39	E, c, A_1, K, S, Fy^b, Jk^b	None	No signs or symptoms; platelet transfusions only	? 2 months

Serological techniques used – DHTRs only

Antibody screening was undertaken using a variety of automated systems, broadly representative of those used routinely in the UK. Of those answering the question, 19 undertook an IAT crossmatch (7 of these had a positive antibody screen), 3 an immediate spin, and 14 electronic issue.

Use of eluates

In 24/39 (62%) of cases an eluate was made from the patient's post-transfusion red cells and tested for antibody. This is similar to last year (63%). Of these eluates, 17 were performed in reference laboratories and 6 in-house (one unknown). In 16 cases (67%) a specific antibody(ies) was identified. In 1 case (D18), anti-Jk^{a} was detectable only in the eluate.

Retrospective testing findings

Retrospective testing of the pre-transfusion sample was undertaken in house in 7 (18%) cases: the same results were obtained in all 7 cases. However, in 4/7, no different or additional testing was undertaken, and none was confirmed by a reference centre. In most cases the pre-transfusion sample had been discarded, even though in 2 cases the reaction occurred within 3 days of transfusion.

DHTR cases

Case D34

Major morbidity in patient with sickle cell disease

A female patient with SCD and a history of transfusion but no alloantibodies had an 8 unit red cell exchange. Seven days later she returned to the ED with several signs of severe haemolysis, her Hb having fallen from 10.4 g/dL to 4.2 g/dL. The reporter queries an element of hyperhaemolysis as well as DHTR. The DAT was strongly positive with IgG coating, and anti-Fy^{a}, -Fy3 and -S were identified in the plasma, but no eluate was performed. The patient required ITU admission but made a full recovery. As a result of this reaction, the hospital is changing its transfusion policy for patients with SCD, to give Fy(a-) red cells to Fy(a-) individuals.

Case D32

A 7-year-old patient with SCD and a historical record of anti-M, not currently detectable, was transfused with 2 units of M negative red cells (Rh and K matched). The Hb fell from 8.6 g/dL immediately post transfusion to 4.1 g/dL 48 hours later, 1 g/dL lower than the pre-transfusion Hb of 5.1 g/dL. Other signs of haemolysis were dark urine, and rising bilirubin and LDH. The patient was transferred to a second hospital which the patient had attended 2 months earlier, when anti-S had been identified in addition to anti-M. One of the units transfused had been S positive, and the patient was found to have a positive DAT, though an eluate was non-reactive. Anti-S and anti-M became detectable 3 days post transfusion. This appears to be a case of HTR due to anti-S combined with hyperhaemolysis.

Learning points

- '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 hospitals should actively seek a transfusion and antibody history.
- Where care is shared between hospitals there should be a system for communicating important serological information between sites.

Case D30

No specificity identified

A woman required an emergency transfusion of 5 units of red cells and 2 units FFP at delivery. Nine days later her DAT was weakly positive, Hb had fallen by 3 g/dL, haptoglobins became undetectable and LDH was raised. The blood service identified weak anti-C by enzyme techniques only and obtained a strong reaction with a single panel cell, but were unable to identify a specificity. The patient had received a massive transfusion at delivery several years earlier.

Table 40
DHTRs – New specificities by blood group system

Antibody specificity by blood group system	No. cases	Sole *new* antibody
Kidd		
Jk^a	12	8
Jk^b	6	4
Rh		
C	4	
E	7	2
c	5	2
D	2	3
C^w	1	2
Auto anti-D	1	
Kell		
K	7	3
Duffy		
Fy^a	2	1
Fy^b	1	
Fy3	2	1
MNSs		
S	4	1
M	1	
Other		
Lu^a	1	
A_1	1	

COMMENTARY

- Antibodies not commonly associated with haemolytic transfusion reactions were identified in several patients following AHTRs. It is likely in some cases that these antibodies were not responsible for the reaction.
- Patients with sickle cell disease are once again prominent in both AHTR and DHTR cases. These patients are particularly vulnerable to haemolytic reactions as they have a higher incidence of sensitisation, are prone to episodes of hyperhaemolysis and have clinical symptoms which can mask HTRs. In addition they often move between different treatment centres. As the result of a serious DHTR, one centre has changed its policy to routinely provide Fy(a-) blood to Fy(a-) patients with SCD.
- HLA antibodies (Bg) were apparently the cause of a severe AHTR. Although Bg antibodies are usually benign, there have been a few associated cases of HTR reported in the literature.[35,36]
- In 3 cases (one acute, and 2 delayed), an antibody specificity was identified in an eluate made from the patient's post-transfusion red cells which had not been detected in the plasma. This highlights the vital role played by this test in the investigation of an HTR.

RECOMMENDATIONS

There are no new recommendations this year; however, previous recommendations remain relevant and those in the table below are pertinent to this year's report. The second, recommending a national register of patients with antibodies, is now redirected to the newly formed IT subgroup of the NBTC and its counterparts in Scotland, Wales and Northern Ireland.

Previous recommendations relevant to this year's report

Year first made	Recommendation	Target	Progress
2008	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.	**Hospital blood transfusion laboratories**	The Shared Care document is now nationally available and can be used for patients with sickle cell disease. www.sicklecellsociety.org/pdf/CareBook.pdf
2008	A national register of patients with antibodies, linked between the red cell reference laboratories, should be considered.	**UK blood services**	For 2010 this task is directed to the newly formed IT subgroup of the NBTC.
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 last year, compared with 35% in 2006 and 50% in 2005, suggesting sustained progress.
2001/02	Consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being crossmatched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.	**The CMO's NBTC and its counterparts in Scotland, Wales and Northern Ireland**	This recommendation was made in the BCSH Guidelines (BCSH 2004).

13. 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	**21**	*Implicated components*		*Mortality/morbidity*	
Highly likely/probable	**9**	Red cells	**2**	Deaths due to transfusion	**0**
Possible/unlikely	**12**	FFP	**2**	Deaths in which reaction was implicated	**2**
		Platelets	**3**	Major morbidity	**18**
		Red cells and cryo	**1**		
		Unknown	**13**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**9**	18 years+	**19**	Emergency		ED	
Female	**12**	16 years+ to 18 years	**2**	Routine		Theatre	
Unknown	**0**	1 year+ to 16 years	**0**	Not known	**21**	ITU/NNU/HDU/Recovery	
		28 days+ to 1 year	**0**			Wards	
		Birth to 28 days	**0**	In core hours		Community	
		Unknown	**0**	Out of core hours		Outpatient/day unit	
		Total	**21**	Not known/applicable	**21**	Not known	**21**

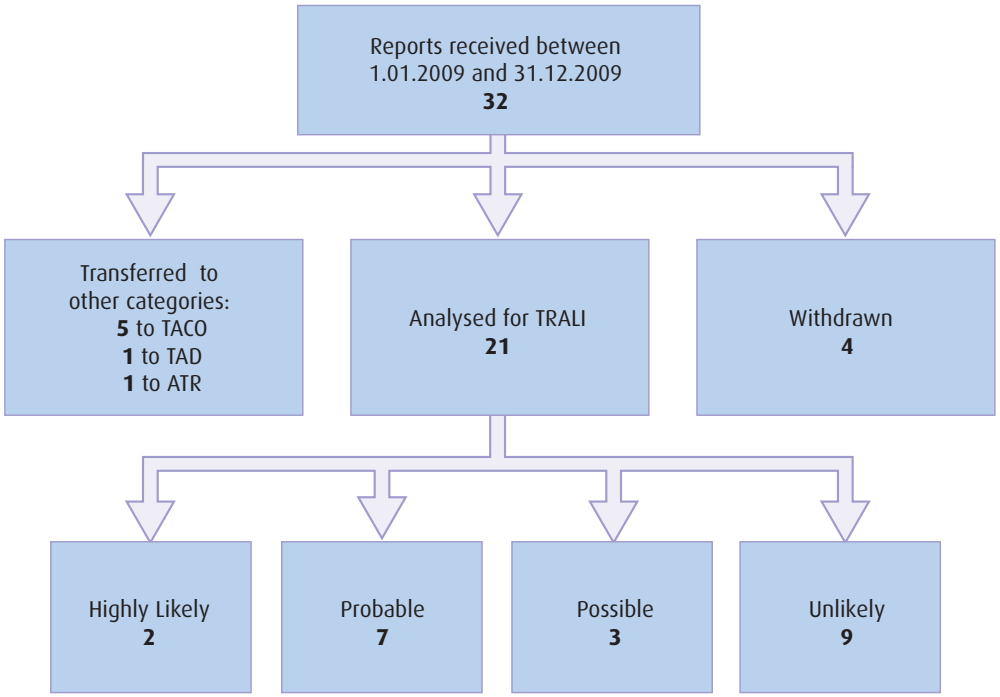
In all, 32 questionnaires were received in 2009: 7 were transferred to other categories – 5 to TACO, 1 to TAD and 1 to ATR – and 4 were withdrawn, leaving 21 reports in this section.

Two of the 4 withdrawn cases were withdrawn by the hospital reporter. One occurred before transfusion and the other was found to have bronchopneumonia. The other 2 cases were withdrawn by the analyst because they did not meet the SHOT definition for TRALI:

- 1 reaction occurred more than 6 hours after transfusion (12 to 24 hours) and there had been no change in respiratory status.
- 1 patient with severe alcoholic liver disease developed worsening respiratory function before transfusion began. This patient had been treated with palliative care because of poor prognosis.

Twenty-one cases were analysed and the assessed probability of TRALI is shown in Figure 15. Two patients died, 1 had probable TRALI after RBC (Case 1, page 113) and the other had possible TRALI after RBC and FFP (Case 3). All other patients recovered fully from the event. Seven of 21 analysed cases concerned late reporting of incidents which had occurred in 2008.

Figure 15
Summary of cases



Assessment of TRALI Cases

There is no diagnostic test for TRALI and it is easily confused with other causes of acute lung injury, circulatory overload or infection. More than one cause may have contributed to the respiratory impairment in many cases and TRALI may co-exist with other conditions. The likelihood of TRALI has been assessed in each case. Clinical factors which influence this assessment of cases include: time from transfusion to 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 to 48 hours and response to diuretics. Serological results are also taken into account. Cases are still included in this report if it is thought that both TRALI and another risk factor such as cardiac failure contributed to the clinical events.

Two intensive care specialists and a transfusion medicine expert (TRALI expert panel) have initially assessed the cases concerning NHSBT components (17 of 21 cases) before laboratory investigation has commenced. NIBTS are now also referring cases to the intensive care specialists for assessment. A transfusion medicine specialist, who has previously reviewed SHOT TRALI cases for the past 6 years, has subsequently assessed all cases including the results of TRALI investigations. Complete results of investigations were not available in 4 cases; 1 of these was not investigated because the TRALI expert panel considered that the clinical picture was much more likely to be due to alternative reasons.

As in previous years, cases were divided into 4 groups (as shown in Figure 15):

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 Canadian Consensus Criteria[37,38]

All 21 analysed reports and the 4 withdrawn cases were also classified using the Canadian Consensus Criteria. This gave the following results:

- TRALI 5
- Possible TRALI 12
- Outside criteria 8

The cases which were outside the consensus criteria had features of cardiac failure (6), bronchopneumonia (1) and delayed event with pneumonia (1).

Website tables

Data extracted from individual TRALI questionnaires and laboratory results are tabulated on the SHOT website www.shot-uk.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, outcomes, investigation results and likelihood of case being TRALI.

Age

Patient ages ranged from 16 to 85 years with a median age of 50. Two patients were aged less than 18 years (one was aged 16 and the other 17; both cases were classified as probable TRALI).

Clinical specialty

This year the most frequent specialty was surgery (7 cases) followed by haematology/oncology (6), general medicine (5) and obstetrics and gynaecology (3).

Analysis of cumulative figures since 1996 from 257 reports of suspected TRALI has shown that haematology/oncology combined has provided the highest number of reports of suspected TRALI (89, 35%) and surgery the second highest (83, 32%). General medicine was reported as the specialty in 30 cases (12%). Denominator data are not available.

Clinical features

Clinical presentation

All cases, by definition, had been dyspnoeic and hypoxic with CXR features of acute lung injury. Eighteen patients were treated in ITU; of these 5 were already on ITU before the event. Ten patients required mechanical ventilation continuing between 1 and 22 days (median 3 days). Fever and/or rigors were present in 3 patients, absent in 16 and not recorded in 2. Hypotension was part of the event in 8 cases, absent in 12 and not recorded in 1.

Patient outcomes

Two patients died; 1 case was probably related to TRALI (Case 1) and the other possibly related to TRALI (Case 3). Nineteen patients made a full recovery from the event.

Laboratory results

All cases were referred to the BTS and 20 were subsequently investigated at reference laboratories. TRALI investigations were incomplete in 3 of the referred cases.

Donor antibodies

Concordant donor HLA antibodies were found in donors of components transfused within 6 hours of the event in 8 cases (5 HLA class I only, 2 both HLA class I and class II, and 1 with HLA class II only). No case had proven concordant granulocyte antibodies but 1 recipient of massive transfusion received cryoprecipitate containing HNA-3a antibodies in addition to components from 4 other donors with concordant HLA class I antibodies. In this case, a sample from the patient was not obtained for crossmatch to assess concordance of the HNA-3a antibody but the frequency of HNA-3a is 99% in Europeans making it highly likely that it would have been concordant.

All donors found to have concordant leucocyte antibodies were female. Males with a history of transfusion were investigated but none was identified with concordant antibodies. Untransfused males were generally investigated only if all other donors had been investigated and excluded and no other likely cause for respiratory deterioration was present. All individuals who have been transfused since 1980 have been excluded from donation in the UK since 2004.

Patient antibodies

Testing for HLA and HNA antibodies in patients is no longer routinely performed because all components except granulocytes are now leucodepleted in the UK. Such testing is now confined to recipients of granulocytes (apheresis or buffy coat).

Components

All implicated components with proven concordant donor leucocyte antibodies were donated by females. Platelet pools were implicated in 3 cases; in each of these the implicated donor had contributed only a buffy coat to the unit. Two cases followed female FFP and 3 followed RBC OA. All cases which occurred following relatively little transfused plasma (buffy coats and RBC OA) also had other factors which may have caused or contributed to the events.

The reported risk of TRALI in 2009 following transfusion of components with concordant donor leucocyte antibodies was 1 in 6884 issued units of female FFP and 0 cases following male FFP, 1 in 88,771 units of platelets, 1 in 121,555 units of cryoprecipitate, and 1 in 736,384 RBC.

Table 41
Cases with concordant donor antibodies – specificities and implicated components

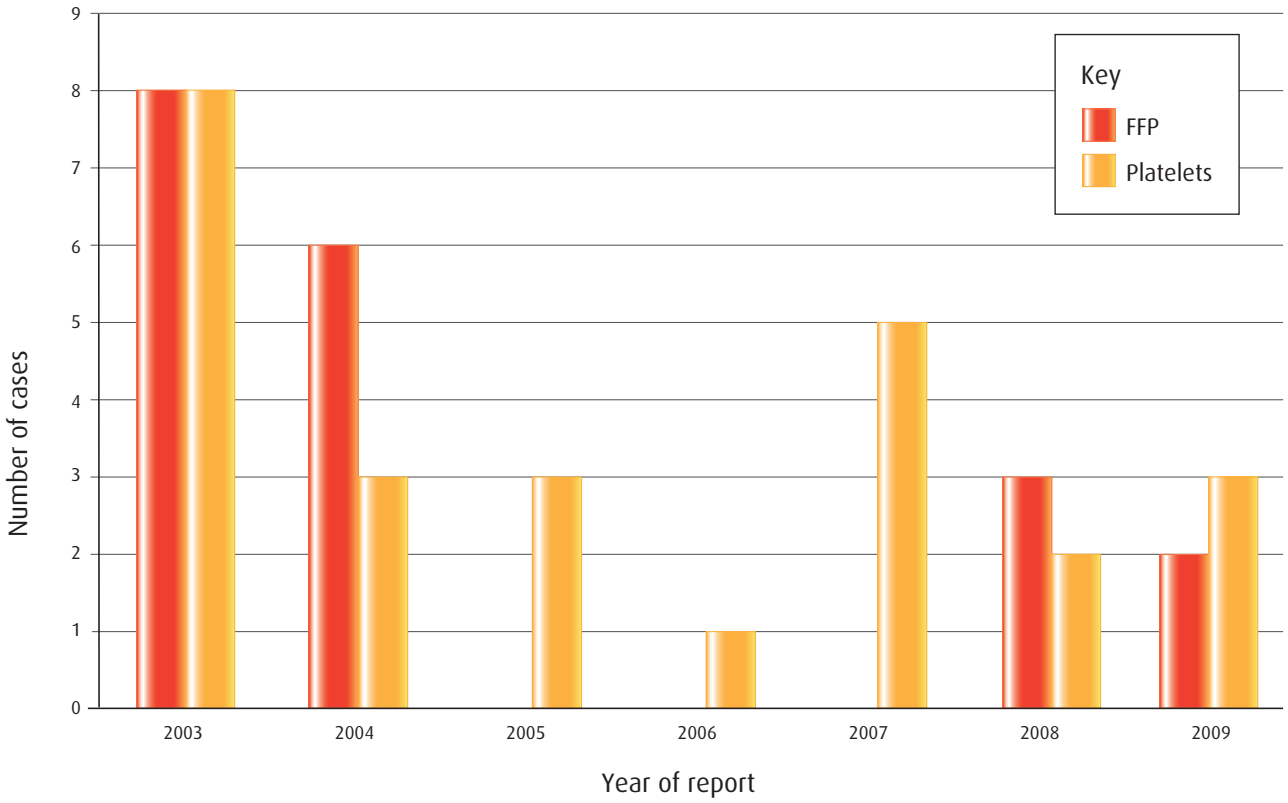
ANTIBODY	SPECIFICITY/IES	COMPONENT/S *	OTHER RISK FACTORS
HLA class I	HLA-B8	FFP	None
HLA class I	HLA-B45	Platelet pool (buffy coat only)*	Possible left ventricular failure
HLA class I	HLA-B35	RBC OA	Sepsis
HLA class I	HLA-A26, B60	Platelet pool (buffy coat only)*	2.1 L positive fluid balance
HLA class I	HLA-B44, Cw7	RBC OA x 3, cryoprecipitate x 2	Multiple trauma, shock, pulmonary contusions, rib fractures, massive transfusion
HLA class I and class II	HLA-B60, DR13, DR52, DQ6	RBC OA	Ischaemic heart disease, pitting oedema to below knee before transfusion
HLA class I and class II	HLA-A2, DR13, DR52, DQ6	FFP	None
HLA class II	HLA-DR53	Platelet pool (buffy coat only)*	Signs of cardiac failure

** 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.*

Comparative data on implicated components since 2003

TRALI cases associated with concordant leucocyte antibodies have been analysed by implicated component from 2003 to 2009. Results are shown in Figure 16. Disappointingly, a further 2 cases of TRALI have been reported this year following implicated female donor FFP (one was actually transfused in 2008 and the other in 2009).

Figure 16
Cases of TRALI with concordant donor antibody in FFP or platelet components 2003–2009



Annual reports and deaths 1996–2009

The annual number of reports of suspected TRALI and deaths at least possibly due to TRALI each year from 1996 to 2009 are shown in Figures 17 and 18. 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.

Owing to the time taken to complete TRALI investigations on donors, some cases are reported in the calendar year following the one in which the transfusion reaction occurred.

Figure 17 shows the annual number of reports based upon the date of receipt of the completed SHOT questionnaire.

Figure 17
Deaths at least possibly due to TRALI and number of suspected TRALI reports by year

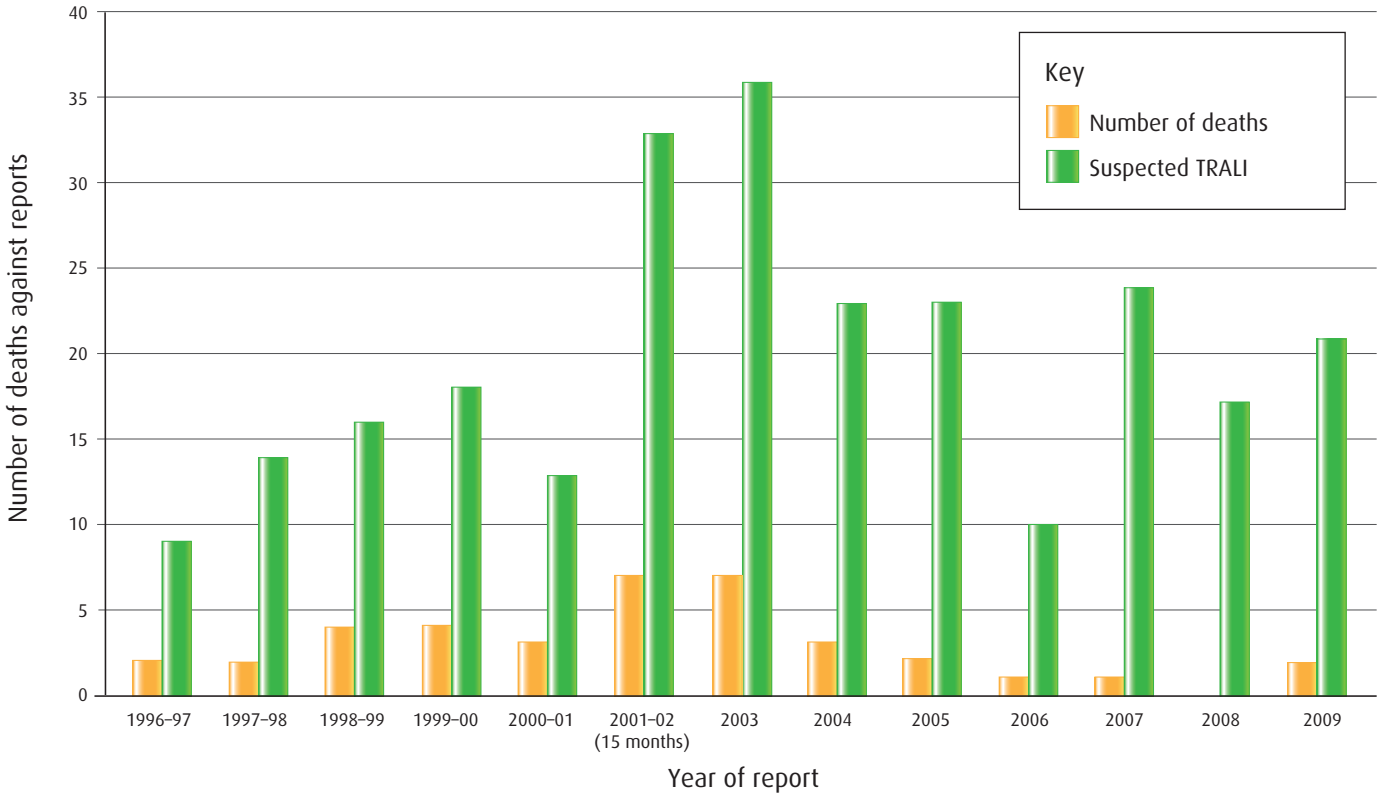
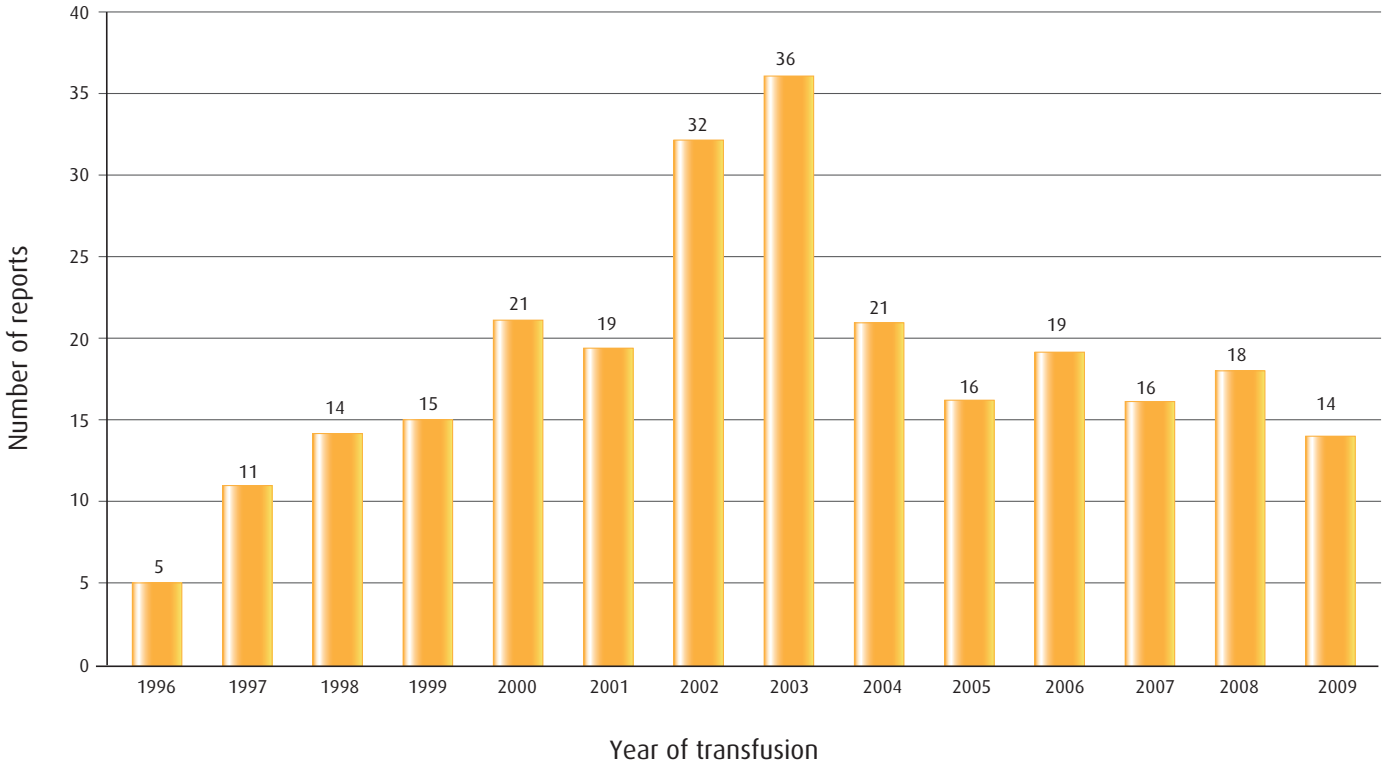


Figure 18 presents the annual numbers of completed reports analysed by year of transfusion instead of year of report.

Figure 18
TRALI by year of transfusion *n* = 257



Case Histories

TRALI probable

Case 1

Probable TRALI following transfusion of RBC OA to treat symptomatic tumour anaemia

A man had disseminated rectal cancer plus severe coronary artery disease, left ventricular hypertrophy, and bilateral peripheral oedema extending to just below his knees. He was transfused with 3 RBC OA units. Six hours later during transfusion of the third unit he developed chills, rigors, breathlessness, wheeze, and his JVP was raised. He died an hour later. At postmortem he had severe pulmonary oedema with no evidence of MI or PE. Lung histology showed increased numbers of neutrophils in the interstitial fluid.

Investigations revealed that the female RBC donor of the third unit had multiple HLA class I and class II antibodies concordant with patient HLA-B60, DR13, DR52 and DQ6. The implicated blood pack was also cultured for bacteria and grew *Enterobacter* species, *Pantoea* species and *Enterococcus faecalis* but, because the blood pack had been unspigoted, these findings were considered most likely to have been due to contamination (as discussed in the SHOT Annual Report 2008, page 128). This case was assessed as probable TRALI because cardiac failure may also have contributed to the pulmonary oedema.

TRALI highly likely

Case 2

TRALI follows receipt of female FFP during treatment of TTP

A patient received 4 units FFP and was being transferred to another hospital between 2 and 6 hours later when she suddenly developed respiratory distress. The ambulance diverted to the nearest hospital where the patient became increasingly hypoxic and hypotensive. Her chest was described as 'bubbly' and her CXR as 'bilateral white-out'. She suffered cardio-respiratory arrest from which she was successfully resuscitated but required mechanical ventilation for 2 days. She made a full recovery from this event.

One female donor was found to have multiple HLA class I antibodies including HLA B8 antibodies concordant with this patient. This case was assessed as highly likely to be TRALI.

TRALI possible

Case 3

Middle-aged woman developed possible TRALI after transfusion to treat variceal bleeding

This patient had cirrhosis, portal hypertension and a large gastric varix. She was admitted with Hb 3.7 g/dL following upper GI bleeding. She received 4 packs of RBC over the next 3 days for continued GI bleeding. Six days after admission she bled further and E. coli was cultured from her urine. She had repeat endoscopy and injection of a bleeding gastric varix. Terlipressin was commenced and she was transfused with 1 unit of male RBC OA which was discontinued due to a febrile reaction. Five hours later transfusion was recommenced. After 1 male FFP and 2 male RBC she developed a drop in O_2 saturation from 100% to 94% and was started on O_2 support 4 L/min with improvement. She then received 1 male FFP and 2 female RBC OA units. Her respiratory rate gradually increased and CXR around 9 hours after the initial drop in O_2 level was reported as 'suboptimal inspiration... but there is strong impression of bilateral airspace shadowing compatible with consolidation'. Terlipressin was discontinued with some symptomatic improvement. A few hours later she had cardiopulmonary arrest and resuscitation was unsuccessful. Postmortem examination found pulmonary oedema and early stage ARDS but no evidence of MI.

The 2 female RBC donors were tested: the male donors were excluded from investigation. One female donor had HLA class II antibodies with concordance at HLA-DR51 and DQ6 but this donation had not been commenced until 2 hours after the patient's respiratory deterioration had already begun. The other female donor did not have concordant HLA or HNA antibodies. This case was assessed as possible TRALI due to the timing of events and the presence of other risk factors for respiratory deterioration.

COMMENTARY

- Observed rates of TRALI remain lower than in 2003 when TRALI risk reduction strategies were first initiated.
- Two deaths occurred, 1 probably caused by TRALI and 1 possibly related.
- Female donors were implicated in all cases where concordant donor antibody was found (8 cases, 12 components).
- Disappointingly, 2 cases of highly likely TRALI have been reported again this year following transfusion of female FFP containing concordant donor HLA antibodies. One of these was transfused in 2008. This reinforces the absolute requirement to achieve 100% use of male plasma for FFP across the UK.
- In 2009 the Welsh Blood Service, Northern Ireland Blood Transfusion Service and Scottish National Blood Transfusion Service produced 100% FFP and plasma for platelet pools from male donors. NHSBT produced 97% of FFP and 95% plasma for platelet pools from male donors in 2009 and has confirmed that no female FFP has been issued from NHSBT since early February 2010.
- The use of SD-FFP is recommended for the treatment of TTP rather than standard FFP.[39]
- Three cases followed transfusion of platelet pools. In each case the implicated donor contributed only a buffy coat to the pool. Each patient also had other risk factors for respiratory deterioration; 2 had evidence of cardiac failure and 1 had a markedly positive fluid balance.

RECOMMENDATIONS

New recommendations

There are no new recommendations this year.

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2008	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.	**NHSBT**	
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 emphasises the importance of avoiding transfusing whole blood.	**Blood services, clinical users of blood and consultant haematologists with responsibility for transfusion**	

14. 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	34

Implicated components	
RBC only (OA, PR, WB)	22
Platelets only	1
FFP only (MB-FFP)	1
RBC + platelets	5
RBC + FFP (untreated)	3
RBC + FFP + platelets	1
RBC + FFP + platelets + cryo	1

Mortality/morbidity	
Deaths due to transfusion	0
Deaths in which reaction was implicated	4
Major morbidity	9

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	11	18 years+	34	Emergency	6	ED	0
Female	23	16 years+ to 18 years		Routine	6	Theatre	1
Unknown	0	1 year+ to 16 years		Not known	22	ITU/NNU/HDU/Recovery	3
		28 days+ to 1 year				Wards	16
		Birth to 28 days		In core hours	17	Community	0
		Unknown		Out of core hours	17	Other*	4
		Total	34	Not known/applicable	0	Not known	10

* *Emergency Assessment Unit/Clinical Decision Unit*

Twenty questionnaires on TACO were received; 9 were transferred in from the ATR section and 5 from the TRALI section, resulting in a total of 34 cases which are reported in this chapter.

Definition

Cases were assessed by the reviewer for probability of a diagnosis of TACO based on the International Society of Blood Transfusion (ISBT) definition.[14] Five of 34 cases were assessed to be highly likely, 14 probable and 15 possible.

Patients

There were 11 men and 23 women. The median age was 72.5 (range 27 to 89) years, with 20 patients (58.8%) 70 years or over and 5 patients under 50 years. There were no patients under 18 years.

Table 42
Cases classified according to diagnostic criteria, probability of TACO and imputability

NS: not stated by reporter
NR: not recorded in the clinical records

Case no.	Age Sex	Acute respiratory distress	Tachycardia	Increased BP	Acute or worsening pulmonary oedema	Evidence of positive fluid balance	Probability of TACO	Imputability
1*	F89+	Yes	NS	NS	Yes	NS	Possible	1
2	F59	Yes	Yes	Yes	Yes	NR	Highly likely	3
3	F75	Yes	Yes	Yes	NS	Yes	Probable	2
4	F61	Yes	Yes	Yes	NS	NR	Possible	1
5**	F62++	Yes	NS	NS	Yes	Yes	Probable	2
6*	F84	Yes	NS	NS	Yes	NS	Probable	2
7**	F29	Yes	NS	NS	Yes	Yes	Probable	1
8**	F68	Yes	Yes	Yes	NS	No	Possible	1
9	M67	Yes	No	No	Yes	NS	Possible	1
10	M74	Yes	Yes	Yes	NS	NR	Possible	1
11	F83	Yes	NR	NR	NR	Yes	Possible^^^	1
12*	M86	Yes	Yes	Yes	NS	NS	Possible	1
13	F86	Yes	No	Yes	Yes	NS	Probable	2
14	F71+++	Yes	Yes	Yes	Yes	NR	Possible^^	1
15*	M84	Yes	NS	NS	NS	NS	Possible	1
16*	F83	NS	Yes	NS	NS	NS	Possible	1
17	M78	Yes	Yes	No	Probably	Yes	Probable	2
18*	M88	Yes	NS	No	Yes	NS	Probable	2
19	F68	Yes	Yes	Yes	No	Yes	Probable	2
20	M32	Yes	Yes	No	No	NR	Possible	1
21	F30	Yes	No	No	Yes	Yes	Probable	2
22	M64	Yes	Yes	Yes	Yes	Yes	Highly likely	3
23	F85^	Yes	NS	Yes	Probably	NS	Possible	1
24*	M75	Yes	Yes	Yes	Yes	NS	Highly likely	3
25	F65	Yes	No	Yes	Probably	Yes	Probable^^^	2
26	F27	Yes	Yes	Yes	Yes	NR	Highly likely	3
27	F87	Yes	NS	No	Yes	NR	Probable^^	2
28	F69	Yes	NS	No	Yes	Yes	Probable	2
29*	M88	Yes	Yes	Yes	Yes	NS	Probable	2
30	F40	Yes	NR	NR	Yes	Yes	Probable	2
31	F84	Yes	NS	Yes	Probably	NR	Possible	1
32*	F76	Yes	Yes	Yes	NS	NS	Possible	1
33**	M61	Yes	No	No	Yes	Yes	Possible^^	1
34**	F70	Yes	Yes	Yes	Yes	No	Highly likely	3

** Transferred from ATR section*
*** Transferred from TRALI section*
^ hypertensive on admission
^^ onset 6–12 hours after transfusion
^^^ onset 12–24 hours after transfusion

+ chest pain and raised troponin t
++ pneumocystis pneumonia on bronchoscopy
+++ new lateral wall changes on ECG, ST down, T down

Mortality *n* = 4

There were 4 deaths (4/34; 12%) where the transfusion reaction was thought by the reporter to be probably (Case 28 and Case 34) or possibly (Case 7 and Case 33) contributory. Two further patients died, but in both, the deaths were thought by the reporter to be unrelated to the transfusion (Case 10 and Case 16).

Case 28

Patient with myeloma, cardiac failure and renal impairment develops probable TACO

A 69-year-old woman on chemotherapy for myeloma was pancytopenic, with Hb 9.9 g/dL and platelets 7 x 10^9/L. She had a history of angina, atrial fibrillation, type 2 diabetes, asthma and COPD. She had cardiac failure on admission and her fluid input was 912 mL with anuria. After 1 pool of platelets and 1¾ RBC units she developed acute respiratory distress with hypoxia, hypercapnia and worsening pulmonary oedema. The BP was 140/90 and pulse not stated. She required ITU admission and received respiratory support with O_2 and CPAP. She received diuretic therapy with no diuretic response. Her condition deteriorated and she died.

Case 34

Single RBC unit transfusion to patient with hypoalbuminaemia results in TACO

A woman had rheumatoid arthritis with pulmonary fibrosis and hypoalbuminaemia, and had an Hb of 7.4 g/dL. She was transfused 1 RBC unit over 4+ hours. At 4 hours she developed acute severe dyspnoea and persistent hypoxia (pO_2 6.93 kPa) which was unresponsive to high flow O_2 and CPAP. The pulse was 133 bpm and BP 150/90. Furosemide and antibiotic therapy were also administered. Her condition deteriorated and she died.

Case 7

Patient with complex medical problems on ITU complicated by TACO

A 29-year-old woman had sepsis due to necrotising fasciitis, DIC with bleeding and hypoalbuminaemia. She had been in ITU and ventilated long term prior to transfusion of > 2000 mL of blood components over approximately 3 hours. Fluid balance was 1716 mL positive. An hour after the last component, her pO_2 dropped to 88%, requiring manual mask ventilation with O_2, and further respiratory support. Within 6 hours of transfusion her PEEP requirement and CVP increased. A CXR showed bilateral pulmonary infiltrates. She was given IV furosemide 50 mg resulting in a diuresis of 2280 mL in 4 hours. She improved initially but deteriorated and died 5 days later. Six of 8 blood culture bottles grew Gram-positive staphylococci.

Case 33

Transfusion of RBC and FFP for massive gastrointestinal haemorrhage resulting in TACO

This 61-year-old man had a massive gastrointestinal haemorrhage with a decrease in Hb to 5.5 g/dL. He was transfused 6 units RBC and 4 units FFP, but 6–12 hours after completion of the transfusion he developed SOB and his pO_2 fell to 8 kPa, with the CXR consistent with pulmonary oedema. The pulse was 98 bpm and the BP 87/40. He was already receiving O_2, and as a result of the reaction also required CPAP. He developed ARDS and died.

Major morbidity *n* = 9

In 9 of the remaining 29 cases (26.5% of the total 34), the reporter stated that the patient was transferred to the ITU as a result of the reaction. Of these, 4 had highly likely, 2 had probable and 3 had possible TACO. Three other patients (Case 3, Case 20 and Case 31) were already in ITU at the time of the reaction.

Minor morbidity *n* = 19

All 19 patients with highly likely, probable or possible TACO experienced symptoms and/or signs. Eight of these 19 patients were reported to be given oxygen and 2 required CPAP.

Clinical details and transfused fluids in TACO cases

Table 43 summarises the clinical diagnosis or indication for transfusion in each case, along with the blood components transfused and the rate of transfusion, as well as fluid balance in the 24 hours preceding the reaction. Details of the rate of transfusion were reported in 21/34 cases (62%). Fluid balance was supplied by the reporter in 14/34 cases (41%) and not recorded or not stated in the remainder.

The median time between the transfusion and the onset of symptoms was 0–2 hours in 17/34 cases (50%), 2–6 hours in 12 cases (35%), and > 6 hours in the remainder (15%; 6–12 hours in 3 (1 probable and 2 possible cases) and 12–24 hours in 2 cases (1 probable and 1 possible)).

Acute haemorrhage cases 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 for acute major haemorrhage (Case 7, Case 9, Case 21 and Case 3). Two of the 4 patients (Cases 7 and 21) were ≤ 30 years old and the other 2 were 67 and 61 years respectively.

Case 21

Young woman develops TACO after transfusion for massive obstetric haemorrhage

A 30-year-old woman had an emergency CS for pre-eclampsia with an estimated blood loss of 3000 mL associated with DIC. She received 1500 mL colloid, 3500 mL crystalloid, 9 units (2546 mL) RBC and 4 units of FFP (1127 mL). In the 24 hours prior to the reaction she was in positive fluid balance of 1813 mL. She developed dyspnoea, hypoxia and hypercapnia associated with pulmonary oedema. Her pulse was 82 bpm and BP 109/82. O_2 was administered and she was transferred to ITU for ventilation. She was given diuretic therapy resulting in a 'good diuresis' and, after a second dose of diuretic, clinical improvement was evident.

Table 43
Diagnosis/Indication for transfusion, components/products transfused and fluid balance

NS: not stated by reporter
NR: not recorded in the clinical records

Case no.	Age Sex	Diagnosis/Indication for transfusion	RBC Units	FFP mL	Other	Rate of transfusion	Fluid Balance 24 hrs mL	Concomitant medical conditions that increase risk of TACO
1*	F89*	Ca vulva, Hb 8.1	2	-	-	NS	NS	NS
2	F59	microcytic anaemia, IHD, COPD Hb 4.8	2	-	-	1 unit/2 hrs	NR	NS
3	F75	Post-op Hb 6.0	1	-	-	1 unit/4 hrs	+3242	Hypoalbuminaemia and fluid overload
4	F61	AML, Hb 7.6, plts 22	~2	-	Plts 1 pool	Total: 8 hrs	NR	-
5**	F62	AML, thrombocytopenia	1	-	Plts 1 pool	RBC: 1 unit/2 hr Plts: 30 mins	+3119	NS
6*	F84	PR bleeding	~2	-	-	'too fast'	NR	Cardiac failure
7**	F29	IVDU, sepsis, DIC, bleeding	2	1200	Plts 1 pool Cryo 2 pools	Total: ~3 hrs	+1716	Hypoalbuminaemia and fluid overload
8**	F68	NHL, chemo, t'penia, pneumonia, progressive pulm. disease, rec. pulm. oedema	-	-	Plts 1 pool	NS	-1460^ (8040 in 9500 out)	Hypoalbuminaemia
9	M67	Bleeding DU Hb 15 dropped to 7	7+	600		Total: ~15 hrs	NS	NS

10	M74	MDS, bleeding varices/ ulcers, Hb 8.2	1+	-	-	NS	NR	Cardiac failure, renal impairment
11	F83	CLL, AIHA, Hb 4.7	4	-	-	1 unit/ ~3–4 hrs	+2374	Fluid overload
12*	M86	TKR, falling Hb post-op	2	-	-	2nd unit ~ 1.5 hr	NS	NS
13	F86	?Myeloma, Hb 6.6	3	-	-	1 unit /2 hrs	NR	Cardiac failure
14	F71	Post-op TKR, Hb 8, symptomatic	1+	-	-	1 unit/3 hrs	NR	NS
15*	M84	MDS, COPD	2	-	Plts 1 pool	NS	NS	NS
16*	F83	Ca, GI bleed, septic	2+	-	-	NS	NS	NS
17	M78	chest infection, Hb 8.3	1	-	-	1 unit/3 hrs	+900	Renal impairment, fluid overload
18*	M88	Acute on CRF, anaemia	⅔ unit	-	-	NS	NS	Renal impairment
19	F68	Bleeding DU, Hb 11 dropped to 8	5	-	-	Total: 90 min	+6710	Hypoalbuminaemia renal impairment, fluid overload
20	M32	GI bleed secondary to NSAID, Hb 5.5	5	-	-	Total: 3 hrs	NR	NS
21	F30	Massive obst. haemorrh	9	1127	-	Total: rapid	+1813	Fluid overload
22	M64	CRF, anaemia Hb 6.4	4	-	-	1 unit/3 hrs	+1933	Renal impairment
23	F85	ARF, type II resp failure, Hb 7.7	1	-	-	1 unit/4 hrs	+13^^	Renal impairment
24*	M75	ET + anaemia	1	-	-	NS	NS	Cardiac failure
25	F65	TTP	-	2636 MB-FPP	-	15–30 min/ unit	+3787	Fluid overload
26	F27	Crohn's post hemicolectomy, Hb 8.6	2	-	-	-	NR In 3000	Hypoalbuminaemia
27	F87	MDS, Hb 5.8	4	-	Plts 1 pool	1 unit RBC/4 hrs	NR	Cardiac failure, fluid overload
28	F70	Myeloma, chemo, Hb 9.9, plts 7	1¾	-	Plts 1 pool	1 unit RBC/3 hrs	+912 Out 0	Cardiac failure, fluid overload
29*	M88	Post-op cardiac surgery	< 1	-	-	NS	NS	NS
30	F40	ALL, MOF, HL insertion	2	-	Plts 2 pools	30 mins	In 5250 ↓ urine output	Renal impairment, fluid overload
31	F84	Anaemia ?cause, Hb 5.6	2	-	-	1 unit/4 hrs	NR	Cardiac failure, renal impairment
32*	F76	Bleeding ?Ca bowel	3	-	-	NS	NS	NS
33**	M61	GI bleed Hb 5.5, ARDS	6	1200	-	NS	+488^	NS
34**	F70	RA, pulm. fibrosis, periph. oedema, Hb 7.4	1	-	-	> 4 hrs	-3569^	Hypoalbuminaemia

** transferred from ATR section*
*** transferred from TRALI section*
^ over preceding 48 hours
^^ over preceding 12 hours

Cases in which RBC transfusion was implicated *n* = 32

In 32/34 cases (94%) red blood cells (RBC) were given. RBC were transfused for anaemia associated with acute haemorrhage (or probable acute haemorrhage in 14/32 cases (4 noted above)), and in the absence of acute haemorrhage in 18/32 (median age of these 18 patients 77.5 years (range 59 to 89)). Twelve of these 18 cases and 21 of the total 34 cases (information not stated in 12) had concomitant medical conditions that increase the risk of TACO (cardiac failure, renal impairment, hypoalbuminaemia or fluid overload). The onset of symptoms occurred after transfusion of ≤ 1 unit in 8 cases, ≤ 2 units in 13 cases and ≤ 3 units in 3 cases.

Details are given above in Table 43 and in selected cases below.

Case 11

Possible TACO occurring after 12–24 hours in an elderly patient with fluid overload

An elderly woman had CLL associated with AIHA with Hb 4.7 g/dL. Twelve to 24 hours after completion of a 4 unit RBC transfusion she developed sudden SOB and was noted to be in positive fluid balance (+2374). Staff did not record observations so the reporter was unable to establish if there were other symptoms.

Case 4

Possible TACO without any concomitant condition that could increase the risk

A 61-year-old woman with AML on chemotherapy received an RBC transfusion for anaemia (Hb 7.6 g/dL) and thrombocytopenia (platelets 22 x 10^9/L) in the absence of bleeding. During the second RBC unit she became increasingly SOB and tachycardic (pulse 110 bpm) with wheezing. BP was not raised. CXR showed a whiteout at mid-level down. Fluid balance was not recorded in the preceding 24 hours. O_2 was administered and CPAP following transfer to ITU. Steroid and diuretic therapy were given, but responses not documented.

Cases in which FFP was transfused *n* = 6

There were 6 cases in which transfusion of FFP was implicated in TACO, of which 4 occurred in the presence of acute haemorrhage (Case 7, Case 9, Case 21 and Case 33). Of the remaining 2 cases, in 1 FFP was given to cover a Hickman line insertion in a patient with ALL and multi-organ failure although details regarding coagulopathy were not given. The other case is described below.

Case 25

Repeated large volume MB-FFP without plasma exchange for presumed TTP results in probable TACO

A 65-year-old woman diagnosed to have acute thrombotic thrombocytopenic purpura (TTP) was treated with 12 units of MB-FFP (2636 mL). Each unit was infused over 15–30 minutes and the infusions were repeated for 3 days. The patient did not receive plasma exchange. After 3 days the physiotherapists noticed she was SOB and wheezy. She was also hypertensive, BP 170/95 with pulse 92 bpm, and in positive fluid balance, +3787 mL, in the 24 hours prior to the reaction. She was given furosemide 80 mg and her symptoms improved.

Cases in which platelets were transfused *n* = 8

There were 8 cases in which platelets were transfused, of which 1 occurred in the presence of acute haemorrhage; in 6 cases RBC were also transfused and in 1 case platelets only were transfused.

Case 5

Co-existent ARDS and TACO initially reported as TRALI

A 62-year-old patient with AML became acutely SOB and collapsed after receiving a unit of RBC over 2 hours and a pool of platelets over 30 mins. She had put on 4 kg in weight over the previous few days and had positive fluid balance of 3119 mL in the 24 hours preceding the transfusion. She responded well to furosemide 40 mg on the day of the episode and on each of the next 2 days. She developed a fever after the collapse and was restarted on tazocin and vancomycin, which had been stopped 3 days earlier following positive cultures (CNS on blood and Staph. aureus on hand swab). This case, initially reported as TRALI, appears to be a highly likely case of TACO; however, based on the ISBT criteria, it was classified as a 'probable' case. It illustrates that TACO may co-exist with other conditions, in this case ARDS.

Procedural review

In 88% (30/34) cases, the reaction was reported to the HTC; 16 of these had been reviewed by the HTC at the time of reporting to SHOT. Two cases were reported to the hospital transfusion laboratory only. Three hospitals also reported the reactions to their clinical risk committee/team with a further 4 hospitals reporting the reactions to other forms of risk review group, including the following: Patient Safety Team, Serious Incident Review Group, the Governance Department and the Senior Nurse meeting. In 2 cases there was no form of clinical risk review documented.

Learning points

- TACO is potentially avoidable in many cases. Doctors should consider whether transfusion is appropriate and also take note of concomitant medical conditions that increase the risk. The use of diuretic cover for blood transfusion is likely to reduce the risk of TACO and should also be considered.
- Nurses should monitor the patient's clinical condition during and after the transfusion as TACO may occur during or up to 24 hours after transfusion. This was a main SHOT recommendation last year and has been highlighted in new BCSH guidelines on blood administration.[19] It is also important to monitor the rate of transfusion and fluid balance as these factors influence the risk of a patient developing TACO.

COMMENTARY

- TACO has caused the most cases of transfusion-related major morbidity and mortality in any category in this year's report. There were 4 deaths (approximately 12%) where the transfusion was probably (Case 28 and Case 34) or possibly (Case 7 and Case 10) contributory; 9 patients (31%) required ITU admission and a further 2 patients required CPAP. TACO appears to be common in critically ill patients on ITU where it may be difficult to avoid.[40] Cases of greater relevance to SHOT are those where TACO is potentially avoidable.
- In this second year of TACO as a separate SHOT category, there were 34 cases compared with 18 in 2008, i.e. an 89% increase. Nine of 20 patients, where the case was initially reported as TACO, had haematological disorders, which probably reflects awareness of TACO among haematologists. However, TACO probably remains under-reported.
- TACO is associated with the transfusion of relatively modest volumes of RBC, particularly in the elderly. In the 18 (of 32) patients in whom RBC were transfused in the absence of haemorrhage (median age 77.5 years), the onset of symptoms occurred after transfusion of ≤ 1 unit in 8 cases and ≤ 2 units in 13 cases. Twelve of these 18 cases and 21 of the total 34 cases were known to have concomitant medical conditions that increase the risk of TACO (cardiac failure, renal impairment, hypoalbuminaemia or fluid overload).
- Approximately 60% of TACO cases occurred in patients > 70 years and 15% occurred in patients < 50 years. The incidence of TACO in the UK paediatric hospital population remains unknown.
- The classification of cases according to diagnostic criteria is critically dependent upon the information provided, and distinctions between TACO, TRALI and TAD may not always be clear-cut. Some cases which appeared to be TACO did not fulfil ISBT diagnostic criteria and, particularly in critically ill patients, TACO may co-exist with other conditions (Case 5) which may modify classical diagnostic features of TACO. Five cases of TACO (2 probable and 3 possible) occurred after 6 hours, therefore the 6 hour cut-off for diagnosis of TACO merits reconsideration (see Key Messages and Main Recommendations, page 21).
- In 1 case (Case 25) large volumes of MB-FFP were infused to treat an adult with presumed TTP. The mainstay of the treatment of TTP is plasma exchange with FFP replacement. Prior to its institution mortality rates were in excess of 90% and have now fallen to ~20%. Plasma exchange is associated with a significantly higher survival rate than is plasma infusion.[41,42] Furthermore, MB-FFP appears to be less effective than FFP for plasma

exchange in patients with TTP.[43] In January 2006 the DH recommended SD-FFP for plasma exchange in adult patients with TTP.[39] The diagnosis of TTP should be confirmed by measurement of ADAMTS13 activity and antibody levels (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13; also known as von Willebrand factor-cleaving protease); a UK MRC registry (Haemostasis Research Unit, University College, London) provides a service for these assays. New BCSH guidelines on TTP are in preparation.[44]

- In 2009, 1 case of TACO was reported following major obstetric haemorrhage; there were 2 in 2008. This is a clinically challenging situation where there are difficulties in estimating actual blood loss, particularly because of the changing blood volume and circulatory capacity: delivery, obligate blood loss, pre-partum increased blood volume and cardiac output, peripartum disconnection of placenta and fetus, and massive constriction of uterus and natural reduction in blood volume. As a result, patients may be over-transfused. There may also be failure to recognise TACO in these young individuals who are often regarded to be 'immune' to TACO. A good quality echocardiogram to assess cardiac function during major obstetric haemorrhage will aid assessment; however, this may be difficult to achieve during the emergency situation.

- A patient with AML and a platelet count of 22 (Case 4) was transfused platelets without any explanation. In this scenario, a threshold platelet count of < 10 for prophylactic platelets is generally accepted. A higher threshold is required for patients with bleeding or severe sepsis.[45]

RECOMMENDATIONS

New recommendation

- Patients with TTP should have plasma exchange at presentation (and ideally within 24 hours of presentation),[42] with plasma infusion alone administered prior to transfer to a unit or hospital that can offer plasma exchange and appropriate management.

  Action: Consultant haematologists and SHAs

Previous recommendations still relevant

Year first made	Recommendation	Target	Progress
2008	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.	**HTT**	The number of cases of TACO have increased; however, it almost certainly remains under-reported.
2008	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.	**NBTC**	This year's report highlights the need for a national initiative to address these issues.
2008	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. 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.	**HTT, BCSH**	a) The new BCSH guidelines on the administration of blood components have addressed issues related to the rate of transfusion.[19] b) The BCSH guidelines do not address clinical assessment prior to transfusion, which could be addressed in a national initiative led by NBTC (see above recommendation).
2008	If it is necessary to transfuse RBC to a patient with chronic anaemia, the risk of precipitating congestive cardiac failure may be minimised by administering a diuretic. The decision to give a diuretic must be based on clinical assessment of the patient.	**HTT, BCSH**	As b) above
2008	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 completion. Out-of-hours transfusions should be avoided unless appropriate facilities are available. BCSH guidelines on blood administration in preparation should address these issues.	**HTT, BCSH**	The new BCSH guidelines on the administration of blood components have addressed these issues, and also advise that patients discharged home after a transfusion should be counselled with systems available to ensure that patients have 24 hour access to clinical advice.[19]

15. Transfusion-Associated Dyspnoea (TAD)

Definition

The category TAD has been introduced by the ISBT. TAD is characterised by respiratory distress within 24 hours of transfusion that does 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.[14] 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	4	*Implicated components*		*Mortality/morbidity*	
		Red cells	4	Deaths due to transfusion	0
		FFP	0	Deaths in which reaction was implicated	0
		Platelets	0	Major morbidity	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	4	16 years+ to 18 years		Routine		Theatre	
Unknown	0	1 year+ to 16 years		Not known	4	ITU/NNU/HDU/Recovery	
		28 days+ to 1 year				Wards	2
		Birth to 28 days		In core hours		Community	
		Unknown		Out of core hours		Other (haematology day care)	
		Total	4	Not known/applicable	4	Not known	2

Two reports of TAD were received (Case 1 and Case 2); 2 more cases were transferred in – 1 from the ATR section (Case 3) and 1 from the TRALI section (Case 4) – and all 4 are reported in this chapter.

Mortality and major morbidity *n* = 0

Minor morbidity *n* = 4

One of the 4 patients required CPAP as a result of the reaction.

Table 44
Diagnosis/Indication for transfusion, components/products transfused and fluid balance

Case no.	Age Sex	Diagnosis/Indication for transfusion	RBC Units	FFP mL	Other	Rate of transfusion	Fluid balance 24 hrs mL	Probability of TAD
1	F81	Anaemia	1+	-	-	1 unit /2 hrs	NS	Possible
2	F74	Myeloma, chemo	< 1	-	-	NS	NS	Possible
3	F84	Ca bowel, acute hepatic failure, Hb fall from 8.5 to 6.2 g/dL	1+	-	-	NS	NS	Possible
4	F65	Ca lung, COPD, ?pneumonia, Hb 8.2 g/dL	2	-	-	NS	NR	Possible

Case studies

In all 4 cases a key feature was respiratory distress. None of the 4 cases met the criteria for TACO or TRALI, and did not have classical features of an allergic reaction. They were therefore categorised as (possible) cases of TAD. In cases 1, 2 and 3 the symptoms occurred within 2 hours of the transfusion, and in Case 4 within 12–24 hours.

Case 1

An 81-year-old woman with anaemia was written up for a 2 unit RBC transfusion – each unit over 2 hours. Ten minutes into the second unit she developed SOB with a rise in her respiratory rate from 16 to 40 per minute. Her O_2 saturation remained normal at 96%. The reaction was associated with vomiting and flushing. The transfusion was stopped and her symptoms resolved.

Case 2

A 74-year-old woman with myeloma on chemotherapy was prescribed a 2 unit RBC transfusion. She had been hypertensive, BP 197/114, prior to transfusion. Ninety minutes into the first unit she developed SOB, with a fall in her O_2 saturation to 88%. The transfusion was stopped, she was treated with IV furosemide and GTN and admitted to the ward. Her symptoms resolved over the next 48 hours.

Case 3

An elderly woman with acute hepatic failure dropped her Hb from 8.5 to 6.2 g/dL over 48 hours, and an RBC transfusion was commenced. Twenty minutes into the second unit she developed dyspnoea associated with a rise in RR from 14 to 32 pm and a fall in O_2 saturation from 94% to 91%. Her pulse rose from 120 to 135 bpm and her BP fell from 122/82 to 99/65. The transfusion was stopped and her symptoms resolved.

Case 4

A 65-year-old woman with lung malignancy and COPD had an Hb of 8.2 g/dL and was transfused 2 units of RBC. Twelve to 24 hours later she became SOB and was brought back to the hospital by ambulance. Fluid balance was not documented, but clinically there was no fluid overload and she was possibly a bit dry. Pulse was raised at 111 bpm and BP low at 96/58. A CXR showed bilateral interstitial changes which had not been present 24 hours previously. She had hypoalbuminaemia. She was treated with antibiotic therapy, O_2 and CPAP, and a diuretic 36 hours later, when she developed pulmonary oedema. Her symptoms resolved.

COMMENTARY

- TAD appears to be a clinically heterogeneous entity and perhaps includes cases with more than one physiological mechanism. More information about this group of complications is required to enable a systematic approach to the investigation and management of pulmonary complications of transfusion (see Key Messages and Recommendations, page 21).

- TAD appears to be able to occur during or up to 24 hours after transfusion, highlighting the need for appropriate monitoring during administration of blood components, as detailed in the new BCSH guidelines.[19]

RECOMMENDATIONS

There are no new recommendations.

Previous recommendation still relevant

Year first made	Recommendation	Target	Progress
2008	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.	**HTTs**	TAD reporting has not increased appreciably over the past year; however, it is hoped that growing awareness about this new category will result in more reports.

16. 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.

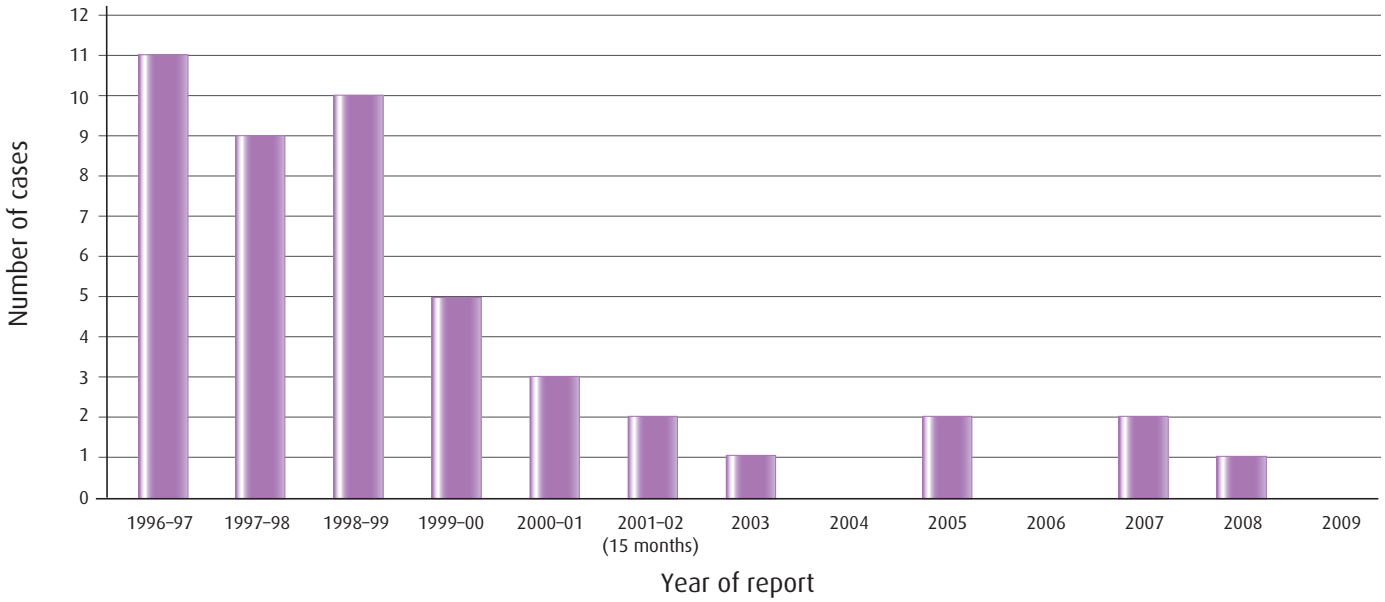
Two questionnaires were received but both were withdrawn because neither had alloantibodies directed against HPA.

Cumulative data 1996–2009

Figure 19 shows reports to SHOT since 1996 of the annual numbers of cases of PTP with confirmed HPA alloantibodies: a total of 46 reports. A sustained decrease in the number of these cases has been seen 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%) have 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 one 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



Further information about PTP is available in *Practical Transfusion Medicine.*[46]

RECOMMENDATIONS

Clinicians are encouraged to contact Blood Services if they suspect PTP.

Recommendations still active from previous years

- Clinicians need to maintain awareness of this rare but treatable complication of transfusion.

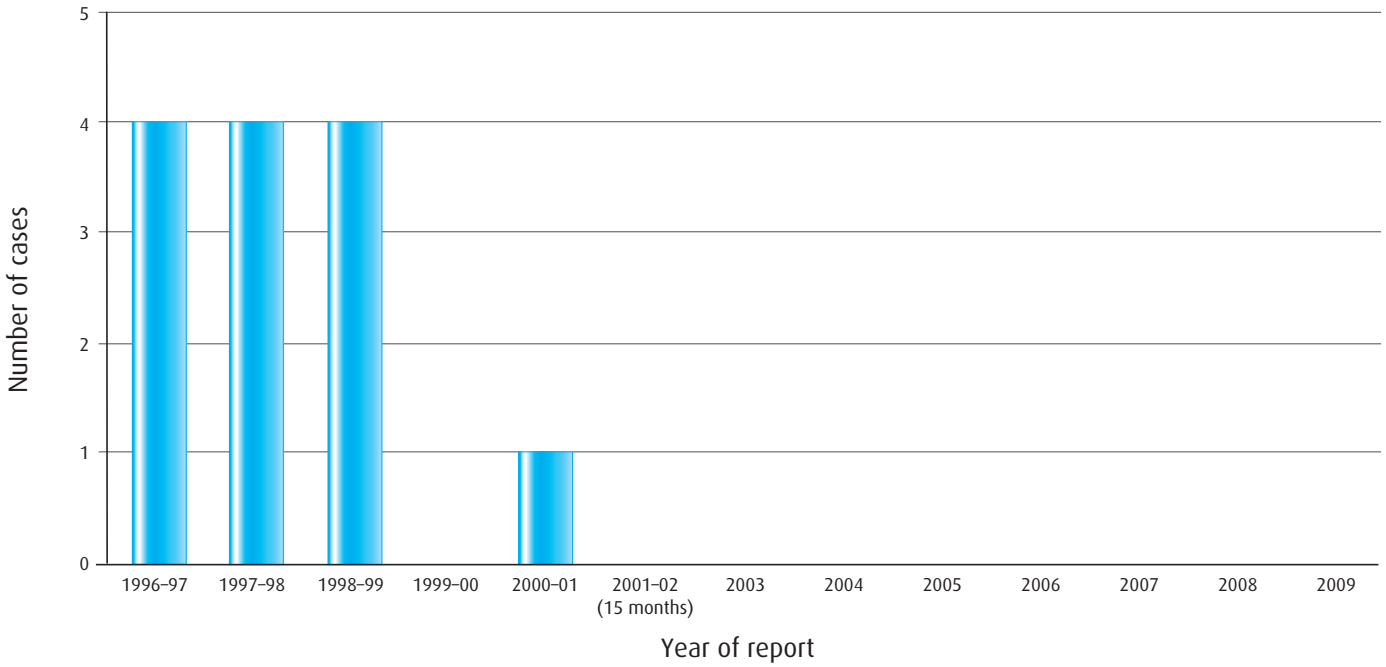
17. Transfusion-Associated Graft-versus-Host Disease (TA-GvHD)

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 deoxyribose nucleic acid (DNA) in the patient's blood and/or affected tissues.

No new case of TA-GvHD was reported in 2009.

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 8 years.
- A total of 13 cases of TA-GvHD have been reported to SHOT since 1996, all of which were fatal.
- Two cases have followed transfusion of leucodepleted components. One case occurred before the introduction of leucodepletion of all cellular components (except granulocytes/buffy coats), which took place in late 1999. This followed transfusion of a leucodepleted component to a patient and was reported in 1998–99. Another case occurred since the introduction of universal leucodepletion which was reported in 2000–2001.
- This year SHOT received reports of 91 patients with a requirement to receive irradiated blood in accordance with BCSH guidelines[20] who received non-irradiated components in error. Of these, 69 were attributed to clinical errors and 22 to laboratory errors: fortunately none developed TA-GvHD. In the last 7 years a total of 596 such cases have been reported, none of whom developed TA-GvHD.

- The requirement to irradiate blood components remains essential for patients at risk. Approximately 300,000 irradiated components were issued from UK blood services in 2008–2009. By far the majority of patients at risk of TA-GvHD receive irradiated components as indicated. Irradiation is a proven, effective intervention to prevent this catastrophic complication. The absence of new cases, given the numbers involved, is a testament to its successful prevention: it would be imprudent to interpret it as a sign there is no longer a risk of TA-GvHD.

RECOMMENDATIONS

Recommendations from this report

There are no new recommendations from this report.

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2007	The importance of irradiation, and the rationale behind it, should be focused on during teaching of junior haematology and oncology doctors. This education is part of the curriculum for Specialist Trainees, but foundation year doctors in these specialities may remain ignorant despite being frequently called upon to order components.	**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**	
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**	
2003	Gamma or X-ray irradiation to 25 Gy of blood components for those at risk of GvHD remains essential. BCSH Blood Transfusion Task Force Guidelines, 1996, define groups requiring this prophylaxis.	**Hospital Trusts, Medical Schools, NBTC, Royal Colleges, Specialty Training Committees, GMC, BCSH**	An update of the BCSH guidelines is still in progress. A more recent table of indications can be found in the *Transfusion Handbook*, 4th edition.
2003	Good communication is required in all cases but particularly when patient care is shared between different hospitals. Hospitals must have clear protocols to ensure accurate information relating to this risk is communicated in a timely manner. Utilisation of a patient card and leaflet are recommended: an example is the BCSH/NBS leaflet available from NBS Hospital Liaison or via the NBS hospitals website.	**Hospital Trusts, Hospital Liaison networks, BBT network, SHOT Transfusion Practitioner network**	

18. Transfusion-Transmitted Infection (TTI)

Definition

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

- The recipient had evidence of infection following transfusion with blood components, 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.

DATA SUMMARY

Total number of incidents	**2**	*Implicated components*		*Mortality/morbidity*	
Total number of recipients	**3**	Red cells	**1**	Deaths due to transfusion	**1**
		FFP	**0**	Deaths in which reaction was implicated	**0**
		Platelets	**2**	Major morbidity	**2**
		Other (specify)	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**3**	18 years+	**2**	Emergency	**0**	ED	**0**
Female	**0**	16 years+ to 18 years	**0**	Routine	**3**	Theatre	**0**
Unknown	**0**	1 year+ to 16 years	**0**	Not known	**0**	ITU/NNU/HDU/Recovery	**0**
		28 days+ to 1 year	**1**			Wards	**3**
		Birth to 28 days	**0**	In core hours	**2**	Community	**0**
		Unknown	**0**	Out of core hours	**1**	Outpatient/day unit	**0**
		Total	**3**	Not known/applicable	**0**	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 Epidemiology Unit. From here, data are included in the SHOT report. A number of reports were also received from SHOT via the MHRA's online reporting system for Serious Adverse Blood Reactions and Events (SABRE).

Incidents are included for the year in which they were reported, even if the investigation is not yet complete, as the investigation into some suspected viral TTIs can take several months.

During 2009, 39 suspected TTI incidents were reported by blood centres and hospitals throughout the UK. A number of ATRs were reported which did not meet the criteria for TTI, either because there was no evidence of infection in the recipient or because an alternative source of infection was identified. Many of these cases were reported to the NHSBT/HPA Epidemiology Unit only and not to SHOT. It is recommended that such reactions be reported to SHOT and it is likely that most cases could be recorded as febrile reactions.

Two incidents (both bacterial, described below) were confirmed as TTIs according to the above definition. Thirty investigations were concluded as not TTI, including 11 hepatitis B (HBV) incidents, 1 vCJD investigation, 1 hepatitis C (HCV), 3 HIV, 1 herpes simplex virus, and 13 bacterial incidents.

There were 4 undetermined TTI investigations in 2009 – 3 bacterial and 1 HIV. In 2 of the bacterial cases clinical suspicion was that bacterial contamination was not the cause of the reaction, but it could not be ruled out. In 2 cases there was growth from the patient blood cultures but the transfused packs had been discarded and so were not available for culture. In the third case, coagulase negative staphylococci were isolated from a unit of transfused platelets at the hospital microbiology laboratory, but environmental contamination of the pack during testing could not be ruled out, and the packs were not returned to the blood services for investigation. Patient blood cultures were negative, but these had been taken 4 days after the patient had been started on antibiotics.

The undetermined HIV investigation was a complex case involving a large number of donors (116). All but 1 of the donors (115/116) were re-tested; none was found to have markers of HIV infection. It was not possible to trace the remaining donor (donor has possibly left the country); however, it was subsequently discovered that the recipient was exposed to another risk of HIV infection (sexual contact), which was thought more likely to have been the source of infection.

Three incidents reported in 2009 are pending complete investigation (1 HTLV, 1 HBV and 1 HCV).

Confirmed Incidents

Report of transfusion-transmitted *Streptococcus pneumoniae*

An un-issued, expired unit of apheresis platelets was referred for microbiological testing after routine quality monitoring found the pack to have a low pH and abnormal colouration. *Streptococcus pneumoniae* was isolated from the unit. Four associated units had been transfused into 2 patients with acute myeloid leukaemia (AML) – 1 unit to an adult and 3 neonatal units to a baby.

Retrospective investigations revealed that both patients had experienced transfusion reactions (including a fever of 39.8°C in the adult patient and 40.5°C in the baby), but these were thought at the time to have been related to the patients' underlying conditions. All of the transfused packs had been discarded but a blood sample taken from the adult patient yielded *S. pneumoniae*. Blood cultures from the neonatal patient were negative, but the patient was on antibiotics at the time of transfusion.

The organisms isolated from both the contaminated index pack and the adult patient were compared using molecular techniques (Pulse Field Gel Electrophoresis, Multi Locus Sequence Typing, and Variable Number Tandem Repeat analyses) and were found to be indistinguishable from one another. Nose and throat swabs taken from the donor were negative; however, *S. pneumoniae* is known to be difficult to culture from swabs.[47,48] Approximately 4–8% of adults carry *S. pneumoniae*.[48,49] It is thought that the organism may have originated from the throat of the donor or donor carer and been transferred from there to the venepuncture site by fingers or a cough/sneeze or from an underlying asymptomatic bacteraemia in the donor.

Report of transfusion-transmitted *Pseudomonas koreensis*

Three units of red cells were transfused into an elderly man receiving palliative care for cancer of the rectum and liver cirrhosis. Approximately 2 hours into transfusion of the third unit the patient became unwell with hypotension, fever (39.6°C), and abdominal pain and vomiting; he died later the same day.

Pseudomonas koreensis was cultured from the remains of the red cell unit at the microbiology laboratories of both the hospital and the blood service, and also from the patient blood cultures. All 3 isolates were found to be indistinguishable on molecular typing. *P. koreensis* is associated with cold temperatures and it was thought that contamination of the unit may have occurred within a cold storage room or processing area at the blood service or the hospital. Skin carriage of *P. koreensis* is rare. The donor was recalled and swabs were taken from the arms but these were negative. The donor was thought unlikely to have been the source of the contaminating bacteria. Despite extensive environmental sampling

of processing and cold storage areas at the hospital and blood services, the source of the contamination could not be identified. The red cell pack was pressure tested but this did not reveal any holes or defects and so it is unclear how the bacteria may have entered the pack. The incident has led to an extensive review of cold room cleaning protocols within processing and issues areas.

Other Incidents

Near Miss

Staphylococcus aureus was isolated from 2 of 3 un-issued, 4-day-old units of apheresis platelets after visible clumps/aggregates were noted in the packs. The donor was sampled and *S. aureus* was isolated from the nose, throat and venepuncture site pre arm-cleansing. Coagulase negative staphylococci were isolated from the venepuncture site post cleansing. The isolates identified from the donor and platelet packs were found to be a single clonal type. In light of the results of the swabs taken from the donor it was agreed that he should be permanently deferred from the panel due to *S. aureus* colonisation. Carriage of this organism varies. It is suggested that between 20 – 40% of the population carry it in their nose.[50] Increased carriage of *S. aureus* on the skin is associated with eczema and other dermatological conditions.

Investigations reported as pending in previous years

The investigations reported as pending in 2008 are now complete (1 HBV, 2 HCV). No donor was found to have evidence of infection, therefore all 3 incidents were concluded as not transfusion-transmitted infection.

Cumulative Data

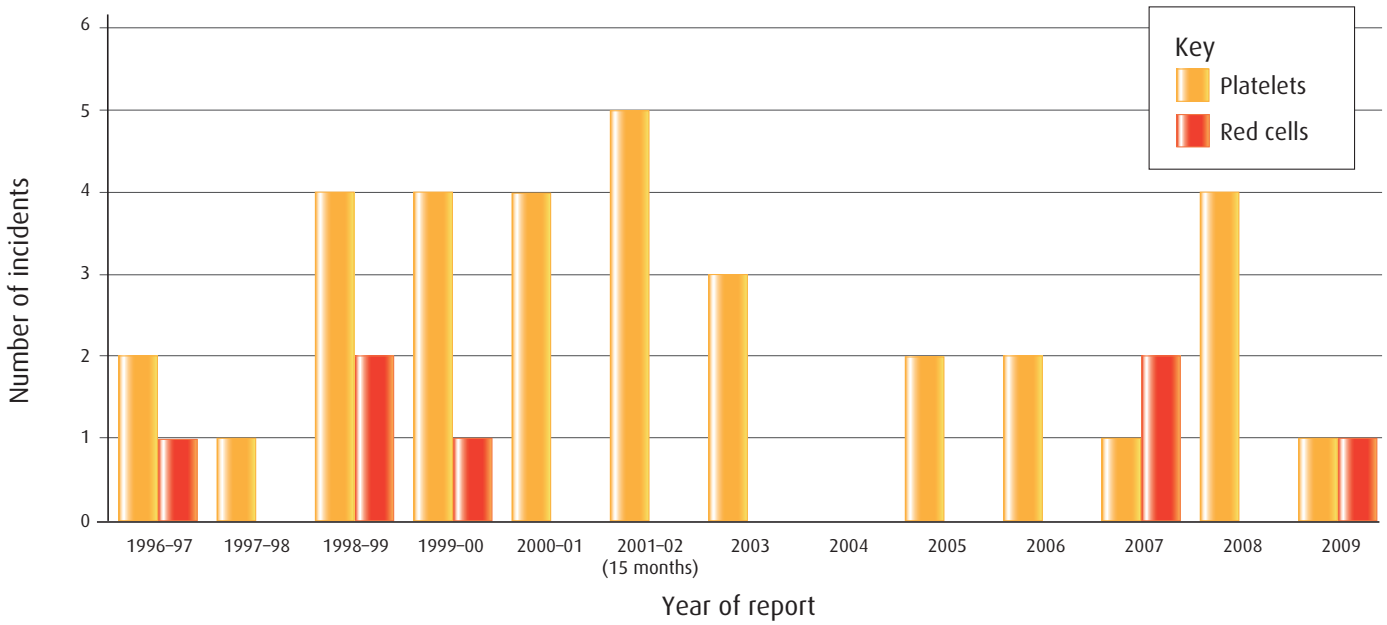
Bacterial TTIs

Since 1996, 40 bacterial TTI incidents have been confirmed involving a total of 43 recipients (Figure 21 and Table 45), 11 of whom died (death due to infection or in which transfusion reaction was implicated). A total of 33 incidents have related to the transfusion of platelets whereas only 7 have related to the transfusion of red cells.

In Figure 21:

- The histogram shows the number of incidents, not infected recipients identified. For 2 incidents in 2008, and 1 in 2009, 2 infected recipients were identified.
- In 2004 there was a further incident (not included in Figure 21) involving the contamination of a pooled platelet pack with *S. epidermidis* which did not meet the TTI definition because transmission to the recipient was not confirmed, although it was likely.

Figure 21
Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from 10/1998)



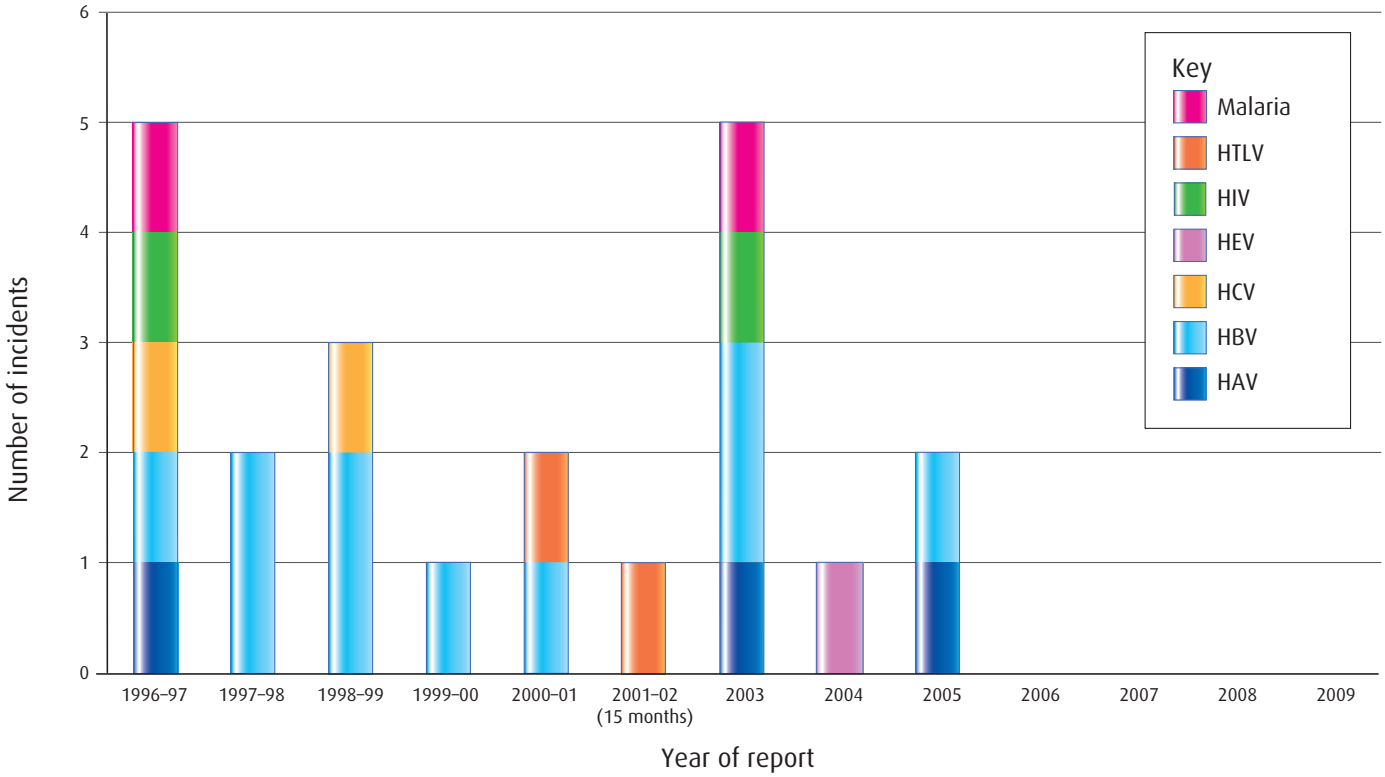
Viral and parasitic TTIs

Since 1996, 22 confirmed incidents of transfusion-transmitted viral and parasitic infections have been reported, involving a total of 25 recipients (Figure 22 and Table 45), 1 of whom died (malarial transmission). There have been no confirmed transfusion-transmitted viral or parasitic infections in recent years – the last confirmed incident was in 2005.

In Figure 22:

- 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 viral infections. Figure shows number of *incidents*, not infected recipients identified. For 1 incident in 1996–97 (HIV), and 1 in 1999–2000 (HBV), 3 and 2 infected recipients were identified respectively.
- 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 22).
- No screening was in place for the following TTIs at the time of transfusion: HAV, HEV, HTLV.

Figure 22
Number of viral and parasitic TTI incidents, by year of report and infection type (Scotland included from 10/1998)



Variant Creutzfeld Jakob disease (vCJD)

There was 1 vCJD investigation in 2009 which was concluded not TTI due to blood components. A person with haemophilia was found to have evidence of abnormal prion protein in his spleen at postmortem. The patient received red cell transfusions between 1998 and 2007, but had also been treated with multiple batches of UK sourced clotting factors in the 1990s, including 2 batches of Factor VIII that were manufactured using plasma from a donor who went on to develop vCJD. It was thought that Factor VIII was the most likely source of infection.[51]

To date, there have been 4 incidents involving the transmission of vCJD/prion infection via red cell transfusion. Reporting of suspected vCJD transmissions differs from that of other infections: the cases reported were among a small group of recipients 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 (MB-FFP) obtained outside the UK for children under 16 years old (2002)
- importation of plasma for fractionation (1998)
- imported solvent detergent (SD) treated FFP for adult patients with thrombotic thrombocytopenic purpura (TTP) (2006)[39]
- exclusion of donors who have received a blood transfusion in the UK since 1980 (2004).

Table 45
Number of confirmed TTI incidents, infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2009 (Scotland included from October 1998)
NB No screening in place for the following TTIs at the time of transfusion: HAV, HEV, HTLV, vCJD/prion

Infection	Number of Incidents	Number of Infected Recipients	Death due to, or contributed to, by TTI	Major morbidity	Minor morbidity
Bacteria	40	43	11	28	4
HAV	3	3	0	2	1
HBV	10	11	0	11	0
HCV	2	2	0	2	0
HEV	1	1	0	0	1
HIV	2	4	0	4	0
HTLV-I	2	2	0	2	0
Malaria	2	2	1	1	0
Prion	1	1	0	1	0
vCJD	3	3	3	0	0
Total	**66**	**72**	**15**	**51**	**6**

COMMENTARY

Currently the greatest risk of transfusion-transmitted infection is associated with bacterial contamination, although there is likely to be under-reporting of both viral and bacterial incidents. A BCSH guideline on the management of acute transfusion reactions is currently in preparation, and a revised protocol is being devised by NHSBT. One of the confirmed bacterial incidents in 2009 was revealed only upon retrospective investigation after an expired unit of platelets was found to have a low pH and abnormal colouration, when the fate of associated components was investigated. This case demonstrates that acute transfusion reactions can be difficult to recognise, particularly when patients have other underlying symptoms and/or are taking antibiotics, which may mask their symptoms. This case was also the first known report of transfusion-transmitted *Streptococcus pneumoniae* infection in the UK.

If bacterial contamination is suspected, staff should report the incident to the blood services as soon as possible, in order to facilitate the return of implicated packs and the recall of any associated units. A BCSH guideline on the management of acute transfusion reactions is currently in preparation, and a revised protocol is being devised by NHSBT. Attention should be paid to the sampling and storage of implicated units or their residues to avoid environmental contamination of the pack. Guidance for English hospitals can be found at: http://www.blood.co.uk/hospitals/library/request_forms/aer/. For other services please contact the local blood supply centre.

The most likely source of the organism in the *Pseudomonas koreensis* case was thought to have been environmental contamination within a cold storage room or issues area. While the MHRA's 'Orange Guide' includes recommendations on standards of environmental cleanliness for 'clean' rooms (where sterile conditions are maintained),[28] there are no guidelines covering acceptable levels of cleanliness within cold storage areas. Nonetheless, cleaning protocols for such areas should be reviewed regularly and compliance with these should be audited.

Strategies to reduce the bacterial contamination of blood components should be under continual review. At a meeting in July 2009, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) did not recommend the adoption of pathogen inactivation (PI) of platelets at present, until further data on the cost benefit and safety of this method become available. Most of the UK blood services already screen platelet donations for bacterial contamination and this is planned for introduction in England in early 2011. It should be noted that the effectiveness of screening is influenced by the methodology used and data from a number of studies have shown that bacterial screening is unlikely to prevent all transmissions.[52] The UK Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) have tasked a subgroup to recommend how bacterial screening should be performed.

The current estimated risks of transmission of HBV, HCV, HIV and HTLV via blood transfusion are low (1.09 per million donations for HBV, 0.01 per million for HCV, 0.19 for HIV and 0.04 for HTLV-1).[53]

Learning point

Clinicians investigating suspected viral TTIs should explore all possible risk exposures (e.g. surgery, or discuss with the patient any sexual risks, injecting drug use, occupational exposure) in parallel with the blood service investigations, as highlighted by the undetermined HIV investigation this year.

RECOMMENDATIONS

- Staff should maintain a high index of suspicion for bacterial causes when managing acute transfusion reactions. Symptoms may appear to be related to the patient's underlying condition, and temperature rises may be small or absent altogether.

  Action: Hospital Transfusion Teams

- Processing and issues teams at the UK blood services and hospital transfusion teams should be vigilant to any abnormalities or clumps present in packs prior to transfusion, as highlighted by the Near Miss case in 2009.

  Action: Hospital Transfusion Teams, UK blood services

- Cleaning protocols for cold rooms and processing and storage areas should be reviewed regularly. Compliance with these should be audited.

  Action: Hospital Transfusion Teams, UK blood services

- Clinicians investigating suspected viral TTIs should explore all possible risk exposures in parallel with the blood service investigations, in order to determine the patient's most likely source of infection.

  Action: Clinicians, UK blood services

Recommendations still active from previous years, with modifications

Year first made	Recommendation	Target	Progress
2008	Staff must maintain a high index of suspicion of bacterial causes when managing acute transfusion reactions. Symptoms may appear to be allergic in nature, but cultures must still be performed whenever bacterial contamination is a possibility.	**Hospital transfusion teams**	A BCSH guideline on the management of acute transfusion reactions is in preparation.
2005, 2008, 2009	Where bacterial contamination is suspected, staff should report the incident to the blood services as soon as possible in order to facilitate the return of implicated packs and the recall of any associated units. Attention should be paid to the sampling and storage of implicated units or their residues to avoid environmental contamination of the pack.	**Hospital transfusion teams, UK blood services**	Guidance for English hospitals can be found on the NHSBT hospitals website: http://www.blood.co.uk/hospitals/library/request_forms/aer/ For other services please discuss with the local blood supply centre.
2003, 2008	Strategies to reduce bacterial contamination of blood components should continually be reviewed. 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 - Consideration of bacterial screening interventions and/or pathogen inactivation - Adherence to BCSH guidelines (2009) with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion.	**UK blood services, SaBTO, 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 all possible incidents of post-transfusion infection via appropriate local and national reporting routes.	**Hospital transfusion teams**	Serious Adverse Reactions must be reported under the terms of the BSQR 2005. Reporting to SHOT is required for compliance with HSC/2002/009 'Better Blood Transfusion' and is a standard for the Clinical Negligence Scheme for Trusts in England.

19. Autologous Transfusion

Definition

Any adverse event or reaction associated with autologous transfusion including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution or preoperative autologous donation.

DATA SUMMARY

Total number of cases	**14**	*Implicated components*		*Mortality/morbidity*	
		Autologous Red cells	**14**	Deaths due to transfusion	**0**
		FFP		Deaths in which reaction was implicated	**0**
		Platelets		Major morbidity	**0**

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**5**	18 years+	**13**	Emergency	**2**	ED	
Female	**2**	16 years+ to 18 years	**1**	Routine	**11**	Theatre + ITU/NNU/	
Unknown	**7**	1 year+ to 16 years	**0**	Not known	**1**	HDU/Recovery	**6**
		28 days+ to 1 year	**0**			Wards	**8**
		Birth to 28 days	**0**	In core hours	**5**	Community	
				Out of core hours	**1**	Other	
		Total	**14**	Not known/applicable	**8**	Not known	

Fourteen questionnaires were received; none was withdrawn or transferred to another section and 7 were transferred in from other categories. This section describes the main findings from 14 completed questionnaires.

There were no reports submitted during this reporting period relating to adverse events while undertaking acute normovolaemic haemodilution (ANH) or preoperative autologous donation (PAD). Both these techniques are rarely undertaken and their use is not routinely recommended. There is a reduction in the number of reports compared with last year (2008) when a pilot was undertaken as a joint initiative between SHOT and the UK Cell Salvage Action Group. However, cell salvage adverse events are now part of the SHOT system and as such should be reported through the new online reporting system.

Adverse events by specialty

Orthopaedic – 10 events; general surgery – 2 events; urology – 1 event; obstetrics – 1 event.

Adverse events by type of autologous transfusion

Intraoperative cell salvage (ICS) – 6; postoperative cell salvage (PCS) – 8.

PCS incidents *n = 8*

- 1 system not assembled correctly
- 1 wrong infusion set used
- 5 pyrexia, rigor or bradycardia
- 1 excessive time to transfuse

ICS incidents *n = 6*

- Operator errors
  - Heparinised saline used in wrong bag, 1 case
- Machine errors
  - Faulty optic – red cells spilled into waste bag, 2 cases
- Clinical adverse events
  - Hypotension, 3 cases

Case 1

Hypotension

Patient had massive transfusion due to acute haemorrhage for placenta accreta. Allogeneic (donor) blood and intraoperative salvaged blood were transfused. Cell salvaged blood was administered and 5–10 minutes after this, the patient developed hypotension, with BP dropping from 88/25 to 61/28. The transfusion was stopped and BP returned to 90/30. Transfusion restarted and BP dropped to 66/34, with complete resolution when transfusion was again stopped. The patient had been given 3500 mL crystalloid and 4 units of allogeneic blood. Patient also had 2 or 3 episodes of hypotension prior to this event due to hypovolaemia.

This year there were 5 cases of adverse reactions reported to postoperative, unwashed autologous transfusion. Previous reports to SHOT on this type of event have been sporadic but with the advent of the online reporting system it is envisaged that these reports may be a feature of future reports.

In 2009 there were 3 reports of hypotension related to the reinfusion of cell salvaged blood. While an attempt has been made to analyse the clinical scenarios of each report the common factors, certainly in 2 cases, appear to be:

- Use of ACD as an anticoagulant
- Use of a leucodepletion filter (LDF) during the reinfusion of autologous washed red cells.

There are a number of other clinical issues:

- Use of bedside LDF, which is known to cause hypotension when used with allogeneic blood as previously recognised.[54]
- These patients may be hypovolaemic and therefore more susceptible to the effect of reinfused vasoactive cytokines.
- All patients experienced transient but clinically significant hypotension, a blood pressure drop of 20% or more from the starting value, corrected by the cessation of infusion and/or vasopressors.
- No long term sequelae of this hypotension were noted.

These phenomena will require further in-depth analysis to fully understand the consequences of such incidents. At this stage it is important to recognise this as a possible adverse event and treat by discontinuation of the infusion of salvaged red cells and with appropriate vasopressors.

RECOMMENDATIONS

There are no new recommendations for this year.

Recommendations still relevant from last year

Year first made	Recommendation	Target	Progress
2008	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	**Cell salvage leads /HTT**	Online survey currently being undertaken by the UK Cell Salvage Action Group, asking about training and competency. Education workbook produced and available on the website.
2008	All ICS and PCS related adverse events should be reported to SHOT.	**Cell salvage leads /HTT**	There is a specially designed section of the new web-based SHOT reporting system to facilitate this.
2008	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 leads /HTT**	
2008	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.	**Cell salvage leads /HTT**	

20. Paediatric Cases

Definition

Paediatric cases comprise all those occurring in patients under 18 years of age.

Paediatric cases 2009

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 been subdivided by age groups – neonates ≤ 28 days; infants > 4 weeks and < 1 year old; and children < 16 years – because each of these has recommendations regarding blood components. The chapter particularly highlights the cases related to the age of the patient.

Table 46
Summary of paediatric cases 2009

Category of case	No. ≤ 4 wks	No. > 4 wks – < 1 yr	No. 1 – < 16 yrs	No. 16 – < 18 yrs	Total paediatric cases
IBCT	**7**	**9**	**21**	**3**	**40**
Administration	4	1	0	0	5
Lab error	1	4	4	1	10
SRNM (total)	2	4	17	2	25
Irrad/CMV negative	2	3	7	2	14
MB-FFP requirement (or SD-FFP)	0	1	6	0	7
Others	0	0	4	0	4
WBIT	0	0	0	0	0
Handling and Storage	**6**	**0**	**2**	**1**	**9**
Inappropriate & unnecessary	**4**	**2**	**7**	**2**	**15**
Anti-D related	**0**	**0**	**0**	**3**	**3**
ATR	**2**	**3**	**28**	**4**	**37**
HTR	**0**	**0**	**2**	**0**	**2**
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**	**1**	**0**	**0**	**1**
Autologous (cell salvage)	**0**	**0**	**0**	**1**	**1**
TOTAL	**19**	**15**	**60**	**16**	**110**

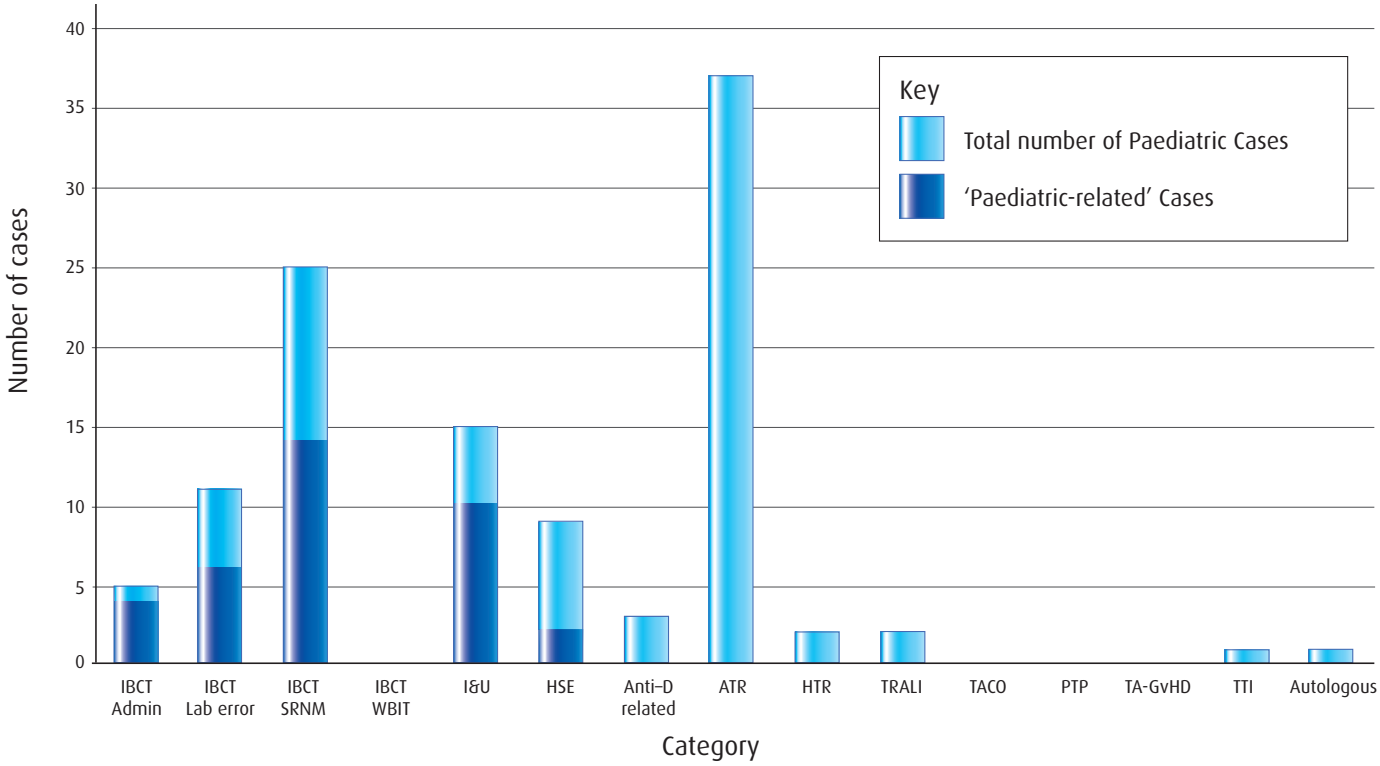
Introduction and overall trends

In 2009, 110 of the total 1279 reports (8.6%) involved patients < 18 years (yr). Furthermore, 94/1279 (7.3%) reports were in children < 16 yr, 34/1279 (2.7%) in infants < 1 yr, and 19/1279 (1.5%) in neonates ≤ 4 weeks. Although this represented an increase in the total number of paediatric reports compared with previously, it mirrors the overall increase in reports; the proportions in different age groups are similar to those in 2008. Thirty-four (31%) of paediatric reports were from infants < 1yr of age, of whom 19/34 (56%) were neonates ≤ 4 weeks old. As discussed previously, there is a disproportionally high number of reports in children compared with adults (see SHOT 2008 for further discussion of paediatric reporting trends).

As before, the majority of paediatric reports were error related (IBCT, handling and storage, inappropriate and unnecessary), comprising 64/110 (58%) reports. For the infant age group, error reports are a higher proportion, with 28/34 (82%) this year. This compares with the adult figure of 570/1279 (45%). The factors leading to many types of errors are the same in adults and children. However, some factors may be more likely to occur in the paediatric age group, including those that are unique to these patients such as age-related special component requirements. Reports involving these factors are described as 'paediatric-related' in the chapter, and this year were estimated to be 35/64 (55%) of all paediatric error reports with a higher proportion in the infant age group, at 23/28 (82%).

ATR cases followed the trend established in 2008, with 37/110 (34%) paediatric cases, an increase in total cases from the 25 reported last year.

Figure 23
Number of paediatric cases in each reporting category
For the error reports, the proportion of 'paediatric-related' cases is also illustrated



ERROR-RELATED REPORTS *n* = 64

Incorrect blood component transfused (IBCT)

IBCT – Special requirements not met (SRNM) *n* = 25

SRNM continues to be the largest subgroup of paediatric reports, with 25/110 cases (23%), 14 of which were considered to be paediatric-related. For infants < 1 year, there were 5 cases of failure to give irradiated blood when indicated, of which 3 involved patients who had had intrauterine transfusions (IUT) and 1 where a diagnosis of SCID was being queried. For the children ≥ 1 yr there were a total of 19 cases. Eight were considered paediatric-related, 6 of which reported the giving of standard FFP rather than imported pathogen inactivated FFP and 2 where non-apheresis platelets were used. However, there were also 6 cases where irradiated blood was not given and 3 where the CMV negative requirement alone was missed, where the reasons for special requirements (such as bone marrow transplantation, BMT) could have occurred at any age. In 1 case the need for platelets in platelet additive solution was missed, as the laboratory flag was unclear.

Fourteen of the SRNM errors could be attributed primarily to the laboratory, 5 primarily to clinicians, and 6 to both groups. Two of the reports where non-irradiated components were given to BMT patients involved problems with flags being removed from the laboratory computer system. There were also 2 reports of poor communication as part of shared care. These reports highlight the difficulty in putting tight systems in place to communicate special requirement needs, both between hospitals and within hospitals.

Case 1

Lack of awareness of the need for irradiated blood post IUT

A baby who had undergone IUT for HDN and with no signs of haemolysis at birth was admitted aged 7 weeks with an Hb of 4.4 g/dL and transfused with a paedipak of non-irradiated blood. Neither the request form nor the prescription indicated that irradiated blood was required. The laboratory SOP was unclear, and the BMS believed that blood for a top-up transfusion post IUT did not require irradiation. Finally, the nursing staff did not notice that the baby required irradiated blood.

This case illustrates poor clinical and laboratory understanding of the implications of fetal transfusions and the need for these to be highlighted adequately postnatally.

IBCT – Lab error *n* = 10

The second largest subgroup of error reports were lab errors with 10 cases, none of which had adverse outcomes recorded. The 5 infant cases were all < 2 months old and in 3 of these there were issues over maternal grouping/antibodies. In the first, a preterm neonate was grouped as A D negative but there was no evidence that the mother's group and antibody status was sought. The baby was given group A D negative paedipaks rather than group O D negative. A 1-month-old infant was manually grouped as O D positive and given group O red cells and platelets. The child was subsequently grouped as AB D positive. In the third case, a 1-month-old infant of a mother with multiple red cell antibodies including Jk^b was given Jk^b positive blood. The red cells were crossmatched against the infant's plasma and issued as compatible but they should have been antigen negative, and crossmatched with the maternal plasma if possible. A fourth case involved complications due to a 1-month-old infant having 2 hospital numbers, 1 which recorded the presence of maternal anti-D and the other which didn't. Blood was erroneously issued without crossmatch as a result of this confusion. The 5 cases in older children were not considered paediatric-related.

In addition to paediatric reports in the laboratory error category, the laboratory contributed to errors in other categories: 19/25 SRNM and 4/9 HSE reports. This gives a total of 33/110 (30%) paediatric reports in which laboratory error was a factor, although in many of these cases there were multiple contributory steps where clinical staff either contributed to the error or subsequently failed to detect that it had been made.

IBCT – Administration *n* = 5

All of the paediatric cases in this IBCT subcategory (administration errors) involved errors with 'flying squad' red cells. Three paediatric patients received emergency group O D negative blood that was intended for adult use despite paedipak group O D negative units suitable for neonates being available. In 1 case a crossmatched group O D negative unit labelled for an individual patient was collected and transfused instead of the available emergency units. In a further

incident group O D negative units were inappropriately transfused to a neonate with HDN due to anti-c which was well documented, and mother and baby had attended for management of this throughout the pregnancy.

Case 2

Doctor unaware of provision of emergency neonatal specification units in satellite fridge

A baby was delivered prematurely by emergency LSCS and had an Hb of 6.2 g/dL requiring emergency transfusion. The staff grade doctor borrowed a midwife's blood fridge access ID card. He removed a unit of adult emergency group O D negative blood, not the paediatric emergency unit which was also present. The baby received 100 mL of the adult unit with no adverse reaction. The incident came to light when the satellite fridge was being restocked by the transfusion laboratory BMS.

This case highlights a lack of knowledge in the doctor, but it is also an example of abuse of the ID-based electronic fridge system, which was in place to help prevent such errors.

Case 3

Baby with known anti-c HDN given group O D negative red cells in error

A baby was born by emergency LSCS with HDN secondary to maternal anti-c which had been known to be at a very high titre throughout pregnancy. In the emergency, group O D negative blood was requested but was unsuitable due to high maternal anti-c detected in pregnancy. The 'flying squad' blood was then removed without informing the laboratory of the need for emergency transfusion. The laboratory at first prepared group O D negative blood, but as the crossmatch was positive it was not issued. Subsequently, with some delay, group O D positive c negative blood was supplied. After receiving the standard 'flying squad' blood the baby suffered an immediate mild reaction, which fully resolved. The bilirubin climbed further, requiring exchange, and this may have been accelerated by the incompatible transfusion.

This case is likely to be as much due to lack of knowing the details of the particular patient as lack of understanding about HDN – all compounded by communication deficiencies.

These cases suggest a worrying problem with confusion of adult and neonatal blood for emergency perinatal use, and in some cases confusion over where to go for emergency blood.

Handling and storage errors *n* = 9

Most of the 9 paediatric reports were considered unrelated to the age of recipient. Six reports were from neonates and 3 from older children. The neonatal reports included 1 case of red cells and 2 of platelets being given after expiry without being noticed at the bedside check, and 1 where the transfusion was not complete until 4 hours 45 minutes after removal from cold storage. There were 3 reports in older children, including the use of an IV giving set instead of a transfusion set, a cold chain error, and inadequate packing of red cells and platelets for transfer with a patient.

Inappropriate and unnecessary transfusion *n* = 15

There were twice as many reports in this category as in 2008. Ten reports involved paediatric-related situations. In 3 the doctor prescribed too much blood. The first related to 3 separate preterm neonatal prescriptions by the same junior doctor who increased the transfusion volume by 20 mL to account for the volume of blood in lines. In the second, the doctor miscalculated the volume needed for a 2 year-old, and in the third a doctor prescribed 2 adult units for a 5 year-old with sickle cell disease, raising the Hb to 14.9 g/dL from 7.0 g/dL. There were 5 paediatric reports where there were nursing errors potentially causing over-transfusion. These involved a combination of wrong pump settings and confusion over administering units as opposed to mL of blood. One neonate received 30 mL of blood instead of 20 mL due to incorrect pump settings. A 750g neonate on restricted fluids was prescribed 11 mL red cells over 4 hours. The pump was initially set too slowly, but then at too high a rate in order to catch up, before a senior nurse noted the risk of over-transfusion. For a 4 year-old, in calculating the hourly infusion rate needed to give a red cell unit over 2 hours, the nurses multiplied the volume of the unit by 2 instead of dividing it; this was discovered rapidly so there was no

adverse outcome. In that report, a unit of blood was prescribed rather than the exact volume. The following 2 cases involve clinically significant over-transfusion.

Case 4

A request was made for 110 mL of blood as a top-up transfusion for a 12-month-old child with endocarditis being ventilated and on inotropes on paediatric intensive care. One adult unit of blood (230 mL) was issued, and the nursing staff transfused the entire unit. The post-transfusion Hb was 19 g/dL and the patient required venesection.

Case 5

A prescription was made for 140 mL of red cells for a 6-month-old infant on intensive care following surgery for congenital heart disease. The nurse asked the doctor if she should give 1 unit, and he agreed. The unit issued was an adult bag with 257 mL. The entire unit was transfused but there was no adverse outcome other than excessive flushing.

One neonate had a delayed transfusion due to communication failures, misunderstandings and portering delays (see I&U chapter, page 66). In the final paediatric-related report there was confusion between the results for twin neonates. One had a low platelet count but platelets were requested and transfused to the other twin.

There were 5 reports where age of the recipient was not a major factor in accounting for the problem. In 3 of these the patients were transfused platelets based on an initial platelet count that was subsequently highlighted as erroneous due to platelet clumping. One patient with lethargy and pallor was transfused on the basis of a low Hb of 7.8 g/dL later discovered to be from the week before. The Hb from the day of transfusion was 11 g/dL.

TRANSFUSION REACTIONS *n* = 42

Acute transfusion reaction *n* = 37

In 2008 there was a striking increase in the number of paediatric ATRs reported, particularly from platelets (18 reported). This year, there were a similar number of reactions to platelets (14/37; 38%), but the majority of cases were in red cells with an increase in reports to 19/37 (51%). There were only a few ATR reports after FFP transfusion (3/37; 8%). These proportions are similar to the paediatric summary data 1996–2005.[55]

Only 5/37 (14%) paediatric ATR reports were in infants < 1 yr old, including 2 in the neonatal group of which 1 was an anaphylactic reaction to platelets. A high proportion of reports in the ≥ 1 yr age group are of ATR, accounting for 32/76 (42%) total reports for this group, similar to 2008.

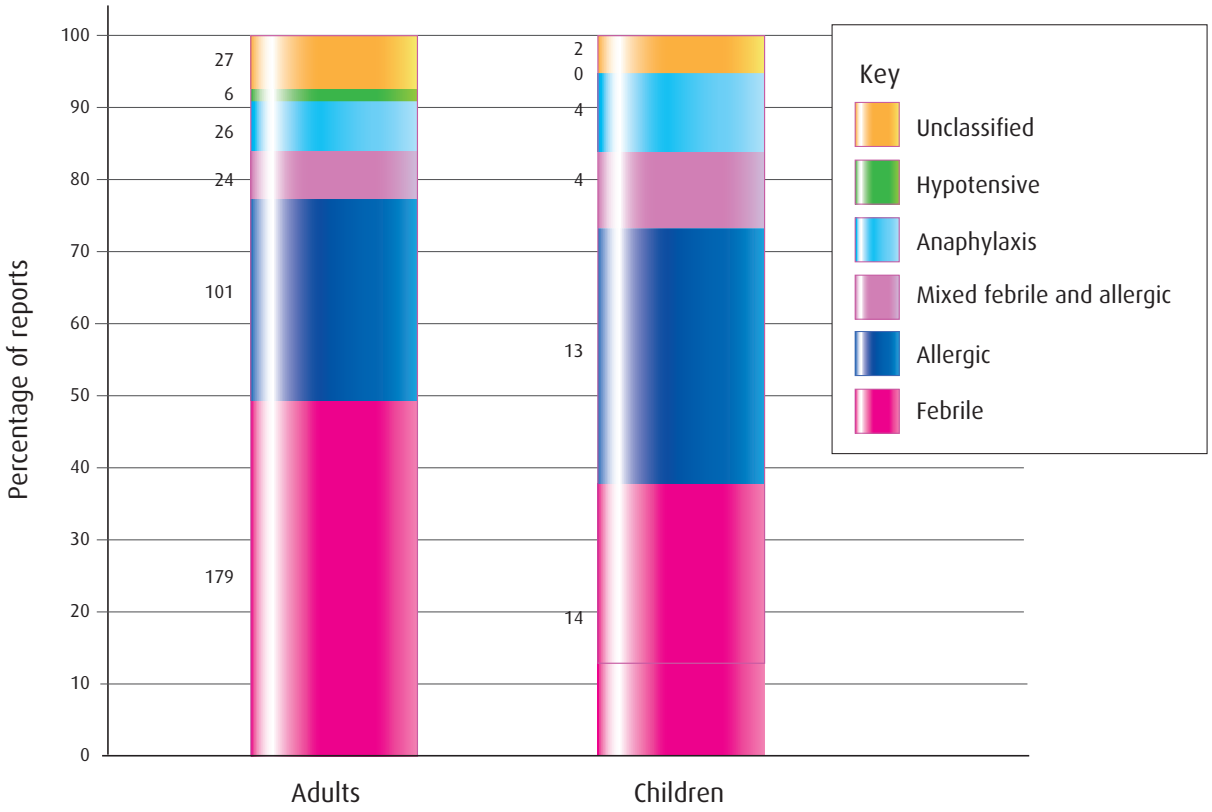
Paediatric reports constitute 7% of all red cell ATR, but 16% of platelet ATR. The types of reactions reported are in broadly similar proportions to adults (see Figure 24), and there were more paediatric febrile reactions to red cells reported this year than in 2008. Allergic reactions mostly constituted rashes, frequently treated with antihistamines.

One paediatric ATR report involved 3 paedipaks from the same donor being given to 3 different children and in each case there was an allergic reaction with rashes (see ATR chapter, page 88 for description). Paedipaks are usually employed for multiple transfusions to the same neonate in order to reduce donor exposure. This report does highlight that on occasion there can be disadvantages to having multiple donations from the same donor.

Table 47
Types of reactions for each component comparing paediatric with adult reports

Reaction	Red cells		Total platelets		FFP		Multiple components		Total	
	Adults	< 18 yrs	Adults	< 18 yrs	Adults	< 18 yrs	Adults	< 18 yrs	Adults	< 18 yrs
Febrile	158	9	16	4	4	1	1	0	179	14
Allergic	43	5	34	8	22	0	2	0	101	13
Mixed febrile and allergic	14	2	6	0	4	2	0	0	24	4
Anaphylaxis	4	1	10	2	10	0	2	1	26	4
Hypotensive	5	0	1	0	0	0	0	0	6	0
Unclassified	21	2	5	0	1	0	0	0	27	2
Total	**245**	**19**	**72**	**14**	**41**	**3**	**5**	**1**	**363**	**37**

Figure 24
Type of acute transfusion reactions – comparison between adult and paediatric reports



Haemolytic transfusion reaction *n* = 2

Both paediatric HTR reports were in patients with sickle cell disease, aged 4 and 7 years. One developed probably mild haemolysis post transfusion with JK^b positive units and was found to have developed an anti-JK^b. The second had had anti-M and anti-S detected at another hospital and was subsequently transfused with an S-positive unit (see HTR chapter, page 98, for further details).

Transfusion-related acute lung injury *n* = 2

Both paediatric reports of TRALI were in patients between 16 and 17 years of age. One developed symptoms of TRALI 4 hours after red cell transfusion following sepsis and a laparotomy. The second became symptomatic 1 hour after red cell transfusion for bleeding after an incomplete miscarriage. As previously noted, there have been only rare reports of children in younger age groups and this may be due to a lack of recognition (see SHOT 2008 report).

TACO, PTP, TA-GvHD

There were no paediatric cases in these categories.

Transfusion-transmitted infection *n* = 1

The single paediatric TTI was of *Strep. pneumoniae* in an 8-month-old baby with refractory AML following platelet transfusion (see TTI chapter for more details). The baby was given 3 of 4 neonatal packs on 3 subsequent days. Following both the second and third transfusions, the baby became acutely unwell with a high fever but this was felt at the time to be due to the patient's general condition so was not reported as a transfusion reaction. The case has been highlighted in a letter from NHSBT to paediatricians and neonatologists.

OTHER *n* = 4

Anti-D related events *n* = 3

There were 3 reports in the 16–17 age group, none of which had a paediatric-related reason for the error.

Autologous transfusion *n* = 1

The single report was from a patient aged 17 years.

COMMENTARY AND LEARNING POINTS

- The proportion of reports that were paediatric, and their pattern, was similar to before. This year the types of ATR in children were fairly similar in distribution to those in adults, partly reflecting an increase in the number of reports of febrile reactions to red cells. In contrast to previous years, there were no reports of haemolysis following transfusion of group O platelets to non-group O recipients. As before, there were few adverse reactions reported in the neonatal and infant age groups; clinicians need to be alert to possible paediatric transfusion reactions, highlighted this year by the missed bacterial contamination of platelets given to a neonate.

- Errors in neonatal pre-transfusion testing continue to occur in the laboratory, emphasising the need to check the maternal results and to follow the BCSH transfusion guidelines for neonates and older children (2004).[24] Future guidelines should further clarify the length of time that the maternal sample should be used for red cell compatibility testing in situations where there is a maternal antibody present.

- Children frequently have special transfusion requirements. The recent BCSH guidelines on the administration of blood components (2009)[19] separated these into clinical special requirements, defined by the patient's underlying condition, as opposed to automatic special requirements for a particular age group. The former will

always require notification by clinicians, but the latter should be flagged for and automatically provided by the laboratory. The varied causes of the recurrent paediatric SRNM cases include missed or erroneously removed laboratory flags and inadequate clinical processes with lack of communication of special requirements to the lab and inadequate bedside checks. There is need for continuing education and awareness, laboratory IT systems that reliably retain special requirement flags, and better clinical communication systems such as improved prescription chart design to facilitate adequate prescribing.

- The requirement for irradiation of neonatal red cells following IUT needs particular emphasis, both for clinicians and laboratory staff. As transfusions to affected neonates may take place in a different hospital to the IUT, adequate communication between hospitals is vital. It is also important that the parents are informed that transfusions given to the baby would need to be irradiated, and that they are given an irradiation card.

- There were a striking number of reports of over-transfusion and this is a concerning recurrent issue. Although some were due to incorrect prescription including specifying units rather than a specific volume as previously, there were several nursing errors in setting up infusion pumps (see recommendations below).

- There are repeated reports of confusion over 'flying squad' blood, particularly the use of obstetric adult 'flying squad' blood for neonates. There need to be rigorous local procedures and training to ensure that red cells for neonatal resuscitation are available, clearly distinguishable from obstetric emergency blood, and that nurses and doctors are aware of the distinction.

- The HSE case of a neonatal transfusion which took 4 hours and 45 minutes is a reminder that although neonatal transfusions frequently take 4 hours, for this group it is still emphasised that there should be no more than 30 minutes between removing the component from the temperature controlled environment and starting the transfusion; the transfusion itself should take no more than 4 hours.[19]

RECOMMENDATIONS

New recommendations from this year

- The correct prescription of paediatric transfusions is vital and an area of recurrent errors. Local consideration should be given to the design of paediatric prescription charts in order to facilitate the correct prescription of both blood component volumes/rates and clinical special requirements.

  Action: HTCs, HTTs, pharmacists

- Nursing staff involved in paediatric transfusion must be sufficiently skilled and competent in the use of pumps/blood infusion devices, appropriate transfusion volumes/rates, and the need for special requirements in order to reduce these types of errors. These aspects should be included in their transfusion training as required by the BCSH (2009) guidelines on the administration of blood components.[19]

  Action: HTCs, HTTs, RCN, RCM, NMC

Recommendations still active from previous years

Year first made	Recommendation	Target	Progress
2008	The trend in increasing ATR cases, in particular in relation to platelets, needs careful monitoring.	**SHOT**	This year there was a similar proportion of paediatric ATR cases, but the number of platelet cases was stable, and fewer than cases involving red cells.
2008	Clinical staff should be encouraged to report all ward-based reactions and events including possible TACO and TRALI and neonatal ATR cases.	**HTTs**	There has been little change in reporting patterns, and without a prospective clinical study it may be difficult to capture these cases. The need for clinicians to be alert to transfusion reactions has been illustrated by the 2009 paediatric TTI report.
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 continues to need emphasis in 2009, and laboratories need sufficient manpower and IT support. 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 2009 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**	This has been re-emphasised by the 2009 BCSH administration guidelines. By separating 'clinical special requirements' from those related to requirements automatic for certain ages, it may now be more practical to include clinical requirements on the prescription chart, helping to improve clinical communication.
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' was produced 2006. SHOT in obstetrics was produced in 2007. NBS Paediatric conference was held in Feb 2007.

21. 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.

Near Miss events have long been recognised as a good indicator of strengths and weaknesses within areas seemingly as disparate as the aircraft industry and blood transfusion, but where the common aim is to constantly strive to improve safety. 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 last year's annual report SHOT described phase 1 of a pilot study in which reporters were asked to submit data on sample errors detected during the 'booking in' process. This study showed that on average 3.8% samples received in transfusion laboratories are rejected because of a labelling error, though this ranged from 0.4% to more than 13% of samples received.

This type of error is not reportable to SHOT as a Near Miss event, but needs to be monitored and trended at a local level.

In phase 2 of the pilot study, reporters were asked to submit data on samples that appeared to be correctly labelled but that were found to be incorrect in some way during testing in the laboratory. These 'Wrong Blood In Tube' errors have the potential to result in issue of ABO-incompatible blood components to the patient, especially if there is no historical record available on laboratory computer systems, and are reportable as Near Miss events.

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. However, the percentage of sample errors attributed to medical staff (45%) seems disproportionately high, and it would be instructive to obtain denominator data as to what proportion of all samples are taken by which group of staff.

This would be an intensive and difficult data-gathering exercise for reporters already fully committed to national and local audit activities, but even in the absence of the denominator data it should be noted that the figures obtained are comparable with previous SHOT annual reports.

What is clear from the pilot study is the need for training and adherence to policies for venepuncture and sample labelling among all staff groups, including doctors.

In 2009, there were 797 reports submitted under the heading of Near Miss, but as in previous years there has not been the resource within the SHOT team to analyse these effectively.

The introduction of the new SHOT web-based reporting system in January 2010 allows the reporting of the whole range of Near Miss events, including WBIT errors, component selection and handling errors, and collection and pre-administration errors, and this coupled with two new members of the SHOT team should make the analysis of these reports much more straightforward.

22. References

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23. Glossary

ACD	Acid citrate dextrose
AHTR	Acute haemolytic transfusion reaction
AIHA	Auto immune haemolytic anaemia
ALI	Acute lung injury
ALL	Acute lymphoblastic leukaemia
AML	Acute myelotic leukaemia
ARDS	Acute respiratory distress syndrome
ARF	Acute renal failure
ATR	Acute transfusion reaction
BBT	Better Blood Transfusion
BBTS	British Blood Transfusion Society
BCSH	British Committee for Standards in Haematology
BMS	Biomedical Scientist
BMT	Bone marrow transplant
BP	Blood pressure
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventative actions
CCF	Congestive cardiac failure
CEO	Chief Executive Officer
CDC	Complement dependent cytotoxicity
CfH	Connecting for Health
CLL	Chronic lymphocytic leukaemia
CMO	Chief Medical Officer
CMV	Cytomegalovirus
COPD	Chronic obstructive pulmonary disease
CPA	Clinical pathology accreditation
CPAP	Continuous positive airway pressure
CRF	Chronic renal failure
Cryo	Cryoprecipitate
CS	Caesarean section
CTS	Controlled temperature storage
CXR	Chest X-ray
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation
DNA	Deoxyribose nucleic acid
DTR	Delayed transfusion reaction
DU	Duodenal ulcer
ECMO	Extracorporeal membrane oxygenation
ED	Emergency department
EDTA	Ethylenediaminetetraacetic acid
EI	Electronic issue
ET	Endotracheal
EWTD	European Working Time Directive
FBC	Full blood count
FFP	Fresh frozen plasma
FY	Foundation year
G&S	Group and save
GI	Gastrointestinal
GMC	General Medical Council
GP	General Practitioner
HAV	Hepatitis A virus
Hb	Haemoglobin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDN	Haemolytic disease of the newborn
HDU	High dependency unit
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HL	Hickman line
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen *or* Health Protection Agency
HSC	Health service circular
HTC	Hospital Transfusion Committee
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
IHD	Ischaemic heart disease
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
ITU	Intensive Therapy Unit
IUT	Intrauterine transfusion
IV	Intravenous
JVP	Jugular venous pressure
LDF	Leucocyte depletion filter
LDH	Lactate dehydrogenase enzyme
LIMS	Laboratory information management system
MB-FFP	Methylene-blue fresh frozen plasma
MCT	Mast cell tryptase
MDS	Myelodysplastic syndrome
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	Medical laboratory assistant
MOF	Multi-organ failure
NBS	National Blood Service
NBTC	National Blood Transfusion Committee
NHL	Non-Hodgkin's lymphoma
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
NICU	Neonatal Intensive Care Unit
NISS	Normal ionic strength saline
NMC	Nursing and Midwifery Council
NOS	National occupational standards
NPSA	National Patient Safety Agency
NR	Normal range
NSAID	Non-steroidal anti-inflammatory drug
OA	Optimal additive
PAD	Preoperative autologous deposit
PAS	Platelet additive solution
PBSC	Peripheral blood stem cells
PCS	Postoperative cell salvage
PMETB	Postgraduate Medical Education and Training Board
POCT	Point of care testing
PR	Per rectum
PTP	Post-transfusion purpura
RA	Rheumatoid arthritis
RAADP	Routine ante-natal anti-D prophylaxis
RBC	Red blood cells
RBRP	Right blood right patient
RCA	Root cause analysis
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
SCD	Sickle cell disease
SCID	Severe combined immunodeficiency
SCT	Stem cell transplant
SD	Solvent detergent
SG	Steering Group
SHA	Strategic Health Authority
SNBTS	Scottish National Blood Transfusion Service
SOB	Shortness of breath
SOP	Standard operating procedure
SPN	Safer practice notice
SpR	Specialist Registrar
SRNM	Special requirements not met
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TA-GvHD	Transfusion-associated graft-versus-host disease
TKR	Total knee replacement
TP	Transfusion practitioner
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenic purpura
UKTLC	UK Transfusion Laboratory Collaborative
vCJD	Variant Creutzfeld Jakob Disease
WBIT	Wrong blood in tube
WBS	Welsh Blood Service
WCC	White cell count
WEG	Working Expert Group

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