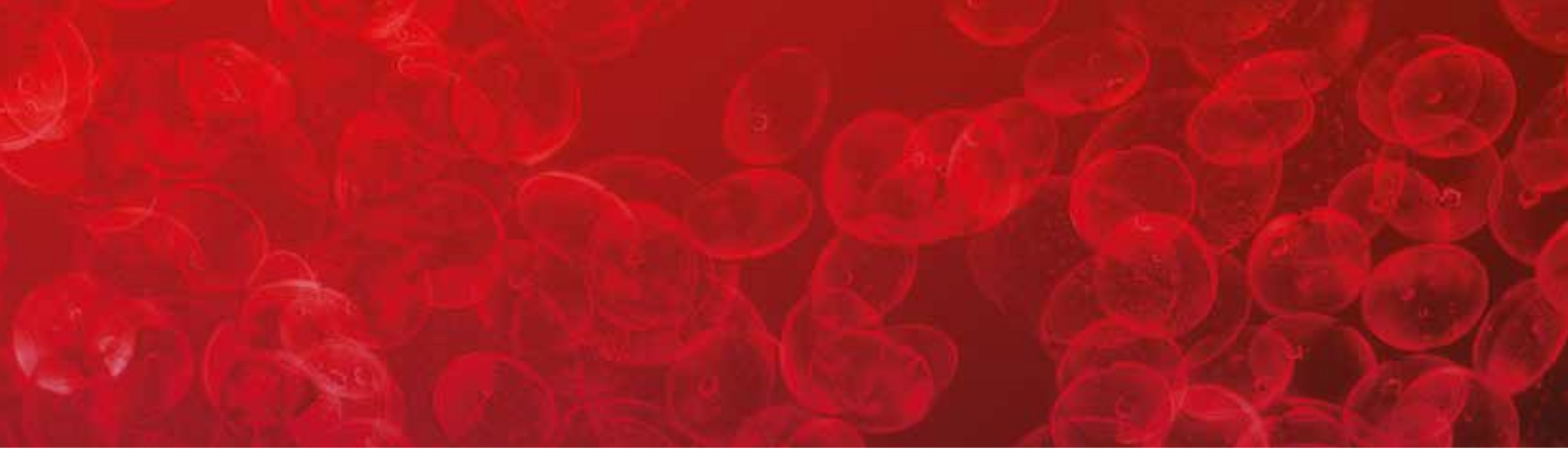

ANNUAL SHOT REPORT 2012

Affiliated to the Royal College of Pathologists

The Steering Group includes members representing the following professional bodies:

British Blood Transfusion Society
British Society for Haematology
British Society of Gastroenterology
British Committee for Standards in Haematology
Faculty of Public Health
Institute of Biomedical Science
Public Health England
(formerly the Health Protection Agency)
NHS Confederation
Royal College of Anaesthetists
Royal College of Nursing
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Physicians
Royal College of Surgeons
Royal College of Paediatrics and Child Health
Intensive Care Society
Faculty of Intensive Care Medicine
The College of Emergency Medicine
Defence Medical Services
UK Forum

Serious Hazards of Transfusion (SHOT)

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Please cite this work as:

PHB Bolton-Maggs (Ed), D Poles, A Watt, D Thomas and H Cohen on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2012 Annual SHOT Report (2013)

This work was undertaken by SHOT. The work was funded by NHS Blood and Transplant, Northern Ireland Blood Transfusion Service, Scottish National Blood Transfusion Service and the Welsh Blood Service through the UK Forum.

Published July 2013

ISBN 978-0-9558648-5-8

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Foreword

1

Authors: Paula Bolton-Maggs and Dafydd Thomas

We are pleased to present the outcome of the reports submitted to SHOT and completed in 2012. The general trends are unchanged with an increase to virtually universal participation by National Health Service (NHS) Hospitals, Trusts and Health Boards to 99.5% registered, with 97.8% submitting reports. Each year some reports are withdrawn as they do not meet SHOT definitions. The number of reports submitted for 2012 was 3545, which represents a 3.2% increase in reports compared with 2011. Of these 3545 reports, 2466 have been analysed and included in this report; 881 were withdrawn; 154 were subsequently completed after the cut off date for inclusion in the 2012 report and 44 are still incomplete at the time of writing. In addition, 172 reports are carried over from 2011 as they were not completed in time for last year's report, bringing the total reports analysed to 2638. Some adverse incidents are difficult to categorise and the final category may be revised from the original submission. These data are shown in Chapter 2. In addition we receive reports of severe reactions which cannot be easily classified. Although these have been called 'previously uncategorised complications of transfusion' (PUCT) in SHOT, we have a short chapter (Chapter 23) containing these miscellaneous incidents called 'Unclassifiable Complications of Transfusion' (UCT) in keeping with the International Society of Blood Transfusion (ISBT) definition[1]. Reporting these may enable others to realise they have seen similar problems which may contribute to better recognition of uncommon but significant incidents such as those described with intravenous immunoglobulin both this year and last year (see Chapters 23 and 24).

In 2012 there was 1 death definitely attributable to transfusion (imputability 3), caused by transfusion-associated graft versus host disease (TA-GvHD). This death from TA-GvHD is the first case since 2001. An intrauterine transfusion was performed using maternal blood (non-leucodepleted, non-irradiated and related) at 21 weeks gestation but the infant was born with evidence of immune suppression and subsequently died with confirmed TA-GvHD. This case prompted both a review of practice across the UK in fetal medicine units and dialogue with the Blood Services about availability of suitable blood for intrauterine transfusion in an emergency, and is discussed in detail in Chapter 20.

There were 3 other deaths where transfusion contributed to the death (imputability 2). One death occurred in a patient treated with intravenous immunoglobulin (IVIg) who developed haemolysis complicated by renal failure and is reported in Chapter 23 (UCT). Interestingly there was also a case of haemolysis related to IVIg reported in 2011[2]. The second case was due to transfusion-associated circulatory overload (TACO), and the third case was related to a haemolytic transfusion reaction.

There were 5 other deaths where the transfusion complication was possibly contributory (imputability 1), and all of these were cases of TACO. TACO in one case was caused by an inappropriately large volume transfusion in a patient of low body weight.

Major morbidity was reported for 134 patients.

Three transfusion-transmitted viral infections were also noted in 2012, none having been reported since 2005. There were no bacterial infections (the last year this was reported was 2009). This indicates the importance of continued vigilance. The death and morbidity rate relating to transfusion is small but real. Medical staff need to be sure that any transfusion of blood or its components is indicated and appropriately monitored.

The proportion of reported incidents due to error remains high, at 62.4% (1026/1645), excluding reports of 'right blood right patient' and 'near miss' events. Similar findings are reported from the Medicines and

Healthcare products Regulatory Agency (MHRA) in Chapter 6. Continued effort is needed to understand the human factors leading to errors, and errors are helpfully classified within the MHRA chapter. The Francis report on the Mid Staffordshire NHS Foundation Trust Public Enquiry stated that there remains a culture of fear to report concerns and that there is a need to continue to encourage 'openness, transparency and candour'[3]. The increased participation rate is therefore encouraging, but the number of reports from different hospitals with comparable blood usage is very variable. The reasons for this should be explored by reporting organisations, using the individual participation benchmarking reports distributed by SHOT.

The headlines from 2012 reporting are a continued high rate of error related to omission of essential procedural steps and communication failures. Many errors could be prevented by good communication at all levels, and between departments and institutions, both primary and secondary care, and particularly by ensuring confirmation of identity at every stage of the transfusion process. Several examples were noted where the adverse outcome followed serial errors. Examples can be found in the chapters on anti-D, laboratory errors, clinical incorrect blood component transfused and transfusion-related circulatory overload. As emphasised before there are dangers in a multistep process where several different professional groups are involved. Introduction of a checklist for the transfusion steps was recommended by SHOT in 2011[2] to reduce errors and a model is available on the website (www.shotuk.org/wp-content/uploads/2010/03/SHOT-Transfusion-Process-Checklist-May-2012.pdf). Again the Francis report reminds us that there is no place for complacency, and the continued need to have a 'relentless focus on patient safety'[3]. The General Medical Council published new guidance for doctors in March 2013 which states that 'patients must be able to trust doctors with their lives and health. You must make the care of your patient your first concern' and reminds doctors that we 'must contribute to confidential enquiries and to adverse event recognition'[4]. Adverse incident reporting is therefore mandatory not voluntary.

SHOT continues to work closely with the MHRA SABRE team towards the creation of a new unified Haemovigilance UK reporting mechanism. Improved links between the two existing systems were implemented in January 2013 to reduce duplication and this has been welcomed by reporters.

We wish to acknowledge two individuals who have made a great contribution to SHOT since the beginning in 1996. Hannah Cohen has been chair of the Steering Group since SHOT's inception in December 1995 and Deborah Asher has been our laboratory expert since the 1998/1999 Annual SHOT Report until both stepped down last year. We thank them for their inspiration, dedication and hard work over the many years. We are glad that Hannah continues to chair our publications committee, to support us with her experience and knowledge, to co-edit and co-author the Annual SHOT Report.

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Medical Director, Serious Hazards of Transfusion

Dr. Dafydd Thomas
Chair, SHOT Steering Group

Participation in the SHOT Haemovigilance Reporting Scheme 2

Authors: Debbi Poles and Paula Bolton-Maggs

The steady increase in both participation (number of Trusts, Hospitals and Health Boards registered for reporting) and the number of reports continues. Unlike the Medicines and Healthcare products Regulatory Agency (MHRA) reporting which has tended to plateau over the past 2 years, the trend in most categories for SHOT is still upwards. Where there are fewer reports this is in part due to changes in our definitions (see below).

Calendar year participation 2012

The total number of reports made in 2012 was 3545, compared to 3435 in 2011, an increase of 110 or 3.2%.

Reporting organisations 2012

Overall there is now virtually universal participation in SHOT with the number of NHS Trusts/Health Boards registered for reporting 99.5% (182/183) and the number of NHS Trusts/Health boards who actively reported during 2012 97.8% (179/183).

There were 224 reporting organisations (registered on the SHOT database), 182 NHS Trusts/Health Boards and 42 non-NHS organisations. The number of NHS organisations has reduced because 6 Trusts merged with other Trusts between November 2011 and July 2012. One of these was not previously registered to report to SHOT but has now merged with a Trust that does report. Another of these was previously registered but has not made any reports since 2010. One NHS Foundation Trust remains not registered on the SHOT database, a specialist hospital which may make reports indirectly via another transfusion laboratory.

There were 3 other Trusts/Health Boards who are registered but did not report in 2012. Two are low users, but the other one is an Acute Care Foundation Trust who registered in 2011, made 2 reports and has not reported since.

It is more difficult to obtain denominator data for non-NHS hospitals. Some may receive their blood and components from NHS Trusts/Health Boards, and may be reporting by that route.

A table showing the participation breakdown for NHS Trusts/Health Boards for 2012 may be viewed in the supplementary material for the annual report 2012, on the SHOT website.

Number of reports by UK country

	2009		2010		2011		2012	
	Number	%	Number	%	Number	%	Number	%
England	1983	80.2	2511	78.5	2749*	80.0	2860*	80.7
Northern Ireland	70	2.8	154	4.8	150	4.4	156	4.4
Scotland	189	7.6	332	10.4	352	10.2	326	9.2
Wales	233	9.4	203	6.3	184	5.4	203	5.7
United Kingdom	**2475**	100.0	**3200**	100.0	**3435**	100.0	**3545**	100.0

**Includes reports from Ministry of Defence overseas*

Table 2.1: Total number of reports to SHOT by UK country 2009-2012

Table 2.2: Total issues of blood components from the Blood Services of the UK in calendar year 2012

	Red Cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo*	Totals
NHS Blood & Transplant	1,815,335	268,565	242,990	69,479	13,643	38,530	2,448,542
Northern Ireland Blood Transfusion Service	55,907	8,348	5,750	1,520	485	1,100	73,110
Scottish National Blood Transfusion Service	189,378	25,243	21,416	5,280	1,558	4,100	246,975
Welsh Blood Service	86,163	9,581	12,565	1,390	208	378	110,285
Totals	**2,146,783**	**311,737**	**282,721**	**77,669**	**15,894**	**44,108**	**2,878,912**

FFP fresh frozen plasma; SD solvent detergent-sterilised; MB methylene blue-treated.

**Cryoprecipitate figures for 2012 reflect the use of both pools (adult dose = pool of 5 donations) and single donations, including MB components for paediatric patients. Hence there is a noticeable change in some totals from previous years when pools were converted and expressed as single donations.*

Table 2.3: Total number of reports per 10,000 components by UK country 2009-2012

	2009	2010*	2010**	2011	2012
England	8.1	8.9	10.1	10.9	11.7
Northern Ireland	10.5	16.0	20.8	21.1	21.3
Scotland	6.8	10.6	12.2	14.3	13.2
Wales	19.6	15.2	18.1	16.4	18.4
United Kingdom	**8.5**	**9.5**	**10.9**	**11.6**	**12.3**

** Column 1 for 2010 reports is calculated using the total number of completed reports in 2010, which is directly comparable to the historical data.*

*** Column 2 for 2010 is calculated using the total number of reports that have been started in 2010 (3200), including those that are not completed and were therefore not analysed in the rest of the 2010 report. These figures are not directly comparable to historical data, but are more indicative of the actual participation in 2010 and correlate to the figure used to monitor participation 2011 and forthcoming years.*

Cases included in the 2012 Annual Report

Cases included in the 2012 report include some reported in 2011 but not completed until 2012. Similarly some of the 3545 cases reported to SHOT in 2012 are currently incomplete and will roll over to the 2013 report.

The total number of reports analysed for 2012 is 2638. This is a decrease from 3038 in 2011 by 400 (13.2%). A large part of this decrease is due to the withdrawal of mild acute transfusion reactions (169 cases) which no longer need to be reported, and the exclusion of some handling and storage reports where the transfusion time was less than 5 hours to complete.

The number of reports excluding 'near miss' and 'right blood right patient' (where by definition the patient suffers no harm) is 1516.

This chapter on participation concentrates on the actual reports made to the online SHOT database. However, there have been more cases reported this year that affect more than one patient. Those additional patients are included in the numbers within the rest of the report as if all patients had been reported as individual cases. Reports containing multiple patients were made in the handling and storage errors category (Chapter 14) – 12 reports covering 129 individual patients, and also in the Anti-D category (Chapter 15) – 4 reports covering 16 individual patients. Therefore the total number of cases included in the analysis for 2012 are 1645 excluding 'near miss' and 'right blood right patient', or 2767 including 'near miss' and 'right blood right patient'.

As in previous years the categorisation of incidents can be difficult and many cases are moved from the initial category to a more appropriate one. Transfers are shown in Table 2.5.

Table 2.5: Number of reports transferred between categories for 2012

Original category	Transferred to category													
	AntiD	ATR	CS	ALLO	HSE	HTR	ADU	IBCT	NM	UCT	RBRP	TAD	TACO	Total
AntiD									9		1			10
ATR						2			1	4		11	14	32
CS														0
HSE							3	2	3		7			15
HTR		5		8				5		2				20
ADU					7			5					1	13
IBCT	2	1			9		1				2			15
NM	19		1		1		8	6			2			37
UCT		10		1										11
RBRP		1			15	2	4	10	2					34
TAD													6	6
TACO							1							1
TRALI		2										1	5	8
TTI		5												5
Total	**21**	**24**	**1**	**9**	**32**	**4**	**17**	**28**	**15**	**6**	**12**	**12**	**26**	**207**

** AntiD=errors with anti-D immunoglobulin administration; ATR=acute transfusion reactions; CS=cell salvage and autologous; ALLO=alloimmunisation; HSE=handling and storage errors; HTR=haemolytic transfusion reactions; ADU=avoidable, delayed or undertransfusion; IBCT=incorrect blood component transfused; NM=near miss; UCT=unclassifiable complications of transfusion; RBRP=right blood right patient; TAD=transfusion-associated dyspnoea; TACO=transfusion-associated circulatory overload; TRALI=transfusion-related acute lung injury; TTI=transfusion-transmitted infection.*

In 2012 a new pulmonary questionnaire was introduced to try and standardise the data collected for transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO) and transfusion-associated dyspnoea (TAD), and also to attempt to make the transfer of cases easier from acute transfusion reactions (ATR) to the pulmonary categories. This questionnaire is generated for any ATR report where the predominant characteristic is respiratory distress. However, in 2012 there were 25 transfers from ATR to TAD & TACO, with only 9 (36.0%) of these reports having triggered the pulmonary questionnaire.

Data by location and specialty

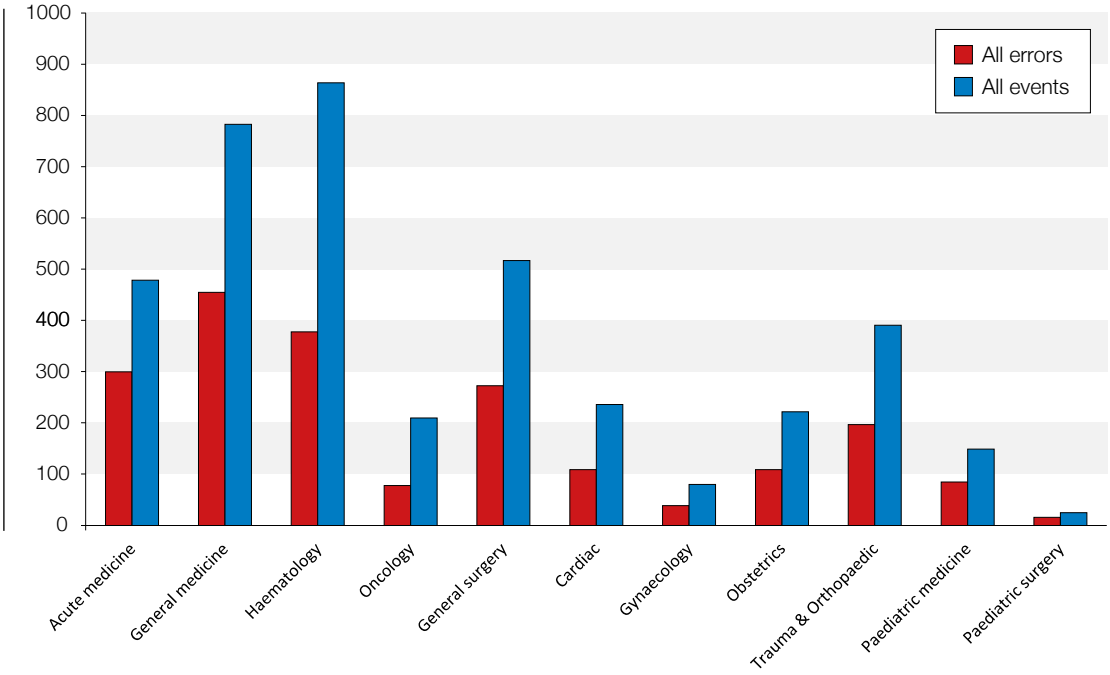
Most SHOT questionnaires ask for information about where the event happened and what specialty the patient was under. For the first time this year we have analysed this and present data from a three year period, 2010 to 2012. The location of the transfusion or event was recorded in 4263 reports, and the specialty given in 3956 reports (excluding 'near miss', but including 'right blood right patient').

Transfusions in the cases reported to SHOT most often take place in wards, 2600/4263 (61%) over the three year period. It is notable that a small number take place in the community, 50/4263 (1.2%) either in a hospice or community hospital, and for this location 3 incidents were acute transfusion reactions. This reinforces the advice given before and in Chapter 16, that transfusions should only take place where the staff supervising the transfusion are able to recognise and treat anaphylaxis and other acute reactions.

The number of incidents by specialty is shown for the three year period 2010 to 2012 in Figure 2.1. For this analysis some specialties have been combined. 'Acute medicine' (479/3956 (12.1%) of all incidents) includes reports from medical admissions units and emergency departments. General medicine (783/3956 (19.8%) of all incidents) includes some specialty areas where the numbers were small, for example dermatology and endocrinology. General surgery (517/3956 (13.1%) of all incidents) includes subspecialties such as plastic surgery and maxillofacial surgery. However, trauma and orthopaedics have been reported as a separate category because of the large number (391/3956 (9.9%) of all reported incidents). Incidents related to cell salvage were mainly reported from orthopaedics (43/68 (63.2%) of cell salvage incidents). The greatest number of incidents overall is reported from haematology (864/3956

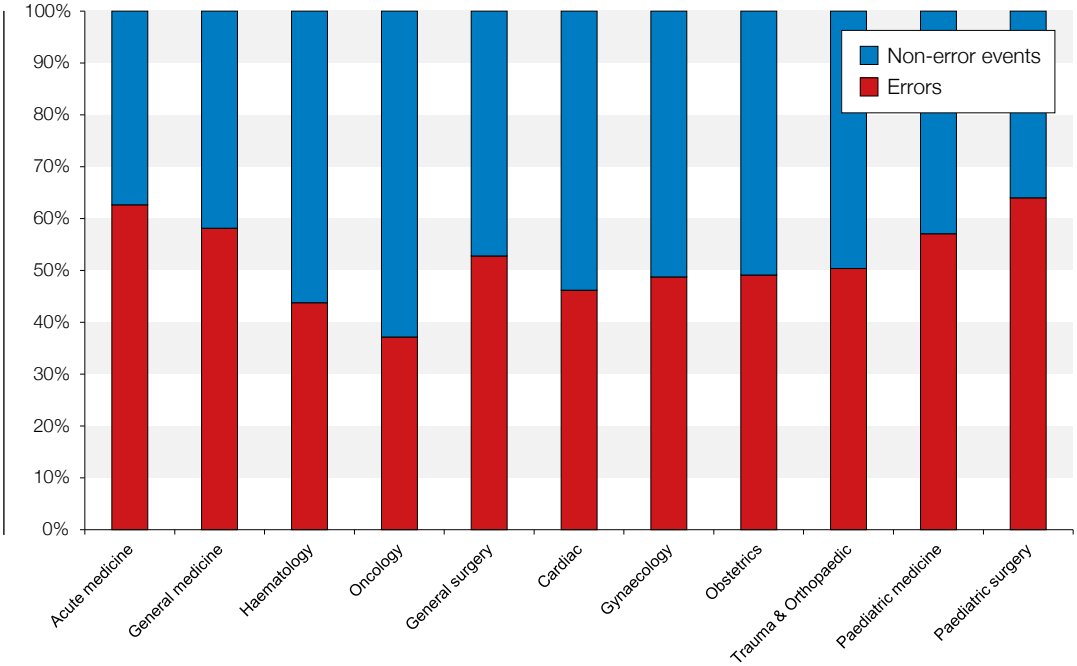
(21.8%) of all incidents). This is consistent with the observation that this is a highly transfused group. Although SHOT has no denominator data for numbers of transfused patients, this proportion is similar to the observation that haematology patients accounted for 18% of transfused patients in the 10 year observation period of red cell transfusion in the North of England[5]. Overall about 60% of transfusions are given to medical patients, and our figure of 62.8% is close to this, suggesting that the proportion of reports by specialty reflect the rates of transfusion rather than any variability in reporting practice.

Figure 2.1: The number of incidents by specialty for the three year period 2010 to 2012 (n=3956)



For the total reports analysed by specialty in 2010-2012, including 'right blood right patient' but excluding 'near miss' events, 2039/3956 (51.5%) are related to errors. When broken down by specialty it is clear that some areas report a higher proportion of errors.

Figure 2.2: The same data as Figure 2.1 but showing the proportion of all incidents in each specialty caused by error (excluding 'near miss')



The highest percentage of errors are reported for acute medicine (300/479 (62.6%)) and paediatric surgery (although the numbers in the latter group are small – 16/25 (64.0%)). The lowest proportion of errors is seen in haematology and oncology where one might expect the staff to have a better knowledge of transfusion.

Over the three year period, 2485/3956 (62.8%) incidents were reported in medical specialties, including oncology and haematology, and 1471/3956 (37.2%) in all surgical specialties including obstetrics and gynaecology, cardiothoracic, cardiology and anaesthesia. These exclude 'near miss' events, but include 'right blood right patient' events. This is the expected split given that audits have shown about 60% of transfusions are given to medical patients, about 30% to surgical patients and 6% to obstetrics patients[6].

Recent concern has been expressed by the Royal College of Physicians about training in general medicine in their report 'Hospital workforce fit for the future?'[7] that notes the extreme pressure that junior physicians are under and the problems with recruitment into the specialty. These observations are supported by Blakey and colleagues who highlight the increasing number and complexity of medical admissions, the poor working arrangements and falling recruitment[8]. The Royal College of Physicians also note the 'out of hours care breakdown' and a 'looming crisis in the medical workforce'[9]. These factors may contribute to the error rate in medical practice related to rushing, stress, lack of time to fully assess patients for transfusion, and poor handover.

The distribution of report types varies in different areas. Figure 2.3a shows the proportion of incidents in haematology compared with emergency and general medicine in Figures 2.3b and 2.3c. Avoidable, delayed or undertransfusions (ADU) were responsible for 96/783 (12.3%) and 75/479 (15.7%) of reports from general and emergency medicine but only 22/864 (2.5%) of haematology reports. Similar rates for ADU are found in general surgery 57/517 (11.0%), and in trauma and orthopaedics 37/391 (9.5%), Figures 2.3d and 2.3e.

Handling and storage errors (HSE) were common in general and emergency medicine (179/783 (22.9%) and 94/479 (19.6%)) and in surgical specialities (101/517 (19.5%) general surgery, 92/391 (23.5%) of trauma and orthopaedics reports). Haematology reports demonstrated a much higher proportion of missed specific requirements 165/864 (19.1%) (usually irradiation in those at risk) that probably reflects the higher proportion of haematology patients with specific requirements.

Figure 2.3: Proportions of incidents in different specialties

Fig 2.3a – All events in haematology

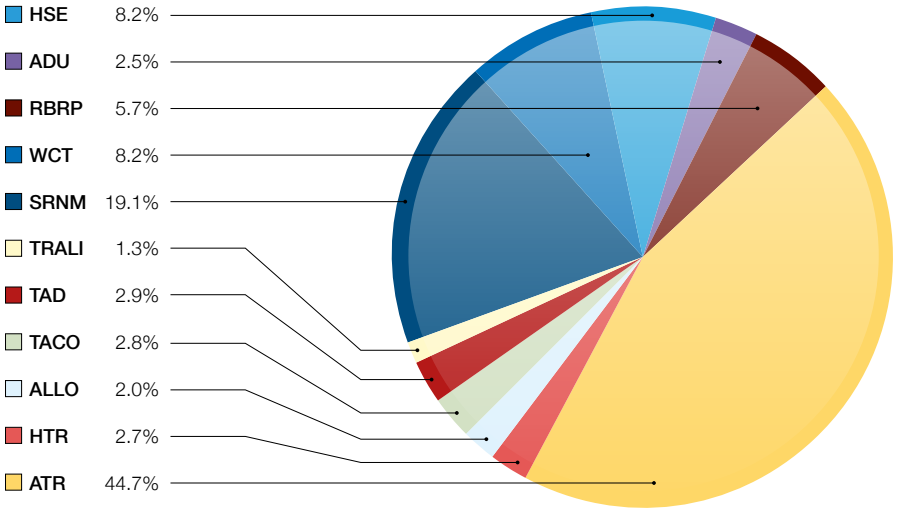


Fig 2.3b – All events in emergency medicine

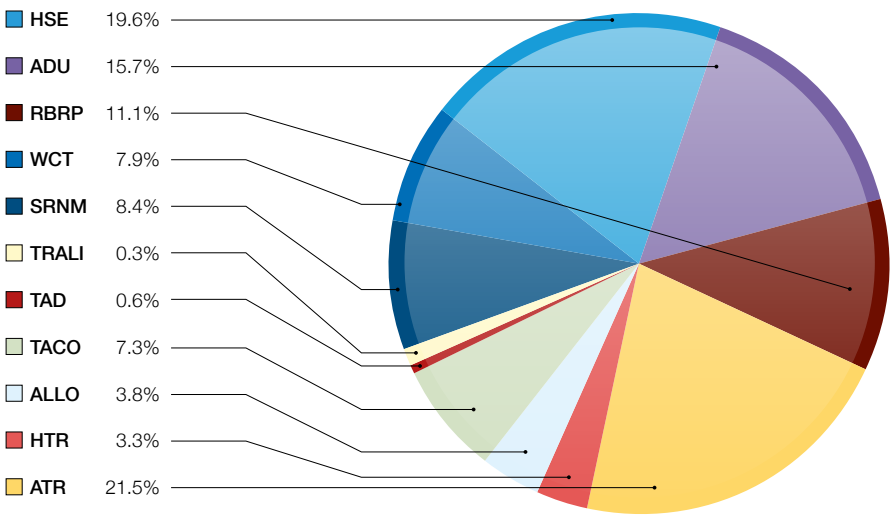


Fig 2.3c – All events in general medicine

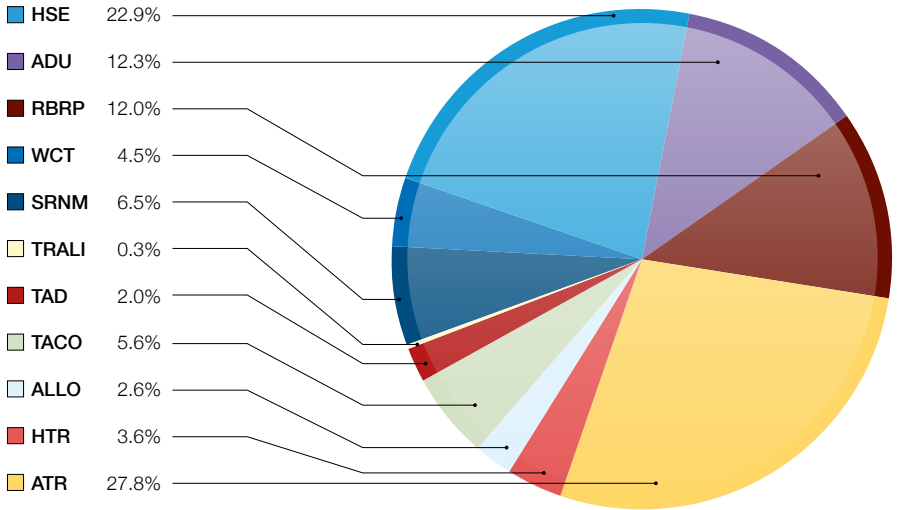


Fig 2.3d – All events in trauma & orthopaedics

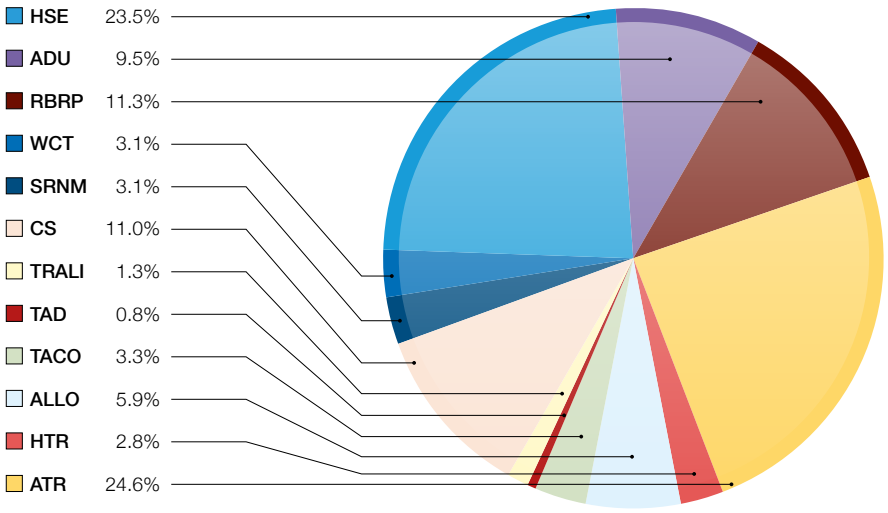
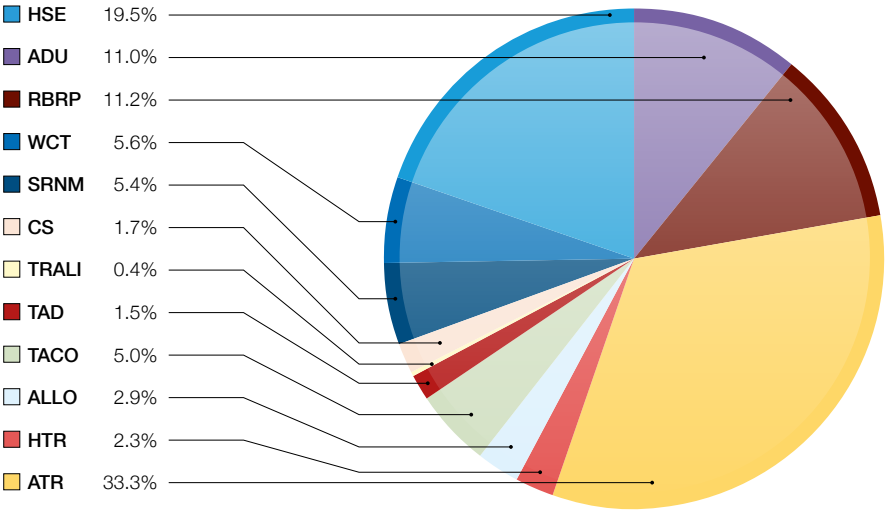


Fig 2.3e – All events in general surgery



Key:

- **HSE:** handling and storage errors
- **ADU:** avoidable, delayed or undertransfusion
- **RBRP:** right blood right patient
- **WCT:** IBCT-WCT: incorrect blood component transfused – wrong component transfused
- **SRNM:** IBCT-SRNM: incorrect blood component transfused – specific requirements not met
- **CS:** cell salvage
- **TRALI:** transfusion-related acute lung injury
- **TAD:** transfusion-associated dyspnoea
- **TACO:** transfusion-associated circulatory overload
- **ALLO:** alloimmunisation
- **HTR:** haemolytic transfusion reactions
- **ATR:** acute transfusion reactions

Recommendation

- Different specialty areas have particular errors which should be addressed by attention to training and communication – to reduce handling and storage errors in medicine and surgery, and to reduce the number of cases where specific requirements are not met in haematology patients

Action: Hospital Transfusion Teams working with specialties in their Hospitals/Health Boards

Benchmarking participation data 2011-2012

During 2012 the first benchmarking participation data exercise using 2010 data was distributed to participating reporting organisations. This exercise has been repeated using 2011 data, and also contains an individual comparison of the number of reports made by each reporting organisation in 2011 compared to 2010.

This exercise builds on recommendations made in the 2008 and 2009 Annual SHOT Reports, which encouraged reporters to establish current levels of reporting, compare with that of similar organisations, and monitor how levels of reporting have changed over time.

Recommendation

- Benchmarked participation data are both interesting and useful. Reporters should use this information to ensure their organisation is participating fully across all types of incident reporting i.e. errors, pathological reactions, anti-D and 'near miss' events

Action: Hospital Transfusion Teams with support from their Risk Managers and Chief Executive Officers

SHOT Updates and Developments 3

Author: Paula Bolton-Maggs

Updated definitions

Definitions for the SHOT categories have been reviewed and updated. These can be viewed on the SHOT website at www.shotuk.org/wp-content/uploads/2010/03/SHOT-definitions-Nov012-final.pdf. More detail is given about what to report. In addition we have changed the name of the category 'Inappropriate and Unnecessary' to 'Avoidable, Delayed or Undertransfusion (ADU)' to capture delays and inadequate transfusions in addition to those that should have been avoided (inappropriate and unnecessary).

We are no longer collecting information about mild acute transfusion reactions (ATR), and more information is given about this in the ATR chapter (Chapter 16). In relation to handling errors, where a unit of blood has been transfused beyond 4 hours, we only require reporting of units which have been transfused over more than 5 hours (see Chapter 14, Handling and Storage Errors).

A new questionnaire has been introduced from January 2013 to collect information about women who have developed a new immune anti-D that is detected during pregnancy, at delivery or in a subsequent pregnancy. This questionnaire is currently not available on the SHOT online reporting system.

Recommendation

- Reporters should inform the SHOT office when they find a case of a woman who has developed a new immune anti-D that is detected during pregnancy, at delivery, or in a subsequent pregnancy, and a questionnaire will be provided

Action: Hospital Transfusion Teams, SHOT office

Work towards a unified haemovigilance system in the UK

A first step has been to introduce improved links between the two systems so that reporters only need to enter the demographic data once (active from January 2013). Several workshops have taken place during the past 12 months to develop an algorithm that will satisfy the requirements of both European law (which provides the basis of what the Medicines and Healthcare products Regulatory Agency (MHRA) have to collect) and the more extensive clinical detail that is the strength of SHOT. We have worked well with Judy Langham from the MHRA, who has contributed to three chapters in this report; she is now moving to a new post and we record our thanks to her for her very useful collaborative work with SHOT.

Update on methylene blue-treated fresh frozen plasma (MB-FFP)

Following the withdrawal of MB-FFP in France last year because of a suspicion of increased serious allergic reactions, the UK SHOT data have been carefully reviewed and a position statement published on the Joint United Kingdom Blood Transfusion Services/Health Protection Agency Professional Advisory Committee (JPAC) website[10]. There is currently no evidence of a higher frequency of allergic reactions to MB-FFP than to any other kind of FFP and no changes to policy are necessary. The reports to SHOT for 2012 do not show any apparent excess of reactions to MB-FFP (see Chapter 16, Acute Transfusion Reactions).

Progress with recommendations from previous years

A SHOT recommendation in 2009[11] underpinned the launch of the Better Blood Transfusion national campaign to remind all staff and patients about the importance of patient identification, and materials are available for use across the UK on their website: 'Do you know who I am'[12].

Following the recommendation last year that the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) should consider making patient identification as well as knowledge of transfusion medicine and prescribing of blood components core clinical skills we met with representatives of the GMC to discuss what could be done. Several useful suggestions were made and are being taken forward. The Foundation Curriculum published in July 2012 does not contain any reference to patient identification and as a result of correspondence with Dr. David Kessel, Chair of the Academy Foundation Committee at the Academy of Royal Medical Colleges, this will be revised later this year. At the same time, the education subgroup of the Chief Medical Officer (CMO)'s National Blood Transfusion Committee (NBTC) has been reviewing the transfusion training content of all under- and post-graduate curricula. The results of surveys of the undergraduate medical and foundation year schools have been presented and published in abstract[13,14]. Review of the specialty curricula shows variable content and more work is needed to encourage better transfusion training. Targeting nursing and midwifery training is proving more challenging as the content of curricula is devolved locally, and although broad principles exist, there is no standardised training. It is clear from SHOT data that competency assessments alone are not sufficient, and in both clinical and laboratory training work is continuing to improve the knowledge of all those involved in transfusion.

Moving on from the initiatives of Better Blood Transfusion an update on hospital blood transfusion practice was launched in 2012 with a day on 'Patient Blood Management'. Following this meeting, a working group from the NBTC has developed a programme[15] for hospitals which will be submitted to Sir Bruce Keogh, the National Health Service (NHS) Medical Director. This recommends the development of an evidence-based multidisciplinary approach to transfusion, acknowledging the need to ensure that patients are carefully assessed prior to transfusion, to ensure that transfusion is appropriate and timely, and to correct any treatable causes of anaemia.

The National Institute for Health and Care Excellence (NICE) is developing transfusion guidelines and the scope is currently being considered. Professor Mike Murphy is chair of this guideline group.

Publications and presentations

The SHOT team has been active over the past 12 months with many teaching and training presentations. If your organisation would like a presentation please contact the SHOT office. In the past 12 months (January to December 2012) SHOT staff gave a total of 53 presentations including 4 at international conferences. A list of abstracts and publications is available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Human factors in hospital practice

In response to the first report about the tragic incidents at Mid Staffordshire NHS Foundation Trust a Human Factors Reference Group[16] was set up by Sir Bruce Keogh. 'Human factors is the science explaining the interrelationship of humans to their environment and to each other' or 'enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings'[17]. This report notes 'the significant role that good handover and communication has to play in delivering safe care'. The errors described in this SHOT report consistently demonstrate failures in communication and handover that lead to adverse incidents, some life-threatening, in transfusion practice.

The Department of Health report 'An Organisation with a Memory: report of an expert group on learning from adverse incidents in the NHS' drew attention several years ago to the role of errors in the National Health Service. Central reporting was recommended in order to learn common

lessons, because analysis of many reports helps to identify systems failures[18]. The National Patient Safety Agency (NPSA) was established as a result of this. This report has been archived, but is reviewed by Donaldson[19]. Since 2003 the National Reporting and Learning System (NRLS) collates data on patient safety incidents in England and Wales, and the summary data can be viewed at http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/. The participation by NHS organisations varies and is currently just over 70% with more than 350,000 incidents reported per three months (data for April to June 2012). While about 25% of these are patient accidents, more than 20% relate to medication or treatment and procedure events. Despite these numerous reports, there does not seem to be any evidence that the NHS is learning from them, and the reports about incidents at Mid Staffordshire NHS Foundation Trust have sadly confirmed this[3]. SHOT reporting shows similar data – year on year about half or more of all incidents are caused by errors, and from the same root causes, failure to identify the correct patient, omission of essential steps in the processes, and failure to complete the final check at the bedside. How can this be changed?

The purpose of Keogh's report[16] is to identify how human factors could be embedded in the future NHS. This builds on the recognition that there are likely to be systems factors in adverse incidents, and that health care workers and providers can learn from these, as identified in 'An Organisation with a Memory'[18].

The 'Human Factors' executive summary makes several recommendations including a need for a shift in attitudes and behaviours, and plans to work over the next 5 years. This will include a review of 'never events'[20] to identify human factors lessons common to or distinct to each theme. NHS Boards will be supported to understand human factors and the Medical Director of the NHS Commissioning Board is to support an inter-collegiate round table with all health professional bodies facilitated by the Academy of Royal Medical Colleges to 'identify actions that would encourage adoption of human factors best practice at the frontline'. The GMC and NMC have made a joint statement of professional values[21]. This includes the obligation to act without delay if a patient is put at risk for any reason.

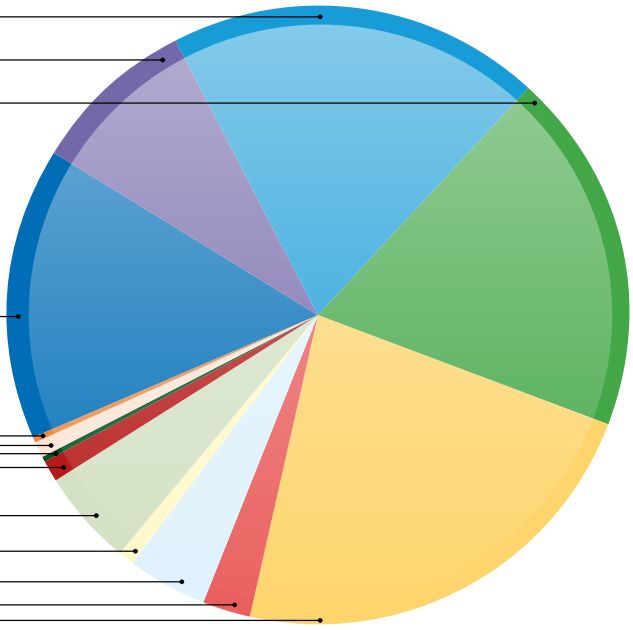
4 Summary of Main Findings and Cumulative Results

Authors: Paula Bolton-Maggs and Debbi Poles

Two classes of pathological incident occurred in 2012 that have not been seen for some years. A child died of transfusion-associated graft versus host disease after an emergency intrauterine transfusion from the mother (discussed fully in Chapter 20), and three viral transmissions were reported (discussed in Chapter 21).

Figure 4.1: Cases reviewed in 2012

HSE	316	19.2%
ADU	145	8.8%
Anti-D	313	19.0%
IBCT	252	15.3%
TA-GvHD	1	0.1%
TTI	3	0.2%
PTP	1	0.1%
CS	11	0.7%
UCT	8	0.5%
TAD	19	1.2%
TACO	82	5.0%
TRALI	11	0.7%
ALLO	69	4.2%
HTR	42	2.6%
ATR	372	22.6%
TOTAL	**1645**	**100.0%**



☒ = *The number of cases for TA-GvHD and PTP are too small to be represented on this Figure 4.1.*

A review of the overall number of reports analysed this year shows a total of 2638 relating to 2767 incidents (multiple incidents in single reports for some categories) of which 'near miss' incidents (NM) account for 980 and 'right blood right patient' (RBRP) incidents account for 142. Excluding these two categories, which by definition do no harm to patients, there were 1645 incidents, 1026 (62.4%) caused by errors and 619 (37.6%) reports of pathological incidents. Acute transfusion reactions (ATR) are the commonest pathological incidents: 60.1% (372/619), followed by haemolytic transfusion reactions (HTR) and alloimmunisation at 17.9% (111/619) and transfusion-related circulatory overload (TACO) at 13.2% (82/619) Figure 4.1. The cumulative data are shown in Figure 4.2. The overall number of error-related events is increased from 970/1815 (53.4%) reported last year.

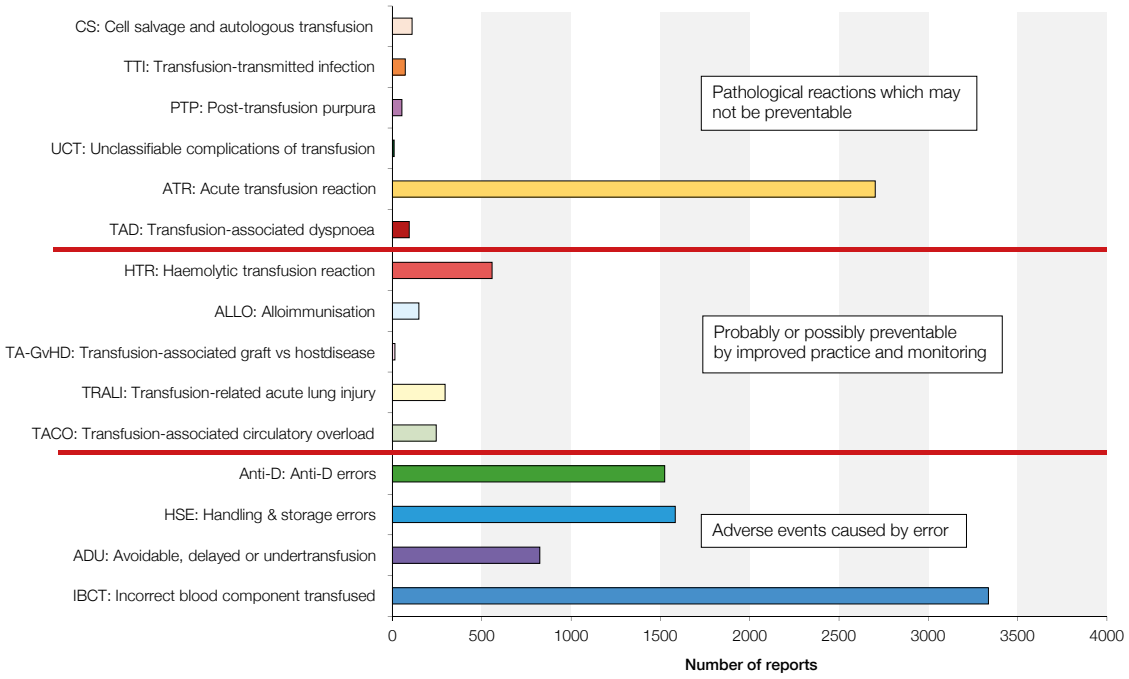


Figure 4.2: Cumulative data for SHOT categories 1996/7-2012 n=11,570

Although transfusion remains very safe it is disappointing that errors continue to put patients' lives at risk, particularly from ABO incompatible transfusions (4 'never events' reported in 2012). Several errors resulted from incorrect components given to transplant patients that are described in a new chapter, Chapter 29. In several instances, multiple errors contribute to an incident, a feature noted since the first Annual SHOT Report and analysed in some detail in the Annual SHOT Report for 2003[22]. In that year 2 errors were reported for 135/348 (38.7%) wrong transfusions, and 3 errors in 38 (10.9%). The final check at the patient's side is an opportunity to catch errors made before this step. Examples of cases compounded by multiple errors are found in the chapters on incorrect blood component transfused (IBCT) (Chapter 9), right blood right patient (RBRP) (Chapter 13), Anti-D (Chapter 15), transfusion-associated circulatory overload (TACO) (Chapter 25) and the chapter on haemoglobinopathies (Chapter 28). These cases demonstrate the importance of correct completion of all the steps in the transfusion process, particularly the final check at the bedside, and not making any assumptions about the safety of the steps prior to this.

Risk of major morbidity and mortality per 1,000,000 components issued in 2012	
Total morbidity	**46.5 (39.9 in 2011)**
Total mortality	**3.1 (2.7 in 2011)**

	Mortality	Major morbidity	Total cases
All errors	0.0	5.9	356.4
Acute transfusion reactions	0.0	23.6	129.2
Haemolytic transfusion reactions	0.3	3.1	14.6
Transfusion-related acute lung injury	0.0	2.8	3.8
Transfusion-associated circulatory overload	2.1	10.1	28.5
Transfusion-associated dyspnoea	0.0	0.0	6.6
Transfusion-associated graft versus host disease	0.3	0.0	0.3
Post-transfusion purpura	0.0	0.0	0.3
Cell salvage	0.0	0.0	3.8
Transfusion-transmitted infection	0.0	1.0	1.0
Unclassifiable complications of transfusion	0.3	0.0	2.8
Paediatric cases	0.3	2.8	38.2

Table 4.1: Relative risks of major morbidity and mortality based on data for 2012 overall and by incident group

ABO incompatible transfusions n=13 (red cells n=10, FFP n=3) (12 incompatible red cell transfusions in 2011)

There were 13 ABO incompatible transfusions of which 4 transfusions of incompatible red cells resulted in major morbidity ('never events'[20]). Eleven originated from clinical errors: 3 wrong blood samples, 1 error in both collection and administration, and 5 mistakes in administration alone. Two haemopoietic stem cell transplant patients received incompatible red cells because the clinical area had not informed the laboratory about the transplant (these and other transplant issues are discussed in Chapter 29). Two laboratory errors resulted in ABO incompatible fresh frozen plasma (FFP) transfusions.

Review of mortality and morbidity data

Definitions of imputability used in this report (see also the Annual SHOT Report 2010 www.shotuk.org).

0 = excluded or 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 – the evidence is clearly in favour of attributing the reaction to the blood or blood component.

3 = certain – there is conclusive evidence beyond reasonable doubt attributing the adverse reaction to the blood or blood component.

Deaths n=9 (8 in 2011)

Transfusion-associated graft versus host disease (TA-GvHD) n=1 imputability 3 (none since 2000-2001)

A fetus with anaemia related to maternal parvovirus received an intrauterine transfusion with maternal blood (non-irradiated, non-leucodepleted and HLA-related) and died from TA-GvHD three months after birth.

Unclassifiable complications of transfusion (UCT) n=1 imputability 2 (1 in 2011)

One patient died after receiving intravenous immunoglobulin (IVIg) that led to severe haemolysis and renal failure. An additional possible case of TRALI was reported in relation to IVIg contributing to morbidity.

Haemolytic transfusion reactions (HTR) n=1 imputability 2 (0 in 2011)

A man with myelodysplastic syndrome developed jaundice and died 8 days after a transfusion and was found to have anti-Jk^{a} (undetectable before transfusion) that contributed to the death of an already sick man.

Transfusion-associated circulatory overload (TACO) n=6 (2 in 2011)

1 of these was 'likely' – imputability 2. This was a woman of low body weight transfused to a Hb of 176 g/L; 5 other deaths were classified as 'possibly' related to the transfusion – imputability 1.

Major morbidity n=134 (117 in 2011)

Acute transfusion reactions (allergic, hypotensive and severe febrile) (ATR) n=68 (53 in 2011)

Fifty of these were severe or life-threatening, and 18 were admitted to the intensive care/high dependency unit (ITU/HDU) or had renal dysfunction. It can be difficult to determine whether cases fit the SHOT definition of major morbidity as some may have serious but transient symptoms because they are treated effectively. These reports include 29 cases of anaphylaxis.

Transfusion-associated circulatory overload (TACO) n=29 (24 in 2011)

TACO is the category with the highest mortality and morbidity rate. Together the deaths and major morbidity made up 35/82 (42.7%) of TACO cases confirming that this is a serious complication of transfusion; 28 patients were admitted to/deteriorated in ITU/HDU and 1 other required renal dialysis.

Incorrect blood component transfused n=11 (2 in 2011)

Five women of childbearing potential who received K positive units developed anti-K; 2 patients developed haemolytic transfusion reactions when clinically significant antibodies were missed in pre-transfusion testing.

Three patients received ABO incompatible red cell transfusions resulting in severe haemolysis and renal impairment. These were caused by clinical errors and are categorised as 'never events'[20]. An additional patient received a wrong ABO transfusion after haemopoietic stem cell transplantation and as this caused haemolysis is also regarded as a 'never event' bringing the total to 4.

In addition 2 RhD negative women of childbearing potential received RhD positive red cells putting them at risk of major morbidity because of the potential for developing anti-D antibodies.

Haemolytic transfusion reactions (HTR) n=9 (11 in 2011)

Five of nine cases occurred in patients with sickle cell disease. Acute haemolytic reactions occurred in 2/9 and delayed reactions in 7/9.

Transfusion-related acute lung injury (TRALI) n=8 (8 in 2011)

Two patients already on ventilation deteriorated, 3 were newly ventilated, 2 patients were admitted to high dependency units, and 1 developed acute hypoxia needing immediate medical intervention.

Anti-D errors n=4 (9 in 2011)

Four women developed immune anti-D following delay or omission of prophylaxis during the current or previous pregnancy.

Transfusion-transmitted infections (TTI) n=3 (none since 2005)

There were 3 incidents reported to SHOT. A child with sickle cell disease developed an acute illness and demonstrated seroconversion to parvovirus, and 2 patients developed hepatitis B virus infection from one donor. One hepatitis E transmission was noted by the Public Health England Epidemiology Unit but this has not currently been reported to SHOT.

Avoidable, delayed or undertransfusion (ADU formerly I&U) n=2 (5 in 2011)

A patient of low body weight was repeatedly transfused resulting in polycythaemia, symptoms of fluid overload and long term renal impairment, and an infant was overtransfused to a Hb of 270g/L.

Categories of reports where no harm was done

Near miss events n=980 (1080 in 2011)

The majority of these, 694/980 (70.8%), originated in clinical areas and most of these, 534/694 (76.9%), were sample errors due to wrong blood in tube in 505/534 (94.6%). As noted last year, most of these occur because the patient is not correctly identified or the sample is not labelled at the bedside, 402/505 (79.6%). Doctors were the largest group responsible for wrong blood in tube, 223/505 (44.2%) with nurses and midwives together making up 186/505 (36.8%).

Right blood right patient n=142 (159 in 2011)

The majority of these errors originated in the clinical environment, 80/142 (56.3%).

Reports where incidents were caused by human error n=1026

Anti-D immunoglobulin n=313 (301 questionnaires)

Handling and storage errors n=316 (199 questionnaires)

Avoidable, delayed or undertransfusion n=145

Specific requirements not met n=176 (70 laboratory and 106 clinical)

Wrong component transfused n=76 (31 laboratory and 45 clinical)

Where information is collected about competency assessment, again we observe that the majority of personnel involved have passed their assessment (Table 4.2). Work continues through the CMO's National Blood Transfusion Committee subgroups to improve education and to develop competency assessments that probe for better knowledge and understanding of the transfusion process.

Table 4.2: Competency assessment in relation to errors

Competency assessment 2012	Yes	No	Not known or blank
Errors with Anti-D			
Pre-administration sample (n=21)	6	1	14
Laboratory procedures (n=67)	54	6	7
Collection of anti-D (n=23)	11	3	9
Laboratory errors where the Specific Requirements were Not Met (n=69)			
Competency assessed for procedure	61	6	2
Where applicable, competency assessed on LIMS	*53*	*7*	*9*
Incorrect blood component transfused			
Sample collection (n=7)	3	0	4
Laboratory errors (n=35)	24	4	7
Collection (n=12)	8	3	1
Total n=234*	**167 71.4%**	**23 9.8%**	**44 18.8%**

**Numbers in this table include all instances where competency assessment questions were answered regardless of the eventual categorisation of the individual report.*

COMMENTARY

Reports of incidents caused by human error have formed a greater proportion of incidents reported to SHOT this year 1026/1645 (62.4%) including multiples but excluding 'near miss' and 'right blood right patient' events). In part this is related to changes in SHOT definitions, reducing reports in two categories, acute transfusion reactions (ATR), and handling and storage errors (HSE). Minor febrile reactions are no longer reportable as ATRs (see new definitions on the SHOT website[23]). In addition we no longer take reports in HSE where the duration of transfusion of a single unit of blood is between 4 and 5 hours, only those where the duration is more than 5 hours. Review of aggregated data from a 30 month period from January 2010 to June 2012 demonstrated no adverse clinical incidents related to either delays of more than 30 minutes before a unit was set up for transfusion, or in 248 instances where a unit was transfused for a duration of more than 4 hours, 145 of these for more than 5 hours, 19 more than 8 hours[24].

Nevertheless, the overall number of incidents caused by error is worrying, and the addition of categories where patients were not harmed, 'near miss' (980) and 'right blood right patient' (142) n=1122 means that errors account for 77.6% (2148/2767) of all incidents and near misses reported to SHOT.

Additional tables showing report types by year and cumulative morbidity and mortality data (4.3, 4.4 and 4.5) are available in the Annual Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Key Messages and Recommendations

5

Authors: Paula Bolton-Maggs, Hannah Cohen and Dafydd Thomas

Confirmation of identity at every stage of the transfusion process and good communication are essential to prevent errors

Although transfusion has an excellent safety record it is worrying that so many patients continue to be put at risk by mistakes. These occur because of failure to follow basic steps in the transfusion process at every stage by individuals of several professional groups.

Correct identification of patients is key and is a critical point throughout the transfusion process but is applicable to all interactions with the patient. The recent British Committee for Standards in Haematology (BCSH) guidance for two blood samples to confirm correct blood group (the second is an identity check) should be followed[26]. Identity bands should only be generated from the point of admission and not be changed or updated unless it can be shown categorically that the revised information is accurate.

Many of the errors that appear in this year's report continue to be related to identity issues. These comprise either incorrect data presented by the patient administration system (PAS) or an inability to confirm the patient's identity using open questions as recommended by the BCSH guidelines[27]. Once the patient identity band is in place subsequent changes must only occur by reaffirming who they are through open questions or replacing as like for like. Each patient is an individual and each task should be completed before moving on i.e. label the sample at the bedside ensuring the patient has been positively identified.

Medical care is increasingly fragmented at all points with contributory factors such as shift systems for nurses and doctors, short staffing on the wards, a reduction in highly trained transfusion laboratory scientists coupled with increasing movement of acutely ill patients around hospital wards ('safari ward rounds', as medical staff try to find their patients transferred out of emergency departments, was noted at the Royal College of Nursing meeting April 2013 and reported in The Times, Wednesday April 24). Consultant responsibility in these situations is not clearly defined and poor or incomplete communication at handover has been responsible for some of these incidents. Perhaps there is a tendency to 'assume' that someone else is responsible. Failures of handover occur as the patient travels between different wards and departments within a hospital, also between clinicians in different shared care hospitals, and between hospital and the community settings. The use of a common numbering system such as the National Health Service (NHS) number will improve patient safety enabling the link up of patient records across different parts of the NHS. This should not be hindered by information governance regulations, safe patient care must come first. There is also a strong argument to share electronically the laboratory information about patients with alloantibodies that is recorded in red cell immunohaematology laboratories between hospitals and the Blood Services to aid 'right result to right patient at right time'. It is encouraging that a recent review of information governance under Caldicott's leadership has added a new principle which states that 'the duty to share information can be as important as the duty to protect patient confidentiality'[25].

The reports of a fatal case of transfusion-associated graft versus host disease (TA-GvHD), and three transfusion-transmitted viral infections are a reminder that serious unexpected incidents may occur. The main causes of serious morbidity continue to be transfusion-associated circulatory overload, acute transfusion reactions (allergic, hypotensive and severe febrile) and haemolytic transfusion reactions. TA-GvHD has been reported only twice in the early years after the advent of leucodepletion.

Review of SHOT reports shows that the final reporting step, the local hospital review and outcome with appropriate corrective and preventative action, is infrequently completed and yet this is a key part of the process. The purpose of reporting to SHOT and the Medicines and Healthcare products Regulatory Agency (MHRA) is to learn from what has taken place, to review the event and make changes (corrective and preventative actions) to reduce the risk of recurrence. For this reason we have included a chapter this year on incident investigation and root cause analysis to remind reporters of the importance and value of this (Chapter 8). The reporting of 'near miss' events is also very important because review of these detects patterns (such as the high incidence of wrong blood samples taken by doctors) that can result in changes of practice which prevent patients coming to harm. It is notable for example that for every event where a patient has received a wrong transfusion caused by a 'wrong blood in tube' event, approximately 100 near misses occur (Chapter 7). Reporting and analysis of 'near miss' events can therefore lead to valuable lessons.

Don't know, don't guess! The knowledge base and application of knowledge about blood transfusion appears to be lacking and this is shown in incidents in both the laboratory and clinical areas. Staff should be able to be open and honest and we should encourage individuals to ask for help when they do not understand what to do or when it should be done.

Clearing the hurdle – zero tolerance. Since wrong blood component and other infusions or medications may be given as a result of other wrong blood samples, for example wrong biochemistry results leading to inappropriate potassium-containing infusions, there should be a zero tolerance policy for the identification of all pathology laboratory samples.

Human error is frequently identified as the cause in SHOT reports, but further questioning as part of the incident investigation can identify a system fault. The '5 whys' method is helpful for this, meaning continue to ask 'why' until the causes are clear (not necessarily 5 whys, might be fewer or more). For example:

- The staff did not have the correct knowledge – WHY?
- The training was not up to date – WHY?
- No time for training – WHY?
- Staff vacancies not being filled – WHY?

Laboratory errors are more likely to occur when manual procedures are used, or when warning flags on the information technology (IT) systems are ignored or overridden.

In addition, many of the incidents result from a series of errors, as many as 7, as has been reported from SHOT before[22] including in the very first report[28]. If correct checks were performed properly many incidents would be avoided.

Receiving a blood transfusion or component should be treated in the same way as having a surgical procedure; the patient should be correctly and positively identified, it should be done in the right place (not across various wards) with appropriate resuscitation facilities, on the correct patient, and the right time (i.e. not overnight unless urgent or emergency), by the right person (i.e. staff who are trained in pre-transfusion clinical review and recognising and treating immediate complications) under the care of a single named consultant and with appropriate review and follow up.

A framework for the provision of blood transfusion out of the acute hospital setting is available at http://www.transfusionguidelines.org.uk/docs/pdfs/bbt-01_sp_tx-framework-v3.pdf and the London Shared Care Working Group have templates to assist communication between treating and referring hospitals for patients with specific requirements which can be viewed at http://www.transfusionguidelines.org/Index.aspx?pageid=7694&section=28&publication=RTC.

Key Recommendations:

- **Patient identification:** Correct and positive patient identification at every step remains absolutely essential, and is the responsibility of every member of staff. Hospitals/Trust/Health Boards should review their identification procedures to ensure that patients are safely identified throughout their hospital journey. All UK patient safety programmes should take the identification agenda forward as part of person-centred care

Action: Patient safety programmes – for England, the NHS Commissioning Board Special Health Authority; and equivalent bodies in Scotland, Wales and Northern Ireland. Hospital, Trust and Health Board Chief Executive Officers, Risk Managers, Pathology Laboratory Managers and all staff involved in blood transfusion

- **A zero tolerance policy** is recommended for the identification of all pathology specimens. In other words, samples should not be accepted by the laboratory for analysis without the standard 4 identifiers used for transfusion samples, first name, surname, date of birth and an identity number, ideally the National Health Service (NHS) number. All pathology samples should be taken only after confirmation of identity, and be labelled at the patient's side

Action: Hospital Trust and Health Board Pathology Managers, supported by Chief Executive Officers

- **Communication and handover:** Hospital and primary care staff should work at building relationships to improve communication and handover. Communication failures within hospitals, between hospitals and between hospital and primary care are all responsible for adverse incidents. Good communication is required between laboratories and clinical staff and vice versa to ensure specific requirements are met, and correct results communicated to clinical areas

Action: All clinical and laboratory staff in Hospitals, Trusts and Health Boards, General Practice and Community Hospitals

Additional Recommendations

- **Transfusion reactions:** all staff responsible for blood transfusion must know how to recognise anaphylaxis and other acute transfusion reactions. Transfusions should only take place where there are facilities to recognise and treat anaphylaxis and other adverse incidents, and local policies must ensure that procedures are in place to manage any adverse event or incident, including transfusions in the community

Action: Hospital Transfusion Teams, all clinicians involved in transfusion

- **Learn from adverse incidents:** Incident reviews and root cause analyses should be completed and the findings reported back to the participants and the patients to ensure that lessons are learned which may reduce future errors

Action: Hospital Risk Managers; Hospital Transfusion Teams; all clinicians

- **Near miss reporting:** Hospital staff should report near miss as well as actual incidents in keeping with good medical practice as defined by the General Medical Council (GMC)[4]. Reporting is mandatory, not voluntary, to ensure that the focus is improved patient safety

Action: Hospital Transfusion Teams

6 Medicines and Healthcare products Regulatory Agency (MHRA) Report on Blood Safety and Quality Regulation in 2012

Author: Judy Langham

MHRA objectives

Safeguarding public health by implementing the requirements of the relevant European Union (EU) Directives[29-32] and also ensuring compliance with the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898[33] (BSQR 2005).

Introduction

As the designated UK Competent Authority it is the MHRA's responsibility to provide a mechanism for Blood Establishments, hospital blood banks and blood facilities to report and record serious adverse blood reactions (SARs) and serious adverse events (SAEs), via the online reporting system: Serious Adverse Blood Reactions and Events (SABRE).

Data collated from SABRE reports over the last twelve months may help all those in the transfusion community find ways of reducing common errors and improving patient safety. These data include a number of reports which although notified to MHRA in 2011 were not confirmed until 2012 and so they appear in the data for this year.

Summary data

Table 6.1: Number and type of reports submitted to SABRE 2012 (confirmed by December 31st 2012)

Report type	No. of reports
Serious Adverse Events (SAE)	930
Serious Adverse Reactions (SAR)	342
Excluded reports	188
Total No. of reports for year	**1460**

Reporting data since implementation of the Blood Safety and Quality Regulations in 2005 is supplied for comparison purposes below:

Table 6.2: All reports submitted to SABRE since November 8th 2005 (by calendar year)

	2005	2006	2007	2008	2009	2010	2011	2012
SAE	33	549	654	808	994	905	844	930
SAR	26	237	287	448	481	573	417	342
Excluded	31	84	100	265	286	284	295	188
Total	**90**	**870**	**1041**	**1521**	**1761**	**1762**	**1556**	**1460**

It is reassuring to note the consistent reduction in the total number of reports made to SABRE over the last three years as this may indicate the positive effects of both blood safety and quality regulation and robust haemovigilance. However, the decline in SAR reports may be attributed in part to a more rigorous approach to ensuring that only those reactions meeting the EU Commission definition of 'serious' are included in the annual report.

The slight increase in the number of SAEs reported in 2012 reflects changes in the way Blood Establishments reported indeterminate positive results when undertaking bacterial testing of platelets. Please see the section on Blood Establishment data for more details of this.

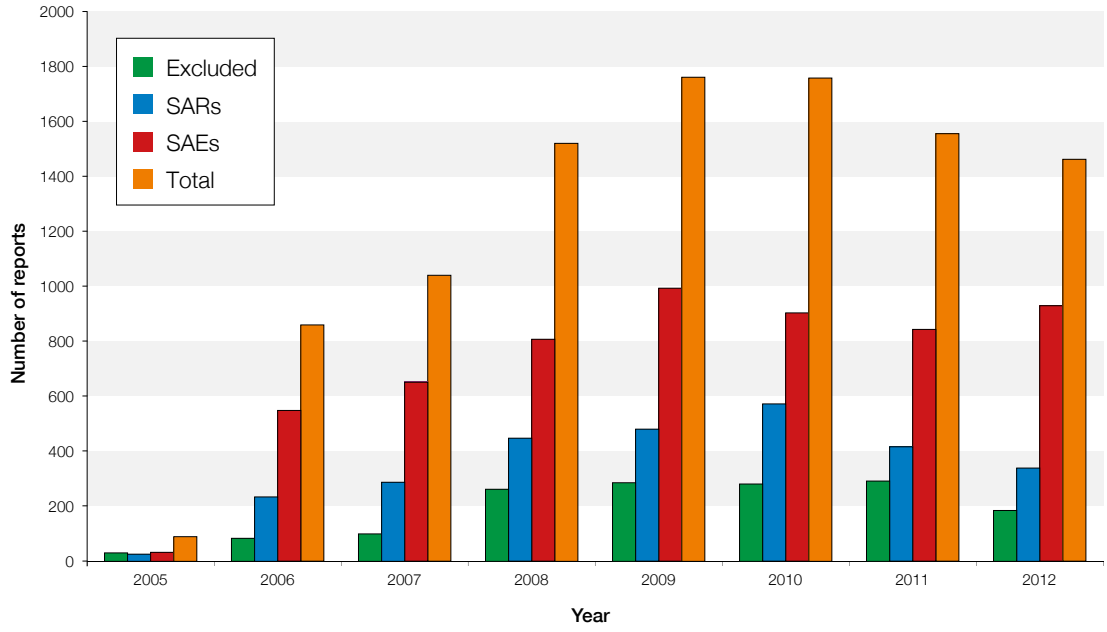


Figure 6.1: Graph to show total number of SABRE reports submitted by calendar year

Excluded reports in 2012 n=188

Each year a significant number of reports submitted to SABRE are excluded from the final annual summary report which is sent to the EU Commission. This is because they do not meet the specific EU reporting requirements. However, reports are only ever withdrawn after discussion with the reporter and with their full understanding and agreement.

In 2012 the most common reason for excluding reports was because the incident occurred in the clinical setting e.g. a phlebotomy error leading to a 'wrong blood in tube' event or a bedside administration error leading to transfusion of the wrong component. These types of incident fall outside the remit of Competent Authority regulation but are SHOT-reportable.

SABRE reporters are also reminded that adverse reactions involving blood products (which are licensed as medicines) e.g. Anti-D immunoglobulin, Octaplas, or coagulation factor concentrates including PCCs should be reported to the MHRA via the medicines Yellow Card scheme (http://yellowcard.mhra.gov.uk).

Registration data for 2012

There has been a notable reduction in the number of organisations reporting to SABRE as many regions and private sector laboratories adopt a 'hub and spoke' operating model with the large centre taking responsibility for SABRE reporting. However, any site which retains a blood transfusion laboratory must still submit an annual blood compliance report.

Data submitted by these organisations indicate that 2,691,563 units of blood and blood components were issued in 2012 and that 2,432,687 of these were transfused to 446,609 patients.

In 2012 there were 334 organisations registered as SABRE reporters, representing National Health Service (NHS) and private hospital blood banks and the UK Blood Establishments of England (including the Ministry Of Defence), Scotland, Northern Ireland and Wales.

Serious Adverse Events

Definitions

All italicised quotes are from the UK legislation[34].

'Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.'

Reporting requirements

'Blood establishments/the person responsible for the management of a hospital blood bank shall notify… any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the blood establishment which may have an influence on their quality and safety'

Each year the MHRA prepare an annual summary report of all data submitted to SABRE for the EU Commission. These data may include reports which were notified in the previous calendar year but were not confirmed until the current year. For example, a notification report of a suspected transfusion-related acute lung injury may be received in October 2011 but the investigations and confirmation report may not be completed until March 2012 – these data will appear in the 2012 annual summary report.

Table 6.3: Annual summary report for all UK serious adverse events 2012 (n=930)

SAE deviation	Total number	Product defect	Equipment failure	Human error	Other
Whole blood collection	**91**	67	0	24	0
Apheresis collection	**11**	8	0	3	0
Testing of donations	**3**	0	1	2	0
Processing	**14**	0	0	14	0
Storage	**217**	0	8	207	2
Distribution	**60**	0	0	60	0
Materials	**3**	1	1	1	0
Other	**531**	1	5	525	0
Overall Total:	**930**	**77**	**15**	**837**	**2**

The functions of whole blood collection, apheresis collection and testing of donations are only undertaken by the UK Blood Establishments i.e. NHS Blood and Transplant (NHSBT), the Welsh Blood Service (WBS), the Northern Ireland Blood Transfusion Service (NIBTS) and the Scottish National Blood Transfusion Service (SNBTS). Some of the larger hospital blood banks may also hold Blood Establishment authorisation and as such may undertake some processing of blood components e.g. irradiation. For this reason it is useful to separate the reports submitted by Blood Establishments (BE) and hospital blood banks and examine the reporting trends across their respective organisations.

It is very interesting to note that UK Blood Services are responsible for the collection, testing and processing of some 2,859,932 units of blood components and yet the number of serious adverse event reports made by them accounts for only 16.5% of all SAEs submitted in 2012. This may be because they have extremely well-developed quality management systems or reflect the fact that their activities have been regulated for many years more than hospital blood banks, giving them time to initiate more quality improvements.

Table 6.4: Blood Establishment reports 2012 (n=153)

SAE deviation	Total number	Product defect	Equipment failure	Human error	Other
Whole blood collection	**91**	67	0	24	0
Apheresis collection	**11**	8	0	3	0
Testing of donations	**3**	0	1	2	0
Processing	**3**	0	0	3	0
Storage	**3**	0	0	3	0
Distribution	**18**	0	0	18	0
Materials	**2**	1	0	1	0
Other	**22**	1	0	21	0
Overall Total:	**153**	**77**	**1**	**75**	**0**

Whole blood collection errors n=91

In 2012 there was a three-fold increase in the reporting of whole blood collection errors and associated product defects. This can be explained by increased reporting of indeterminate positive results being generated by the new system for the bacterial screening of platelets. Initially all components which had been issued and were subsequently found to have positive or indeterminate positive bacterial alerts were reported to SABRE as potential product defects. However, subsequent investigations generally failed to highlight any quality system errors in the component collection, testing, processing or storage processes. After much consideration by the MHRA's Blood Consultative Committee a new system for reporting these incidents has been agreed. Blood Establishments are now expected to conduct an internal investigation into any positive/indeterminate cases but are only required to report these to SABRE if there is clear evidence of an error having been made in the collection, testing, processing or storage phases of component handling, or if there have been any delays in recalling these components. Hospital blood banks are of course still required to report any serious adverse reactions to any contaminated components and should also be aware that they MUST respond promptly in the event of a component recall. Failure to recall a unit within an appropriate time frame (generally one hour is considered acceptable) is reportable as a serious adverse event even if the component has not been transfused.

Learning point

- Failure to initiate recall/quarantine of components within a reasonable time frame is a Serious Adverse Blood Reaction and Event (SABRE) reportable event

Recall process for Blood Establishments

1) Ensure Recall is initiated and conducted as required.
   Report to SABRE if the following timeframes are exceeded (unless exceptional circumstances prevail):
   - From "Initial Reactive" result to confirmation that component has been successfully quarantined = 4 hours
   - From contact made with hospital to unit removal from supply chain = 1 hour time limit
2) Confirm hospital response – Unit quarantined/disposed of/transfused.
3) For units reported as transfused, confirm that the transfusion time was prior to the time the hospital was contacted.

Blood Establishments are responsible for reporting components which are NOT recalled within a reasonable time frame.

Hospital blood banks are responsible for reporting components which are not quarantined/disposed of within 1 hour of receiving notification of a recall from their blood establishments as well as those which cause a serious adverse reaction in the recipient.

Twenty four whole blood collection errors were given the specification of 'human error'. The majority of these were donor deferral errors where a blood collection was taken in spite of the donor having travelled to a high risk area (for malaria or for West Nile virus), or subsequently revealing that they were being treated for a medical condition which should have precluded them from donation. None of these incidents resulted in a transfusion-transmitted infection.

Apheresis collection errors n=11

There were 11 apheresis collection errors reported and the pattern of product defects due to bacterial alerts or donor deferral errors mirrors the whole blood collection error reports.

Testing of donations errors n=3

Three incident reports were submitted in this category, one involving equipment failure whilst the other two were the result of human errors. In both the latter cases it was identified that staff failed to follow the correct procedures for managing indeterminate positive results after the bacterial screening of platelet packs.

Processing errors n=3

Three incident reports were submitted in this category and all cases were related to human error where members of staff failed to follow component irradiation processes correctly.

Storage errors n=3

It is interesting to note the comparatively low number of storage errors being made by Blood Establishments when compared with hospital blood banks. In 2012 there were only three reports of serious adverse events relating to incorrect component storage and all were attributable to human error. In each instance staff failed to respond to refrigerator alarms correctly and failed to quarantine the affected components adequately. The root cause in each case was attributed to ineffective training and a lack of understanding of the correct quarantine procedures.

Distribution errors n=18

Of the 18 distribution errors reported, 11 resulted in delays to component supply. The reasons for these delays were variable but included drivers delivering to the wrong address, local hospital transport being used rather than a dedicated courier and in one case components were 'lost in transit' due to there being a complete absence of any delivery or receipt documentation. In all cases the root cause was a failure to adhere to the specified procedure.

The remaining 7 other cases involved issuing components incorrectly through the Blood Establishment's stock management IT system, again due to not following procedures because of concentration lapses or distractions.

Material errors n=2

Serious adverse events involving the materials used in the production of blood and blood components are rare and only two were reported in 2012.

In the first case large clots were noticed in the bag of red cells as they were about to be transfused. The unit was returned to the Blood Establishment but there was no evidence of bacterial contamination. Two potential root causes were suggested; firstly it was considered possible that the bag may have been supplied without the optimal levels of anticoagulant present. However, this was presumed unlikely given that the clots were not noticed when issued by the Blood Establishment or by the hospital blood bank. The other possibility was that the giving set used to deliver the red cells had been pre-used by ward staff to give drugs. However, this was not proven and so the report retained a specification of a possible product defect.

The second case reported was in response to the discovery that a unit of red cells had been collected into a blood pack which did not have a port to allow the insertion of a giving set. This report was forwarded to colleagues in the medical device adverse incident centre. Their work with the specific pack manufacturer resulted in the issue of a field safety notice to all organisations supplied with these packs. This raised awareness of the issue, informed them of the corrective measures undertaken to reduce the occurrence of the defect and encouraged vigilance at the point of issue from Blood Establishments.

Other errors n=22

There were 22 'other' errors reported of which 21 were attributed to human error and only one was a product defect. In this case a unit was returned to the Blood Establishment when a visual inspection at the hospital blood bank indicated haemolysis. Both initial and confirmatory cultures grew *Pseudomonas fluorescens*, but this organism was not subsequently isolated from the donor's venepuncture site. The source of the contamination could not be determined. The further breakdown of the human error incidents is as follows:

Table 6.5: Breakdown of Blood Establishment 'Other/ human error' errors (n=21)

SAE deviation 'Other' breakdown	No. of reports
Failed recall	9
Incorrect blood component issued	3
Data entry errors	3
Pre-transfusion testing errors	3
Component labelling errors	2
Delayed component supply	1

The following data are taken from reports supplied by UK hospital blood banks and blood facilities:

SAE deviation	Total number	Product defect	Equipment failure	Human error	Other
Processing	**11**	0	0	11	0
Storage	**214**	0	8	204	2
Distribution	**40**	0	0	40	0
Materials	**1**	0	1	0	0
Other	**511**	0	5	506	0
Overall Total:	**777**	**0**	**14**	**762**	**2**

Table 6.6: Hospital blood bank reports 2012 (n=777)

Processing errors n=11

The 11 processing errors reported by hospital blood banks originate from the larger organisations which undertake component irradiation and hold Blood Establishment authorisations. The most common error is a failure to amend the expiry date of the unit prior to issue.

Storage errors n=214

Hospital blood banks have submitted 214 reports identifying storage incidents.

Eight of these reports were genuine equipment failures where either the refrigerator chart recorder broke or the alarm failed to sound to alert staff to temperature excursions.

Two reports were given the specification of 'other' as they were quite unusual; in one case red cell units were found to have been punctured after storage. This happened on 7 separate occasions. The manufacturers of both blood packs and refrigerators were informed but similar incidents had not been reported by other customers. The reporters reviewed their blood handling procedures and are monitoring the issue closely to see if they can determine a root cause. In the other case two units of red cells were 'lost'. Whilst this is essentially an issue of traceability (which is not reportable to the EU Commission) it did indicate a failure of the laboratory quality system to effectively manage the storage and issue documentation and so was deemed reportable.

The remaining 204 reports were all attributed to human error and these have been broken down into the following categories:

SAE description	Code	No. of reports
Out of temperature control	OTCOL	85
Components available for transfusion past dereservation date	CATPD	56
Expired components available for transfusion	ECAT	27
Incorrect component storage	ICS	26
Component collection error	CCE	10

Table 6.7: Storage error reports attributable to human error (n=204)

It is often quite difficult to determine whether an incident should be reported as storage/human error or other/human error which is why the sub-categories CATPD and ECAT appear in the breakdown of both event deviations. As a general rule the incident will be categorised according to the root cause i.e. the very first point at which the error was made.

For example, if a unit of blood is available for transfusion after its dereservation date (CATPD) then it will be categorised according to whether or not the recall procedure was implemented effectively. So a unit left in the refrigerator/overlooked after a routine recall would be categorised as a 'storage' event whereas a failure to undertake the recall at all would be categorised as an 'other' event.

Distribution errors n=40

Forty distribution errors were reported in 2012 and a review of these indicate two significant trends. The majority of reports refer to blood components being appropriately packed for transfer to satellite sites but not being handled correctly on receipt. In most cases staff at the receiving site fail to acknowledge receipt and/or leave components in the transport boxes beyond validated storage times.

Please see Chapter 14 (Handling and Storage Errors) for a further breakdown of this type of incident.

The other trend relates to delivery drivers who either deliver to the wrong area or are intercepted by clinical teams who urgently require the components. On occasion they persuade the driver to hand over components directly to them rather than to the laboratory team, a dangerous practice which could potentially lead to the transfusion of unlabelled components. This reinforces the need for all delivery drivers to have undertaken Good Manufacturing Practice (GMP) training so that they understand the significance of following procedures and maintaining the integrity of the cold chain.

Other errors n=511

Five deviations were equipment failures and the remaining 506 serious adverse events with the deviation category of 'other' and specification of 'human error' account for 65% of all hospital blood bank reports in 2012. The SABRE haemovigilance team have found it useful to sub-categorise these reports further as follows:

Table 6.8: Sub-categories of Other/human error SAEs 2012 (n=506)

Sub-category	Code	No. of reports
Incorrect blood component selected and issued	IBCI	124
Data entry error	DEE	75
Component labelling error	CLE	74
Sample processing error	SPE	71
Pre-transfusion testing error	PTTE	64
Component available for transfusion past dereservation date	CATPD	37
Component collection error	CCE	28
Failed recall	FR	11
Expired component available for transfusion	ECAT	7
Incorrect blood component ordered	IBCO	4
Incorrect blood component accepted (from supplier)	IBCA	4
Delayed component supply (Blood Establishment only)	DCS	2
Unspecified	UNS	5

Incorrect blood component selected and issued (IBCI) n=124

Incorrect blood component issued continues to be the most common human error occurring in laboratories, accounting for some 24.5% (124/506) of the 'other'/human error reports. Occasionally these reports state that the wrong component entirely has been selected and issued e.g. cryoprecipitate instead of fresh frozen plasma (FFP), but most often the specific requirements have been overlooked and the right component is issued but it is not cytomegalovirus (CMV) negative or irradiated.

More information on this type of incident can be found in Chapter 9 – Section 9.2.2: Specific requirements not met – incidents originating in the hospital transfusion laboratory.

Component labelling errors (CLE), sample processing errors (SPE) and data entry errors (DEE) n=220

Collectively these incidents account for 43.5% (220/506) of all hospital blood bank reports in the 'other'/human error category. The root cause is most often a simple concentration lapse and the individual staff members involved are encouraged to undertake reflective practice to help them understand how to manage distractions and maintain focus on the task in hand.

More information on this type of incident can be found in Chapter 13 – Right Blood Right Patient, and Chapter 11 – Incidents Related to Information Technology (IT).

Pre-transfusion testing errors (PTTE) n=64

The pre-transfusion testing error accounted for 12.6% (64/506) of all 'other'/human error reports in 2012. The most common failure was incomplete testing leading to either electronic issue of blood components which should have been fully crossmatched, or the issue of crossmatched blood without full antibody identification having taken place. In most cases staff were aware of the correct procedure they should

have followed but again became distracted before completing the task, in some cases even overriding computer warning flags. Often a simple reminder to read and respond to warning flags is all that is required to reduce this type of error.

More information on this type of incident can be found in Chapter 10 – Summary of events originating in the transfusion laboratory.

Component collection errors (CCE) n=28

This type of error is most commonly made by porters or nursing staff but they are reportable to SABRE as they can indicate a significant gap in the transfusion quality system/training process. There have been several errors reported where there has been insufficient understanding of the electronic blood tracking system. This has lead to overriding warning screens and the removal of expired components which have subsequently been transfused.

Component available for transfusion after dereservation (CATPD) and expired components available for transfusion (ECAT) n=44

Many sites still do not have electronic blood tracking systems and for them managing components in satellite and issue refrigerators can pose a challenge. A robust process for stock control and component recall is essential to ensure that components do not remain available for collection after their dereservation or expiry times.

Failed recalls (FR) n=11

There have been 11 recorded incidents where a Blood Establishment has issued a recall of components which the hospital blood bank has failed to act upon. In all of these cases a patient has been transfused with the recalled component although no serious adverse reaction has ensued. It is possible that there are more cases where units have not been recalled within the expected timeframe, (ideally within one hour of BE notification), but these have not been reported as the component has ultimately been successfully retrieved and discarded. Reporters are reminded that failure to act promptly on a recall for any reason is reportable as a serious adverse event.

Effective incident management

EU Directive 2005/61/EC[31] requires Blood Establishments and hospital blood banks to include a root cause analysis (RCA) and a statement of their corrective and preventive actions (CAPA) in all SAE reports.

The MHRA continues to encourage thorough root cause analysis of all serious adverse events to ensure that CAPA are appropriately targeted and that quality risk management is effectively applied.

The recommended tools for effective incident management are discussed further in Chapter 8 – Root cause analysis.

Of the 930 serious adverse event reports in the 2012 SABRE annual summary report, 90% (837/930) were attributed to human error. The SABRE team have conducted a review of the root causes of these errors and have found that in most cases the fundamental issue has been a failure to follow the documented procedure. Asking those involved why they think they failed to follow the procedure is usually the most useful part of any investigation. Most staff will undertake an annual update in good practice (formerly good manufacturing practice, GMP) and it should be impressed upon them at this stage that their primary professional responsibility is to adhere to written procedures and keep up to date with any changes.

Of those questioned about why they deviated from protocols, most admitted to either a temporary lapse of concentration due to distracting circumstances or concluded that they were rushing and inadvertently cutting corners. Contributory factors are often cited as being short-staffed or lone-working. In these cases it has proved useful for the laboratory management to undertake workload reviews and assess staffing levels over peak periods. At some sites this has provided sufficient information to build a business case to ensure that there are either more senior staff present on all shifts or that staff are appropriately supported by additional laboratory assistants.

Serious Adverse Reactions

Definitions

All italicised quotes are from the UK legislation[34].

*'an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is **fatal**, **life-threatening**, **disabling or incapacitating**, or which results in or prolongs hospitalisation or morbidity'*

'blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components –

(i) collected, tested, processed, stored or distributed by the blood establishment, or

(ii) issued for transfusion by the hospital blood bank'

Table 6.9: Annual summary report for all UK serious adverse reactions 2012

Type of reaction		Imputability Not assessable	Imputability Level 0 (unlikely)	Imputability Level 1 (possible)	Imputability Level 2 (probable)	Imputability Level 3 (certain)
Immunological haemolysis due to ABO incompatibility:						
• Red cells	**Total: 3**	0	1	0	**0**	**2**
Immunological haemolysis due to other alloantibody						
• Red cells	**Total: 40**	0	2	6	**17**	**15**
Non-immunological haemolysis						
• Red cells	**Total: 2**	1	1	0	**0**	**0**
Transfusion-transmitted bacterial infection						
• Red cells	**Total: 6**	0	6	0	**0**	**0**
• Platelets	**Total: 8**	0	7	1	**0**	**0**
• Plasma	**Total: 1**	0	1	0	**0**	**0**
Anaphylaxis/hypersensitivity						
• Red cells	**Total: 52**	0	6	19	**24**	**3**
• Platelets	**Total: 43**	0	3	13	**23**	**4**
• Plasma	**Total: 20**	0	0	8	**10**	**2**
• Other	**Total: 6**	0	0	2	**2**	**2**
Transfusion-related acute lung injury						
• Red cells	**Total: 4**	0	2	2	**0**	**0**
• Platelets	**Total: 1**	0	0	0	**1**	**0**
• Plasma	**Total: 2**	0	0	2	**0**	**0**
• Other	**Total: 7**	0	5	1	**1**	**0**
	Deaths: 1	0	0	1	**0**	**0**
Transfusion-transmitted viral infection (HBV)						
• Red cells	**Total: 4**	0	3	0	**0**	**1**
• Platelets	**Total: 1**	0	1	0	**0**	**0**
• Plasma	**Total: 1**	0	0	0	**0**	**1**
• Other	**Total: 1**	0	1	0	**0**	**0**
Transfusion-transmitted viral infection (Other) Parvovirus						
• Red cells	**Total: 1**	0	0	0	**1**	**0**
Post-transfusion purpura						
• Platelets	**Total: 2**	0	0	0	**1**	**1**
Transfusion-associated graft versus host disease						
• Whole blood	**Total: 1**	0	0	0	**0**	**1**
	Deaths: 1	0	0	0	**0**	**1**
Other						
• Red cells	**Total: 109**	0	9	67	**27**	**6**
• Platelets	**Total: 9**	0	1	6	**2**	**0**
• Plasma	**Total: 7**	0	0	3	**4**	**0**
• Other	**Total: 12**	1	0	4	**6**	**1**
	Deaths: 4	1	0	2	**0**	**1**

**Other components (includes buffy coats, granulocytes and multiple components).*

NB. Imputability level is defined as the likelihood that the serious adverse reaction in the recipient can be attributed to the component transfused.

No reports have been submitted for any blood component in the following reportable reaction types:

- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted parasitical infection (Malaria)

As in previous years the majority of reports received are for 'Anaphylaxis/hypersensitivity' type reactions. The total number of reports in this category for 2012 was 121, a significant decrease since 2010 when the total was 287.

A total of 137 reports were submitted in the 'other' reaction type. However, only 46 of these were found to be probably or certainly attributable to the component transfused. These are subcategorised as follows:

Reaction type sub-category	Code	No. of reports
Febrile non-haemolytic transfusion reaction	FNHTR	20
Transfusion-associated circulatory overload	TACO	19
Transfusion-associated dyspnoea/ARDS	TAD	4
Other	Other	3

Table 6.10: Sub-categorisation of reaction type Other, Imputability level ≥ 2 (n=46)

In August 2012 the EU commission asked all member states to make recommendations for amendments to the EU Directive 2002/98/EC. One of the changes that the UK proposed was to further define the 'other' reaction type so that notable reactions such as TACO and TAD would appear as a specific reaction types.

Deaths

Total No. of deaths reported in 2012 n=6

No. of deaths where imputability level ≥2 n=2

Case 1 = TA-GvHD – please see detailed report in Chapter 20

Case 2 = Other/TACO – please see detailed report in Chapter 25

MHRA Inspection data 2011/12

From the 2011/12 blood compliance report (BCR) submissions 55 'for cause' and 9 control inspections (64 in total) were planned for completion in the 2012/13 inspection round.

So far, 25 inspections have been completed (to the end of February 2013).

From the inspections completed so far, the key areas of weakness are:

- More extensive use of Trust risk management systems for the reporting of deficiencies with a reduction in the use of local systems. Trust risk management systems (e.g. Datix) tend to report only where there is actual harm. This results in events that have the potential for serious harm but have not so far resulted in harm not being prioritised, leading to a lack of RCA and CAPA being applied. Also more minor events tend not to be reported through this system. There is a clear misunderstanding as to the difference between risk management which focuses on risks to the business such as media attention and financial penalties, and quality risk management which should focus on remediation of potential harm events
- A lack of suitable controls on the merging of patient data files on both the local hospital transfusion laboratory information management system (LIMS) and the hospital patient administration database (PAS). Incompatible components have been issued due to poor controls at the PAS level
- Traceability is poor on some sites – some have set key performance improvement targets (KPI's) at ~95% and as they are just falling within the KPI target they do not introduce measures to improve on this. On large user sites this can mean more than 1000 untraced units per month
- Poor implementation of change control and equipment/process validation

- Lack of robust competency assessment for out of hours working (including the application of the deviation management and recall systems)

MHRA Haemovigilance activity in 2012

The MHRA Haemovigilance Team have a responsibility to check every report submitted via SABRE for quality, timeliness and accuracy. Alongside this they run a telephone helpdesk and are committed to supporting reporters with help, advice and education whenever possible.

The table below details some of the other activities the team have been involved in during the course of 2012:

Table 6.11: MHRA external activity

MHRA Haemovigilance team external activity	Number of visits
Competent Authority/EU working party meetings	2
Blood Consultative Committee meetings	2
National Transfusion Committee meetings	2
Regional Transfusion Committee (RTC) Educational seminars	4
BBTS/NEQAS presentations	2
Poster presentations	2
Informal site visits	6
Haemovigilance presentation to Turkish delegation	1
Presentation to TRAB (Trainee Doctors Advisory Board)	1

Near Miss Reporting (NM) 7

Author: Alison Watt

Definition:

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

DATA SUMMARY
Total number of cases: 980

Implicated components		Mortality/morbidity	
Red cells	0	Deaths due to transfusion	0
FFP	0	Deaths probably/likely due to transfusion	0
Platelets	0	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	0
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	0		
Unknown/Not applicable	980		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where incident took place	
Male	350	≥ 18 years	846	Emergency	0	Emergency Department	87
Female	566	16 years to <18 years	8	Urgent	0	Theatre	12
Not known	64	1 year to <16 years	26	Routine	0	ITU/NNU/HDU/Recovery	50
		>28 days to <1 year	10	Not known	980	Wards	302
		Birth to ≤28 days	40			Delivery Ward	0
		Not known	50	In core hours	730	Postnatal	0
				Out of core hours	218	Medical Assessment Unit	11
				Not known/Not applicable	32	Community	2
						Outpatient/day unit	15
						Hospice	1
						Antenatal Clinic	35
						Hospital Transfusion Laboratory	242
						Obstetrics	89
						Other/Unknown	134

The 980 near misses in 2012 represent a reduction of 100 from 1080 reported in 2011.

Category of incidents	Number of cases	Percentage of cases
Clinical errors	694	70.8%
Laboratory errors	284	29.0%
Blood Establishment errors*	2	0.2%
Total	**980**	**100.0%**

**red cells labelled as irradiated, but the indicator label showed they were not; red cells in a satellite pack which had no port for administration.*

Table 7.1: Numbers of near misses originating in clinical or laboratory areas

Near misses are often dangerous errors that could have serious consequences if not detected. Detection of 'near miss' incidents may be enhanced by a good quality management system (QMS), but quite often the discovery is made by chance. They should not be discounted as trivial incidents and SHOT encourages continued reporting and investigation of 'near misses' as many important lessons can be learned.

Learning point

- 'Near miss' events should be treated with the same level of concern as all other incidents and, as appropriate, should be fully investigated for root causes with appropriate corrective and preventative actions applied

The near misses have been analysed this year in two broad categories 'Clinical' and 'Laboratory'. This will allow 'near misses' to be compared more easily to the incidents discussed in other chapters.

Clinical errors n=694

Table 7.2: Clinical errors according to category

Category of clinical errors	Number of cases	Percentage of cases
Sample errors	534	76.9%
Request errors	42	6.1%
Component collection/administration errors	62	8.9%
Cold chain errors	38	5.5%
Other = clinical anti-D immunoglobulin errors*	18	2.6%
Total	**694**	**100.0%**

**Clinical anti-D 'near miss' cases show the same issues as discussed in Chapter 15 (Adverse events related to anti-D immunoglobulin).*

Sample errors n=534

Table 7.3: Sample errors

Category of sample errors	Number of cases	Percentage of cases
Wrong blood in tube (WBIT)*	505	94.6%
SHOT-reportable sample labelling errors	28	5.2%
Other (Case 1)	1	0.2%
Total	**534**	**100.0%**

**Includes 2 full blood count (FBC) 'wrong blood in tube' errors where transfusions nearly took place based on the incorrect results.*

SHOT does not require reporting of sample labelling errors that are detected by the quality system at the first opportunity, i.e. at 'booking-in' of the sample. Therefore, the SHOT-reportable sample labelling errors (n= 28) were incidents where the samples had incorrect patient identifiers, but were not detectable until later in the process; often at the bedside when the labelling on the component issued did not match the patient's identity band. A recommendation is made about continuing to monitor poor sample labelling and zero tolerance.

The sample error defined as 'other' was an incident (Case 1) which showed there might be problems implementing the group check sample requirement as suggested in the new British Committee for Standards in Haematology (BCSH) Guidelines for pre-transfusion compatibility testing[35].

Case 1: An attempt to circumvent group check sample (2 sample) requirement

A single sample was decanted into two bottles and labelled as being taken 40 minutes apart. This was discovered when the laboratory noticed both samples showed the same level of haemolysis.

Learning point

- Improved communication is needed between laboratories and the clinical area to ensure the request for a second group check sample is fully understood as a safety check to confirm that the patient has been correctly identified and will be transfused with the appropriate group blood

Callum et al[36] have described their experiences in Toronto, Canada, where using the term of 'second sample' prompted the practice of simultaneous collection of two transfusion samples. Therefore, the terminology was changed from 'second sample' to 'group check'.

Learning point

- The phrase 'group check sample' should be used in preference to 'two samples' to reinforce the positive message of independently taken samples

Case 2: Patient asked to confirm identification details which were incorrect

A long-term patient had two records in the patient administration system (PAS) with different dates of birth. She became irritated and then non-compliant after being asked many times to confirm the wrong date of birth, so began confirming both dates, resulting in the details being changed incorrectly in the laboratory information management system (LIMS).

Learning point

- Positive identification techniques should be used, requiring the patient to give their details, such as date of birth, not merely to confirm the date of birth already on their record, and the reasons explained to the patient

Wrong blood in tube n=505

Definition of 'wrong blood in tube' incidents:

- Blood is taken from the wrong patient and is labelled with the intended patient's details
- Blood is taken from the intended patient, but labelled with another patient's details

An additional group of 'wrong blood in tube' incidents (n=27/505, 5.3%) have been included this year. These were samples recalled prior to testing, because the sample taker realised their error. In previous years such incidents were withdrawn, but no laboratory quality system could guarantee detection of these errors, so they are now included.

'Wrong blood in tube' errors are serious incidents that could result in death due to incompatible transfusion. In the clinical section of the 'incorrect blood component transfused' chapter (Chapter 9) a total of 6 incidents are reported where an incorrect component was transfused due to 'wrong blood in tube' errors, 2 of which involved ABO incompatible transfusions, which could have caused major morbidity or death.

Table 7.4: Staff responsible for 'wrong blood in tube' incidents

Staff member responsible for taking sample	Number of cases	Percentage of cases
Doctor	223	44.2%
Midwife	95	18.8%
Nurse	91	18.0%
Healthcare assistant	34	6.7%
Phlebotomist	20	4.0%
Medical student	1	0.2%
Other/unknown	41	8.1%
Total	**505**	**100.0%**

Table 7.5: Practices leading to 'wrong blood in tube'

Practices leading to 'wrong blood in tube'	Number of cases	Percentage of cases
Sample not labelled at bedside	232	45.9%
Patient not identified correctly	170	33.7%
Sample not labelled by person taking blood	15	3.0%
Pre-labelled sample used	3	0.6%
Maternal and baby samples transposed*	32	6.3%
Other/unknown	53	10.5%
Total	**505**	**100.0%**

**Includes three reports of twin cord samples being transposed.*

Failure to identify patients properly and systematically at every stage of the transfusion process is a recurring theme throughout the Annual SHOT Reports. This can be the result of the incorrect patient record having been assigned initially.

Cases 3 and 4: Two cases of daughters' samples being labelled with mothers' details

Case 3: A 15 year-old patient was identified with her mother's details, because they had exactly the same name and address. The doctor who took the sample did not check the patient's date of birth, so did not realise the mistake.

Case 4: In an emergency situation, a patient was identified with her mother's details, because she had her mother's credit card in her possession and the police presumed these were her details.

Learning point

- If patients cannot clearly identify themselves, consideration should be given to using emergency identifiers according to local policy, until an accurate identity can be assured. The balance of risks should be fully assessed, because a group check sample on a patient labelled as 'unknown' may be safer than wrong assumptions about a person's identity

The merging of patient information technology (IT) records, such as those held on PAS and LIMS can be responsible for patient misidentifications. These are discussed further in the IT chapter (Chapter 11).

Case 5: Two patient records merged outside the transfusion laboratory

A patient grouped as B RhD positive, but the patient's record showed an archived group of A RhD positive from 15 years ago. A repeat sample confirmed the patient's group really was B RhD positive and the patient's record on the patient admission system had been merged incorrectly.

How 'wrong blood in tube' error was detected	Number of cases	Percentage of cases
During testing	185	36.6%
At authorisation	157	31.1%
Prior to testing	61	12.1%
Sample taker realised	45	8.9%
Further sample differed	29	5.7%
Pre-administration checks	11	2.2%
Results from non-transfusion samples (e.g. FBC)	9	1.8%
Other/unknown	8	1.6%
Total	**505**	**100.0%**

Table 7.6: Circumstances leading to the detection of 'wrong blood in tube'

Potentially other 'wrong blood in tube' errors remain undetected because they do not have a historical group or because the patient suffers no identifiable harm, as they were either never transfused or they fortuitously received units of a compatible ABO group.

Approximately one incorrect blood component is transfused due to a 'wrong blood in tube' error for every 100 near miss incidents.

This proportion of about 1 in 100 has been consistent over the last three years of SHOT reporting, 2010-2012.

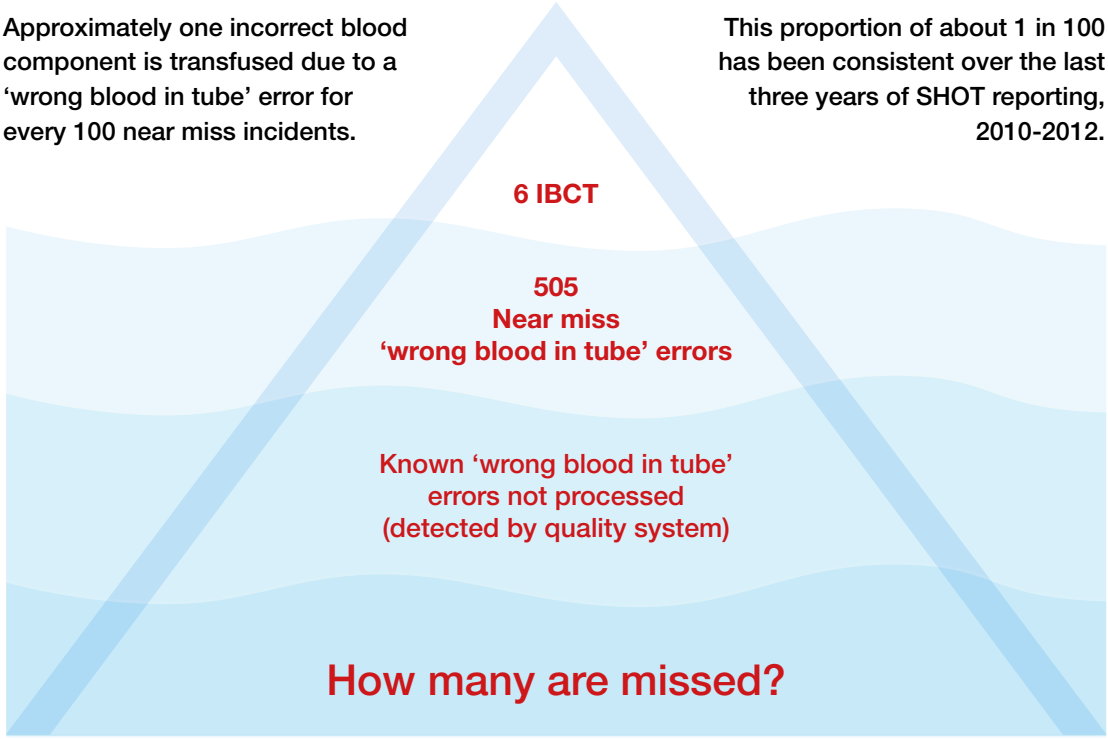


Figure 7.1: Comparison of known 'wrong blood in tube' errors and potentially undetected errors

Request errors n=42

Request errors	Number of cases	Percentage of cases
Specific requirements not requested	30	71.5%
Request based on erroneous test results	3	7.1%
Request for incorrect patient	9	21.4%
Total	**42**	**100.0%**

Table 7.7: Categories of request errors

Specific requirements not requested n=30

Table 7.8: Mode of detection that specific requirements had not been requested

Mode of detection	Number of cases	Percentage of cases
Bedside pre-administration check	17	56.7%
In laboratory	13	43.3%
Total	**30**	**100.0%**

Component collection/administration errors n=62

Table 7.9: Component collection/ administration errors

Collection/administration errors	Number of cases	Percentage of cases
Incorrect units collected by ward staff/porters	43	69.4%
Wrong details on collection slip	16	25.8%
Attempted administration to incorrect patient	3	4.8%
Total	**62**	**100.0%**

Case 6: Patient's identity band changed to match the incorrect blood unit

Particular care was required as two patients were being transfused in the same bay on a haematology ward. The hospital uses single nurse checking of blood, combined with an electronic identification system. Several errors were made and opportunities to detect the problem before it moved to the next error were ignored.

1. *Blood was prescribed for both patients and both prescriptions were on the nurses' station within the bay. The staff nurse requested the health care assistant collect blood for patient X but handed her the prescription for patient Y.*
2. *The nurse checked the blood with the patient's identity band using the electronic bedside verification system and the scanner audibly alarmed to warn that there was a mismatch.*
3. *The nurse contacted the laboratory and was advised that a new identity band should be printed to exclude problems with a corrupted barcode. The nurse used the details on the blood to generate a new identity band.*
4. *This incorrect identity band was applied to the patient without any identification checks. The unit was rescanned and the system now accepted this was the right blood for the identity band scanned.*
5. *Fortunately the patient queried why the blood was not irradiated and on investigation the nurse realised she had the blood for the other patient in the bay.*

Learning point

- Identity bands should only be generated at point of admission with positive patient identification and should not be changed or updated unless it can be shown categorically that the revised identity information is accurate. Replacement of patient identity bands must follow National Patient Safety Agency (NPSA) guidance[37, 38]. Where there is any doubt about a patient's identity in relation to transfusion, a pre-transfusion sample should be retaken for confirmation of identity and group

Errors related to management of the cold chain n=38

Cold chain error	Number of cases	Percentage of cases
Components stored inappropriately	19	50%
Incorrect transport/packing of units	11	29%
Satellite refrigerator failures	4	10.5%
Returned to stock after out of temperature controlled environment >30 minutes	4	10.5%
Total	**38**	**100.0%**

Table 7.10: Errors related to management of the cold chain

Laboratory errors n=284

To enable comparisons to be made, the laboratory errors reported as 'near misses' have been sub-categorised into the same groups as those used in the Laboratory Errors chapter (Chapter 10). The commentary and learning points from these incidents will mostly be the same as those described in that chapter, so further comments will not be added here.

Category of laboratory errors	Number of cases	Percentage of cases
Sample receipt and registration	49	17.2%
Testing	50	17.6%
Component selection	61	21.5%
Component labelling, availability, & handling and storage errors	123	43.3%
Other = analyser misreading sample barcode	1	0.4%
Total	**284**	**100.0%**

Table 7.11: Categories of laboratory errors made

These have been categorised according to the normal flow of routine testing and processing within the laboratory.

Sample receipt and registration n=49

Sample receipt and registration errors	Number of cases	Percentage of cases
Incorrect identifiers entered onto LIMS	23	46.9%
Specific requirements not met (failure to notice information on the request form or the patient's historical record)	20	40.8%
Sample booked under incorrect record*	6	12.3%
Total	**49**	**100.0%**

** includes an incident where two patient records were merged on the LIMS.*

Table 7.12: Sample receipt and registration errors

Testing n=50

Testing errors	Number of cases	Percentage of cases
Transcription errors	16	32%
Incomplete testing	11	22%
ABO & RhD grouping errors (all manual testing)	9	18%
Interpretation	7	14%
Anti-D immunoglobulin issued to RhD positive patient	7	14%
Total	**50**	**100%**

Table 7.13: Testing errors

Component selection n=61

Table 7.14: Component selection errors

Component requirement or specification missed	Number of cases	Percentage of cases
Incorrect component selected	29	47.5%
Anti-D immunoglobulin errors	9	14.8%
Irradiated	9	14.8%
Red cell phenotype	7	11.5%
Cytomegalovirus (CMV) negative	6	9.8%
CMV negative and irradiated	1	1.6%
Total	**61**	**100.0%**

Component labelling, availability, and handling and storage errors n=123

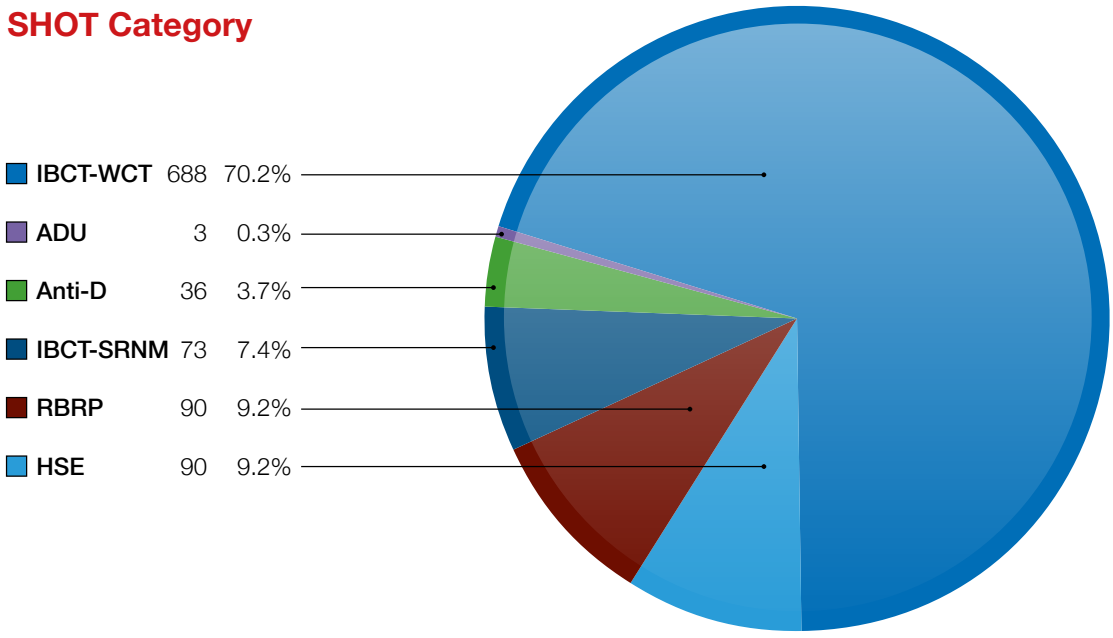
Table 7.15: Component labelling, availability, and handling and storage errors

Component errors	Number of cases	Percentage of cases
Component labels transposed	51	41.5%
Incorrect patient information on label	28	22.7%
Time-expired component available	19	15.4%
Cold chain errors	12	9.8%
Available past dereservation date/time	6	4.9%
Handling and storage errors	4	3.3%
Exceeded BCSH sample timing guidelines[35]	3	2.4%
Total	**123**	**100.0%**

COMMENTARY

Many of the 'near miss' errors give the opportunity for the same lessons to be learned as incidents reported in other categories. If the 'near misses' had progressed to full incidents and components had actually been transfused, they would have been categorised as shown in Figure 7.2.

Figure 7.2: Categorisation of all 'near misses' according to SHOT definitions



The total number of 'near miss' reports analysed in 2012 was 980, compared to 1080 in 2011. The percentage of 'wrong blood in tube' incidents rose from 43.4% (469/1080) in 2011 to 51.5% (505/980) in 2012. Continued reporting of 'near misses' should be strongly encouraged because important lessons can be learnt for safer practice.

It is known that the incidence of sample labelling errors is very much higher than it appears in the SHOT data, where only the most serious potential hazards have been reported. This is an important issue and the quality implications should be monitored by local audit. There should be zero tolerance of mislabelled samples, not only in transfusion laboratories, but across all pathology disciplines, because of the risks associated with assigning diagnostic results to a misidentified patient. Incidents of incorrect haemoglobin results leading to inappropriate transfusion are analysed in the 'avoidable, delayed or undertransfusion' chapter (Chapter 12).

The new BCSH guidelines for pre-transfusion compatibility testing[35] recommend the use of a second group check sample. Good communication between all parties will be needed in order to get the most benefit from this extra safety measure as recommended in these BCSH guidelines:

'Unless secure electronic patient identification systems are in place, a second sample should be requested for confirmation of the ABO group of a first time patient prior to transfusion, where this does not impede the delivery of urgent red cells or other components.'

Communication will be particularly vital in circumstances where the situation is judged to be too urgent to wait for a group check sample.

Recommendations

- Laboratory and clinical areas should continue to report 'near miss' errors, as these are a useful indication of potential failings, allowing corrective and preventative actions to be taken before any harm is done

Action: Hospital Transfusion Committees (HTC)

- There should be zero tolerance of sample labelling errors across all pathology disciplines (see also Chapter 12) and local audits of sample labelling should continue to be undertaken to identify the ongoing risks of patient misidentification

Action: Chief Executive Officers of Hospitals, Trusts/Health Boards, Pathology Laboratory Managers

- There should be strict adherence to the requirement for a group check sample on patients without a historical blood group as detailed in the British Committee for Standards in Haematology (BCSH) guidelines for pre-transfusion compatibility testing[35]

Action: Hospital Transfusion Committees (HTC)

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

8 Investigating Transfusion Incidents using Root Cause Analysis

Authors: Tony Davies and Judy Langham

Definition:

Root cause analysis (RCA) is methodology that enables investigators to ask the questions 'How' and 'Why' in a structured and objective way, to reveal all the influencing and causal factors that have led to a patient safety incident. A root cause is a fundamental contributory factor which, if resolved, will eradicate or have the most significant effect on reducing likelihood of recurrence.

Introduction

A culture of reporting when things go wrong is essential in healthcare, but is only part of the process of improving patient safety. It is equally important that organisations look at the underlying causes of patient safety incidents and learn how to prevent them from happening again.

Extensive guidance on incident investigation and management can be found in the Medicines and Healthcare products Regulatory Agency (MHRA) 'Report on the UK Regulation of Blood Safety and Quality 2005–2010'[39] but it is timely to reiterate many of the points once again.

Investigations often find that similar scenarios have occurred previously, but for a variety of reasons did not result in serious consequences. The practice of following up 'near misses' can be as valuable as investigating incidents which result in patient mortality or morbidity.

Failures and mistakes do not just happen by themselves; organisations may inadvertently permit environments and systems that encourage direct causes to develop. It is unfortunate that the phrase; 'human error' is usually interpreted to mean that the person was at fault in some way.

While human error plays some part in the majority of incidents, people are not generally stupid, lazy, forgetful or wilfully negligent, and it is misguided to set out on an investigation with the aim of finding someone to blame. The way that people behave at work depends on a number of different factors, including the culture of the organisation in which they work, the nature of the work they are doing and their own personal issues and beliefs.

Understanding which type of human error has occurred can help to identify why the error occurred and indicate the most appropriate corrective measures to take:

- Attention lapses due to distraction or interruption in the middle of a task
- Genuine ('cognitive') errors, where the person had every intention of carrying out the correct procedure but failed
- Misperceptions of what the task actually involves
- Misplaced priorities, perhaps mixed messages over clinical priorities
- Deliberate non-compliance by failure to follow policy perhaps because of a perception that it is acceptable to take short cuts.

In December 2010 Sir Bruce Keogh, Medical Director Department of Health (DH) and National Health Service (NHS) Commissioning Board, established a reference group to consider how human factors might be better acknowledged and integrated in the NHS in England, to benefit service delivery and

safer patient care. Their efforts resulted in production of a consensus report with recommendations, which was submitted to the DH in March 2012[40].

Many investigations make the mistake of raising actions which deal only with the direct causes, putting in a 'quick fix' or simply adding extra levels of checking, while ignoring the root and underlying causes. Not only do they miss the opportunity to reduce the risk of recurrence of the incident, but also leave open the possibility that other, dissimilar incidents may occur, arising from the same common root cause.

Good planning of the investigation ensures that it is systematic and complete, identifies the resources needed, identifies the personnel who will need to be involved and how long it is likely to take.

In 2004, the National Patient Safety Agency (NPSA) produced their 7-step guide to reporting and learning from incidents. On 1 June 2012 the key functions and expertise for patient safety developed by the NPSA transferred to the NHS Commissioning Board Special Health Authority, but the resources to support incident investigation are still accessible via the National Learning and Reporting System (NRLS) website at www.nrls.npsa.nhs.uk/.

A RCA approach to incident investigation will benefit the organisation in a number of ways:

- Providing a structured and consistent approach to incident investigation
- Identifying specifically what went wrong and why
- Avoiding putting a great deal of effort into fixing the wrong thing
- Avoiding over-burdening existing procedures with extra checking stages that may not be necessary
- Shifting the focus away from individuals and on to the system to help build an open and fair culture
- Increasing awareness of patient safety issues
- Helping engage patients in the investigation
- Demonstrating the benefits of reporting incidents
- Identifying more effective and targeted corrective measures, recommendations and change as a result of identifying the root cause(s) of an incident

It is helpful to have a facilitator to co-ordinate a RCA. Other team members would be involved gathering and exploring information, while the people who were actually involved in the incident may also contribute to the investigation by being interviewed.

Organising a full, multi-disciplinary or externally led process is expensive both in terms of time and resources, and if performed for every incident may lead to 'paralysis by investigation'. Such a level of investigation should be reserved for more **serious events** where patients have suffered serious morbidity or died, and where there could be serious implications for the reporting organisation. In such an instance the following should be considered:

- Ensure all staff are aware of their responsibility to report **WHAT** happened as soon as known – ideally within 48 hours
- Implement remedial action as soon as possible
- Complete the incident investigation within one month of the incident occurring
- Establish both **HOW** and **WHY** the incident occurred
- Consider all possible root causes/contributory factors
- Agree the appropriate corrective action with all stakeholders and put together an implementation plan within one month
- Consider the incident in a wider context with the potential for further preventive action and any potential process improvements
- Share lessons learnt with staff and use as part of Good Practice updates

- Encourage a culture of reflective practice – ideally this should take place at all levels of the hierarchy and not just be undertaken by individuals
- A reflective approach to transfusion service delivery may question current practice and can assist with a team approach to continuous quality improvement and better patient safety

The benefits of carrying out a **concise investigation** (perhaps a narrative or a timeline is enough in some cases) must be balanced against the severity or implications of the incident that has occurred, and the likelihood that it will be repeated.

The 5x5 **risk assessment matrix** below is a composite of many examples used by industry, risk management companies and by the NPSA. Some authors also recommend 9x9 matrices to give better granularity to incident classifications and allowing further refinement to risk scoring.

A risk score is achieved by multiplying the potential (or actual) severity of the incident against the likelihood of it occurring (or reoccurring). This relatively objective numeric score may be used to initiate further action or to include on a hospital risk register. For example, the consequences of a 'wrong blood in tube' error could be catastrophic for a patient and rightly score 5 for severity, then multiplying by a likelihood factor of 3 (occasional – 1/2000) would give a risk rating of 15 – 'Urgent action required' on this matrix.

A potential anaphylactic reaction to anti-D would again be severe (or 'catastrophic') and score 5, but the likelihood is improbable (at around 1/1,000,000) and so the risk rating would be only 5 and the outcome would be to monitor for further events rather than take positive action.

Figure 8.1 Risk assessment matrix

KEY

- No action
- Monitor
- Action
- Urgent Action
- Critical

Severity						
	Catastrophic 5	5	10	15	20	25
	Significant 4	4	8	12	16	20
	Moderate 3	3	6	9	12	15
	Low 2	2	4	6	8	10
	Negligible 1	1	2	3	4	5
RISK RATING = Likelihood x Severity		**1 Improbable**	**2 Remote**	**3 Occasional**	**4 Probable**	**5 Frequent**
		Likelihood				

Gathering the Data

Information should be gathered about what happened from the location of the incident, from staff involved, equipment used, policies and guidelines that impact on the situation, the patient's notes and other documentation such as laboratory computer records, telephone logs, collection slips.

Organising the data

The information gathered needs to be mapped or ordered in a useful way. This will clarify what is known and identify any gaps. Tools to assist with this process include 'Narrative Chronology', a straightforward chronological account of what happened, and 'Tabular Timelines' that map the chronological chain of events involved in an incident where it is anticipated that the incident contains more than one isolated episode of procedural failure. The whole incident can be viewed on one diagram and it will help identify gaps and questions needed for interviews. In many cases, simply arranging events in chronological order may well be enough to clarify perceptions and perhaps misunderstandings that inevitably arise around a transfusion incident.

Identifying the problems

A review meeting may be organised by the facilitator to help identify the key problems that emerge, and these may be divided up into Care Delivery Problems (CDPs) and Service Delivery Problems (SDPs).

- CDPs are problems that arise in the process of care; usually actions or omissions by staff e.g. failure to carry out a bedside pre-transfusion check, failure to monitor a patient undergoing transfusion, failure to observe or act, or not seeking help when necessary
- SDPs are significant latent system failures identified during the analysis of the patient safety incident, such as reduced staffing levels, lack of supervision, design of ward areas or lack of equipment or facilities

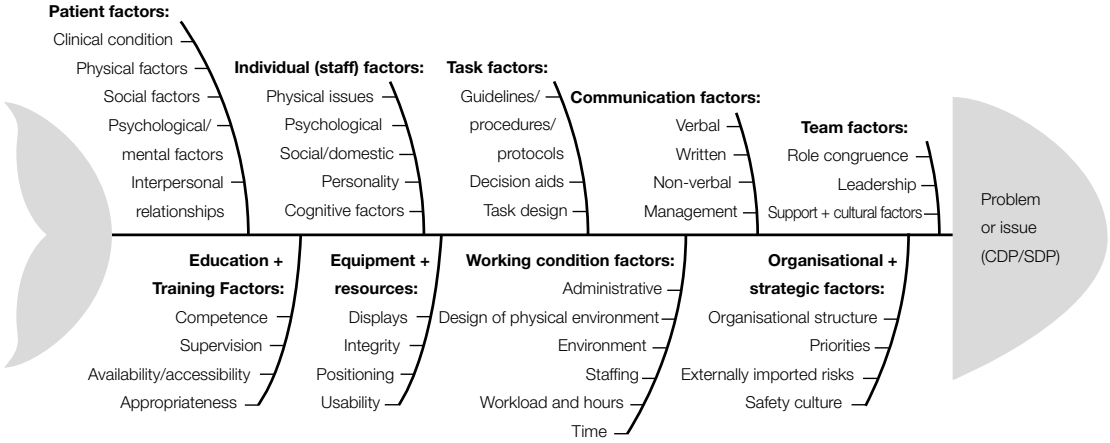
The application of an incident decision tree as promoted by the NRLS to complement the RCA toolkit enables an investigation team to look more closely at the role of an individual in an adverse event and can help differentiate between individual error and system failure. Several useful documents can be accessed on the risk assessment/management pages of the NRLS website[41].

Analysing the problems

Once data has been collected and ordered and problems have been identified and clarified, it is then necessary to prioritise problems and issues for analysis and identify contributory factors using a variety of tools:

- Continuously questioning **why** an incident has occurred remains the most effective way of uncovering the root cause(s) and any contributory factors. The '5 Whys' technique allows deeper questioning as to the cause of the problem identified whether it is a symptom or a root cause. Factors that contributed to the incident may vary in significance of impact, whether from a positive or negative point of view
- A barrier analysis is a review of all the controls which were in place and which should have stopped the problem occurring or mitigated its impact. Each barrier is identified – did it succeed, if not why not? If it failed, was it a causal or an influencing factor? The transfusion process has a number of well-established critical break-points designed to prevent error, from sample taking, sample receipt into the laboratory quality system, collection and receipt of components, and bedside administration and monitoring of the patient
- A 'fishbone diagram' is a diagrammatic tool used to capture causes contributing to a single problem. The head of the fish represents the specific issue, or problem being explored while the spines show the factors influencing the problem. The following example is taken from the NPSA toolkit.

Figure 8.2 Fishbone diagram for incident investigation



Identifying and agreeing the root causes

Identify the contributory factors which have the highest impact on each problem and find those that are behind more than one problem, to enable the team to agree the root cause(s) that needs to be addressed.

Making recommendations and reporting

It is important that the lessons learned from the RCA can be used to improve patient safety, by identifying the root causes, generating solutions and writing a report that includes recommendations. This needs to be followed up with an action plan that includes roles, responsibilities and time-frames for completion, which need to be monitored so that solutions are implemented and their effectiveness evaluated.

Examples of both concise and comprehensive report templates may be found at:
http://www.nrls.npsa.nhs.uk/resources/?entryid45=75419

When writing the incident investigation report:

- Keep it simple – not everyone will understand acronyms and terminology used in the laboratory or clinical area
- Consider who will read or needs to read the report
  - Patient and carers
  - Other Trust/Health Board Management Committees
  - Health Authority
  - Coroner's Office
  - Trust or Health Board executive management
  - Department of Health
  - NHS Litigation Authority/Solicitors
  - Local or national media
  - The general public
- Summarise the nature of the incident and its consequences
- Describe the investigation: methodology, incident grading information, the findings – CDPs, SDPs and contributory factors and root cause(s)
- Document positive features of the incident and good practice identified
- Include recommendations/key learning points

The SHOT office receives examples of RCA during the course of a reporting year. Many are excellent, well written, thorough and clearly identify the root cause(s) of an incident, along with recommendations to minimise the risk of the incident recurring. Some others unfortunately are very poor, paying lip service to a structured investigation while constructed around assumptions and prejudices which do nothing to clarify the situation or inform an effective action plan.

An excellent example of a RCA is summarised below, by kind permission of the reporter. The incident involved a 15 year old child with thalassaemia major attending a paediatric haematology day unit for a regular top-up transfusion, and who received a small volume (3 mL) of red cells intended for another patient on the day unit at the same time.

The investigation report:

- Rated the incident in terms of likelihood of recurrence and severity as High Risk
- Clearly described the membership of the investigating team (3 senior people)
- Clearly identified the purpose, objectives and scope of the investigation
- Detailed which members of staff were interviewed
- Described the incident as a narrative timeline
- Described the normal practices in place on the day unit
- Described the support given to patient, family and staff
- Described immediate action taken in the wake of the incident
- Highlighted the fact that effective action was taken in a timely manner, as well as the openness, honesty and reflection of the staff involved during the investigation process
- Produced some key findings:
  - Only one unit of blood should be removed from storage at any time – the nurse collecting took three units for three separate patients at the same time
  - The final administration check should always be conducted next to the patient by two registered nurses, and once all checks have been completed, the transfusion should be started immediately – the staff did not commence transfusion immediately after an initial check of the units, but placed the units on a table before picking them up again, so the final bedside check was not performed properly
  - Transfusion must only take place where there are enough staff available to monitor the patient and when the patient can readily be observed – a second nurse who had assisted in the checking procedures had returned to her ward, leaving one nurse in the day unit to administer and monitor three transfusions, including leaving the ward unsupervised while she went to collect further units
- Noted some contributory factors;
  - Both nurses were out of date with the necessary competency assessment (one was two years and the other nine months out of date)
  - The layout of the ward, the position of the recliners and tables, made it easier for a nurse to pick up the wrong unit of blood
  - During staff interviews, it became apparent that there was ‘a culture of acceptance of low staffing levels’
- Identified the root cause – that the nurse failed to adhere to Trust policy that stated only one unit of blood should be collected at one time

- Identified lessons learned:
  - The incident could have been avoided by adherence to policy but the low staffing level resulted in a seemingly pragmatic but in reality unsafe alternative
  - There was a need to alter the layout of the ward to reduce the risk of recurrence
  - The need for at least one nurse to be present on the unit at all times
  - Only one unit of blood to be collected at one time – had the staff training and competency been up to date, they may have realised that they should only collect one unit at a time
  - Had the staff administration competency been up to date, the risk of the incident occurring might have been reduced
  - Where clinical practice is recognised as being contradictory to policy due to reduced staffing, then this must be added to the Divisional Risk Register
- Noted problems with care and service delivery:
  - The Trust care pathway for children with thalassaemia major states that transfusion observations should be carried out every 15 minutes for the first hour – an audit of records showed that only 42% of observation charts complied with this, due to pressure on lone workers
- Made recommendations:
  - To employ an extra member of staff
  - To ensure safe practice by having two members of staff readily available to independently perform pre-administration checks and monitor the transfusions
  - To ensure that plans are put in place for training and competency assessment of all staff on the ward
  - To review the thalassaemia major care pathway via the Hospital Transfusion Committee to ensure that the level of patient observations is necessary and achievable
  - To change the current layout of the ward
- Produced an action plan, with identified accountable leads and timescales for completion

As a result of the RCA investigation and the highlighting of the risk at Trust level, a second nurse has been employed on the unit.

Recommendations

- All reported adverse incidents should be graded according to severity and risk of recurrence in order to determine the level of appropriate investigation. Low risk incidents need not trigger a time-consuming process, but valuable lessons may be learned from review of these
- Serious incidents require a full root cause analysis with feedback to all staff involved. The level of investigation must be governed by consideration for patient safety

Action: Hospital Transfusion Teams with support from their Chief Executive Officers.

Further Reading

The National Reporting and Learning Service – Seven steps to patient safety[42]

SHOT Annual Reports 1997 – 2011 www.shotuk.org

Interim Report 1st March 2012 – Department of Health Human Factors Reference Group[16]

Health and Safety Executive – Introduction to Human Factors[43]

Analysis of Cases Due to Errors

9 Incorrect Blood Component Transfused (IBCT) (clinical and laboratory errors)

including wrong components transfused and where specific requirements were not met

Authors: Clinical incidents: Julie Ball and Paula Bolton-Maggs;
Laboratory incidents: Hema Mistry and Christine Gallagher

Definition:

The category of incorrect blood component transfused (IBCT) includes all reported episodes where a patient was transfused with a component that was intended for another patient, was a component of different type than that requested or did not meet the specific transfusion requirements of the patient.

DATA SUMMARY – Incorrect Blood Component Transfused & Specific Requirements Not Met
Total number of cases = 252

Implicated components		Mortality/morbidity	
Red cells	202	Deaths due to transfusion	0
FFP	15	Deaths probably/likely due to transfusion	0
Platelets	19	Deaths possibly due to transfusion	0
Cryoprecipitate	2	Major morbidity	11
Granulocytes	0	Potential for major morbidity (anti-D or -K only)	5
Anti-D Ig	0		
Multiple components	14		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where incident took place	
Male	119	≥ 18 years	207	Emergency	35	Emergency department	13
Female	124	16 years to <18 years	3	Urgent	58	Theatre	18
Not known	9	1 year to <16 years	22	Routine	152	ITU/NNU/HDU/Recovery	28
		>28 days to <1 year	4	Not known	7	Wards	145
		Birth to ≤28 days	8			Delivery Ward	1
		Not known	8	In core hours	177	Postnatal	1
				Out of core hours	67	Medical Assessment Unit	14
				Not known/Not applicable	8	Community	2
						Outpatient/day unit	20
						Hospice	1
						Antenatal Clinic	3
						Unknown	6

This chapter is confined to the following errors in the transfusion process:

- Phlebotomy errors resulting in 'wrong blood in tube'
- Laboratory procedural and testing errors
- Component collection and bedside administration errors
- Transfusion of component not meeting the patient's specific requirements

In 2012 there were 252 incidents where the incorrect blood component was transfused, an increase in comparison with 247 reports in 2011. In 176/252 (69.8%) cases the patient's specific requirements were not met.

This chapter is divided into four sections:

- Section 9.1.1 Incorrect blood components transfused (IBCT) – incidents originating in the clinical area
- Section 9.1.2 Incorrect blood components transfused (IBCT) – incidents originating in the hospital transfusion laboratory
- Section 9.2.1 Specific requirements not met (SRNM) – incidents originating in the clinical area
- Section 9.2.2 Specific requirements not met (SRNM) – incidents originating in the hospital transfusion laboratory

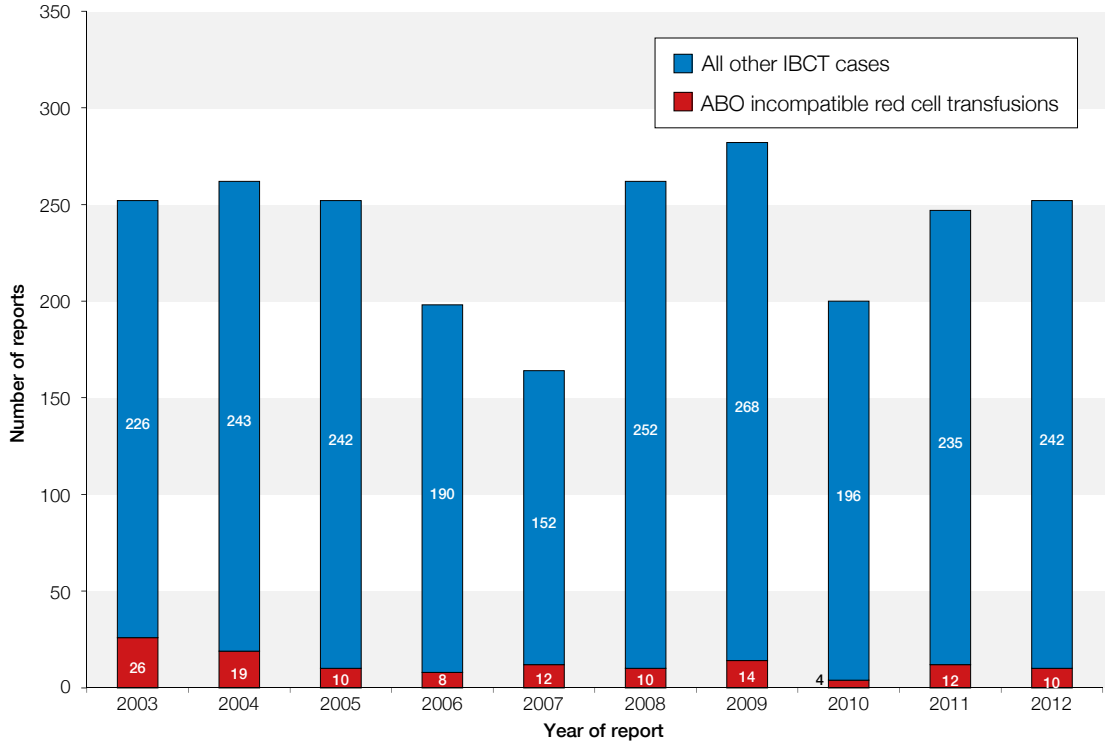


Figure 9.1: Wrong blood incidents 2003-2012 showing ABO incompatible red cell transfusions

It is sometimes the case that selection of components of a different ABO and/or Rh group from that of the patient is a deliberate decision based on individual clinical assessment, and influenced by age, gender and component availability. These pragmatic decisions are not reportable to SHOT (unless of course there is demonstrable adverse outcome for the patient). All cases reported in this chapter involve errors at some point leading to the provision of blood components and have been classified as 'non-identical' where a different blood group is fortuitously compatible with the patient or 'incompatible' where there is the potential for an acute haemolytic reaction.

Table 9.1: Summary of incorrect blood component transfused cases

Type of event	No. of incompatible ABO red cell cases	No. of incorrect ABO/RhD cases	Total number
Collection and administration of incorrect blood component			**32**
ABO incompatible red cells	6		
RhD mismatched red cells		1	
ABO non-identical and RhD mismatched red cells		1	
ABO non-identical red cells		4	
ABO identical red cells		10	
Others		10	
'Wrong blood in tube'			**6**
ABO incompatible red cells	2		
RhD mismatched red cells		1*	
ABO non identical red cells		2	
ABO identical red cells		0	
Other		1	
Laboratory errors			**21**
ABO incompatible red cells	0		
RhD mismatched red cells		9	
ABO non identical red cells		4	
ABO identical red cells		1	
Other		7**	
Incorrect ABO/RhD group transfused to haemopoietic stem cell transplant patients (HSCT)			**14**
Clinical	2	2	
Laboratory		10	
Clinically based cases of specific requirements not met			**106**
Laboratory based cases of specific requirements not met			**70**
Clinical miscellaneous			**3**
Total	**10**	**63**	**252**

** This also included, in addition to red cells, a transfusion of O RhD positive fresh frozen plasma (FFP) to a B RhD negative recipient.*

*** There were 2 ABO incompatible FFP transfusions in paediatric patients.*

Summary of key data for all incorrect blood component transfused cases

Mortality n=0

There were no fatal wrong blood incidents reported.

Major morbidity n=11

There were 2 'wrong blood in tube' incidents and 1 administration error which resulted in ABO incompatible red cell transfusions. In 7 cases involving laboratory errors, 5 resulted in the development of anti-K in women of childbearing potential who had been transfused with K positive red cells following incorrect component selection. In the remaining 2 cases, two patients experienced transfusion reactions after misinterpretation of antibody panels and subsequent issue of antigen positive units. In one case a patient receiving a minor ABO mismatched haemopoietic stem cell transplant (HSCT) developed evidence of haemolysis with increased bilirubin and falling haemoglobin when transfused with red cells of the wrong ABO group 10 days after the transplant.

ABO incompatible red cell transfusions n=10

These were all clinical incidents and are summarised in Section 9.1.1.

ABO non-identical and RhD mismatch red cell transfusions n=1

This was due to a clinical administration error.

RhD mismatched red cell transfusions n=11

There were 11 cases, 2 occurred in the clinical area (1 due to 'wrong blood in tube', 1 due to a component collection and administration error). The other 9 were caused by laboratory errors: 7 component selection errors, 2 RhD grouping errors (one as a result of a transcription error and the other due to misinterpretation).

Incorrect ABO or RhD type blood components for haemopoietic stem cell transplant patients (HSCT) n=14

There were 9 cases in which HSCT patients received a component of an incorrect ABO group (4 red cells, 3 platelets and 2 FFP). The remaining 5 cases resulted in RhD mismatched components (4 red cells, 1 platelets) being transfused.

These are summarised and the errors discussed in Chapter 29 – Analysis of Incidents Related to Transplant Cases. One case of major morbidity after HSCT is described above and in Chapter 29.

Section 9.1 Incorrect blood component transfused (IBCT): Total n=76

Definition:

Where a patient was transfused with a blood component of an incorrect blood group, or which was intended for another patient and was incompatible with the recipient, which was intended for another recipient but happened to be compatible with the recipient, or which was other than that prescribed, e.g. platelets instead of red cells.

Section 9.1.1 IBCT – incidents originating in the clinical area n=45

Authors: Julie Ball and Paula Bolton-Maggs

Overview

Forty-five clinical case reports were analysed. There were 24 reports relating to male and 18 to female patients and in 3 cases of intrauterine transfusion (IUT) gender was unknown. The median age was 62, range 0-89 years. Nine reports related to children, in 2 cases children received adult emergency O RhD negative units when more suitable paedipacks were available and in three cases emergency non-irradiated O RhD negative paedipacks were used for IUT. The paediatric cases are discussed in more detail in the Paediatric chapter (Chapter 27).

Deaths due to wrong transfusion n=0

There were 7 deaths reported but in all cases they were stated to be unrelated to the transfusion.

Major morbidity n=3

These 3 incidents where each patient suffered 'severe harm as a result of the inadvertent transfusion of ABO incompatible blood' are classified as 'Never Events'[20] by the Department of Health (DH).

Case 1: Incompatible transfusion due to mislabelled sample in a person with multiple trauma treated in several medical facilities

A 27 year old male with major trauma was grouped at the first emergency hospital as O RhD positive, was transferred to a larger hospital where he was misgrouped as A RhD positive – the sample was from another patient. He received multiple transfusions (4 units of O RhD negative and 24 units of A RhD positive red cells, 5 units of group A platelets in addition to AB FFP). He subsequently received care in 3 further hospitals. At the first of these he was noted to have a transfusion reaction with evidence of haemolysis which complicated the management of his major trauma, but he made a full recovery without needing renal dialysis.

Case 2: Patient symptoms failed to lead to recognition of incompatible ABO transfusion

An 88 year old man scheduled for repair of fractured neck of femur grouped as O RhD positive. However it was noted that several months earlier during a previous admission he had grouped as A RhD positive and had received a group A RhD positive unit. He was recorded as having developed rigors, hypertension, hypoxia and vomiting. Although the staff decided not to continue with further units of blood on the previous admission, the incident was not recognised or investigated at the time as an acute transfusion reaction.

Case 3: Patient symptoms lead to recognition of incompatible ABO blood transfusion

A patient received a unit of blood intended for another patient because of failure to conduct the bedside checks correctly. The error was only noted when the patient developed a haemolytic transfusion reaction, complaining of feeling unwell with rigors, increased respiratory rate and pulse rate and his temperature rose from a baseline of 36.6°C to 39.4°C. The oxygen saturation fell from 97% to 75%. The post-transfusion blood group was not interpretable on the analyser and the direct antiglobulin test (DAT) was positive. The patient's blood group was O RhD positive and the

incompatible unit was group A RhD positive. Both members of staff involved had been trained and competency assessed.

Learning point

- Clinical staff need to be educated to recognise a transfusion reaction when any symptoms such as those described in Case 2 occur following a transfusion

ABO incompatible red cell transfusions n=10

The 10 ABO red cell incompatible transfusions were the result of 2 'wrong blood in tube' incidents, 1 collection and administration error, 5 errors of administration alone and 2 incidents relating to HSCT patients discussed in more detail in the transplant chapter (Chapter 29).

In a further case, O RhD positive FFP and red cells were given to a B RhD positive recipient due to a 'wrong blood in tube' phlebotomy error.

RhD mismatch n=3

In all 3 cases of unintended RhD mismatch, the recipients were RhD negative men ≥ 65 years of age who received RhD positive components, but the RhD group change was not a deliberate decision.

'Wrong blood in tube' incidents n=6

There were 6 reports where a component (red cells/fresh frozen plasma) of a different group was transfused because of a 'wrong blood in tube' (WBIT), 2 of these incidents resulted in the transfusion of ABO incompatible red cells, (Cases 1 and 2), and 1 led to the transfusion of ABO incompatible FFP.

Case 4: Patient identification error on admission due to wrong patient selection on the computer system results in a wrong blood transfusion

A transcription error was made by a bed manager when admitting a patient (M) onto the hospital system. The incorrect identifiers were then used for records and identification wristband. The patient was confused and unable to confirm his/her identity. The details used belonged to a different patient (P) with same year of birth. The correct patient (M) was bled but the other patient's history (P) was accessed on the information technology (IT) system. Patient M had an antibody history with anti-Jk^a recorded in the laboratory. Patient P's transfusion history was different so Jk^a negative blood was not selected. The patient identification error was discovered by the infection control nurse when the patient was transferred to another ward within the hospital.

There was some evidence of a possible delayed haemolytic transfusion reaction with a subclinical response (a rise in anti-Jk^a titre) identified during further investigation by the Blood Service red cell immunohaematology laboratory, but the phenotype of the donor was unknown.

In 4/6 reports of 'wrong blood in tube' incidents, the error was detected at a subsequent hospital admission when a new blood sample gave an ABO group that was different to the historical record. This was confirmed by a second sample during this subsequent admission. In all 4 cases, the patients had been transfused with an incorrect blood component during the previous admission. In one case this was only detected 12 years later.

In the other 2/6 cases, sample labelling errors were confirmed during the same admission.

Incorrect blood components transfused to haemopoietic stem cell transplant recipients n=4

These cases are discussed in the chapter on transplants (Chapter 29).

Combined collection and administration errors n=16

Incorrect component type collected n=12

There were 12 cases where patients received an incorrect component type i.e. a different component than the one prescribed/required. In 9 of these 12 cases the situation was an emergency or urgent. The other 3 were routine transfusions.

Table 9.2: Collection errors

Prescribed/required component	Component collected	Collector	Detected by
Emergency O RhD negative red cells	Stock O RhD negative red cells from a refrigerator fitted with an electronic tracking system	Nursing staff	Completed stock units were returned to the hub laboratory with handwritten labels attached
Neonatal emergency O RhD negative red cells	Adult emergency O RhD negative red cells (Cytomegalovirus (CMV) negative, K negative)	Porter (sent with blood collection form for mother completed in error by midwife)	Midwife realised that the units requested were for the baby after discussion with paediatric registrar
Neonatal emergency O RhD negative red cells	Adult emergency O RhD negative red cells	Midwife	Unspecified
Emergency O RhD negative red cells	O RhD negative unit that was labelled for another patient	Clinical staff	Routine traceability checks by laboratory
FFP	Platelets	Unknown	Clinical staff noticed platelets in progress instead of FFP
Platelets	FFP	Porter	Laboratory when ward staff requested FFP but all units had been taken
FFP	Platelets	Porter	Biomedical scientist realised that platelets were missing from the agitator
FFP	Platelets	HCA*	Realised by a doctor the following morning
FFP	Red cells	Porter	Discovered at 15 minute observations
Platelets	Red cells	Nurse	Nurse realised error when transfusion in progress
Platelets	Red cells	Nurse	When nurse went to collect second unit of platelets
FFP	Platelets	Porter	When the ward contacted the laboratory to request platelets

**HCA Health Care Assistant.*

The common elements in these cases were communication issues between the requestor and the collector about what was required, misinterpretation of prescription or instructions, a lack of awareness of component types and their suitability for individual patient groups, and haste in an emergency.

Units collected that were intended for another patient n=4

In 4 additional cases, patients were transfused with components that were intended for another patient. Errors identified were: using a colleague's identity card to access the blood refrigerator, carrying 2 collection slips for two different patients at the same time, not using a collection slip for reference and components being delivered to the wrong ward.

Learning point

- Components delivered to the clinical area should be checked as the correct component by a trained and competent staff member before accepting them, in addition to confirmation of patient identity[27]

Administration alone n=15

In 14 cases the erroneous transfusion related to red cell units and one related to platelets. In 5/15 cases the transfusion was ABO incompatible.

Case 5: Incorrect request for red cells leads to wrong transfusion

Two patients on the same ward with anaemia had blood available in the transfusion laboratory issue refrigerator. One patient (X) was prescribed a transfusion. A nurse mistakenly requested it for another patient (Y). The same nurse then administered the unit issued for Y to patient X, having "checked" the unit with another nurse. Neither nurse involved noticed that the blood was labelled for patient Y. The error was detected a short while later by the relatives of patient X who noticed that the name on the transfusion chart was different from their relative. The unit labelled for patient Y was retrospectively crossmatched against patient X who received it and found to be compatible.

In 5 reports the incorrect component was connected but none of the erroneous component was transfused. Fortunately the error was identified before the patient received any of the erroneous component but these cases are included here because the final bedside checks had failed so these meet the ISBT definition of 'transfused component'[1]. These would have resulted in 2 cases of ABO incompatibility, 1 case of ABO and RhD incompatibility and 1 RhD mismatch had the error not been detected. In the 5th case the component was ABO and RhD identical to the recipient.

Component ordering and selection error n=1

Case 6: Platelets requested for wrong patient leads to wrong transfusion

There were two patients with same name on a haematology ward. Platelets were ordered for the incorrect patient; these were O RhD positive and irradiated. When they arrived in the laboratory they were tagged and placed on the agitator with only the patient's name on the label. Following a change of shifts, a request form was received for 3 bags of platelets for the other patient on the ward with the same name. This patient had a different group (B RhD positive) and complicated critical notes with a record of send away tests and transfusion at other hospitals. The critical notes stated that the patient should receive crossmatched O RhD positive red cells but did not recommend a group for plasma components. The BMS labelled and issued the three group O RhD positive platelets assuming that they had been specifically ordered for this patient, and since it was a haematology patient the platelets must have been authorised. The BMS checked they were 'high titre negative' prior to issue and as the patient had received group O platelets at another hospital assumed they were suitable.

This patient was of a different group and was being treated at 3 hospitals. The group was finally confirmed as B RhD positive.

Miscellaneous reports n=3

There were 3 cases where emergency paediatric O RhD negative units were used for intrauterine transfusion. These are discussed further in the Paediatric chapter (Chapter 27).

COMMENTARY

The final 'bedside' check is the last opportunity to ensure that the correct unit or component has been collected for the patient receiving the transfusion. Complete and thorough bedside checks involving one or two staff members must be completed independently and without interruption[27].

The Department of Health 'Never Events 2012/13' lists the inadvertent transfusion of ABO incompatible components where death or serious harm resulted, and the misidentification of patients as two serious, preventable errors[20].

The transfusion awareness campaign 'Do you know who I am?' was launched in October 2012 following a SHOT recommendation in 2009 regarding patient identification. It encourages patients to confirm their identity with staff at every intervention, and especially prior to transfusion. A wide range of campaign posters and other educational materials have been produced by National Health Service Blood &

Transplant (NHSBT)[44] to be displayed in the clinical area which are aimed at both staff and patients. These include advice regarding transfusion of patients who are unable to positively identify themselves and/or not wearing a wristband.

A key recommendation in the new British Committee for Standards in Haematology (BCSH) pre-transfusion compatibility guidelines[35] states 'unless a secure electronic patient identification system is in place, a second sample should be requested for confirmation of the ABO group of a first time patient prior to transfusion, where this does not impede the delivery of urgent red cells or other components'. If this practice had been in place 4 wrong transfusions reported here could have been prevented.

Recommendations

- It is essential that medical and nursing staff are educated to recognise and act on transfusion reactions as this might be the first sign of ABO incompatibility or anaphylaxis where prompt management may be lifesaving (see also Chapter 16, Acute Transfusion Reactions)

Action: Hospital Transfusion Teams, Royal College of Nursing, Royal College of Midwifery, General Medical Council (for all medical curricula)

- A recommendation from 2011 continues to be important. Every person in the transfusion process must perform rigorous identity checks at each point and ensure that the component collected is the one prescribed. The use of a transfusion checklist is recommended

Action: Hospital Transfusion Teams (HTT)

Section 9.1.2 Incorrect blood components transfused (IBCT) – incidents originating in the hospital transfusion laboratory n=31

Authors: Hema Mistry and Christine Gallagher

Overview

In 2012 a total of 31 instances of wrong component transfused were reported in which the primary error occurred in the laboratory, representing 40.8% of the total 76 IBCT cases. A third of these laboratory cases, 10/31, were in haemopoietic stem cell transplant (HSCT) patients and these are analysed in detail in Chapter 29.

Deaths n=0

There were no transfusion-related deaths reported.

Major morbidity n=1

In one case a patient who had received a minor ABO mismatched HSCT developed evidence of haemolysis and this case is discussed in the transplant chapter, Chapter 29.

Potential for major morbidity n=2

In 2 cases, RhD positive red cells were given to RhD negative women of childbearing potential. In both cases the incorrect component was selected and the laboratory computer system gave a warning that was overridden by the issuing biomedical scientist (BMS). There was potential risk of RhD sensitisation in these patients but no follow up data was available at the time of reporting.

ABO/RhD	No. of reports	Blood component
ABO incompatible FFP	**2**	
ABO non-identical	**11**	
	6	Red cells
	3	FFP
	2	Platelets
RhD mismatch	**14**	
	13	Red cells
	1	Platelets
Wrong component	**3**	
	1	Red cells
	2	Cryoprecipitate
ABO identical	**1**	
	1	Red cells

Table 9.3: Summary of IBCT reports of errors originating in the laboratory

**Included in the table above are 10 cases where the incorrect ABO/Rh type was transfused to HSCT patients.*

ABO incompatible and non-identical, and RhD mismatched transfusions n=27

Two patients received ABO incompatible solvent detergent-treated fresh frozen plasma (SD-FFP) transfusions, one due to a grouping error and the second due to a component selection error. In one case SD-FFP of the wrong ABO group was issued to a 1 month old female and this case is discussed further in the Paediatric chapter. The second case is detailed below. There were 10/27 (37.0%) cases where HSCT patients received blood components of a non-identical ABO/RhD group which are discussed further in Chapter 29 (Transplant cases).

Case 1: A patient received incompatible fresh frozen plasma (FFP) due to a component selection error

A 15 year old male patient, blood group A RhD positive, required FFP. Four units of group AB SD-FFP were selected and transfused. Later a further 2 group AB and 2 group O SD-FFP were issued by a biomedical scientist (BMS) who does not routinely work in transfusion laboratory and these were also transfused.

There were 11 non-identical ABO transfusions, 5 were in HSCT patients and are described in Chapter 29 (Transplant cases). The other 6 are described below:

- 4 red cells
  - 3 females received ABO non-identical transfusions as a result of transcription errors
  - 1 male received an ABO non-identical transfusion due to the selection of the wrong sample for testing
- 1 platelets
  - 1 female patient group A RhD negative received group B platelets as a result of a grouping error when the BMS misinterpreted the manual tile group and subsequently issued group B RhD negative platelets (see Case 2 below)
- 1 FFP
  - 1 male patient received ABO non-identical FFP as a result of failure to follow standard operating procedure (SOP)

Case 2: Misinterpretation of manual tile group results in an ABO non-identical transfusion

A group and screen sample with an urgent request for one unit of platelets was received in the laboratory. The BMS performed a manual tile group, so that platelets could be ordered urgently from the Blood Service, and interpreted the result as B RhD negative. A second BMS manually entered the group into the laboratory information management system (LIMS) as B RhD negative and issued the platelets based on this result. The sample was then grouped on the automated analyser and found to be A RhD negative. The group was confirmed as A RhD negative by two independent senior BMS. The BMS performing the initial testing failed to follow the standard operating procedure (SOP) which required a check on the manual group by testing the sample on the automated analyser. Then, following a shift handover, the second BMS assumed that the group had been checked on the analyser but did not confirm this.

Learning point

- Staff should not short cut established procedures. Transfusion laboratories should have a standard operating procedure (SOP) for abbreviated pre-transfusion testing for the provision of blood components in emergencies

There were 14 RhD mismatched red cell transfusions, 5 occurred in HSCT patients and are described in Chapter 29 (Transplants). The other 9 are described below.

Three RhD negative females, two of childbearing potential, received transfusions of RhD positive red cells. The 2 women of childbearing potential received RhD positive red cells as a result of component selection errors. In one case the laboratory computer system (LIMS) gave a warning that was overridden by the issuing BMS who was newly qualified and should have been supervised by a senior BMS. In the other case the woman received RhD positive red cells as a result of a transcription error when the RhD type was incorrectly transcribed into the LIMS.

Five RhD negative males received transfusions of RhD positive red cells, 4 as a result of component selection errors and 1 as the result of a grouping error due to misinterpretation of a mixed field reaction as RhD positive.

An additional patient (gender not indicated) received RhD mismatched red cells after the information technology (IT) warning flag highlighting the error was overridden during the issue process.

Wrong components transfused n=3

Two patients were transfused with a component other than that prescribed: cryoprecipitate was requested for both patients but one patient received FFP that was selected, thawed and issued in error. The second case is described below:

Case 3: Cryodepleted plasma ordered in error from the blood service and issued as cryoprecipitate

Cryodepleted plasma (CDP) was ordered instead of cryoprecipitate from the Blood Centre. The hospital received a telephone call stating this component would have to be sought from another Blood Centre and there would therefore be a slight delay, but the inexperienced BMS who took the message did not relay this information to anyone. When the component arrived the BMS could not scan the component barcode when trying to enter the units into stock via the laboratory information management system (LIMS) because the code for CDP was not defined on the system. The BMS assumed it was an electronic problem and so entered the details manually, but erroneously entered the component as cryoprecipitate. A request was received for cryoprecipitate for a bleeding patient and the cryodepleted plasma was removed from storage, thawed and issued for the patient. The LIMS did not alert the issuing BMS as the system recognised the component as cryoprecipitate from the manual data entry. The patient was transfused 2 units of the incorrect component. The error was spotted during an ad hoc stock check when the third and fourth units were found.

Cryodepleted FFP does not contain fibrinogen so is an inappropriate component to transfuse to a patient who is bleeding due to low fibrinogen levels. There were multiple errors in this case in the laboratory processes of ordering, stock entry and selection culminating in the issue of an incorrect component. The final bedside check offers an opportunity to detect an incorrect component type, but the subtle difference between CDP and cryoprecipitate (and virtually identical pack presentation) means that this did not happen in this case.

Learning point

- Biomedical scientists and clinical ward staff need to be aware that plasma components look similar to each other and must be carefully confirmed against the request and prescription
- In addition to checking that the patient identity matches that on the component, it is essential to ensure that the correct type of component is being administered, and also that it is not out of date

In the remaining case inappropriate blood components were issued and transfused for a neonate requiring an exchange transfusion. The two units were issued as compatible but were not of an appropriate specification for exchange transfusion.

ABO identical transfusions n=1

A request for FFP and red cells for a patient was received by the laboratory. The BMS misread the age of the patient to be 1 year when the patient was actually only 1 month of age. The sample grouped as A RhD positive and group A components were issued and transfused. The laboratory policy based on national guidance is to issue group O red cell components in this situation, as there was no record of the maternal group or antibody status[45].

COMMENTARY

Errors in component selection continue to occur and are the biggest contributing factor to wrong transfusions (64.5% – 20/31). In 10 cases HSCT patients received transfusions of the wrong blood group.

There were 6 ABO grouping errors in 2012, all of which involved manual intervention and these are highlighted in the chapter on Laboratory Errors (Chapter 10). ABO and RhD grouping errors are shown in Table 9.4.

Despite 6 ABO grouping errors, there were no reported cases of ABO incompatible red cell transfusions caused by laboratory error this year.

Table 9.4: Summary of ABO incompatible and RhD mismatched transfusions (with a potential for major morbidity) resulting from errors originating in the laboratory

ABO incompatible or RhD mismatch	Component	Patient group	Transfused group	Type of error	Outcome
ABO incompatible FFP	SD-FFP	AB RhD positive	O RhD positive	Grouping error	No adverse reaction
ABO incompatible FFP	SD-FFP	A RhD positive	O RhD positive	Component selection error	No adverse reaction
RhD mismatch	Red cells	B RhD negative	O RhD positive	Component selection error	Potential to develop Anti-D
RhD mismatch	Red cells	B RhD negative	B RhD positive	Component selection error	Potential to develop Anti-D
ABO non-identical	Red cells	A RhD positive	O RhD negative	Grouping error	No adverse reaction
ABO non-identical	Red cells	B RhD positive	O RhD positive	Grouping error	No adverse reaction
ABO non-identical	Red cells	A RhD negative	O RhD negative	Wrong sample	No adverse reaction
ABO non-identical	Red cells	A RhD positive	O RhD positive	Grouping error	No adverse reaction

**There were two further cases where ABO non-identical red cells were transfused to HSCT patients. These are not included in this table.*

Tables showing the trends in ABO and RhD grouping errors over time are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Learning points

- SHOT reports have consistently demonstrated that the majority of ABO/RhD grouping errors result from manual testing or interventions. The ABO and RhD group must wherever possible be verified against previous results and the validated grouping method in use in the laboratory
- The information technology (IT) system should be configured to flag a discrepancy between the component type requested and the component selected for issue and this should be fully validated. If this is not possible locally then these development requirements must be raised with the laboratory information management system (LIMS) suppliers
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings on the laboratory information management system (LIMS) or an analyser
- The qualified biomedical scientist (BMS) who performs crossmatching of red cells or issuing components must take responsibility for checking all available patient information to ensure that components issued are of the correct specification

Specific requirements not met (SRNM): Total n=176 Section 9.2

Definition:

Where a patient was transfused with a blood component that did not meet their specific transfusion requirements for example irradiated components, HLA-matched platelets when indicated; antigen-negative red cell units for a patient with known antibodies, red cells of extended phenotype for a patient with a specific clinical condition (e.g. haemoglobinopathy), or components with a neonatal specification where indicated. (This does not include cases where a clinical decision was taken to knowingly transfuse components not meeting the specification in view of clinical urgency).

SRNM – incidents originating in the clinical area n=106 Section 9.2.1

Authors: Julie Ball and Paula Bolton-Maggs

Overview

There were 106 cases where clinical specific requirements were not met, 51 female and 53 male patients and in 2 reports gender was not specified. The median age of the patients was 58 (range 0 days to 85 years). The patient age was not given in 8 reports.

Specific requirement not met	Total
Irradiated	82
CMV screened	18*
Irradiated and CMV	2
Phenotyped units for sickle cell patients	2
Emergency O RhD negative blood given to patient with known anti-c	1
K negative unit required	1

Table 9.5: Specific requirements not met where the error was clinical

**CMV requirements changed with recommendations from The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in March and reports received after 1st April 2012 have been reviewed based on the new recommendations.*

Of the 84 clinically based omissions for irradiated components (82+2 who also required CMV screened units) the indications were as follows:

- 35 treated with fludarabine or other purine analogue
- 18 current or historical Hodgkin lymphoma
- 8 after treatment with antithymocyte globulin
- 8 treated with Campath® (alemtuzumab)
- 3 haemopoietic stem cell transplants (HSCT)
- 6 patients with non-Hodgkin lymphoma (indication for irradiation unclear in these unless due to unspecified chemotherapy)
- 1 case of aplastic anaemia
- 4 acute leukaemia (rationale for requesting irradiated components unclear unless determined by type of chemotherapy which was not given in the reports, or prior to HSCT)
- 1 irradiated unit of red cells not requested for neonate following intrauterine transfusion

The number of non-irradiated units transfused prior to recognition of the missed requirement ranged from 1 to 26. Three patients received substantial numbers, 19, 22 and 26 units. In two cases this was due to failure to elicit and act upon a prior history of Hodgkin lymphoma. The third case was a child receiving shared care between two hospitals who received 19 transfusions over a 6 month period before the missed requirement was identified. This was confused by two contradictory discharge summaries from the primary centre.

Errors identified:

A major reason for failure to provide irradiated units again this year was poor communication between clinical and laboratory staff for several different reasons particularly not indicating this on the request forms. Some patients should have been flagged up by pharmacy notifications but were transfused before the flag appeared. Another common problem is a lack of knowledge about the requirement for irradiated components in patients treated with purine analogues and other T-cell depleting agents, particularly where patients were admitted to other specialties.

COMMENTARY

As in previous years, the most common missed specific requirement was for irradiated units in patients at risk of transfusion-associated graft versus host disease (TA-GvHD)**.** Fortunately over the last 11 years of SHOT reporting, following the introduction of leucodepletion, no TA-GvHD has been reported in relation to missed irradiation in 877 cases[46]**.** However a fatal case of TA-GvHD occurred in 2012 where blood for an intrauterine transfusion was neither leucodepleted nor irradiated and is discussed in detail in the chapter on TA-GvHD, Chapter 20.

The indications for CMV screening have changed. In March 2012, The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) issued a position statement outlining its recommendations for specific patient groups who require CMV negative components[47]. In view of this, some groups of patients who previously qualified for CMV screened components are no longer included, and SHOT ceased accepting cases relating to these where the blood was transfused after 1st April 2012.

Learning point

- Failure to provide appropriate units for patients with sickle cell disease can have serious consequences with alloimmunisation and delayed haemolytic transfusion reactions (which are further discussed in the appropriate chapters – Haemolytic Transfusion Reactions Chapter 17 and Haemoglobinopathies Chapter 28)

Recommendations

Recommendations from last year are still active as are others from previous years:

2011 – **Care needs for patients with specific transfusion requirements**

- Patients who require irradiation and other specific components should be provided with an appropriate card as recommended by the British Committee for Standards in Haematology (BCSH)[48]
- Patients with cards noting specific requirements should be educated about their meaning and importance, in particular always to show these to clinical staff on admission to any hospital.
- Haematologists are advised to confirm that there has been appropriate handover of information and to audit this process
- Patients with sickle cell disease should be identified to the transfusion laboratory whenever admitted to hospital
- All patients with irregular antibodies should be issued with antibody cards, and be educated about their importance. General practitioners can also note important transfusion requirements and include these in the referral to hospital whether emergency or elective

Action: Hospital Transfusion Teams and consultant haematologists

SRNM – incidents originating in the hospital transfusion laboratory n=70 Section 9.2.2

Authors: Hema Mistry and Christine Gallagher

Overview

There has been a disappointing increase in the number of cases reported in 2012 where specific requirements were not met, 70 cases in 2012 compared with 51 cases in 2011 and these are summarised in Table 9.6. There were 31/70 cases that involved errors relating to IT systems and these have been analysed in more detail in the IT chapter (Chapter 11).

Deaths n=0

There were no transfusion-related deaths reported.

Major morbidity n=7

There were 7 women of childbearing potential who received K positive units, of whom 5 were sensitised and produced anti-K.

Two patients experienced transfusion reactions after misinterpretation of antibody panel results. As a result Kidd antibodies were missed and the patients did not receive appropriate antigen negative units.

Potential for major morbidity n=2

The K status was inconclusive or unconfirmed for 2 women of childbearing potential.

Specific requirement not met	Number of cases
Incorrect phenotype	33
Incomplete testing/failure to follow SOP	*13*
Incorrect component selected	*10*
Interpretation error	*5*
Failure to heed patient history	*3*
Wrong sample	*1*
Transcription error	*1*
Irradiated units	12
Cytomegalovirus (CMV) negative units	2
Irradiated and CMV negative units	1
K negative units for females of childbearing potential	7
Pathogen-inactivated Fresh Frozen Plasma or Cryoprecipitate	7
Human Leucocyte Antigen (HLA) matched platelets	1
Miscellaneous	7
Total	**70**

Table 9.6: Summary of specific requirements not met n=70

Incorrect phenotype issued by the laboratory n=33

Case 1: Anti-E missed in antibody identification panels performed out of hours.

The patient was known to have anti-Fy^a and anti-S, which masked an anti-E in the indirect antiglobulin test (IAT) panel. Crossmatch-compatible red cells were issued and transfused overnight and the error was noticed the following morning. The anti-E was subsequently shown to react only with homozygous E positive cells. The phenotypes of the transfused units were checked and one unit was found to be heterozygous E positive.

Interpretation of antibody identification results requires serological knowledge and experience and, as a manual process, is vulnerable to error. Laboratories performing antibody identification should be registered with an accredited external quality assessment scheme and follow appropriate guidelines[35].

Failure to recognise the specific requirements of a particular patient group n=30

There were 30 cases where the specific requirement for a patient was not met. These are shown in Table 9.7.

Table 9.7: Failure to supply components with the required specification

Specific requirement not met	Causes			
	Failure to notice information on request form	Incorrect component selected	Labelling error	Total
Irradiated units	7	5		**12**
CMV negative units	1	1		**2**
Irradiated/CMV negative units		1		**1**
Methylene blue (MB)-FFP/ Cryoprecipitate		7		**7**
K negative units to women of childbearing potential		7		**7**
HLA matched platelets			1	**1**

In 9/12 cases where irradiated units were required, IT errors contributed to the failures. In 3 cases warning flags were not in place, in 3 cases they were ignored, and 1 flag had been removed. In the remaining 2 cases there was more than one patient record.

Selecting K negative units for females under the age of 60 has been accepted as good practice[45] but this has recently been revised to 50 years[35]. IT systems should be used to their full potential to prompt staff about specific requirements either through algorithms based on date of birth and/or gender, or via warning flags. Errors relating to warning flags are discussed in the IT chapter (Chapter 11).

Miscellaneous n=7

There were 7 cases where electronic issue (EI) was used inappropriately following manual edits of grouping results. The LIMS could not identify the edited results as part of the EI algorithm so the BMS should have added the patients to the EI exclusion list[49]. This had not been done.

COMMENTARY

Errors associated with pre-transfusion testing mirror those of previous years:

The main mistakes were procedural such as incomplete testing and wrong component selection. The failure of laboratory staff to select appropriate components when warning flags are present is hard to understand, especially as 46/70 (65.7%) of laboratory procedures were performed during normal working hours. IT could have prevented 31 of the cases if used appropriately. Staff must have both a level of knowledge and be competency assessed to ensure that they fully understand all alerts/prompts and warning flags.

(For learning points and recommendations on laboratory incidents please see Chapter 10).

Summary of Events originating in the Hospital Transfusion Laboratory 10

Authors: Christine Gallagher and Hema Mistry

Analysis of all cases reported to SHOT in 2012 (excluding 'near miss' events) shows that 1168/1787 (65.4%) were adverse events caused by error and of these 430/1168 (36.8%) originated in the laboratory. In this chapter we highlight the critical points in the laboratory process where errors occur.

Analysis of laboratory errors derived from data in other chapters in this annual report shows:

- 182/430 (42.3%) reports of transfusion episodes in which, during the transfusion process, inappropriate handling and storage errors (HSE) may have rendered the component less safe
- 80/430 (18.6%) reports related to errors in the administration of anti-D immunoglobulin to women of childbearing potential
- 70/430 (16.3%) reports of errors which resulted in the transfusion of components that did not meet the patient's specific requirements (specific requirement not met – SRNM)
- 62/430 (14.4%) reports where a patient was transfused correctly despite one or more serious laboratory error(s) (right blood right patient – RBRP)
- 31/430 (7.2%) reports of errors which resulted in the transfusion of an incorrect blood component (incorrect blood component transfused – IBCT)
- 5/430 (1.2%) reports of avoidable, delayed, or undertransfusion (ADU)

The reports are broken down into the categories shown in Table 10.1

Table 10.1: Laboratory errors by category n=430

Critical point in the laboratory process	Total	Chapter					
		IBCT	SRNM	HSE	RBRP	ANTI-D	ADU
Sample receipt & registration	**39**		11		25	3	
Testing	**63**	8	24		1	28	2
Component selection	**81**	22	33			25	1
Component labelling, availability & HSE	**243**		2	180*	36	23*	2
Misc	**4**	1		2		1	
Total	**430**	**31**	**70**	**182***	**62**	**80***	**5**

** There were 10 HSE reports with multiple cases which provided details for 121 patients. This makes the total HSE cases 182 from 71 reports. There were 2 Anti-D reports with multiple cases, one report with 2 and another with 10 making a total number of 80 patients affected from 70 reports.*

Sample receipt and registration errors n=39

- There were 25/39 (64.1%) reports of patients who received the correct component but had one or more patient identification errors, including incorrect spelling of the name (12) or incorrect date of birth (7). These were sample labelling errors that should have been detected at 'booking in'
- In 11/39 (28.2%) reports patients were transfused components that did not meet their specific requirements. This information had been indicated on the request form (8) or in the patient's historic record (3)
- In 3/39 (7.7%) reports women of childbearing potential received anti-D immunoglobulin (Ig) despite the availability of historic information indicating the patient was RhD positive (2) or had immune anti-D (1)

Case 1: Transcription error of patient identification details

Two units of red cells were issued using an incorrect spelling of the patient's surname, even though the request form and blood sample were correctly labelled, and the first unit was transfused. The ward staff realised the error when performing the bedside administration checks on the second unit. This unit was returned to the hospital transfusion laboratory and the unit was re-issued with the correct patient details.

COMMENTARY

Laboratory staff working in transfusion must be diligent at all times to avoid making errors. During the 'booking in' process it is vital to take into account any historic patient information and ensure all previous results and any specific requirements have been taken into consideration. There is national guidance available on the minimum dataset required for samples and requests[27,50].

Learning points

- Correct patient identification is imperative and must always be ensured at each critical point of the laboratory process starting with entering patient demographics onto the laboratory information management system (LIMS)
- Maintaining an accurate patient database is a critical safety measure in the treatment of patients and transfusion laboratories must have a robust search protocol in place to identify historic patient records

Testing errors n=63

- In 28/63 (44.4%) testing errors were related to the administration of anti-D Ig to women of childbearing potential, and included errors in testing maternal and neonatal samples.

Table 10.2: Testing errors related to the administration of anti-D Ig

Testing errors related to the administration of anti-D Ig			28/63
Maternal sample errors			**20**
RhD errors	5 patients were weak RhD positive and reported as RhD negative by manual tube technique; (2 of these patients were known weak RhD positive, 2 had equivocal reactions by automated techniques, 1 was RhD positive by automated techniques) 1 patient had a confirmed D variant but was reported to the clinical area as RhD positive and not requiring anti-D Ig prophylaxis	*6*	
Errors in the estimation of fetomaternal haemorrhage (FMH)		*5*	
Misinterpretation of anti-D antibodies assuming them to be from prophylaxis rather than immune		*5*	
Post delivery samples not processed within 72 hours		*3*	
RhD transcription error		*1*	
Transposition of cord and maternal samples			**1**
Neonatal sample errors			**7**
Cases where the cord sample was incorrectly reported as RhD positive when a positive direct antiglobulin test (DAT) invalidated the results		*3*	
RhD transcription errors		*2*	
Incomplete cord D-typing		*2*	

- 24/63 (38.1%) resulted in a failure to meet the patient's specific requirements

Testing errors resulting in a failure to meet the patient's specific requirements	24/63
Antibody identification/exclusions not performed following a positive antibody screen result	**11**
Manual ABO errors	**6**
Inappropriate use of electronic issue	**5**
Errors in interpreting antibody identification results	**2**

Table 10.3: Testing errors resulting in a failure to meet the patient's specific requirements

- 8/63 (12.7%) testing errors resulted in the transfusion of an incorrect blood component

Testing errors resulting in the transfusion of an incorrect blood component		8/63
Manual ABO errors		**6**
Transcription errors	*3*	
Interpretation errors	*2*	
Selection of the wrong sample for testing	*1*	
Manual RhD errors		**2**
Interpretation error – mixed field reaction misinterpreted as RhD positive	*1*	
Manual transcription error	*1*	

Table 10.4: Testing errors resulting in the transfusion of an incorrect blood component

- 2/63 (3.2%) testing errors resulted in inappropriate and unnecessary transfusions

Testing errors resulting in inappropriate and unnecessary transfusions	2/63
False low haemoglobin – clotted sample – 2 units of red cells transfused	**1**
False low platelet count – platelet clumps were seen on blood film examination – but the low result was reported nevertheless – as a consequence 2 paediatric platelet packs were transfused	**1**

Table 10.5: Testing errors resulting in inappropriate and unnecessary transfusions

- 1/63 (1.6%) testing errors resulted in the right blood being transfused to the right patient (Case 2)

Case 2: Failure to exclude the presence of additional alloantibodies

Two units of red cells were requested for a patient with known anti-c and anti-E. Two units of R1R1 red cells were selected, crossmatched and issued but an antibody identification panel was not performed on this sample to exclude the presence of additional alloantibodies.

COMMENTARY

All ABO and RhD typing errors occurred as a result of manual interventions. Manual testing is known to carry a high risk of error and should only be used when urgent clinical situations demand. If a positive antibody screen result is obtained, the specificity should be determined and the clinical significance assessed. Any patient with known alloantibodies should have each new sample fully tested to exclude the presence of further alloantibodies[35].

Learning points

- Successive SHOT reports have demonstrated that the majority of ABO/RhD grouping errors result from manual procedures and this extends to other manual techniques including antibody identification and estimation of fetomaternal haemorrhage (FMH)
- The ABO and RhD group must wherever possible be verified against previous results

Component selection errors n=81

- In 33/81 (40.7%) cases patients were transfused with components that did not meet their specific transfusion requirements. These were all patients where details of their specific requirements were available on the historic record

Table 10.6: Cases where patients were transfused with components that did not meet their specific transfusion requirements

Cases where patients were transfused with components that did not meet their specific transfusion requirements		33/81
Warning flag failures were identified		**15**
Not implemented or updated	*8*	
Erroneously overridden or ignored	*7*	
Cases where there was no information relating to information technology (IT) systems to identify whether flag failures were involved		**18**

- 25/81 (30.9%) cases resulted in the inappropriate administration of anti-D Ig

Table 10.7: Cases resulting in the inappropriate administration of anti-D Ig

Cases resulting in the inappropriate administration of anti-D Ig	25/81
Women known to have immune anti-D	**7**
Administration of the wrong dose of anti-D Ig	**5**
Mothers of RhD negative infants	**4**
RhD positive women	**4**
RhD negative women did not receive anti-D Ig prophylaxis when RhD positive platelets transfused	**4**
RhD negative male inappropriately received anti-D Ig prophylaxis when RhD positive platelets transfused	**1**

- In 22/81 (27.2%) cases an incorrect blood component was selected and transfused

Table 10.8: Cases where an incorrect blood component was selected and transfused

Cases where an incorrect blood component was selected and transfused		22/81
Haemopoietic stem cell transplant (HSCT) patients		**10**
RhD negative recipients received RhD positive red cells		**7**
Cases where an inappropriate unit was issued		**5**
Fresh frozen plasma (FFP)	1 patient received FFP when cryoprecipitate was requested 1 patient received ABO non identical FFP following a renal transplant 1 patient received ABO non identical SD-FFP for a plasma exchange	*3*
A neonate received a transfusion of a red cell unit that was not suitable for exchange transfusion		*1*
In 1 case group specific red cells and FFP were issued for a neonate when the age was misread as 1 year when the patient was 1 month old. The laboratory policy was to issue group O red cells and group AB FFP to neonates when there was no record of the maternal group or antibody status[35].		*1*

- 1/81 (1.2%) cases resulted in an inappropriate transfusion where FFP was issued and transfused when platelets were requested

Case 3: RhD mismatched transfusion due to component selection error

Two units of group B RhD positive red cells were issued and subsequently transfused to a group B RhD negative female patient of childbearing potential. The laboratory information management system (LIMS) gave a warning that was overridden by the biomedical scientist (BMS). At the time the BMS was newly qualified and under the supervision of another BMS.

COMMENTARY

The RhD mismatches reported are those that resulted from errors. In some cases the selection of RhD non-identical components is a pragmatic decision based on a combination of individual patient assessment, clinical urgency and availability, and these cases are not SHOT reportable.

Learning points

- The information technology (IT) system should be configured to flag a component discrepancy and this should be fully validated. If this is not possible locally then these development requirements must be raised with the laboratory information management system (LIMS) suppliers
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings on the laboratory information management system (LIMS) or an analyser.
- Laboratories need to look critically at the way in which mother and baby records are linked and how robust this linkage is
- The qualified biomedical scientist (BMS) crossmatching red cells or issuing components must take responsibility for checking all historic patient information to ensure that components issued are of the correct specification

Component labelling, availability, handling and storage errors n=243

- In 180/243 (74.1%) cases there were errors associated with handling and storage which could have rendered the component unsafe to transfuse

Cases where there were errors associated with handling and storage, which could have rendered the component unsafe to transfuse	180/243
Cold chain not monitored (121 patients from 10 incidents)	154
Samples exceeded the recommended time intervals (following transfusion within the last 3 months) between sampling and pre-transfusion compatibility testing[45].	18
Patients were transfused expired units	8

Table 10.9: Cases where there were errors associated with handling and storage, which could have rendered the component unsafe to transfuse

- In 36/243 (14.8%) cases a patient was transfused with the correct component despite component labelling errors – RBRP. Causes were:

Cases where a patient was transfused with the correct component despite component labelling errors – RBRP	36/243
Transposed labels	25
Labels contained incorrect patient details	9
No labels attached to component	2

Table 10.10: Cases where a patient was transfused with the correct component despite component labelling errors – RBRP

- In 23/243 (9.5%) cases there were errors relating to the labelling, availability, handling and storage of anti-D Ig

Cases where there were errors relating to the labelling, availability, handling and storage of anti-D Ig	23/243
Anti-D Ig not issued to the clinical area within 72 hours of delivery or a potentially sensitising episode	10
Cases from 2 reports (10 in one incident) anti-D Ig issued with an incorrect batch number	11
Expired anti-D Ig administered (both cases from one incident)	2

Table 10.11: Cases where there were errors relating to the labelling, availability, handling and storage of anti-D Ig

The remaining 4 were isolated cases

Isolated cases		4/243
Labelling errors		**2**
Transposed label meant a patient received a unit intended for a different patient	*1*	
Patient was transfused blood that had not been serologically crossmatched as the wrong units were labelled	*1*	
Cases of delayed transfusions caused by the lack of availability		**2**
Platelets required urgently but were delayed, as the BMS did not place a 'blue light' order with the Blood Service	*1*	
Crossmatched units were transported to the wrong hospital site and unavailable when the patient was in theatre	*1*	

Table 10.12: Isolated cases

Learning points

- When issuing components always check the component label and the compatibility tag
- Laboratory staff must ensure that all components are made available for issue within date

Miscellaneous n=4

The 4 miscellaneous cases included

- 1 cryodepleted plasma (CDP) was mistakenly ordered and issued when cryoprecipitate was indicated for the patient
- 2 failures to follow standard operating procedures (SOPs) requiring the quarantine of components on receipt of fax as part of Blood Service recall procedures
- 1 mother failed to receive post delivery anti-D Ig. Consent to take a repeat sample from the baby was denied by the mother after the initial sample was rejected for testing

Recommendations

- Regular practice and competency-assessment of manual techniques is important, where possible this should include checks of the critical steps by a second person when manual methods are employed

Action: Transfusion Laboratory Managers

- Competency assessment in laboratories must be linked to process. Biomedical scientist (BMS) staff must be competent 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 (NOS) will enable this, as NOS have both 'Performance' criteria and 'Knowledge and Understanding' criteria

Action: Transfusion Laboratory Managers

- Hospital Transfusion Teams (HTTs) should perform a local risk assessment on the way in which the transfusion laboratory is informed by clinicians of either specific requirements, or previous history provided by patients direct to clinicians. For example, having a robust process to inform the laboratory when treatment on purine analogues starts, rather than when blood is requested, has merit

Action: Transfusion Laboratory Managers, Pathology Information Technology (IT) Managers, Laboratory information management systems (LIMS) providers, Hospital Transfusion Teams (HTTs)

- Warning flags must be clear and appear on all relevant screens in the transfusion process and if overridden, should include a positive response from the user with rational behind the decision

Action: Transfusion Laboratory Managers, Pathology IT Managers, LIMS providers, HTTs

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Errors Related to Information Technology (IT)

11

Author: Megan Rowley

This chapter covers transfusion adverse incidents that relate to laboratory information management systems (LIMS) as well as other information technology (IT) systems and associated equipment, that are used in the delivery of hospital transfusion services.

The cases included are drawn from the other chapters of this report, as shown in Table 11.1. Cases selected include incidents where IT systems may have caused or contributed to the errors reported, where IT systems have been used incorrectly and also includes cases where IT systems could have prevented errors but were not used.

Error	
Incorrect blood component transfused (IBCT)	21
Specific requirements not met (SRNM)	31
Right blood right patient (RBRP)	8
Avoidable, delayed or undertransfusion (ADU)	3
Handling and storage errors (HSE)	15
Haemolytic transfusion reaction (HTR)	2
Total	**80**

Table 11.1: Source of cases included in this chapter

In 2012 there were 80 reported incidents of errors related to IT systems (see Table 11.2) compared with 74 in 2011, 56 in 2010, 61 in 2009 and 44 in 2008.

In 2012, 85% (68/80) of the incidents originated in the transfusion laboratory. A total of 71 cases involved red cells, 5 platelets (1 platelets and plasma) and 4 related to plasma components alone.

Six of the 80 cases occurred in children (1 was below the age of one year).

The majority, 65% (52/80) of the incidents occurred during core working hours. In relation to the requests, 55% (44/80) of the transfusions were considered routine, 22.5% (18/80) urgent and 17.5% (14/80) were emergencies. In 4 cases the urgency of the request was not stated.

Table 11.2: Categories of IT system errors

Error	Reports	Right blood component	Wrong blood component	Component transfused where specific requirements were not met		Wrong group after *HSCT	Unit expired, or out of temp. control	Avoidable, delayed or under-transfused
				Not irradiated	Ag positive unit			
Failure to consult or identify historical record	**9**		1	1	2	4	1	
Failure to link, merge or reconcile computer records	**7**	5			2			
Warning flag in place but not heeded	**16**		2	2	4	2	5	1
Warning flag not updated or disabled	**10**	1	3	2	2	2		
Failure to use flags and/or logic rules	**15**		6	5	4			
Incorrect result entered or accessed manually	**6**	1	3					2
Computer or other IT systems failure	**4**	2			1		1	
Errors related to computer system	**1**			1				
Errors related to electronic blood management system	**12**		4				8	
Total	**80**	**9**	**19**	**11**	**15**	**8**	**15**	**3**

**Haemopoietic stem cell transplant (HSCT).*

Deaths n=0

There were no transfusion-related deaths where IT systems contributed.

Potential for major morbidity n=3

There were three cases where IT systems contributed to a potential for major morbidity.

A patient's antibody history was not flagged correctly and the patient developed a delayed haemolytic transfusion reaction after receiving an exchange transfusion with antigen positive blood.

A major haemorrhage protocol was activated for a patient with a gastrointestinal bleed but the biomedical scientist (BMS) was unable to issue blood immediately because the patient had a red cell antibody and the BMS was not familiar with the mechanism for overriding the alert. This resulted in a delay to emergency transfusion but blood was provided after assistance was sought from another BMS.

In an urgent situation, a warning flag indicating the age of a woman was not heeded and one of the units of blood issued was K-positive. The woman subsequently developed anti-K.

Errors due to non-availability or inaccuracy of the historical record n=16

There were nine cases where failure to identify or consult a historical transfusion record held on the computer led to problems and a further seven cases where errors arose from a situation where transfusion records were not merged, linked or reconciled.

This resulted in five cases where specific requirements were not met; in 4/5 cases antigen negative blood was not provided for patients with red cell antibodies or patients who required extended-phenotyped blood to prevent sensitisation.

There were six examples of the right blood being transfused where a patient's hospital number and/or date of birth did not agree between the patient's ID wristband and compatibility tag attached to the blood component because the records on the patient administration system (PAS) and laboratory information management system (LIMS) were different.

Another consequence of the non-availability or inaccuracy of the historical record is the failure to provide the correct blood components to patients who have had a HSCT. These are complex cases and a complete historical record is very important (see also Chapter 29 – Analysis of Incidents Related to Transplant Cases).

In one case >100 mL RhD positive blood was transfused to a RhD negative woman of childbearing potential because of a laboratory error where the historical record was not consulted and the wrong component was selected. She required anti-D Ig treatment to prevent sensitisation. In another case, a reference laboratory did not check all available historical records which led to the supply of blood that was matched for only three out of the four known red cell antibodies. Consistent use of the National Health Service (NHS) number to link records from different hospitals may have prevented this error.

Trusts/Health Boards where hospitals have merged but retained separate patient numbering systems for individual hospitals, rather than implementing a common numbering system or the NHS number (or equivalent national health numbering systems), have sometimes failed to pick up clinical and transfusion information where patients move around hospital sites to receive treatment from different specialists.

Learning point

In previous reports, it was identified that electronic access to the blood group and antibody information from reference laboratories by hospital transfusion laboratories would be helpful when managing the transfusion support of complex patients, particularly if patients are treated in different hospitals and/or different geographical areas. This system is in the process of being implemented by NHS Blood & Transplant (NHSBT) and is known as Sp-ICE (Specialist Services Electronic Reporting using Sunquest ICE). The success of such a system in delivering safer patient care is dependent on a number of factors:

- That hospitals use common patient identifiers such as NHS number (or equivalent) when sending samples to reference laboratories
- Those hospitals allow their patient data to be entered on the system, which is provided by an NHS organisation and used by other NHS organisations to improve the safety of the transfusion support of individual patients
- That hospitals train all transfusion laboratory staff to use the system, including those providing an out-of-hours service

Errors due to failure of warning flags or logic rules n=41

As in previous reports, the computer ‘warning flags’, ‘alerts’ and ‘logic rules’ that are essential for the safe selection of correct blood components for patient safety provide the largest category of error reports. These flags/alerts should provide a reminder of specific requirements at the very least but preferably they should prevent the issue of wrong blood or blood that is unsuitable for transfusion.

Sixteen cases were reported where alerts or warning flags were not heeded, or were ignored or overridden. There were 10 cases where alerts or warning flags were ineffective because the information had not been updated or the updated information had been inaccurate. In a few cases, alerts or warning flags had been incorrectly disabled or deleted.

A further 15 cases were identified where alerts or warning flags should have been activated but were not – either because there was an oversight on behalf of the laboratory, or because the LIMS did not provide a sufficiently robust system.

Within this category there were 7 cases where electronic issue (EI) was used inappropriately; in 6 cases because the patients were not flagged as unsuitable for EI and in one case the flag was in place but not heeded.

The consequence in all but one case was issue of blood that did not meet specific requirements, most commonly because it was not antigen matched for a red cell antibody although one case should have been excluded from EI because the direct antiglobulin test (DAT) was positive due to a suspected autoimmune haemolytic anaemia.

Case 1: Multiple 'specific requirement' flags result in selection of incorrect blood components for a stem cell transplant patient

A patient was given components of the wrong blood group on three occasions by three different transfusion biomedical scientists (BMS) because the alert that stated 'D negative cellular components' was overlooked. This was in the context of multiple alerts for specific requirements on the patient's transfusion record; the patient needed irradiated blood as well as other specific requirements, all of which had been successfully provided.

Case 2: Incorrect configuration of the specific requirements flag on laboratory information management system (LIMS) fails to prevent remote issue

The transfusion department was notified that a patient needed irradiated components and added the specific requirements flag against the patient's record on the LIMS. The patient attended the following day for a 2-unit blood transfusion but, when the ward staff checked the patient's status, the LIMS appeared to indicate the patient was suitable for 'remote issue'. As a result, non-irradiated blood was transfused to the patient. Investigation of the incident showed that two flags need to be applied in this situation – one for irradiation and one to indicate the ineligibility of the patient for remote electronic issue.

Case 3: Immediate registration of an emergency admission is essential for all interoperable information technology (IT) systems

An infant admitted to the paediatric intensive care unit (PICU) needed cytomegalovirus (CMV) negative and irradiated blood and a specific requirement form was completed. The child had not yet been registered on the patient administration system and this prevented the transfusion record, and associated specific requirement flag, being set up on the laboratory information management system (LIMS). By the time the patient administration system (PAS) registration was complete, the specific requirement flag had been forgotten and the child was transfused blood without the necessary specific requirements.

Learning points

- As stated in the 2011 recommendations, and in the current chapter on laboratory errors (Chapter 10), the use of computer alerts and warning flags is important for safe transfusion laboratory practice
- These alerts and warning flags should be associated with the patient record and should be visible whenever blood components are selected and/or issued. It should also be possible to have multiple alerts or warning flags on an individual patient
- Laboratory staff should recognise the potential pitfall of failing to comply with all of the specific requirements where multiple flags are in place

Errors due to computer downtime or failure of other systems n=5

There were fewer errors in this category in 2012. In 2011 there were 13 cases.

Hospitals reported working with IT providers to resolve software problems and to improve the functionality of IT systems to support safe transfusion practice. Some reported that problems had been successfully highlighted through IT validation rather than clinical errors.

Learning points

- Current UK guidelines[51] for the validation of information technology (IT) systems require the validation process be robust enough to ensure that the laboratory information management system (LIMS) provides the expected safety systems to prevent issue of wrong blood in a range of different scenarios that reflect the clinical practice of the unit
- If corrective and preventative action from an incident or error requires changes to the laboratory information management system (LIMS), the system should be revalidated to ensure it is working correctly

Laboratory errors arising from manual data entry where electronic transfer of data would have been safer n=6

There will always be manual steps required in transfusion laboratories and in clinical areas. Four cases were reported where reliance on manual data entry into a computer or transcription of data from IT systems into notes resulted in the selection of wrong blood components and, in one further case, an unnecessary transfusion.

One case was included because the wrong mode of delivery was selected on the electronic blood ordering system from the NHSBT (OBOS) and this led to a delayed platelet transfusion.

Errors arising from IT systems used outside the laboratory

Electronic blood management systems n=12

In this category 4 of the 12 cases related to wrong blood components collected from blood issue refrigerators bypassing the safety mechanisms in place. These safety features include preventing staff access if they are not assessed as competent to use the system and ensuring blood is collected for the right patient. The use of an emergency access override button is a feature on some blood refrigerators which are otherwise under electronic control. This is seen by some clinicians as an essential feature to prevent blood delays but cases have been reported where blood intended for another patient, rather than the emergency O RhD negative blood, was removed by an untrained clinician using this emergency button.

Eight cases have been reported where blood no longer valid for transfusion has been collected from a refrigerator under electronic control. These blood components were collected despite the fact that they were expired or the validity of the sample used to provide the blood had expired.

Case 4: Wrong blood collected with someone else's identity (ID) card

A patient was admitted with massive upper gastrointestinal bleeding due to an aortic fistula. In an extreme emergency, a nurse collected blood without the patient's ID and accessed the issue refrigerator controlled by an electronic blood management system with an ID card that belonged to another member of staff. The wrong blood was removed from the refrigerator and transfused. The blood collected was group O and the recipient was group A. Despite active resuscitation, the patient died due to the underlying condition, not due to the wrong blood.

Case 5: Emergency access button used to collect the wrong patient's blood

A patient experiencing massive blood loss and numerous life threatening injuries after a road traffic accident was given blood intended for another 'unknown male' because the trauma nurse sent to collect the blood used the emergency button to bypass the blood refrigerator lock. No checks of patient identification were made at the refrigerator or at the bedside. Fortunately, although the wrong blood was transfused, it was compatible with the patient.

Learning point

- The training delivered to healthcare and support staff involved in the blood transfusion process should include relevant SHOT case examples to explain the consequences of bypassing security systems in place to prevent wrong blood collection

Anti-D Ig errors

Table 11.3: IT errors related to administration of prophylactic anti-D Ig n=13

Error	Reports	Unnecessary anti-D Ig administered	Failure to administer anti-D Ig, or excessive delay
Error when manually transcribing data	**4**	1	3
Failure to consult historical record	**6**	4	2
Failure to use flags, logic rules	**2**	2	
Incorrect merging or linking of results	**1**	1	
Total	**13**	**8**	**5**

There were 13 reports in 2012 where laboratory IT-related errors or problems led to unnecessary administration of anti-D Ig (8 cases) or delay in giving anti-D Ig prophylaxis (5 cases).

Two cases were reported where anti-D was given to women with immune anti-D because the information about the antibody was either not input into the LIMS or was not easily accessible and was therefore overlooked.

For the cases where anti-D was given to RhD positive women because the D-group was incorrectly recorded this was more to do with the incorrect group than any failure of the IT system.

Most of these cases occurred within normal working hours.

COMMENTARY

The number of cases where IT systems may have caused or contributed to the errors reported, been used incorrectly or could have been used to prevent errors has remained stable this year. The themes noted are similar to the previous two years.

Laboratory errors where IT systems played a role demonstrate how critically dependent the modern transfusion laboratory is on laboratory information management systems and how the LIMS has to be robust to support safe transfusion laboratory practice.

Hospital mergers (and associated laboratory mergers) have been shown to cause errors in the correct identification of historical transfusion records with the result that information that may inform the correct selection of blood components is lacking. Sometimes the problem has arisen outside the laboratory because of the decisions made about patient numbering systems without understanding the importance of correctly linking or merging to the patient's historical transfusion record.

The use of the NHS number (or equivalent national patient numbering system) has been recommended for many years and was the subject of an National Patient Safety Agency (NPSA) safer practice notice in 2009[52] (SPN 002) but in 2011 only 16% of English NHS Trusts stated that it was being used in transfusion practice[53]. The NHS number (or equivalent) is a very effective way of linking patient records in reference laboratories, particularly as Blood Services are making these reference results available to hospitals so that historical records for patients with complex serological problems who are treated in different hospitals can be consulted in a timely way.

The use of alerts or warning flags on the LIMS, as well as logic rules to link the gender or the age of patients to specific blood component requirements, are extremely important IT measures to support safe transfusion laboratory practice. Errors reported this year, and in previous years, demonstrate how failure of these warning flags and alerts can lead to wrong blood or component specification errors. As

well as ensuring that these alerts or warning flags are robust and are tested to function as intended, it is important that they can still allow blood to be issued in an extreme emergency.

It is also necessary to be able to update and reconfigure the alerts or warning flags on the LIMS if transfusion guidelines change, as they have recently. Examples might include the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidance on selection of CMV negative components[47] and the sample validity rules in the updated British Committee for Standards in Haematology (BCSH) guidelines for pre-transfusion compatibility procedures in hospital transfusion laboratories[35].

Outside the transfusion laboratory, interoperable systems (i.e. computer systems which interface with each other and exchange information such as the patient information system with the laboratory pathology system) are increasingly used to support safe transfusion practice. Although largely effective at preventing errors, examples are given where trained and untrained staff use electronic blood management systems incorrectly. These examples can be used to demonstrate the benefits of these systems and the consequences of not using them correctly.

Recommendation

- Hospital transfusion laboratories should be encouraged to participate in the national electronic access scheme for blood group and antibody information which is being developed by National Health Service Blood & Transplant (NHSBT) (called Sp-ICE), and equivalent systems in Wales, Scotland and Northern Ireland for patients with complex transfusion requirements, and as recommended by National Patient Safety Agency (NPSA) safer practice notice, to use the NHS number or equivalent national patient numbering system

Action: Hospital Transfusion Laboratory Managers; Pathology Managers

12 Avoidable, Delayed or Undertransfusion (ADU) (formerly Inappropriate and Unnecessary I&U)

Authors: Julie Ball and Paula Bolton-Maggs

Definitions:

(Please note these have been updated[23]. The terminology has been changed from 'inappropriate and unnecessary' as the word 'avoidable' is preferable, and the category is now more explicit about delays or a transfusion of insufficient quantity of blood for the clinical circumstances)

- **Where the intended transfusion is carried out, and the blood/blood component is suitable for transfusion, but where the decision leading to the transfusion is flawed including transfusions given on the basis of erroneous, spurious or incorrectly documented laboratory testing results for haemoglobin, platelets and coagulation tests**
- **Transfusions given as a result of poor understanding and knowledge of transfusion medicine, such that the decision to transfuse puts the patient at significant risk, or was harmful**
- **Avoidable use of emergency O RhD negative blood where group-specific or crossmatched blood was readily available for the patient**
- **Where a transfusion of blood/blood component was clinically indicated but was not undertaken or was significantly delayed (there is no defined time limit: this is a clinical judgement when 'delay' puts the patient at risk of, or causes harm)**

DATA SUMMARY
Total number of cases: 145

Implicated components		Mortality/morbidity	
Red cells	114	Deaths due to transfusion	0
FFP	16	Deaths probably/likely due to transfusion	0
Platelets	8	Deaths possibly due to transfusion	0
Cryoprecipitate	4	Major morbidity	2
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	N/A
Anti-D Ig	N/A		
Multiple components	2		
Unknown	1		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	52	≥ 18 years	132	Emergency	36	Emergency Departments	21
Female	88	16 years to <18 years	1	Urgent	44	Theatre	14
Not known	5	1 year to <16 years	6	Routine	53	ITU/CCU/NNU/HDU/ Recovery	15
		>28 days to <1 year	1	Not known	12	Wards	80
		Birth to ≤28 days	5			Delivery Ward	4
		Not known	0	In core hours	93	Postnatal	0
				Out of core hours	49	Medical Assessment Unit	7
				Not known/Not applicable	3	Community	0
						Outpatient/day unit	2
						Hospice	0
						Antenatal Clinic	0
						Unknown	2

Overview

A total of 145 reports were analysed relating to 52 male patients and 88 female patients. In 5 reports the gender was not specified. Thirteen reports related to children and are discussed in the Paediatric chapter (Chapter 27). The median age was 67 (range 0 days to 92 years). Nineteen cases of delayed transfusion are included in these numbers.

Deaths n=0

There were no deaths associated with avoidable, delayed or undertransfusion in 2012.

Major morbidity n=2

There were 2 cases of major morbidity. One case is described below, and the other, a child who was transfused to a Hb of 270 g/L, is discussed in the Paediatric chapter (Chapter 27).

Case 1: A patient of low body weight repeatedly overtransfused

A patient weighing 35.1kg with small bowel angiodysplasia and anaemia received 6 red cell transfusions over a 3 month period. A fall precipitated her admission and her Hb was then found to be 222 g/L and she was generally deteriorating. She was dyspnoeic with a tachycardia and had symptoms consistent with polycythaemia. A haematology specialist registrar noted the patient was plethoric and she then required repeated venesection. She developed renal impairment with long term morbidity.

An incident investigation showed that the patient had been overtransfused on at least 6 occasions. Review showed that despite having normal and increasing haemoglobin results, transfusions were regularly given (Hb 134 g/L and 3 units given, Hb 158 g/L and 3 units given, Hb 182 g/L and 3 units given). The repeat prescriptions were authorised by a consultant.

This patient was attending the haematology outpatient department but was also under the care of the gastroenterology department.

Learning point

- A named consultant should take responsibility for each patient receiving a transfusion. Having more than one team involved with a patient may result in confusion over 'ownership' i.e. whose responsibility it was to review results, but no transfusion should be prescribed or given without proper assessment of the patient including review of the latest haemoglobin results

Cause of erroneous results that led to avoidable transfusions n=46

Cause	Total
Dilute sample (most common cause was sample from drip arm)	12
Point of care test/Blood gas analyser	9
'Wrong blood in tube' – full blood count sample	9
Hb error (transcription, wrong patient results used, communication issues)	8
Inadequate sample e.g. short/poor sample/contaminated	5
Clumped platelets	1
Clotted sample	1
Erroneous Hb result – unknown cause	1

Table 12.1: Cause of erroneous results that led to avoidable transfusions n=46

It is notable that as in previous years, the leading causes of erroneous results were the use of dilute and/or inadequate samples.

Learning point

- The use of point of care haemoglobin machines or blood gas analysers may lead to wrong results. It is essential that any point of care machines are properly quality assured for Hb results and that they are used only by staff who have received appropriate training. A UK National External Quality Assurance Scheme (UKNEQAS) is now available for haemoglobin analysis on blood gas machines – contact haem@ukneqas.org.uk for further information

Case 2: Telephoned result leads to wrong patient being readmitted and transfused

A 17 year old man with acute myeloid leukaemia in remission was recalled after a day case visit and transfused on the basis of his apparent Hb result. His true Hb was 140 g/L but a telephoned abnormal low Hb had been received on the ward when the nurse misheard the name, and despite repeating back the name, the biomedical scientist (BMS) thought he heard the right name.

The laboratory protocol for telephoned results had included only the name and as a result of this case has been modified to include all four essential patient identifiers (i.e. to include first name, surname, case note number and date of birth).

Avoidable/delayed transfusions due to full blood count (FBC) 'wrong blood in tube' n=9

It is not only transfusion samples labelled with the wrong patient details which are dangerous. Wrong blood count samples can also have serious consequences. In 9/145 (6.2%) reports, patients received an avoidable or delayed blood transfusion based on a 'wrong blood in tube' full blood count sample. Wrong coagulation or biochemistry samples are also dangerous and can lead to inappropriate treatment. The same standard of identification and labelling should apply to all patient samples.

Table 12.2: Errors relating to 'wrong blood in tube' – full blood count sample n=9

Urgency	Error	Detected by	Outcome
Urgent	FBC sample taken from wrong patient	Doctor coincidentally reviewing patient's results noted that previous results were within normal limits	Patient was prescribed 2 pools of platelets. First pool in progress when error identified and transfusion stopped
Routine	FBC sample from Patient X was labelled with Patient Y's details by phlebotomist	A repeat FBC sample taken the following day showed the Hb had risen from 75 g/L pre transfusion to 137 g/L after 1 unit of red cells	Unnecessary unit of red cells transfused.
Urgent	Two patients bled on the same ward for FBC. Samples transposed during labelling by phlebotomist	Clinical chemistry reviewing the results the following day	Patient had already received an unnecessary 2 units of red cells before the error was detected
Routine	Samples put on the desk and wrong ones picked up for labelling	Patient Hb post transfusion had risen from 76 g/L to 116 g/L	Unnecessary unit of red cells transfused
Urgent	FBC sample from Patient X was labelled with Patient Y's details	Detected by ward staff – unspecified	Patient X received an unnecessary 2 unit red cell transfusion
Emergency	FBC sample labelled with incorrect details	Initial FBC sample taken in A&E was discrepant with FBC sample from GP which arrived later. Urgent repeat FBC matched the Hb from the GP sample	1 unit transfusion based on the erroneous initial Hb sample taken in A&E
Urgent	FBC sample labelled away from bedside with another patient's barcode	Further testing the following day identified normal platelet count	Patient received 2 units red cells and 1 pool of platelets
Routine	Wrong addressograph label on FBC sample	Detected by lab staff – unspecified	Patient received 2 units red cells transfusion
Routine	Correct patient bled but form and sample labelled with another patient's details	No results available for the patient	Delayed transfusion

Avoidable use of O RhD negative blood n=6

Case 3: Emergency O RhD negative blood used when it might have been unsafe because the patient has irregular red cell antibodies

A 53 year old woman was known to have a complicated antibody history (anti-E, anti-K, anti-Jk^a, and a positive direct antiglobulin test). The BMS in the hospital transfusion laboratory advised the ward staff that a repeat sample would need to be taken if the patient required transfusion. No repeat sample was sent then, nor before an elective surgical procedure, angioplasty of her foot, which began in the radiology department 2 days later.

The patient began bleeding during surgery and was transferred from the radiology intervention room to theatre for vascular surgery. Blood was requested, a sample sent, but this sample was clotted and the request form was also incorrect so that the laboratory staff required a repeat sample. The surgical staff did tell the laboratory the urgency of the situation. The anaesthetist determined from near patient testing that the Hb was 31 g/L, and transfused emergency O RhD negative units.

The BMS realised that emergency O RhD negative units had been removed from the satellite refrigerator (computer flag) and alerted the doctor that the patient had many antibodies (so emergency O RhD negative units may not be safe). However the patient was now stable. The patient died unrelated to the transfusion a few hours later.

A good root cause analysis (RCA) was performed with many lessons learnt, particularly that radiology departments where vascular interventions take place need to have transfusion protocols including the management of major haemorrhage. Review of postgraduate training curricula in all specialties has been undertaken by the Education Subgroup of the National Blood Transfusion Committee (NBTC). This group noted that there is no reference to blood transfusion training in this specialty (report made to NBTC April 2013).

1. This case demonstrates a lack of understanding concerning O RhD negative red cells, that they are not universally safe.
2. There was evidence of poor communication between the laboratory and ward staff, since a repeat sample for transfusion could have been sent prior to the procedure.
3. Staff in radiology departments may not consider that knowledge of transfusion and activation of major haemorrhage protocols is relevant to their practice. However, following this event the departmental guidelines were revised to include indications for blood group and antibody screening with new checklists. Radiology medical and nursing staff are now required to attend mandatory transfusion training.
4. The clinical area referring the patient to radiology also agreed to provide a registered nurse escort to ensure adequate handover of clinical information.

Recommendation

- Hospital transfusion committees should review their transfusion protocols and training to ensure that all relevant departments in their hospitals, including radiology and any others where invasive procedures are performed, have appropriate measures in place

Action: Hospital Transfusion Committees; Hospital Transfusion Teams

In one of the other 5 cases where emergency O RhD negative units could have been avoided, an acutely bleeding patient was repeatedly given emergency O RhD negative units despite the consultant haematologist informing the clinical area that crossmatched blood was now available.

In 2 reports, the group and screen samples were rejected by the laboratory due to sample labelling errors. One patient had 3 separate samples taken and all were rejected due to missing details on the tube.

In 2 further cases, no group and antibody screen sample was available for patients undergoing surgery resulting in emergency O RhD negative units being used to prevent any delay to surgery.

Case 4: 'Wrong blood in tube' from clinical area leads to delay in provision of compatible group specific blood

Blood was requested for an obstetric patient (Patient X) in theatre with a ruptured uterus. A sample had apparently already been sent. The BMS advised the ward that a sample for Patient X had not yet been received and repeatedly requested that one should be sent. The sample eventually arrived in the laboratory over an hour later. Emergency O RhD negative units were issued to theatre in the meantime.

Two FBC requests and a single request for group and screen had previously been received for Patient Y. It was subsequently discovered that the sample for Patient Y grouped as O RhD positive although her historic group on the laboratory system was A RhD positive.

The junior doctor telephoned the laboratory to say that one of the FBC samples could not have been from Patient Y as she was only bled once – other sample was from Patient X. The sample subsequently received on Patient X also grouped as O RhD positive. The junior doctor had recently arrived in UK and had not had the usual induction in the obstetrics department.

Inappropriate transfusion to patients with objections to transfusion n=3

Three patients who had a religious objection to cellular blood components were transfused with red cells. These inappropriate transfusions resulted from failure in correct procedure of informed consent for blood transfusion (unrecognised language barrier), communication and documentation procedures (specific instructions moved from front page to elsewhere in case notes where they were not seen). One of the patients was not able to give consent being unconscious but the specific instruction was in the case notes and overlooked.

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) issued guidelines for patient consent for blood transfusion in 2011, and these outline the necessary steps to obtain informed consent[54].

The Blood Services produce patient information leaflets which are available in many different languages. The 'Hospital Liaison Committee Network' was established by the Jehovah's Witness community. Their representatives are trained to facilitate communication between patients and medical staff and to provide information and support for both. The Better Blood Transfusion – 'appropriate use of blood toolkit'[55], also provides information for the management of patients who express their wish to refuse blood components.

Inappropriate management of anticoagulant reversal n=6

Case 5: Inappropriate use of fresh frozen plasma (FFP) to reverse warfarin causes mild allergic reaction

An elderly woman presented with a rectal bleed; she was also being treated with warfarin (for atrial flutter). The INR (international normalised ratio) on admission was 5.8, however it was 2.9 just prior to transfusion. The patient's Hb had dropped from 104 g/L to 79 g/L. Following the FFP transfusion (she had also received 2 units of red cells), the patient experienced a mild allergic reaction with an itchy rash on the face and arms. The symptoms subsided following administration of antihistamine and hydrocortisone. Prothrombin complex concentrate (PCC) could have been made available by discussion with the consultant haematologist.

(This case is one of 3 acute transfusion reactions that took place following inappropriate transfusions).

Learning point

- Transfusion laboratories should have protocols in place to ensure that fresh frozen plasma (FFP) is not used inappropriately for warfarin reversal. The correct treatment as recommended in British Committee for Standards in Haematology (BCSH) guidelines is to use PCC[56]

Case 6: Inappropriate transfusion of cryoprecipitate for a false derived fibrinogen result in a patient on dabigatran

An 87 year old woman on dabigatran for atrial fibrillation was admitted with melaena, vomiting and dizziness. Her coagulation tests were deranged with an elevated prothrombin time (PT) of 27 seconds, activated partial thromboplastin time (APTT) of 70 seconds and a low fibrinogen of 0.35 g/L.On the advice of a haematology registrar she received prothrombin complex for the deranged PT and APTT, and cryoprecipitate to correct the apparently low fibrinogen.

A false low derived fibrinogen is a recognised problem with this anticoagulant and the cryoprecipitate was unnecessary. There are marked variations in fibrinogen measurements with different reagents[57].

This is the first case SHOT has received relating to the newer anticoagulants. Guidelines are available to assist in the management of patients with haemorrhage who are receiving the newer anticoagulants[58].

Learning point

- When assessing coagulation tests in patients on dabigatran a derived fibrinogen is not reliable

Failure to review patient results and/or instructions in casenotes or failure to make an appropriate request for assistance n=33

In 33/145 (22.8%) cases, patients received unnecessary transfusions due to failure to review available blood results, not waiting until the results were available prior to transfusion or not following instructions for the patient's management detailed in the patient casenotes. One of these resulted in major morbidity for the patient (Case 1). A patient received repeated FFP infusions which were not effective and not indicated for his condition; a referral for a haematology opinion would have been more appropriate. In addition, 4 patients were transfused red cells unnecessarily, 3 for iron deficiency anaemia, and 1 for megaloblastic anaemia. Another patient was prescribed 2 units of red cells, one to be given each day on two consecutive days with diuretic, but both were given on the same day without diuretic and the patient suffered from transfusion-associated circulatory overload.

Case 7: Repeated cancellation of surgery results in unnecessary transfusion and wastage of fresh frozen plasma (FFP)

A patient with congenital factor V deficiency was due for a cholecystectomy but after having the necessary FFP infusion, the procedure was cancelled; this happened on 3 separate days.

A written plan for surgery in patients with inherited bleeding disorders is recommended with good communication not only between surgeon and haematologist but also with surgical co-ordinators who plan the lists[59,60].

Delayed transfusion n=20

There were 7 reports where there was delay in transfusion and the patient died, but in all cases the deaths were unrelated to the delay in transfusion.

In 2/20 cases the delay was caused by failure to authorise urgent overnight transfusion because it was hospital policy not to transfuse at night. Other causes of delay include poor communication across disciplines including poor handover. An additional case of delayed transfusion was described earlier in the section on FBC 'wrong blood in tube' incidents.

Case 8: Delayed transfusion as a consequence of poor handover

A 77 year old man was admitted with melaena. His Hb was 58 g/L. Four units of red cells were prescribed at 17:00. He was transferred from the emergency department to a ward at 22:00. A verbal non-documented handover was made stating that he was stable and did not require transfusion. At 01:00 he developed signs of decompensation with tachycardia and hypotension and was given fluids, but not transfused until 05:00, 10 hours after the blood was prescribed.

Learning point

- Caution is required in the strict application of guidelines when the clinical needs of the patient warrant a properly managed deviation from the routine protocol

Case 9: Patient put at risk by wrong labelling of Hb sample

A patient required an Hb estimation following surgery (total hip replacement). Although the correct patient had been bled, addressograph labels from another patient were attached to the form and sample and no result could be issued. This resulted in a delay in transfusion.

Case 10: Fire drill/evacuation during massive haemorrhage

The transfusion laboratory was informed at 08:30 that a unit of emergency O RhD negative blood had been transfused. Ten minutes later a second unit of emergency blood had been used for the same patient. Within the next 5 minutes the laboratory issued and replaced the O RhD negative units that had been used. At 09:30, the patient's Hb was now 30 g/L (result from blood gas analyser) and further units were requested urgently. At 09:40 the pre-transfusion sample testing was incomplete so 6 emergency uncrossmatched red cell units were issued. During the issue process, the fire alarm sounded and the printer ran out of compatibility labels. Three of 6 units had already been labelled but due to the urgency of the situation, all 6 units were boxed and transported to the clinical area.

This is similar to a report submitted in this section in 2011. The two reporters involved requested permission via SHOT to contact each other to share their RCA and lessons learned. Feedback from the reporters was that this was a very positive exercise and they both gained a great deal from sharing their respective experience. The end result was a change in policy relating to fire drills in the new reporting Hospital B. Using a shared example of an action plan for a real fire alarm from Hospital A, further work was being done to develop this in the Hospital B.

Learning point

- Good incident investigations with root cause analysis (RCA) may be very helpful to share with other hospitals. Reporters are encouraged to give permission to SHOT to share the anonymised RCA via a page on the SHOT website (see also Chapter 8 on investigation of incidents and root cause analysis)

Overtransfusion n=13

The reasons for overtransfusion are the same as in previous years. In 4 cases, the patient's low body weight was not taken into consideration or the amount of blood to be transfused was incorrectly calculated (see also Chapter 25, transfusion-associated circulatory overload, and the recent addendum to the guidelines on the administration of blood[26]).

In one case, a small child was overtransfused to haemoglobin of 270 g/L. This case is discussed in more detail in the paediatric chapter (Chapter 27).

Undertransfusion of FFP n=4

In all cases the FFP transfusions were indicated according to BCSH guidelines[61] but an insufficient

dose given. The causes were erroneous and unclear prescribing, misunderstanding, communication failure between two doctors, and simple failure to give 3 of the 4 units prescribed. These findings are consistent with those of the National Audit of FFP (2009) which showed that in 40% of transfusions to adults (873/2186) the dose given was subtherapeutic, being less than 10mL/kg[62].

Prescription errors n=12

In 4/12 cases components were given that were not prescribed. In a further 2/12 cases, components were transfused using a prescription that was not signed.

The incorrect volume of cryoprecipitate was prescribed in 3/12 cases due to confusion over doses. Clinicians made requests for 6 or 10 units, expecting single donor units and not realising that this component is now supplied as pools of 5 single donations. Requestors included junior and senior haematologists.

Learning point

- Biomedical scientific staff (BMS) and consultant haematologists need to educate users about the change in presentation of cryoprecipitate. BMS staff should be encouraged to challenge orders which seem inappropriate. Clinical staff should heed the advice of transfusion experts and check their request carefully

Miscellaneous n=2

A blood sample taken from a patient was not sent to the laboratory in a timely manner, but retained on the ward for 6 hours. Then when the patient bled in theatre uncrossmatched group-compatible blood had to be issued.

A patient was transferred to another hospital with a transfusion in progress without informing the consultant haematologist or the laboratory, and the patient was not accompanied by appropriately qualified staff.

COMMENTARY

Cases of avoidable, delayed or undertransfusion were reported with the same causes as in previous years, for example excessive volumes prescribed for children or adults of low body weight, patients transfused for treatable anaemias (iron deficiency and megaloblastic anaemia), patients transfused on the basis of wrong Hb results and patients receiving the wrong component. In one case the prescriber used unfamiliar terminology (PRP – platelet rich plasma – for platelets) which was misinterpreted as FFP by the laboratory. These errors occur because of poor practice, failure to follow protocols, short cuts and hurry, especially in the emergency situation, and poor communication and handover as patients are moved between different wards and departments. As patients are moved around hospitals they become the responsibility of a series of different teams (and shifts) without any consultant having clear ownership. Good handover and clear lines of responsibility would help prevent many errors.

There have been incidents this year where a blood transfusion was inappropriately delayed because of misinterpretation of the overnight blood transfusion policy.

In 2005, SHOT made a recommendation that transfusion outside core hours should be avoided unless clinically essential because of evidence that pre-transfusion testing and blood administration were less safe and SHOT also recommended that auditing the number of patient safety incidents during different time periods may be useful[63].

In January 2008, the National Comparative Audit of overnight red cell transfusion[62] identified that 32% of patients transfused at night had no clinical indication to be transfused ‘out of hours’. Overnight transfusion can be more of a risk because many ward areas are poorly illuminated with fewer staff available to monitor the transfusion. However, clearly some patients have an urgent need for transfusion which overrides such a policy.

Summary of learning points:

- Confusion over 'ownership' of patients may contribute to poor management (Case 1: whose responsibility it was to review results), but no transfusion should be prescribed or given without proper assessment of the patient including review of the latest Hb results
- The use of point of care haemoglobin machines or blood gas analysers may lead to wrong results. It is essential that any point of care machines are properly quality assured for Hb results and that they are used only by staff who have received appropriate training. A UK NEQAS scheme is now available for haemoglobin results from blood gas machines since April 2013, contact haem@ukneqas.org.uk for details
- Hospital transfusion committees should review their transfusion protocols and training to ensure that all relevant departments in their hospitals, including radiology and any others where invasive procedures are performed, have appropriate measures in place
- Transfusion laboratories should have protocols in place to ensure that FFP is not used inappropriately for warfarin reversal and that prothrombin complex concentrates are available
- Caution is required when interpreting coagulation tests in patients receiving the new anticoagulants (direct thrombin inhibitors such as dabigatran, or direct anti-Xa inhibitors such as rivaroxaban and apixaban). Guidelines for managing haemorrhage in these patients are available[58]. When assessing coagulation tests in patients on dabigatran a derived fibrinogen is not reliable
- Good incident investigations with root cause analysis may be very helpful to share with other hospitals. Reporters are encouraged to inform SHOT if permission is granted to share the anonymised RCA via a page on the SHOT website
- Biomedical scientific staff (BMS) and consultant haematologists need to educate users about the change in presentation of cryoprecipitate. BMS staff should be encouraged to challenge orders which seem inappropriate and clinical staff should heed their advice where appropriate

Recommendations

- A zero tolerance policy should be introduced for labelling of all patient samples and not restricted to transfusion samples. Dangerous consequences can arise from wrong full blood count, wrong coagulation and wrong biochemistry results

Action: Trust/Hospital/Health Board Chief Executive Officers (CEOs) Hospital Pathology Managers; Hospital Transfusion Teams (HTT)

- Particular attention should be paid to the correct labelling of all samples at the patient's side, particularly in emergencies where additional delays resulting from a need for repeat samples may increase risks to the patient

Action: Trust/Hospital/Health Board CEOs; Hospital Pathology Managers; HTT

Right Blood Right Patient (RBRP) 13

Authors Alexandra Gray and Hema Mistry

Definition:

Incidents where a patient was transfused correctly despite one or more serious errors that in other circumstances might have led to an incorrect blood component being transfused (IBCT).

DATA SUMMARY
Total number of cases: 142

Implicated components	
Red cells	120
FFP	5
Platelets	10
Cryoprecipitate	0
Granulocytes	0
Anti-D Ig	0
Multiple components	6
Unknown	1

Mortality/morbidity	
Deaths due to transfusion	0
Deaths probably/likely due to transfusion	0
Deaths possibly due to transfusion	0
Major morbidity	0
Potential for major morbidity (Anti-D or K only)	0

Gender	
Male	64
Female	77
Not known	1

Age	
≥18 years	130
16 years to <18 years	0
1 year to <16 years	2
>28 days to <1 year	1
Birth to ≤28 days	6
Not known	3

Emergency vs. routine and core hours vs. out of core hours	
Emergency	26
Urgent	34
Routine	72
Not known	10
In core hours	100
Out of core hours	39
Not known/Not applicable	3

Where incident took place	
Accident & Emergency	13
Theatre	11
ITU/NNU/HDU/Recovery	24
Wards	69
Delivery Ward	4
Postnatal	1
Medical Assessment Unit	11
Community	0
Outpatient/day unit	4
Hospice	0
Antenatal Clinic	0
Unknown	5

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 may have led to the unit being rejected or an incomplete documentation trail being available for that transfusion episode. These errors do not fit into the definition of IBCT but have been included to inform practice. They are not included in the overall numbers of IBCT cases. There were 142 cases analysed in 2012, representing a 10.7% decrease from 159 in 2011. Table 13.1 describes the findings from 142 completed questionnaires.

Table 13.1: RBRP episodes n=142

Elements that were wrong on blood packs, documentation, identity bands etc	2011	2012
Patient identification errors	**100**	**102**
Name alone or with other elements	37	49
Date of birth (DOB) alone or with other elements	30	28
Wristband* missing/wrong wristband in place at final bedside checking procedure	14	9
Hospital or National Health Service (NHS number)	17	14
Address alone or with other elements	1	1
Patient identification (ID) details missing on sample tube	-	1
Gender	1	-
Labelling errors	**55**	**31**
Transposed labels	38	18
Other labelling errors	17	13
Miscellaneous errors	**4**	**9**
Prescription error	2	5
No final patient ID check undertaken prior to administration of component	-	2
Issue procedures errors	-	2
Access cards	2	-
Total	**159**	**142**

**'Wristband' refers to identification wristband (or risk assessed equivalent) as defined in the British Committee for Standards in Haematology (BCSH) Guideline on the Administration of Blood Components (2010)[27].*

The RBRP events continue to provide an insight into how, when and possibly why errors occur. In 2012 80 of 142 errors (56.3%) originated in the clinical environment; the 62/142 (43.7%) cases where the primary error originated in the hospital transfusion laboratory are discussed fully in the Laboratory chapter (Chapter 10) and further reference to similar errors can also be found in the Medicines and Healthcare products Regulatory Agency (MHRA) chapter (Chapter 6).

Errors continue to occur across the transfusion process: root cause analysis has identified a number of key practices that caused the primary error. These include transcription errors at admission and sample registration, patient identification (ID) errors at sampling, failure to check the component at issue, collection and/or receipt in the clinical area and during pre-administration checks of both the component and the associated documents. The final opportunity to recognise the error is then missed at the patient identity check prior to the transfusion commencing.

The aim this year is to focus on incidents where there were opportunities to identify and/or prevent an error occurring, however staff failed to recognise or respond to inaccuracies or ignored or changed the information presented to match an existing patient record.

Case 1: Multiple errors lead to patient identification error

A patient was admitted and during admission a different patient with the same first name and second name was selected on the hospital computer system. A group and screen sample was sent to the laboratory, but the date of birth (DOB) did not match with the laboratory computer system. The DOB was changed by the ward to match all the details on the crossmatch form and sample after the lab notified the ward of the discrepancy. This resulted in the correct first name, second name and DOB, but incorrect hospital number on the wristband and also a different address on the stickers. This information was printed and put on the patient's notes and not picked up for the entire admission.

This case illustrates at least five occasions where the error could have been corrected, at admission, sampling, sample registration, collection and administration. An inconsistency was picked up at sample registration, however this resulted in an incomplete correction; the patient was still associated with the wrong patient record, however they received the right blood.

Case 2: Patient alerts staff to identification error but no action taken

A patient received a red cell transfusion but the patient's surname on the prescription did not match with the surname on the wristband and the blood product. When the patient was asked to confirm her surname it was a different spelling to the one on her wristband. The patient had stated that the wristband was spelt incorrectly and she had alerted staff; the prescription chart had a different surname to the wristband and traceability tag, when the patient was questioned she had stated none of the documentation was correct. An historical error in the patient notes resulted in two different spellings of the surname being used during this admission.

The error could have been corrected on a number of occasions, the patient had alerted the staff to the incorrect spelling of her surname but no action was taken.

Case 3: Failure at multiple points to identify wrong patient identification details

A patient was registered in the Emergency Department with the wrong date of birth (DOB) but details were later amended. The biomedical scientist (BMS) in the hospital transfusion laboratory selected a previous episode for the patient, which was attached to the wrong DOB. The discrepancy was not noticed at sample verification, issue of red blood cells (RBC), collection of RBC or bedside administration check.

Similar to Case 1 the primary error was made on admission, however the mistake was missed when the blood sample was taken and compounded by the BMS selecting a previous electronic record with the incorrect date of birth. The error was then missed during issue, collection and administration checks.

COMMENTARY

All the RBRP errors were preventable. Members of staff have a personal and professional responsibility to adhere to the correct patient identification procedures at: admission, sampling, on receipt of the sample and entering the patient ID details into the information technology (IT) system and during the collection and administration processes. The final patient identification check at the bedside prior to the administration is the last opportunity to pick up any errors, however **every** person involved in the transfusion process is responsible for making sure their part of the process is undertaken accurately and that they follow the correct hospital procedures at all times.

Recommendations

There are no new recommendations for 2012

Recommendations still remain active from previous years:

- 2011 – It is imperative that staff are vigilant at all times in the laboratory and clinical areas when participating in the patient identification process, especially when the patient is admitted

Action: Hospital Transfusion Teams; Patient Administration System Managers

14 Handling and Storage Errors (HSE)

Authors: Alexandra Gray and Hema Mistry

Definition:

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 for transfusion.

DATA SUMMARY
Total number of cases: 316*

Implicated components		Mortality/morbidity	
Red cells	290	Deaths due to transfusion	0
FFP	6	Deaths probably/likely due to transfusion	0
Platelets	13	Deaths possibly due to transfusion	0
Cryoprecipitate	6	Major morbidity	0
Granulocytes	1	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	0		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	89	≥18 years	173	Emergency	23	Emergency department	6
Female	96	16 years to <18 years	3	Urgent	39	Theatre	12
Not known	131	1 year to <16 years	6	Routine	131	ITU/NNU/HDU/Recovery	43
		>28 days to <1 year	4	Not known	123	Wards	111
		Birth to ≤28 days	3			Delivery Ward	10
		Not known	127	In core hours	233	Postnatal	3
				Out of core hours	80	Medical Assessment Unit	20
				Not known/Not applicable	3	Community	3
						Outpatient/day unit	5
						Hospice	0
						Antenatal Clinic	0
						Unknown	103

**This section describes the main findings from 199 completed questionnaires. 13 questionnaires refer to multiple patients so the total number of events analysed is 316. In 1 of these cases there was insufficient information available to determine the number of patients affected.*

The categories as in previous years remain the same. There has been a significant (38.2%) decrease in the number of actual reports submitted under the HSE category in 2012 (199 reports) compared with 2011 (322 reports), however as 12 reports in 2012 gave details of multiple patients being transfused, the total number of events analysed remains similar to that in 2011 (325 in 2011, 316 in 2012); this reduction in report numbers includes 38 cases where the excessive time to transfuse took less than 5hrs to complete. In total 69 cases were withdrawn (including the 38 cases mentioned above); 32 cases were transferred from other categories, including right blood right patient (RBRP), avoidable, delayed or undertransfusion (ADU), incorrect blood component transfused (IBCT) and near miss (NM). Thirteen multiple cases were reported involving 129 patients (1 report did not give details of the number of patients involved). Sixteen cases involved paediatric patients including 3 neonates and 4 children

less than a year old. In 127 cases the age was not given. All other cases were in adults over 18 years of age. In 41.5% (131/316) of reports the incidents occurred in a routine setting, 19.6% (62/316) were urgent or emergencies and 38.9% (123/316) were unknown. There were no transfusion-related cases of morbidity or mortality reported.

Technical transfusion errors n=31

There were 31 technical administration errors, an increase of 34.8% from 23 in 2011. In 16/31 (51.6%) of cases the report resulted from the use of the wrong type of giving set. The integrity of the pack was compromised in 2 cases; a unit of red cells was punctured when spiking the pack but the transfusion continued, the second case is described below (Case 1) and is also referred to in the Medicines and Healthcare products Regulatory Agency (MHRA) chapter (Chapter 6). In two of the paediatric cases the patients were over-transfused due to errors when setting up the blood pump, these errors are discussed in the Paediatric chapter (Chapter 27).

Case 1: Failure in communication leads to a transfusion from a defective pack

A unit of red cells was issued with no port available to allow the insertion of the giving set. The laboratory staff failed to notice the defect. The ward staff queried the fault with the duty laboratory biomedical scientist (BMS) but the BMS failed to understand the question, thinking that the query was regarding which giving set to use. The ward was therefore told that the laboratory could not help. Instead of clarifying the issue the ward staff opted to gain access to the pack by cutting the main collection line of the bag. The patient was then transfused from the defective pack.

Transfusion of expired blood components n=25

Eleven errors originated in the clinical environment; all clinical errors resulted from components being issued with a short expiry date (n=4) or still being available for collection close to or after the expiry date (n=7); in two cases the person collecting the component ignored an electronic warning that the component had expired. The reports described below illustrate the risks associated with issuing components due to expire close to the recommended transfusion times. The 14 cases originating in the laboratory are discussed in the Laboratory chapter (Chapter 10).

Case 2: Failure to heed warning leads to transfusion of expired unit

A unit of red cells was removed from the blood storage unit for a patient. A sticker stating that the red cells should be used by 16:30 on 15/12/2011 was clearly visible on the hospital transfusion laboratory register slip. The unit of red cells was removed at 16:30 on 15/12/2011 and transfused.

Case 3: Expired unit transfused despite advice

One unit of red cells was collected but was returned to the hospital transfusion laboratory (HTL) 45 minutes later. The porter returning the unit informed the laboratory staff who took the unit out of the routine issue refrigerator and placed it in the quarantine area of the laboratory refrigerator. The ward was also contacted informing them that the unit would be discarded if not used within 4 hours. The unit was subsequently re-collected 10 minutes before expiry and transfusion commenced 2 minutes post expiry. No completion time was documented on the prescription chart.

Case 4: Communication confusion leads to transfusion of expired unit of platelets

A patient was prescribed 2 bags of platelets. Both of these bags were due to expire at midnight. The staff were informed by the haematology associate specialist that 1 bag was to be transfused during the afternoon, and 1 later in the evening. Both bags were issued by the hospital transfusion laboratory (HTL) for the patient at 11:14. The ward was informed by the HTL that the units were available, was given information regarding the expiry time and that they should not be transfused past this time. Nursing staff documentation prior to 21:00 stated that haematology had been contacted about the platelets and were informed that the laboratory staff would ring when they were ready but they had not yet done so. The nursing staff on night shift rang the on-call doctor to inform him the platelets had not been given. The doctor contacted haematology and was told the platelets had

been ready since early evening. The first bag of platelets was commenced at 22:40, however, the patient's intravenous cannula tissued. Re-cannulation was done by an anaesthetist. The second bag of platelets was collected at 23:50. The anaesthetist contacted the on-call consultant haematologist regarding the expiry time, and the consultant haematologist was happy for platelets to be transfused up until 01:00. The platelet transfusion was completed at 0:40.

These cases all involved staff from different departments and in most cases there were a number of times that the error could have been prevented but it was missed. It is the responsibility of the laboratory staff to ensure that blood components are only issued when there is a reasonable expectation that they will be transfused and are cleared from storage locations in a timely manner (see the MHRA chapter, Chapter 6). It is the responsibility of the staff involved in the collection and distribution of blood components to check the expiry date before issuing or removing the component from the cold chain. It is the responsibility of the staff in the clinical area when taking receipt of the component and at the final identity check to ensure the component is within the expiry and prescription times before commencing the transfusion.

Excessive time to transfuse n=62

There has been a significant reduction in the number of 'excessive time to transfuse' cases this year; in the 2011 SHOT report[2] SHOT focussed only on transfusions that took more than 5 hours to complete. In this report we have withdrawn all cases where the transfusion took less than 5 hours to complete (n=38). The recommended times for transfusing blood components are available in current guidelines[64]. Twenty cases (32.2%) took more than 6 hours (range 6–11 hours). In 23/62 cases (37.1%) the error resulted from a delay in commencing the transfusion; less than half of events (28/62 (45.2%)) took place during core hours (see Table 14.1).

Table 14.1: Breakdown of time of 61 transfusions that took excessive time to run

Time period	In core hours/out of core hours	Number*
08:00 to 20:00	Core hours	28
20:00 to 00:00	Out of core hours	23
00:00 to 08:00	Out of core hours	10

**1 unknown.*

Case 5: Failure in communication as patient was transferred during the transfusion episode

Following handover to the night shift, the staff nurse noticed that a transfusion of red cells that had been commenced at 15:30 was still being infused at 23:00. After the start of the transfusion the patient had been transferred from the assessment unit to the adult medical ward.

Case 6: Multiple factors lead to delay in starting a transfusion

One unit of red blood cells was removed from blood refrigerator at 17:15, transfusion started at 19:30 and finished at 23:15. There was an initial delay due to the patient's intravenous cannula tissuing; when the nurse queried the transfusion time allowed, the advice given by the laboratory biomedical scientist (BMS) was incorrect leading to a total transfusion time of 6 hours.

There were 5 paediatric cases, in 1 case the patient was less than one month old; 2 of the cases were due to poor venous access, in 1 case an error was made when setting up the infusion pump and the other case was due to the baby's underlying condition. No explanation for the excessive transfusion time was provided in the fifth case.

As described in the 'expired unit transfused' category above, the clinical staff are responsible for ensuring any blood component is transfused within the advised time and according to the prescription. Particular attention should be paid to patients with poor venous access.

Cold chain errors n=196

Type of error	No. of cases 2011	No. of cases 2012
Alarm-related (where staff failed to carry out the correct procedure following an alarm being set off on a refrigerator)	7	18
Equipment failure (as a result of either a power failure or suspected refrigerator failure which failed to activate the alarm)	8	101
Transport or delivery of components	4	12
Inappropriate storage of components (Table 14.3)	52	65
Total	**71***	**196****

Table 14.2: Cold chain errors (n=71 in 2011 and n=196 in 2012, including 12 multiple cases)

** In 2011 six cases of multiple reports are included on the table above (3 are equipment failures and 3 are alarm-related).*

*** In 2012 twelve cases of multiple reports are included on the table above (2 alarm-related, 4 equipment failure, 1 transport or delivery of components, 5 inappropriate storage).*

Type of inappropriate storage error	2011	2012
Returned to stock when they should have been discarded	16	20
Returned to a satellite refrigerator when they should have been discarded	3	1
Without any/incomplete/inaccurate cold chain documentation or traceability	8	2
Stored inappropriately in clinical area	8	4
Stored inappropriately in laboratory area	0	5
Units transfused in which interval between sampling and transfusion had exceeded *BCSH guidelines – Failure to clear the refrigerator	17	14
Units transfused in which interval between sampling and transfusion had exceeded *BCSH guidelines – Where sample was invalid	0	18
Other – scanning error	0	1
Total	**52**	**65**

Table 14.3: Cold chain errors: breakdown of causes of inappropriate storage of components (n=52 in 2011 and n=65 in 2012)

** British Committee for Standards in Haematology.*

The number of handling and storage error reports that resulted from cold chain errors in 2012 has increased compared to 2011. Eleven cases could have been prevented if warning flags were heeded, and these information technology (IT) related incidents are discussed in the IT chapter (Chapter 11). In addition there were 50 cases related to management of the cold chain in the Near Miss chapter (Chapter 7).

Fourteen out of the 196 cold chain errors occurred in a clinical setting, whereas all the rest were due to laboratory errors. 2012 shows a 25% increase in the number of errors associated with the storage of components. In previous years components have been stored inappropriately in clinical areas, whereas this year there have been 5 cases reported where blood components (3 fresh frozen plasma (FFP), 2 red blood cells) were inappropriately stored in the laboratory which subsequently resulted in blood components that were stored at inappropriate temperatures being transfused to a number of patients. UK guidelines for the administration of blood components state that FFP should be stored in a designated temperature controlled freezer with a core temperature of –25°C[27].

The number of cases relating to the use of transport boxes for storing and delivering blood to theatre and wards has tripled from 4 in 2011 to 12 in 2012. Components were either packed incorrectly or left in the transport boxes beyond validation; see Case 7.

Case 7: Incorrect transport of units results in out-of-temperature units being transfused

Two units of blood were sent in a transit box for transfusion at the local hospital. The transit box was sent without the required cold packs for correct temperature control. The first unit was transfused within two hours of the box leaving the laboratory but transfusion of the second unit began 6 hours after the transit box was dispatched. Subsequent download of temperature monitor on return of the box showed that the temperature was 12°C when the unit was transfused. There were no adverse effects to the patient reported following transfusion.

Keeping track of transport boxes and managing components to ensure they remain within controlled temperature guidelines can be a challenge for busy laboratories. To support the effective management of the cold chain, all staff should be aware of their local policies and trained to the appropriate competencies.

Incidents where a unit of red blood cells was transfused when it should have been cleared from the blood refrigerator as the interval between sampling and transfusion had exceeded BCSH guidelines remain similar to those reported in 2011[27].

Case 8: Failure to remove the blood from the issue refrigerator results in the transfusion of a unit after the sample validity was exceeded

A unit of red cells was collected and transfused to a patient when it should have been returned to stock; the sample used to issue the component against was unsuitable as it exceeded the time at which the transfusion was expected to be completed. The unit had to be transfused by 13:00, but remained in the issue refrigerator and was collected by a health care assistant (HCA) at 14:20. The transfusion was then commenced. The error was noted by laboratory staff when they came to remove the unit from the issue refrigerator and realised it had been collected. They telephoned the ward; however the transfusion had started approximately 10 minutes previously. The transfusion was stopped and the unit returned to the laboratory for disposal. The collection slip had a warning sticker on stating the time the blood must be transfused by (13:00) and not to transfuse after this time. The warning sticker was missed on collection of blood by the HCA. The laboratory staff had also failed to remove the blood from issue refrigerator in timely fashion.

All staff involved in the transfusion process are reminded to be vigilant, when selecting and storing blood components and when transfusing patients. Whilst the collection of a component and the final bedside checks can assist in identifying errors associated with sample timing (and units passed their dereservation), especially where warning labels have been attached to components stating not to transfuse after a certain time, the primary responsibility lies with the laboratory. It is the responsibility of the hospital transfusion laboratory to clear the blood refrigerator thereby ensuring the removal of blood components that are past the dereservation time, in excess of sample validity or time-expired. The issue surrounding routine refrigerator checks has been highlighted in the Laboratory chapter (Chapter 10).

Miscellaneous reports n=2

There were 2 errors related to laboratory recall procedures; in both cases a telephone call from the Blood Service was received advising the BMS to recall a component (1 pack of platelets, 1 red blood cell component). In both cases a follow up fax was also sent by the Blood Service. In one case the fax was not actioned immediately as it was located under paperwork in the hospital transfusion laboratory which subsequently resulted in the platelets being transfused. The BMS issuing the platelets had no way of knowing that the pack had been recalled as it had not been quarantined. In the second case the fax machine had run out of paper so did not print. Due to a shift handover, ineffective communication and unclear handover instructions, the recall was not followed up until the next day where the patient at this point was being transfused. The unit of blood was taken down and returned to the laboratory and on both occasions no harm came to the patient.

Reporters are reminded that where components have not been recalled efficiently and subsequently transfused these cases are reportable to SHOT and the MHRA. A further 10 cases of failure to recall components have been reported to the MHRA.

Learning points

The learning points from 2011 remain active:

- It is imperative that staff are vigilant at all times during the transfusion process; when monitoring a patient they should include observation of the prescribed transfusion rate
- Where staff have deviated from their local transfusion policy, e.g. failed to sign in/out components from controlled temperature storage (CTS) or transfused a component over the recommended transfusion time and these digressions are identified during local audit or review, hospital transfusion teams should ensure they are systematically reviewed and that any lessons learnt are disseminated to all relevant staff groups
- Red cell units CANNOT be returned to CTS or reissued if they have been out of CTS for more than 30 minutes. There should be a clearly designated area assigned in the blood refrigerator for units returned from the clinical area for discard
- The use of a transfusion record or checklist can improve the documentation and handover processes, and a model is available on the SHOT website (http://www.shotuk.org/resources/current-resources/)
- Hospitals should have robust processes for stock control and component recall ensuring that components are not available for collection after their dereservation or expiry times or if recalled for safety reasons

Recommendations

There are no new recommendations.

The recommendations from 2011 remain active.

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

15 Adverse Events Related to Anti-D Immunoglobulin

Author: Tony Davies

Definition:

An adverse event relating to anti-D Ig is defined as relating to the prescription, requesting, 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: 313							
Implicated components				**Mortality/morbidity**			
Red cells			0	Deaths due to transfusion			0
FFP			0	Deaths probably/likely due to transfusion			0
Platelets			0	Deaths possibly due to transfusion			0
Cryoprecipitate			0	Major morbidity			4
Granulocytes			0	Potential for major morbidity (Anti-D or K only)			200
Anti-D Ig			313				
Multiple components			0				
Unknown			0				
Gender		**Age**		**Emergency vs. routine and core hours vs. out of core hours**		**Where anti-D Ig administration took place**	
Male	1	≥18 years	305	Emergency	0	Emergency Department	0
Female	312	16 years to <18 years	7	Urgent	9	Theatre	0
Not known	0	1 year to <16 years	1	Routine	304	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	0	Wards	259
		Birth to ≤28 days	0			Delivery Ward	0
		Not known	0	In core hours	304	Postnatal	0
				Out of core hours	9	Medical Assessment Unit	0
				Not known/Not applicable	0	Community	54
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Unknown	0

This section describes the main findings from 301 completed questionnaires. Three questionnaires in the 'Handling and Storage Error' category and one in the 'administration to a RhD positive woman' category refer to 16 separate events, so the total number of cases analysed is actually 313.

This continues the upward trend in reporting since SHOT reporting commenced in 1996 (Figure 15.1), and is probably a reflection of an increasing awareness of the need to report rather than a decline in standards of practice.

In addition 26 reports were withdrawn as they did not meet the reporting criteria. Nine reports were moved to the Near Miss chapter (Chapter 6), and 1 report to the Right Blood Right Patient chapter (Chapter 13). Nineteen reports were added from 'near miss', and 2 from 'incorrect blood component transfused'.

The reports are broken down into the reporting categories shown in Table 15.1.

Under current legislation[65], adverse events related to the prescription and administration of anti-D Ig are reportable as 'SHOT-only'. Clinical reactions to anti-D Ig are reportable via the Medicines and Healthcare products Regulatory Agency (MHRA) 'Yellow Card' scheme (www.yellowcard.mhra.gov.uk).

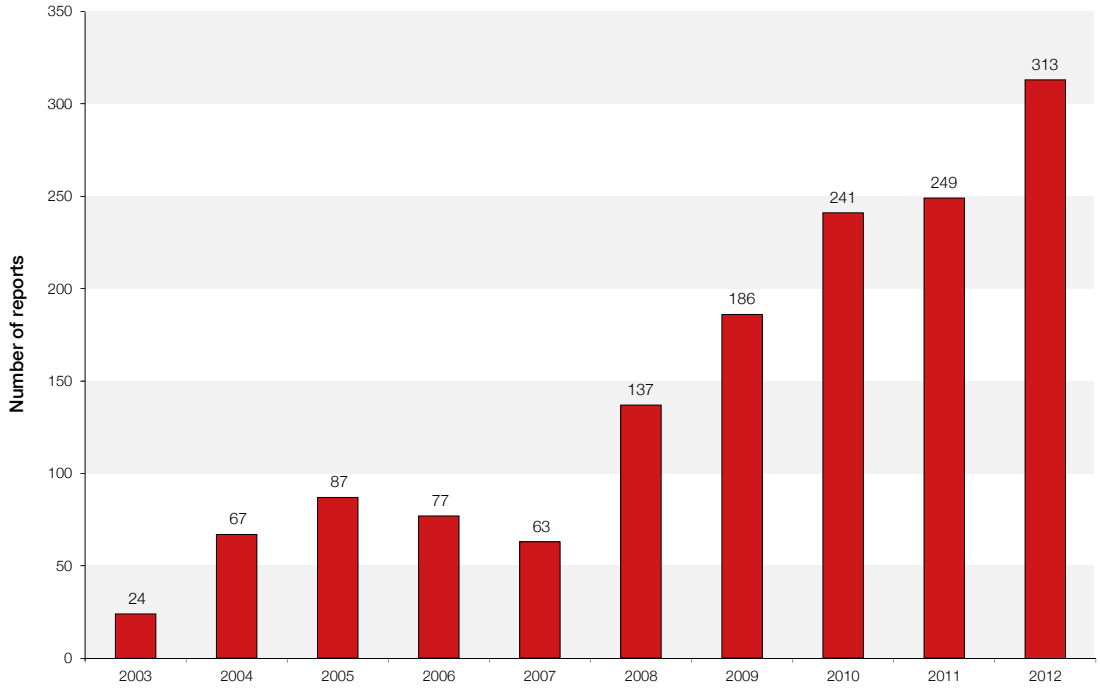


Figure 15.1: Cumulative data for anti-D events 2003-2012

Category of adverse event	Number of cases
Omission or late administration of anti-D immunoglobulin	204
Inappropriate administration of anti-D immunoglobulin	63
To a RhD positive woman	*28*
To a woman with immune anti-D	*20*
Erroneously to a mother of a RhD negative infant	*10*
Given to the wrong woman	*5*
Wrong dose of anti-D Ig given according to local policy	20
Handling and storage errors relating to anti-D Ig	26
Total	**313**

Table 15.1: Reporting categories

Deaths n=0

There was no reported fetal mortality following the omission or delay in administration of anti-D Ig.

Major morbidity n=4

There were 4 cases where a woman developed an immune anti-D following delay or omission in prophylaxis during the current or previous pregnancy.

Potential for major morbidity n=200

In a further 200 cases anti-D Ig was administered more than 72 hours following a potentially sensitising event, or omitted altogether, resulting in the potential for sensitisation of the woman to the D antigen. This satisfies the current SHOT definition of potential major morbidity.

Clinical versus laboratory errors

For the reporting year 2012, 313 events relating to anti-D Ig administration are summarised in Table 15.2 below, with a breakdown of the proportion of clinical and laboratory errors that were primarily responsible.

Table 15.2: Adverse incidents involving anti-D Ig administration, with site of primary error

Type of event	Cases	Number of primary errors		
		Nurse/ midwife	Laboratory	Doctor
Omission or late administration of anti-D Ig	**204**	177	20	7
Anti-D Ig given to RhD positive woman	**28**	16	11	1
Anti-D Ig given to woman with immune anti-D	**20**	6	14	0
Anti-D Ig given to mother of RhD negative infant	**10**	0	10	0
Anti-D given to wrong woman	**5**	5	0	0
Wrong dose of anti-D given	**20**	10	10	0
Anti-D Ig handling & storage errors	**26**	11	15	0
Totals	**313**	**225**	**80**	**8**

This year follows the pattern of 2009-2011 with clinical errors by midwives, nurses and doctors accounting for 233/313 (74.4%), and laboratory errors 80/313 (25.6%) of the total reports relating to prescription, requesting and administration of anti-D Ig.

Omission or late administration of anti-D Ig n=204

In 177/204 (86.8%) cases the primary error was made by a nurse or midwife, and in 7/204 (3.4%) cases by a doctor. In 20/204 (9.8%) cases, the errors originated from failures in the laboratory.

The location was in the community for 38 cases, and in a hospital setting for 166 cases. As in last year's report, there are multiple examples where anti-D Ig has been issued by the laboratory and not collected, or collected only to be found days or weeks later in maternity refrigerators. All 7 cases relating to medical staff involved poor decision making about the need for anti-D Ig which was not in line with national guidance.

Case 1: Poorly phrased communication from the laboratory

The laboratory telephoned results to the clinical area, advising that further anti-D Ig was not required to cover a transplacental haemorrhage of 1.2 mL fetal cells, not realising that the standard postnatal dose had not yet been administered from clinical stock. The message was recorded as 'no anti-D Ig required' and the woman was discharged without receiving any anti-D Ig.

Learning point

- Messages from the laboratory regarding the need for anti-D Ig (or for further investigations) must be clear and unambiguous

Case 2: Student midwife relies on patient to confirm anti-D Ig administration

A student midwife asked a postnatal woman whether she had received her anti-D Ig and the woman confirmed that she had. The administration was confirmed on the electronic patient record and the woman was discharged. The anti-D Ig labelled for the woman was found some days later in the maternity refrigerator, and it transpired that the woman had in fact received an injection of Syntometrine (oxytocin with ergometrine). She was recalled and given her anti-D Ig injection a week late.

Case 3: Poor decision by obstetric registrar when further administration of anti-D Ig was required

A woman presented with a bleed at 34 weeks gestation. She was discharged by the obstetric registrar who told her that no anti-D Ig was required as she had received routine antenatal anti-D Ig prophylaxis (RAADP) at 28 weeks. The woman was concerned and contacted her midwife, who arranged administration of anti-D Ig 5 days post-event.

Case 4: Failure to issue anti-D Ig cover for RhD-incompatible platelets

A 4 year old female child with acute lymphoblastic leukaemia whose group is A RhD negative was issued with RhD positive platelets. The trainee biomedical scientist (BMS) did not issue anti-D Ig as cover, even though it was clearly stated in the laboratory standard operating procedure (SOP) and clinical protocols, thus putting this child at risk of sensitisation to the D antigen and therefore compromising her future childbearing potential.

Inappropriate administration of anti-D n=63

This group is further subdivided into four categories:

1. Anti-D Ig given to RhD positive women n=28

Overall 16/28 (57.1%) errors were made by a nurse or midwife, 1/28 (3.6%) by a doctor, and 11/28 (39.3%) primary errors arose in the laboratory.

- 25/28 (89.3%) errors were made in the hospital setting, with 3 in the community
- 6/17 of the clinical cases involved incorrect transcription of blood grouping results onto notes, care plans and discharge sheets in the clinical area
- 5/11 of the laboratory errors involved failures of manual D-typing
- 6/11 of the laboratory errors involved failure to consult historical information technology (IT) records prior to issue of anti-D Ig

Case 5: Grouping report misread by doctor

A doctor looked at the blood grouping report for a woman on the Early Pregnancy Unit, misread the negative antibody screen as the RhD status, and subsequently prescribed anti-D Ig for a RhD positive woman.

Case 6: Group change following merger of patient records

Two patient records with identical names were merged in the laboratory computer, although one patient was O RhD negative, and the other was B RhD positive. The merged record showed the patient as having blood group O RhD negative, on which basis anti-D Ig was issued. The current sample from the pregnant woman was erroneously rejected as a 'wrong blood in tube' by the laboratory as it grouped as B RhD positive and was discrepant with the blood group on record.

Case 7: Catalogue of errors leads to incorrect administration of anti-D Ig

A woman told her consultant that she was RhD negative, and anti-D Ig was requested on that basis. The biomedical scientist (BMS) issued anti-D Ig even though the laboratory information management system (LIMS) record clearly showed the woman to be RhD positive, and the midwife administered the anti-D Ig, knowing the woman was RhD positive, because the consultant had prescribed it.

2. Anti-D Ig given to women with immune anti-D n=20

Of these 20 cases 6/20 (30%) resulted from a primary clinical error and 14/20 (70%) from a laboratory error.

- The majority,17/20 cases, occurred in the hospital setting, with 3/20 in the community
- Three quarters,15/20 cases, involved failure to check laboratory records or take note of grouping reports before requesting or issuing anti-D Ig

- In 4/20 cases an assumption was made in the laboratory that positive antibody screens were due to residual prophylactic anti-D Ig, even though there was a computer record of the women having immune anti-D in 3 of those cases

Case 8: Erroneous advice from the laboratory to the ward

A woman known to have immune anti-D delivered a clinically unaffected baby. The presence of maternal anti-D was confirmed, and D-typing on the baby gave discrepant results due to a 4+ direct antiglobulin test (due to maternal antibody crossing the placenta). The laboratory sent a fax to the ward indicating that the baby was RhD positive and that the woman required anti-D Ig, which was subsequently administered.

Case 9: Failure to check historical laboratory records and lack of understanding by the midwife

A biomedical scientist (BMS) was busy and failed to check computer records before issuing anti-D Ig for a woman known to have immune anti-D. The midwife assumed that because the laboratory had issued it, it should be given, citing a lack of understanding of the 'science' of anti-D. She also carried out a 'straw poll' of her midwifery colleagues that indicated every one of them would have administered the anti-D Ig because it had been issued by the laboratory.

Case 10: Failure to take heed of laboratory reports

A woman with immune anti-D was being regularly monitored, and the notes contained laboratory reports showing a steadily rising level of anti-D antibody. She presented with a bleed at 27/40 and was inappropriately administered anti-D Ig from stock held in the clinical area.

3. Anti-D Ig given erroneously to mothers of RhD negative infants n=10

All 10 of these errors originated in the laboratory in the hospital setting.

- 2/10 cases involved manual transposition of cord results before telephoning the ward
- 2/10 involved issue of anti-D Ig before cord D-typing was complete
- 3/10 involved issue of anti-D Ig without reference to cord grouping
- 3/10 involved issue of anti-D where the cord group was discrepant due to a positive direct antiglobulin test (DAT)

Case 11: Transposition of cord grouping results

A cord sample grouped as A RhD negative, but the result was transposed on the results sheet with another cord grouped as O RhD positive. Anti-D Ig was issued erroneously to the mother of the A RhD negative baby. The error was discovered in time to issue anti-D Ig within 72 hrs to the mother who had initially been told that she did not require any.

4. Anti-D Ig given to the wrong woman n=5

These were exclusively clinical errors, involving failure by nurses or midwives to identify the correct woman. Of these, 4/5 cases occurred in the hospital, and 1/5 in the community.

Case 12: Misidentification in the antenatal clinic

Routine antenatal anti-D Ig prophylaxis was administered to the wrong woman, when two women with similar 'eastern European-sounding' names were present in clinic at the same time.

Case 13: Misidentification at the GP surgery

Routine antenatal anti-D Ig prophylaxis was administered to the wrong woman, who had the same surname, and ABO group, and was at the same gestation as the intended recipient.

Wrong dose of anti-D given n=20

- 10/20 errors were made by nurses or midwives, and 10/20 errors occurred in the laboratory, 16/20 cases occurred in hospital and 3/20 in the community

- 1/20 involved an incorrect reporting of flow cytometry results as 0 mL by a Blood Service laboratory due to reagent failure

Case 14: Overestimation of transplacental haemorrhage (TPH)

A biomedical scientist (BMS) interpreted a fetomaternal haemorrhage (FMH) (Kleihauer) test as showing a TPH of 39 mL fetal cells, and the woman was administered 5000 IU anti-D Ig. On review by a senior BMS, the TPH was actually <2 mL.

Case 15: Overestimation of transplacental haemorrhage (TPH) due to high levels of haemoglobin F (HbF)

The laboratory reported a TPH of 37 mL fetal cells following a fetal death in utero (FDIU), and issued 6000 IU anti-D, which was administered. Confirmation by flow cytometry indicated a bleed of 0 mL. The woman was a beta thalassaemia carrier and had a raised level (5%) of HbF.

Learning point

- The previous two cases illustrate the difficulties in using the acid-elution (Kleihauer) test to determine transplacental haemorrhage, especially where the situation may be confused by staining of cells due to persistent HbF, and support the case for timely access to flow cytometry methodology

It may of course also be the case that the 37 mL fetal bleed reported in Case 15 represented cells from a RhD negative fetus and the count was accurate. In cases of FDIU, it is unusual to obtain a fetal blood group, and the established principle is to administer anti-D Ig regardless. However in Case 15 significantly more anti-D Ig was administered than was strictly necessary – 6000 IU was given, when a dose of 3700 IU given intravenously would have sufficed (more than covered by 3 x 1500 IU fixed-dose syringes of the IV preparation).

Case 16: Incorrect route of administration results in an inadequate dose

A woman required a large dose of anti-D Ig following a reported transplacental haemorrhage (TPH) of 100 mL fetal cells. Seven 1500 IU vials of anti-D Ig were sourced from another hospital; the dose was calculated assuming they were to be given intravenously (100 IU/mL). Due to unfamiliarity with the particular formulation of anti-D Ig in the receiving hospital, all 7 vials were administered intramuscularly (IM). Not only was this extremely uncomfortable for the woman, but it also resulted in an underdosing by 2000 IU if calculated according to recommendations for IM route of administration (125 IU/mL).

Handling and storage errors related to anti-D n=26

Some errors, 11/26 (42.3%), occurred in the clinical area and 15/26 (57.7%) were laboratory errors. Most, 20 errors, occurred in hospital, and 6 in the community. Expired anti-D Ig was given in 7/26 cases from stock held in the clinical area. The laboratory issued anti-D Ig under the incorrect batch number in 11/26 cases (10 in one incident). Anti-D Ig was stored in a clinical refrigerator that had been out of temperature control for three days in 2/26 cases.

Case 17: Inappropriate administration of anti-D Ig to a male patient

An 84 year old O RhD negative male presented in the emergency department with a gastrointestinal bleed and was given a unit of O RhD positive red cells. The duty biomedical scientist (BMS) issued a dose of anti-D Ig 'in case the patient made immune anti-D'.

Case 18: Expired anti-D Ig administered in the community

Anti-D Ig that had expired two months earlier was administered in the community antenatal setting. On investigation, it transpired that the community clinic had 15 expired doses of anti-D Ig in stock still available for issue.

COMMENTARY

Recurring themes throughout the case reports include:

- Decision making, issuing and administration of anti-D Ig without reference to blood grouping results, in both the laboratory and clinical area
- Manual transcription of blood grouping results onto notes, care plans and discharge sheets in the clinical area
- A lack of understanding of the principles behind anti-D Ig prophylaxis, compounded by availability of uncontrolled anti-D Ig stocks held by clinics
- Failure of inventory management in both laboratory and clinical area, especially in the community setting
- Failure of the post-natal discharge checklist was mentioned in 58 cases this year and early discharge was cited as a reason in many of these
- Poor advice given to women and poor decision making by doctors regarding the need for anti-D Ig following sensitising events
- The misinterpretation of FMH (Kleihauer) tests in hospital laboratories leading to errors in dosing with anti-D Ig

This year's report again highlights a number of key issues in the provision of anti-D Ig, including poor knowledge and understanding in both the laboratory and the clinical area about the use of anti-D Ig, failure to utilise computer management systems (IT) to increase the security of the process, failure to refer to current grouping and antibody screening results, manual transcription of grouping results in the clinical area, and inadequate inventory management.

The use of checklists to improve processes has been described in many different areas of practice, including surgery[66], and to this end SHOT has produced both a flowchart and checklist covering key points in the process that may be used as an aide memoire, poster or as an audit tool, and these may be found at http://www.shotuk.org/resources/current-resources/. They are of necessity generic and hospitals wishing to adapt the resources to better fit their own practice should apply to the SHOT office staff who will arrange a bespoke version including the individual trust logo and version number.

Recommendations

- Current blood grouping and antibody screen results must be referred to when making decisions whether to issue or administer anti-D Ig
- SHOT recommends the use of a flowchart or checklist reflecting national guidance to aid decision making and ensure that an appropriate dose of anti-D Ig is issued and administered
- Cases where a new immune anti-D is discovered at booking, during pregnancy or at delivery should be reported to SHOT by contacting the office (further information in Chapter 3)

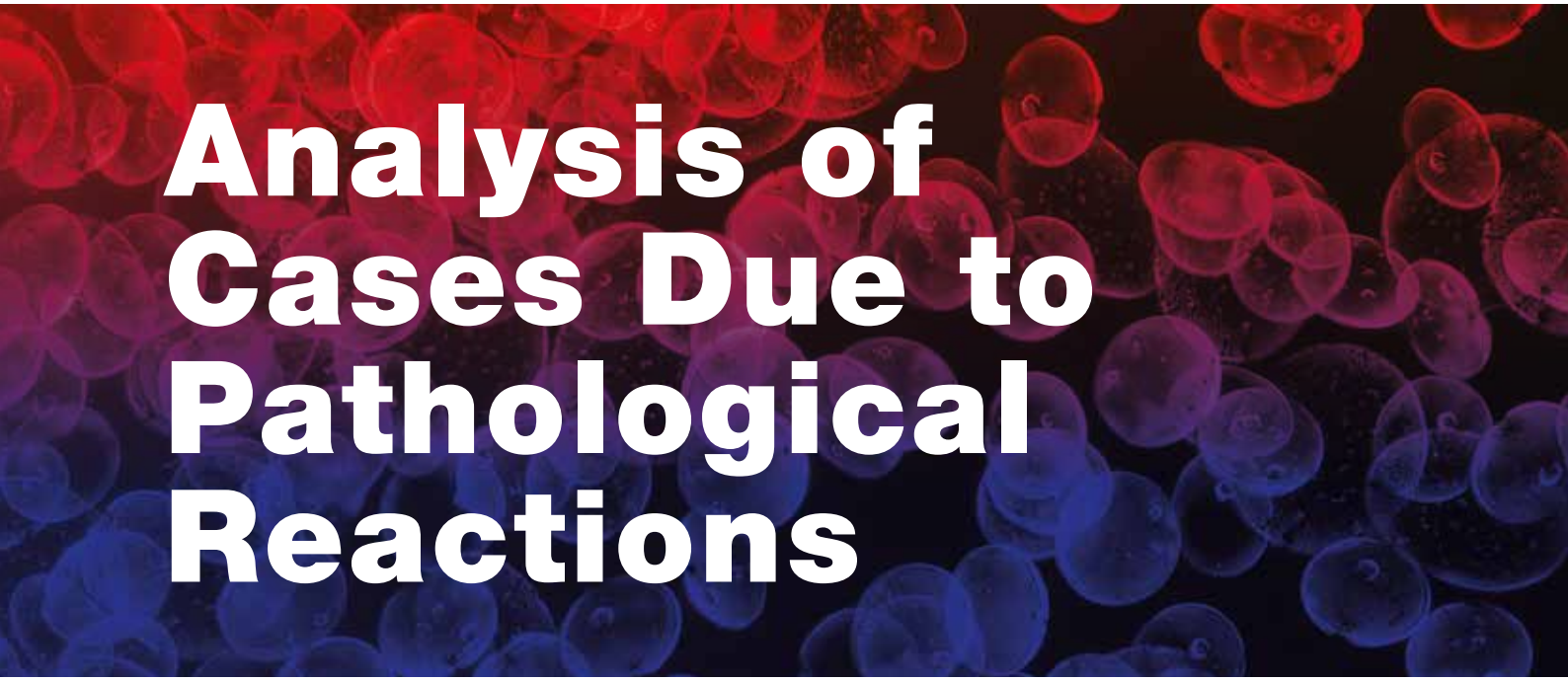
Action: Obstetric Departments, Community Midwifery Teams, Hospital Transfusion Teams (HTTs)

Repeated from last year

- Samples which in a FMH (Kleihauer) test suggests a TPH of >2 mL, or gives equivocal results, should be referred for flow cytometry at the earliest opportunity.
- Laboratories performing FMH (Kleihauer) tests must participate in an accredited EQA scheme such as the UK NEQAS FMH external quality assessment scheme

Action: Hospital Transfusion Laboratories, HTTs, Trust/Health Board Chief Executive Officers

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.



Analysis of Cases Due to Pathological Reactions

16 Acute Transfusion Reactions (ATR) (Allergic, Hypotensive and Severe Febrile)

Authors: Hazel Tinegate and Fiona Regan

Definition:

Acute transfusion reactions (ATR) 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), transfusion-associated circulatory overload (TACO), transfusion-associated dyspnoea (TAD) or those due to bacterial contamination of the component. However, the possibility that a reaction could belong to one of these serious categories must be kept in mind during recognition, initial assessment and treatment.

DATA SUMMARY
Total number of cases: 372

Implicated components		Mortality/morbidity	
Red cells	250	Deaths due to transfusion	0
FFP	29	Deaths probably/likely due to transfusion	0
Platelets	79	Deaths possibly due to transfusion	0
Cryoprecipitate	3	Major morbidity	68
Granulocytes	2	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	9		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	183	≥18 years	342	Emergency	28	Emergency department	2
Female	183	16 years to <18 years	2	Urgent	76	Theatre	17
Not known	6	1 year to <16 years	22	Routine	246	ITU/NNU/HDU/Recovery	44
		>28 days to <1 year	2	Not known	22	Wards	218
		Birth to ≤28 days	2			Delivery Ward	12
		Not known	2	In core hours	276	Postnatal	3
				Out of core hours	92	Medical Assessment Unit	17
				Not known	4	Community	3
						Outpatient/day unit	51
						Hospice	1
						Antenatal Clinic	0
						Unknown	4

A total of 372 cases have been included in the analysis. This includes 5 cases transferred from 'haemolytic transfusion reactions' (HTR), 10 from the unclassifiable group, 5 from 'transfusion-transmitted infections' (TTI), 2 from TRALI, 1 from 'incorrect blood component transfused' (IBCT), and 1 from 'right blood right patient' (RBRP). A further 11 cases with predominantly respiratory features were transferred to TAD and 14 to TACO. Twenty cases were withdrawn as the reporters subsequently attributed the clinical features to other causes. A total of 169 were classified as mild: 76 febrile, 88 allergic and 5 mixed febrile/allergic and these have now been excluded from the main analysis, according to recent SHOT guidance (see revised definitions on SHOT website[23]).

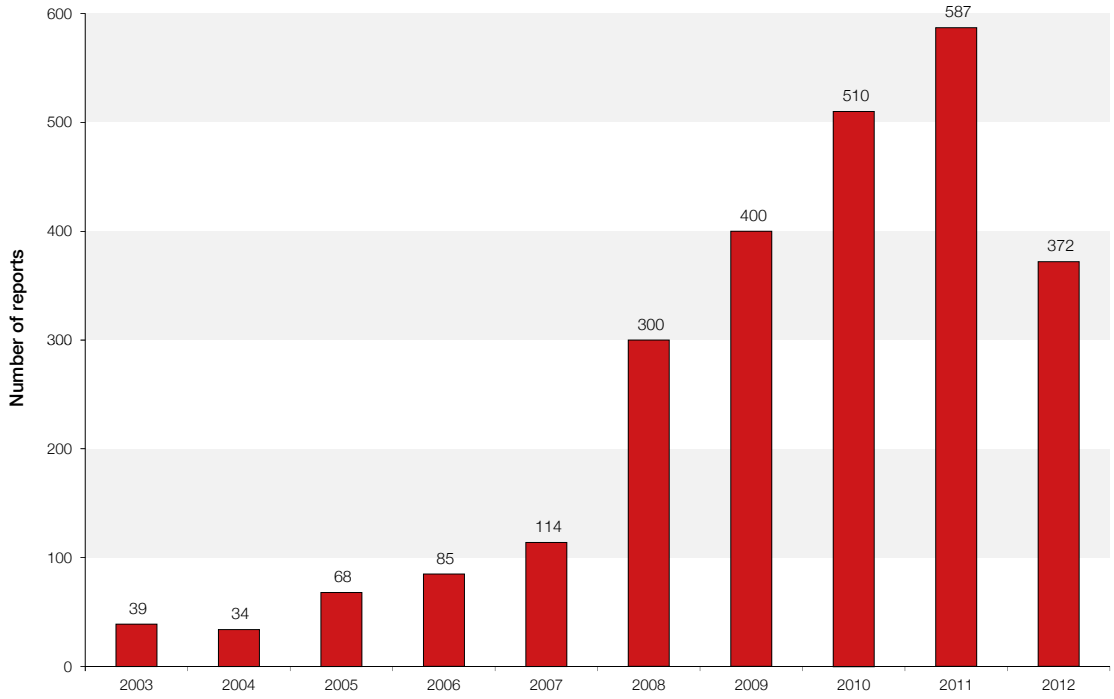


Figure 16.1: Numbers of cases of acute transfusion reactions 2003 to 2012

Introduction

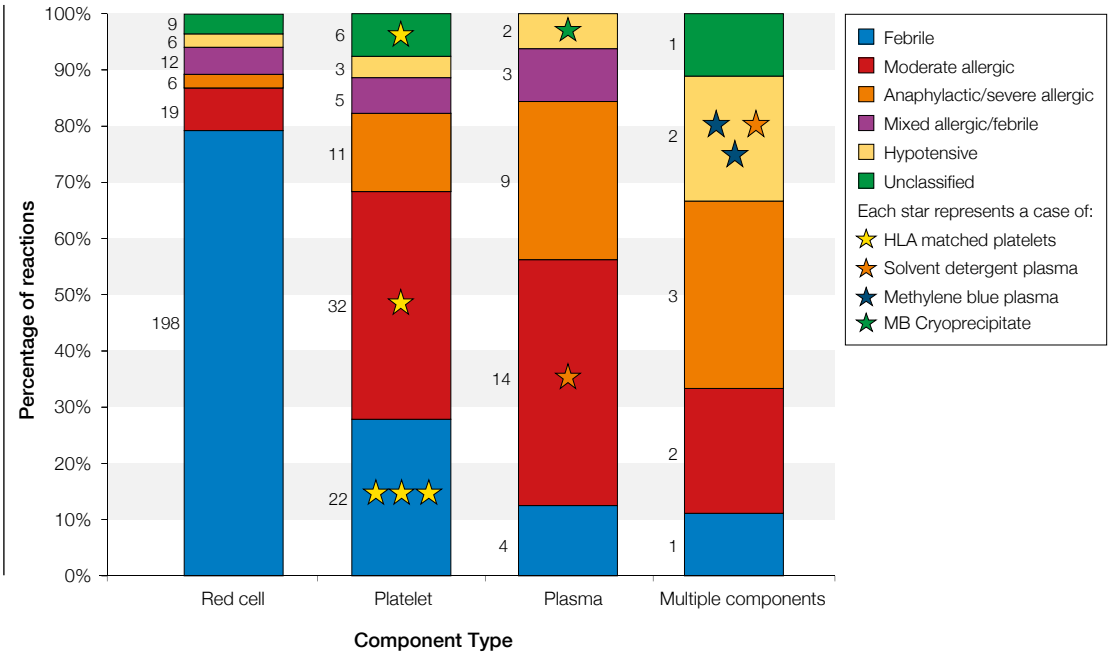
The total number of ATR cases reported has fallen slightly since last year, from 587 to 541 (including mild reactions). Withdrawal of 169 mild reactions leaves 372 for analysis. The pattern of reactions remains similar (see Figure 16.2, reactions by component type) and numbers for anaphylaxis and severe reactions are similar. Where possible, reactions have been classified according to the latest International Haemovigilance Network/International Society for Blood Transfusion (IHN/ISBT) draft definitions which have recently been published[1] and which were used in the recent British Committee for Standards in Haematology (BCSH) guideline on acute transfusion reactions[68]. As in previous years, many reactions are difficult to classify. In many cases, symptoms and signs may be due to either the patient's underlying condition or to transfusion, and this particularly appears to be the case for reactions where multiple components were given and where patients are likely to have complex clinical problems.

Types of reactions

As far as possible, reactions have been classified and the following figures obtained:

- 226 febrile (210 moderate, 16 severe)
- 97 allergic (67 moderate and 30 anaphylactic or severe allergic)
- 20 mixed allergic/febrile
- 13 hypotensive
- 16 unclassifiable

Figure 16.2: Reaction by component type



In addition to the 370 cases in this figure, there was one anaphylactic reaction to granulocytes of unspecified type and one febrile reaction to buffy coat granulocytes.

Reactions in children

There were 28 reactions in children aged less than 18, and these are covered in the Paediatric chapter (Chapter 27).

Imputability

Reporters were asked to assess imputability in the case of adverse reaction or death.

Imputability was given as:

- Certain in 14 cases (12 minor morbidity, 2 major)
- Likely/probable: in 68 (54 minor morbidity, 14 major)
- Possible: 140 (121 minor morbidity, 18 major, 1 no reaction – fever only)
- Excluded/unlikely, not assessable or left blank: 150 (134 minor morbidity, 12 major, 4 no reaction – fever only)

There are clearly many cases where reporters experience difficulty in determining whether clinical features are due to the component or other factors, in what are often complex clinical situations, as in Case 3, described in the section on severe febrile reactions.

Deaths n=0

Whilst there were 8 deaths reported in patients having ATRs, none were thought to be related to the transfusion. There was one case of anaphylaxis where the reporter stated that the patient recovered from the reaction, but later died of their underlying illness.

Severe reactions n=68

The 372 cases included 68 which were considered as having severe reactions. The IHN describes reactions as life-threatening if major intervention such as use of vasopressors or admission to intensive care is required to prevent death, or severe if the reaction requires, or prolongs, hospitalisation[1].

Reactions were classified as severe in 50 cases, according to IHN/ISBT/BCSH/SHOT guidelines (not all of which had been categorised as severe/life-threatening or associated with major morbidity by reporters). These included 30 cases of anaphylaxis an example of which is given in Case 1 below, or severe allergy, 11 severe febrile reactions, an example of which is given in the vignette below (Case 3), 7 severe hypotensive reactions and 2 mixed febrile and allergic reactions.

In addition to these 50 cases, a further 18 were included under the 'severe' heading as they fulfilled the SHOT definition of major morbidity: they either required high dependency admission and/or ventilation; or they required dialysis and/or had renal impairment (n=18). One patient was reported as needing to start dialysis but their underlying clinical condition was described as 'unstable'. Eight patients were reported as requiring transfer to the intensive therapy unit (ITU) but this included three with massive haemorrhage and two others with acute blood loss. The imputability that the transfusion had caused the reaction was reported as likely in one case, possible in 5 cases, and was not given in two cases.

These cases demonstrate that ascribing major morbidity can be difficult in acute transfusion reactions. Morbidity may be due to the underlying illness. In other cases signs and symptoms of the reaction can be severe, but they are often transient.

Of note, 29 patients were admitted from the outpatient setting, and two were admitted who had received transfusions in the community. This number includes 19 outpatients for whom the imputability that the transfusion caused the symptoms was given as 'certain' or 'likely/probable'. These cases indicate that transfusion reactions, although rarely associated with prolonged morbidity, may nevertheless have an impact on the patient and on hospital resources. Clinicians and managers who arrange for blood transfusion to take place in an out of hospital setting should follow recent guidelines to ensure appropriate policies are in place for the management of adverse incidents (http://www.transfusionguidelines.org.uk/docs/pdfs/bbt-01_sp_tx-framework-v3.pdf).

Specific types of reactions

Anaphylactic reactions n=30

Anaphylaxis is defined by the UK Resuscitation Council (UKRC) [69] and National Institute for Health & Care Excellence (NICE)[70] as: '....a severe, life-threatening, generalised or systemic hypersensitivity reaction..... characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes'.

Thirty reactions were consistent with anaphylaxis or severe allergy. Only three of these were in paediatric patients. Thirteen reactions occurred on wards, 6 in theatre, 5 in ITU, 2 in recovery, 2 in outpatients, and 1 each in delivery suite and medical admissions unit (MAU). Only 15 patients with anaphylaxis were recorded as being given adrenaline (or noradrenaline), the former stated as being the first line drug treatment in anaphylaxis by the UKRC.

Case 1: Anaphylaxis in the setting of massive obstetric haemorrhage

A young woman experienced a massive obstetric haemorrhage requiring over 30 units of red cells, 8 adult platelet doses and 12 units of plasma including solvent detergent plasma (not implicated), prothrombin complex concentrates, 6 L crystalloid and 2 L colloid. When the 12th unit of plasma was transfused during surgery, she developed sudden urticaria, dropped her mean arterial pressure to 40 mm (normal 70-110 mm) and had reduced tidal volumes and wheeze. The anaesthetist experienced difficulty giving adequate sedation due to the hypotension. The blood pressure improved with boluses of metaraminol, noradrenaline and hydrocortisone and colloids. Despite the severity of this event, the patient recovered rapidly and was able to be discharged one week later. IgA level was normal.

Moderate allergic reactions n=67

These include reactions with respiratory symptoms that are not severe enough to be termed anaphylaxis, or those with angioedema.

Hypotensive reactions n=13

Thirteen reactions were classified as being hypotensive, 7 being severe. Details of treatment were available for 6/7 who had experienced severe hypotensive reactions. Six of the reports were associated with cardiothoracic procedures, including two patients on extracorporeal membrane oxygenation (ECMO): one adult and one neonate. Six reactions occurred in ITU/high dependency unit (HDU), two in the operating theatre and one on the neonatal ward. Four occurred on general wards. Three of the severe cases involved children aged 1 year or less.

Three reactions were associated with methylene blue-treated components, plasma in two cases and cryoprecipitate in one case. The underlying condition of the patients was very severe: meningococcal septicaemia in a 1 year old child, one cardiac surgery, and one ECMO, both in neonates.

The diagnosis of a hypotensive reaction can be difficult, especially in a patient in whom haemorrhage is suspected. There was evidence of haemorrhage in only two of the cases of hypotensive reaction, including Case 2, below.

Case 2: Reaction associated with hypotension in an obstetric patient

An obstetric patient suffered a post partum haemorrhage and was transfused with red cells in theatre. Towards the end of one unit, she became faint and was noted to have mottled skin. Her diastolic blood pressure was unrecordable. As anaphylaxis was suspected, she was given adrenaline, with supplementary hydrocortisone and antihistamine: however serial mast cell tryptase measurements were normal.

Severe febrile reactions n=16

Sixteen febrile reactions were classifiable as severe: 10 cases were associated with red cell transfusion, 5 with platelet transfusions (two of which were human leucocyte antigen (HLA)-matched) and one with plasma. In contrast to last year's report, only one patient had a temperature >39°C (40°C). The additional factors which led to a classification as 'severe' were hypotension and/or hypoxia. In 7 cases, the unit was cultured. No cases of transfusion-transmitted bacterial infection were identified. Patient blood cultures were performed in 6 cases (5 patients had both unit and blood cultures). One blood culture grew coagulase negative staphylococci. Four patients had no cultures. In the majority of these cases, the patient's underlying condition may have caused the clinical features which led to the reaction being classified as severe. Case 3 demonstrates the diagnostic difficulty.

Case 3: Severe febrile symptoms during removal of retained products of conception

Two weeks after delivery, a young woman experienced heavy vaginal loss and severe abdominal pain, and was found to have retained products of conception. Her Hb was 69 g/L. She was transfused with red cells, then surgery was performed, with spinal anaesthetic. During surgery she experienced myalgia, nausea and vomiting, loin pain and flushing. Her blood pressure at one point was unrecordable. Blood or unit cultures were not performed. The reaction occurred two hours after the red cell transfusion: it cannot be determined whether the reaction was related to the red cells or to a concealed haemorrhage.

Mixed febrile/allergic reactions n=20

These included 2 severe and 18 moderate reactions. This classification was usually made because of the combination of rigors and a rash. This type of reaction was seen with approximately equal frequency with all components.

Speed of onset

The time of onset of symptoms from the start of transfusion was recorded in 155 cases. The median time was 45 minutes (range 1–270 minutes).

Management of transfusion reactions

Stopping the transfusion

In the case of a suspected transfusion reaction it is important to stop the transfusion temporarily, to confirm the identity of the component and the patient, and check for obvious contamination. In severe reactions, the component should be taken down and retained for further investigation if necessary, and venous access maintained by physiological saline. (However, clinical judgement is required in the case of hypotension in a bleeding patient, where continuation of the transfusion may be life-saving). There is no published evidence which will guide clinicians as to whether continuation of transfusions in milder reactions would be of harm. In 2012, the following actions were recorded:

- 263 reports mentioned stopping the transfusion completely
- 6 transfusions were continued then stopped as symptoms recurred or worsened
- 3 continued at same rate
- 5 continued at slower rate
- 13 were stopped temporarily for observation: it was not clear what the subsequent management was
- 65 reports stated that the transfusion had been completed already
- 17 reports did not state how the transfusion was managed

Treatment

In 253 cases the reports indicated that medication was given, in most cases in combinations of two drugs or more. Treatment for febrile reactions did differ from allergic reactions, as can be seen in Figure 16.3. Only allergic reactions received adrenaline, whilst proportionately more paracetamol was given to patients with febrile reactions. However, considerable numbers of patients in each group were given hydrocortisone. Hydrocortisone and antihistamine are recommended as having a role in second line treatment of anaphylaxis[69] but outside this clinical indication, hydrocortisone does not have a clear role.

Additional medication included antibiotics and diuretics. Of the 6 patients with severe hypotensive reactions, 4 received adrenaline and/or noradrenaline, one vasopressin and one a plasma expander. One patient classified as having anaphylaxis, and two patients with moderate febrile reactions, received pethidine.

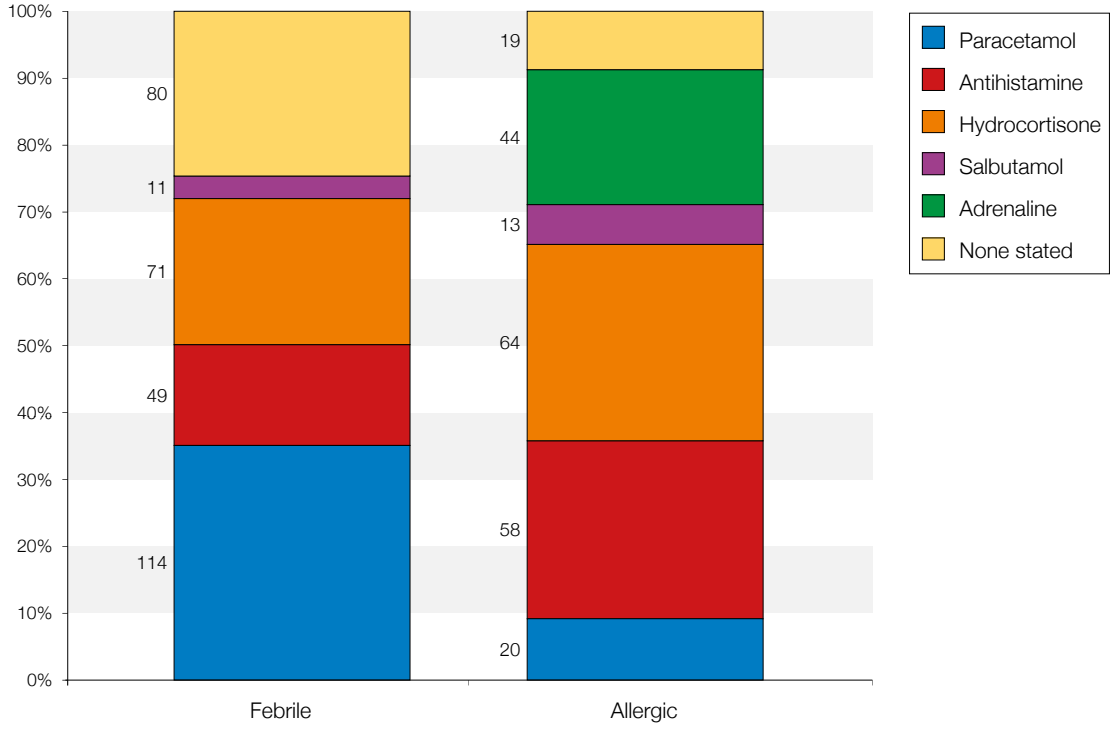


Figure 16.3: Treatments given and type of reaction. Most patients received more than one drug

Investigations

The purpose of investigations should be to contribute to patient management, for example, by excluding other causes for the patient's symptoms/signs, or by guiding management of further transfusions by identifying a likely cause for the present reaction. Data for 2012 show a positive finding: that, in many cases, investigations are directed towards the patient's presenting condition. However, there is still evidence that inappropriate testing for HLA, human platelet antigen (HPA) and granulocyte antibodies is being carried out.

Respiratory investigations

A chest X-ray was reported to have been taken in 19 cases. Three cases showed pulmonary oedema, one was consistent with infection and one showed pleural effusions. Oxygen saturations were reported as performed in 61 patients (24 allergic, 30 febrile, 5 mixed allergic/febrile and 2 other reactions) and results were given in 49 reports: saturations were low in 29 cases.

Investigations for IgA deficiency

Immunoglobulin A levels were measured in 54 patients: 22 with allergic, 19 febrile, 8 mixed allergic/febrile, 3 hypotensive and 2 other reactions. Four patients were reported to have very low levels. One had anti IgA antibodies at a high titre of 1280, two had low titre antibodies and one had none. All had received red cells: the patient with high titre anti IgA antibodies experienced anaphylaxis, another case had a severe febrile reaction, one a moderate febrile reaction and one a mixed allergic/febrile reaction. IgA deficiency has not been described as being associated with febrile reactions, but rather with anaphylaxis. It is not known whether the IgA deficiency was implicated in the three patients' reactions that were not anaphylaxis.

Immunologists define IgA deficiency as an IgA level <0.07 g/L, in the presence of normal levels of other immunoglobulins, in patients aged 4 years or more. It may form part of the spectrum of common variable immunodeficiency. Severe allergic transfusion reactions have been linked to severe IgA deficiency, <0.0016 g/L, often in the presence of anti-IgA antibodies. In practice, about 1 in 500 of the UK population have a level as low as this, and 25% of people with very low IgA levels also have anti IgA antibodies[71]. IgA levels are now frequently measured as part of the investigation of coeliac disease and other auto-immune diseases and, in the absence of a history of transfusion reactions, even a very low level is not considered to be a risk factor for reactions[72].

Mast cell tryptase

There were only two reports showing a slight 'rise and fall pattern': one in a patient with anaphylaxis and one with a moderate allergic reaction. Several reports contained only one elevated result, and in one case three serial results were moderately high, a situation often seen with chronic pruritus, which did not seem to be the case in this patient. Mast cell tryptase testing is not routinely required, but if needed because the clinical diagnosis of anaphylaxis is in doubt, to be of value, serial mast cell tryptase levels are needed: a single result is of little diagnostic value.

HLA/HPA/granulocyte antibodies

Twenty one patients were tested for HLA antibodies (8 after red cell transfusion, 12 after platelets including 3 receiving HLA-matched platelets, and one after plasma transfusion) and antibodies were detected in 9 cases. A further 6 had HPA antibodies tested including one patient who was also tested for granulocyte antibodies. These investigations are rarely indicated in investigation of ATRs, unless there is evidence of platelet refractoriness or in rare reactions associated with sudden onset of neutropenia or thrombocytopenia[68].

Investigations to exclude bacterial contamination

Despite the fact that there have been no cases of bacterial transfusion-transmitted infection of blood components reported by the UK Blood Services in the last three years (including 2012), bacterial contamination should remain part of the differential diagnosis to consider when a patient presents with marked rise in temperature or severe rigors, especially when there is evidence of hypoxia, hypotension

or shock. Patient blood cultures were performed in 154 cases, the majority having febrile reactions (112 cases). These were positive in 23 instances: 20 febrile, 1 allergic and 2 'other' reactions.

In 146 reports the unit was cultured: in 98 cases by the hospital laboratory and in 41 cases by the Blood Service (and unknown in 7 cases). Although information is not available from the reports, in the experience of the authors, sometimes initial hospital cultures of the unit have been positive but negative on re-testing by Blood Services, and the initial positive finding was thought to be due to contamination on culturing. In this group of 146 reports of units cultured, the investigation was not always appropriate, for example, there were 16 pack cultures for moderate allergic reactions and 11 for severe allergic/anaphylaxis. Seven packs associated with severe febrile reactions were not cultured, although it probably would have been appropriate to do so.

Learning point

- Where appropriate, units causing reactions that could be a result of bacterial contamination should be sent for microbiological culture. In such instances the reaction must be discussed with a Blood Service consultant in case a recall of associated components is required (see also Chapter 21, Transfusion-Transmitted Infections)

Reactions to methylene blue-treated plasma components (MB-FFP or cryoprecipitate) or solvent detergent-treated plasma (SD-FFP) n=4 patients in total

Methylene blue-treated components

There were three reactions: one severe hypotensive reaction in a neonate who was given methylene blue-treated cryoprecipitate immediately post cardiac surgery. She then received SD-FFP without problems. Another neonate, who experienced bleeding whilst undergoing ECMO, also experienced a severe hypotensive reaction shortly after receiving MB-FFP and a unit of platelets. The imputability was given by the reporter as low. A 1 year old child with meningococcal septicaemia had hypotensive reactions to MB-FFP as well as to platelets and SD-FFP. Investigations as to the cause are still continuing. IgA level was normal.

Solvent detergent plasma

In addition to the reaction in the 1 year old patient described above, there was also a moderate allergic reaction in a young woman undergoing plasma exchange for haemolytic uraemic syndrome.

COMMENTARY

Despite removing mild cases from analysis, the pattern of reactions according to components appears similar to previous years.

Reactions to MB-FFP are unusual, and not increased compared to standard FFP[73] but when they do occur, appear to be severe and associated with hypotension.

Historically, hypotensive reactions are stated to be more common in patients on angiotensin converting enzyme (ACE)-inhibitors and in patients with abnormal bradykinin metabolism[74,75].

SHOT data suggest that hypotensive reactions frequently occur during or shortly after cardiac bypass procedures. The factors surrounding these reactions should be examined more closely.

Recommendations

- Transfusions should only be performed where there are facilities to recognise and treat anaphylaxis, according to UK Resuscitation Council (UKRC) guidelines[69,76]. This recommendation is also relevant for other transfusion-related emergencies such as respiratory distress caused by transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI). In supplying to community hospitals or for home transfusions, providers must ensure that staff caring for patients have the competency and facilities to deal with adverse incidents. This is particularly relevant in the light of proposed increase in treatment of patients outside the secondary care setting

Action: Hospital Transfusion Teams (HTT), General Practitioners

- In anaphylaxis, mast cell tryptase testing is not routinely required, but if needed because the clinical diagnosis of anaphylaxis is in doubt, to be of value, serial mast cell tryptase levels are needed: a single result is of little diagnostic value

Action: HTT

- Mild acute transfusion reactions (ATRs) as defined by International Haemovigilance Network/ International Society for Blood Transfusion (IHN/ISBT) (i.e. fever ≥38°C and a rise of 1–2°C from pre-transfusion values, but no other symptoms; or transient flushing, urticaria or rash) should not be reported to SHOT

Action: Reporters, HTT

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Haemolytic Transfusion Reactions (HTR) 17

Author: Clare Milkins

Definition:

Acute haemolytic transfusion reactions (AHTRs) are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; confirmed by one or more of the following: a fall of Hb, rise in lactate dehydrogenase (LDH), positive direct antiglobulin test (DAT), positive crossmatch.

Delayed haemolytic transfusion reactions (DHTRs) are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion; confirmed by one or more of the following: a fall in Hb or failure of increment, rise in bilirubin, incompatible crossmatch not detectable pre-transfusion.

NB – Simple serological reactions (development of antibody with or without a positive DAT but without clinical or laboratory evidence of haemolysis) may be reported in the Alloimmunisation category.

DATA SUMMARY
Total number of cases: 42

Implicated components		Mortality/morbidity	
Red cells	42	Deaths due to transfusion	0
FFP	0	Deaths probably/likely due to transfusion	1
Platelets	0	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	9
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Multiple components	0		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	14	≥18 years	42	Emergency	3	Emergency department	1
Female	28	16 years to <18 years	0	Urgent	13	Theatre	3
Not known	0	1 year to <16 years	0	Routine	25	ITU/NNU/HDU/Recovery	5
		>28 days to <1 year	0	Not known	1	Wards	21
		Birth to ≤28 days	0			Delivery Ward	1
		Not known	0	In core hours	0	Postnatal	1
				Out of core hours	0	Medical Assessment Unit	6
				Not known/Not applicable	42	Community	0
						Outpatient/day unit	4
						Hospice	0
						Antenatal Clinic	0

A total of 42 cases are described, 9 acute and 33 delayed. In addition, 20 cases were reported as HTRs but transferred to other categories, including incorrect blood component transfused (IBCT), specific requirements not met (SRNM), acute transfusion reactions (ATR), alloimmunisation and unclassifiable complications of transfusion (UCT), and another was withdrawn. One of the transferred cases was a death related to a severe acute haemolytic transfusion reaction following high dose intravenous immunoglobulin (IVIg), and this is described fully in Chapter 23 rather than here, as IVIg is a blood product rather than a component. In some cases there is an overlap between SRNM and HTR.

One case was transferred to HTR from SRNM as the patient suffered significant morbidity, so it is included in the numbers for this chapter.

Age range and median

All reports were in adult patients, with an age range of 23 to 88 years and a median of 61.5 years.

Deaths n=1

There was one case where the haemolytic transfusion reaction contributed to the patient's death:

Case 1: Death following a delayed and acute reaction due to anti-Jk^a

An elderly patient with myelodysplastic syndrome (MDS) and persistent sepsis and hypotension became jaundiced and was transferred to the intensive therapy unit (ITU), where she subsequently died. The patient had received a two-unit transfusion 8 days earlier, when no antibodies were detected. Pre-transfusion testing on the current sample, showed panagglutinins by Capture-R®, and anti-Fy^a plus a couple of additional weak reactions by Bio-Rad, with a positive direct antiglobulin test (DAT). The two units issued were crossmatch-compatible Fy(a–). The post-transfusion sample demonstrated anti-Jk^a in addition to anti-Fy^a, but the eluate was non-reactive. The patient's bilirubin rose from 55 to 174 micromol/L post the most recent transfusion and the Hb fell by 20 g/L to the pre-transfusion level.

Jk^a types were not available on any of the units transfused, nor Fy^a types on the initial units transfused. This patient was probably having a delayed haemolytic reaction to anti-Fy^a, anti-Jk^a or both, from the transfusion 8 days earlier, and possibly an acute haemolytic reaction due to anti-Jk^a. Although the delayed reaction could not have been prevented, subsequent transfusion of Jk^a untyped units might have been avoided, and the acute reaction subsequently prevented. If a delayed reaction had been suspected and more extensive serology undertaken, the anti-Jk^a would probably have been identified, by using an enzyme indirect antiglobulin test (IAT) panel and testing an eluate before issuing crossmatch-compatible units. Although the patient was very sick, the reporter felt that the reaction probably contributed to the patient's death.

Learning points

- Anti-Jk^a is often only weakly detectable and more sensitive techniques such as enzyme indirect antiglobulin test (IAT) may be required for detection or identification
- If weak, apparently non-specific reactions are detected, particularly post transfusion, additional techniques should be undertaken to elucidate all the antibodies present. Unless appropriate validated in-house techniques are available, samples will need to be referred to a red cell reference laboratory

Major morbidity n=9

There were 9 cases of major morbidity, 2 relating to acute and 7 to delayed reactions. Overall, 4 involved renal impairment, 3 required ITU admission (including one case of hyperhaemolysis), and two further cases of hyperhaemolysis involved a life-threatening drop in Hb. Five of the 9 were patients with sickle cell disease, which are discussed in further detail in the Haemoglobinopathy chapter (Chapter 28). Three cases of particular interest are described below.

Case 2: Major morbidity possibly due to hyperhaemolysis

A patient received 2 units of red cells following a miscarriage. Two weeks later, she was admitted with anaemia and infection. During a second unit of red cells, the patient developed a tachycardia, became febrile and hypertensive, and went on to develop acute renal impairment with a creatinine of 351 micromol/L. The post-transfusion sample was haemolysed and the direct antiglobulin test (DAT) was positive but the antibody screen was negative. The bilirubin rose from normal to 252 micromol/L and the lactate dehydrogenase (LDH) rose to 2248 IU/L. The Hb fell from 68 g/L pre transfusion to 59 g/L post transfusion. Although the patient had human leucocyte antigen (HLA) antibodies, no red cell antibodies were identified by the Blood Service reference laboratory using a whole range of techniques. The conclusion of the reporter is that, although rarely reported other than in patients with sickle cell disease, this is a case of hyperhaemolysis.

Case 3: Major morbidity due to anti-Wr^a

A patient with myelodysplastic syndrome (MDS) had diarrhoea, vomiting and hypotension 100 mL into a red cell transfusion on the day unit, and subsequently became jaundiced. She was moved to resuscitation and then to the intensive therapy unit (ITU). The bilirubin rose from 6 to 29 micromol/L suggesting haemolysis and there was some evidence of disseminated intravascular coagulation (DIC). Anti-Wr^a was identified in the pre- and post-transfusion samples, and the donation was confirmed to be Wr(a+), but the DAT was negative. The units of blood had been issued electronically following a negative antibody screen.

Case 4: Major morbidity not recognised as a delayed haemolytic transfusion reaction (DHTR)

A patient with an Hb of 82 g/L required a pre-operative transfusion. The Blood Service reference laboratory identified anti-Jk^a+S+ce and a positive DAT and provided antigen-negative crossmatch-compatible red cells. The patient spiked a temperature during the transfusion and 2 days later developed signs of haemolysis, including a raised bilirubin and lactate dehydrogenase (LDH) and increasing renal impairment. A transfusion reaction investigation did not demonstrate any additional alloantibodies and the DAT was still 1+ positive, but an eluate was not tested. Although this was initially reported as an acute HTR, it was subsequently concluded that this was not due to red cell immune haemolysis. However, the reporter did not consider that a transfusion given 14 days earlier might have been implicated in the reaction. On that occasion, the DAT was still positive but only anti-Jk^a was detected; both of the transfused units were S positive, and it is likely that this is a case of DHTR due to anti-S.

Learning point

- Delayed haemolytic transfusion reactions commonly occur up to at least 14 days after a transfusion, and the most recent transfusion may not be the cause of a haemolytic reaction. An eluate made from the patient's post-transfusion red cells, might have revealed the presence of the causative antibody, and should have been tested even though the pre-transfusion direct antiglobulin test (DAT) was also positive

Clinical signs and symptoms

Acute haemolytic transfusion reactions n=9

Table 17.1: Details of cases with acute haemolytic reactions

Antibody	Clinical signs	Indicators of haemolysis	Morbidity and imputability
Anti-Jk^a	Hypotension, jaundice	bilirubin↑;Hb↓	ITU admission and death. Probably contributory
Anti-Wr^a	Rigors, fever and hypertension	bilirubin↑;no Hb increment	Probable
Anti-E?	Chills, rigors; hypertension; low O2 sats	bilirubin↑;Hb↓; Hburia; slightly haemolysed plasma	Full recovery. Certain
None (hyperhaemolysis)	Tachycardia, fever, hypertension	bilirubin↑;Hb↓; haemolysed plasma; LDH↑; creatinine↑	Acute renal impairment with full recovery. Certain
Enzyme-only anti-E	Back pain, chest pain, pyrexia, jaundice	bilirubin↑;Hb↓; red urine; LDH↑	Full recovery. Probable
Autoantibody	Pyrexia, nausea, chest pain, rigors	bilirubin↑;Hb did not increment as expected	Full recovery. Probable
Anti-Wr^a	Diarrhoea, vomiting, hypotension, jaundice	bilirubin↑;evidence of DIC	ITU admission with full recovery. Probable
Unspecified antibody to low frequency antigen	Back pain and vomiting	bilirubin↑;	Full recovery. Possible
?auto	Fever	No Hb increment	Full recovery

Delayed haemolytic transfusion reactions n=33

Table 17.2: Serology, laboratory signs and timing of reaction – This table is available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Summary of the causes of the serological findings

Acute

There were three cases where an antibody to a low incidence antigen caused the acute reaction, following transfusion with red cells matched by electronic issue: two anti-Wr^a and one unspecified.

An enzyme-only anti-E caused an acute reaction, following transfusion of 3 units of E positive red cells; there were clear signs of haemolysis, including jaundice, red urine, raised bilirubin and LDH, and a fall in Hb. The patient also suffered back pain, chest pain and pyrexia, and may also have been experiencing a delayed reaction to 2 units of E positive red cells transfused 10 days earlier.

As described earlier, anti-Jk^a was implicated in one case (Case1).

The cause of the remaining reactions is less clear-cut. In one case anti-E was detected post transfusion reaction, but the patient had a reaction a few days later to E negative units, when a weak cold autoantibody was also detected. Further transfusions of E negative red cells given through a blood warmer were tolerated.

No alloantibodies were identified in the remaining cases. One was thought to be due to hyperhaemolysis as described above (Case 2), and another two, to autohaemolysis.

Antibody specificity by blood group system and antigen	No. cases	No. cases where this was the sole new antibody
Kidd		
Jk^a	15	8
Jk^b	5	2
Rh		
E	8	1
c	4	1
C	2	0
C^w	1	0
ce (f)	1	0
Duffy		
Fy^a	4	1
Fy^b	1	1
Fy3	1	1
Kell		
K	4	2
MNS		
M	1	0
S	4	1
U	1	0

Table 17.3: Delayed HTR – specificity of antibody

There were 5 cases where the alloantibodies were not fully identifiable using standard IAT techniques:

Case 5: Transformation from auto to alloantibodies only detectable in different phases

A patient with multiple myeloma had weak panagglutinating autoantibodies by Bio-Rad (but negative in tube), and a 1+ positive DAT (IgA coating only). The Blood Service reference laboratory provided compatible red cells on 4 occasions over the course of 10 days. By this time the DAT was 1+ with anti-IgG and 3+ with anti-IgA. The antibody screen became negative by Bio-Rad, the DAT became more strongly positive, and the hospital provided crossmatch compatible red cells on 3 further occasions. Seventeen days after presentation, the antibody screen was again positive and samples were referred back to the reference laboratory. Anti-Fy^a was detected in the plasma and eluate, anti-Jk^a was detected in the plasma but only by an enzyme indirect antiglobulin test (IAT), and anti-E was detected by enzyme only. The patient only started to have the expected increment in Hb once antigen-negative red cells were transfused.

This case is interesting in that the panagglutinins, which were only detectable in the column technology, disappeared and the IgA coating on the red cells was replaced by IgG and C3d over the course of two weeks. There is no way of knowing for sure, but had an eluate been tested during the time when the DAT first became positive by IgG it might have revealed an alloantibody sooner.

Case 6: Anti-S identifiable only in an eluate

A patient with known anti-Fy^a, presented 10 days post transfusion with signs of haemolysis. The direct antiglobulin test (DAT) showed a mixed field and an enzyme-only anti-D plus ?anti-Jk^a were initially identified in the plasma. However, subsequent testing revealed anti-S in the eluate, and anti-Jk^a was excluded.

Case 7: A range of techniques required

A patient was admitted 7 days post transfusion with jaundice and a low Hb and generally unwell. Anti-Jk^b was identified in the plasma and the DAT was positive. The Blood Service reference laboratory confirmed the presence of anti-Jk^b in the plasma and in an eluate, but also identified an enzyme-only anti-E and anti-S by polybrene IAT.

Case 8: Anti-Jk^a not detectable by IAT

A patient showed signs of haemolysis 4 days post transfusion and the DAT was positive. The Blood Service reference laboratory identified anti-Jk^a in the plasma by enzyme only, as well as an enzyme autoantibody. The eluate was negative.

Case 9: Haemolysis started several days before antibodies detectable by IAT

A very sick patient in critical care received transfusion on 5 occasions over 10 days before the antibody screen became positive and anti-Jk^a, anti-E and anti–M were identified by IAT, and the eluate was weakly positive, probably due to anti-M. However, the patient's bilirubin was rising and had peaked 5 days earlier, and the DAT was noted to be positive 4 days earlier (2+ IgG coating). Retrospective testing demonstrated anti-E by enzyme techniques on the same day that the DAT was noted to be positive.

It is quite possible that the patient was having a DHTR several days before the antibody screen became positive. The patient was very sick with signs of DIC and multiorgan failure and a DHTR was not considered as a possible cause of the positive DAT. Had an eluate and more sensitive techniques been used when the DAT became positive, the developing antibodies might have been identified earlier, and antigen-negative blood provided.

Learning points

- When new alloantibodies are developing in response to a transfusion, they are sometimes only detectable in an eluate made from the patient's red cells, because the available antibody is all attached to the transfused antigen-positive red cells
- Kidd antibodies and other newly developing antibodies may only be weakly detectable, and more sensitive techniques are required to ensure that all specificities have been identified. This may require referral to a red cell reference laboratory

Direct antiglobulin tests (DAT) and eluates

Overall, an eluate made from the patient's red cells was tested as part of the investigation in 19/33 (57.6%) cases of delayed HTRs. In 9/19 cases a specific antibody was identified, including one case where the antibody was only identified in the eluate and not the plasma. The majority were undertaken by a Blood Service reference laboratory. In 1/33 case it was not possible to establish whether an eluate had been performed or not.

Of the 13/33 cases where an eluate was not tested, the DAT was negative in 3 cases, in 2 cases was positive with anti-C3d only, and there were insufficient cells available in another. There seems to be some difference in practice between Blood Service reference laboratories regarding the use of eluates, depending on whether the DAT is positive for IgG and on the strength of reaction. Eluates should definitely have been tested in the remaining 7/13 cases. There were 3 instances where a sample was referred to the Blood Service reference laboratory for antibody investigation, but no indication was given that the patient had been recently transfused and that this was part of an HTR investigation (including one case where the DAT was negative). In a further 3 cases, in-house testing did not include an eluate and samples were not referred for further testing. There were 2/7 cases where the DAT was positive with anti-IgG (weakly in one case), but the reference laboratory did not test an eluate.

Learning point

- A positive direct antiglobulin test in a post-transfusion patient should be investigated and an eluate made and tested, as this may be the only way to identify the causative antibody

Timing of reaction

Acute

Four of the reactions occurred during transfusion of red cells, and 5 within 24 hours of transfusion.

Delayed

The delayed reactions were detected between 2 and 35 days of transfusion, with a median of 9 days. In some cases the patient received transfusion over several days and it is not clear which red cell unit was implicated in the reaction; where this is the case the shorter time period has been used in Figure 17.1 and to calculate the median.

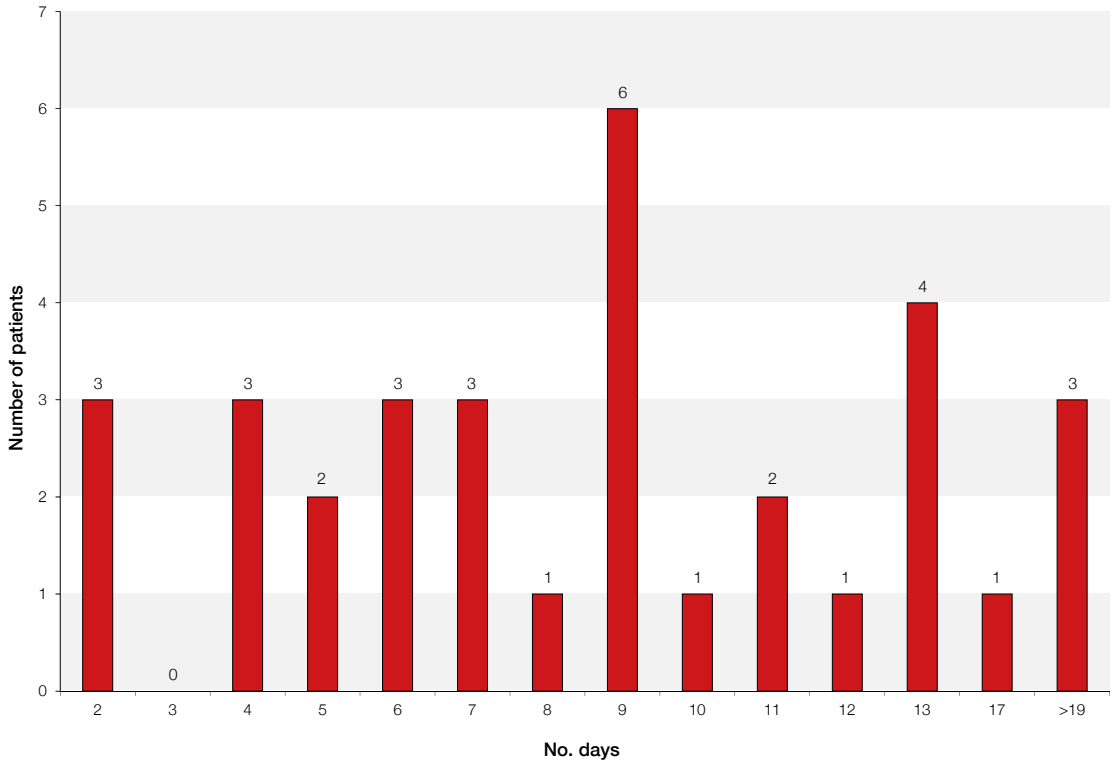


Figure 17.1: Time between transfusion and recognition of the reaction

Technology used and retrospective testing

Pre-transfusion testing was undertaken using automated techniques in 35/38 cases (92.1%) across the range of different IAT technologies. Electronic issue was used in 15/29 (51.7%) of cases where the antibody screen was negative and the question was answered when reporting to SHOT. This pattern reflects what would be expected based on standard practice data collected through United Kingdom National External Quality Assessment Service (UK NEQAS) questionnaires.

Retrospective testing of the pre-transfusion sample was undertaken in 12/33 cases of DHTR (36.4%) as the pre-transfusion sample was unavailable in the majority of cases. Reporters stated that in 3/12 cases they obtained different results retrospectively but no details were provided.

COMMENTARY

The majority of DHTRs are not preventable because the antibody is not detectable in the pre-transfusion sample. However, better communications between different hospitals and between hospitals and Blood Service reference laboratories could help identify patients with known antibodies which are no longer detectable, and thereby prevent some HTRs. Hospital laboratories are encouraged to participate in NHSBT's new Sp-ICE initiative to share information on patients' antibodies.

Signs of an HTR can be overlooked, particularly in very sick patients, and laboratory indicators of haemolysis should be looked for when a recently transfused patient develops a positive DAT or apparent non-specific reactions by IAT. Where signs of haemolysis are apparent, full investigation of weak reactions, using additional and more sensitive techniques, could help prevent both acute and further DHTRs.

Kidd antibodies are once again the most commonly implicated specificity in DHTRs, accounting for 10/18 (55.6%) of cases where a single new antibody was the cause of the reaction. Kidd antibodies are often difficult to identify, sometimes only reacting with cells bearing homozygous expression of the antigen, or by a more sensitive technique, such as an IAT using enzyme-treated cells.

This year, there were 3 cases of acute haemolytic reactions in patients with antibodies to low incidence antigens, not detected because the antigen is not present on the screening cells, and blood is provided by electronic issue. This is a known, but accepted small risk of electronic issue.

Sickle cell patients were once again overrepresented in the DHTR cases, with 7 cases reported, 5 of whom suffered major morbidity. Two of these could have been prevented had appropriately phenotyped blood been selected and there is further discussion of these cases in the Haemoglobinopathy chapter (Chapter 28).

An eluate made from the patient's post transfusion red cells was tested for antibodies in 19/33 DHTR cases; this represents 65% of those cases where the DAT was positive and there were sufficient cells for testing. Again, there was one case this year, where the causative antibody was only identifable in the eluate, demonstrating how important it is to include this test as part of the investigation of an HTR. There were 3 cases where the reference laboratory did not test an eluate because they were unaware that the patient had been recently transfused. British Committee for Standards in Haematology (BCSH) guidelines recommend that an eluate is tested for the presence of specific antibodies in all patients with a positive DAT who have been transfused within the previous month[35].

Recommendation

- Hospital transfusion laboratories should ensure that an eluate is tested as part of the investigation of a haemolytic transfusion reaction (HTR); this may necessitate referring samples to a red cell reference laboratory

Action: Hospital Transfusion Laboratory Managers

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Alloimmunisation (ALLO) 18

Author: Clare Milkins

Definition:

Alloimmunisation is defined as demonstration of clinically significant red cell antibodies after transfusion, which were previously absent (as far as is known), when there are no clinical or laboratory signs of haemolysis. This is an optional reporting category.

DATA SUMMARY Total number of cases: 69							
Implicated components				**Mortality/morbidity**			
Red cells			67	Deaths due to transfusion			0
FFP			1	Deaths probably/likely due to transfusion			0
Platelets			1	Deaths possibly due to transfusion			0
Cryoprecipitate			0	Major morbidity			0
Granulocytes			0	Potential for major morbidity (Anti-D or K only)			0
Anti-D Ig			0				
Multiple components			0				
Unknown			0				
Gender		**Age**		**Emergency vs. routine and core hours vs. out of core hours**		**Where transfusion took place**	
Male	38	≥18 years	68	Emergency	0	Emergency department	0
Female	29	16 years to <18 years	1	Urgent	0	Theatre	0
Not known	2	1 year to <16 years	0	Routine	0	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	69	Wards	0
		Birth to ≤28 days	0			Delivery Ward	0
		Not known	0	In core hours	0	Postnatal	0
				Out of core hours	0	Medical Assessment Unit	0
				Not known/Not applicable	69	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Not applicable	69

There are 69 cases, including 8 transferred from 'haemolytic transfusion reactions'. This is the first time that alloimmunisation has been reported in a separate chapter, as the definition of haemolytic transfusion reaction has now changed to exclude patients who develop a new antibody and a positive direct antiglobulin test post transfusion, but show no clinical signs of a reaction or any laboratory signs of haemolysis.

Age of patients: Patients ranged from 17 to 92 years, with a median of 71 years.

Specificity of new antibodies identified post transfusion

Table 18.1 shows these in order of how commonly they were identified, rather than by blood group system. The definition states that antibodies should be of clinical significance, and some of those reported have been classed as 'unlikely to be of clinical significance'[35], e.g. anti-Le^a and anti-Lu^a, and others as of no clinical significance, e.g. anti-Chido. However, as there is no absolute definition of clinical significance they have all been included.

Table 18.1: Specificity of new antibodies

Specificity	No. cases
E	18
K	11
Mixture including Rh	8 (2 also included Jk^a)
Jk^a	7
c (+/- E)	4
Fy^a	4
D	3
Lu^a	3
C	2
C^w, e, ce(f), Le^a, M, Jk^b, S, Chido	1 of each
Other mixture	1

Development of anti-D

Six adult male patients made anti-D, 3 as a single antibody and 3 in combination with other Rh antibodies. Four had received RhD positive red cells, two in urgent situations and two as routine. The fifth patient had been transfused with RhD positive platelets in a routine situation; this and one of those receiving RhD positive red cells were haematology patients. The sixth is interesting, in that the patient only received fresh frozen plasma (FFP), with anti-D being detected 8 days post transfusion, indicating an anamnestic immune response.

Interval between the transfusion and detection of new antibodies

The time intervals reported ranged from 3 days to weeks, months or even years.

COMMENTARY

This is a voluntary and relatively new reporting category, so the number of reports is quite low. However, it is notable that the profile of the antibodies identified differs from those reported in the 'delayed haemolytic transfusion reaction' (DHTR) category. The majority of antibodies causing DHTRs were anti-Jk^a, whereas the vast majority in this chapter are anti-E and anti-K, reflecting the higher clinical significance of Kidd antibodies.

By definition, none of these patients suffered any morbidity and the production of alloantibodies is in most cases unavoidable. However, British Committee for Standards in Haematology (BCSH) guidelines for pre-transfusion compatibility testing[35] suggest that transfusion-dependent RhD negative male patients should receive RhD negative red cells. No diagnosis was provided for the 2 haematology patients who made anti-D, but one of them was transfused for chronic anaemia, and it may be that it would have been more appropriate for these two patients to have received RhD negative red cell components. Where RhD positive platelets are the only option for timely therapy in such patients, consideration should be given to administering prophylactic anti-D to prevent sensitisation.

It is extremely rare for FFP to be implicated in a red cell immune response, although not unknown[77,78]. The patient who made anti-D following transfusion of RhD positive FFP had received a red cell transfusion 30 years earlier, which presumably caused primary sensitisation to the D antigen. The other case reports referenced also point to secondary rather than primary immunisation. Following a review of the evidence and risks, Joint United Kingdom Blood Transfusion Services/Health Protection Agency Professional Advisory Committee (JPAC) recommended in 1995 that all types of FFP produced by the UK Blood Transfusion Services (UKBTS) can be transfused without regard to RhD type, supporting the recommendations made by the BCSH[61]. Even in females of childbearing potential, the risk of harm is extremely low, as this group of patients would avoid primary sensitisation from transfusion through the provision of RhD negative red cell components.

19 Post Transfusion Purpura (PTP)

Author: Catherine Chapman

Definition:

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

DATA SUMMARY Total number of cases: 1							
Implicated components				**Mortality/morbidity**			
Red cells		0		Deaths due to transfusion		0	
FFP		0		Deaths probably/likely due to transfusion		0	
Platelets		1		Deaths possibly due to transfusion		0	
Cryoprecipitate		0		Major morbidity		0	
Granulocytes		0		Potential for major morbidity (Anti-D or K only)		0	
Anti-D Ig		0					
Multiple components		0					
Unknown		0					
Gender		**Age**		**Emergency vs. routine and core hours vs. out of core hours**		**Where transfusion took place**	
Male	0	≥18 years	1	Emergency	0	Emergency department	0
Female	1	16 years to <18 years	0	Urgent	0	Theatre	0
Not known	0	1 year to <16 years	0	Routine	0	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not applicable	1	Wards	0
		Birth to ≤28 days	0			Delivery Ward	0
		Not known	0	In core hours	0	Postnatal	0
				Out of core hours	0	Medical Assessment Unit	0
				Not known/Not applicable	1	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Not applicable	1

One case of PTP was reported this year. Reports of three suspected cases were initially submitted but two of these were withdrawn because patient HPA antibodies had been excluded. This compares with 2 confirmed cases last year. This year's case followed platelet transfusion rather than red cells and the SHOT definition has now been updated to include such cases.

Cumulative data 1996 to 2012

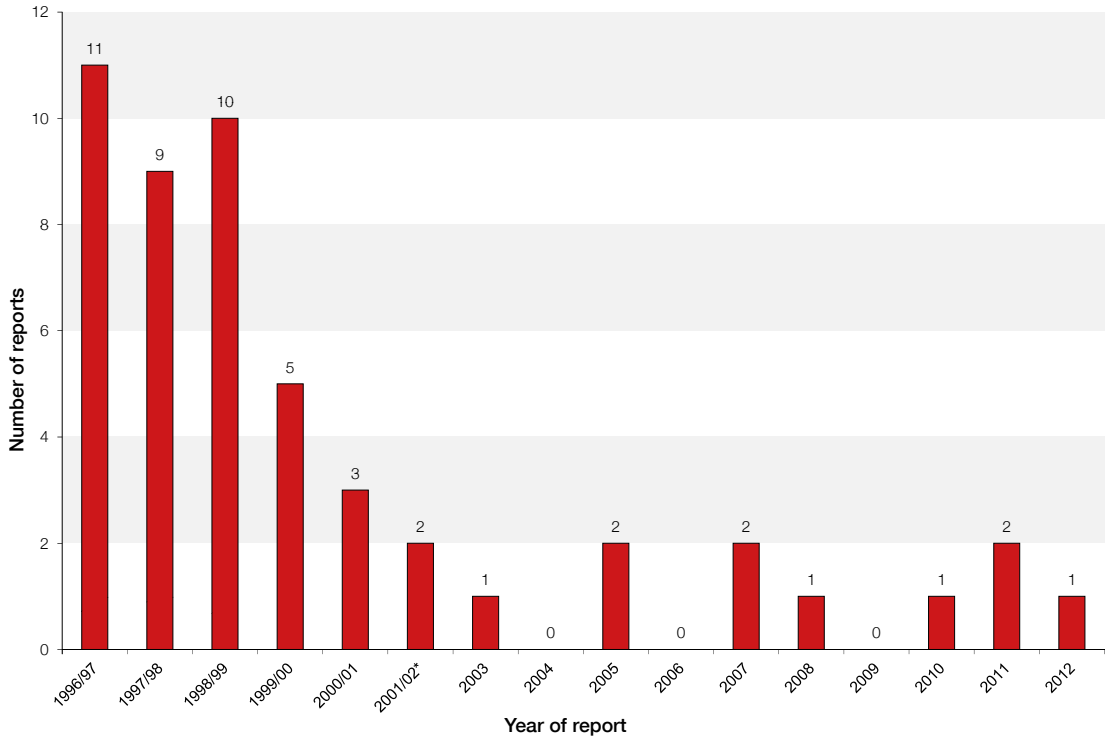


Figure 19.1: The number of cases of PTP with confirmed HPA alloantibodies reported annually to SHOT since 1996, a total of 50 reports

Case 1: Severe thrombocytopenia after platelet transfusion

A 50 year old woman with myeloma received an autologous stem cell transplant; post-autograft she received multiple platelet transfusions with satisfactory increments in her platelet count. About a week after an uneventful platelet transfusion, her platelet count dropped unexpectedly from 56x10^9/L to 6x10^9/L and a bone marrow aspirate was consistent with peripheral destruction. She was treated with intravenous immunoglobulin (IVIg) and two days later her count increased to 21x10^9/L and then 38x10^9/L on the following day. She had no haemorrhagic complication and platelet transfusion was not required. Laboratory investigation showed that she had anti-HPA-5b and multiple human leucocyte antigen (HLA) antibodies; her platelet genotype was HPA-5a/5a. Her platelet count remained at around 50x10^9/L for several months afterwards and this was attributed, at least in part, to haematinic deficiency. She had a history of multiple pregnancies but was not known to have had any affected by alloimmune thrombocytopenia.

A diagnosis of probable PTP due to HPA-5b alloantibody was made.

Analysis of cumulative SHOT data since 1996 has shown that there have been 50 serologically confirmed PTP cases.

Patient sex: Nearly all, 49 of 50 patients reported to SHOT with PTP since 1996 have been female. The male patient with confirmed PTP due to anti-HPA-1b had a past history of transfusion.

Causative antibody specificity	Number of cases
HPA-1a alone	32
HPA-1a with other HPA antibodies	5
Other HPA antibodies (-1b; -2b; -3a; -3b; -5a; -5b and -15a)	13
Total	**50**

Table 19.1: Cumulative PTP cases 1996-2012

As shown in Table 19.1 HPA-1a alloantibodies have been the most common cause of PTP, found in 74% (37/50) patients either alone or in combination with other HPA antibodies. Anti-HPA-1a alone was causative in 15 of the 20 cases which have occurred since the introduction of leucodepletion. The remainder were caused by anti-HPA-5b (3 cases); anti-HPA-5a (1) or anti-HPA-1b (1).

COMMENTARY

The SHOT definition of PTP has been updated from 2013 to include incidents following platelet transfusion[23]. The updated definition is: 'Post-transfusion purpura is defined as thrombocytopenia arising 5-12 days following transfusion of **cellular blood components (red cells or platelets)**, associated with the presence in the patient of antibodies directed against the HPA (human platelet antigen) systems'.

The case of probable PTP this year followed platelet transfusion. Diagnosis of PTP after platelet transfusion can be difficult because of pre-existing thrombocytopenia and clinical overlap with immune and non-immune causes of platelet transfusion refractoriness.

A sustained decrease in annual PTP case reports has occurred since the introduction of leucodepletion in late 1999. Thirty confirmed cases were reported in three years between 1996 and 1999 but only 20 cases in thirteen subsequent years. This reduction has been attributed to the removal from red cell components of most platelets as well as leucocytes by leucodepletion filters.

Further information about PTP and advice on management is available in Practical Transfusion Medicine[79].

Recommendations

There are no new recommendations

Recommendations still active from previous years:

- Clinicians are encouraged to contact Blood Services if they suspect post-transfusion purpura (PTP) (for advice and to arrange for patient investigation at platelet reference laboratory as required)
- Clinicians need to maintain awareness of this rare but treatable complication of transfusion

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

Transfusion-Associated Graft versus Host Disease (TA-GvHD) 20

Authors: Catherine Chapman and Helen New

Definition:

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

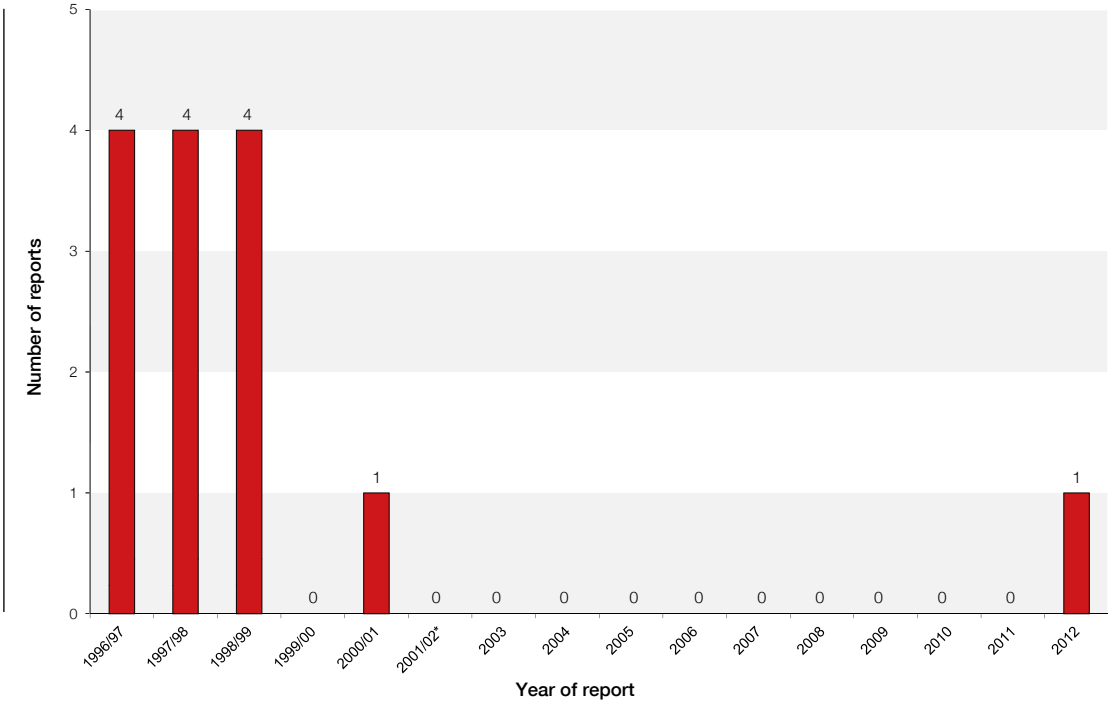
DATA SUMMARY
Total number of cases: 1

Implicated components		Mortality/morbidity	
Red cells	1	Deaths due to transfusion	1
FFP	0	Deaths probably/likely due to transfusion	0
Platelets	0	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	0
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	0		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	0	≥18 years	0	Emergency	1	Accident & Emergency	0
Female	1	16 years to <18 years	0	Urgent	0	Theatre	0
Not known	0	1 year to <16 years	0	Routine	0	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	0	Wards	0
		Birth to ≤28 days	1			Delivery Ward	0
		Not known	0	In core hours	1	Postnatal	0
				Out of core hours	0	Medical Assessment Unit	0
				Not known/Not applicable	0	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Not given	1

One case of TA-GvHD was reported in 2012. This is the first confirmed report since the 2000/2001 SHOT report.

Figure 20.1: Number of cases of TA-GvHD reported to SHOT each year



Case 1: Emergency intrauterine transfusion (IUT) for fetal anaemia

A fetus of 21 weeks gestation with a history of maternal parvovirus infection during pregnancy required an urgent IUT following signs of severe anaemia on ultrasound. Urgent transfusion was considered essential to allow the fetus to survive. As the fetal medicine unit understood that it was not possible to obtain red cells for IUT with less than 24 hrs notice to the Blood Service, they transfused 15 mL maternal blood to the fetus (non-leucodepleted, non-irradiated and related). The fetal Hb rose from 44 g/L to 100 g/L and initially the procedure was uneventful. However, the fetus subsequently developed a bradycardia with poor cardiac output so an emergency intracardiac transfusion with a further 18 mL maternal blood was given, with subsequent improvement in cardiac output.

The baby was delivered by emergency Caesarean section at 32 weeks gestation due to reduced fetal movements and was hydropic with pleural and pericardial effusions requiring chest drains and ventilation. The baby was pancytopenic at birth with Hb 50 g/L, neutrophils 0x10^9/L and platelets 9x10^9/L, and required multiple blood and platelet transfusions. Parvovirus testing gave negative results. She developed conjugated hyperbilirubinaemia and evidence of a fungal chest infection. A bone marrow aspirate at 2 months of age confirmed that the pancytopenia was due to aplasia, and chimerism studies confirmed maternal engraftment. The mother was found to be human leucocyte antigen (HLA) homozygous. A diagnosis of TA-GvHD was made, and the baby underwent a stem cell transplant (maternal donor) but died of pneumonitis a week later.

COMMENTARY

The blood used for emergency IUT in this case was fresh maternal blood which was neither irradiated nor leucodepleted. Each of these factors increased the risk of TA-GvHD. The mother was also subsequently found to be HLA homozygous which was a significant additional risk.

The initial transfusion with maternal blood was an urgent transfusion for extreme fetal anaemia following parvovirus, which has been more common over the last year (see the chapter on transfusion-transmitted infections, Chapter 21). The second transfusion was an emergency because of an acute deterioration. A recent survey of fetal medicine units[80] has established that use of maternal blood for IUT is rare in the UK and that non-irradiated paedipacks have been used in a small number of urgent cases. In most cases it should be possible to obtain specific irradiated IUT blood from the Blood Services within a few hours, sufficient for most urgent situations. However, for acute emergencies, the only option is to use blood already within the hospital. Fetal medicine units should therefore have local protocols detailing the appropriate available red cells for emergency IUT.

A total of 14 cases of TA-GvHD have now been reported to SHOT since 1996; all were fatal.

This is the first case of TA-GvHD reported to SHOT since the 2000-2001 annual report. Only two cases have been reported to SHOT in recipients of non-irradiated, leucodepleted components; one in the 1998-99 report (a patient with myeloma) and one in the 2000-2001 report (a patient with acute lymphoblastic leukaemia). Leucodepletion of all components except granulocytes/buffy coats was introduced in a phased manner during 1999. This markedly reduced, but did not totally eliminate the risk of TA-GvHD. It is not known why the two cases occurred in recipients of leucodepleted components. We cannot be 100% certain that leucodepletion was optimal but it is not feasible for Blood Services to count leucocytes in every donation. Routine quality monitoring involves counting leucocytes in a proportion of components to ensure that 99% contain fewer than $5x10^6$. No case of TA-GvHD has been reported to SHOT in any recipient of a leucodepleted component since the 2000/2001 report.

A report of fatal TA-GvHD in an injured United States (US) soldier in Afghanistan was published in May 2012[81]. He had been transfused with fresh non-irradiated, non-leucodepleted blood and blood components. Donor testing was incomplete but the clinical picture and chimeric DNA profile were consistent with this diagnosis.

During the last 11 years 877 patients at risk of TA-GvHD[48] have been reported to SHOT who had received non-irradiated blood components in error. This includes 97 patients reported in 2012 (3 of whom also required cytomegalovirus (CMV) negative components). None of these has developed TA-GvHD, suggesting that leucodepletion gives good (but not complete) protection.

Recommendations

- Maternal blood should not be used for intrauterine transfusion (IUT) due to the risk of transfusion-associated graft vs host disease (TA-GvHD). Fetal medicine units in conjunction with Hospital Transfusion Teams should develop local written protocols with education regarding the appropriate blood for emergency fetal transfusion. Whenever possible, irradiated red cells specific for IUT should be used
- In situations of immediate life-threatening emergency where there is not time to obtain specific IUT blood, alternatives include neonatal exchange units or paedipacks (likely to be non-irradiated in an emergency). The risk of TA-GvHD using these alternatives will be significantly lower, although not eliminated, than using maternal blood because these components have been leucodepleted and in most cases there will be no shared haplotype between donor and recipient

Action: British Maternal and Fetal Medicine Society, Hospital Transfusion Teams with their local Blood Centres and Consultant Haematologists

- The Blood Services should review their protocols for production of units for intrauterine transfusion (IUT), and establish the minimum time required to issue such units, even in an emergency. This should be communicated to hospitals

Action: UK Blood Services

- Requests for units for urgent intrauterine transfusion (IUT) should involve early direct discussion between a hospital clinician and a Blood Service consultant
- Update national irradiation guidelines via the British Committee for Standards in Haematology (BCSH)

Action: BCSH Transfusion Task Force

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.

21 Transfusion-Transmitted Infections (TTI)

Authors: Claire Reynolds and Su Brailsford

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 cases: 3

Implicated components		Mortality/morbidity	
Red cells	2	Deaths due to transfusion	0
FFP	1	Deaths probably/likely due to transfusion	0
Platelets	0	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	3
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	0		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	1	≥18 years	2	Emergency	1	Emergency department	0
Female	2	16 years to <18 years	0	Urgent	0	Theatre	1
Not known		1 year to <16 years	1	Routine	0	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	2	Wards	1
		Birth to ≤28 days	0			Delivery Ward	0
		Not known	0	In core hours	0	Postnatal	0
				Out of core hours	0	Medical Assessment Unit	0
				Not known/Not applicable	3	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Not known/Not applicable	1

** The data summary table shows cases reported to SHOT in 2012 (Cases 1 and 2). Incidents are described in the chapter for the year in which they were reported to the NHSBT/Public Health England Epidemiology Unit.*

Reporting

Most reports of suspected viral and bacterial transfusion-transmitted infections (TTI) are received and investigated by the UK Blood Services and reported to the NHS Blood and Transplant (NHSBT)/Public Health England (PHE) Epidemiology Unit. From here, data are included in the SHOT report even if the investigation is not yet complete, as the investigation into suspected viral TTI can take several months. These are reconciled with TTI reports made to the SHOT online reporting system which in most cases will also have been reported to the Medicines and Healthcare products Regulatory Agency (MHRA)'s online reporting system for Serious Adverse Blood Reactions and Events (SABRE). Incidents are described in this chapter for all reports made to the NHSBT/PHE Epidemiology unit in 2012. The data summary table shows cases reported to SHOT in 2012. These may differ from the cases reported to the NHSBT/PHE Epidemiology unit described in this chapter depending on the timing of reporting.

Guidance on initiating an investigation and the required reporting forms for suspected transfusion-transmitted infections (TTIs) for hospitals served by NHSBT can be found on the Requests for Investigation of Adverse Events & Reactions page at http://www.blood.co.uk/hospitals/library/request_forms/aer/.

For other Blood Services please contact the local Blood Centre.

Summary of reports made to the NHSBT/PHE Epidemiology Unit in 2012

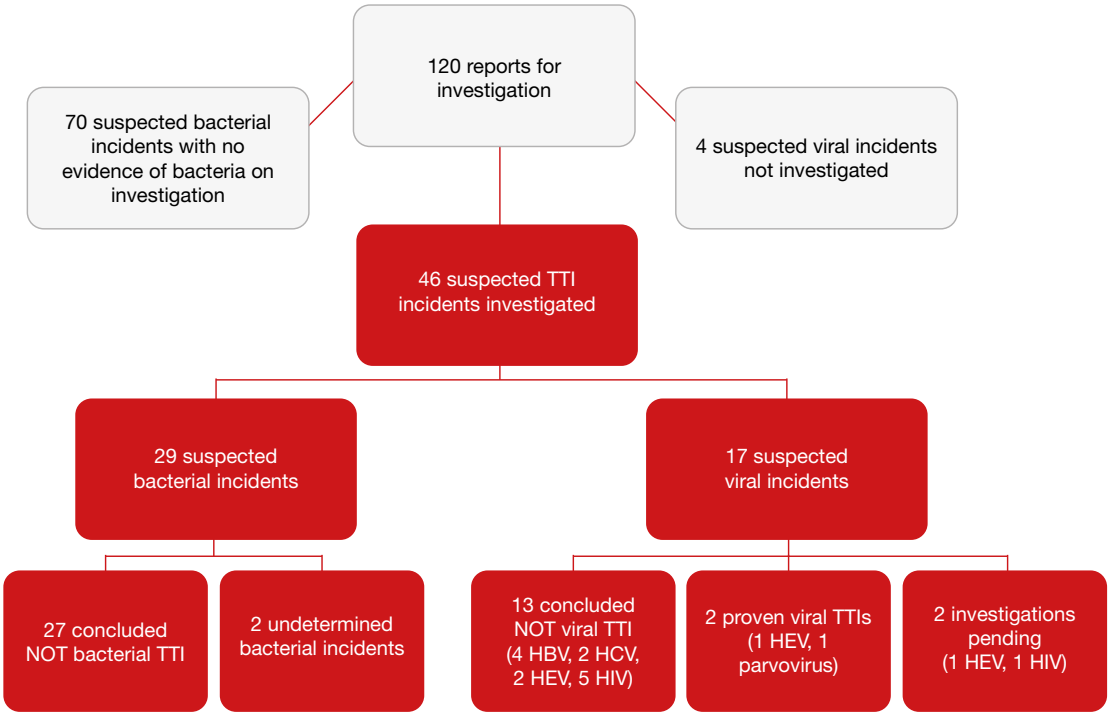


Figure 21.1: Outcome of reports of suspected TTIs made to the NHSBT/PHE Epidemiology Unit in 2012

During 2012, 46 suspected TTI incidents were reported by Blood Services and hospitals throughout the UK.

A further 70 investigations into reports of suspected bacterial incidents found no evidence of bacteria in either the recipient or the pack and were reclassified as possible transfusion reactions (see the chapter on acute transfusion reactions, Chapter 16, for reactions transferred from TTI).

A further four viral incidents were not investigated because either infection was not confirmed (1 hepatitis C); results were shown to be due to passive transfer (1 hepatitis B); infection was present prior to transfusion (1 hepatitis E); or historic hospital records were not available (1 human immunodeficiency virus (HIV)).

Learning point

- Immunoglobulin therapy can lead to passive transfer of antibodies which may be confused with infection. Careful review of the markers and timing can rule out infection before a report is made to the Blood Service. See Chapter 23 on 'unclassifiable complications of transfusion' for more information on passive transfer

Proven transfusion-transmitted infections reported in 2012

Two incidents were confirmed as TTI according to the above definition. Both were viral, one parvovirus incident (reported to SHOT in 2012, see data summary table) and one hepatitis E virus (HEV) incident (not yet reported to SHOT at the time of writing). Neither infection is currently screened for by the UK Blood Services.

Thirteen investigations of viral infections were concluded as not TTI including 2 HEV incidents.

Learning point

- Clinicians investigating suspected viral transfusion-transmitted infections (TTI) 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

Undetermined cases reported in 2012

Two bacterial cases were undetermined, as satisfactory investigation was impossible due to missing or leaking packs.

Learning point

- A lack of packs for microbiological culture can hinder the investigation of suspected bacterial transfusion-transmitted infections (TTI). Hospitals need to retain packs, even if near empty, for return to the Blood Service as the residue can be washed out and cultured. If sampling packs locally for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack

Near miss

There was one near miss in a red cell pack as described in the MHRA chapter, Chapter 6.

Variant Creutzfeld-Jakob Disease (vCJD)

There were no vCJD investigations in 2012.

Investigations pending in 2011

One hepatitis B virus (HBV) TTI incident reported as pending in the SHOT 2011 report has been confirmed as proven and was reported to SHOT in 2012 (see data summary table).

Case reports of TTI from investigations started or concluded in 2012

Case 1: Jaundice and high liver enzymes 17 weeks after transfusion, hepatitis B (HBV) transmission to two recipients

A recipient of multiple transfusions during emergency cardiac surgery in August 2011 was diagnosed with acute HBV after jaundice and a high alanine aminotransferase (ALT) test result prompted HBV testing in December 2011. The recipient was not immunosuppressed and was shown to be anti-HBc (hepatitis B core antibody) negative on an archived sample from December 2008. Another identified risk was dental treatment in September 2011. The recipient gradually cleared the HBV infection over the following months.

The recipient had received red cells, fresh frozen plasma (FFP) and apheresis platelets; 15 of 16 donors of these units were cleared. One donor whose FFP had been transfused to the recipient was shown to have evidence of exposure and immunity to HBV (anti-HBc positive/anti-HB surface antibodies >100 mIU/ml) on a donation 4 months after the implicated index donation. The index donation had been HBsAg screen negative (individual sample testing) and HBV NAT negative in testing of pooled samples. Retrospective individual sample testing of the archived sample of the index donation detected HBV DNA in one of two PCR tests used in the reference laboratory. Retrospective testing of three archived donation samples given before July 2011 showed no evidence of exposure to HBV.

Lookback into the fate of the associated red cell component from the July index donation revealed chronic asymptomatic HBV infection (HBsAg and HBeAg positive) in the elderly female recipient. The recipient of red cells from the subsequent donation, at which time the donor had immunity to HBV, was HBV negative.

The white-British male donor was asymptomatic and unaware of his HBV infection. The only possible reported risk was participation in contact sports. Two transmissions occurred as a result of a donor with no reported deferrable risks donating with an early HBV infection undetectable by the screening tests in place at the time. Although HBV DNA is not a mandatory blood donation screening test it is included in the Triplex NAT screening test currently used on all donations. It was concluded that the level of HBV DNA was too low to be detected in the pooled NAT screening test.

Learning points

- Jaundice post transfusion can be due to a ‘flare up’ of existing HBV infection. This is less likely when the recipient is not immunosuppressed and can be ruled out prior to reporting to the Blood Service for investigation if the recipient can be shown to be negative prior to transfusion

Case 2: Pyrexia and lymphopenia 48 hours post transfusion, parvovirus transmission

A child given a red cell transfusion for sickle cell anaemia in September 2012 had a temperature of 41°C and lymphopenia 48 hours later. Parvovirus B19 DNA and IgG and IgM antibodies were detected approximately two weeks post transfusion.

The implicated donation was found to be parvovirus B19 DNA positive, IgM negative and IgG equivocal. A subsequent sample from the donor was positive for DNA, IgM and IgG. Both recipient and donor shared the same B19 genotype, although it was a very common form. Although classed for SHOT purposes as major morbidity, the patient recovered from the infection and was reported well by the next scheduled transfusion two weeks later although the haemoglobin was lower than expected. The 25 year old repeat donor was asymptomatic and did not report any illness before or after donation.

Case 3: Abnormal liver enzymes after multiple transfusions, hepatitis E (HEV) transmission

An adult female recipient who underwent a stem cell transplant with associated transfusion support over the autumn of 2011 developed abnormal liver function tests (LFTs) in May 2012. Testing of stored samples established that the recipient had been HEV negative in December 2011 but HEV RNA positive in February 2012. Unfortunately the recipient died in autumn 2012 from causes unrelated to the HEV infection. The stem cell donor was HEV negative.

Thirty-four donations were investigated and two donors were confirmed to be HEV RNA positive at the time of donation: Donor A had sequence data that matched that in the recipient, whereas Donor B had a virus with a divergent sequence. The recipient had received FFP from Donor A, and red cells from Donor B. Lookback on the red cell component from Donor A's donation identified an adult female transfused for a haematological condition. This second recipient was HEV RNA negative, but positive for HEV antibodies (IgG and IgM) a year after transfusion, consistent with a previous HEV infection. It was therefore likely that transmission had occurred from Donor A although the lack of HEV RNA positivity in the second recipient precluded typing to confirm Donor A as the source of the HEV infection. Donor A, a 22 year old repeat male, had not reported any illness prior to the index donation and had cleared the infection and seroconverted when tested six months later.

Learning point

- Samples pre and post-transfusion from a recipient where viral transmission is suspected are often invaluable to an investigation into a possible TTI to help exclude a pre-existing infection and date the acquisition of infection. It may be useful to search for samples in other pathology departments

Cumulative data

Table 21.1: Number of confirmed TTI incidents, by year of report with total infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2012 (Scotland included from October 1998)

Year of report	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV	Parvo-virus B19	Malaria	vCJD/ prion
1996-97	3	1	1	1	0	1	0	0	1	0
1997-98	1	0	2	0	0	0	0	0	0	0
1998-99	6	0	2	1	0	0	0	0	0	0
1999-00	5	0	1	0	0	0	0	0	0	0
2000-01	4	0	1	0	0	0	1	0	0	0
2001-02	5	0	0	0	0	0	1	0	0	0
2003	3	1	2	0	0	1	0	0	1	1
2004	0	0	0	0	1	0	0	0	0	0
2005	2	1	1	0	0	0	0	0	0	1
2006	2	0	0	0	0	0	0	0	0	1
2007	3	0	0	0	0	0	0	0	0	0
2008	4	0	0	0	0	0	0	0	0	0
2009	2	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0
2011	0	0	1	0	0	0	0	0	0	0
2012	0	0	0	0	1	0	0	1	0	0
Number of incidents	**40**	**3**	**11**	**2**	**2**	**2**	**2**	**1**	**2**	**3**
Number of infected recipients	**43**	**3**	**13**	**2**	**3**	**4**	**2**	**1**	**2**	**4**
Death due to, or contributed to, by TTI	11	0	0	0	0	0	0	0	1	3
Major morbidity	28	2	13	2	1	4	2	1	1	1
Minor morbidity	4	1	0	0	2	0	0	0	0	0

Bacterial infection

The last reported confirmed bacterial TTI was in 2009. This predates universal bacterial screening throughout the UK Blood Services and is not necessarily a consequence of screening as packs are released as 'negative-to-date' which may be before bacteria have multiplied sufficiently to trigger an initial screening reaction. A total of 33 bacterial incidents have been due to the transfusion of platelets.

Learning points

- It is important to remain vigilant for potential bacterial transmission because bacterial screening of platelets will not prevent release of all contaminated packs. See the chapter on acute transfusion reactions, Chapter 16, for advice on when to request bacterial investigations following an acute transfusion reaction
- Be aware that bacterial transmissions also have the potential to occur via red cells

Viral infection

The year of transfusion may have been many years prior to the year in which the case is investigated and reported to SHOT because of the chronic nature of some viral infections. Since 1996, 23 confirmed incidents of transfusion-transmitted viral infections have been reported, involving a total of 28 recipients. HBV is the most commonly reported proven viral TTI in the UK.

No screening was in place for human T cell lymphotropic virus (HTLV) at the time of the documented transmissions. There is currently no screening for hepatitis A (HAV), HEV or parvovirus B19.

The two HIV incidents were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included in Table 21.1.

Parasitic infection

In both malaria transmissions, malaria antibody testing was not applicable at the time according to information supplied at donation.

vCJD

The vCJD incidents took place in 1996/97 prior to the introduction of leucodepletion and other measures taken by the UK Blood Services to reduce the risk of vCJD transmission by blood, plasma and tissue products[82].

The outcome for one infected recipient was assigned to major morbidity (Table 21.1) because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death.

Despite international research efforts there is currently no suitable test available for screening blood donations for vCJD.

COMMENTARY

Although documented HBV transfusion transmission had not, until recently, been reported in the UK since 2005, HBV remains the most commonly reported viral TTI. Although very low, the risks for an infectious HBV donation entering the blood supply in the UK[83] remain higher than for HIV and HCV because the window period (the period when virus is present and the donation is infectious but not detected by screening tests) for HBV is longer than for the other two viruses. The latest incident involved a donor with no reported deferrable risk who donated in the very early stages of infection, before levels of DNA and HBsAg had reached levels detectable by the screening tests. The 10 incidents previously recorded in SHOT were also due to acute infection with undetectable HBsAg on screening. HBV DNA testing on pools of 24 has been performed by the UK Blood Services since 2009 as part of the triplex HBV/HCV/HIV NAT test employed, but is not mandatory for blood donations in the UK. Between April 2009 and December 2012 HBV NAT screening in the UK has identified five cases of acute HBV in blood donors that were not detected by HBsAg screening.

The parvovirus incident was the first case of proven parvovirus B19 (B19V) transmission in the UK since SHOT started in 1996. Three other possible parvovirus cases reported to the NHSBT/PHE unit in 2007, 2008 and 2010 were not concluded to be TTI. Red cells were implicated in this case but there are case reports in the literature of B19V transmissions from all blood components[84,85]. Infection is usually asymptomatic and the consequences were limited in this incident but depend on the host[86]. Those at greatest risk of a serious outcome are seronegative patients with increased erythropoiesis, pregnant women and immunocompromised patients. However, B19V is common, with infection generally conferring lifelong immunity, and a high proportion of blood recipients will be immune. In the UK outbreaks often occur in late winter and early spring on a 3-4 year epidemic cycle[87] with 2012 being an epidemic year. Donors are often asymptomatic at the time of highest viraemia, and cannot be reliably excluded based on symptoms. The UK Blood Services do not perform parvovirus screening on blood donations although plasma products are screened for high titres of B19V RNA by the manufacturers.

The HEV transmission was the second proven HEV TTI incident in the UK since SHOT began. The first incident, reported in 2004, was investigated after a repeat donor reported onset of jaundice 23 days post donation. Lookback identified two recipients: one who had received red cells and developed mild jaundice and abnormal liver function tests with rapid recovery, and one who had received platelets and had no evidence of infection. It is possible that this second recipient had received passive transfer of antibody in the plasma included in the platelet pool, or from other transfused components. HEV is usually self limiting but sometimes has a more chronic outcome in immunocompromised cases [88,89]. Previously HEV has been associated with consuming contaminated food and water in endemic countries where sanitation may be poor. However there are increasing reports of HEV infection acquired in industrialised countries. This includes the UK, where numbers of cases have increased substantially since 2010, with non-travel cases accounting for the majority of cases in 2011/12[90]. There was an increase in reports of suspected HEV transmissions, five in all, made to the Blood Service in 2012 probably due to increased awareness of the potential for HEV to be transmitted via blood[91]. The UK Blood Services do not perform HEV screening on blood donations. A study is currently underway to investigate HEV incidence and transmissibility in blood donations in England.

Although no proven bacterial TTIs have been reported in SHOT since 2009 it is important to remain vigilant[92] as bacterial screening will not prevent all bacterial contamination. Possible transmissions should be reported as soon as possible to ensure that the associated packs can be recalled (see the MHRA chapter, Chapter 6 on recall fails and the recommendation in the chapter on acute transfusion reactions, Chapter 16). Ideally packs should be returned to the Blood Service for testing to avoid contamination when sampling the pack.

Recommendations

- Retain suspected bacterially contaminated packs, even if near empty, for return to the Blood Service as the residue can be washed out and cultured. Report a suspected bacterial transfusion-transmitted infection (TTI) promptly to the Blood Service to allow recall of any associated packs for testing. If sampling packs locally for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack

Action: Clinicians, Transfusion and Microbiology Laboratory Managers (see also the chapter on acute transfusion reactions, Chapter 16, previous recommendation on recall)

- Hospitals and Blood Centres investigating a possible viral TTI are reminded of the importance of locating any archived recipient samples (transfusion-related or not) for testing. It is important that laboratories facilitate access to those samples (with due consent of appropriate parties including the patient)

Action: Clinicians, Transfusion Laboratory Managers, Hospital Transfusion Team (HTT)

Previous recommendations still active

- Even if TTI is excluded in a case of ATR, the case should still be reported to SHOT as an ATR If necessary

Action: HTTs, Clinicians

- 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. This includes checking records and testing samples taken prior to the implicated transfusion(s) to check that the recipient was not infected prior to transfusion

Action: Clinicians, UK Blood Services

22 Cell Salvage and Autologous Transfusion (CS)

Authors: Joan Jones, Dafydd Thomas and John Thompson

Definition:

Any adverse event or reaction associated with autologous transfusion including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution or pre-operative autologous donation.

Additional specific definitions for cell salvage incidents are as follows:

- **Adverse incidents due to operator error or machine failure where the event impacts on the care of the patient**
- **Non-availability of trained staff precluding the use of cell salvage or which has other impact on the patient**
- **Adverse intra-operative clinical incidents during the cell salvage process**
- **Pathological reactions to *reinfused* blood**

DATA SUMMARY
Total number of cases: 11

Implicated components		Mortality/morbidity	
Red cells	11	Deaths due to transfusion	0
FFP	0	Deaths probably/likely due to transfusion	0
Platelets	0	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	0
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	0		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	6	≥18 years	11	Emergency	1	Emergency department	0
Female	5	16 years to <18 years	0	Urgent	0	Theatre	0
Not known	0	1 year to <16 years	0	Routine	9	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	1	Wards	0
		Birth to ≤28 days	0			Delivery Ward	0
		Not known	0	In core hours	8	Postnatal	0
				Out of core hours	2	Medical Assessment Unit	0
				Not known/Not applicable	1	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0
						Unknown	11

Twenty four cases were reviewed and 13 were withdrawn. One case was transferred from the Near Miss report category.

This year we have concentrated on adverse clinical incidents following reinfusion of salvaged blood.

Withdrawn cases

There were no adverse clinical outcomes in the 13 withdrawn cases. Reports in this category were as follows:

- 5 cases of operator error where 2 of these could have potentially caused patient harm if not recognised: use of Hartmann's solution to rinse swabs, collection of blood intraoperatively following the use of Fibrillar™, a topical cellulose-based haemostatic agent. Haemostats have the potential to cause clotting within the reservoir
- 3 cases where clots or particulate matter were observed in the reservoir prior to reinfusion
- 5 case reports classified as machine error. On review two of these could have been due to operator error

Specialty involved

Of the 11 cases that were reviewed the following specialties were involved:

- Orthopaedics 8
- Vascular surgery 1
- Obstetrics 1
- Not stated 1

One adverse event concerned acute normovolaemic haemodilution (ANH).The collected blood was stored in a blood refrigerator rather than kept with the patient. The benefits of ANH are not proven.

Adverse reactions n=5

There were five adverse reactions. Two occurred in postoperative reinfusion systems leading to minor morbidity. In both cases the patients experienced low-grade pyrexia and mild rigors. Three reactions occurred during intraoperative cell salvage, leading to minor morbidity. There was one case of hypotension, which occurred during reinfusion of cell salvage blood through a leucodepletion filter. The anticoagulant was acid-citrate-dextrose. A further hypotensive episode was noted without a leucodepletion filter, but the patient was on an angiotensin-converting enzyme (ACE) inhibitor. The third case is described below:

Case 1: Hypovolaemia in a young person

A patient with known posterior placenta praevia, with no previous uterine scar, was having an elective caesarian section. There was a 2000 mL blood loss and intraoperative cell salvage was used. 500 mL of cell salvage blood was ready for reinfusion at the end of the procedure. After 5 minutes of reinfusion via a leucodepletion filter, the patient complained of feeling unwell with nausea and retrosternal chest heaviness. On examination she had a rash across shoulders and a heart rate of 100 to 120 bpm. She remained normotensive. Reinfusion was stopped after approximately 50 mL. The patient felt well again within 5 minutes.

The explanation of this reaction is unclear, but it was temporally associated with the reinfusion of the cell saved blood. Cardiac ischaemia seems unlikely in a fit young woman who apart from a mild tachycardia seemed to be compensating well for a 2000 mL blood loss. The associated skin rash may suggest a form of allergic response but there was no documented hypotension.

This case has been included to remind clinicians to be vigilant for similar adverse reactions and to encourage reporting to SHOT if they occur.

Adverse events n=6

There were six reports in this category (one associated with ANH is described above). Two involved the use of inappropriate intravenous (IV) fluids. One fluid was sterile but non IV saline. In the other case Ringer's lactate was administered immediately following the reinfusion of salvaged red cells. Black particulate matter was found in the filter post reinfusion. (Ringer's lactate should not be administered simultaneously with blood through the same administration set because of the risk of coagulation). Another event was a reported malfunction with the intraoperative system where the staff were told not to reinfuse the blood. However, the salvaged red cells were reinfused and the patient had no adverse outcome.

There were two cases where reinfusion took place beyond the specified expiry time written on the label.

COMMENTARY

There are continued reports of hypotension following the reinfusion of red cells collected by cell salvage, but the relationship with the use of filters remains unclear.

Learning points

- Adequate knowledge and training is required for all involved in the use of both intra and postoperative cell salvage systems
- Staff need to know which solutions/surgical products can safely be used with intraoperative cell salvage

Recommendation

- All organisations should develop a robust system for reporting all adverse incidents/reactions during the use of autologous blood techniques, preferably reporting to the hospital transfusion committee and onward to SHOT

Action: Hospital Transfusion Committee, Hospital Transfusion Teams

Unclassifiable Complications of Transfusion (UCT) 23

Authors: Paula Bolton-Maggs, Catherine Chapman, Clare Milkins, Megan Rowley, Helen New

Definition:

Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined transfusion event and with no risk factor other than transfusion, and no other explanation.

DATA SUMMARY
Total number of cases: 8

Implicated components		Mortality/morbidity	
Red cells	5	Deaths due to transfusion	0
FFP	0	Deaths probably/likely due to transfusion	1
Platelets	2	Deaths possibly due to transfusion	0
Cryoprecipitate	0	Major morbidity	0
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	1		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	5	≥18 years	5	Emergency	0	Emergency Department	0
Female	3	16 years to <18 years	1	Urgent	1	Theatre	0
Not known	0	1 year to <16 years	0	Routine	7	ITU/NNU/HDU/Recovery	2
		>28 days to <1 year	0	Not known	0	Wards	5
		Birth to ≤28 days	2			Delivery Ward	0
		Not known	0	In core hours	6	Postnatal	1
				Out of core hours	2	Medical Assessment Unit	0
				Not known/Not applicable	0	Community	0
						Outpatient/day unit	0
						Hospice	0
						Antenatal Clinic	0

Transfusion-related alloimmune neutropenia (TRAIN)

Case 1: Post transfusion neutropenia without significant clinical problems

An 80 year old man was transfused with 2 units of red cells (in optimal additive solution) to treat symptomatic anaemia associated with colonic cancer. The transfusion was reported as uneventful but he subsequently developed neutropenia. His Hb was 75 g/L and neutrophil count 4.79x10^9/L before transfusion. On the following day his Hb was 100 g/L and neutrophil count 2.27x10^9/L. Ten days later his neutrophil count was 0.68x10^9/L with no apparent cause.

Investigations showed that one female donor had HNA (human neutrophil antigen) (HNA-1c) and HLA (human leucocyte antigen) (HLA-B38, -B44, -C05, -C12) antibodies which matched patient antigens (concordant). The patient had neither granulocyte nor lymphocyte antibodies.

The donor's HNA-1c antibodies were concluded to be the most likely cause of the patient's neutropenia. HNA-1c is found in around 5% of Caucasians. A possible role for the HLA antibodies could not be completely excluded but was considered unlikely because the volume of plasma was small and HLA is widely distributed. In contrast, HNA-1c is confined to granulocytes.

COMMENTARY

TRAIN is a rarely recognised complication of transfusion which was first described by Wallis et al in a report of rapid onset neutropenia following a transfusion containing concordant HNA-1b alloantibodies[93]. The child in that report had no pulmonary symptoms. That report has been followed by others[94] describing leucopenia after transfusion of neutrophil-specific antibodies.

Unexpected severe complications from intravenous immunoglobulin (IVIg) infusion

Case 2: Death in a blood group A patient following treatment with high-dose IVIg

A blood group A patient with myelodysplastic syndrome (MDS), neutropenic sepsis and a subdural haematoma, received group B pooled platelets and high dose IVIg (2x80g in one day). Two days later, plasma received for crossmatching was noted to be haemolysed, the direct antiglobulin test was positive, group A red cells were incompatible, and anti-A was eluted from the red cells. The patient's Hb fell by 50 g/L to 43 g/L and the patient was admitted to the intensive therapy unit (ITU). Her bilirubin rose from normal to 118 micromol/L, lactate dehydrogenase peaked at 1984 U/L and her creatinine rose to 600 micromol/L. She required renal dialysis and subsequently died. The cause of death was concluded to be a combination of MDS and haemolytic transfusion reaction.

Although the laboratory signs of haemolysis were not noted until 2 days after the IVIg was given, it is likely that acute intravascular haemolysis started before this. The platelets were confirmed to be ABO high titre negative, and although no in-house testing was undertaken on the IVIg, it was concluded that the cause of the haemolysis was passive anti-A derived from the large doses of IVIg.

We reported a similar case of haemolysis due to anti-A from IVIg in the annual report for cases from 2011[2]. The patient developed massive haemoglobinuria and a fall in Hb from 153 g/L to 85 g/L. That case was proven to be caused by anti-A in the infused IVIg. A further case has recently been published[95].

COMMENTARY

It is likely that most episodes of haemolysis due to IVIg are mild and go unnoticed. Please see additional comments in the report from last year[2] (page 106, Chapter 14)

IVIg may also cause pulmonary complications including transfusion-related acute lung injury (TRALI)[96] and a possible case is reported this year in the chapter on TRALI (Chapter 24).

These severe complications of IVIg are usually in association with treatment with massive doses of a pooled blood product.

Review of data reported to the Medicines and Healthcare products Regulatory Agency (MHRA) 'yellow card' scheme (accessed 15 April 2013) demonstrated a total of 18 deaths in 957 reactions following IVIg between 17 November 1985 and 12 April 2013. Haemolytic anaemia or haemolysis was reported in 8 cases and none of these was fatal. Anaphylactic and anaphylactoid reactions were more commonly reported in 13 (associated with one death). Renal failure or impairment was reported in association with IVIg in 24 instances (3 deaths). This reporting does not imply cause and effect however and cannot be used to determine the risk of the event. Reporting by this scheme is likely to be incomplete.

There were also two reports in 2012 of possible transfusion-transmitted infections (TTI) which were attributed to passive transfer of antibodies following immunoglobulin therapy. In one case the hospital reported a possible TTI on the basis of a positive anti-HBc test. Twenty-one donors were investigated and cleared. In the other case the recipient had been HBV negative pre transfusion and was discovered to be anti-HBs positive just 9 days post transfusion following immunoglobulin therapy. The Blood Service

concluded there was clear evidence for passive transfer without the need to investigate the donors, and serial samples from the recipient demonstrated falling antibody levels consistent with the disappearance of passively transferred antibody.

Learning point

- Immunoglobulin therapy can lead to passive transfer of antibodies which may be confused with infection. Careful review of the markers and timing can rule infection out before a report is made to the Blood Service
- All complications of IVIg infusion should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the yellow card scheme. SHOT is interested to receive reports of transfusion-related incidents such as those described here

We remind readers of the **Learning points** from last year:

- Large volume transfusion of IVIg can cause significant haemolysis in non-group O recipients, particularly where the patient has an underlying inflammatory condition
- When severe haemolysis occurs in group A, B or AB patients it may be necessary to stop the IVIg therapy and transfuse group O red cells. A different batch of IVIg should be considered for subsequent therapy. A mechanism should be put in place to monitor patients for signs of haemolysis after treatment with high-dose IVIg therapy

Miscellaneous other cases

Case 3: Incompatible platelets in a baby can cause signs of haemolysis

A 22 day old boy receiving extracorporeal membrane oxygenation therapy (ECMO) whose own group was A RhD positive was transfused with group O RhD positive platelets (the only group available at the time). He was bleeding and the transfusion was urgent. The child developed a positive direct antiglobulin test, and anti-A was found in the eluate when referred to the Blood Service reference laboratory. There were no adverse clinical sequelae related to this.

COMMENTARY

This case did not have clinical features of an acute or haemolytic transfusion reaction so did not fit into those SHOT categories.

It is generally considered acceptable to transfuse group O platelets to a group A patient, but haemolysis has been described in this setting[97]. This is a reminder that in small children there is probably a higher risk of adverse incidents when platelets are transfused across ABO groups, and therefore in paediatric patients it is not recommended[98], although in this case the emergency overrode the need to wait for group A platelets. Adults who are group A and who receive multiple transfusions of group O platelets, for example in the setting of massive haemorrhage, may also show signs of haemolysis.

Case 4: Repeated pain and rash associated with transfusion in a patient with thalassaemia limiting her ability to receive adequate transfusion

A 23 year old woman (of West Indian origin) with transfusion-dependent beta thalassaemia major began to experience transfusion reactions in 2011. She developed immediate urticarial rashes and wheals, often in the transfusion arm and sometimes associated with aches and pains subsiding over 24h. She was subsequently transfused with washed red cells but continues to develop severe pain after transfusion and has been bedbound for up to 3 days post transfusion. Premedication with hydrocortisone and chlorphenamine has been of no benefit. She is on long term adequate iron chelation which has not been changed for several years. In May 2012 washed cells were replaced with standard red cells but she experienced more severe reactions. Washed cells were reinstituted. Severe reactions continue with pain in the hips, back and thighs, starting during the first unit. The

pain lasts for 2-3 days. She also develops an itchy red and raised rash. This has not responded to premedication now including prednisolone 40mg daily for 3 days in addition to hydrocortisone. Negative investigations include mast cell tryptase, complement levels, c-reactive protein, bilirubin and lactate dehydrogenase are not elevated. She does have 2+ haemoglobinuria.

COMMENTARY

This has proved very difficult to manage. The cause of the pain is not understood, but possible causes under consideration include an incompatibility not detected by standard serology, some agent in plasma or in the transfusion system. The management of transfusion in this patient continues to be very difficult.

Pain has recently been noted to be a serious and under-recognised problem for patients with thalassaemia[99].

Case 5: Unexplained haemolysis in a transfused neonate

A 17 day old preterm twin who was already jaundiced, had a neonatal blood transfusion through a 24 gauge peripheral cannula. The baby had a lower than expected rise in Hb, an unexpected rise in bilirubin from 69 micromol/L two days pre transfusion to 222 micromol/L within 24h of transfusion, and evidence of schistocytes, red cell fragments and polychromasia on the film. The baby also developed transient signs of increased work of breathing a few hours post transfusion. The reporters considered that this might have been mechanical haemolysis related to the small bore cannula as they could not identify another cause for the probable haemolysis, but this size cannula is routinely used for neonates including for transfusion so this is less likely than an underlying haemolysis causing the anaemia requiring transfusion.

Learning point

- In addition to the usual investigations for haemolysis, in cases of unexpected haemolysis in preterm neonates it is important to consider unusual non-immune causes such as G6PD deficiency, or glutathione peroxidise deficiency[100]. This latter condition is transient, occurring at 1 to 6 weeks of age, sometimes requiring transfusion, and resolves over a few weeks
- Mechanical haemolysis is reported in adults where pumps are used to increase the rate of red cell transfusion in massive trauma

Minor unclassifiable and unexplained reactions

A 17 year old man complained of headache, nausea and breathing difficulties during a platelet transfusion. The platelet transfusion was discontinued and the symptoms resolved spontaneously.

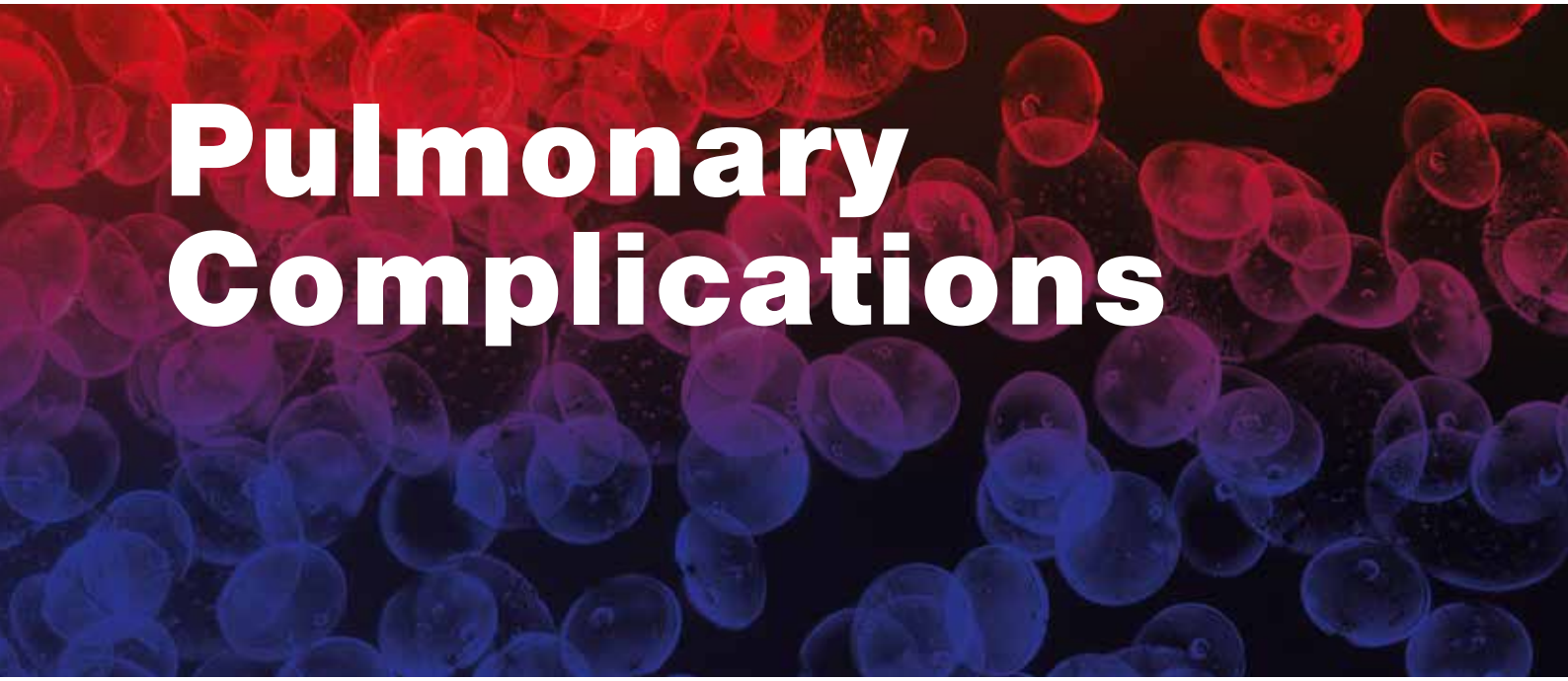
A 38 year old woman complained of headache during the 2nd unit of red cells. The transfusion was stopped. The symptoms resolved but recurred on resuming the red cells. The indication for transfusion was post partum anaemia.

An 88 year old man (a haematology patient with chronic anaemia) became aggressive and agitated during transfusion of red cells.

Recommendation

- Reactions and incidents after transfusion which do not fit into any of SHOT's current reporting categories may have important learning points and prompt others to report similar cases. Please continue to discuss and submit such cases to SHOT

Action: Hospital Transfusion Teams



Pulmonary Complications

24 Transfusion-Related Acute Lung Injury (TRALI)

Author: Catherine Chapman

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: 11

Implicated components with confirmed antibody concordance n=6	
Red cells	2
FFP	0
Platelets	1
Cryoprecipitate	0
Buffy coat Granulocytes	1
Anti-D Ig	0
Multiple components	0
Not investigated	2

Mortality/morbidity	
Deaths due to transfusion	0
Deaths probably/likely due to transfusion	0
Deaths possibly due to transfusion	0
Major morbidity	8
Potential for major morbidity (Anti-D or K only)	N/A

Gender	
Male	5
Female	6
Not known	0

Age	
≥18 years	10
16 years to <18 years	0
1 year to <16 years	1
>28 days to <1 year	0
Birth to ≤28 days	0
Not known	0

Emergency vs. routine and core hours vs. out of core hours	
Emergency	1
Urgent	2
Routine	8
Not known	0
In core hours	0
Out of core hours	0
Not applicable	11

Where transfusion took place	
Emergency department	0
Theatre	0
ITU/NNU/HDU/Recovery	0
Wards	0
Delivery ward	0
Postnatal	0
Medical Assessment Unit	0
Community	0
Outpatient/day unit	0
Hospice	0
Antenatal Clinic	0
Not applicable	11

Eleven cases of suspected TRALI have been included this year. Eight other reports were transferred to another SHOT category following review, seven to transfusion-associated circulatory overload (TACO) (2 having first been transferred to acute transfusion reactions (ATR) before going to TACO), and 1 to transfusion-associated dyspnoea (TAD).

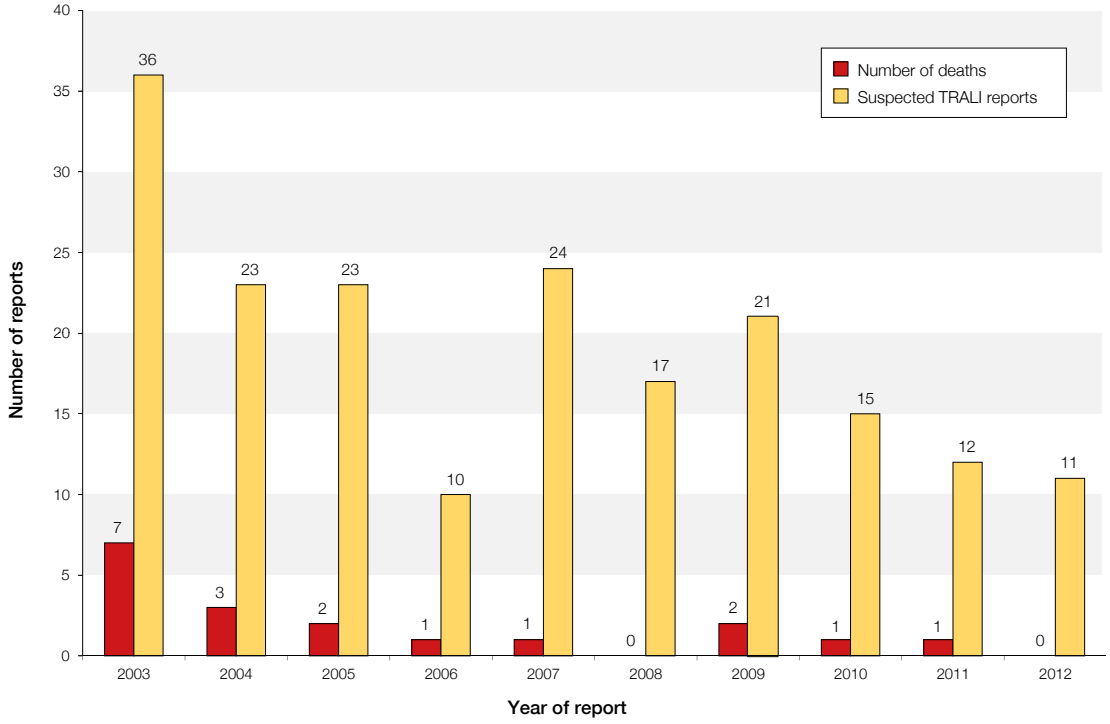


Figure 24.1: Number of suspected TRALI cases and deaths at least possibly related to TRALI by year of report

Deaths n=0

Table 24.2 shows the assessed probability of TRALI in these eleven cases. One patient died; the cause of death was attributed to bronchopneumonia, confirmed by post mortem examination (imputability 0).

Major morbidity n=8

Apart from the one patient who died, and despite major morbidity in 8, these and the other 2 all made full recoveries from their respiratory incidents (10/11). The number of TRALI reports in 2012 is similar to that in 2011 (12 cases). Those classified as major morbidity included 2 already on intensive care ventilation who deteriorated, 3 patients needing ventilation who were not already on this, 2 who required admission to high dependency units and 1 who developed significant hypoxia requiring emergency intervention with oxygen.

Assessment of TRALI cases

There is no diagnostic test for TRALI and it is difficult to distinguish from other causes of acute lung injury, circulatory overload or infection. Most reported cases are complex with several possible contributory factors. The probability of TRALI has been assessed in each case using the criteria in Table 24.1. Clinical factors which influence this assessment include: timing; radiological features; possibility of infection; other risk factors for acute lung injury or acute respiratory distress syndrome; evidence of circulatory overload and/or impairment of cardiac function; pre-existing cardiac, pulmonary, renal, hepatic or other disease and response to diuretics. Serological results are also considered.

Two intensive care specialists and a transfusion medicine expert (TRALI expert panel) assessed clinical details of all NHSBT cases (8 of 11 reported cases) before laboratory investigation. Cases are subsequently categorised to take account of the laboratory results. As in previous years, cases have been divided into four groups (as shown in Table 24.1).

Table 24.1: Assessment of TRALI cases

Assessment of TRALI cases	
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

Table 24.2: Assessment against criteria in Table 24.1 for the 11 cases reported in 2012

TRALI case imputability (SHOT criteria)	Number of cases
Highly likely	1
Probable	3
Possible	3
Unlikely	4
Total	**11**

Additional information is available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012:

This includes data extracted from individual TRALI questionnaires and the associated laboratory results.

TRALI Table 1 Patient characteristics and component details

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

Patients reported in 2012

Age

Patient ages ranged from 3 to 86 years. Only one patient was aged less than 18 years (3 years); this paediatric case was classified as possible TRALI.

Clinical specialty

This year the most frequent case specialty was haematology (4 cases), 3 cases were medical, 3 in obstetrics and gynaecology and 1 in oncology. Analysis of cumulative data since 1996 including 295 reports of suspected TRALI has shown that haematology/oncology combined has provided the highest number of reports of suspected TRALI (101/295, 34.2%) and surgery the second highest (94/295, 31.9%). Denominator data are not available.

Clinical presentation

All patients had been hypoxic. All except one had bilateral pulmonary infiltrates on chest X-ray (CXR) or pulmonary angiogram; one patient died before CXR was possible. Five patients were treated in the intensive therapy unit (ITU), of these, two were already on ITU before the event. Three patients required invasive mechanical ventilation; one was ventilated for one day, another for seven days and the duration of ventilation was not reported for the third. Two patients were transferred to the high dependency unit (HDU).

Fever was present in six patients, absent in three and was not reported in two. Hypotension was present in three, absent in six and unreported in two. Signs of heart failure were present in two, absent in seven and unreported in two.

Patient outcomes

One patient died of bronchopneumonia which was confirmed at post-mortem. TRALI was determined as unlikely and death unrelated (imputability 0). All other patients recovered fully from their respiratory event.

Laboratory investigations

Complete TRALI investigation results were available in nine cases, results were incomplete in one case and investigations had not been undertaken in the case which followed intravenous immunoglobulin (IVIg) infusion. The reference laboratory advised that meaningful HLA (human leucocyte antigen) and granulocyte antibody results could not be obtained when testing IVIg due to high level non–specific binding of immunoglobulin.

Donor antibodies

Concordant donor leucocyte antibodies were found in five donors (four recipients). The antibody specificities are reported in Table 24.3. Three of these four cases were classified as probable and one as highly likely TRALI (Case 1).

The other seven cases were classified as possible (3) or unlikely (4) to have been TRALI. All had other potential risk factors for respiratory deterioration and none was found to have significant concordant antibody (5 of 7 were fully investigated).

Donor antibody	Concordant specificities	Component/s	Other risk factors
HLA class I Case 1	A2	Buffy coat granulocytes (30 mL plasma)	Sepsis
HNA Case 1	HNA-2	Buffy coat granulocytes	Sepsis
HLA class II	DR14, DQ5	Platelet pool; buffy coat donor (30 mL plasma)	Sepsis
HLA class I and class II	A2, A24, B60, C9, C10, DR4, DR13, DQ6	RBC* in optimal additive solution (approx 20 mL plasma)	Circulatory overload
HLA class I and class II Case 2	A24, B8, DR4, DR17	RBC plasma-reduced	Multi-organ failure, on ventilator and dialysis

**Red blood cells.*

Table 24.3: Concordant donor antibodies – specificities and implicated components

Patient antibodies

Patients who have suspected TRALI no longer require to be tested for leucocyte antibodies because all components except granulocytes are now leucodepleted in the UK. Patient antibody investigation is required for recipients of granulocytes (apheresis or buffy coat). One case this year followed transfused granulocytes (Case 1); this patient had been tested and found negative for HLA and granulocyte antibodies.

Classification of cases according to Canadian consensus criteria[101,102]

All 11 reports have also been separately classified using the Canadian consensus criteria to allow international comparison (Table 24.4).

TRALI probability (consensus panel criteria)	Number of cases
TRALI	1
Possible TRALI	10
Total	**11**

Table 24.4: TRALI case probability (Canadian consensus criteria)

Case reports

Case 1: Highly likely TRALI

A 60 year old man had received induction treatment for acute myeloid leukaemia and developed neutropenic sepsis with colitis and pneumonia. He was transfused with 14 buffy coats to provide granulocyte support. During the last pack his temperature increased from 37.8 to 38.9°C, he developed rigors, dyspnoea, wheeze, hypoxia, tachycardia and bilateral pulmonary infiltrates on CXR. He had been on continuous positive airway pressure (CPAP) ventilation before transfusion but was being weaned off oxygen before he was transfused. This event was treated with CPAP, salbutamol, diamorphine, hydrocortisone, chlorphenamine and furosemide with full recovery.

Results of TRALI investigations showed that two female donors had concordant antibodies; one had granulocyte specific antibody (anti-HNA-2) and the other had HLA (human leucocyte antigen) class I antibody (anti-HLA-A2).The patient did not have anti-HLA or granulocyte antibodies.

Case 2: Probable TRALI

A 30 year old man was admitted following poisoning and developed multi-organ failure. He had required extensive resection of ischaemic bowel and was ventilated and on dialysis in the intensive therapy unit (ITU). One unit of red cells was transfused because of post operative oozing. Four hours later his respiratory rate and oxygen requirement had increased and continued to increase overnight. His BP increased from 169/85 to 190/92. He was in negative fluid balance. CXR had shown partial infiltrates before transfusion but this progressed to extensive bilateral infiltrates after transfusion. Treatment comprised increased respiratory support. He had returned to pre-transfusion respiratory rate and oxygen requirements 24 hours later.

Results of investigations showed that the female red cell donor had multiple HLA class I and class II antibodies including concordant anti-HLA-A24, -B8, -DR4 and -DR17.

Case 3: Respiratory distress after intravenous immunoglobulin (IVIg)

A 20 year old patient with acute lymphoblastic leukaemia had received an allogeneic haemopoietic stem cell transplant four months previously and had renal impairment. She had experienced acute reactions to platelet transfusion previously and had antibodies to HLA and HNA. She was treated with rituximab for possible immune thrombocytopenia, followed four days later with IVIg and developed a 'mild reaction' following her first dose. She was treated with antibiotics for presumed infection. Next day, she had her second dose of IVIg and developed itching and facial swelling during and after infusion which was treated with IV hydrocortisone and chlorphenamine. Three hours later, she became severely hypoxic and tachypnoeic (respiratory rate 46 breaths/min) needing intubation and mechanical ventilation for seven days. The CXR showed 'bilateral white out appearances'. She made a full recovery from this respiratory event. The acute allergic reaction which she experienced initially was atypical for TRALI. Laboratory investigation of the IVIg was not undertaken. The National Reference Laboratory advised that the level of non-specific binding which occurs with IVIg would invalidate any antibody test results.

This case was classified as possible TRALI.

COMMENTARY

One death occurred which was unrelated to TRALI. Concordant donor antibody was found in four cases. In each case there were also other potential risk factors for respiratory deterioration and components containing more than one concordant HLA or HNA antibody specificity had been transfused.

A case of possible TRALI was reported to SHOT this year after IVIg infusion. There have been several reports in the literature of non-cardiogenic pulmonary oedema following IVIg[96,103].

No case of TRALI has been linked to transfusion of female plasma rich components (FFP, apheresis platelets, plasma contribution to platelet pool) containing concordant antibody this year.

Reported rates of TRALI remain consistently lower than in 2003/2004 when TRALI risk reduction strategies were first initiated.

All UK Blood Services currently use male donors to provide 100% FFP and plasma for platelet pooling. It is not yet feasible for all Blood Services to prepare pooled granulocytes from male donors only.

Recommendations

- Reporters are asked to provide as much of the information requested on the SHOT pulmonary questionnaire as possible. There is significant overlap between categories of pulmonary complications and clinical detail is essential to allow accurate assessment of these cases
- Transfusions should only take place where there are facilities and staff trained to recognise and manage adverse incidents (see also ATR chapter, Chapter 16)

Action: Hospital Transfusion Teams and Reporters

25 Transfusion-Associated Circulatory Overload (TACO)

Author: Hannah Cohen

Definition:

TACO includes any 4 of the following that occur within 6 hours of transfusion[1]

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

DATA SUMMARY
Total number of cases: 82

Implicated components		Mortality/morbidity	
Red cells	53	Deaths due to transfusion	0
FFP	7	Deaths probably/likely due to transfusion	1
Platelets	1	Deaths possibly due to transfusion	5
Cryoprecipitate	0	Major morbidity	29
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	21		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	39	≥18 years	82	Emergency	15	Emergency department	2
Female	43	16 years to <18 years	0	Urgent	20	Theatre	5
Not known	0	1 year to <16 years	0	Routine	47	ITU/NNU/HDU/Recovery	14
		>28 days to <1 year	0	Not known	0	Wards	39
		Birth to ≤28 days	0			Delivery Ward	4
		Not known	0	In core hours	35	Postnatal	0
				Out of core hours	47	Medical Assessment Unit	11
				Not known/Not applicable	0	Community	2
						Outpatient/day unit	5
						Hospice	0
						Antenatal Clinic	0

A total of 82 cases of TACO are analysed, compared with 71 in 2011, which represents a 15.5% increase. Sixty-one questionnaires on TACO were received, 2 initially reported as acute transfusion reactions (ATR) and 3 as transfusion-related acute lung injury (TRALI), 6 were transferred in from the 'transfusion-associated dyspnoea' (TAD) chapter, 12 additional cases from ATR, 2 from TRALI, and 1 from the 'avoidable, delayed or undertransfusion' (ADU) group. The SHOT pulmonary questionnaire, to which reporters are directed if the predominant feature is respiratory distress, was completed in 5 of 12 ATR cases subsequently categorized as TACO.

Patients

There were 39 males and 43 females. The median age was 71 (range 18–99) years (with the median age of cases initially reported as TACO 74 years and of those transferred from other categories 65 years). Forty-four patients (53.7%) were aged 70 years or more and 21 (25.6%) 50 years or less.

Diagnosis of TACO

Cases were assessed by the reviewer for probability of a diagnosis of TACO based on the International Society for Blood Transfusion (ISBT) definition[1], available on the SHOT website (www.shotuk.org)

TACO case probability (ISBT criteria)*	Number of cases
Highly likely	13
Probable	12
Possible	53
Excluded/unlikely	2
Not assessable	2
Total	**82**

Table 25.1: TACO case probability

**10 cases where TACO was observed between 6 hours and 24 hours, and one fatal case which was diagnosed 2 days post-transfusion, are also included.*

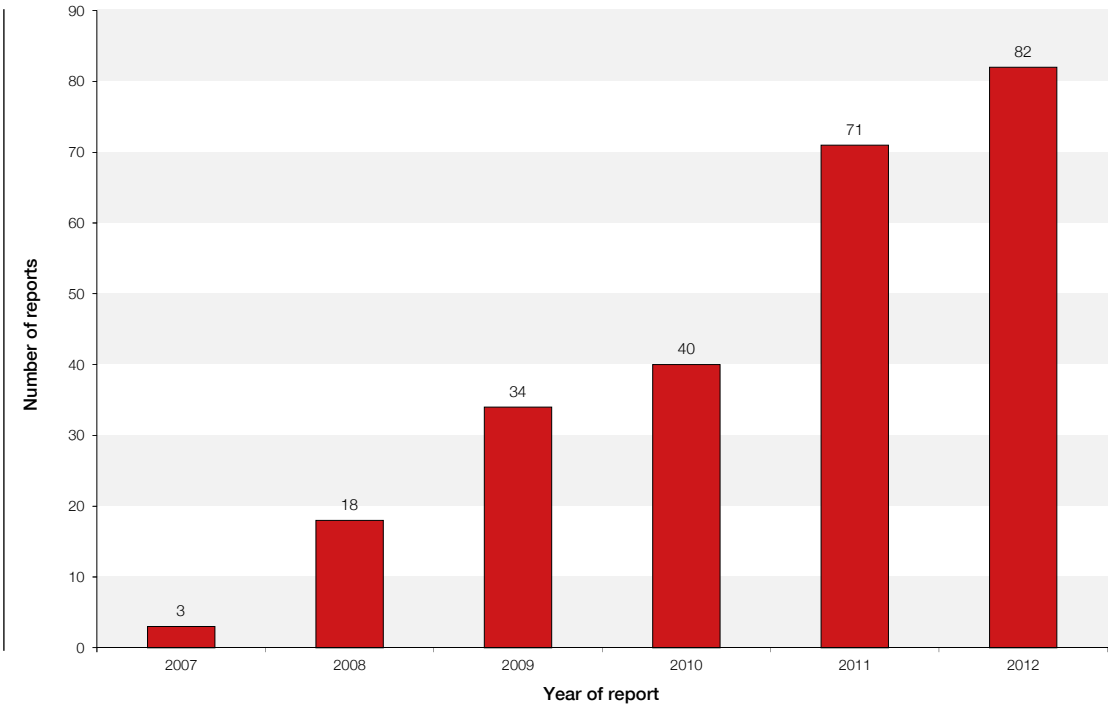
Case 1: A case of possible TACO with features of ATR and TRALI

An elderly female received an emergency transfusion for upper gastrointestinal bleeding with 2 units of red cells, 2 of fresh frozen plasma (FFP) and 1 unit of apheresis platelets, transfused rapidly. She also received 2325 mL crystalloid. On commencement of the second unit of red cells she was noted to have developed a generalised rash. There was no wheeze, airway obstruction or tongue swelling. She was treated with hydrocortisone and chlorphenamine. Two hours later her O2 saturation dropped to 80% on 40% O2. A chest X-ray showed bilateral infiltrates and suggested fluid overload. She was afebrile, pre- and post-reaction observations respectively showed pulse rate 90 and 95 beats per minute, blood pressure (BP) 140/80 and 103/70, respiratory rate 16 and 19/min, and post-reaction the pO2 was 6.7 kPa and pCO2.5 kPa, with central venous pressure (CVP) 6 cm. She was documented to be in positive fluid balance of +2565 mL in the 24 hours prior to the reaction. She was admitted to the high dependency unit (HDU) and treated with diuretic therapy. Continuous positive airway pressure (CPAP) or invasive ventilation were not required. Fluid balance on the day of the reaction was 1000 mL in and 3000 mL out. An electrocardiogram (ECG) showed no acute changes, however troponin was significantly raised and she was diagnosed to have a non ST segment elevation myocardial infarction (NSTEMI). An echocardiogram (ECHO) showed mild left ventricular impairment, severe mitral calcification, no stenosis, and mitral and aortic valve disease. Investigations for TRALI showed that one donor who donated one of the red cell units had HLA antibodies (A2, A11, B13 and DR7) to which the patient had a cognate antigen A2. However, these findings were probably coincidental as she had evidence of pulmonary oedema with contributory factors being her myocardial infarction and fluid resuscitation for hypotension as a result of bleeding.

Learning point

- It can be difficult to accurately diagnose pulmonary complications of transfusion, particularly where features of other pathological reactions coexist. The SHOT pulmonary questionnaire, to which reporters are directed if the predominant feature is respiratory distress, provides a common dataset which enables accurate categorization of pulmonary complications of transfusion. It should be used for all patients who develop respiratory distress in association with a blood transfusion. Accurate characterisation of pulmonary complications of transfusion underpins the development of targeted strategies to reduce these hazards of transfusion

Figure 25.1: Number of cases of TACO reported to SHOT each year



A further case of TACO resulted from an unnecessary transfusion given on the basis of an inaccurate haemoglobin result (ADU chapter (Chapter 12)).

Deaths n=6

TACO was possibly (n=5) or probably/likely (n=1; described below) contributory to death in 6 patients. There were a further 9 deaths; in 7 the reporter considered that the transfusion was excluded/unlikely to be contributory to death and in 2 it was not assessable.

Case 2: Fatal TACO after over-transfusion to low body weight individual

A 65 year old female was admitted to hospital with a gradual decline in health, weight loss and shortness of breath. She had 'short gut' syndrome and was of low body weight (35 kg) with severe anaemia, Hb 49 g/L, and renal impairment. She received 4 units of red cells transfused over 12 hours plus intravenous (IV) fluid, with 3 of the red cell units transfused overnight. Her cardiorespiratory manifestations came to light when she developed diarrhoea 40 hours after transfusion, when a chest X-ray, clear on admission, showed evidence of pulmonary oedema 2 days after transfusion. A blood count 3 days post transfusion showed polycythaemia with Hb 176 g/L. Her condition continued to deteriorate following the transfusion and she died.

Learning points

- Low body weight and renal impairment are risk factors for transfusion-associated circulatory overload (TACO). These and other risk factors, which include cardiac failure, hypoalbuminaemia and fluid overload, can be identified by pre-transfusion clinical assessment so that measures can be taken to avoid TACO. The concept that one unit of red cells gives a Hb increment of 10 g/L should only be applied as an approximation for a 70-80 kg patient. For patients of lower body weight the prescription should be reduced as detailed in the 2012 British Committee for Standards in Haematology (BCSH) addendum to the guidelines on blood administration[26,27], which is based on SHOT observations and recommendations
- As recommended in previous SHOT Annual Reports and BCSH guidelines[27], transfusion must only take place when there are enough staff available to monitor the patient and when the patient can be readily observed
- It is not clear when TACO developed in this case, as there appears to have been a delay in diagnosis. SHOT has consistently observed a small proportion of cases, that otherwise meet the International Society for Blood Transfusion (ISBT) criteria for TACO, between 6-24 hours post-transfusion, and it is important to undertake post-transfusion clinical assessment and monitor patients for evidence of TACO during the first 24 hours after transfusion so that appropriate and timely management can be instituted

Major morbidity n=29

Twenty nine patients developed major morbidity, 28 of whom required intensive care/high dependency admission +/-ventilation, and one required dialysis (Case 2).

Clinical details and transfused fluids in TACO cases

One or more concomitant medical conditions that increase the risk of TACO (cardiac failure, renal impairment, hypoalbuminaemia or fluid overload) were reported in 48/82 (58.5%) of cases. This year we requested body weights (BW) on the SHOT questionnaires, as low body weight is also a risk factor for TACO. These were provided by the reporter in 17/82 (20.7%) cases. Three of these patients had a BW of less than 50 kg, with 2 (adults) at 35 and 26.5 kg.

Complete details on fluid balance were supplied by the reporter in 20/82 (24.4%) of cases (10/71, 14.1% last year). The time interval between the transfusion and the onset of symptoms (information was available in 79/82 cases), was 0-2 hours in 45.1% (37/82), 2-6 hours in 39.0% (32/82) and between 6-24 hours in 12.2% (10/82) patients.

Two patients with chronic iron deficiency developed TACO following blood transfusion.

Learning points

- Close attention to fluid balance and its documentation is essential in all patients receiving transfusion of blood components
- Blood transfusion is not an appropriate treatment for iron deficiency anaemia, and puts individuals, particularly the elderly, at risk of TACO. Iron deficiency should be treated with iron and the underlying cause established and treated

The importance of appropriate clinical assessment of patients who receive transfusion of blood component(s) and the hazards of transfusion in patients transferred during a transfusion episode are highlighted in the 3 cases (3, 4 and 5) below.

Case 3: Over-transfusion due to inadequate assessment and monitoring leading to polycythaemia and circulatory overload

A 42 year old female, BW 69 kg, in end stage renal failure (ESRF) was admitted for a brachio-axillary bypass graft. Her Hb on admission was 117 g/L with BP 120/80 falling to 96/58 just prior to surgery. The patient was on 2L of oxygen. The estimated perioperative blood loss was approximately 700 mL. She was given 1L of fluid in theatre (500 mL modified fluid gelatin and 500 mL normal saline). She remained hypotensive, and her Hb 2 hours post surgery was 58 g/L. Her BP fell further to 65/45 five and a half hours post surgery, and she was commenced on a 4 unit red cell transfusion. There was no overt bleeding. Her Hb approximately 3 hours later was 93 g/L and 30 minutes later, when the 4th red cell unit was underway, 102 g/L. Her BP at this time was 95/57. Two further red cell units were transfused over the next hour. Following this, the Hb rose to 162 g/L and potassium to 6.5 mmol/L. Her oxygen saturations remained normal throughout on 2L of oxygen. She was therefore venesected and dialysed for hyperkalaemia and volume overload. A root cause analysis identified a failure to recognise that sufficient blood had been transfused when the Hb was 102 g/L and also an inappropriate reliance on lower limb BP readings.

Learning point

- The risk of TACO can be minimised by pre-transfusion assessment such that an appropriate volume of red cells is prescribed as per the BCSH addendum[26]. This addendum states that in patients with minor but ongoing blood loss, Hb should be regularly monitored, as a minimum after every 2-3 units of red cells. This should also be applied when the volume of blood loss is uncertain

Case 4: Poor clinical handover resulting in inadequate clinical assessment and TACO

An elderly female, BW 49.6 kg, with a history of hypertension and angina, was given a 3 unit red cell transfusion for anaemia associated with metastatic carcinoma of the breast. She was identified to be at risk for TACO and had 7 sets of observations done for the first unit, following which she was moved to another ward where the transfusion was completed. The concern about her risk of TACO was not picked up in the notes by this ward. Between 12 and 24 hours later she developed shortness of breath and her O2 saturation dropped from 94 to 65%. This was associated with tachycardia and hypertension, with pre- and post pulse 76 and 122 beats per minute and pre and post BP 168/87 and 193/111 respectively. She also had clinical evidence of pulmonary oedema.

Case 5: TACO after patient transfer between hospitals for transfusion with no handover and no pre-transfusion clinical assessment

A 79 year old female with anaemia (Hb 75 g/L) associated with haematological malignancy, and who also had a history of cardiac failure and renal impairment, was sent from the main hospital to a satellite hospital day unit for a 3 unit red cell transfusion. No case notes, consent or prescription accompanied the patient. Nursing staff therefore went to the clinic area in the satellite hospital where some pressure was exerted on a doctor, as the patient had already suffered a delay in starting her intended treatment, who prescribed 3 units of red cells. Her BP rose steadily during the transfusion, however the transfusion was continued regardless of this. The first unit was transfused over 3 hrs, the 2nd unit over 90 mins, and the 3rd unit over 2 hrs. The nurse caring for the patient stated that she contacted a haematology registrar at the main hospital. She was advised to stop the transfusion (possibly at the start of the third unit) for 45 mins to re-assess the BP – recorded as 165/85 although the time was not documented. The next BP was 219/105 when the transfusion was stopped and the patient was transferred back to the main hospital. There was no written documentation of the nursing staff actions during this patient's transfusion (other than observations and the volume of red cells infused). The reaction was not reported to the transfusion team or hospital transfusion laboratory until 1 week later.

This case demonstrates multiple errors: failure to handover on transfer between hospitals, failure of pre-transfusion clinical assessment prior to prescription of red cells and therefore the rate of transfusion was too fast with no diuretic cover, failure to act appropriately on the observation of a rising BP, and delay in reporting the reaction to the hospital transfusion team.

Learning points

- Risk factors for TACO include age (70 years or more), cardiac failure, renal impairment, hypoalbuminaemia, fluid overload as well as low body weight, and these should be taken into account in all patients who receive transfusion of blood component(s)
- Transfer of patients during a transfusion episode is potentially hazardous and should be avoided wherever possible. If unavoidable, clinical handover templates should include information on measures to reduce the risk of TACO in patients identified to be at risk by clinical assessment pre transfusion

Acute haemorrhage cases in which more than one component was transfused n=16

There were 16 cases of acute haemorrhage where more than 1 blood component was transfused. Red cells and fresh frozen plasma (FFP) were transfused in 4 cases of gastrointestinal (GI) haemorrhage and 1 retroperitoneal bleed; and together with platelets in 4 cases of obstetric haemorrhage; and together with platelets in 4 cases of obstetric haemorrhage, 1 case of trauma and 1 retroperitoneal haematoma. Red cells and platelets were transfused in 1 case of GI haemorrhage and 1 placental abruption; and red cells, FFP and cryoprecipitate were transfused in 1 case of trauma, and with platelets in 1 case of ruptured ectopic pregnancy.

Cases in which red cell transfusion was implicated n=74 (some had multiple components)

Red cells were implicated in 53 cases (and in a further 21 cases multiple components were transfused). In 32/53 cases red cells were transfused in the absence of suspected acute haemorrhage. The median duration of transfusion/red cell unit, where details were given, was 3.0 (range 1–5) hours. TACO was observed after 1 unit of red cells or less in 14 cases and after 2 units or less in 9 cases.

Learning point

- As in previous Annual SHOT Reports, it is emphasised that TACO can occur after relatively small volumes of red cells, even 1 unit or less, particularly in patients at increased risk of developing TACO in whom the rate of transfusion should be carefully assessed and the use of diuretics considered

Cases in which FFP was transfused n=22 (some had multiple components)

There were 22 cases where FFP was transfused, 14 during acute haemorrhage. In one case 1750 mL FFP was reported to be administered for the immediate reversal of warfarin anticoagulation to a 56 year old female (body weight not reported) with a history of excess alcohol intake who was admitted with abdominal pain secondary to a life-threatening retroperitoneal bleed.

Learning point

- Prothrombin complex concentrate (PCC), and not FFP, should be used for warfarin reversal when this is indicated as per the BCSH guidelines[105] and as highlighted in previous Annual SHOT Reports

Cases in which platelets were transfused n=16 (some had multiple components)

There were 16 cases where platelets were transfused, and in 9/16 this was in the context of acute haemorrhage. In the remaining 7 cases, platelets were transfused prophylactically in 4 patients with haematological malignancies, 2 with thrombocytopenia related to hepatic disease, and prior to endoscopy in an individual with a platelet count of $56x10^9$/L.

COMMENTARY

TACO remains an important cause of transfusion-related morbidity and mortality. This year TACO was contributory to death in 6 patients (possibly n=5 or probably/likely n=1) and to major morbidity in 29, with these serious outcomes together comprising 42.7% (35/82) of TACO cases analysed.

There has been a slight further increase of 15.5% (from 71 cases in 2011 to 82 in 2012) in the number of TACO cases reported, however TACO probably remains under-reported. The median age of TACO cases at 71 years is comparable with that of 73 years in the 2011 National Comparative Audit (NCA) of the use of blood in medical patients (personal communication, Dr Kate Pendry, consultant haematologist, NHSBT). The median age of cases initially reported as TACO was higher (74 years) than those transferred from other categories (65 years), and it is possible that there is a bias towards identifying TACO in older individuals.

The 2012 BCSH addendum to the guidelines on blood administration, based on SHOT observations and recommendations, highlight the importance of undertaking clinical assessment prior to a blood transfusion to identify patients at increased risk of TACO, so that measures can be taken to reduce the risk of TACO. It states that for patients identified at risk of TACO, a written request should be made that during the administration of blood components, specific attention should be given to monitoring the patient for signs of circulatory overload, including fluid balance[26]. A pre-transfusion checklist to reduce the risk of TACO has been suggested[106].

Risk factors for TACO include cardiac failure, renal impairment, hypoalbuminaemia and fluid overload. Low body weight is also an important risk factor for TACO, highlighted in Case 2 above. In addition, pre-eclampsia remains an important cause of hypertensive acute pulmonary oedema in pregnancy[107] and affected women are therefore potentially also at risk of TACO. The 2011 NCA of the use of blood in medical patients showed that there was an over-transfusion rate of 33% (defined as Hb increment of more than 20 g/L above the threshold set for that patient or more than 20 g above the starting Hb in patients with reversible anaemia), and has demonstrated a correlation between low body weight and increasing Hb increment (personal communication, Dr Kate Pendry, consultant haematologist, NHSBT). The BCSH addendum[26] guidance includes the following: as a general guide, transfusing a volume of 4 mL/kg will typically give a Hb increment of 10 g/L. The concept that one unit of red cells gives a Hb increment of 10 g/L should only be applied as an approximation for a 70-80 kg patient. For patients of lower body weight the prescription should be reduced. Paediatric transfusions should be prescribed in mL. Single unit red cell transfusions are recommended where possible, especially in non-bleeding patients.

The median duration of transfusion/red cell unit where red cells were transfused in the absence of suspected haemorrhage was 3.0 (range 1-5) hours, and TACO continues to be observed after transfusion of relatively small volumes, even 1 red cell unit or less. It is emphasised that, particularly in patients at increased risk of developing TACO, risk factors should be documented, and considered when prescribing the volume and rate of transfusion, and in deciding whether diuretics should be prescribed[26].

Transfer of patients during a transfusion episode has emerged as a further risk factor for TACO and should be avoided wherever possible. SHOT highlighted in the 2011 Annual SHOT Report[2] that appropriate clinical handover templates should be used whenever patients move between wards or hospitals or between shifts and these should be improved to include information about specific requirements. In patients identified to be at risk of TACO, clinical handover templates should also include information on measures to avoid TACO, such as furosemide and a slower rate of transfusion, as well as appropriate monitoring for symptoms and signs of TACO.

Complete details on fluid balance were supplied by the reporter in 20/82 (24.4%) cases compared with 10/71 (14.1%) last year. This modest increase is encouraging. Close attention to fluid balance and its documentation is essential in all patient receiving transfusion of blood components.

In one case, FFP was given for warfarin reversal. PCC is the therapeutic product of choice for warfarin reversal[56] and FFP should not be used for this indication.

Five cases of TACO in patients with obstetric haemorrhage were reported this year, bringing these to a total of 15 cases reported since 2008, and highlighting that this complication does occur in these young individuals who are often regarded to be 'immune' to TACO. Contributory factors are difficulties in estimating actual blood loss, particularly because of the changing blood volume and circulatory capacity.

Of the 82 TACO cases analysed, 61 (74.4%) were reported as TACO, with the remainder transferred from several other categories and 1 case transferred out. The SHOT pulmonary questionnaire, launched on 1 January 2012, prompts collection of relevant information in all cases reported where respiratory distress is prominent. It provides a common dataset, which enables accurate categorization of pulmonary complications of transfusion, and is particularly useful in a number of cases where it is difficult to accurately diagnose pulmonary complications of transfusion because features of other pathological reactions coexist. Accurate characterisation of pulmonary complications of transfusion underpins the development of targeted strategies to reduce these hazards of transfusion.

A small proportion of cases continue to be observed to occur between 6-24 hours after transfusion, with the total after 6 hours 12.2% (10/82). It is important to be alert to evidence for TACO, particularly in patients with risk factors, during the 24 hours after transfusion.

A number of cases were observed where the case probability of TACO was designated to be possibly lower than it was. Examples are pulmonary oedema occurring post transfusion where the pulse and BP have not been provided by the reporter, or patients where a clinical picture suggestive of TACO is associated with hypotension rather than hypertension, particularly but not exclusively in cases associated with acute haemorrhage. These observations, and the occurrence of TACO cases after 6 hours as detailed above, suggest that criteria for the definition of TACO should be revisited. Improved recognition of TACO would enable early institution of treatment which in turn may reduce the associated morbidity and mortality.

Recommendations

New recommendations from this report

- The 2012 British Committee for Standards in Haematology (BCSH) addendum to the blood administration guidelines[26] on measures to reduce the risk of transfusion-associated circulatory overload (TACO) should be followed
- Transfer of patients during a transfusion episode is potentially hazardous and should be avoided wherever possible. If unavoidable, clinical handover templates should include information on measures to reduce the risk of TACO and appropriate monitoring in patients identified to be at risk by clinical assessment pre transfusion
- Post-transfusion clinical assessment should be also be undertaken and patients monitored for evidence of TACO during the first 24 hours after transfusion so that appropriate and timely management can be instituted
- Transfusions should only take place where there are facilities and trained staff to monitor and manage adverse incidents (see also Chapter 16)

Action: All clinicians

26 Transfusion-Associated Dyspnoea (TAD)

Author: Hannah Cohen

Definition:

Cases were assessed by the reviewer for probability of a diagnosis of TAD based on the International Society of Blood Transfusion (ISBT) definition[1]. A standardised definition, which is under review, will help haemovigilance organisations generate data that will be comparable at an international level.

The cases included in this chapter are heterogeneous, with the unifying salient feature respiratory distress, the essential diagnostic feature of TAD.

DATA SUMMARY
Total number of cases: 19

Implicated components		Mortality/morbidity	
Red cells	14	Deaths due to transfusion	0
FFP	1	Deaths probably/likely due to transfusion	0
Platelets	2	Deaths possibly due to transfusion	0
Cryoprecipitate	1	Major morbidity	0
Granulocytes	0	Potential for major morbidity (Anti-D or K only)	0
Anti-D Ig	0		
Multiple components	1		
Unknown	0		

Gender		Age		Emergency vs. routine and core hours vs. out of core hours		Where transfusion took place	
Male	8	≥18 years	18	Emergency	0	Emergency Department	0
Female	11	16 years to <18 years	1	Urgent	6	Theatre	2
Not known	0	1 year to <16 years	0	Routine	12	ITU/NNU/HDU/Recovery	0
		>28 days to <1 year	0	Not known	1	Wards	12
		Birth to ≤28 days	0			Delivery Ward	1
		Not known	0	In core hours	13	Postnatal	0
				Out of core hours	6	Medical Assessment Unit	2
				Not known/Not applicable	0	Community	0
						Outpatient/day unit	1
						Hospice	0
						Antenatal Clinic	0
						Unknown	1

TAD is a diagnosis of exclusion. Cases considered to be TAD may contain elements of transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI) or allergic reactions, but they do not meet the criteria for any of these. Cases designated as TAD should also not be explained by the patient's underlying condition or any other known cause, although these can be difficult to exclude definitively. The SHOT pulmonary questionnaire, to which reporters are directed when the predominant feature is respiratory distress, provides a common dataset, which enables accurate categorization of pulmonary complications of transfusion. It should be used for all patients who develop respiratory distress in association with a blood transfusion.

A total of 19 cases of TAD are analysed, just over half (54.3%) the number of 35 cases analysed last year (Figure 26.1). Fourteen questionnaires on TAD were received (compared with 13 last year), 1 initially reported as an acute transfusion reaction (ATR) and 1 as TRALI; 6 of these were transferred to the TACO chapter, 10 cases were transferred in from ATR (19 the previous year), with the SHOT pulmonary questionnaire completed in 4 of these cases.

Patients

There were 8 males and 11 females. The median age was 61 (range 17 to 83) years.

Table 26.1: TAD case probability based on ISBT criteria

TAD case probability	Number of cases
Highly likely	0
Probable	0
Possible	17
Excluded/unlikely	2

Table 26.1: TAD case probability based on ISBT criteria

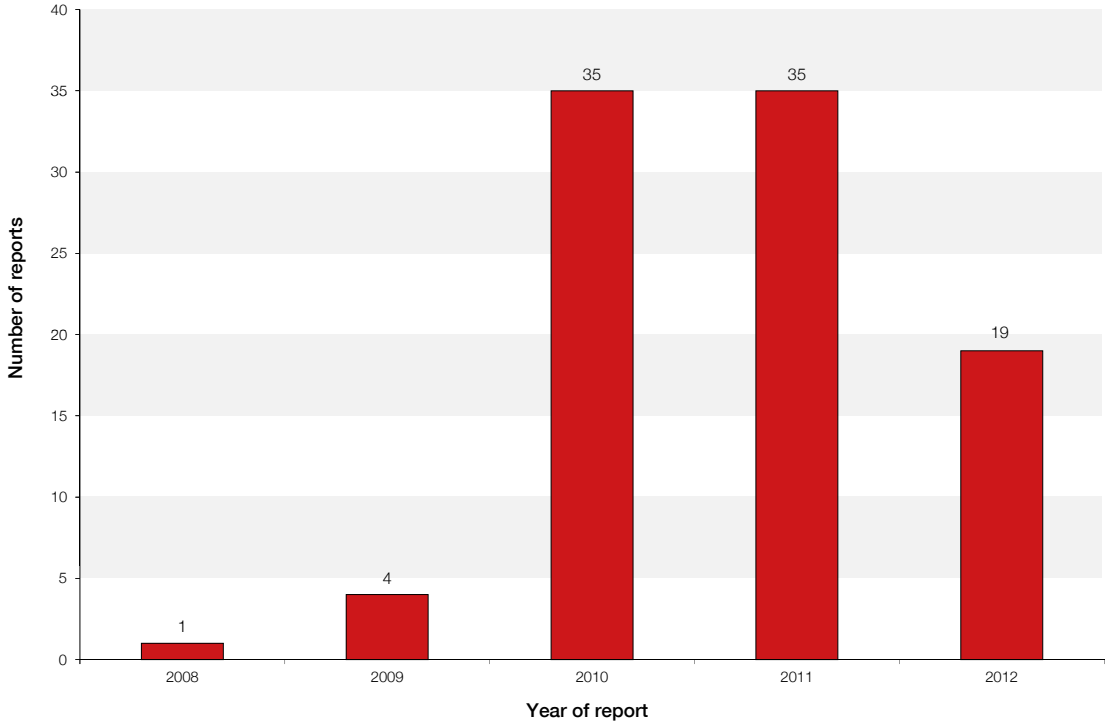


Figure 26.1: Number of cases of TAD reported each year*

* TAD was introduced as a SHOT reporting category in 2009.

Deaths n=0

There were 2 deaths where the pulmonary reaction was thought by the reporter to have possibly arisen as a result of the transfusion, however, in both cases the transfusion was assessed to be unlikely or excluded from being contributory to the patient's death.

These 2 cases depict fairly typical scenarios where TAD is a possible diagnosis. They highlight that as TAD is a diagnosis of exclusion, it may be difficult to distinguish it from the underlying medical condition, with thorough clinical assessment and investigation required.

Two possible cases of TAD

Case 1: An elderly male with breathlessness

An elderly male, body weight 64 kg, with chronic anaemia secondary to carcinoma of the bladder associated with a urinary tract infection and renal failure developed a steadily rising temperature during the day (37°C at 06:00, 37.7°C at 17:10 when the red cell transfusion started). During transfusion, there was a gradual rise in his temperature to 38.2°C by 20:30, as well as a tachycardia with his pulse rising from 80 bpm pre transfusion to 110 bpm, with BP remaining stable at 145/85 and 140/80 respectively. He also became dyspnoeic with a fall in his O2 saturation to 70%, rising rapidly to 99% on oxygen. Intravenous (IV) hydrocortisone and IV paracetamol were administered and his vital signs normalised by 22:00. A chest X-ray was reported to be normal. Blood cultures were negative. His symptoms were thought to be due to underlying sepsis or a possible transfusion reaction. He subsequently died, with the death stated to be unlikely to be related to the transfusion or reaction.

Case 2: Breathless during transfusion

A 43-year old male with chronic anaemia related to chronic kidney disease, liver disease and a chest infection, was commenced on a red cell transfusion of 1 unit over 2 hours during dialysis. Fifteen minutes after starting the transfusion, routine clinical observations showed a rise in temperature to 37.5°C and the patient complained of shortness of breath. His O2 saturation dropped to 84% on 8 L/min O2 via a face mask. The transfusion was stopped immediately. The junior doctor was contacted and the O2 therapy was changed to 100% via a reservoir mask at 10 L/min. Blood cultures were negative. The consultant nephrologist did not think that it was possible to reach a definite conclusion – there were alternative explanations for the patient's symptoms, although he did appear to have acute symptoms temporally related to the transfusion.

Major morbidity n=0

There were no cases of major morbidity.

Clinical features

Symptoms and signs

The reaction was stated to have occurred within 0-2 hours of the transfusion in 16 (and reported to have occurred at 15 minutes or less in 8 of these cases); and at 2-6 hours in 3 cases. All patients had respiratory distress, with dyspnoea reported in 16/19 cases and reduced pO2 observed in the remaining 3 cases. Eight patients were stated to have developed associated tachycardia, 3 to have hypertension with none reported to have hypotension. Eight patients developed associated fever and 4 had rigors. Blood samples were taken from the patient for culture in 8 patients with negative results in all cases.

Investigations

Oxygen saturation/arterial blood gases and chest X-rays were reported to have been performed in 57.9% (11/19) and 36.8% (7/19) of cases respectively, with neither reported in 36.8% (7/19) of cases.

Implicated components

The majority of cases (15/19; 78.9%) were related to red cell transfusion. In one case red cells were transfused together with a prophylactic (apheresis) platelet transfusion to a patient with acute myeloid leukaemia with platelets under $10x10^9$/L. Platelets (apheresis) alone were transfused prophylactically in one case of myelodysplasia where the platelet count was under $10x10^9$/L. In a third case, a pool of platelets was transfused for bleeding during cardiothoracic surgery. A possible case of TAD was associated with 3 units of fresh frozen plasma (FFP) administered for coagulopathy associated with hepatic disease. In one case 2 units of cryoprecipitate were transfused to a patient with disseminated intravascular coagulation related to angiosarcoma.

COMMENTARY

The number of TAD cases reported this year has decreased by 45.7% to 19 from 35 last year. The total number of cases initially reported as TAD remained similar at 14, with the observed decrease predominantly due to a reduction in cases transferred from the ATR chapter.

There were no cases of major morbidity or mortality associated with TAD this year. However, since SHOT began receiving reports of TAD in 2008, there have been 10/94 (10.6%) cases associated with major morbidity.

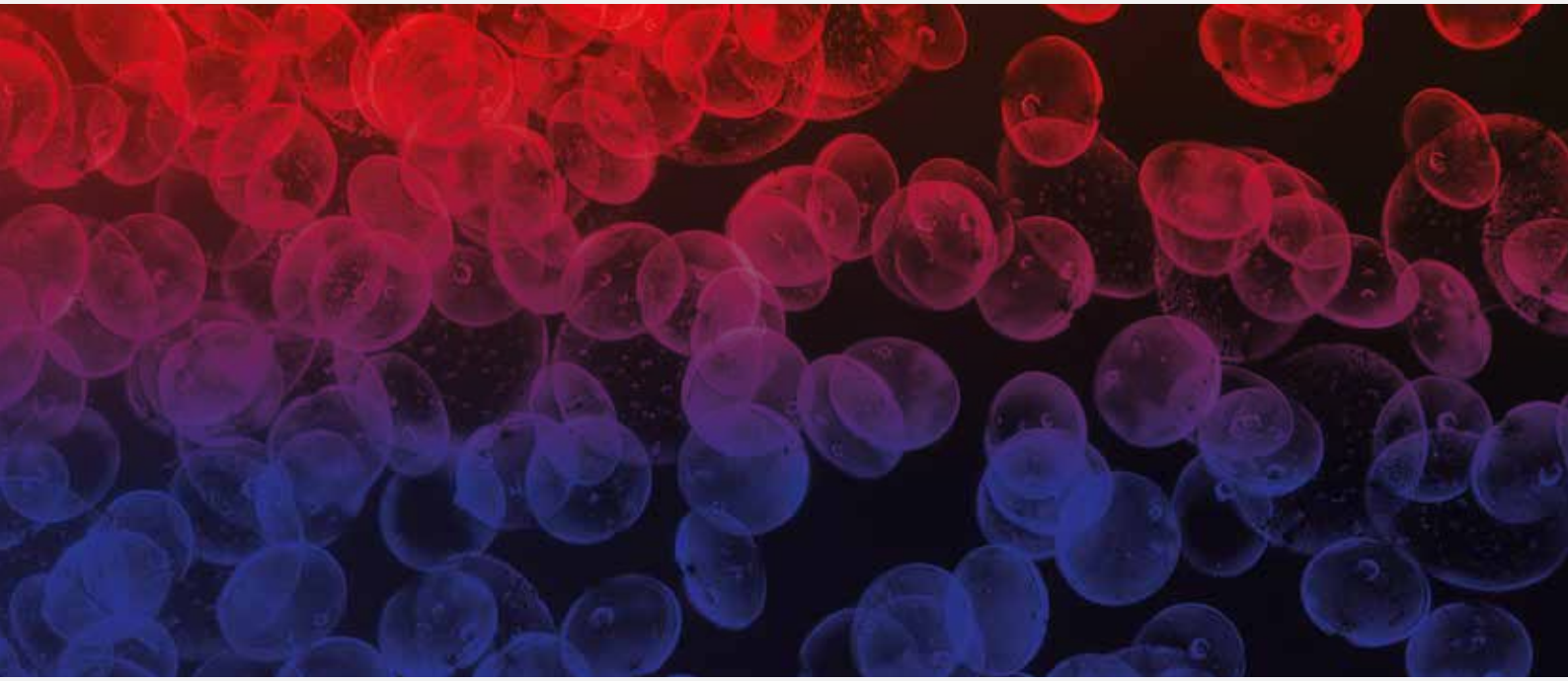
Appropriate investigation of patients with respiratory distress, which should include assessment of oxygen saturation/arterial blood gases and a chest X-ray, is required for appropriate patient care. Oxygen saturation/arterial blood gases and chest X-rays were reported to have been performed in 11/19 (57.9%) and 7/19 (36.8%) of cases respectively, however neither reported to have been performed in 7/19 (36.8%) of cases.

Particularly as TAD is a diagnosis of exclusion, adequate information is of key importance in its identification. The SHOT pulmonary questionnaire, to which reporters are directed when the predominant feature is respiratory distress, provides a common dataset, which enables accurate categorisation of pulmonary complications of transfusion. It should be used for all patients who develop respiratory distress in association with a blood transfusion. This questionnaire will provide relevant information, which will enable a more systematic delineation of the clinical and diagnostic characteristics of TAD, as well as other transfusion-related pulmonary complications. This in turn will provide a basis for a systematic approach toward the recognition, investigation and management of TAD.

Recommendations

There are no new recommendations this year.

Recommendations still active from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012.



Special Clinical Groups

27 Paediatric Cases

Author: Helen New

Definition:

Paediatric cases comprise all those occurring in patients under 18 years of age. This chapter analyses the data on paediatric cases from the other chapters in this annual report. All the cases are also included in the data in their respective chapters. All children <18 years of age are included and have been subdivided by age groups: neonates ≤28 days; infants >28 days and <1 year old; and children ≥1 year to <16 years.

Table 27.1: Summary of paediatric cases 2012

Category of case	No ≤28 days	No > 28 days to <1 year	No 1 to <16 years	No 16 to <18 years	Total paediatric cases
Incorrect blood component transfused (IBCT)	8	4	22	3	**37**
Avoidable, delayed or undertransfusion (ADU)	5	1	6	1	**13**
Handling and storage errors (HSE)	3	4	6	3	**16**
Anti-D related	0	0	1	7	**8**
Acute transfusion reactions (ATR)	2	2	22	2	**28**
Alloimmunisation (Allo)	0	0	0	1	**1**
Transfusion-related acute lung injury (TRALI)	0	0	1	0	**1**
Transfusion-associated dyspnoea (TAD)	0	0	0	1	**1**
Transfusion-associated graft vs host disease (TA-GvHD)	1	0	0	0	**1**
Transfusion-transmitted infections (TTI)	0	0	1	0	**1**
Unclassifiable complications of transfusion (UCT)	2	0	0	1	**3**
Total	**21**	**11**	**59**	**19**	**110**
Near miss (NM)	40	10	26	8	**84**
Right blood right patient (RBRP)	6	1	2	0	**9**

Note: There were no paediatric cases from the other chapters, so those headings are omitted from table. Near miss and RBRP numbers are shown separately.

General trends

The overall number of paediatric reports is similar to the last three years, and appears to have plateaued since 2009 (see analysis in SHOT 2011 report). For 2012, paediatric cases were 110/1645 (6.7%) of total SHOT reports, and 203/2767 (7.3%) if NM and RBRP are included. For 2012, the main difference was a striking reduction in the number of ATR reports, to 28 (25.5% of paediatric reports) from ≥ 48 for the last 2 years, partly due to the withdrawal of several mild ones as the definition has changed. Following from this, the proportion of error-related reports (IBCT, HSE, ADU and anti-D) increased to 67.3% (74/110) of paediatric reports (50.4%, 60/119, in 2011). A total of 26/74 (35.1%) errors originated primarily in the laboratory (6 wrong blood component transfused, 15 specific requirements not met, 3 handling and storage errors, 1 avoidable, delayed or undertransfused, 1 anti-D), a similar number to 2011. Transfusion of an incorrect blood component remained a significant proportion of paediatric reports, at 33.6% (37/110) for 2012, and this percentage is higher for paediatric than for total reports (Figure 27.1).

There was a fatal case of transfusion-associated graft versus host disease (TA-GvHD), discussed in detail in Chapter 20, with significant implications for fetal transfusion practice in urgent situations. No further reports to SHOT of suspected transfusion-associated necrotising enterocolitis (NEC) were received.

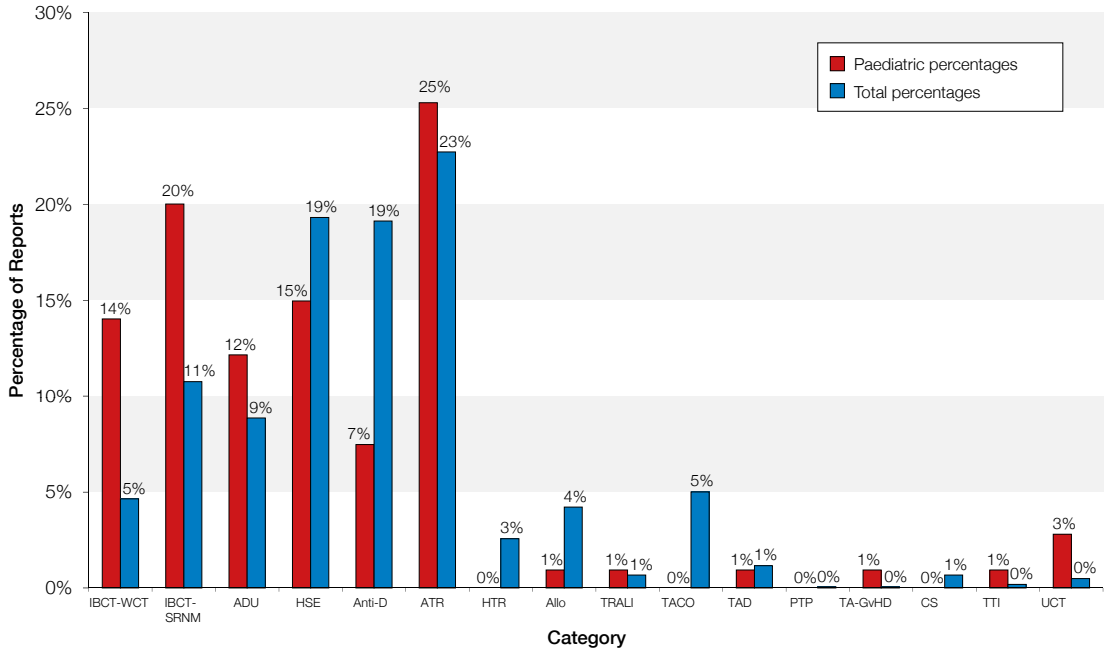


Figure 27.1: Percentages of paediatric and total reports in each category

Deaths and major morbidity

Deaths due to transfusion n=1 (TA-GvHD)

There were 5 other paediatric patients reported who died unrelated to the transfusion. Two neonates died following, but probably not due to, delay in provision of blood; two 1 month old infants given components of the wrong group both died; a newborn transfused with non-irradiated blood following an intrauterine transfusion also died, but of other causes.

Major morbidity n=8

One infant was overtransfused to an Hb of 270 g/L and required transfer to intensive care. One child with sickle cell anaemia developed infection with parvovirus and there were 6 severe acute transfusion reactions.

ERROR-RELATED REPORTS n=74

Incorrect blood component transfused (IBCT) n=37

Category of case	No ≤28 days	No > 28 days to <1 year	No 1 to <16 years	No 16 to <18 years	Total paediatric cases
IBCT wrong component transfused (IBCT WCT)	**6**	**4**	**5**	**0**	**15**
IBCT WCT Clinical	*5*	*1*	*3*	*0*	***9***
IBCT WCT Laboratory	*1*	*3*	*2*	*0*	***6***
Specific requirements not met (SRNM)	**2**	**0**	**17**	**3**	**22**
Irradiated	*2*	*0*	*6*	*1*	***9***
CMV negative	*0*	*0*	*1*	*1*	***2***
MB-FFP	*0*	*0*	*8*	*0*	***8***
Others	*0*	*0*	*2*	*1*	***3***
Total	**8**	**4**	**22**	**3**	**37**

MB: Methylene blue-treated; CMV: cytomegalovirus.

Table 27.2: Breakdown of incorrect blood component transfusion reports

IBCT-wrong component transfused (WCT) n=15

IBCT-WCT clinical error n=9

There were 5 reports where the incorrect component was given for fetal/neonatal transfusions. Three of these were the use of non-irradiated neonatal paedipacks for fetal transfusion rather than the specific intrauterine transfusion (IUT) component. This occurred in urgent clinical situations as a result of complex communication difficulties between the several specialist units involved in each case and a lack of understanding of the availability of IUT components from the Blood Services at short notice. While neonatal paedipacks may be appropriate components to choose in a life-threatening emergency, this use of components other than IUT red cells should be specified by local protocols (see recommendations below). The other two reports involved use of obstetric emergency adult O RhD negative blood for neonatal resuscitation. One was a case of poor communication: the midwife thought that the blood was being requested for the mother, not the baby.

There were 4 bedside errors in older infants and children. A 2 month infant was given a paedipack labelled for another patient. A 1 year old child in paediatric intensive care (PICU) needing emergency extracorporeal membrane oxygenation (ECMO) was given red cells intended for another patient; the identity band was missing and the checking procedure not carried out properly. A 14 year old haemopoietic stem cell transplant (HSCT) patient was given group O platelets post transplant when they should have had group A according to the donor group; the HSCT protocol had not been communicated to the laboratory. A 15 year old with thalassaemia major was given group A red cells instead of group O (see Chapter 9 for incorrect blood component transfused and Chapter 8 for the root cause analysis).

IBCT-WCT laboratory error n=6

A neonate requiring an exchange transfusion was given irradiated, CMV negative standard red cells rather than neonatal exchange units as the laboratory biomedical scientist (BMS) did not know how to request the appropriate component.

Case 1: Provision of incorrect red cells for neonatal exchange transfusion

A 1 day old neonate diagnosed with haemolytic disease of the newborn due to ABO incompatibility (mother group O RhD negative, baby group A RhD positive) required an exchange transfusion for rising bilirubin levels. The BMS ordered 2 units of group A RhD positive CMV negative, irradiated standard red cells without realising either that exchange transfusion units should have been requested or that group A was not compatible with the maternal group. Following the exchange, the bilirubin level had improved although was still high.

There were 4 cases where the wrong component was selected. One was related to the age of the patient: a 1 month infant in A&E, blood group A, was given group A blood without checking the maternal record as it was thought that the baby was 1 year old. A 1 month RhD negative male infant was given RhD positive blood, a 2 year old child post HSCT was given group O (his original group) platelets instead of group A (donor group) post engraftment. Finally, a 15 yr old, group A, with a ruptured hepatic artery following major trauma was given 4 units group AB solvent-detergent FFP (SD-FFP) then needed more FFP. Whilst awaiting the order, he was given 2 units of group A and 2 of group O SD-FFP (therefore incompatible) in preference to standard non pathogen-inactivated FFP of the correct group which would have been appropriate for an emergency.

There was one testing error resulting in the issue of SD-FFP of the incorrect group to an infant.

Case 2: Failure to follow standard operating procedures led to transfusion of ABO incompatible SD-FFP

A 1 month old preterm female infant was transferred urgently with suspected bowel perforation. Only one valid patient sample was received and tested by the laboratory due to mislabelling of the second. The patient grouped as O RhD negative and was given group O SD-FFP on the basis of clinical urgency. On subsequent testing of a further sample mixed field reactions were obtained. Investigation revealed the patient had received multiple group O red cell transfusions at another hospital and her true group was AB RhD positive. Local policy when a single sample has been received was to use the laboratory information management system to permit the issue of group O red cells and group AB plasma only and this was not followed.

Early communication between the transferring and receiving hospital laboratories would have helped to prevent the transfusion of the incorrect group. As this case was an infant less than 4 months of age, information on maternal group and antibody status, infant group and any prior transfusion should have been requested.

IBCT – specific requirements not met (SRNM) n=22

The number of SRNM cases increased from 15 in 2011. Most of these errors, 15/22, originated primarily in the laboratory and 7 were categorised as clinical, although many of the reports demonstrated missed opportunities for detection or prevention at several steps including checking against the prescription chart or specific requirements form. There were 9 reports where irradiated components were not given and note in addition the three non-irradiated paedipacks given for IUTs included as part of the IBCT chapter (Chapter 9). Two were neonates, both following IUT, and in only one case was the laboratory informed of the previous IUT. There were no reports of adverse outcome including for one patient multiply transfused with non-irradiated blood (Case 3).

Case 3: Repeated transfusion of non-irradiated blood to an oncology patient

A 2 year old oncology patient was treated with cladribine (a purine analogue) and given non-irradiated red cells on 19 occasions over a 7 month period. The error came to light when the shared care hospital checked the specific requirements having received conflicting discharge letters from the oncology centre.

There were 8 cases of laboratory failure to provide appropriate pathogen-inactivated plasma, either methylene blue-treated (MB) (7 cases; 1 cryoprecipitate, the others FFP), or SD-FFP (1 case). Some reports commented that the BMS failed to notice the date of birth of the patient and there was no flag on the computer system.

Two patients with sickle cell disease were given inappropriate components. In one case the date of birth was misread and the child was given an uncrossmatched neonatal paedipack, and the other patient was not fully phenotyped and was given a unit of red cells that was not fully matched for the complete Rh phenotype. A 17 yr old with thalassaemia major was given C^w positive red cells despite having a historic anti-C^w. Two children were erroneously given CMV unscreened blood (prior to the changes in policy recommended in 2012 by SaBTO[47]).

Avoidable, delayed or undertransfusion n=13

There were 5 cases of delay in provision of urgent blood, including to 3 newborn babies. One of these infants was born pale and died following an undiagnosed placental abruption. The on-call BMS could not be contacted due to bleep failure but it was thought unlikely that this delay affected the outcome. A 12 year old had some delay in surgery in theatre because three separate mislabelled samples had been sent to the laboratory, including the first from the preadmission clinic. Emergency O RhD negative blood was used while awaiting group-specific blood. A 14 year old had a major haemorrhage in theatre which contributed to a cardiac arrest, and the blood was not immediately available as the portering staff had not transferred it from main blood refrigerator to theatre.

Three paediatric patients were unnecessarily transfused: two neonates, one with platelets and the other with FFP. The platelet count had been reported as 13 x10^9/L, but platelet clumps on the film had been missed, making the count invalid. The FFP was transfused on the basis of an erroneous INR result of 4.4, whereas the true result on retesting the sample was 1.2. A 17 year old was transfused on the basis of another patient's results following a miscommunication and lack of checks.

Five children aged 8 months to 3 years were transfused excessive volumes, 4 of which were due to erroneous prescription, and 1 where 195 mL were prescribed for a 1 year old but the whole unit of 272 mL was given. A 3 year old with haemorrhage from a chest drain and Hb of 79 g/L was prescribed 2 adult units of blood and the post-transfusion Hb was 179 g/L. A 1 year old was overtransfused to a Hb of 270 g/L, resulting in admission to intensive care (Case 4).

Case 4: Massive over transfusion of 1 year old child

The child (weighing 10 kg) with a gastrostomy inserted a few days previously was brought into A&E, pale but alert, following an episode of vomiting blood. His Hb was 98 g/L. He was wrongly diagnosed as having an acute arterial bleed, a major haemorrhage alert was put out and O RhD negative blood requested. The blood was incorrectly prescribed in units rather than mL/kg and he was given a total of 4 units (1122 mL), the first 3 given at a rate of a unit per 20 minutes, and subsequently continuing to receive the 4th unit despite normalisation of his heart rate and blood pressure. He was taken to theatre, found to have no evidence of fresh bleeding in his stomach, and a Hb of 270 g/L. Attempted venesection was difficult and only removed 40 mL blood. He required transfer to a paediatric intensive care unit and made a full recovery.

This case illustrates incorrect prescription by units not mL (he should have only been prescribed 20 mL/kg blood in the first instance) and lack of appropriate clinical reassessment in the emergency situation, allowing continuing over-transfusion.

Handling and storage errors (HSE) n=16

Four of the HSE reports involved problems with pumps or 3-way taps such that blood was either given in an inappropriate volume, rate, or into a saline bag and not the patient. Most of the other reports, including cold chain errors, technical transfusion errors and excessive time to transfuse were unrelated to the recipient being a child and are included in Chapter 14 (Handling and Storage Errors).

Anti-D n=8

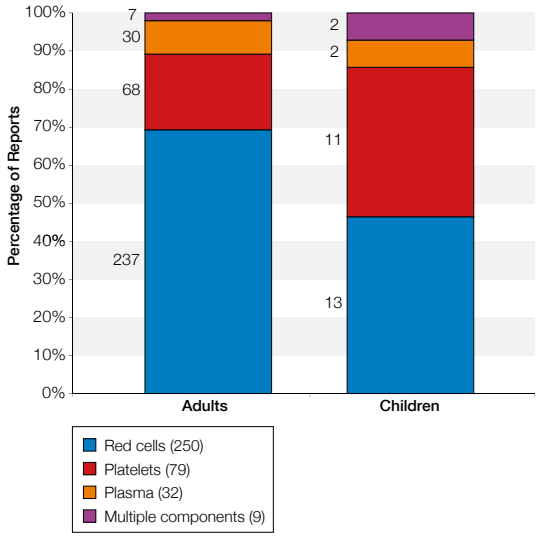
These cases are covered in more detail in the anti-D chapter (Chapter 15). From the paediatric point of view, there was a report of an RhD negative 4 year old girl with acute lymphoblastic leukaemia who was not given anti-D Ig to prevent possible sensitisation following transfusion of a unit of RhD positive platelets.

TRANSFUSION REACTIONS n=36

Acute transfusion reactions (ATR) n=28

The number of acute transfusion reactions has fallen markedly since the 48 in 2011, particularly due to a drop in reports of allergic and febrile reactions to platelets from 26 to 11 (all apheresis platelets). This is partly due to the change in definition (see Chapter 16) and withdrawal of mild cases this year. Paediatric ATRs made up 7.5% (28/372) of all ATR reports and as before had a lower proportion of reactions to red cells than for adults (Fig 27.2a). The paediatric ATRs were classified according to the updated SHOT definitions[23] (see also Chapter 16) and of the 27 that could be classified, 6 (22.2%) were severe and 21 (77.8%) were moderate.

a. Comparison of proportions of adult and paediatric ATRs due to different components.



b. Percentages of reaction types for each component for paediatric reports.

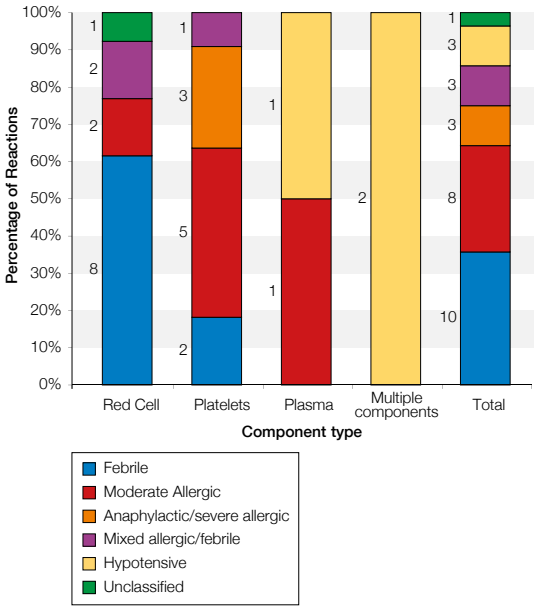


Figure 27.2: Paediatric ATR reports

Despite the fall in the number of reactions to platelets, these remain the most common cause of allergic reaction reports in children, and the only three cases of severe allergic/anaphylactic reactions were to platelets (Fig 27.2b, Table 27.3). There were 4 cases with reactions to plasma (3 FFP, 1 cryoprecipitate), two of which were combined transfusions with FFP and platelets. As one of the FFP transfusions was, in error, with non pathogen-inactivated standard plasma alone (to a 15 yr old), there were only 3 reports of reactions to MB-plasma: two to MB-FFP and one to MB-cryoprecipitate. The MB-plasma reactions were all severe hypotensive reactions which could also be associated with the underlying clinical conditions. Two were in neonates undergoing cardiac surgery and the third was a 13 month old with meningococcal sepsis who also received and reacted to SD-FFP (see also Chapter 16, Acute Transfusion Reactions).

Reaction	Red cells	Platelets	Plasma	Mixed	Total
Febrile	8	2	0	0	**10**
Moderate allergic	2	5	1	0	**8**
Anaphylactic/severe allergic	0	3	0	0	**3**
Mixed febrile and allergic	2	1	0	0	**3**
Hypotensive	0	0	1	2	**3**
Unclassified	1	0	0	0	**1**
Total	**13**	**11**	**2 (1 FFP, 1 cryo)**	**2 (FFP + plts)**	**28**

Table 27.3: Type of reaction for each component for paediatric reports classified as in ATR chapter (Chapter 16)

Case 5: Severe ATR to multiple components in a child with meningococcal sepsis

A 13 month old child with disseminated intravascular coagulation secondary to meningococcal sepsis was given platelets and FFP to support insertion of central lines. The child reacted to SD-FFP, then to MB-FFP, to IgA-deficient FFP and also to platelets, including platelets suspended in platelet additive solution. He reacted with severe hypotension, requiring fluids and increasing doses of noradrenaline. There were no reactions to red cells and IgA levels were normal. This case illustrates the great difficulty in treating patients who react to all plasma components.

Alloimmunisation n=1

There was a single case, a 17 year old renal patient who developed anti-Lu^{a} post transfusion.

Transfusion-related acute lung injury (TRALI) n=1

There was a report of suspected TRALI in a 3 year old oncology patient who became breathless an hour into the transfusion and who had bilateral ground-glass opacification throughout the lung fields on the chest X-ray. The case was classified as possible TRALI as although the clinical picture was consistent, the donor was negative for HLA and HNA antibodies.

Transfusion-associated dyspnoea (TAD) n=1

A 17 year old developed pulmonary oedema during platelet transfusion in association with cardiac surgery (see Chapter 26, TAD).

Transfusion–associated graft versus host disease (TA-GvHD) n=1

A neonate was born with TA-GvHD following emergency intrauterine transfusion using maternal blood. The case and its implications for recommendations are discussed fully in Chapter 20 (TA-GvHD).

Transfusion-transmitted infections (TTI) n=1

A 9 year old with sickle cell disease developed parvovirus related to red cell transfusion (see Chapter 21, TTI).

Unclassifiable complications of transfusion (UCT) n=3

There were 3 reports of unclassified cases, as discussed in Chapter 23 (UCT). One was a neonate, reported as having possible mechanical haemolysis, but this is considered unlikely.

COMMENTARY

There were several examples of transfusion to fetuses or neonates using blood that was not the optimal specific component that could have been provided by the Blood Services. Most of these occurred in urgent or emergency situations and sometimes it is appropriate to provide a suitable alternative in a life-threatening emergency.

Learning point

- Some of the cases illustrate a need for improved local protocols and communication to ensure clear pathways for urgent provision of blood which is appropriate for neonatal and fetal recipients (see also Chapter 20 – TA-GvHD)

There were several cases where irradiated components were not given. Clinicians should be familiar with irradiation guidelines[48] including knowledge about the individual immunosuppressive drugs for which irradiation is recommended.

Two cases of significant overtransfusion following prescription in units, not mL/kg illustrate ongoing problems with paediatric blood prescription by medical staff. One of these occurred during an emergency situation and was compounded by lack of appropriate clinical reassessment.

Learning point

- Prescribing of blood components for children should be done in mL/kg with particular care to ensure appropriate volumes are transfused[27]

Recommendations

- Hospital transfusion teams and clinical specialists should review local protocols and communication pathways for emergency provision of blood for fetal and neonatal transfusion

Action: Hospital Transfusion Teams, British Maternal and Fetal Medicine Society (see also Chapter 20: TA-GvHD for further details)

- Appropriate paediatric transfusion volumes and prescriptions should be the focus of ongoing education in hospitals, particularly in situations of emergency transfusion, such as accident and emergency departments

Action: Hospital Transfusion Teams, Accident and Emergency Department Leads

Recommendations from previous years are available in the Annual SHOT Report 2012 Supplement located on the SHOT website, www.shotuk.org under SHOT Annual Reports and Summaries, Report, Summary and Supplement 2012

28 Transfusion Complications in Patients with Haemoglobin Disorders

Author: Paula Bolton-Maggs

Thirty-two cases were reported in patients with haemoglobin disorders in 2012. The median age of this group of patients is 23 years, range 1 to 41 years.

Table 28.1: Cumulative data for 3 years: Adverse incidents in haemoglobinopathy patients[#]

Category	Sickle cell disease (SCD)			Beta thalassaemia			Total in 3 yrs	Cumulative outcome
	2010	2011	2012	2010	2011	2012		
ATR	4	3	2	6	3	3	21	minor morbidity
HTR	4	5	7	0	0	0	16	1 death, 10 major morbidity
TACO	0	1	0	0	0	0	1	1 major morbidity
TAD	0	1	0	0	0	0	1	
ADU	0	1	1	0	0	0	2	
SRNM*	3	6	7	0	2	2	21*	1 alloimmunisation
HSE	0	0	1	1	2	0	4	
NM	2	2	0	0	0	1	5	
RBRP	0	0	0	0	0	1	1	
IBCT	0	0	0	0	0	2	2	
TTI	0	0	1	0	0	0	1	

(ATR=acute transfusion reactions; HTR= haemolytic transfusion reactions; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; ADU=avoidable, delayed or undertransfusion; SRNM=specific requirements not met; HSE=handling and storage errors; NM=near miss events; RBRP=right blood right patient; IBCT=incorrect blood component transfused; TTI=transfusion-transmitted infection).

**This total includes an additional woman in 2012 with HbH disease who did not receive CMV-screened blood because the clinicians did not inform the laboratory that she was pregnant.*

[#] Three additional cases from 2012 are not included in this table: 1 anti-D error, and 1 additional alloimmunisation (anti-K in a man with SCD). The third case is discussed in Chapter 23; a patient with thalassaemia major who experiences pain with every transfusion.

Table 28.1 shows that acute transfusion reactions, haemolytic transfusion reactions and missing specific requirements in choice of red cells are the main problems for patients with haemoglobin disorders.

Again this year patients with sickle cell disease experienced haemolytic transfusion reaction (7 cases) with major morbidity in 5 cases and significant but less serious symptoms in the other 2 cases. In three cases, the features suggested hyperhaemolysis. Over the 3 years reviewed here, 11/16 (68.8%) patients with sickle cell disease who experienced haemolytic reactions suffered death or major morbidity, and the remaining patients had minor morbidity.

Four of the 5 cases where haemolysis was associated with major morbidity in 2012 are described below. The additional case demonstrated significant renal impairment.

Case 1: Delayed transfusion reaction after transfusion during surgery

A 29 year old man with sickle cell disease received two units of blood during surgery for a shoulder hemiarthroplasty. His Hb was 86 g/L. He returned 9 days later with Hb 49 g/L with dark urine, jaundice (bilirubin elevated to 56 micromol/L) and a positive direct antiglobulin test (DAT). The lactate dehydrogenase (LDH) was markedly raised at 2798 U/L and he was admitted to ITU. He had received appropriately phenotyped units (E–, K– and Fy(a–)) and investigation revealed a pan-reacting antibody which was identified as anti-Fy3. This case exhibits features suggestive of both delayed haemolysis and hyperhaemolysis.

Case 2: Delayed haemolytic transfusion reaction with major morbidity due to a currently undetectable but historically known antibody

A patient with sickle cell disease received an exchange transfusion with units which were not appropriate for her known anti-U because this was not currently detectable although it had been previously detected at another hospital. She presented 10 days later with major morbidity from haemolysis requiring admission to the intensive care unit. On this readmission her Hb was 48 g/L, she had tachycardia, fever, an increased respiratory rate and was drowsy. She made a full recovery. The U antigen is part of the MNS system, and 1% of sickle cell disease patients are U-negative[108].

Case 3: A pregnant woman with sickle cell disease develops delayed haemolysis and hyperhaemolysis after transfusion

A 31 year old woman pregnant with twins (28/40 weeks gestation) was transfused at Hb 73 g/L to a level of 86 g/L, and returned 7 days later with fever, rigors, back pain, dark urine confirmed as haemoglobinuria. Her Hb had fallen to 43 g/L and despite the recent transfusion her HbA was only 3%. She had known anti-Fy^a and anti-E; the units were negative for these antigens and no new specific antibodies were detected, the DAT was negative, but she had a weak panagglutinating antibody in the eluate.

These clinical and laboratory features are consistent with a sickle crisis and hyperhaemolysis and illustrate how difficult it can be to determine the cause of a rapidly falling Hb. The clinicians decided to manage her without further transfusion if possible and the patient was managed on the high dependency unit (HDU) for 10 days in order to ensure close observation, not because of her clinical condition (so not classified as major morbidity).

Case 4: Delayed transfusion reaction with hyperhaemolysis

A 23 year old man with sickle cell disease was transfused with three compatible units for a sickle crisis. He presented 7 days later with a significant rise in bilirubin and fall in Hb from 78 g/L to 48 g/L. The DAT was negative and although the antibody screen was positive, no new alloantibodies were detected.

Hyperhaemolysis

It is notable that in many cases of delayed haemolytic transfusion reactions (DHTR) in sickle cell disease patients, as evidenced in the cases above, the Hb falls to below the pre-transfusion level suggesting hyperhaemolysis as part of the event. Three of 7 cases of haemolysis reported in sickle cell disease had evidence of hyperhaemolysis. Some suggest that hyperhaemolysis does not exist, but there is good evidence that some patients develop severe haemolysis after transfusion with a fall in Hb to below the pre-transfusion level, in the absence of detectable auto- or allo-antibodies, and other instances such as Case 1 and Case 3 above appear to have hyperhaemolysis in addition to a DHTR. Many mechanisms have been suggested for this with some experimental evidence (reviewed in[108]), moreover the 'cytokine storm' associated with haemolysis may itself contribute to a vaso-occlusive crisis. DHTR may be missed and confused with a sickle cell crisis. The management is difficult as although steroids may reduce the antibody-induced haemolysis, they have been associated with rebound sickling symptoms[109]. IVIg may be effective and recently rituximab has been used with some success, but clinical trials are needed. It may be difficult to decide whether to continue transfusions in a patient with hyperhaemolysis and each case must be evaluated individually.

Thalassaemia

The most commonly reported problems for patients with thalassaemia continue to be acute transfusion reactions, which may not be preventable. All three cases in patients with beta thalassaemia experienced minor morbidity. This illustrates the importance of proper monitoring of all patients before, during and after transfusion.

When patients are transfused regularly there can be a danger of complacency as shown in Case 6 below.

Case 5: ABO incompatible transfusion

A 15 year old patient on a regular transfusion regimen for beta thalassaemia major received a potentially lethal small amount of an ABO incompatible unit (unit blood group A, patient group O) which fortunately was rapidly recognised (see Chapter 9, incorrect blood component transfused, clinical).

The excellent root cause analysis (RCA) identified several remediable issues leading to this, particularly regular (75% of the time) solo staffing of the day-case unit which made it almost impossible to perform transfusions safely, the root cause here was the collection of three units for three different patients from the hospital transfusion laboratory at the same time. Each was checked at the bedside with another nurse borrowed from a nearby ward and set on tables between the patients. The wrong unit was connected to the first patient (a final bedside check was not performed) and the mistake was recognised when the nurse set up the unit for the second patient.

The outcome of the RCA was employment of a health care worker on the day case unit (this case is discussed in the chapter on RCA, Chapter 8). Note also that this case was associated with 2 major failures of procedure and would have been prevented by the final bedside check. Audit of transfusions on this unit demonstrated that the routine transfusion observations were only performed 47% of the time, and a similar issue was identified in another hospital described below.

Case 6: Routine ward transfusion audit detects inadequate identity and monitoring issues

A 14 year old boy with thalassaemia major was transfused without an identity wristband, without the local hospital transfusion checklist being completed, without any observations being performed and an incomplete prescription.

This series of 4 errors was identified by a routine ward audit and demonstrates slack practice associated with over-familiarity with the patient and process. (The patient received a correct unit so this is classified as RBRP).

Transfusion-transmitted infection

A child aged 9 years with sickle cell disease developed parvovirus convincingly related to transfusion and this case is further discussed in the TTI chapter (Chapter 21).

Specific requirements not met

10 cases (4 clinical and 6 laboratory errors).

Failure to provide appropriate red cells, particularly for patients with sickle cell disease, continues to be a significant problem. It is notable that in 6 cases (including one with a haemolytic transfusion reaction not included in the 10 cases) where appropriate cells were not provided, IT systems had not been appropriately set up, for example appropriate flags not added. In 3 other cases the clinicians failed to inform the laboratory that the patient had a sickle cell disease and in the 4th, that the patient was pregnant.

Case 7: Failure of Blood Service to provide correctly phenotyped unit

In this case the Blood Service provided an inappropriate unit (C^w positive in a patient with a historical but not currently detectable anti-C^w) for a patient with beta thalassaemia following allogeneic stem cell transplant. Transfusion of this unit had already begun when the error was drawn to the attention of the clinicians and stopped, but there was no adverse outcome.

Literature review update:

Indications for and complications of transfusion in sickle cell disease have been recently reviewed[110]. These authors note the high risk of alloimmunisation, and also the high frequency of autoantibodies which can be associated with severe life-threatening haemolysis; these are often panagglutinins making selection of suitable units extremely difficult[111,112]. Autoantibody production is associated with alloantibody production in 6-10% of haemoglobinopathy patients which further complicates selection of suitable red cell units, as in Case 3 above.

Sickle cell disease is a chronic inflammatory state and this is likely to be a risk factor for alloimmunisation. A previous febrile reaction to platelets is associated with a higher risk of alloimmunisation[113] although there were no sickle cell disease patients in that study. Delayed haemolytic transfusion reactions, which may be life-threatening, occur in 4–11% of transfused sickle cell disease patients. Red cell donors are predominantly white Caucasians with a different range of polymorphisms of red cell antigens compared with sickle cell patients who are predominantly of African descent, thus in future, molecular methods for red cell antigen typing, particularly of the Rh system, may contribute to reduction of risk of alloimmunisation. This subject has been recently reviewed in detail[108].

A study of red cell alloimmunisation rates in sickle cell disease for 2010 was undertaken in the USA by centres participating in a research network[114]. Most patients (75.8%) had been transfused in the past. At least one alloantibody was present in 34/237 (14.4%), and half these patients had more than one. The baseline alloimmunisation rate in the general population is thought to be about 1%[115]. Most participating hospital centres (83%) were antigen matching for at least C, E, and K. Interestingly there was no difference in alloimmunisation between centres that provided closer antigen matches (14.8%) and those who did not (13.7%). It is possible that patients who develop alloantibodies are genetically distinct group with a higher risk, but even in this group only 30% will develop antibodies[116]. There is an increased risk associated with some HLA haplotypes. The mechanisms of alloimmunisation have been reviewed[108] and the published rates are as high as 20-50% of transfused patients. Interestingly studies of transfused sickle cell patients from Uganda[117] and Jamaica[118] showed a much lower incidence of immunisation (6.1% and 2.6%) suggesting benefit from a closer population match. However patients in these locations are also less frequently transfused. Alloimmunisation in thalassaemia is reported at about 10%.

For the reasons above it is vital that good transfusion records are kept and evidence of any sensitisations shared between laboratories in areas where the patients may visit different sites. This is a problem that remains to be solved in the UK.

Regular transfusion is associated with iron overload and the pattern is different in sickle cell disease compared with thalassaemia with more evidence of renal impairment in the former[110]. The ferritin may be less reliable as a measure of iron loading because of chronic inflammation. Assessment of iron loading in SCD has become more important with the advent of long term prophylactic transfusion regimens and these patients will need iron chelation therapy.

Update on recommendations from 2011

The recommendations from 2011 still stand. A notable feature is the problem associated with patients having transfusion records in different hospitals so that a historical antibody which is no longer detectable is missed and units with an appropriate phenotype are not selected.

Guidelines on haemoglobinopathy transfusion management are in progress by the transfusion and general haematology task forces of the British Committee for Standards in Haematology, and a national audit of the management of patients with haemoglobinopathies (NHSBT) is planned for the autumn of 2013, anticipated to reporting in the spring of 2014.

The Education subgroup of the National Blood Transfusion Committee has made progress assessing the content of all undergraduate and postgraduate foundation and specialist curricula with regard to haemoglobin disorders and will be making further recommendations in 2013.

Recommendation

In previous reports, it was identified that electronic access to the blood group and antibody information from reference laboratories by hospital transfusion laboratories would be helpful when managing the transfusion support of complex patients, particularly if patients are treated in different hospitals and/or different geographical areas. This system is in the process of being implemented by the NHSBT and is known as Sp-ICE. The success of such a system in delivering safer patient care is dependent on a number of factors:

- That hospitals use common patient identifiers such as NHS number (or equivalent) when sending samples to reference laboratories
- Those hospitals allow their patient data to be entered on the system, which is provided by an NHS organisation and used by other NHS organisations to improve the safety of the transfusion support of individual patients
- That hospitals train all transfusion laboratory staff to use the system, including those providing an out-of-hours service

Action: for Hospitals supplied by NHSBT: Hospital Transfusion Teams, Transfusion Laboratory Managers with the support of their Chief Executive Officers

Analysis of Incidents Related to Transplant Cases

29

Authors: Alison Watt and Paula Bolton-Maggs

Patients receiving transplants (solid organ or haemopoietic stem cells) present particular problems in provision of blood component support, especially when donor and recipient are ABO or RhD non-identical.

Decisions on which ABO/RhD group to transfuse have to take account not only of the ABO and RhD non-identity but also the transitional period until the stem cells have engrafted and the patient converts fully to their new group.

Two main issues require attention: firstly good communication between the transplant team and the transfusion laboratory would prevent many of the incidents, and secondly within the laboratory great care is required to correctly record the changes in blood group and timings.

Definitions:

Major ABO incompatibility is defined as the presence in the recipient's plasma of anti-A, –B or –A, B alloagglutinins reactive with the donor's red cells, e.g. donor group A and recipient of group O.

Minor ABO incompatibility is defined as the presence of anti-A, –B or –A, B alloagglutinins in the donor's plasma reactive with the recipient's red cells, e.g. donor group O and recipient group A.

Major plus minor (i.e. bidirectional) incompatibility is defined as the presence in both the donor and recipient plasma of anti-A, –B or –A, B alloagglutinins reactive with the recipient and donor cells respectively, e.g. donor group A and recipient group B.

Summary of errors made in transplant cases n=37

Two main errors have been identified in transfusion of transplant patients:

- ABO and/or RhD group incompatible or inappropriate components given to recipients of ABO/RhD mismatched transplants
- Specific requirements not met (SRNM), most commonly the failure to give irradiated components to transplant recipients according to guidelines[48]

Type of transplant	ABO/RhD errors	SRNM	Total
Haemopoietic stem cell transplant (HSCT)	16	11	**27**
Renal (includes one with pancreas transplant)	2	5	**7**
Other – Cardiac, Pancreas, Multiple organ	0	3	**3**
Total	**18**	**19**	**37**

Table 29.1: Errors made in transplant cases n=37

The ABO and RhD errors mainly involved haemopoietic stem cell transplant (HSCT) patients, but two patients with ABO mismatched renal transplants were also given inappropriate ABO group components.

The error for 5 renal and 3 other solid organ transplant patients was the failure to provide specific requirements. The cardiac transplant patient did not receive CMV negative components, which were required at the time, but the guidance has recently been revised and CMV screened components are no longer indicated in this setting (SaBTO)[47]. All other specific requirement errors for solid organ transplants

involved the failure to give irradiated components to patients who had received alemtuzumab, an anti-CD52 monoclonal antibody used for T cell depletion. This is likely to be under-reported since solid organ transplant groups may not have been aware of this requirement despite it being in the summary of product characteristics (SPC) for alemtuzumab. The BCSH irradiation guidelines are under review, particularly with a view to assessing evidence from the literature concerning risks for transfusion-associated graft versus host disease (TA-GvHD) in immunosuppressed solid organ transplant patients, and an addendum has been published on the website in the interim[119].

Table 29.2: ABO/RhD errors n=18

SHOT category	ABO error	RhD error	Total
IBCT laboratory error	5	5	**10**
IBCT clinical error	4	0	**4**
Near miss laboratory error	2	0	**2**
Near miss clinical error	2	0	**2**
Total	**13**	**5**	**18**

IBCT=incorrect blood component transfused.

Table 29.3: Summary of transplant-related ABO/RhD non-identical transfusions and near misses n=18

ABO/RhD non-identical	Component	Gender	Patient group	Transplant	Group transfused	Outcome
Laboratory errors:						
ABO	FFP	Male	O	B	O	No adverse reaction
ABO	FFP	Female	O	A	O	No adverse reaction
ABO	Red cells	Male	A	B	A	No adverse reaction
ABO	Red cells	Female	A	O	A	HTR*
ABO	Platelets	Female	O	A	O	No adverse reaction
RhD	Red cells	Male	RhD–	RhD+	RhD+	No adverse reaction
RhD	Red cells	Male	RhD+	RhD–	RhD+	No adverse reaction
RhD	Red cells	Male	RhD+	RhD–	RhD+	No adverse reaction
RhD	Red cells	Male	RhD+	RhD–	RhD+	No adverse reaction
RhD	Platelets	Female	RhD+	RhD–	RhD+	No adverse reaction
Clinical errors:						
ABO	Platelets	Female	O	B	O	No adverse reaction
ABO	Red cells	Male	A	O	A	No adverse reaction
ABO	Platelets	Female	O	B	O	No adverse reaction
ABO	Red cells	Male	B	A	B	No adverse reaction
Near misses – no components transfused. Intended components and groups listed where appropriate:						
ABO	Platelets	Female	O	A	O	Near miss
ABO	N/A	Male	A	B	N/A	Near miss
ABO	Platelets	Female	A	O	B	Near miss
ABO	N/A	Male	Potential ABO – wrong blood in tube			Near miss

**This patient with a minor ABO mismatched transplant developed evidence of a haemolytic transfusion reaction (HTR) with increased bilirubin and falling Hb when transfused 10 days after the transplant with the wrong group. This may be caused by passenger lymphocyte syndrome[120].*

Table 29.4: Failure to provide components with specific requirements n=19

SHOT category	Irradiated	CMV neg	Irradiated & CMV neg	Total
SRNM clinical error	8	4	1	**13**
Near miss clinical error	3	1	0	**4**
Near miss laboratory error	1	1	0	**2**
Total	**12**	**6**	**1**	**19**

There were no reported laboratory failures to meet specific requirements (SRNM errors) resulting in an incorrect transfusion, but there were two near misses.

Type of error	ABO/RhD error	SRNM	Total
Clinical error – protocol or communication	4	17	**21**
Laboratory error – protocol or communication	2	0	**2**
Laboratory error – LIMS flags not heeded or updated	8	2	**10**
Laboratory error – other/unknown (both near misses)	2	0	**2**
Clinical error – other/unknown (both near misses)	2	0	**2**
Total	**18**	**19**	**37**

Table 29.5: Causes of errors, including near miss errors

Failure of communication is a recurring theme in case reports received by SHOT (Case 1), but even when communication has taken place, there are worrying laboratory failures to heed or update the laboratory information management system (LIMS) (n=10).

Case 1: Incorrect ABO blood group transfused due to lack of communication

A staff nurse noticed a patient was being transfused with group A red cells, but knew the patient had received a haemopoietic stem cell transplant from his blood group O sister 7 days previously. The staff nurse contacted the transfusion laboratory, but there was no indication on the laboratory information management system (LIMS) that the patient had received an ABO incompatible transplant. The BMS confirmed that group O units should have been issued to the patient and the transfusion was stopped when the patient was receiving the second unit of group A red cells.

The local standard operating procedure was revised to ensure the transfusion laboratory is made aware by the clinical transplant team of patients who undergo an ABO incompatible HSCT. A review of all patients who have received an ABO mismatched HSCT in this unit was undertaken and other patients could have been implicated in the same error, but no specific instances were identified.

Current guidance about what groups to transfuse during and after HSCT are confusing and contradictory. The BCSH Guidelines for assessment of pre-transfusion compatibility advise that group O red cells should be transfused immediately after a haemopoietic stem cell transplant and the new group can be transfused when the direct antiglobulin test is negative and any ABO antibodies to the donor group are no longer detectable[35].

Learning point

- Advice should be sought from the consultant haematologist responsible for the transfusion laboratory in association with the clinician responsible for the patient if there is any doubt as to the correct group to transfuse

Haemopoietic stem cell transplantation is a complex process, often requiring testing of multiple potential donors. Case 2 highlights an error related to that procedure.

Case 2: Potential HSCT donor group mistakenly entered into the recipient's record

A group had been entered into the patient's record as B RhD Positive, but the current specimen from the patient was found to be A RhD Positive. Investigation identified a transcription error, because a specimen had been received from the planned HSCT donor for the patient. This was grouped as B RhD Positive and entered against the patient's record and not the donor's.

COMMENTARY

The changing transfusion requirements during HSCT may be complex. Guidelines are available for transfusion in relation to transplantation from both the EBMT[121] and NHSBT[122]. It is surprising that these significant communication problems occurred since in many transplant centres care is taken to produce an individualised timetable which is provided to all parties, including the transfusion laboratory. Transplant centres are accredited against international standards from JACIE (Joint Accreditation Committee – International Society for Cellular Therapy (ISCT) and the European Group for Blood and Marrow Transplantation (EBMT)). Most centres reporting the incidents described here are large transplant units who are JACIE accredited. However, the JACIE standards do not include any reference to the arrangements between the transplant unit and their local transfusion laboratory. We did not find any other national guidelines, so there appears to be no standardised procedure for making transfusion laboratories aware of patients undergoing ABO mismatched haemopoietic stem cell transplantation. This should be addressed in the planned BCSH guidelines on transfusion in transplant recipients.

In addition to these issues within the transplant centre, patients continue to be at risk when they transfer to their local referring hospital. It is important that good information is transferred to these shared care centres which includes instructions about transfusion. The need for irradiated cellular components is often missed but the problem is wider than that where the HSCT results in a change in blood group in the patient.

An additional issue may be that some hospitals with transplant centres have a data protection policy that will not allow a local hospital laboratory to be informed directly by the transplant centre laboratory about the changes in blood group and other requirements, particularly the continuing need for irradiated components. In this situation the laboratory in the local hospital depends on the clinical teams managing the patient to communicate this complex information. Similar issues apply to patients with haemoglobin disorders who may have shared care and/or be admitted to different hospitals. Information-sharing of this kind may be easier with the publication of an updated ‘information governance review’ led by Caldicott. A new principle has been added which states that ‘the duty to share information can be as important as the duty to protect patient confidentiality’[25].

In previous reports, it was identified that electronic access to the blood group and antibody information from reference laboratories by hospital transfusion laboratories would be helpful when managing the transfusion support of complex patients, particularly if patients are treated in different hospitals and/or different geographical areas. This system is in the process of being implemented by NHSBT and is known as Sp-ICE. The success of such a system in delivering safer patient care is dependent on a number of factors:

- That hospitals use common patient identifiers such as NHS number (or equivalent) when sending samples to reference laboratories
- Those hospitals allow their patient data to be entered on the system, which is provided by an NHS organisation and used by other NHS organisations to improve the safety of the transfusion support of individual patients
- That hospitals train all transfusion laboratory staff to use the system, including those providing an out-of-hours service

Errors in managing transfusion of transplant patients highlight a lack of effective control on this vital aspect of patient care. Communication is a key element both within the transplant hospital and also because patients will often be under shared care between the transplant centre and their local hospital. It appears that the transfusion laboratory are sometimes not made aware of the transplant at all, and then cannot meet the patient’s specific needs, particularly where transfusion may need to change to a different ABO or RhD group from the patient’s historical group.

It should be an intrinsic part of laboratory routine for a patient’s diagnosis, history and blood group to be checked, where available, to inform transfusion decisions. In normal circumstances a patient’s historical blood group will never change, but for ABO and RhD mismatched transplants this information might need to be altered. Carefully controlled procedures are needed to allow updating of the laboratory

patient records when transplant-related information has been communicated. This might include the need to track a changing blood group, during haemopoietic stem cell transplant engraftment, or the need to update other specific patient requirements, e.g. for irradiated components. Where appropriate, warning flags should be added to the LIMS and staff should receive training to ensure such warnings are understood and not overlooked or ignored.

Learning points

- Robust written communication is needed to ensure the specific transfusion needs of transplant patients are met between:
  - clinical transplant teams and their supporting transfusion laboratory
  - clinical teams at the transplant centres and shared care hospitals
  - the clinical team of shared care hospital and their transfusion laboratory
  - the transfusion laboratory at the transplant unit and the shared care transfusion laboratory
- Laboratories should have written procedures to ensure patient needs are recorded in the laboratory information management system (LIMS) transfusion record and in particular the blood group as it changes through the transplant period. Laboratory staff must be vigilant and in particular pay heed to LIMS warning flags

Recommendation

- To minimise transfusion errors, a written transplant programme detailing key dates and blood group information, should be developed for each transplant recipient. This should be sent, with written confirmation of receipt, to the transfusion laboratory in the hospital where the transplant is being undertaken, the shared care centre and its transfusion laboratory

Action: Clinical transplant teams; Transfusion Laboratory managers, Hospital Transfusion Teams

- Guidelines should be developed that cover the procedures, particularly communication protocols, necessary for managing transplant patients, especially where ABO/RhD mismatched transplants have been given. This should be a standard for all transplant centres

Action: The BCSH Transfusion Task Force; the British Society of Blood and Marrow Transplantation (BSBMT)

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Acknowledgements

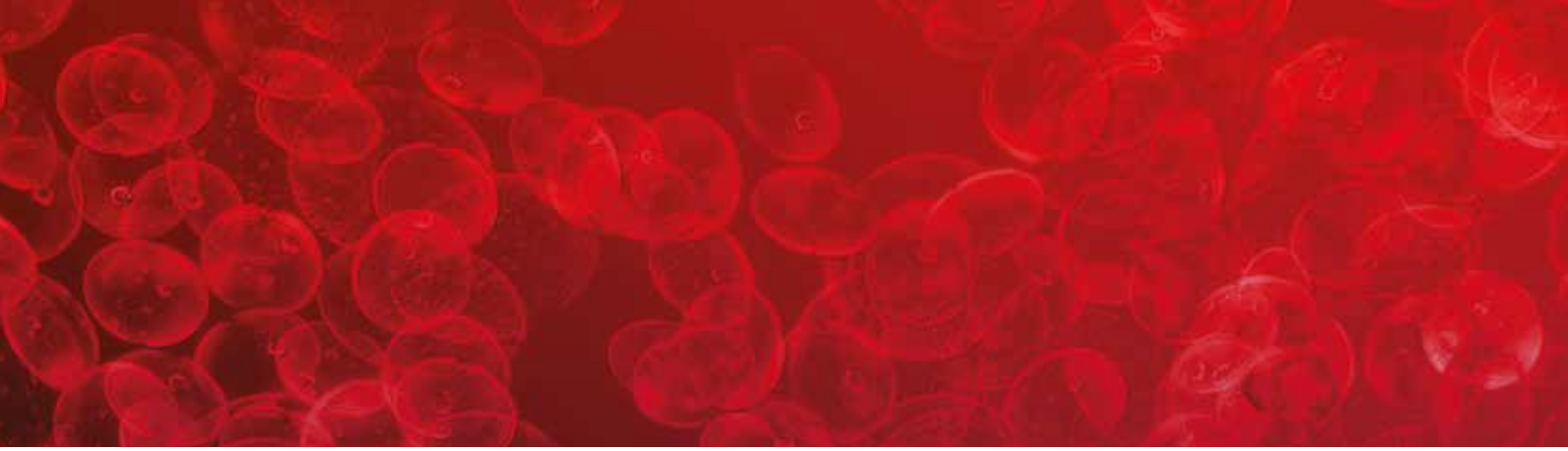
The steering group take this opportunity to thank the following individuals and organisations for their contributions without which the publication of this 16th Annual SHOT Report would not have been possible:

- The Blood Services of the United Kingdom for funding and support
- The Royal College of Pathologists to which SHOT is affiliated
- The Blood Services of the United Kingdom for the provision of data relating to the issue of blood components:
  - Mrs Sue Holdsworth, National Stock Planning Manager, NHSBT
  - Ms Amanda Stewart, Principle Transfusion Data Analysis Manager, SNBTS
  - Mrs Samantha Rainbird, Head of Processing, Verification and Issue, WBS
  - Mrs Barbara Mullin, Hospital Services Deputy Manager, NIBTS
- The expert group who reviewed TRALI cases:
  - Dr Neil Soni, Chelsea and Westminster Hospital
  - Dr Cliff Morgan, Royal Brompton Hospital
  - Dr Tom Latham, NHSBT Bristol
  - Dr Nay Win, NHSBT Tooting
  - Dr Peter Davis, Bristol University Hospitals NHS Foundation Trust
- Expert input on the practice of Fetal Medicine:
  - Professor Mark Kilby, Birmingham Women's Foundation Trust; President of the British Maternal and Fetal Medicine Society, London
- Neil Hoggarth, Business Manager, Octaplas LG, UK and Ireland. Octapharma Ltd for providing data about SD-FFP
- Clinical and scientific staff, in hospitals and reference laboratories, who have contributed to the clinical and laboratory investigation of cases
- Toast Design Consultancy Ltd for maintenance of the SHOT website
- Dendrite Clinical Systems for the update of the online reporting system
- Victoria Peake, SHOT information officer
- Suzie Baillie, SHOT information officer
- Jean Sigauke, SHOT information officer
- Christine Smith, personal assistant to Hannah Cohen
- Hazel Macauley, personal assistant to Paula Bolton-Maggs
- Tower Printing & Design Ltd for design and production of the report
- Hospital Transfusion Teams for submitting case reports to the scheme

Glossary

AAA	Abdominal aortic aneurysm
A&E	Accident and Emergency
AAGBI	Association of Anaesthetists Great Britain and Ireland
ACD	Acid citrate dextrose
ACE	Acetylcholinesterase
ACS	Acute coronary syndrome
ADU	Avoidable, delayed or undertransfusion
ANC	Antenatal clinic
AHTR	Acute haemolytic transfusion reaction
AIHA	Auto immune haemolytic anaemia
ALI	Acute lung injury
ALL	Acute lymphoblastic leukaemia
ALT	Alanine aminotransferase
AML	Acute myeloid leukaemia
ANH	Acute normovolaemic haemodilution
ARDS	Acute respiratory distress syndrome
ARF	Acute renal failure
ATD	Adult therapeutic dose
ATG	Anti-thymocyte globulin
ATR	Acute transfusion reaction
ATRA	All-trans retinoic acid
B19V	Parvovirus B19
BBT	Better Blood Transfusion
BBTS	British Blood Transfusion Society
BCR	Blood compliance report (BCR)
BCSH	British Committee for Standards in Haematology
BiPAP	Variable/bilevel positive airway pressure
BMI	Body Mass Index
BMS	Biomedical Scientist
BMT	Bone marrow transplant
BP	Blood pressure
bpm	Beats per minute
BS	Blood service
BSQR	Blood Safety and Quality Regulations
BW	Body weight
CABG	Coronary artery bypass graft
CAPA	Corrective and preventative actions
CATPD	Components available for transfusion past dereservation date
CCE	Cold chain error (SHOT definition)
CCE	Component collection error (MHRA definition)
CCF	Congestive cardiac failure
CD	Component donation
CDC	Complement dependent cytotoxicity
CDP	Cryodepleted plasma
CDP	Care delivery problem
CEO	Chief Executive Officer
CfH	Connecting for Health
CLE	Component labelling error
CLL	Chronic lymphocytic leukaemia
CML	Chronic myeloid leukaemia
CMO	Chief Medical Officer
CMV	Cytomegalovirus
COPD	Chronic obstructive pulmonary disease
CPA	Clinical pathology accreditation
CPAP	Continuous positive airway pressure
CPR	Cardiopulmonary resuscitation
CRF	Chronic renal failure
Cryo	Cryoprecipitate
CS	Caesarean section or Cell salvage
CTS	Controlled temperature storage
CVP	Central venous pressure
CXR	Chest X-ray
DAT	Direct antiglobulin test
DAEDS	Donor adverse events of donation
DCS	Delayed component supply (Blood Establishment only)
DEE	Data entry error
DH	Department of Health
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation
DNA	Deoxyribonucleic acid
DOB	Date of birth
DSTR	Delayed serological transfusion reaction
DTR	Delayed transfusion reaction
DU	Duodenal ulcer
EBMS	Electronic blood management system
EBMT	European Group for Blood and Marrow Transplantation
ECAT	Expired components available for transfusion
ECG	Electrocardiogram
ECHO	Echocardiogram
ECMO	Extracorporeal membrane oxygenation
ED	Emergency department
EDTA	Ethylenediaminetetraacetic acid
EDN	Electronic delivery note
EI	Electronic issue
ESH	European School of Haematology
ESRF	End stage renal failure
ET	Exchange transfusion
EU	European Union
EWTD	European Working Time Directive
FBC	Full blood count
FDIU	fetal death in utero
FFP	Fresh frozen plasma
FMH	Fetomaternal haemorrhage
FNHTR	Febrile non-haemolytic transfusion reaction
FR	Failed recall
FY	Foundation year
G&S	Group & Save
GI	Gastrointestinal
GCS	Glasgow Coma Scale/Score
GMC	General Medical Council
GMP	Good Manufacturing Practice
GP	General Practitioner
Gynae	Gynaecology
HAV	Hepatitis A virus
Hb	Haemoglobin
HBV	Hepatitis B virus
HbsAg	Hepatitis B surface antigen
HbeAg	Hepatitis B “e” antigen
HCA	Health care assistant
HCV	Hepatitis C virus
HDFN	Haemolytic disease of the fetus and newborn
HDN	Haemolytic disease of the newborn
HDU	High dependency unit
HEV	Hepatitis E virus
HHTR	Hyperhaemolytic transfusion reaction
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen or Health Protection Agency
HPLC	High-performance liquid chromotography
HSC	Health service circular
HSCT	Haemopoietic Stem Cell Transplant
HSE	Handling and storage errors
HT	High titre
HTC	Hospital Transfusion Committee
HTL	Hospital Transfusion Laboratory
HTLV	Human T-lymphotropic virus
HTR	Haemolytic transfusion reaction
HTT	Hospital Transfusion Team

I&U Inappropriate, unnecessary, under/delayed transfusion
IAT Indirect antiglobulin test
IBCA Incorrect blood component accepted (from supplier)
IBCI Incorrect blood component selected and issued
IBCO Incorrect blood component ordered
IBCT Incorrect blood component transfused
IBGRL International Blood Group Reference Laboratory
IBMS Institute of Biomedical Science
ICS Intraoperative cell salvage
ICS Incorrect component storage (MHRA definition)
ID Identification
Ig Immunoglobulin
IgAD IgA deficiency
IU International units
IHD Ischaemic heart disease
IHN International Haemovigilance Network
IM Intramuscular
INR International Normalized Ratio
ISBT International Society of Blood Transfusion
IT Information technology
ITU Intensive Therapy Unit
IUT Intrauterine transfusion
IV Intravenous
IVIg Intravenous immunoglobulin
JACIE Joint Accreditation Committee – International Society for Cellular Therapy (ISCT) and the European Group for Blood and Marrow Transplantation (EBMT)
JVP Jugular venous pressure
LDF Leucocyte depletion filter
kPa Kilo Pascal
KPI Key performance indicator
LDH Lactate dehydrogenase enzyme
LIMS Laboratory information management system
LFT Liver function test
LVF Left ventricular failure
MAU Medical assessment unit
MB-FFP Methylene blue-treated fresh frozen plasma
MCT Mast cell tryptase
MDS Myelodysplastic syndrome
MHRA Medicines and Healthcare products Regulatory Agency
MI Myocardial infarction
MLA Medical laboratory assistant
MM Major morbidity
MOF Multi-organ failure
NAITP Neonatal alloimmune thrombocytopenia
NBTC National Blood Transfusion Committee
NCA National Comparative Audit
Neg Negative
NHL Non-Hodgkin lymphoma
NHS National Health Service
NHSBT NHS Blood and Transplant
NIBTS Northern Ireland Blood Transfusion Service
NICE National Institute for Health and Care Excellence
NICU Neonatal Intensive Care Unit
NISS Normal ionic strength saline
NMC Nursing and Midwifery Council
NNU Neonatal unit
NOS National occupational standards
NPSA National Patient Safety Agency
NR Normal range
NSAID Non-steroidal anti-inflammatory drug
NSTEMI Non ST segment elevation myocardial infarction
NWIS NHS Wales Informatics Service
OAS Optimal additive solution
OBOS Online blood ordering system
Obs Obstetric
OCP Official contact person
ODP Operating Department Practitioner
O&G Obstetrics and Gynaecology
OTCOL Out of temperature control
PAD Preoperative autologous deposit
PAS Platelet additive solution or Patient Administration System
PBSC Peripheral blood stem cells
PCC Prothrombin complex concentrate
PCR Polymerase chain reaction
PCS Postoperative cell salvage
PE Pulmonary embolism
PEA Pulseless electrical activity
PEX Plasma exchange
PHE Public Health England
PID Patient identifiable data or Patient ID
PICU Paediatric intensive care unit
POCT Point of care testing
Pos positive
pO2 Partial pressure of oxygen
PPH Post partum haemorrhage
PR Per rectum
PSE Potentially sensitising episode
PSM Platelet suspension medium
PTP Post-transfusion purpura
PTTE Pre-transfusion testing error
PUCT Previously uncategorised complication of transfusion
PV Per vaginum
RA Rheumatoid arthritis
RAADP Routine antenatal anti-D Ig prophylaxis
RBC Red blood cells
RBCOA Red blood cells in optimal additive solution
RBRP Right blood right patient
RCA Root cause analysis
RCI Red cell immunohaematology
RCP Royal College of Physicians
RNA Ribonucleic acid
RR Respiratory rate
RTA Road traffic accident
RTC Regional transfusion committee or Road traffic collision
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
SCA Sickle cell anaemia
SCD Sickle cell disease
SCT Stem cell transplant
SCTAC Scottish Clinical Transfusion Advisory Committee
SD Solvent detergent
SD-FFP Solvent detergent-treated fresh frozen plasma
SDP Service delivery problem
SG Steering Group
SHO Senior house officer
SNBTS Scottish National Blood Transfusion Service
SOB Shortness of breath
SOP Standard operating procedure
SPC Summary of product characteristics
SPE Sample processing error
SPN Safer practice notice
SpR Specialist registrar
SRNM Specific requirements not met
ST Electrocardiogram ST segment
TACO Transfusion-associated circulatory overload
TAD Transfusion-associated dyspnoea
TA-GvHD Transfusion-associated graft versus host disease
THR Total hip replacement
TKR Total knee replacement
TP Transfusion practitioner
TPH Transplacental Haemorrhage
TRAB Trainee Doctors Advisory Board
TRALI Transfusion-related acute lung injury
TRAIN Transfusion-related alloimmune neutropenia
TTI Transfusion-transmitted infection
TTP Thrombotic thrombocytopenic purpura
Tx Transfusion (can also mean treatment)
U&E Urea and electrolytes
UCT Unclassifiable complication of transfusion
UK United Kingdom
UK NEQAS BTLP UK National External Quality Assessment Service for Blood Transfusion Laboratory Practice
UKTLC UK Transfusion Laboratory Collaborative
UKRC UK Resuscitation Council
UNS Unspecified
vCJD Variant Creutzfeld-Jakob Disease
WBIT Wrong blood in tube
WBS Welsh Blood Service
WCC White cell count
WEG Working Expert Group
WNOT Wrong name on tube



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